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

FORM 10-Q

(Mark One)

☒ **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the quarterly period ended September 30, 2021

or

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the transition period from to

Commission File Number: 001-33500

JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY

(Exact name of registrant as specified in its charter)

Ireland	**98-1032470**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

Fifth Floor, Waterloo Exchange,
Waterloo Road, Dublin 4, Ireland D04 E5W7
011-353-1-634-7800
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary shares, nominal value $0.0001 per share	JAZZ	The Nasdaq Stock Market LLC

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 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

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

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

As of November 2, 2021, 61,469,645 ordinary shares of the registrant, nominal value $0.0001 per share, were outstanding.

JAZZ PHARMACEUTICALS PLC
QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 2021

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We own or have rights to various copyrights, trademarks, and trade names used in our business in the U.S. and/or other countries, including the following: Jazz Pharmaceuticals®, Xyrem® (sodium oxybate) oral solution, Xywav® (calcium, magnesium, potassium, and sodium oxybates) oral solution, Epidiolex® (cannabidiol) oral solution, Epidyolex® (the trade name in Europe for Epidiolex), Sunosi® (solriamfetol), Defitelio® (defibrotide sodium), Defitelio® (defibrotide), CombiPlex®, Vyxeos® (daunorubicin and cytarabine) liposome for injection, Vyxeos® liposomal 44 mg/100 mg powder for concentrate for solution for infusion, Zepzelca® (lurbinectedin), Rylaze™ (recombinant Erwinia asparaginase) and Sativex® (nabiximols) oral solution. This report also includes trademarks, service marks and trade names of other companies. Trademarks, service marks and trade names appearing in this Quarterly Report on Form 10-Q are the property of their respective owners.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

JAZZ PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands)
(Unaudited)

	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 671,780	$ 1,057,769
Investments	—	1,075,000
Accounts receivable, net of allowances	499,023	396,490
Inventories	1,137,851	95,396
Prepaid expenses	94,474	62,422
Other current assets	225,098	152,491
Total current assets	2,628,226	2,839,568
Property, plant and equipment, net	255,006	127,935
Operating lease assets	89,628	129,169
Intangible assets, net	7,282,579	2,195,051
Goodwill	1,849,547	958,303
Deferred tax assets, net	314,666	254,916
Deferred financing costs	12,724	5,238
Other non-current assets	45,776	25,721
Total assets	$ 12,478,152	$ 6,535,901
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 63,815	$ 26,945
Accrued liabilities	603,715	352,732
Current portion of long-term debt	31,000	246,322
Income taxes payable	34,256	25,200
Deferred revenue	2,267	2,546
Total current liabilities	735,053	653,745
Deferred revenue, non-current	986	2,315
Long-term debt, less current portion	6,247,287	1,848,516
Operating lease liabilities, less current portion	89,359	140,035
Deferred tax liabilities, net	1,329,184	130,397
Other non-current liabilities	137,806	101,148
Commitments and contingencies (Note 11)		
Shareholders' equity:		
Ordinary shares	6	6
Non-voting euro deferred shares	55	55
Capital redemption reserve	472	472
Additional paid-in capital	3,469,884	2,633,670
Accumulated other comprehensive loss	(397,517)	(134,352)
Retained earnings	865,577	1,159,894
Total shareholders' equity	3,938,477	3,659,745
Total liabilities and shareholders' equity	$ 12,478,152	$ 6,535,901

The accompanying notes are an integral part of these condensed consolidated financial statements.

JAZZ PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF INCOME (LOSS)
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues:				
Product sales, net	$ 834,247	$ 596,949	$ 2,186,118	$ 1,685,357
Royalties and contract revenues	3,868	3,939	11,389	12,693
Total revenues	838,115	600,888	2,197,507	1,698,050
Operating expenses:				
Cost of product sales (excluding amortization of acquired developed technologies)	145,224	42,095	304,607	98,760
Selling, general and administrative	363,682	207,255	1,053,221	607,061
Research and development	141,036	78,647	350,305	243,676
Intangible asset amortization	159,804	66,684	368,476	192,505
Acquired in-process research and development	—	10,000	—	215,250
Impairment charge	—	—	—	136,139
Total operating expenses	809,746	404,681	2,076,609	1,493,391
Income from operations	28,369	196,207	120,898	204,659
Interest expense, net	(93,372)	(27,428)	(190,168)	(72,134)
Foreign exchange gain (loss)	(2,631)	(639)	1,262	(2,235)
Income (loss) before income tax provision (benefit) and equity in (gain) loss of investees	(67,634)	168,140	(68,008)	130,290
Income tax provision (benefit)	(18,057)	19,283	228,583	22,750
Equity in (gain) loss of investees	3,256	623	(2,274)	2,338
Net income (loss)	$ (52,833)	$ 148,234	$ (294,317)	$ 105,202
Net income (loss) per ordinary share:				
Basic	$ (0.86)	$ 2.67	$ (4.98)	$ 1.89
Diluted	$ (0.86)	$ 2.64	$ (4.98)	$ 1.87
Weighted-average ordinary shares used in per share calculations - basic	61,284	55,545	59,084	55,637
Weighted-average ordinary shares used in per share calculations - diluted	61,284	56,236	59,084	56,297

The accompanying notes are an integral part of these condensed consolidated financial statements.

JAZZ PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(In thousands)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net income (loss)	$ (52,833)	$ 148,234	$ (294,317)	$ 105,202
Other comprehensive income (loss):				
Foreign currency translation adjustments	(206,819)	47,139	(265,342)	37,879
Unrealized gain (loss) on cash flow hedging activities, net of income tax provision (benefit) of $22, $167, $353 and ($327), respectively	153	1,169	2,468	(2,287)
Unrealized gain (loss) on fair value hedging activities, net of income tax provision (benefit) of $28, $—, ($97) and $—, respectively	84	—	(291)	—
Other comprehensive income (loss)	(206,582)	48,308	(263,165)	35,592
Total comprehensive income (loss)	$ (259,415)	$ 196,542	$ (557,482)	$ 140,794

The accompanying notes are an integral part of these condensed consolidated financial statements.

JAZZ PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(In thousands)
(Unaudited)

	Ordinary Shares		Non-voting Euro Deferred		Capital Redemption Reserve	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Retained Earnings	Total Equity
	Shares	Amount	Shares	Amount					
Balance at December 31, 2020	56,171	$ 6	4,000	$ 55	$ 472	$ 2,633,670	$ (134,352)	$ 1,159,894	$ 3,659,745
Issuance of ordinary shares in conjunction with exercise of share options	408	—	—	—	—	50,407	—	—	50,407
Issuance of ordinary shares in conjunction with vesting of restricted stock units	294	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(23,784)	—	—	(23,784)
Share-based compensation	—	—	—	—	—	34,565	—	—	34,565
Other comprehensive loss	—	—	—	—	—	—	(45,076)	—	(45,076)
Net income	—	—	—	—	—	—	—	121,832	121,832
Balance at March 31, 2021	56,873	$ 6	4,000	$ 55	$ 472	$ 2,694,858	$ (179,428)	$ 1,281,726	$ 3,797,689
Issuance of ordinary shares in connection with the acquisition of GW Pharmaceuticals plc	3,798	—	—	—	—	608,456	—	—	608,456
Share-based payment - pre-combination service in connection with the acquisition of GW Pharmaceuticals plc	—	—	—	—	—	3,555	—	—	3,555
Issuance of ordinary shares in conjunction with exercise of share options	328	—	—	—	—	43,600	—	—	43,600
Issuance of ordinary shares under employee stock purchase plan	79	—	—	—	—	8,282	—	—	8,282
Issuance of ordinary shares in conjunction with vesting of restricted stock units	37	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(3,388)	—	—	(3,388)
Share-based compensation	—	—	—	—	—	48,119	—	—	48,119
Other comprehensive loss	—	—	—	—	—	—	(11,507)	—	(11,507)
Net loss	—	—	—	—	—	—	—	(363,316)	(363,316)
Balance at June 30, 2021	61,115	$ 6	4,000	$ 55	$ 472	$ 3,403,482	$ (190,935)	$ 918,410	$ 4,131,490
Issuance of ordinary shares in conjunction with exercise of share options	202	—	—	—	—	14,822	—	—	14,822
Issuance of ordinary shares in conjunction with vesting of restricted stock units	63	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(2,431)	—	—	(2,431)
Share-based compensation	—	—	—	—	—	54,011	—	—	54,011
Other comprehensive loss	—	—	—	—	—	—	(206,582)	—	(206,582)
Net loss	—	—	—	—	—	—	—	(52,833)	(52,833)
Balance at September 30, 2021	61,380	$ 6	4,000	$ 55	$ 472	$ 3,469,884	$ (397,517)	$ 865,577	$ 3,938,477

JAZZ PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
(In thousands)
(Unaudited)

	Ordinary Shares		Non-voting Euro Deferred		Capital Redemption Reserve	Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Retained Earnings	Total Equity
	Shares	Amount	Shares	Amount					
Balance at December 31, 2019	56,140	$ 6	4,000	$ 55	$ 472	$ 2,266,026	$ (223,393)	$ 1,067,815	$ 3,110,981
Issuance of ordinary shares in conjunction with exercise of share options	145	—	—	—	—	13,264	—	—	13,264
Issuance of ordinary shares in conjunction with vesting of restricted stock units	214	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(13,547)	—	—	(13,547)
Share-based compensation	—	—	—	—	—	28,731	—	—	28,731
Shares repurchased	(1,131)	—	—	—	—	—	—	(139,053)	(139,053)
Other comprehensive loss	—	—	—	—	—	—	(34,043)	—	(34,043)
Net loss	—	—	—	—	—	—	—	(157,833)	(157,833)
Balance at March 31, 2020	55,368	$ 6	4,000	$ 55	$ 472	$ 2,294,474	$ (257,436)	$ 770,929	$ 2,808,500
Issuance of Exchangeable Senior Notes, due 2026	—	—	—	—	—	176,260	—	—	176,260
Partial repurchase of Exchangeable Senior Notes, due 2021	—	—	—	—	—	(12,069)	—	—	(12,069)
Issuance of ordinary shares in conjunction with exercise of share options	74	—	—	—	—	4,440	—	—	4,440
Issuance of ordinary shares under employee stock purchase plan	65	—	—	—	—	6,547	—	—	6,547
Issuance of ordinary shares in conjunction with vesting of restricted stock units	19	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(1,116)	—	—	(1,116)
Share-based compensation	—	—	—	—	—	30,599	—	—	30,599
Shares repurchased	(70)	—	—	—	—	—	—	(7,484)	(7,484)
Other comprehensive income	—	—	—	—	—	—	21,327	—	21,327
Net income	—	—	—	—	—	—	—	114,801	114,801
Balance at June 30, 2020	55,456	$ 6	4,000	$ 55	$ 472	$ 2,499,135	$ (236,109)	$ 878,246	$ 3,141,805
Partial repurchase of Exchangeable Senior Notes, due 2021	—	—	—	—	—	(444)	—	—	(444)
Issuance of ordinary shares in conjunction with exercise of share options	96	—	—	—	—	10,088	—	—	10,088
Issuance of ordinary shares in conjunction with vesting of restricted stock units	40	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(1,097)	—	—	(1,097)
Share-based compensation	—	—	—	—	—	30,307	—	—	30,307
Other comprehensive income	—	—	—	—	—	—	48,308	—	48,308
Net income	—	—	—	—	—	—	—	148,234	148,234
Balance at September 30, 2020	55,592	$ 6	4,000	$ 55	$ 472	$ 2,537,989	$ (187,801)	$ 1,026,480	$ 3,377,201

The accompanying notes are an integral part of these condensed consolidated financial statements.

JAZZ PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2021	**2020**
Operating activities		
Net income (loss)	$ (294,317)	$ 105,202
Adjustments to reconcile net loss to net cash provided by operating activities:		
Intangible asset amortization	368,476	192,505
Acquisition accounting inventory fair value step-up adjustment	148,637	—
Share-based compensation	135,887	89,614
Deferred tax provision (benefit)	96,593	(120,909)
Non-cash interest expense	66,055	45,702
Depreciation	19,387	14,076
Provision for losses on accounts receivable and inventory	13,444	9,148
Impairment charge	—	136,139
Acquired in-process research and development	—	215,250
Other non-cash transactions	9,622	12,672
Changes in assets and liabilities:		
Accounts receivable	(27,956)	(5,004)
Inventories	(33,891)	(21,861)
Prepaid expenses and other current assets	(34,722)	(64,902)
Operating lease assets	12,054	9,730
Other non-current assets	(1,837)	13,941
Accounts payable	19,167	20,645
Accrued liabilities	93,534	26,510
Income taxes payable	9,171	15,089
Deferred revenue	(1,608)	(3,540)
Operating lease liabilities, less current portion	(13,423)	(9,884)
Other non-current liabilities	16,479	33,254
Net cash provided by operating activities	600,752	713,377
Investing activities		
Proceeds from maturity of investments	1,095,000	920,000
Purchases of property, plant and equipment	(17,674)	(10,889)
Acquisition of intangible assets	(17,891)	(113,000)
Acquisition of investments	(26,694)	(1,661,750)
Acquisition of a business, net of cash acquired	(6,234,792)	—
Acquired in-process research and development	—	(215,250)
Net cash used in investing activities	(5,202,051)	(1,080,889)
Financing activities		
Net proceeds from issuance of borrowings under credit agreement	3,719,930	—
Net proceeds from issuance of Senior Secured Notes, due 2029	1,471,533	—
Proceeds from employee equity incentive and purchase plans	117,111	34,339
Payment of employee withholding taxes related to share-based awards	(29,603)	(15,760)
Payments for repurchase of Exchangeable Senior Notes, due 2021	(218,812)	(356,188)
Repayments of long-term debt	(843,028)	(25,040)
Net proceeds from issuance of Exchangeable Senior Notes, due 2026	—	981,381
Net proceeds from revolving credit facility	—	500,000
Share repurchases	—	(146,537)
Repayments under revolving credit facility	—	(500,000)
Net cash provided by financing activities	4,217,131	472,195
Effect of exchange rates on cash and cash equivalents	(1,821)	(85)
Net increase (decrease) in cash and cash equivalents	(385,989)	104,598
Cash and cash equivalents, at beginning of period	1,057,769	637,344
Cash and cash equivalents, at end of period	$ 671,780	$ 741,942

The accompanying notes are an integral part of these condensed consolidated financial statements.

JAZZ PHARMACEUTICALS PLC
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. The Company and Summary of Significant Accounting Policies

Jazz Pharmaceuticals plc is a global biopharmaceutical company whose purpose is to innovate to transform the lives of patients and their families. We are dedicated to developing life-changing medicines for people with serious diseases - often with limited or no therapeutic options. We have a diverse portfolio of marketed medicines and novel product candidates, from early- to late-stage development, in neuroscience and oncology. Within these therapeutic areas, we are identifying new options for patients by actively exploring small molecules and biologics, and through innovative delivery technologies and cannabinoid science.

Our lead marketed products are:

Neuroscience

- **Xywav® (calcium, magnesium, potassium, and sodium oxybates) oral solution**, a product that contains 92% less sodium than Xyrem, approved by FDA and launched in the U.S. in November 2020 for the treatment of cataplexy or EDS in narcolepsy patients seven years of age and older and approved by FDA in August 2021 for the treatment of adults with idiopathic hypersomnia and launched in the U.S. in November 2021;
- **Xyrem® (sodium oxybate) oral solution**, a product approved by the U.S. Food and Drug Administration, or FDA, and marketed in the U.S. for the treatment of both cataplexy and excessive daytime sleepiness, or EDS, in narcolepsy patients seven years of age and older; Jazz also markets Xyrem in Canada for the treatment of cataplexy in patients with narcolepsy;
- **Epidiolex® (cannabidiol) oral solution**, a product approved by FDA and launched in the U.S. in 2018 by GW Pharmaceuticals plc, or GW, for the treatments of seizures associated with Lennox-Gastaut syndrome, Dravet syndrome, or tuberous sclerosis complex in patients one year of age or older; in Europe (where it is marketed as Epidyolex®) and other markets, it is approved for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome, in conjunction with clobazam, in patients 2 years of age and older and for adjunctive treatment of seizures associated with tuberous sclerosis complex in patients 2 years of age and older (note that the clobazam restriction is limited to EU and UK);
- **Sunosi® (solriamfetol)**, a product approved by FDA and marketed in the U.S. and in Europe to improve wakefulness in adult patients with EDS associated with narcolepsy or obstructive sleep apnea; and
- **Sativex® (nabiximols) oral solution**, a product marketed in Europe as treatment for symptom improvement in adult patients with moderate to severe spasticity due to multiple sclerosis, or MS, who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity-related symptoms during an initial trial of therapy.

Oncology

- **Zepzelca® (lurbinectedin)**, a product approved by FDA in June 2020 and launched in the U.S. in July 2020 for the treatment of adult patients with metastatic small cell lung cancer, or SCLC, with disease progression on or after platinum-based chemotherapy; in Canada, Zepzelca was approved in September 2021 for the treatment of adults with Stage III or metastatic SCLC, who have progressed on or after platinum-containing therapy;
- **Rylaze™** (recombinant Erwinia asparaginase), a product approved by FDA in June 2021 and launched in the U.S. in July 2021 for use as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia, or ALL, or lymphoblastic lymphoma, or LBL, in adults and pediatric patients who have developed hypersensitivity or silent inactivation to *E. coli*-derived asparaginase;
- **Vyxeos® (daunorubicin and cytarabine) liposome for injection**, a product approved in the U.S., Europe, U.K., and Canada (where it is marketed as Vyxeos® liposomal 44 mg/100 mg powder for concentrate for solution for infusion) for the treatment of adults with newly-diagnosed therapy-related acute myeloid leukemia, or AML, or AML with myelodysplasia-related changes; and

- **Defitelio® (defibrotide sodium)**, a product approved in the U.S. for the treatment of adult and pediatric patients with hepatic veno-occlusive disease, or VOD, also known as sinusoidal obstruction syndrome, with renal or pulmonary dysfunction following hematopoietic stem cell transplantation, or HSCT, and Internationally (where it is marketed as Defitelio® (defibrotide)) for the treatment of severe VOD in adults and children following HSCT therapy.

In May 2021, we acquired GW with the objectives of broadening our neuroscience portfolio, further diversifying our revenue and driving sustainable, long-term value creation opportunities. The total consideration paid by us for the entire issued share capital of GW was $7.2 billion. The acquisition, which we refer to as the GW Acquisition, closed on May 5, 2021. For further information regarding the GW Acquisition, please see Note 2.

Throughout this report, unless otherwise indicated or the context otherwise requires, all references to “Jazz Pharmaceuticals,” “the registrant,” "the Company", “we,” “us,” and “our” refer to Jazz Pharmaceuticals plc and its consolidated subsidiaries. Throughout this report, all references to “ordinary shares” refer to Jazz Pharmaceuticals plc’s ordinary shares.

Basis of Presentation

These unaudited condensed consolidated financial statements have been prepared following the requirements of the U.S. Securities and Exchange Commission for interim reporting. As permitted under those rules, certain footnotes and other financial information that are normally required by U.S. generally accepted accounting principles, or U.S. GAAP, can be condensed or omitted. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with our annual consolidated financial statements and accompanying notes included in our Annual Report on Form 10-K for the year ended December 31, 2020.

In the opinion of management, these condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and include all adjustments, consisting only of normal recurring adjustments, considered necessary for the fair presentation of our financial position and operating results. The results for the three and nine months ended September 30, 2021 are not necessarily indicative of the results to be expected for the year ending December 31, 2021, for any other interim period or for any future period.

Our significant accounting policies have not changed substantially from those previously described in our Annual Report on Form 10-K for the year ended December 31, 2020, other than as described below.

These condensed consolidated financial statements include the accounts of Jazz Pharmaceuticals plc and our subsidiaries, and intercompany transactions and balances have been eliminated.

The results of operations of the acquired GW business, along with the estimated fair values of the assets acquired and liabilities assumed in the GW Acquisition, have been included in our condensed consolidated financial statements since the closing of the GW Acquisition on May 5, 2021.

Our operating segment is reported in a manner consistent with the internal reporting provided to the chief operating decision maker, or CODM. Our CODM has been identified as our chief executive officer. We have determined that we operate in one business segment, which is the identification, development and commercialization of meaningful pharmaceutical products that address unmet medical needs.

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, liabilities, revenues and expenses, and related disclosures in the condensed consolidated financial statements and accompanying notes. Management bases its estimates on historical experience and on assumptions believed to be reasonable under the circumstances. Actual results could differ materially from those estimates.

Adoption of New Accounting Standards

In December 2019, the Financial Accounting Standards Board, or FASB, issued ASU No. 2019-12, "Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes", which simplifies the accounting for income taxes by removing certain exceptions to the general principles in the existing guidance for income taxes and making other minor improvements. We adopted this standard on January 1, 2021 and adoption did not have a material impact on our consolidated financial statements.

Performance-Based Restricted Stock Unit Awards

Performance-based restricted stock units, or PRSUs, awarded to employees vest upon the achievement of certain performance criteria at the end of a specified performance period, subject to a relative total shareholder return, or TSR, modifier. The estimated fair value of these PRSUs is based on a Monte Carlo simulation model. Compensation expense for PRSUs is recognized from the date the Company determines the performance criteria probable of being achieved to the date the award, or relevant portion of the award, is expected to vest. Cumulative adjustments are recorded on a quarterly basis to reflect subsequent changes to the estimated outcome of the performance criteria until the date results are determined.

Inventories

Inventories are valued at the lower of cost or net realizable value. Cost is determined using the first-in, first-out method for all inventories. Our policy is to write down inventory that has become obsolete, inventory that has a cost basis in excess of its expected net realizable value and inventory in excess of expected requirements. The estimate of excess quantities is subjective and primarily dependent on our estimates of future demand for a particular product. If our estimate of future demand changes, we consider the impact on the reserve for excess inventory and adjust the reserve as required. Increases in the reserve are recorded as charges in cost of product sales.

We capitalize inventory costs associated with our products prior to 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 as research and development. The determination to capitalize inventory costs is based on various factors, including status and expectations of the regulatory approval process, any known safety or efficacy concerns, potential labeling restrictions, and any other impediments to obtaining regulatory approval. We had no pre-approval inventory on our condensed consolidated balance sheets as of September 30, 2021 or December 31, 2020.

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

Derivative Instruments and Hedging Activities

We record the fair value of derivative instruments as either assets or liabilities on the condensed consolidated balance sheets. Changes in the fair value of derivative instruments are recorded each period in current earnings or other comprehensive income (loss), depending on whether a derivative instrument is designated as part of a hedging transaction and, if it is, the type of hedging transaction. For a derivative to qualify as a hedge at inception and throughout the hedged period, we formally document the nature and relationships between the hedging instruments and hedged item.

For derivatives formally designated as hedges, we assess both at inception and quarterly thereafter, whether the hedging derivatives are highly effective in offsetting changes in either the fair value or cash flows of the hedged item.

Gains or losses on cash flow hedges are reclassified from other comprehensive income (loss) to earnings when the hedged transaction occurs. If we determine that a forecasted transaction is no longer probable of occurring, we discontinue hedge accounting and any related unrealized gain or loss on the derivative instrument is recognized in current earnings.

We designate cross-currency interest rate swaps as fair value hedges to hedge foreign currency risks related to our borrowings denominated in currencies other than the U.S. dollar. Fair value hedge amounts included in the assessment of hedge effectiveness are recognized in foreign exchange gain (loss) within the condensed consolidated statements of income (loss), along with the offsetting gains and losses of the related hedged item. We have elected to exclude the total forward points or currency basis from the assessment of hedge effectiveness and account for them as excluded components. The initial fair value of the excluded component is amortized to foreign exchange gain (loss) and the difference between changes in fair value of the excluded component and the amount recorded in earnings is recorded in other comprehensive income (loss).

Derivatives that are not designated and do not qualify as hedges are adjusted to fair value through current earnings.

Variable Interest Entity

In the nine months ended September 30, 2021, we invested in a cell of a protected cell company, or the protected cell, as part of our directors’ and officers’ liability risk financing strategy. Based on our control and the structure of the protected cell, we concluded that Jazz is the primary beneficiary of the protected cell and is required to consolidate the protected cell. The insurance premium payable to the protected cell for the three and nine months ended September 30, 2021 and the protected cell’s assets and liabilities as of September 30, 2021 were immaterial.

Significant Risks and Uncertainties

We have implemented a comprehensive response strategy designed to manage the ongoing impact of the COVID-19 pandemic on our employees, patients and our business. The prolonged nature of the pandemic is negatively impacting our business in a limited and varied manner due to the emergence of the Delta variant and other variants with increased transmissibility, even in some cases in vaccinated people, limited access to health care provider offices and institutions and the willingness of patients or parents of patients to seek treatment. We expect that our business, financial condition, results of operations and growth prospects may continue to be negatively impacted by the pandemic on a limited basis that may vary depending on the context. With respect to our commercialization activities, while there continues to be some negative impact on demand, new patient starts and treatments for our products arising from the pandemic, primarily due to the inherent limitations of telemedicine and a reprioritization of healthcare resources toward COVID-19, we have seen improvements as healthcare systems have adapted to cope with the ongoing situation. However, for Epidiolex/Epidyolex, reports from the field indicate that COVID-19 and the lack of access to and limited availability of COVID-19 vaccines, especially for children under 12 years of age, have impacted the willingness of parents of pediatric patients to bring their children to a health care provider office, which can increase the risk of COVID exposure through contact with the healthcare system. We believe these dynamics have negatively impacted new patient starts in the U.S. and Europe. The extent of the impact on our ability to generate sales of approved products, execute on new product launches, our clinical development and regulatory efforts, our corporate development objectives and the value of and market for our ordinary shares, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time. Such developments include continued spread of the Delta variant in the U.S. and other countries and the potential emergence of other SARS-CoV-2 variants that may prove especially contagious or virulent, the ultimate duration and severity of the pandemic, governmental “stay-at-home” orders and travel restrictions, quarantines, social distancing and business closure requirements in the U.S., Ireland and other countries, and the effectiveness of vaccination programs and other actions taken globally to contain and treat the disease.

Our business has been substantially dependent on Xyrem and while we expect that our business will continue to be substantially dependent on oxybate product sales from both Xyrem and Xywav, there is no guarantee that we can maintain oxybate revenues at or near current levels, or that oxybate revenues will continue to grow. Our ability to maintain or increase oxybate revenues and realize the anticipated benefits from our investment in Xywav are subject to a number of risks and uncertainties including, without limitation, those related to the launch of Xywav for the treatment of idiopathic hypersomnia in adults and adoption in that indication; competition from the introduction of authorized generic and generic versions of sodium oxybate and new products for treatment of cataplexy and/or EDS in narcolepsy in the U.S. market and from other competitors; the current and potential impacts of the COVID-19 pandemic, including the current and expected future negative impact on demand for our products; increased pricing pressure from, changes in policies by, or restrictions on reimbursement imposed by, third party payors, including our ability to maintain adequate coverage and reimbursement for Xywav; increased rebates required to maintain access to our products; challenges to our intellectual property around Xyrem and/or Xywav, including pending antitrust and intellectual property litigation; and continued acceptance of Xyrem by physicians and patients and acceptance of Xywav by payors, physicians and patients.

In addition to risks related specifically to Xyrem and Xywav, we are subject to other challenges and risks related to successfully commercializing a portfolio of oncology products and other neuroscience products, including Epidiolex, Sunosi, Defitelio, Vyxeos, Rylaze and Zepzelca, and other risks specific to our business and our ability to execute on our strategy, as well as risks and uncertainties common to companies in the pharmaceutical industry with development and commercial operations, including, without limitation, risks and uncertainties associated with: ongoing clinical research activity and related outcomes, obtaining regulatory approval of our late-stage product candidates; effectively commercializing our recently approved or acquired products such as Xywav, Epidiolex, Zepzelca, Rylaze and Sunosi; obtaining and maintaining adequate coverage and reimbursement for our products; contracting and rebates to pharmacy benefit managers that reduces our net revenue; increasing scrutiny of pharmaceutical product pricing and resulting changes in healthcare laws and policy; market acceptance; regulatory concerns with controlled substances generally and the potential for abuse; future legislation, DEA action or FDA action authorizing the sale, distribution, use, and insurance reimbursement of non-FDA approved cannabinoid products; delays or problems in the supply of our products, loss of single source suppliers or failure to comply with manufacturing regulations; delays or problems with third parties that are part of our manufacturing and supply chain; identifying, acquiring or in-licensing additional products or product candidates; pharmaceutical product development and the inherent uncertainty of clinical success; the challenges of protecting and enhancing our intellectual property rights; complying with applicable regulatory requirements; and possible restrictions on our ability and flexibility to pursue certain future opportunities as a result of our substantial outstanding debt obligations. In addition, the success of the GW acquisition will depend, in part, on our ability to realize the anticipated benefits from successfully combining our and GW's historical businesses and the integration of our business practices and operations with GW's so that we can fully realize the anticipated benefits of the acquisition. The anticipated benefits to us of the GW Acquisition may not be realized fully within the expected timeframe or at all or may take longer to realize or cost more than expected, which could materially and adversely affect our business, financial condition, results of operations and growth prospects. Moreover, to the extent the COVID-19 pandemic continues to adversely affect our

business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties discussed above.

Concentrations of Risk

Financial instruments that potentially subject us to concentrations of credit risk consist of cash, cash equivalents, investments and derivative contracts. Our investment policy permits investments in U.S. federal government and federal agency securities, corporate bonds or commercial paper issued by U.S. corporations, money market instruments, certain qualifying money market mutual funds, certain repurchase agreements, and tax-exempt obligations of U.S. states, agencies and municipalities and places restrictions on credit ratings, maturities, and concentration by type and issuer. We are exposed to credit risk in the event of a default by the financial institutions holding our cash, cash equivalents and investments to the extent recorded on the balance sheet.

We manage our foreign currency transaction risk and interest rate risk within specified guidelines through the use of derivatives. All of our derivative instruments are utilized for risk management purposes, and we do not use derivatives for speculative trading purposes. As of September 30, 2021, we had foreign exchange forward contracts with notional amounts totaling $407.7 million. As of September 30, 2021, the outstanding foreign exchange forward contracts had a net liability fair value of $9.3 million. As of September 30, 2021, we had a cross-currency interest rate swap contract with a notional amount of $502.0 million. This outstanding cross-currency interest rate swap contract had a net liability fair value of $20.0 million as of September 30, 2021. The counterparties to these contracts are large multinational commercial banks, and we believe the risk of nonperformance is not significant.

We are also subject to credit risk from our accounts receivable related to our product sales. We monitor our exposure within accounts receivable and record a reserve against uncollectible accounts receivable as necessary. We extend credit to pharmaceutical wholesale distributors and specialty pharmaceutical distribution companies, primarily in the U.S., and to other international distributors and hospitals. Customer creditworthiness is monitored and collateral is not required. We monitor economic conditions in certain European countries which may result in variability of the timing of cash receipts and an increase in the average length of time that it takes to collect accounts receivable outstanding. Historically, we have not experienced significant credit losses on our accounts receivable and as of September 30, 2021 and December 31, 2020, allowances on receivables were not material. As of September 30, 2021, three customers accounted for 77% of gross accounts receivable, Express Scripts Specialty Distribution Services, Inc. and its affiliates, or ESSDS, which accounted for 57% of gross accounts receivable, McKesson Corporation and affiliates, or McKesson, which accounted for 11% of gross accounts receivable, and Cardinal Health, Inc., or Cardinal, which accounted for 9% of gross accounts receivable. As of December 31, 2020, three customers accounted for 84% of gross accounts receivable, ESSDS, which accounted for 68% of gross accounts receivable, McKesson, which accounted for 12% of gross accounts receivable, and Cardinal, which accounted for 4% of gross accounts receivable.

We depend on single source suppliers for most of our products, product candidates and their active pharmaceutical ingredients, or APIs. With respect to our oxybate products, the API is manufactured for us by a single source supplier and the finished products are manufactured both by us in our facility in Athlone, Ireland and by our U.S.-based supplier.

Recent Accounting Pronouncements

In August 2020, the FASB issued ASU No. 2020-06, “Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging— Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity”, which simplifies the accounting for convertible instruments by eliminating the requirement to separate embedded conversion features from the host contract when the conversion features are not required to be accounted for as derivatives under Topic 815, Derivatives and Hedging, or that do not result in substantial premiums accounted for as paid-in capital. By removing the separation model, a convertible debt instrument will be reported as a single liability instrument with no separate accounting for embedded conversion features. This new standard also removes certain settlement conditions that are required for contracts to qualify for equity classification and eliminates the treasury stock method to calculate diluted earnings per share for convertible instruments and requires the use of the if-converted method. This new standard will be effective for us for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than the fiscal year beginning after December 15, 2020. We may elect to apply the amendments on a retrospective or modified retrospective basis. We are currently evaluating the method of adoption and overall impact of this standard on our consolidated financial statements.

2. Business Combination

GW Acquisition

On May 5, 2021, or the Closing Date, we acquired the entire issued share capital of GW. As a result, GW became an indirect wholly owned subsidiary of the Company.

We acquired GW with the objective of broadening our neuroscience portfolio, further diversifying our revenue and driving sustainable, long-term value creation opportunities. GW was a global leader in discovering, developing, manufacturing and commercializing novel, regulatory approved therapeutics from its proprietary cannabinoid research platform to address a broad range of diseases.

The aggregate consideration for the GW Acquisition was $7.2 billion as follows (all amounts in thousands except American Depositary Shares, or ADS, and per GW ADS amounts):

GW ADS outstanding May 5, 2021		31,556,200
Cash consideration per GW ADS	$	200
Total cash consideration to GW ADS holders	$	6,311,240
Cash consideration to GW share option holders (inclusive of payroll taxes)		267,450
Total cash consideration		6,578,690
Equity consideration to GW ADS holders (1)		608,456
Consideration related to replacement share option pre-combination service		3,555
Total equity consideration		612,011
Total purchase consideration	$	7,190,701

(1) 3.8 million ordinary shares were issued to GW ADS holders. The closing price of the ordinary shares on May 4, 2021 ($160.20) was used to determine the fair value of this equity consideration because the closing of the transaction on May 5, 2021 occurred prior to the opening of regular trading.

In April 2021, we closed an offering of $1.5 billion in aggregate principal amount of 4.375% senior secured notes, due 2029, or the Secured Notes. In May 2021, we entered into a credit agreement, or the Credit Agreement, that provides for (i) a seven-year $3.1 billion term loan B facility, or the Dollar Term Loan, (ii) a seven-year €625.0 million term loan B facility, or the Euro Term Loan and, together with the Dollar Term Loan, collectively known as the Term Loan and (iii) a five-year $500.0 million revolving credit facility, or the Revolving Credit Facility. We financed the cash portion of the GW Acquisition consideration through a combination of cash on hand and borrowings under the Term Loan and the Secured Notes. For further information on the Term Loan and the Secured Notes, please see Note 9.

The GW Acquisition was accounted for as a business combination using the acquisition method under which assets and liabilities of GW were recorded at their respective estimated fair values as of the Closing Date and added to the assets and liabilities of the Company, including an amount for goodwill representing the difference between the acquisition consideration and the estimated fair value of the identifiable net assets. The results of operations of GW and the estimated fair values of the assets acquired and liabilities assumed have been included in our condensed consolidated financial statements since the Closing Date.

In the three and nine months ended September 30, 2021, we incurred $1.4 million and $85.4 million, respectively, in acquisition-related costs related to the GW Acquisition, which primarily consisted of banking, legal, accounting and valuation-related expenses. These expenses were recorded in selling, general and administrative expense in the accompanying condensed consolidated statements of income (loss).

During the three and nine months ended September 30, 2021, our condensed consolidated statements of income (loss) included revenues of $166.5 million and $277.9 million, and a net loss of $158.1 million and $552.7 million, respectively, from the acquired GW business, as measured from the Closing Date.

The fair values of assets acquired and liabilities assumed at the Closing Date are summarized below (in thousands):

	Estimated fair values of assets acquired and liabilities assumed
Cash and cash equivalents	$ 343,898
Accounts receivable	76,355
Inventory	1,206,290
Prepaid expenses and other current assets	72,758
Property, plant and equipment	154,407
Acquired developed technologies	5,480,000
In-process research and development	160,000
Total acquired identifiable intangible assets	5,640,000
Goodwill	947,831
Deferred tax liabilities, net	(1,083,673)
Accrued liabilities	(131,971)
Other assets/liabilities	(35,194)
Total purchase consideration	$ 7,190,701

The fair value estimates for the assets acquired and liabilities assumed were based upon preliminary calculations, and our estimates and assumptions are subject to change as we obtain additional information for our estimates during the measurement period (up to one year from the Closing Date).

Inventory

Inventories acquired included raw materials, work in progress and finished goods. Inventories were recorded at their estimated fair values. The inventory was valued at estimated selling price less the estimated costs to be incurred to complete (in the case of work in progress) and sell the inventory, the associated margins on these activities and holding costs. A step-up in value of inventory of $1,062.6 million was recorded in connection with the GW Acquisition. The step-up expense will be recorded in cost of product sales on our condensed consolidated statements of income (loss) as the inventory is sold to customers from the Closing Date.

Intangible assets

The fair value of acquired intangible assets was $5,640.0 million. The intangible assets include acquired developed technologies, primarily related to Epidiolex, and in-process research and development, or IPR&D.

The fair value of the Epidiolex acquired developed technology asset was determined by applying the income approach, which recognizes that the fair value of an asset is premised upon the expected receipt of future economic benefits such as earnings and cash inflows based on current sales projections and estimated direct costs, using a discount rate of 9.4% that reflects the return requirements of the market. This intangible asset is being amortized over an estimated useful life of 12 years.

Acquired IPR&D relates to nabiximols, which is currently in Phase 3 clinical trials for the treatment of spasticity associated with multiple sclerosis and spinal cord injury. The fair value of acquired IPR&D was determined using the income approach, including the application of probability factors related to the likelihood of success of nabiximols reaching final development and commercialization. The fair value of acquired IPR&D was capitalized as of the Closing Date and is subsequently accounted for as an indefinite-lived intangible asset until completion or abandonment of the associated research and development efforts. Accordingly, during the development period after the Closing Date, this asset will not be amortized into earnings; instead, it will be subject to periodic impairment testing.

Some of the more significant assumptions inherent in the development of intangible asset fair values include: the amount and timing of projected future cash flows (including revenue, cost of sales, research and development cost and sales and marketing expenses); probability of success; the discount rate selected to measure inherent risk of future cash flows; and the assessment of the asset’s life cycle and the competitive trends impacting the asset, among other factors.

Deferred tax liabilities, net

The net deferred tax liability relates to the difference between the book basis and tax basis of acquired intangible assets and inventory, partially offset by acquired net operating losses and temporary differences.

Other tangible assets and liabilities

Other tangible assets and liabilities were valued at their respective carrying amounts as management believes that these amounts approximated their acquisition-date fair values.

Goodwill

Goodwill represents the excess of the total purchase consideration over the estimated fair value of net assets acquired and was recorded in the consolidated balance sheet as of the Closing Date. The goodwill was primarily attributable to the establishment of the deferred tax liability for the acquired intangible assets and inventory. We do not expect any portion of this goodwill to be deductible for tax purposes.

Pro Forma Financial Information (Unaudited)

The following unaudited supplemental pro forma information presents the combined historical results of income (loss) of the Company and GW for the three and nine months ended September 30, 2021 and 2020, respectively, as if the GW Acquisition had been completed on January 1, 2020. The primary pro forma adjustments include:

- The exclusion of acquisition-related and integration expenses of $30.5 million and $330.4 million in the three and nine months ended September 30, 2021 and related tax provision of $2.9 million and $24.7 million in each period, respectively. The inclusion of acquisition-related and integration expenses of $25.8 million and $373.5 million in the three and nine months ended September 30, 2020 and related tax benefit of $2.5 million and $29.3 million in each period, respectively.
- No impact on the amortization expense in the three months ended September 30, 2021. An increase in amortization expense of $159.1 million in the nine months ended September 30, 2021 and related tax benefit of $30.2 million. An increase in amortization expense of $116.2 million and $348.5 million in the three and nine months ended September 30, 2020 and related tax benefit of $22.1 million and $66.2 million, in each period, respectively.
- A decrease of $6.4 million and an increase of $80.1 million in cost of product sales in the three and nine months ended September 30, 2021 and related tax provision of $2.7 million and tax benefit of $12.0 million in each period, respectively. An increase in cost of product sales of $74.1 million and $222.2 million in the three and nine months ended September 30, 2020 and related tax benefit of $14.9 million and $44.7 million, in each period, respectively.
- A decrease of $9.5 million and an increase of $65.2 million in interest expense in the three and nine months ended September 30, 2021 and related tax provision of $2.0 million and tax benefit of $14.6 million, in each period, respectively. An increase in interest expense of $64.5 million and $179.0 million in the three and nine months ended September 30, 2020 and related tax benefit of $14.0 million and $39.5 million, in each period, respectively. The increase in interest arose on additional borrowings made to partially fund the GW Acquisition as if the borrowings had occurred on January 1, 2020.

The unaudited pro forma results do not assume any operating efficiencies as a result of the consolidation of operations and are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Total revenues	$ 838,115	$ 737,941	$ 2,397,966	$ 2,077,033
Net loss	$ (13,948)	$ (91,077)	$ (424,783)	$ (867,236)

3. Cash and Available-for-Sale Securities

Cash, cash equivalents and investments consisted of the following (in thousands):

	September 30, 2021					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Investments
Cash	$ 436,082	$ —	$ —	$ 436,082	$ 436,082	$ —
Time deposits	130,000	—	—	130,000	130,000	—
Money market funds	105,697	—	—	105,697	105,697	—
Totals	$ 671,780	$ —	$ —	$ 671,780	$ 671,780	$ —

	December 31, 2020					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Investments
Cash	$ 517,117	$ —	$ —	$ 517,117	$ 517,117	$ —
Time deposits	1,360,000	—	—	1,360,000	285,000	1,075,000
Money market funds	255,652	—	—	255,652	255,652	—
Totals	$ 2,132,769	$ —	$ —	$ 2,132,769	$ 1,057,769	$ 1,075,000

Cash equivalents and investments are considered available-for-sale securities. We use the specific-identification method for calculating realized gains and losses on securities sold and include them in interest expense, net in the condensed consolidated statements of income (loss). Our investment balances comprised time deposits with original maturities of greater than three months and less than one year. Interest income from available-for-sale securities was $0.1 million and $1.7 million in the three and nine months ended September 30, 2021, respectively, and $2.1 million and $9.7 million in the three and nine months ended September 30, 2020, respectively.

4. Fair Value Measurement

The following table summarizes, by major security type, our available-for-sale securities and derivative contracts as of September 30, 2021 and December 31, 2020 that were measured at fair value on a recurring basis and were categorized using the fair value hierarchy (in thousands):

	September 30, 2021			December 31, 2020		
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Total Estimated Fair Value
Assets:						
Available-for-sale securities:						
Money market funds	$ 105,697	$ —	$ 105,697	$ 255,652	$ —	$ 255,652
Time deposits	—	130,000	130,000	—	1,360,000	1,360,000
Foreign exchange forward contracts	—	1,203	1,203	—	11,907	11,907
Totals	$ 105,697	$ 131,203	$ 236,900	$ 255,652	$ 1,371,907	$ 1,627,559
Liabilities:						
Cross-currency interest rate contracts	$ —	$ 19,964	$ 19,964	$ —	$ —	$ —
Foreign exchange forward contracts	—	10,529	10,529	—	790	790
Interest rate contracts	—	—	—	—	2,835	2,835
Totals	$ —	$ 30,493	$ 30,493	$ —	$ 3,625	$ 3,625

As of September 30, 2021, our available-for-sale securities included money market funds and time deposits and their carrying values were approximately equal to their fair values. Money market funds were measured using quoted prices in active markets, which represent Level 1 inputs and time deposits were measured at fair value using Level 2 inputs. Level 2 inputs, obtained from various third party data providers, represent quoted prices for similar assets in active markets, or these inputs were derived from observable market data, or if not directly observable, were derived from or corroborated by other observable market data.

Our derivative assets and liabilities include cross-currency interest rate and foreign exchange derivatives that are measured at fair value using observable market inputs such as forward rates, interest rates, our own credit risk as well as an evaluation of our counterparties' credit risks. Based on these inputs, the derivative assets and liabilities are classified within Level 2 of the fair value hierarchy. The interest rate swap agreements matured in July 2021.

There were no transfers between the different levels of the fair value hierarchy in 2021 or 2020.

As of September 30, 2021, the carrying amount of investments measured using the measurement alternative for equity investments without a readily determinable fair value was $5.0 million. The carrying amount, which is recorded within other non-current assets, is based on the latest observable transaction price.

As of September 30, 2021, the estimated fair values of our 1.50% exchangeable senior notes due 2024, or the 2024 Notes, and our 2.00% exchangeable senior notes due 2026, or the 2026 Notes, were approximately $583 million and $1.2 billion, respectively. The 2024 Notes and the 2026 Notes, together with the 1.875% exchangeable senior notes due 2021, or the 2021 Notes, that were repurchased on maturity on August 15, 2021, are collectively known as the Exchangeable Senior Notes. As of September 30, 2021, the estimated fair value of the Secured Notes, the Dollar Term Loan and the Euro Term Loan, were approximately $1.6 billion, $3.1 billion and $483 million, respectively. The fair values of each of these debt facilities was estimated using quoted market prices obtained from brokers (Level 2).

5. Derivative Instruments and Hedging Activities

We are exposed to certain risks arising from operating internationally, including fluctuations in foreign exchange rates primarily related to the translation of the Euro Term Loan and sterling and euro denominated net monetary liabilities, including intercompany balances, held by subsidiaries with a U.S. dollar functional currency. We manage these exposures within specified guidelines through the use of derivatives. All of our derivative instruments are utilized for risk management purposes, and we do not use derivatives for speculative trading purposes.

In order to hedge our exposure to foreign currency exchange risk associated with our Euro Term Loan, we entered into a cross-currency interest rate swap contract in May 2021 with a maturity date of March 31, 2022. The terms of this contract convert the principal repayments and interest payments on the Euro Term Loan into U.S. dollars. As of September 30, 2021, the cross-currency interest rate swap had a notional amount of $502.0 million which is designated for accounting purposes as a fair value hedge. The carrying amount of the Euro Term Loan and the fair value of the cross-currency interest rate swap contract will be remeasured with changes in the euro to U.S. dollar foreign exchange rates recognized within foreign exchange gain (loss) in the condensed consolidated statements of income (loss).

The impact on accumulated other comprehensive income (loss) and earnings from the cross-currency interest rate swap contract for the three and nine months ended September 30, 2021 was as follows (in thousands):

Cross-Currency Interest Rate Contract:	Three Months Ended September 30, 2021	Nine Months Ended September 30, 2021
Loss recognized in accumulated other comprehensive income (loss), net of tax	$ —	$ (375)
Loss reclassified from accumulated other comprehensive income (loss) to foreign exchange gain (loss)	84	84
Loss recognized in foreign exchange gain (loss)	(13,750)	(26,115)

During the next 12 months, we expect to reclassify $0.3 million of losses, net of tax, on the cross-currency interest rate contract recognized in accumulated other comprehensive income (loss) to foreign exchange gain (loss).

We also enter into foreign exchange forward contracts, with durations of up to 12 months, designed to limit the exposure to fluctuations in foreign exchange rates related to the translation of certain non-U.S. dollar denominated liabilities, including intercompany balances. Hedge accounting is not applied to these derivative instruments as gains and losses on these hedge transactions are designed to offset gains and losses on underlying balance sheet exposures. As of September 30, 2021 and December 31, 2020, the notional amount of foreign exchange contracts where hedge accounting is not applied was $407.7 million and $357.4 million, respectively.

The foreign exchange gain (loss) in our condensed consolidated statements of income (loss) included the following gains (losses) associated with foreign exchange contracts not designated as hedging instruments (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
Foreign Exchange Forward Contracts:	2021	2020	2021	2020
Gain (loss) recognized in foreign exchange gain (loss)	$ (8,231)	$ 9,549	$ (18,264)	$ 6,943

The cash flow effects of our derivative contracts for the nine months ended September 30, 2021 and 2020 are included within net cash provided by operating activities in the condensed consolidated statements of cash flows.

To achieve a desired mix of floating and fixed interest rates on our variable rate debt, we entered into interest rate swap agreements in March 2017. In May 2021, we repaid the term loan to which these interest rate swap agreements related, at which point the interest rate swap contracts were de-designated as cash flow hedges. The interest rate swap agreements matured in July 2021.

The impact on accumulated other comprehensive income (loss) and earnings from interest rate swap contracts for the three and nine months ended September 30, 2021 and 2020 was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
Interest Rate Contracts:	**2021**	**2020**	**2021**	**2020**
Gain (loss) recognized in accumulated other comprehensive income (loss), net of tax	$ —	$ 9	$ (14)	$ (4,515)
Loss reclassified from accumulated other comprehensive income (loss) to interest expense, net of tax	153	1,160	2,482	2,228

The following tables summarize the fair value of outstanding derivatives (in thousands):

	September 30, 2021			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	**Fair Value**	**Balance Sheet Location**	**Fair Value**
Derivatives designated as hedging instruments:				
Cross-currency interest rate contracts	Other current assets	$ —	Accrued liabilities	$ 19,964
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	1,203	Accrued liabilities	10,529
Total fair value of derivative instruments		$ 1,203		$ 30,493

	December 31, 2020			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	**Fair Value**	**Balance Sheet Location**	**Fair Value**
Derivatives designated as hedging instruments:				
Interest rate contracts	Other current assets	$ —	Accrued liabilities	$ 2,835
Derivatives not designated as hedging instruments:				
Foreign exchange forward contracts	Other current assets	11,907	Accrued liabilities	790
Total fair value of derivative instruments		$ 11,907		$ 3,625

Although we do not offset derivative assets and liabilities within our condensed consolidated balance sheets, our International Swap and Derivatives Association agreements provide for net settlement of transactions that are due to or from the same counterparty upon early termination of the agreement due to an event of default or other termination event. The following tables summarize the potential effect on our condensed consolidated balance sheets of offsetting our interest rate contracts and foreign exchange forward contracts subject to such provisions (in thousands):

	September 30, 2021					
				Gross Amounts Not Offset in the Consolidated Balance Sheet		
Description	Gross Amounts of Recognized Assets/ Liabilities	Gross Amounts Offset in the Consolidated Balance Sheet	Net Amounts of Assets/ Liabilities Presented in the Consolidated Balance Sheet	Derivative Financial Instruments	Cash Collateral Received (Pledged)	Net Amount
Derivative assets	$ 1,203	$ —	$ 1,203	$ (1,203)	$ —	$ —
Derivative liabilities	(30,493)	—	(30,493)	1,203	—	(29,290)

	December 31, 2020					
				Gross Amounts Not Offset in the Consolidated Balance Sheet		
Description	Gross Amounts of Recognized Assets/ Liabilities	Gross Amounts Offset in the Consolidated Balance Sheet	Net Amounts of Assets/ Liabilities Presented in the Consolidated Balance Sheet	Derivative Financial Instruments	Cash Collateral Received (Pledged)	Net Amount
Derivative assets	$ 11,907	$ —	$ 11,907	$ (2,207)	$ —	$ 9,700
Derivative liabilities	(3,625)	—	(3,625)	2,207	—	(1,418)

6. Inventories

Inventories consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Raw materials	$ 25,084	$ 16,003
Work in process	1,055,931	45,758
Finished goods	56,836	33,635
Total inventories	$ 1,137,851	$ 95,396

As of September 30, 2021, inventories included $884.0 million related to the purchase accounting inventory fair value step-up on inventory acquired in the GW Acquisition.

7. Goodwill and Intangible Assets

The gross carrying amount of goodwill was as follows (in thousands):

Balance at December 31, 2020	$ 958,303
Goodwill arising from the GW Acquisition	947,831
Foreign exchange	(56,587)
Balance at September 30, 2021	$ 1,849,547

The gross carrying amounts and net book values of our intangible assets were as follows (in thousands):

	September 30, 2021				December 31, 2020		
	Remaining Weighted-Average Useful Life (In years)	Gross Carrying Amount	Accumulated Amortization	Net Book Value	Gross Carrying Amount	Accumulated Amortization	Net Book Value
Acquired developed technologies	11.6	$ 8,176,060	$ (1,048,200)	$ 7,127,860	$ 3,379,162	$ (1,184,111)	$ 2,195,051
Manufacturing contracts	—	12,394	(12,394)	—	13,135	(13,135)	—
Trademarks	—	2,899	(2,899)	—	2,917	(2,917)	—
Total finite-lived intangible assets		8,191,353	(1,063,493)	7,127,860	3,395,214	(1,200,163)	2,195,051
Acquired IPR&D assets		154,719	—	154,719	—	—	—
Total intangible assets		$ 8,346,072	$ (1,063,493)	$ 7,282,579	$ 3,395,214	$ (1,200,163)	$ 2,195,051

The increase in the gross carrying amount of intangible assets as of September 30, 2021 compared to December 31, 2020 primarily reflects the intangible assets arising from the GW Acquisition, as described in Note 2, partially offset by the de-recognition of the fully amortized Erwinaze intangible assets and the negative impact of foreign currency translation adjustments due to the weakening of sterling and euro against the U.S. dollar.

The assumptions and estimates used to determine future cash flows and remaining useful lives of our intangible and other long-lived assets are complex and subjective. They can be affected by various factors, including external factors, such as industry and economic trends, and internal factors such as changes in our business strategy and our forecasts for specific product lines.

Based on finite-lived intangible assets recorded as of September 30, 2021, and assuming the underlying assets will not be impaired and that we will not change the expected lives of the assets, future amortization expenses were estimated as follows (in thousands):

Year Ending December 31,	Estimated Amortization Expense
2021 (remainder)	$ 156,233
2022	624,931
2023	624,931
2024	624,931
2025	624,931
Thereafter	4,471,903
Total	$ 7,127,860

8. Certain Balance Sheet Items

Property, plant and equipment consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Construction-in-progress	$ 83,549	$ 7,262
Manufacturing equipment and machinery	65,713	33,465
Land and buildings	65,385	47,555
Leasehold improvements	63,912	54,113
Computer software	25,817	22,781
Computer equipment	16,390	18,749
Furniture and fixtures	12,836	11,598
Subtotal	333,602	195,523
Less accumulated depreciation and amortization	(78,596)	(67,588)
Property, plant and equipment, net	$ 255,006	$ 127,935

Other current assets consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Deferred charge for taxes on intercompany profit	$ 183,833	$ 114,234
Other	41,265	38,257
Total other current assets	$ 225,098	$ 152,491

Accrued liabilities consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Rebates and other sales deductions	$ 207,793	$ 127,534
Employee compensation and benefits	160,581	102,601
Accrued interest	35,102	5,722
Derivative instrument liabilities	30,493	3,625
Clinical trial accruals	24,731	9,108
Accrued royalties	19,077	15,230
Selling and marketing accruals	18,372	6,742
Current portion of lease liabilities	17,045	14,457
Consulting and professional services	16,424	6,660
Sales return reserve	11,768	18,368
Inventory-related accruals	8,553	9,809
Accrued construction-in-progress	5,031	1,119
Other	48,745	31,757
Total accrued liabilities	$ 603,715	$ 352,732

9. Debt

The following table summarizes the carrying amount of our indebtedness (in thousands):

	September 30, 2021	December 31, 2020
2021 Notes	$ —	$ 218,812
Unamortized discount and debt issuance costs on 2021 Notes	—	(5,883)
2021 Notes, net	—	212,929
2024 Notes	575,000	575,000
Unamortized discount and debt issuance costs on 2024 Notes	(77,459)	(95,275)
2024 Notes, net	497,541	479,725
2026 Notes	1,000,000	1,000,000
Unamortized discount and debt issuance costs on 2026 Notes	(158,222)	(179,518)
2026 Notes, net	841,778	820,482
Secured Notes	1,472,909	—
Term Loan	3,466,059	581,702
Total debt	6,278,287	2,094,838
Less current portion	31,000	246,322
Total long-term debt	$ 6,247,287	$ 1,848,516

Credit Agreement

On May 5, 2021, the Company, Jazz Financing Lux S.à.r.l., or Jazz Lux, and certain of our other subsidiaries, as borrowers, (collectively with the Company and Jazz Lux, the "Borrowers"), entered into the Credit Agreement, that provides for (i) the Dollar Term Loan which was drawn by Jazz Lux on the Closing Date in U.S. dollars (ii) the Euro Term Loan which was drawn by Jazz Lux on the Closing Date in Euros and (iii) the Revolving Credit Facility, which is available to be drawn by any Borrower in U.S. dollars.

We used the proceeds from the Term Loan (i) to repay in full $575.9 million under that certain credit agreement, dated as of June 18, 2015 (as amended) among the Company, and certain of our other subsidiaries as borrowers, the lenders party thereto and Bank of America, N.A., as administrative agent and collateral agent, or the Existing Credit Agreement, (ii) to fund, in part, the cash consideration payable in connection with the GW Acquisition and (iii) to pay related fees and expenses. Upon the repayment in full of loans under the Existing Credit Agreement, it was terminated and all guarantees and liens thereunder were released.

Loans under the Term Loan and Revolving Credit Facility bear interest at a rate equal to (A) in the case of the Dollar Term Loan and the Revolving Credit Facility, at the applicable Borrower's option, either (a) London Inter-Bank Offered Rate, or LIBOR or (b) the prime lending rate and (B) in the case of the Euro Term Loan, Euro Inter-Bank Offered Rate, or EURIBOR, in each case, plus an applicable margin. The applicable margin for the Term Loan is 3.50% (in the case of LIBOR or EURIBOR borrowings) and 2.50% (in the case of borrowings at the prime lending rate). The applicable margin for the Revolving Credit Facility ranges from 3.25% to 2.75% (in the case of LIBOR borrowings) and 2.25% to 1.75% (in the case of borrowings at the prime lending rate), depending on our first lien secured net leverage ratio level. The Dollar Term Loan is subject to a LIBOR floor of 0.50%, the Euro Term Loan and loans under the Revolving Credit Facility are not subject to a EURIBOR or LIBOR (as applicable) floor. The Revolving Credit Facility has a commitment fee payable on the undrawn amount ranging from 0.50% to 0.40% per annum based upon our first lien secured net leverage ratio.

As of September 30, 2021, the interest rate and effective interest rate on the Dollar Term Loan were 4.00% and 4.55%, respectively. The interest rate and effective interest rate on the Euro Term Loan were 4.34% and 4.93%, respectively. As of September 30, 2021, we had an undrawn Revolving Credit Facility totaling $500.0 million.

The Borrowers' obligations under the Credit Agreement and any hedging or cash management obligations entered into with any lender thereunder are guaranteed by the Company, the other borrowers, and each of the Company's other existing or

subsequently acquired or organized direct and indirect subsidiaries (subject to certain exceptions), or the Guarantors. We refer to the Borrowers and the Guarantors collectively as the "Loan Parties."

The Loan Parties' obligations under the Credit Agreement are secured, subject to customary permitted liens and other exceptions, by a security interest in (a) all tangible and intangible assets of the Loan Parties, except for certain excluded assets, and (b) all of the equity interests of the subsidiaries of the Loan Parties held by the Loan Parties.

We may make voluntary prepayments at any time without payment of a premium or penalty, subject to certain exceptions, and are required to make certain mandatory prepayments of outstanding indebtedness under the Credit Agreement in certain circumstances.

Principal repayments of the Dollar Term Loan, which are due quarterly, began in September 2021 and are equal to 1.0% per annum of the original principal amount of $3.1 billion with any remaining balance payable on the maturity date. The Euro Term Loan does not have any mandatory principal repayments during its term, however in September 2021, we made a voluntary prepayment of €208.3 million or $251.0 million.

The Credit Agreement contains customary representations and warranties and customary affirmative and negative covenants applicable to the Company and its restricted subsidiaries, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of junior indebtedness and dividends and other distributions. The Credit Agreement contains financial covenants that require the Company and its restricted subsidiaries to (a) not exceed a maximum first lien secured net leverage ratio and (b) not fall below a minimum interest coverage ratio, provided that such covenants apply only to the Revolving Credit Facility and are applicable only if amounts are drawn (or non-cash collateralized letters of credit in excess of $50 million are outstanding) under the Revolving Credit Facility. The Credit Agreement also contains customary events of default relating to, among other things, failure to make payments, breach of covenants and breach of representations.

2029 Senior Secured Notes

On April 29, 2021, Jazz Securities Designated Activity Company, or Jazz Securities, a direct wholly owned subsidiary of the Company, closed the offering of the Secured Notes in a private placement. We used the proceeds from the Secured Notes to fund, in part, the cash consideration payable in connection with the GW Acquisition.

Interest on the Secured Notes is payable semi-annually in arrears on January 15 and July 15 of each year, beginning on January 15, 2022, at a rate of 4.375% per year. The Secured Notes mature on January 15, 2029.

The Secured Notes are jointly and severally guaranteed by the Company and each of its restricted subsidiaries, other than Jazz Securities, that is a borrower, or a guarantor, under the Credit Agreement. The Secured Notes and related guarantees are secured by a first priority lien (subject to permitted liens and certain other exceptions), equally and ratably with the Credit Agreement, on the collateral securing the Credit Agreement.

Except as described below, the Secured Notes may not be optionally redeemed before July 15, 2024. Thereafter, some or all of the Secured Notes, may be redeemed at any time and from time to time at a specified redemption prices, plus accrued and unpaid interest, if any, to, but excluding, to the redemption date. Jazz Securities may redeem all but not part of the Secured Notes at its option at any time in connection with certain tax-related events and may redeem some or all of the Secured Notes at any time and from time to time prior to July 15, 2024 at a price equal to 100% of the principal amount of the Secured Notes to be redeemed plus a "make whole" premium, plus accrued and unpaid interest, if any, to, but excluding, the redemption date. In addition, Jazz Securities may redeem up to 40% of the aggregate principal amount of the Secured Notes at any time and from time to time prior to July 15, 2024, with the net proceeds of certain equity offerings at a price of 104.375% of the principal amount of such Secured Notes, plus accrued and unpaid interest, if any, to, but excluding, the redemption date. In addition, during each of the three consecutive twelve-month periods commencing on the issue date of the Secured Notes, Jazz Securities may redeem up to 10% of the original aggregate initial principal amount of the Secured Notes at a redemption price of 103% of the principal amount of such Secured Notes, plus accrued and unpaid interest, if any, to, but excluding, the redemption date.

If Jazz undergoes a change of control, Jazz Securities will be required to make an offer to purchase all of the Secured Notes at a purchase price in cash equal to 101% of the principal amount thereof, plus accrued and unpaid interest, if any, to, but excluding, the date of repurchase, subject to certain exceptions.

The indenture governing the Secured Notes contains customary affirmative covenants and negative covenants applicable to the Company and its restricted subsidiaries, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of junior indebtedness and dividends and other distributions. If Jazz Securities or the Company's restricted subsidiaries engage in certain asset sales, Jazz Securities will be required under certain circumstances to make an offer to purchase the Secured Notes at 100% of the principal amount, plus accrued and unpaid interest, if any, to, but excluding, the repurchase date.

As of September 30, 2021, the interest rate and effective interest rate on the Secured Notes were 4.375% and 4.64%, respectively.

Exchangeable Senior Notes

The Exchangeable Senior Notes were issued by Jazz Investments I Limited, or the Issuer, a 100%-owned finance subsidiary of the Company. The remaining outstanding Exchangeable Senior Notes are senior unsecured obligations of the Issuer and are fully and unconditionally guaranteed on a senior unsecured basis by the Company. No subsidiary of the Company guaranteed the Exchangeable Senior Notes. Subject to certain local law restrictions on payment of dividends, among other things, and potential negative tax consequences, we are not aware of any significant restrictions on the ability of the Company to obtain funds from the Issuer or the Company's other subsidiaries by dividend or loan, or any legal or economic restrictions on the ability of the Issuer or the Company's other subsidiaries to transfer funds to the Company in the form of cash dividends, loans or advances. There is no assurance that in the future such restrictions will not be adopted.

On August 15, 2021, the maturity date, we repurchased the remaining $218.8 million aggregate principal amount of the 2021 Notes.

As of September 30, 2021, the carrying values of the equity component of the 2024 Notes and the 2026 Notes, net of equity issuance costs, were $149.8 million and $176.3 million, respectively.

Maturities

Scheduled maturities with respect to our long-term debt principal balances outstanding as of September 30, 2021 were as follows (in thousands):

Year Ending December 31,	Scheduled Long-Term Debt Maturities
2021 (remainder)	$ 7,750
2022	31,000
2023	31,000
2024	606,000
2025	31,000
Thereafter	5,942,958
Total	$ 6,649,708

10. Leases

The components of the lease expense for the three and nine months ended September 30, 2021 and 2020 were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
Lease Cost	**2021**	**2020**	**2021**	**2020**
Operating lease cost	$ 6,632	$ 5,501	$ 18,782	$ 16,201
Short-term lease cost	1,712	943	4,566	2,704
Sublease income	—	—	—	(224)
Finance Lease Cost				
Amortization of leased asset	193	—	201	—
Interest on lease liabilities	114	—	185	—
Net lease cost	$ 8,651	$ 6,444	$ 23,734	$ 18,681

Supplemental balance sheet information related to operating and finance leases were as follows (in thousands):

Leases	Classification	September 30, 2021	December 31, 2020
Assets			
Operating lease assets	Operating lease assets	$ 89,628	$ 129,169
Finance lease assets	Property, plant and equipment	5,853	—
Total lease assets		$ 95,481	$ 129,169
Liabilities			
Current			
Operating lease liabilities	Accrued liabilities	$ 16,643	$ 14,457
Finance lease liabilities	Accrued liabilities	402	—
Non-current			
Operating lease liabilities	Operating lease liabilities, less current portion	89,359	140,035
Finance lease liabilities	Other non-current liabilities	6,360	—
Total lease liabilities		$ 112,764	$ 154,492

Lease Term and Discount Rate	September 30, 2021	December 31, 2020
Weighted-average remaining lease term (years)		
Operating leases	6.7	8.7
Finance leases	13.1	—
Weighted-average discount rate		
Operating leases	5.2 %	5.3 %
Finance leases	7.4 %	— %

Supplemental cash flow information related to operating and finance leases were as follows (in thousands):

	Nine Months Ended September 30,	
	2021	2020
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash outflows from operating leases	$ 19,707	$ 11,404
Operating cash outflows from finance leases	433	—
Financing cash outflows from finance leases	211	—
Non-cash operating activities:		
Operating lease assets obtained in exchange for new operating lease liabilities	$ 7,703	$ 533
Finance lease assets obtained in exchange for new finance lease liabilities	650	—
De-recognition of operating lease asset on lease assignment	56,968	—
De-recognition of operating lease liability on lease assignment	68,064	—

Maturities of operating and finance lease liabilities were as follows (in thousands):

Year Ending December 31,	Operating Leases	Finance Leases
2021 (remainder)	$ 4,059	$ 250
2022	20,777	873
2023	19,941	870
2024	20,892	870
2025	14,559	870
Thereafter	47,278	6,967
Total lease payments	127,506	10,700
Less imputed interest	(21,504)	(3,938)
Present value of lease liabilities	$ 106,002	$ 6,762

11. Commitments and Contingencies

Indemnification

In the normal course of business, we enter into agreements that contain a variety of representations and warranties and provide for general indemnification, including indemnification associated with product liability or infringement of intellectual property rights. Our exposure under these agreements is unknown because it involves future claims that may be made but have not yet been made against us. To date, we have not paid any claims or been required to defend any action related to these indemnification obligations.

We have agreed to indemnify our executive officers, directors and certain other employees for losses and costs incurred in connection with certain events or occurrences, including advancing money to cover certain costs, subject to certain limitations. The maximum potential amount of future payments we could be required to make under the indemnification obligations is unlimited; however, we maintain insurance policies that may limit our exposure and may enable us to recover a portion of any future amounts paid. Assuming the applicability of coverage, the willingness of the insurer to assume coverage, and subject to certain retention, loss limits and other policy provisions, we believe the fair value of these indemnification obligations is not significant. Accordingly, we did not recognize any liabilities relating to these obligations as of September 30, 2021 and December 31, 2020. No assurances can be given that the covering insurers will not attempt to dispute the validity, applicability, or amount of coverage without expensive litigation against these insurers, in which case we may incur substantial liabilities as a result of these indemnification obligations.

Other Commitments

As of September 30, 2021, we had $65.7 million of noncancelable purchase commitments due within one year, primarily related to agreements with third party manufacturers.

Legal Proceedings

We are involved in legal proceedings, including the following matters:

Xyrem Class Action

From June 2020 to October 2021, a number of class action lawsuits were filed on behalf of purported direct and indirect Xyrem purchasers, alleging that the patent litigation settlement agreements we entered with generic drug manufacturers who had filed Abbreviated New Drug Applications, or ANDA, filers violate state and federal antitrust and consumer protection laws, as follows:

On June 17, 2020, a class action lawsuit was filed in the United States District Court for the Northern District of Illinois by Blue Cross and Blue Shield Association, or BCBS, against Jazz Pharmaceuticals plc, Jazz Pharmaceuticals, Inc., and Jazz Pharmaceuticals Ireland Limited, or, collectively, the Company Defendants (hereinafter referred to as the BCBS Lawsuit). The BCBS Lawsuit also names Roxane Laboratories, Inc., Hikma Pharmaceuticals USA Inc., Eurohealth (USA), Inc., Hikma Pharmaceuticals plc, Amneal Pharmaceuticals LLC, Par Pharmaceuticals, Inc., Lupin Ltd., Lupin Pharmaceuticals Inc., and Lupin Inc., or, collectively, the BCBS Defendants.

On June 18 and June 23, 2020, respectively, two additional class action lawsuits were filed against the Company Defendants and the BCBS Defendants: one by the New York State Teamsters Council Health and Hospital Fund in the United States District Court for the Northern District of California, and another by the Government Employees Health Association Inc. in the United States District Court for the Northern District of Illinois (hereinafter referred to as the GEHA Lawsuit).

On June 18, 2020, a class action lawsuit was filed in the United States District Court for the Northern District of California by the City of Providence, Rhode Island, on behalf of itself and all others similarly situated, against Jazz Pharmaceuticals plc, and Roxane Laboratories, Inc., West-Ward Pharmaceuticals Corp., Hikma Labs Inc., Hikma Pharmaceuticals USA Inc., and Hikma Pharmaceuticals plc, or, collectively, the City of Providence Defendants.

On June 30, 2020, a class action lawsuit was filed in the United States District Court for the Northern District of Illinois by UFCW Local 1500 Welfare Fund on behalf of itself and all others similarly situated, against Jazz Pharmaceuticals Ireland Ltd., Jazz Pharmaceuticals, Inc., Roxane Laboratories, Inc., Hikma Pharmaceuticals plc, Eurohealth (USA), Inc. and West-Ward Pharmaceuticals Corp., or collectively the UFCW Defendants (hereinafter referred to as the UFCW Lawsuit).

On July 13, 2020, the plaintiffs in the BCBS Lawsuit and the GEHA Lawsuit dismissed their complaints in the United States District Court for the Northern District of Illinois and refiled their respective lawsuits in the United States District Court for the Northern District of California. On July 14, 2020, the plaintiffs in the UFCW Lawsuit dismissed their complaint in the United States District Court for the Northern District of Illinois and on July 15, 2020, refiled their lawsuit in the United States District Court for the Northern District of California.

On July 31, 2020, a class action lawsuit was filed in the United States District Court for the Southern District of New York by the A.F. of L.-A.G.C Building Trades Welfare Plan on behalf of itself and all others similarly situated, against Jazz Pharmaceuticals plc (hereinafter referred to as the AFL Plan Lawsuit). The AFL Plan Lawsuit also names Roxane Laboratories Inc., West-Ward Pharmaceuticals Corp., Hikma Labs Inc., Hikma Pharmaceuticals plc, Amneal Pharmaceuticals LLC, Par Pharmaceuticals Inc., Lupin Ltd., Lupin Pharmaceuticals, Inc., and Lupin Inc.

On August 14, 2020, an additional class action lawsuit was filed in the United States District Court for the Southern District of New York by the Self-Insured Schools of California on behalf of itself and all others similarly situated, against the Company Defendants, as well as Hikma Pharmaceuticals plc, Eurohealth (USA) Inc., Hikma Pharmaceuticals USA, Inc., West-Ward Pharmaceuticals Corp., Roxane Laboratories, Inc., Amneal Pharmaceuticals LLC, Endo International, plc, Endo Pharmaceuticals LLC, Par Pharmaceutical, Inc., Lupin Ltd., Lupin Pharmaceuticals Inc., Lupin Inc., Sun Pharmaceutical Industries Ltd., Sun Pharmaceutical Holdings USA, Inc., Sun Pharmaceutical Industries, Inc., Ranbaxy Laboratories Ltd., Teva Pharmaceutical Industries Ltd., Watson Laboratories, Inc., Wockhardt Ltd., Morton Grove Pharmaceuticals, Inc., Wockhardt USA LLC, Mallinckrodt plc, and Mallinckrodt LLC (hereinafter the Self-Insured Schools Lawsuit).

On September 16, 2020, an additional class action lawsuit was filed in the United States District Court for the Northern District of California, by Ruth Hollman on behalf of herself and all others similarly situated, against the same defendants named in the Self-Insured Schools Lawsuit.

In December 2020, the above cases were centralized and transferred to the United States District Court for the Northern District of California, where the multidistrict litigation will proceed for the purpose of discovery and pre-trial proceedings. In January 2021, the United States District Court for the Northern District of California issued a Case Management Order that schedules this case for trial in February 2023.

On March 18, 2021, United Healthcare Services, Inc. filed a lawsuit in the United States District Court for the District of Minnesota against the Company Defendants, Hikma Pharmaceuticals plc, Roxane Laboratories, Inc., Hikma Pharmaceuticals USA Inc., Eurohealth (USA) Inc., Amneal Pharmaceuticals LLC, Par Pharmaceutical Inc., Lupin Ltd., and Lupin Pharmaceuticals, Inc., raising similar allegations, or the UHS Lawsuit. On March 24, 2021, the U.S. Judicial Panel on Multidistrict Litigation conditionally transferred the UHS Lawsuit to the United States District Court for the Northern District of California, where it was consolidated for discovery and pre-trial proceedings with the other cases.

On August 13, 2021, the United States District Court for the Northern District of California granted in part and denied in part the Company Defendants motion to dismiss the complaints in the cases referenced above.

On October 8, 2021, Humana Inc. filed a lawsuit in the United States District Court for the Northern District of California against the Company Defendants, Hikma Pharmaceuticals plc, Hikma Pharmaceuticals USA Inc., Hikma Labs, Inc., Eurohealth (USA), Inc., Amneal Pharmaceuticals LLC, Par Pharmaceutical, Inc., Lupin Ltd., Lupin Pharmaceuticals, Inc., and Lupin Inc, raising similar allegations, or the Humana Lawsuit.

On October 8, 2021, Molina Healthcare Inc. filed a lawsuit in the United States District Court for the Northern District of California against the Company Defendants, Hikma Pharmaceuticals plc, Hikma Pharmaceuticals USA Inc., Hikma Labs, Inc., Eurohealth (USA), Inc., Amneal Pharmaceuticals LLC, Par Pharmaceutical, Inc., Lupin Ltd., Lupin Pharmaceuticals, Inc., and Lupin Inc, raising similar allegations, or the Molina Lawsuit.

The plaintiffs in certain of these lawsuits are seeking to represent a class of direct purchasers of Xyrem, and the plaintiffs in the remaining lawsuits are seeking to represent a class of indirect purchasers of Xyrem. Each of the lawsuits generally alleges violations of U.S. federal and state antitrust, consumer protection, and unfair competition laws in connection with the Company Defendants' conduct related to Xyrem, including actions leading up to, and entering into, patent litigation settlement agreements with each of the other named defendants. Each of the lawsuits seeks monetary damages, exemplary damages, equitable relief against the alleged unlawful conduct, including disgorgement of profits and restitution, and injunctive relief. It is possible that additional lawsuits will be filed against the Company Defendants making similar or related allegations. If the plaintiffs were to be successful in their claims, they may be entitled to injunctive relief or we may be required to pay significant monetary damages, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

GW Acquisition Litigation

On March 15, 2021, GW filed a definitive proxy statement, or Proxy Statement, with the Securities and Exchange Commission in connection with the GW Acquisition.

Since the filing of the Proxy Statement, Jazz Pharmaceuticals plc has been named in two lawsuits filed in state and federal courts in New York on March 17, 2021 by purported GW shareholders in connection with the GW Acquisition, the first was filed in the United States District Court for the Southern District New York by James Farrell, referred to as the Farrell Lawsuit, and an additional suit was filed in New York state court by Brian Levy, or the Levy Lawsuit. In addition to Jazz Pharmaceuticals plc, Jazz Pharmaceuticals UK Holdings Ltd., GW Pharmaceuticals plc, and the GW Board of Directors are named as defendants in the Farrell Lawsuit. In the Levy Lawsuit, GW Pharmaceuticals plc, the GW Board of Directors, Centerview Partners LLC, and Goldman Sachs & Co. LLC are named as defendants. In addition to the Farrell Lawsuit and the Levy Lawsuit, ten additional suits have been filed in New York, California, and Pennsylvania federal courts by purported GW shareholders against GW Pharmaceuticals plc and its Board of Directors, but which do not name any Jazz Pharmaceuticals parties, referred to as the GW Litigation, and collectively with the Farrell Lawsuit and the Levy Lawsuit, as the Transaction Litigation. In the Transaction Litigation, the plaintiffs allege that the Proxy Statement omitted material information and contained misrepresentations, and that the individual members of the GW Board of Directors breached their fiduciary duties, in violation of state and federal laws, including the Securities Exchange Act of 1934. The plaintiffs in the Transaction Litigation sought various remedies, including injunctive relief to prevent the consummation of the GW Acquisition unless certain allegedly material information was disclosed, or in the alternative, rescission or damages.

On April 14, 2021, GW filed a Form 8-K containing supplemental disclosures related to the GW Acquisition. Pursuant to a memorandum of understanding between the parties, the Levy Lawsuit was dismissed on April 14, 2021.

On May 27, 2021, a class action lawsuit was filed in the United States District Court for the Southern District of California by plaintiff Kurt Ziegler against GW and its former Directors asserting claims under Sections 14(a) and 20(a) of the Securities Exchange Act of 1934, referred to as the Ziegler Lawsuit. The allegations in the Ziegler Lawsuit are similar to those in the previously dismissed Transaction Litigation.

Patent Infringement Litigation

Avadel Patent Litigation

On May 13, 2021, we filed a patent infringement suit against Avadel Pharmaceuticals plc, or Avadel, and several of its corporate affiliates in the United States District Court for the District of Delaware. The suit alleges that Avadel's product candidate FT-218 will infringe five of our patents related to controlled release formulations of oxybate and the safe and effective distribution of oxybate. The suit seeks an injunction to prevent Avadel from launching a product that would infringe these patents, and an award of monetary damages if Avadel does launch an infringing product. Avadel filed an answer to the complaint and counterclaims asserting that the patents are invalid or not enforceable, and that its product, if approved, will not infringe our patents.

On August 4, 2021, we filed an additional patent infringement suit against Avadel in the United States District Court for the District of Delaware. The second suit alleges that Avadel's product candidate FT-218 will infringe a newly-issued patent related to sustained-release formulations of oxybate. The suit seeks an injunction to prevent Avadel from launching a product that would infringe this patent, and an award of monetary damages if Avadel does launch an infringing product. Avadel filed an answer to the complaint and counterclaims asserting that the patents are invalid or not enforceable, and that its product, if approved, will not infringe our patents.

Canopy Patent Litigation

In December 2020, Canopy Growth Corporation filed a complaint against our subsidiary, GW, in the United States District Court for the Western District of Texas, alleging infringement of its patent, U.S. Patent No. 10,870,632. Canopy claims that our extraction process used to produce material used to produce Epidiolex infringes its patent. Canopy seeks a judgment

that we have infringed their patent and an award of monetary damages. On July 28, 2021, we filed an answer to the amended complaint, and counterclaims seeking judgment that the ‘632 patent is invalid and that we have not infringed the patent. In October 2021, the United States District Court for the Western District of Texas held a claim construction hearing regarding the disputed terms of the ‘632 patent.

Lupin Patent Litigation

In June 2021, we received notice from Lupin Inc., or Lupin, that it has filed with FDA an ANDA, for a generic version of Xywav. The notice from Lupin included a “paragraph IV certification” with respect to ten of our patents listed in FDA’s Orange Book for Xywav on the date of our receipt of the notice. The asserted patents relate generally to the composition and method of use of Xywav, and methods of treatment when Xywav is administered concomitantly with certain other medications. A paragraph IV certification is a certification by a generic applicant that alleges that patents covering the branded product are invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the generic product.

In July 2021, we filed a patent infringement suit against Lupin in the United States District Court for the District of New Jersey. The complaint alleges that by filing its ANDA, Lupin has infringed ten of our Orange Book listed patents. We are seeking a permanent injunction to prevent Lupin from introducing a generic version of Xywav that would infringe our patents. As a result of this lawsuit, we expect that a stay of approval of up to 30 months will be imposed by FDA on Lupin's ANDA. In June 2021, FDA recognized seven years of Orphan Drug Exclusivity for Xywav through July 21, 2027. On October 4, 2021, Lupin filed an answer to the complaint and counterclaims asserting that the patents are invalid or not enforceable, and that its product, if approved, will not infringe our patents.

Otsuka Patent Litigation

In October 2021, Otsuka Pharmaceutical Co., Ltd., or Otsuka, filed claims against GW Pharma Limited and GW Pharmaceuticals Limited, or collectively, the GW Parties, in the English High Court, Patents Court. Otsuka alleges that under a now-expired Research Collaboration and License Agreement between Otsuka and the GW Parties, Otsuka and the GW Parties jointly own certain patents and other intellectual property, that Epidiolex is covered by that intellectual property, and that Otsuka is therefore due a royalty on net sales of Epidiolex.

The Company vigorously enforces its intellectual property rights, but cannot predict the outcome of these matters.

From time to time we are involved in legal proceedings arising in the ordinary course of business. We believe there is no other litigation pending that could have, individually or in the aggregate, a material adverse effect on our results of operations or financial condition.

12. Shareholders’ Equity

Share Repurchase Program

In November 2016, our board of directors authorized a share repurchase program and as of September 30, 2021 had authorized the repurchase of ordinary shares having an aggregate purchase price of up to $1.5 billion, exclusive of any brokerage commissions. Under this program, which has no expiration date, we may repurchase ordinary shares from time to time on the open market. The timing and amount of repurchases will depend on a variety of factors, including the price of our ordinary shares, alternative investment opportunities, restrictions under the Credit Agreement, corporate and regulatory requirements and market conditions. The share repurchase program may be modified, suspended or discontinued at any time without prior notice. During the three and nine months ended September 30, 2021, we did not repurchase any of our ordinary shares under the share repurchase program. As of September 30, 2021, the remaining amount authorized under the share repurchase program was $431.2 million.

Accumulated Other Comprehensive Income (Loss)

The components of accumulated other comprehensive income (loss) as of September 30, 2021 and December 31, 2020 were as follows (in thousands):

	Net Unrealized Loss From Hedging Activities	Foreign Currency Translation Adjustments	Total Accumulated Other Comprehensive Loss
Balance at December 31, 2020	$ (2,467)	$ (131,885)	$ (134,352)
Other comprehensive loss before reclassifications	(389)	(265,342)	(265,731)
Amounts reclassified from accumulated other comprehensive loss	2,566	—	2,566
Other comprehensive income (loss), net	2,177	(265,342)	(263,165)
Balance at September 30, 2021	$ (290)	$ (397,227)	$ (397,517)

During the nine months ended September 30, 2021, other comprehensive loss primarily reflects foreign currency translation adjustments, primarily due to the weakening of the sterling and the euro against the U.S. dollar.

13. Net Income (Loss) per Ordinary Share

Basic net income (loss) per ordinary share is based on the weighted-average number of ordinary shares outstanding. Diluted net income (loss) per ordinary share is based on the weighted-average number of ordinary shares outstanding and potentially dilutive ordinary shares outstanding.

Basic and diluted net income (loss) per ordinary share were computed as follows (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Numerator:				
Net income (loss)	$ (52,833)	$ 148,234	$ (294,317)	$ 105,202
Denominator:				
Weighted-average ordinary shares used in per share calculations - basic	61,284	55,545	59,084	55,637
Dilutive effect of employee equity incentive and purchase plans	—	691	—	660
Weighted-average ordinary shares used in per share calculations - diluted	61,284	56,236	59,084	56,297
Net income (loss) per ordinary share:				
Basic	$ (0.86)	$ 2.67	$ (4.98)	$ 1.89
Diluted	$ (0.86)	$ 2.64	$ (4.98)	$ 1.87

Potentially dilutive ordinary shares from our employee equity incentive and purchase plans and the Exchangeable Senior Notes are determined by applying the treasury stock method to the assumed exercise of share options, the assumed vesting of outstanding Restricted Stock Units, or RSUs and PRSUs, the assumed issuance of ordinary shares under our employee stock purchase plan, or ESPP, and the assumed issuance of ordinary shares upon exchange of the Exchangeable Senior Notes. The average price of our ordinary shares during the three months ended September 30, 2021 did not exceed the effective exchange price per ordinary share of the Exchangeable Senior Notes. The average price of our ordinary shares for the nine months ended September 30, 2021 exceeded the effective exchange price per ordinary share of the 2026 Notes. However, the potential ordinary shares issuable upon exchange were excluded from the calculation of diluted net loss per share because their effect would have been anti-dilutive. The average price of our ordinary shares during the nine months ended September 30, 2021 did not exceed the effective exchange price per ordinary share of the 2021 Notes and 2024 Notes. The potential issue of ordinary shares issuable upon exchange of the Exchangeable Senior Notes had no effect on diluted net income (loss) for the three and nine months ended September 30, 2020 as the average price of our ordinary shares during those periods did not exceed the effective exchange price per ordinary share of the Exchangeable Senior Notes.

The following table represents the weighted-average ordinary shares that were excluded from the calculation of diluted net income (loss) per ordinary share for the periods presented because including them would have an anti-dilutive effect (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Exchangeable Senior Notes	9,579	10,192	9,952	7,390
Employee equity incentive and purchase plans	4,302	5,023	3,375	5,325

14. Revenues

The following table presents a summary of total revenues (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Xyrem	$ 307,333	$ 447,809	$ 977,065	$ 1,302,492
Xywav	153,063	—	352,643	—
Total Oxybate	460,396	447,809	1,329,708	1,302,492
Epidiolex/Epidyolex	160,378	—	269,859	—
Sunosi	19,251	9,116	42,981	19,618
Sativex	6,097	—	8,058	—
Total Neuroscience	646,122	456,925	1,650,606	1,322,110
Zepzelca	71,714	36,941	181,972	36,941
Vyxeos	34,688	30,825	99,296	90,113
Defitelio/defibrotide	57,705	50,241	155,420	140,387
Rylaze	20,674	—	20,674	—
Erwinaze/Erwinase	—	20,145	69,382	90,560
Total Oncology	184,781	138,152	526,744	358,001
Other	3,344	1,872	8,768	5,246
Product sales, net	834,247	596,949	2,186,118	1,685,357
Royalties and contract revenues	3,868	3,939	11,389	12,693
Total revenues	$ 838,115	$ 600,888	$ 2,197,507	$ 1,698,050

The following table presents a summary of total revenues attributed to geographic sources (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
United States	$ 757,227	$ 547,715	$ 1,996,419	$ 1,540,906
Europe	70,730	45,778	164,540	125,229
All other	10,158	7,395	36,548	31,914
Total revenues	$ 838,115	$ 600,888	$ 2,197,507	$ 1,698,050

The following table presents a summary of the percentage of total revenues from customers that represented more than 10% of our total revenues:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
ESSDS	57 %	74 %	62 %	77 %
McKesson	11 %	10 %	12 %	11 %

Financing and payment

Our payment terms vary by the type and location of our customer but payment is generally required in a term ranging from 30 to 45 days.

Contract Liabilities - Deferred Revenue

The deferred revenue balance as of September 30, 2021 primarily related to deferred upfront fees received from Nippon Shinyaku Co., Ltd., or Nippon Shinyaku, in connection with two license, development and commercialization agreements granting Nippon Shinyaku exclusive rights to develop and commercialize each of Defitelio and Vyxeos in Japan. We recognized contract revenues of $0.7 million and $2.1 million during the three and nine months ended September 30, 2021, respectively, relating to these upfront payments. The deferred revenue balances are being recognized over an average of four years representing the period over which we expect to perform our research and developments obligations under each agreement.

The following table presents a reconciliation of our beginning and ending balances in contract liabilities from contracts with customers for the nine months ended September 30, 2021 (in thousands):

	Contract Liabilities
Balance as of December 31, 2020	$ 4,861
Additions	484
Amount recognized within royalties and contract revenues	(2,092)
Balance as of September 30, 2021	$ 3,253

15. Share-Based Compensation

Share-based compensation expense related to share options, RSUs, PRSUs and grants under our ESPP was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Selling, general and administrative	$ 39,117	$ 20,974	$ 97,296	$ 62,590
Research and development	11,866	7,463	31,749	21,511
Cost of product sales	2,256	1,919	6,842	5,513
Total share-based compensation expense, pre-tax	53,239	30,356	135,887	89,614
Income tax benefit from share-based compensation expense	(10,567)	(3,678)	(25,528)	(10,106)
Total share-based compensation expense, net of tax	$ 42,672	$ 26,678	$ 110,359	$ 79,508

Share Options

The table below shows the number of shares underlying options granted to purchase our ordinary shares, the weighted-average assumptions used in the Black-Scholes option pricing model and the resulting weighted-average grant date fair value of share options granted:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Shares underlying options granted (in thousands)	—	159	110	803
Grant date fair value	$ —	$ 37.75	$ 51.39	$ 34.43
Black-Scholes option pricing model assumption information:				
Volatility	— %	36 %	37 %	33 %
Expected term (years)	—	4.6	4.5	4.6
Range of risk-free rates	— %	0.2-0.3%	0.4-0.8%	0.2-1.6%
Expected dividend yield	— %	— %	— %	— %

Nominal Strike Price Options

During the second quarter of 2021, we issued nominal strike price share options to replace certain unvested GW awards in connection with the GW Acquisition.

The table below shows the number of nominal strike price options granted covering an equal number of our ordinary shares and the weighted-average grant date fair value:

	Nine Months Ended September 30, 2021
Nominal strike price share options granted (in thousands)	124
Grant date fair value	$ 170.82

Restricted Stock Units

The table below shows the number of RSUs granted covering an equal number of our ordinary shares and the weighted-average grant date fair value of RSUs granted:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
RSUs granted (in thousands)	75	160	1,707	1,248
Grant date fair value	$ 161.91	$ 123.79	$ 169.69	$ 114.80

The fair value of RSUs is determined on the date of grant based on the market price of our ordinary shares on that date. The fair value of RSUs is expensed ratably over the vesting period, generally over four years.

Performance-Based Restricted Stock Units

In May 2021, the Compensation & Management Development Committee of our board of directors approved awards of PRSUs to certain employees of the Company, subject to vesting on the achievement of certain commercial and pipeline performance criteria to be assessed over a performance period from the date of the grant to December 31, 2023. Following the determination of the Company's achievement with respect to the performance criteria, the amount of shares awarded will be subject to adjustment based on the application of a relative TSR modifier. The number of shares that may be earned ranges between 0% and 200% of the target number of PRSUs granted based on the degree of achievement of the applicable performance metric and the application of the relative TSR modifier.

The table below shows the number of PRSUs granted covering an equal number of our ordinary shares and the weighted-average grant date fair value of PRSUs granted:

	Nine Months Ended September 30, 2021
PRSUs granted (in thousands)	224
Grant date fair value	$ 190.81

As the PRSUs granted in May 2021 are subject to a market condition, the grant date fair value for such PRSUs was based on a Monte Carlo simulation model. The Company evaluated the performance targets in the context of its current long-range financial plan and its product candidate development pipeline and determined that attainment of each performance metric was probable at the target level of 100% as of September 30, 2021.

As of September 30, 2021, compensation cost not yet recognized related to unvested share options, RSUs and PRSUs was $47.9 million, $269.1 million and $27.2 million, respectively, which is expected to be recognized over a weighted-average period of 1.8 years, 2.7 years and 2.3 years, respectively.

16. Income Taxes

Our income tax benefit was $18.1 million and our income tax provision was $228.6 million in the three and nine months ended September 30, 2021, respectively, compared to our income tax provision of $19.3 million and $22.8 million, respectively for the same periods in 2020. Our income tax provision for the nine months ended September 30, 2021 included an expense of $250.6 million arising on the remeasurement of our U.K. net deferred tax liability, which arose primarily in relation to the GW Acquisition, due to a change in the statutory tax rate in the U.K. following enactment of the U.K. Finance Act 2021. Excluding this impact, the increase in benefit for income taxes in the three and nine months ended September 30, 2021 compared to the

same periods in 2020 resulted primarily from the mix of pre-tax income and losses incurred across tax jurisdictions and excess tax benefits recognized on share-based compensation. The income tax provision for the three months ended September 30, 2020 included the impact of the disallowance of certain interest deductions and provision for the settlement reached with the French tax authorities. The income tax provision for the nine months ended September 30, 2020 included the impact of the defibrotide acquired IPR&D asset impairment charge and the impact of the acquired IPR&D expense related to the Pharma Mar, S.A. transaction, partially offset by the impact of the disallowance of certain interest deductions and provision for the settlement reached with the French tax authorities. We do not provide for Irish income taxes on undistributed earnings of our foreign operations that are intended to be indefinitely reinvested in our foreign subsidiaries.

Our net deferred tax liability is primarily related to acquired intangible assets, and is net of deferred tax assets related to U.S. federal and state tax credits, U.S. federal and state and foreign net operating loss carryforwards and other temporary differences. We maintain a valuation allowance against certain foreign and U.S. deferred tax assets. Each reporting period, we evaluate the need for a valuation allowance on our deferred tax assets by jurisdiction and adjust our estimates as more information becomes available.

We are required to recognize the financial statement effects of a tax position when it is more likely than not, based on the technical merits, that the position will be sustained upon examination. As a result, we have recorded an unrecognized tax benefit for certain tax benefits which we judge may not be sustained upon examination. Our most significant tax jurisdictions are Ireland, the U.S. (both at the federal level and in various state jurisdictions) and the U.K. In Ireland we are no longer subject to income tax audits by taxing authorities for the years prior to 2016. The U.S. jurisdictions generally have statute of limitations three to four years from the later of the return due date or the date when the return was filed. However, in the U.S. (at the federal level and in most states), carryforwards that were generated in 2016 and earlier may still be adjusted upon examination by the tax authorities. In the U.K. we are no longer subject to income tax audits by taxing authorities for the years prior to 2017. During the nine months ended September 30, 2021 certain of our subsidiaries were under examination by the French tax authorities for the years ended December 31, 2012, 2013 and 2015 through 2019. Due to the subjective nature of the transfer pricing issues involved, the Company reached an agreement with the French tax authorities to settle the audits for all open years. The Company paid incremental taxes, interest and penalties of $19.7 million during the nine months ended September 30, 2021 to close the audit for all periods under examination. Certain of our Italian subsidiaries are currently under examination by the Italian tax authorities for the year ended December 31, 2017. Certain of our Luxembourg subsidiaries are currently under examination by the Luxembourg tax authorities for the years ended December 31, 2017 and 2018. Our German subsidiary is currently under examination by the German tax authorities for the years ended December 31, 2017, 2018 and 2019.

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

The following discussion of our financial condition and results of operations should be read in conjunction with the condensed consolidated financial statements and the notes to condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q. This discussion contains forward-looking statements that involve risks and uncertainties. When reviewing the discussion below, you should keep in mind the substantial risks and uncertainties that could impact our business. In particular, we encourage you to review the risks and uncertainties described in "Risk Factors" in Part II, Item 1A in this Quarterly Report on Form 10-Q. These risks and uncertainties could cause actual results to differ materially from those projected in forward-looking statements contained in this report or implied by past results and trends. Forward-looking statements are statements that attempt to forecast or anticipate future developments in our business, financial condition or results of operations. See the "Cautionary Note Regarding Forward-Looking Statements" that appears at the end of this discussion. These statements, like all statements in this report, speak only as of the date of this Quarterly Report on Form 10-Q (unless another date is indicated), and we undertake no obligation to update or revise these statements in light of future developments.

Overview

Jazz Pharmaceuticals plc is a global biopharmaceutical company whose purpose is to innovate to transform the lives of patients and their families. We are dedicated to developing life-changing medicines for people with serious diseases - often with limited or no therapeutic options. We have a diverse portfolio of marketed medicines and novel product candidates, from early- to late-stage development, in neuroscience and oncology. Within these therapeutic areas, we are identifying new options for patients by actively exploring small molecules and biologics, and through innovative delivery technologies and cannabinoid science.

Our continued growth is rooted in executing commercial launches and ongoing commercialization initiatives; advancing robust R&D programs and delivering impactful clinical results; effectively deploying capital to strengthen the prospects of achieving our short- and long-term goals through strategic corporate development; and delivering strong financial performance.

In our core therapeutic areas we apply this approach to bring new medicines to patients and to create sustainable shareholder value. Most critically, we focus on patient populations with high unmet needs. We identify and develop differentiated therapies for these patients that we can support with an efficient sales force and that we expect will be long-lived, durable assets. In addition, we leverage our integrated capabilities and global infrastructure to effectively reach patients around the world.

Commercial Achievements

Our marketed products are approved in countries around the world to improve patient care.

Product	Indications	Initial Approval Date	Markets
NEUROSCIENCE			
Xywav® (calcium, magnesium, potassium, and sodium oxybates)	Treatment of cataplexy or excessive daytime sleepiness, or EDS, in patients seven years of age and older with narcolepsy.	July 2020	U.S.
	Treatment of idiopathic hypersomnia, or IH, in adults.	August 2021	U.S.
Xyrem® (sodium oxybate)	Treatment of cataplexy or EDS in patients seven years of age and older with narcolepsy.	July 2002	U.S.
	For the treatment of cataplexy in patients with narcolepsy.	August 2005	Canada

Epidiolex® (cannabidiol)	Treatment of seizures associated with Lennox-Gastaut syndrome, or LGS, or Dravet syndrome, or DS, or tuberous sclerosis complex, or TSC, in patients 1 year of age and older.	June 2018	U.S.
	For use as an adjunctive therapy of seizures associated with LGS or DS, in conjunction with clobazam, for patients 2 years of age and older.*	September 2019	EU, U.K., other markets
Epidyolex® (cannabidiol)	For use as an adjunctive therapy of seizures associated with TSC for patients 2 years of age and older.**	April 2021	EU, U.K., other markets
Sunosi® (solriamfetol)	Improve wakefulness in adult patients with EDS associated with narcolepsy or obstructive sleep apnea, or OSA.	March 2019	U.S.
	Improve wakefulness and reduce EDS in adult patients with narcolepsy (with or without cataplexy) or adult patients with OSA whose EDS has not been satisfactorily treated by primary OSA therapy, such as continuous positive airway pressure (CPAP).	January 2020	EU, U.K.
	Treatment of EDS in adult patients with narcolepsy or OSA.	May 2021	Canada
Sativex® (nabiximols)	Treatment for adult patients with moderate to severe spasticity due to multiple sclerosis, or MS, who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy.	June 2010	U.K. (other markets through licensing agreements with partners)
ONCOLOGY			
Zepzelca® (lurbinectedin)	Treatment of adult patients with metastatic small cell lung cancer, or SCLC, with disease progression on or after platinum-based chemotherapy.	June 2020	U.S. (licensed from Pharma Mar, S.A., or PharmaMar)
	Treatment of adults with Stage III or metastatic SCLC who have progressed on or after platinum-containing therapy.	September 2021	Canada
Rylaze™ (asparaginase erwinia chrysanthemi (recombinant)-rywn)	A component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia, or ALL, and lymphoblastic lymphoma, or LBL, in adult and pediatric patients 1 month or older who have developed hypersensitivity to *E. coli*-derived asparaginase.	June 2021	U.S.

Vyxeos® (daunorubicin and cytarabine) liposome for injection	Treatment of newly-diagnosed therapy-related acute myeloid leukemia, or t-AML, or AML with myelodysplasia-related changes, or AML-MRC in adults and pediatric patients one year and older.	August 2017	U.S.
Vyxeos® liposomal 44 mg/100 mg powder for concentrate for solution for infusion	Treatment of adults with newly-diagnosed t-AML or AML-MRC.	August 2018	EU, U.K.
Vyxeos® Daunorubicin and cytarabine liposome for injection Powder, 44 mg daunorubicin and 100 mg cytarabine per vial, intravenous infusion	Treatment of adults with newly diagnosed therapy-related t-AML or AML with AML-MRC.	April 2021	Canada
Defitelio® (defibrotide sodium)	Treatment of adult and pediatric patients with hepatic veno-occlusive disease, or VOD, also known as sinusoidal obstruction syndrome, or SOS, with renal or pulmonary dysfunction following hematopoietic stem-cell transplantation, or HSCT.	March 2016	U.S.
Defitelio® (defibrotide)	Treatment of severe hepatic VOD, also known as SOS, following HSCT therapy.	October 2013	EU, U.K., other markets

*Clobazam restriction limited to EU and U.K.

**TSC approval pending in certain markets

Neuroscience

We are the global leader in the development and commercialization of oxybate therapy for patients with sleep disorders. We introduced Xyrem in 2002, which has become a standard of care for treating EDS and cataplexy in narcolepsy. In 2020, we received U.S. Food and Drug Administration, or FDA, approval for Xywav for the treatment of cataplexy or EDS, in patients seven years of age and older with narcolepsy. In August 2021, Xywav became the first and only therapy approved by FDA for the treatment of IH in adults. Xywav is an oxybate therapy that contains 92% less sodium than Xyrem.

Since there is no cure for narcolepsy and long-term disease management is needed, we believe that Xywav represents an important new therapeutic option for patients with this sleep disorder. Our commercial efforts are focused on educating patients and physicians about the lifelong impact of high sodium, and how the use of Xywav enables them to address what is a modifiable risk factor.

In June 2021, FDA recognized seven years of Orphan Drug Exclusivity (ODE) for Xywav in narcolepsy. ODE extends through July 2027. In connection with granting ODE, FDA stated that "Xywav is clinically superior to Xyrem by means of greater safety because Xywav provides a greatly reduced chronic sodium burden compared to Xyrem." FDA's summary also stated that "the differences in the sodium content of the two products at the recommended doses will be clinically meaningful in reducing cardiovascular morbidity in a substantial proportion of patients for whom the drug is indicated."

We have seen strong adoption of Xywav in narcolepsy since its launch in November 2020. In the third quarter of 2021, there were 16,000 average active oxybate patients; exiting the quarter, there were 6,000 active Xywav patients. This increased from 5,100 active Xywav patients exiting the second quarter of 2021. We view this as a positive indication that physicians and patients appreciate the benefits of a lower sodium oxybate option. We continue to see Xywav adoption among both existing and new-to-oxybate narcolepsy patients.

We have met our goal to obtain broad payor coverage for Xywav within six months of launch. We now have agreements in place with all three major pharmacy benefit managers, or PBMs, in the U.S. Commercial payor coverage exceeds 80% of covered lives.

On August 12, 2021, FDA approved Xywav for the treatment of IH in adults. Xywav is the first and only FDA-approved therapy to treat IH. We initiated the U.S. commercial launch of Xywav for the treatment of IH in adults on November 1, 2021. IH is a debilitating neurologic sleep disorder characterized by chronic EDS (the inability to stay awake and alert during the day resulting in the irrepressible need to sleep or unplanned lapses into sleep or drowsiness). An estimated 37,000 people in the U.S. have been diagnosed with IH and are actively seeking healthcare.

Sunosi was launched in the U.S. in 2019 as a therapy to improve wakefulness in adult patients with EDS associated with narcolepsy or OSA, and we remain focused on driving the next phase of its growth. We have established broad commercial payor coverage and have invested in an expanded and dedicated sales force and direct-to-consumer initiatives to raise awareness of EDS associated with narcolepsy or OSA. Sunosi was approved in Europe in 2020, and our rolling launch is ongoing. Sunosi was approved in Canada in 2021.

We acquired Epidiolex (Epidyolex outside the U.S.) in May 2021 as part of the acquisition of GW Pharmaceuticals plc, or GW, which we refer to as the GW Acquisition, which expands our growing neuroscience business with a global, high-growth childhood-onset epilepsy franchise. Epidiolex was approved in the U.S. in June 2018 for the treatment of seizures associated with two rare and severe forms of epilepsy, LGS and DS, in patients two years of age and older, and subsequently approved in July 2020 for the treatment of seizures associated with TSC in patients one year of age and older. FDA also approved the expansion of all existing indications, LGS and DS, to patients one year of age and older. The rolling European launch of Epidyolex is also underway following European Commission approval in September 2019. For Epidiolex/Epidyolex, reports from the field indicate that COVID-19 and the lack of access to COVID-19 vaccines, especially for children under 12 years of age, have impacted the willingness of parents of pediatric patients to bring their children to a health care provider office, which can increase the risk of COVID exposure through contact with the healthcare system. We believe these dynamics have negatively impacted new patient starts in the U.S. and Europe, the majority of which are pediatric patients. At the same time, promotional visits to institutional centers are down in the U.S. across the industry, and we see this playing out with Epidiolex. Through the first three quarters of 2021 relative to 2019, our average number of total monthly sales interactions were down 44%, with face-to-face interactions are down 71%. We believe this has a notable negative impact on the growth rate of a newer product like Epidiolex, where education and in-office support for physicians with little or no product experience helps expand trial usage and adoption.

Sativex (nabiximols) is approved in the U.K. and certain other countries for the treatment of adult patients with moderate to severe spasticity due to MS who have not responded adequately to other anti-spasticity medication. We market Sativex directly in the U.K. and through licensing agreements with partners across other countries. We are working toward potential approval of nabiximols in the U.S. with multiple Phase 3 clinical trials in progress.

Oncology

We acquired U.S. development and commercialization rights to Zepzelca in early 2020, and launched six months thereafter with an indication for treatment of patients with SCLC with disease progression on or after platinum-based chemotherapy. Our education and promotional efforts are focused on SCLC-treating physicians. We are seeing increased awareness of Zepzelca across academic and community cancer centers and continued growth in second-line share and overall demand, reflecting the significant unmet need and favorable Zepzelca product profile. In collaboration with F. Hoffmann-La Roche Ltd (Roche), we have initiated a Phase 3 pivotal clinical trial in first-line extensive stage SCLC of Zepzelca in combination with Tecentriq® (atezolizumab). We are also developing Zepzelca in additional indications.

Rylaze was approved by FDA in June 2021 under the Real-Time Oncology Review (RTOR) program, and was launched in the U.S. in July 2021, for use as a component of a multi-agent chemotherapeutic regimen for the treatment of patients with ALL or LBL in pediatric and adult patients one month and older who have developed hypersensitivity to *E. coli*-derived asparaginase. Rylaze is the only recombinant *erwinia* asparaginase manufactured product that maintains a clinically meaningful level of asparaginase activity throughout the entire duration of treatment. We developed Rylaze to address the needs of patients and health care providers for an innovative, high-quality *erwinia* asparaginase with reliable supply. The current indication is for an intramuscular (IM) dosing regimen of 25 mg/m^2 every 48 hours. We plan to submit a supplemental Biologics License Application (sBLA) with additional data in support of a Monday/Wednesday/Friday (M/W/F) IM dosing schedule in early 2022, which has also been granted review under the RTOR program. We anticipate that data from the current development program will support regulatory filings in Europe in mid-2022, with potential for approval in 2023. The Company is also working with a partner for potential submission, approval and launch in Japan.

Vyxeos is a treatment for adults with newly-diagnosed t-AML, or AML-MRC. In March 2021, FDA approved a revised label to include a new indication to treat newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes in pediatric patients aged one year and older. We have a number of ongoing development activities and continue to expand into new markets internationally. Although we saw some recovery in demand for Vyxeos beginning in the end of the second quarter of 2020, due to the ongoing impacts of the COVID-19 pandemic, we continue to expect a negative impact on demand for and utilization of Vyxeos compared to historical periods.

Defitelio provides an important treatment option for patients with VOD following HSCT. There was a significant decline in the number of patients receiving HSCT due to the effects of the COVID-19 pandemic. We anticipate the use of Defitelio will increase to the extent that hospital systems globally are able to move forward with more HSCT procedures. However, we continue to expect a negative impact on demand for and utilization of Defitelio.

Erwinaze, which is approved to treat a limited population of patients with ALL who have developed hypersensitivity to E. coli-derived asparaginase, was licensed from and manufactured by a single source, Porton Biopharma Limited, or PBL. Our license and supply agreement with PBL expired on December 31, 2020. We distributed our final inventory of Erwinaze in June 2021.

Research and Development Progress

Our development activities encompass all stages of development and currently include clinical testing of new product candidates and activities related to clinical improvements of, or additional indications or new clinical data for, our existing marketed products. We have also expanded into preclinical exploration of novel therapies, including precision medicines in hematology and oncology and the GW cannabinoid research platform. We are increasingly leveraging our growing internal research and development function, and we have also entered into collaborations with third parties for the research and development of innovative early-stage product candidates and have supported additional investigator-sponsored trials, or ISTs, that will generate additional data related to our products. We also seek out investment opportunities in support of development of early- and mid-stage technologies in our therapeutic areas and adjacencies. We have a number of licensing and collaboration agreements with third parties, including biotechnology companies, academic institutions and research-based companies and institutions, related to preclinical and clinical research and development activities in hematology and in precision oncology, as well as in neuroscience.

With the approvals and launches of Rylaze and Xywav for IH this year, we accomplished our goal to deliver five product launches through 2020 and 2021. We have taken both Rylaze and Xywav from concept to commercial readiness.

Our neuroscience R&D efforts include the planned initiation of a pivotal Phase 3 clinical trial of Epidiolex for the treatment of Epilepsy with Myoclonic-Atonic Seizures, or EMAS, also known as Doose syndrome, in the first half of 2022. This trial is expected to provide the opportunity to study Epidiolex in a fourth childhood-onset epileptic encephalopathy with high unmet need. EMAS is characterized by generalized myoclonic-atonic seizures, and this trial is designed to provide the first randomized, controlled clinical data with Epidiolex in this seizure type, which we believe will provide a more fulsome view of the potential effectiveness of Epidiolex in treating a broad range of seizure disorders.

For nabiximols, we have three ongoing Phase 3 clinical trials in multiple sclerosis (MS)-related spasticity. Spasticity occurs in up to 84% of MS patients, and approximately one-third of those who experience spasticity live with uncontrolled symptoms. We expect data from the first trial, which is a smaller, shorter trial relative to the other two, in the first half of 2022. If results from this first trial are positive, there is the potential for a regulatory submission in the U.S. in the next 18-24 months. We expect data from the two additional trials, which have larger sample sizes, to read out in late 2022 and early 2023.

Additionally we have initiated a Phase 2 clinical trial for JZP385 for essential tremor, and expect to initiate a Phase 2 trial for JZP150 for post-traumatic stress disorder later this year. These are both patient populations that suffer significant impacts to their quality of life and for whom there are limited current treatment options.

Within our oncology R&D program, there is a robust development plan being executed for Zepzelca. We are collaborating with Roche on a pivotal Phase 3 clinical trial evaluating Zepzelca in combination with Tecentriq in first-line extensive stage SCLC. After discussion with FDA, our partner PharmaMar plans to initiate a confirmatory trial in second-line SCLC later this year. This is expected to be a three-arm trial comparing Zepzelca as either monotherapy or in combination with irinotecan to investigator's choice of irinotecan or topotecan. If positive, this trial would confirm the benefit of Zepzelca in the treatment of SCLC when patients progress following first-line treatment with a platinum-based regimen.

We expect to initiate a Phase 2 basket trial in early 2022 to explore Zepzelca monotherapy in patients with select advanced or metastatic solid tumors. Cohorts will include advanced urothelial cancer, large cell neuroendocrine tumor of the lung, and homologous recombinant deficient positive (HRD+) cancers. In addition, we have initiated a Phase 4 observational study to collect real world safety and outcome data in adult Zepzelca monotherapy patients with extensive stage SCLC who progress on or after prior platinum-containing chemotherapy.

For Rylaze, we plan to submit a sBLA with additional data in support of a Monday/Wednesday/Friday (M/W/F) IM dosing schedule by the end of January 2022, which has been granted review under the RTOR program. Part two of the ongoing Rylaze study is evaluating intravenous administration.

Below is a summary of our key ongoing and planned development projects related to our products and pipeline and their corresponding current stages of development:

Product Candidates	Description
NEUROSCIENCE	
Phase 3	
Epidiolex	Epilepsy with Myoclonic Atonic Seizures (EMAS), also known as Doose syndrome (planned study)
Nabiximols	MS Spasticity (multiple studies ongoing) Spinal cord injury spasticity (planned study)
Phase 2b	
JZP385	Essential tremor (ongoing study)
Phase 2	
JZP150	Post-traumatic stress disorder (planned study)
Additional cannabinoids	Schizophrenia (ongoing study) Autism spectrum disorders (ongoing study)
Phase 1	
JZP324	Oxybate extended-release formulation (planned study)
Additional cannabinoids	Neonatal hypoxic-ischemic encephalopathy (ongoing study) Neuropsychiatry targets (ongoing study)
Preclinical	
Undisclosed targets	Neuroscience Cannabinoids
ONCOLOGY	
Regulatory Review	
Rylaze	ALL/LBL FDA approval on June 30, 2021; plan to submit additional data to support U.S. label update (ongoing study)
Phase 3	
Zepzelca	First-line extensive stage SCLC in combination with Tecentriq (collaboration with Roche) (ongoing study)
Vyxeos	AML or high-risk Myelodysplastic Syndrome, or MDS (AML18) (cooperative group studies) (planned study) Newly diagnosed adults with standard- and high-risk AML (AML Study Group cooperative group study) (ongoing study) Newly diagnosed pediatric patients with AML (Children's Oncology Group cooperative group study) (ongoing study)
Phase 2	
Zepzelca	Basket trial including urothelial cancer, large cell neuroendocrine tumor of the lung, and HRD+ (homologous recombinant deficient) cancers (planned study)
Vyxeos	High-risk MDS (European Myelodysplastic Syndromes Cooperative Group cooperative group study) (ongoing study) Newly diagnosed older adults with high-risk AML (cooperative group study) (planned study)
Vyxeos + venetoclax	De novo or relapsed/refractory, or R/R, AML (MD Anderson collaboration study) (ongoing study)
Phase 1	
Vyxeos	Low intensity dosing for higher risk MDS (MD Anderson collaboration study) (ongoing study)

Product Candidates	Description
Vyxeos + other approved therapies	R/R AML or hypomethylating agent failure MDS (MD Anderson collaboration study) (ongoing study) First-line, fit AML (Phase 1b study) (ongoing study) Low intensity therapy for first-line, unfit AML (Phase 1b study) (ongoing study)
Preclinical	
CombiPlex®	Hematology/oncology exploratory activities
JZP341 (long-acting *Erwinia* asparaginase)	ALL and other hematological malignancies (collaboration with Ligand Pharmaceuticals Incorporated, or Ligand)
Pan-Raf inhibitor program	Raf and Ras mutant tumors (acquired from Redx Pharma, or Redx, which is continuing development)
Undisclosed targets	Ras/Raf/MAP kinase pathway (collaboration with Redx) Oncology
Exosome targets (NRAS and up to 4 others)	Hematological malignancies/solid tumors (collaboration with Codiak BioSciences, Inc., or Codiak)

Acquisition of GW Pharmaceuticals Plc

In May 2021, we acquired GW with the objectives of broadening our neuroscience portfolio, further diversifying our revenue and driving sustainable, long-term value creation opportunities. The total consideration paid by us for the entire issued share capital of GW was $7.2 billion.

In connection with the financing of the transaction, in April 2021 we closed an offering of $1.5 billion in aggregate principal amount of 4.375% senior secured notes, due 2029, or the Secured Notes. In May 2021, we entered into a credit agreement, or the Credit Agreement, that provides for (i) a seven-year $3.1 billion term loan B facility, or the Dollar Term Loan, (ii) a seven-year €625 million term loan B facility, or the Euro Term Loan and, together with the Dollar Term Loan, collectively referred to as the Term Loan, and (iii) a five-year $500 million revolving credit facility, or the Revolving Credit Facility. We funded the cash portion of the GW Acquisition consideration through a combination of cash on hand and borrowings under the Term Loan and the Secured Notes. The Revolving Credit Facility is currently undrawn.

GW's lead product, Epidiolex (cannabidiol) oral solution, is approved in patients one-year and older for the treatment of seizures associated with LGS, DS and TSC, all of which are rare diseases characterized by severe early-onset epilepsy. Epidiolex was the first plant-derived cannabinoid medicine ever approved by FDA, and has also been approved in Europe under the trade name Epidyolex. In addition to the approved indications for Epidiolex, we believe there are considerable opportunities to pursue other indications within the epilepsy field, including other treatment-resistant epilepsies where significant unmet needs of patients exist. We plan to initiate a pivotal Phase 3 clinical trial of Epidiolex for the treatment of seizures associated with EMAS, known as Doose syndrome, in the first half of 2022. EMAS represents the fourth target indication for Epidiolex.

We will continue to leverage the GW cannabinoid research platform and significant expertise in discovering, developing, manufacturing and commercializing therapeutics to address a broad range of diseases. This platform includes nabiximols, which is in Phase 3 clinical trials for the treatment of spasticity associated with multiple sclerosis with an additional planned Phase 3 clinical trial in spasticity associated with spinal cord injury, as well as earlier-stage cannabinoid product candidates.

We view the transaction as consistent with our overall business and capital allocation strategy to expand our neuroscience portfolio and drive substantial value for our shareholders. We expect that product sales, operating expenses and interest expense will be significantly higher in 2021 than in 2020 due to the impact of the inclusion of GW's results of operations and the higher debt balance in connection with the GW Acquisition, as well as the continued growth of the organization.

Operational Excellence

We remain focused on continuing to build excellence in areas that we believe will give us a competitive advantage, including building an increasingly agile and adaptable commercialization engine and strengthening our customer-focused market expertise across patients, providers and payors. We are refining our approach to engaging our customers by strengthening alignment and integration across functions and across regions. This includes a more integrated approach to brand planning, a heightened focus on launch and operational excellence and multichannel customer engagement. We have fully adapted to virtual scientific congresses designed to ensure we can continue to provide promotional and non-promotional interactions and have supported our field-based teams with virtual customer interaction tools, training and content. These initiatives mark a significant operational evolution that is directly linked to our corporate strategy and are designed to better

enable our teams to work collaboratively on an aligned and shared agenda through both virtual and in-person interactions. Our teams will increase the frequency of in-person interactions as medical congresses and healthcare practices begin to resume in-person activities, taking into account applicable public health authority and local government guidelines which are designed to ensure community and employee safety.

COVID-19 Business Update

We have implemented a comprehensive response strategy designed to manage the impact of the COVID-19 pandemic on our employees, patients and our business. The prolonged nature of the pandemic is negatively impacting our business in a limited and varied manner due to the emergence of the Delta variant and other variants with increased transmissibility, even in some cases in vaccinated people, including limited access to health care provider offices and institutions and the willingness of patients or parents of patients to seek treatment or change existing treatments. We expect that our business, financial condition, results of operations and growth prospects may continue to be negatively impacted by the pandemic on a limited basis that may vary depending on the context.

Workplace and Employees

We support broad public health strategies designed to prevent the spread of COVID-19 and are focused on the health and welfare of our employees. Our global organization has mobilized to enable our employees to accomplish our most critical goals through a combination of remote work and in-person initiatives. In addition to rolling out new technologies and collaboration tools, we have implemented processes and resources to support our employees in the event an employee receives a positive COVID-19 diagnosis. We have developed plans regarding the opening of our sites to enable our employees to return to work in our global offices, the field and our manufacturing facilities, which take into account applicable public health authority and local government guidelines and which are designed to ensure community and employee safety. We plan to move to a more flexible mix of virtual and in-person working to advance our culture, drive innovation and agility and enable greater balance and well-being for our workforce. This will also enable us to reconfigure our physical workspaces to optimize the footprint of our company-owned or leased office spaces.

Commercialization

There continues to be some negative impact on demand, new patient starts and treatments for our products arising from the pandemic, primarily due to the inherent limitations of telemedicine and a reprioritization of healthcare resources toward COVID-19. As healthcare systems have adapted to cope with the ongoing situation, we have seen improvements. We are utilizing technology to continue to engage healthcare professionals and other customers virtually to support patient care. As more clinics and institutions begin to allow in-person interactions pursuant to local health authority and government guidelines, our field teams continue to resume in-person interactions with healthcare professionals and clinics combined with virtual engagement. The level of renewed in-person engagement varies by account, region and country and may be adversely impacted in the future as a result of the continuing impact of the COVID-19 pandemic. The lack of access to health care providers has caused, and may continue to cause, delays in appropriate diagnosis, treatment and ongoing care for some patients, which could subsequently impact prescribing and use of our products.

Supply Chain

Our manufacturing facilities in Athlone, Ireland, which produces Xyrem and Xywav, Villa Guardia, Italy, which produces defibrotide, and Kent Science Park, U.K., which produces Epidiolex/Epidyolex and Sativex, are operational with essential staff onsite and office-based staff working remotely. We currently expect to have adequate global supply of all products for the remainder of 2021 and well into 2022.

Research and Development

With respect to our clinical trial activities, we have taken measures to implement remote and virtual approaches, including remote data monitoring where possible, to maintain patient safety and trial continuity and to preserve study integrity. We have seen limited COVID-19-related impact to our mid- and late-stage clinical trial activity, despite delays in initiating trial sites. We rely on contract research organizations or other third parties to assist us with clinical trials, and we cannot guarantee that they will continue to perform their contractual duties in a timely and satisfactory manner as a result of the evolving effects of the COVID-19 pandemic. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as health care providers, may have heightened exposure to COVID-19, may adversely impact our clinical trial operations. Supply chain disruptions related to the pandemic may also impact our ability to initiate clinical trials in a timely manner.

Corporate Development and Other Financial Impacts

We anticipate having sufficient liquidity to continue to make planned investments in our business in support of our long-term growth strategy. However, the COVID-19 pandemic continues to rapidly evolve and has resulted in significant volatility in the global financial markets. If this volatility persists and deepens, we could experience an inability to access additional

capital or our liquidity could otherwise be impacted, which could in the future negatively affect our capacity for certain corporate development transactions or our ability to make other important, opportunistic investments. The effects of the pandemic could also impact our ability to do in-person due diligence, negotiations, and other interactions to identify new opportunities.

Corporate Response

The COVID-19 pandemic has caused a significant burden on health systems globally and has highlighted the need for companies to evaluate existing therapies to assess if they can be utilized beyond their current indications to treat COVID-19 as well as consider developing new therapies. To this end, we have granted requests for several ISTs to evaluate the use of defibrotide in COVID-19 patients experiencing respiratory distress.

In addition, we are supporting our local communities and patient-focused organizations in COVID-19 relief efforts including through corporate donations to charitable organizations providing food and medical relief to communities in which we operate, and other localities where the needs related to the impact of COVID-19 are greatest. We are engaging with patient advocacy organizations to better understand the impact of COVID-19 and working to ensure that patients living with sleep disorders and hematology and oncology conditions continue to have access to treatments and that their other needs are addressed given the impact of COVID-19 on the healthcare system. We are committed to enabling our employees to give back, including allowing licensed healthcare practitioners employed by us to support local response efforts.

Other Challenges, Risks and Trends Related to Our Business

Our business has been substantially dependent on Xyrem. Our future plans assume that our newly launched oxybate product Xywav, with 92% lower sodium compared to Xyrem, depending on the dose, absence of a sodium warning and dosing titration option, will become the treatment of choice for patients who can benefit from oxybate treatment, current Xyrem patients, and patients who previously were not prescribed Xyrem, including those patients for whom sodium content is a concern. In June 2021, FDA recognized seven years of Orphan Drug Exclusivity for Xywav stating that Xywav is clinically superior to Xyrem by means of greater safety due to reduced chronic sodium burden. While we expect that our business will continue to be substantially dependent on oxybate product sales from both Xyrem and Xywav, there is no guarantee that we can maintain oxybate sales at or near historical levels, or that oxybate sales will continue to grow.

Our ability to successfully commercialize Xywav will depend on, among other things, our ability to maintain adequate coverage and reimbursement for Xywav and acceptance of Xywav by payors, physicians and patients, including of Xywav for the treatment of idiopathic hypersomnia in adults. In an effort to support strong adoption of Xywav, we are focused on providing robust patient copay and savings programs and facilitating payor coverage for Xywav. Moreover, we have increasingly experienced pressure from third party payors to agree to discounts, rebates or restrictive pricing terms, and we cannot guarantee we will be able to agree to commercially reasonable terms with PBMs and other third party payors, or that we will be able to ensure patient access and acceptance on institutional formularies. Entering into agreements with PBMs and payors to ensure patient access has and will likely continue to result in higher gross to net deductions. In addition to the COVID-19 related impacts described above, in the future, we expect our oxybate products to face competition from generic and authorized generic versions of sodium oxybate pursuant to the settlement agreements we have entered into with multiple abbreviated new drug application filers. Generic competition can decrease the prices at which Xyrem and Xywav are sold and the number of prescriptions written for Xyrem and Xywav. Xyrem and Xywav may also face increased competition from new branded products for treatment of cataplexy and/or EDS in narcolepsy in the U.S. market.

Our financial condition, results of operations and growth prospects are also dependent on the successful commercialization of Epidiolex/Epidyolex in the U.S. and Europe. Successful commercialization of Epidiolex is subject to many risks and there is no guarantee that we will be able to continue to successfully commercialize Epidiolex for its approved indications. While we have established our Epidiolex commercial team and have hired our U.S. and European sales forces, we will need to continue to maintain and further develop the teams to successfully coordinate the commercialization of Epidiolex. The commercial success of Epidiolex depends on the extent to which patients and physicians accept and adopt Epidiolex as a treatment for LGS, DS and TSC, and we do not know whether our or others' estimates in this regard will be accurate. Physicians may not prescribe Epidiolex and patients may be unwilling to use Epidiolex if coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost. Additionally, any negative development for Epidiolex in the market after launch, in clinical development for additional indications, or in regulatory processes in other jurisdictions, may adversely impact the commercial results and potential of Epidiolex. Thus, significant uncertainty remains regarding the commercial potential of Epidiolex.

As for other products in our neuroscience therapeutic area, if we are unable to successfully commercialize Sunosi in the U.S. and Europe, or if sales of Sunosi do not reach the levels we expect, our anticipated revenue from Sunosi will be negatively affected, which would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition to our neuroscience products and product candidates, we are commercializing a portfolio of oncology products, including Defitelio, Vyxeos, Rylaze and Zepzelca. An inability to effectively commercialize Defitelio, Vyxeos, Rylaze and Zepzelca and to maximize their potential where possible through successful research and development activities could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Our license and supply agreement with PBL, a limited liability company wholly owned by the U.K. Secretary of State for Health, which included an exclusive right to sell Erwinaze, expired on December 31, 2020. Under our agreement with PBL, we had the right to sell certain Erwinaze inventory for a post-termination sales period of 12 months and retain ownership of certain data, know-how and other property interests. We distributed our final available Erwinaze supply in June 2021.

A key aspect of our growth strategy is our continued investment in our evolving and expanding research and development activities. If we are not successful in the clinical development of these or other product candidates, if we are unable to obtain regulatory approval for our product candidates in a timely manner, or at all, or if sales of an approved product do not reach the levels we expect, our anticipated revenue from our product candidates would be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition to continued investment in our research and development pipeline, we intend to continue to grow our business by acquiring or in-licensing, and developing, including with collaboration partners, additional products and product candidates that we believe are highly differentiated and have significant commercial potential. Failure to identify and acquire, in-license or develop additional products or product candidates, successfully manage the risks associated with integrating any products or product candidates into our portfolio or the risks arising from anticipated and unanticipated problems in connection with an acquisition or in-licensing, such as the GW Acquisition, could have a material adverse effect on our business, results of operations and financial condition. In particular, the success of the GW Acquisition will depend, in part, on our ability to realize the anticipated benefits from successfully combining our and GW's businesses and we plan to continue to devote substantial management attention and resources to integrating our business practices and operations with GW's in an effort to fully realize the anticipated benefits of the GW Acquisition. Nonetheless, Epidiolex and the other products and technologies acquired may not be successful or continue to grow at the same rate as when our companies operated independently or they may require significantly greater resources and investments than originally anticipated. Conversely, the liabilities assumed in the GW Acquisition may be greater than originally anticipated. In addition, difficulties may arise during the process of combining the operations of our companies that could result in the failure to achieve the synergies or free cash flow that we anticipate, the failure to integrate operations and internal systems, programs and controls, the loss of key employees that may be difficult to replace in the very competitive pharmaceutical field, the failure to harmonize both companies' corporate cultures, and the disruption of each company's ongoing businesses or inconsistencies in standards, controls, procedures and policies that adversely affect our ability to maintain relationships with customers, suppliers, distributors, collaboration partners, clinical trial investigators or managers of our clinical trials. As a result, the anticipated benefits of the GW Acquisition may not be realized fully within the expected timeframe or at all or may take longer to realize or cost more than expected, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Our industry has been, and is expected to continue to be, subject to healthcare cost containment and drug pricing scrutiny by regulatory agencies in the U.S. and internationally. If healthcare policies or reforms intended to curb healthcare costs are adopted or if we experience negative publicity with respect to pricing of our products or the pricing of pharmaceutical drugs generally, the prices that we charge for our products may be affected, our commercial opportunity may be limited and/or our revenues from sales of our products may be negatively impacted. We are also subject to increasing pricing pressure and restrictions on reimbursement imposed by payors. If we fail to obtain and maintain adequate formulary positions and institutional access for newly-launched products such as Epidiolex, Sunosi, Xywav, Zepzelca, Rylaze and future approved products, we will not be able to achieve a return on our investment and our business, financial condition, results of operations and growth prospects would be materially adversely affected.

While certain preparations of cannabis remain Schedule I controlled substances, if such products are approved by FDA for medical use in the U.S. they are rescheduled to Schedules II-V, since approval by FDA satisfies the "accepted medical use" requirement; or may be removed from control under the Controlled Substances Act entirely. If any of our product candidates receive FDA approval, the Department of Health and Human Services, or HHS, FDA and the U.S. Drug Enforcement Administration, or DEA, will make a scheduling determination. If any foreign regulatory authority determines that Epidyolex may have potential for abuse, or if HHS, FDA or DEA makes a similar determination for nabiximols, it may require us to generate more clinical or other data than we currently anticipate to establish whether or to what extent the substance has an abuse potential, which could increase the cost and/or delay the launch of that product. In addition, there are non-FDA approved cannabidiol preparations being made available from companies through the state-enabled medical marijuana industry, which might attempt to compete with Epidiolex. The medical marijuana industry could provide additional competition for nabiximols, if and when it is approved by FDA. If we are unable to compete successfully, our commercial opportunities will be reduced and our business, results of operations and financial conditions may be materially harmed.

Finally, business practices by pharmaceutical companies, including product formulation improvements, patent litigation settlements, and risk evaluation and mitigation strategy, or REMS, programs, have increasingly drawn public scrutiny from legislators and regulatory agencies, with allegations that such programs are used as a means of improperly blocking or delaying competition. If we become the subject of any future government investigation with respect to our business practices, including as they relate to the Xywav and Xyrem REMS, the launch of Xywav, our Xyrem patent litigation settlement agreements or otherwise, we could incur significant expense and could be distracted from operation of our business and execution of our strategy. From June 2020 to October 2021, a number of class action lawsuits were filed on behalf of purported direct and indirect Xyrem purchasers, alleging that the patent litigation settlement agreements we entered with certain generic companies violate state and federal antitrust and consumer protection laws. For additional information on these class action complaints, see Legal Proceedings in Note 11, Commitments and Contingencies of the notes to the condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q. It is possible that additional lawsuits will be filed against us making similar or related allegations. We cannot predict the outcome of these or potential additional lawsuits or government action; however, if the plaintiffs were to be successful in their claims, they may be entitled to injunctive relief or we may be required to pay significant monetary damages. Any of the foregoing risks and uncertainties could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In addition, to the extent the COVID-19 pandemic continues to adversely affect our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described above. All of these risks and uncertainties are discussed in greater detail, along with other risks and uncertainties, in “Risk Factors” in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Results of Operations

The following table presents our revenues and expenses (in thousands, except percentages):

	Three Months Ended September 30,		Increase/	Nine Months Ended September 30,		Increase/
	2021	2020	(Decrease)	2021 (1)	2020	(Decrease)
Product sales, net	$ 834,247	$ 596,949	40 %	$ 2,186,118	$ 1,685,357	30 %
Royalties and contract revenues	3,868	3,939	(2)%	11,389	12,693	(10)%
Cost of product sales (excluding amortization of acquired developed technologies)	145,224	42,095	N/A(2)	304,607	98,760	N/A(2)
Selling, general and administrative	363,682	207,255	75 %	1,053,221	607,061	73 %
Research and development	141,036	78,647	79 %	350,305	243,676	44 %
Intangible asset amortization	159,804	66,684	140 %	368,476	192,505	91 %
Impairment charge	—	—	—	—	136,139	N/A(2)
Acquired in-process research and development	—	10,000	N/A(2)	—	215,250	N/A(2)
Interest expense, net	93,372	27,428	240 %	190,168	72,134	164 %
Foreign exchange (gain) loss	2,631	639	N/A(2)	(1,262)	2,235	N/A(2)
Income tax provision (benefit)	(18,057)	19,283	N/A(2)	228,583	22,750	N/A(2)
Equity in (gain) loss of investees	3,256	623	N/A(2)	(2,274)	2,338	N/A(2)

(1) The results of operations of the GW business have been included from the closing of the GW Acquisition on May 5, 2021.
(2) Comparison to prior period not meaningful.

Revenues

The following table presents our net product sales, royalties and contract revenues, and total revenues (in thousands, except percentages):

	Three Months Ended September 30,		Increase/	Nine Months Ended September 30,		Increase/
	2021	2020	(Decrease)	2021	2020	(Decrease)
Xyrem	$ 307,333	$ 447,809	(31)%	$ 977,065	$ 1,302,492	(25)%
Xywav	153,063	—	N/A(1)	352,643	—	N/A(1)
Total Oxybate	460,396	447,809	3 %	1,329,708	1,302,492	2 %
Epidiolex/Epidyolex	160,378	—	N/A(2)	269,859	—	N/A(2)
Sunosi	19,251	9,116	111 %	42,981	19,618	119 %
Sativex	6,097	—	N/A(2)	8,058	—	N/A(2)
Total Neuroscience	646,122	456,925	41 %	1,650,606	1,322,110	25 %
Zepzelca	71,714	36,941	94 %	181,972	—	N/A(1)
Vyxeos	34,688	30,825	13 %	99,296	90,113	10 %
Defitelio/defibrotide	57,705	50,241	15 %	155,420	140,387	11 %
Rylaze	20,674	—	N/A(1)	20,674	—	N/A(1)
Erwinaze/Erwinase	—	20,145	N/A(1)	69,382	90,560	(23)%
Total Oncology	184,781	138,152	34 %	526,744	358,001	47 %
Other	3,344	1,872	79 %	8,768	5,246	67 %
Product sales, net	834,247	596,949	40 %	2,186,118	1,685,357	30 %
Royalties and contract revenues	3,868	3,939	(2)%	11,389	12,693	(10)%
Total revenues	$ 838,115	$ 600,888	39 %	$ 2,197,507	$ 1,698,050	29 %

(1) Comparison to prior period not meaningful.
(2) The results of operations of the GW business have been included from the closing of the GW Acquisition on May 5, 2021 and comparison to prior period is not meaningful.

Product Sales, Net

Total oxybate product sales increased in the three and nine months ended September 30, 2021 compared to the same periods in 2020 primarily due to a higher average selling price, partially offset by higher gross to net deductions, and to a lesser extent a decrease in commercial sales volumes. Total oxybate revenue bottle volume decreased by 1% in the three and nine months ended September 30, 2021 compared to the same periods in 2020 reflecting our continued investment in patient access programs during the launch of Xywav. Average active oxybate patients on therapy were approximately 16,000 in the third quarter of 2021, an increase of approximately 6% compared to the same period in 2020. Xyrem product sales decreased in the three and nine months ended September 30, 2021 compared to the same periods in 2020 primarily due to a decrease in sales volume, partially offset by a higher average net selling price. Price increases were instituted in January 2020 and January 2021. Xyrem product sales volume decreased in the three and nine months ended September 30, 2021, compared to the same periods in 2020 due to the strong adoption of Xywav by existing Xyrem patients. Xywav product sales were $153.1 million and $352.6 million in the three and nine months ended September 30, 2021, respectively, following its U.S. launch in November 2020. Epidiolex/Epidyolex product sales in the three months ended September 30, 2021, and from the closing of the GW Acquisition on May 5, 2021 to September 30, 2021 were $160.4 million and $269.9 million, respectively. On a pro forma basis, Epidiolex/Epidyolex product sales increased by 21% and 27% in the three and nine months ended September 30, 2021, respectively, compared to the same periods in 2020, primarily due to an increase in commercial sales volumes. Sunosi product sales increased in the three and nine months ended September 30, 2021, compared to the same periods in 2020 primarily due to an increase in sales volume, partially offset by higher gross to net deductions.

Zepzelca product sales were $71.7 million and $182.0 million in the three and nine months ended September 30, 2021, respectively. Zepzelca launched in the U.S. in July 2020. Zepzelca product sales increased in the three months ended September 30, 2021 compared to the same period in 2020 primarily due to higher sales volumes. Vyxeos product sales increased in the three and nine months ended September 30, 2021, compared to the same periods in 2020 driven by lower gross to net deductions, partially offset by lower volumes. Defitelio/defibrotide product sales increased in the three and nine months ended September 30, 2021 compared to the same periods in 2020 primarily due to higher sales volumes. We distributed our

final Erwinaze inventory in June 2021 following expiration of our license and supply agreement. Rylaze product sales were $20.7 million in the three months ended September 30, 2021, following its U.S. launch in July 2021.

Royalties and Contract Revenues

Royalties and contract revenues decreased in the three and nine months ended September 30, 2021 compared to the same periods in 2020 primarily due to lower revenues from out-licensing agreements.

Cost of Product Sales

Cost of product sales increased in the three and nine months ended September 30, 2021 compared to the same periods in 2020 primarily due to the cost of product sales acquired in the GW Acquisition, including the acquisition accounting inventory fair value step-up expense. Gross margin as a percentage of net product sales was 82.6% and 86.1% for the three and nine months ended September 30, 2021, respectively, compared to 92.9% and 94.1% for the same periods in 2020. The decrease in our gross margin percentage in both periods was primarily due to the impact of the acquisition accounting inventory fair value step-up expense.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased in the three and nine months ended September 30, 2021 compared to the same periods in 2020 primarily due to transaction and integration-related expenses of $53.4 million and $191.2 million in the three and nine months ended September 30, 2021, respectively, related to the GW Acquisition, an increase in compensation-related expenses driven by higher headcount primarily due to the GW Acquisition and the addition of costs related to Epidiolex, as well as an increase in other expenses related to the expansion of our business. Selling, general and administrative expenses also increased in the nine months ended September 30, 2021 compared to the same period in 2020 due to increased investment in sales, marketing and launch activities primarily related to Sunosi, Xywav and Zepzelca in the U.S.

Research and Development Expenses

Research and development expenses consist primarily of costs related to clinical studies and outside services, personnel expenses, and other research and development costs. Clinical study and outside services costs relate primarily to services performed by clinical research organizations, materials and supplies, and other third party fees. Personnel expenses relate primarily to salaries, benefits and share-based compensation. Other research and development expenses primarily include overhead allocations consisting of various support and facilities-related costs. We do not track fully-burdened research and development expenses on a project-by-project basis. We manage our research and development expenses by identifying the research and development activities that we anticipate will be performed during a given period and then prioritizing efforts based on our assessment of which development activities are important to our business and have a reasonable probability of success, and by dynamically allocating resources accordingly. We also continually review our development pipeline projects and the status of their development and, as necessary, reallocate resources among our development pipeline projects that we believe will best support the future growth of our business.

The following table provides a breakout of our research and development expenses by major categories of expense (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Clinical studies and outside services	$ 63,929	$ 37,142	$ 162,140	$ 125,036
Personnel expenses	54,523	33,283	138,678	90,331
Milestone expense	3,000	—	5,000	—
Other	19,584	8,222	44,487	28,309
Total	$ 141,036	$ 78,647	$ 350,305	$ 243,676

Research and development expenses increased by $62.4 million and $106.6 million in the three and nine months ended September 30, 2021, respectively, compared to the same periods in 2020. Clinical studies and outside services costs increased in the three and nine months ended September 30, 2021 compared to the same periods in 2020 primarily due to the addition of costs related to clinical programs for Epidiolex, nabiximols and cannabinoids. Clinical studies and outside services costs also increased in the nine months ended September 30, 2021 compared to the same period in 2020 due to an increase in costs related to JZP385. Personnel expenses increased by $21.2 million and $48.3 million in the three and nine months ended

September 30, 2021, respectively, compared to the same periods in 2020 due to increased headcount primarily driven by the GW Acquisition.

Intangible Asset Amortization

Intangible asset amortization increased by $93.1 million and $176.0 million in the three and nine months ended September 30, 2021, respectively, compared to the same periods in 2020 primarily due to the commencement of amortization on the intangible assets arising from the GW Acquisition in May 2021, primarily related to Epidiolex.

Impairment Charge

In the nine months ended September 30, 2020, we recorded an acquired in-process research and development, or IPR&D, asset impairment charge of $136.1 million following the decision to stop enrollment in our Phase 3 clinical study of defibrotide for the prevention of VOD due to a determination that the study was highly unlikely to reach one of its primary endpoints.

Acquired In-Process Research and Development

Acquired IPR&D expense in the nine months ended September 30, 2020 primarily related to an upfront payment of $200.0 million to PharmaMar in connection with our license agreement.

Interest Expense, Net

Interest expense, net increased by $65.9 million and $118.0 million in the three and nine months ended September 30, 2021, respectively, compared to the same periods in 2020, primarily due to higher interest expense from the Term Loan and the Secured Notes which were used, in part, to finance the cash portion of the GW Acquisition and higher non-cash interest expense following the issuance of our 2.00% exchangeable senior notes due 2026, or the 2026 Notes, in June 2020.

Foreign Exchange (Gain) Loss

The foreign exchange (gain) loss is primarily related to the translation of sterling and euro-denominated net monetary liabilities, primarily intercompany balances, held by subsidiaries with a U.S. dollar functional currency and related foreign exchange forward contracts not designated as hedging instruments.

Income Tax Provision

Our income tax benefit was $18.1 million and our income tax provision was $228.6 million in the three and nine months ended September 30, 2021, respectively, compared to our income tax provision of $19.3 million and $22.8 million for the same periods in 2020. Our income tax provision for the nine months ended September 30, 2021 included an expense of $250.6 million arising on the remeasurement of our U.K. net deferred tax liability, which arose primarily in relation to the GW Acquisition, due to a change in the statutory tax rate in the U.K. following enactment of the U.K. Finance Act 2021. Excluding this impact, the increase in benefit for income taxes in three and nine months ended September 30, 2021 compared to the same periods in 2020 resulted primarily from the mix of pre-tax income and losses incurred across tax jurisdictions and excess tax benefits recognized on share-based compensation. The income tax provision for the three months ended September 30, 2020 included the impact of the disallowance of certain interest deductions and provision for the settlement reached with the French tax authorities. The income tax provision for the nine months ended September 30, 2020 the impact of the defibrotide acquired IPR&D asset impairment charge and the impact of the acquired IPR&D expense related to the PharmaMar transaction, partially offset by the impact of the disallowance of certain interest deductions and provision for the settlement reached with the French tax authorities. We do not provide for Irish income taxes on undistributed earnings of our foreign operations that are intended to be indefinitely reinvested in our foreign subsidiaries.

Equity in (Gain) Loss of Investees

Equity in (gain) loss of investees relates to our share in the net (gain) loss of companies in which we have made investments accounted for under the equity method of accounting.

Liquidity and Capital Resources

As of September 30, 2021, we had cash and cash equivalents of $671.8 million, borrowing availability under our revolving credit facility of $500.0 million and long-term debt principal balance of $6.6 billion. Our long-term debt included $3.6 billion in aggregate principal amount of the Term Loan, $1.5 billion in aggregate principal amount of the Secured Notes,

$575.0 million principal amount of our 1.50% exchangeable senior notes due 2024, or the 2024 Notes, and $1.0 billion principal amount of the 2026 Notes. We generated cash flows from operations of $600.8 million during the nine months ended September 30, 2021, and we expect to continue to generate positive cash flows from operations which will enable us to operate our business and de-lever our balance sheet over time.

In the second quarter of 2021, we issued $1.5 billion in aggregate principal amount of the Secured Notes and we entered into the Credit Agreement that provides for $3.8 billion in aggregate principal amount of the Term Loan, and a five-year $500.0 million Revolving Credit Facility, which is currently undrawn. We used the proceeds from the Term Loan (i) to repay in full $575.9 million that was outstanding under our credit agreement, dated as of June 18, 2015, or the Existing Credit Agreement, (ii) to fund, in part, the cash consideration payable in connection with the GW Acquisition and (iii) to pay related fees and expenses. We expect to use future loans under the Revolving Credit Facility, if any, for general corporate purposes, including potential business development activities.

In the third quarter of 2021, we made a voluntary prepayment of €208.3 million or $251.0 million on the Euro Term Loan and we repurchased the remaining $218.8 million aggregate principal amount of our 1.875% exchangeable senior notes due 2021, or the 2021 Notes.

We have a significant amount of debt outstanding on a consolidated basis. For a more detailed description of our debt arrangements, see Note 9, Debt, of the notes to the condensed consolidated financial statements, included in Part I, Item 1 of this Quarterly Report on Form 10-Q. This substantial level of debt could have important consequences to our business, including, but not limited to the factors set forth in in Part II, Item 1A “Risk Factors” of this Quarterly Report on Form 10-Q under the heading “We have incurred substantial debt, which could impair our flexibility and access to capital and adversely affect our financial position, and our business would be adversely affected if we are unable to service our debt obligations.”

We believe that our existing cash and cash equivalents, cash we expect to generate from operations and funds available under our Revolving Credit Facility will be sufficient to fund our operations and to meet our existing obligations for the foreseeable future. The adequacy of our cash resources depends on many assumptions, including primarily our assumptions with respect to product sales and expenses, as well as the other factors set forth in in Part II, Item 1A “Risk Factors” of this Quarterly Report on Form 10-Q under the headings “Risks Related to our Lead Products and Product Candidates” and “To continue to grow our business, we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate and grow our business.” Our assumptions may prove to be wrong or other factors may adversely affect our business, and as a result we could exhaust or significantly decrease our available cash resources, and we may not be able to generate sufficient cash to service our debt obligations which could, among other things, force us to raise additional funds and/or force us to reduce our expenses, either of which could have a material adverse effect on our business.

To continue to grow our business over the longer term, we plan to commit substantial resources to product acquisition and in-licensing, product development, clinical trials of product candidates and expansion of our commercial, development, manufacturing and other operations. In this regard, we have evaluated and expect to continue to evaluate a wide array of strategic transactions as part of our strategy to acquire or in-license and develop additional products and product candidates. Acquisition opportunities that we pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. In addition, we may pursue new operations or continue the expansion of our existing operations. Accordingly, we expect to continue to opportunistically seek access to additional capital to license or acquire additional products, product candidates or companies to expand our operations or for general corporate purposes. Raising additional capital could be accomplished through one or more public or private debt or equity financings, collaborations or partnering arrangements. However, the COVID-19 pandemic continues to rapidly evolve and has resulted in significant volatility in the global financial markets. If this volatility persists and deepens, we could experience an inability to access additional capital or our liquidity could otherwise be impacted, which could in the future negatively affect our capacity for certain corporate development transactions or our ability to make other important, opportunistic investments. In addition, as a matter of Irish law, when an Irish public limited company issues ordinary shares to new shareholders for cash, the company must first offer those shares on the same or more favorable terms to existing shareholders on a pro rata basis, unless this statutory pre-emption obligation is dis-applied, or opted-out of, by approval of its shareholders. At our extraordinary general meeting of shareholders in September 2021, our shareholders voted to approve our proposal to dis-apply the statutory pre-emption obligation on terms that are substantially more limited than our general pre-emption opt-out authority that had been in effect prior to August 4, 2021, which could adversely affect our ability to effectively use our unissued share capital to fund in-licensing or acquisition opportunities, or to otherwise raise additional capital for our business. In any event, an inability to borrow or raise additional capital in a timely manner and on attractive terms could prevent us from expanding our business or taking advantage of acquisition opportunities, and could otherwise have a material adverse effect on our business and growth prospects. In addition, if we use a substantial amount of our funds to acquire or in-license products or product candidates, we may not have sufficient additional funds to conduct all of our operations in the manner we would otherwise choose.

Furthermore, any equity financing would be dilutive to our shareholders, and could require the consent of the lenders under the Credit Agreement and the indenture for the Secured Notes for certain financings.

In November 2016, our board of directors authorized a share repurchase program and as of September 30, 2021 had authorized the repurchase of ordinary shares having an aggregate purchase price of up to $1.5 billion, exclusive of any brokerage commissions. Under this program, which has no expiration date, we may repurchase ordinary shares from time to time on the open market. The timing and amount of repurchases will depend on a variety of factors, including the price of our ordinary shares, alternative investment opportunities, restrictions under the Credit Agreement and the indenture for the Secured Notes, corporate and regulatory requirements and market conditions. The share repurchase program may be modified, suspended or discontinued at any time without prior notice. During the three and nine months ended September 30, 2021, we did not repurchase any of our ordinary shares. As of September 30, 2021, the remaining amount authorized under the share repurchase program was $431.2 million.

The following table presents a summary of our cash flows for the periods indicated (in thousands):

	Nine Months Ended September 30,	
	2021	2020
Net cash provided by operating activities	$ 600,752	$ 713,377
Net cash used in investing activities	(5,202,051)	(1,080,889)
Net cash provided by financing activities	4,217,131	472,195
Effect of exchange rates on cash and cash equivalents	(1,821)	(85)
Net increase (decrease) in cash and cash equivalents	$ (385,989)	$ 104,598

Operating activities

Net cash provided by operating activities decreased by $112.6 million in the nine months ended September 30, 2021 compared to the same period in 2020, primarily due to the payment of transaction and integration-related costs related to the GW Acquisition.

Investing activities

Net cash used in investing activities increased by $4,121.2 million in the nine months ended September 30, 2021 compared to the same period in 2020, primarily due to the following:

- $6,234.8 million outflow related to the net cash paid for the GW Acquisition; offset by
- $1,810.1 million increase in net proceeds from maturity of investments, primarily time deposits;
- $215.3 million decrease in upfront payments for acquired IPR&D primarily driven by the $200.0 million payment under our license agreement with PharmaMar in the nine months ended September 30, 2020; and
- $95.1 million decrease in acquisition of intangible assets primarily related to the $100.0 million milestone payment to PharmaMar on FDA approval of Zepzelca in the nine months ended September 30, 2020.

Financing activities

Net cash provided by financing activities increased by $3,744.9 million in the nine months ended September 30, 2021 compared to the same period in 2020, primarily due to:

- An increase of $3,529.5 million in debt financing due to:
  - Net proceeds from issuance of borrowings under the Credit Agreement of $3,719.9 million and the Secured Notes of $1,471.5 million, partially offset by $843.0 million in repayment of long-term debt and payments for repurchase of the 2021 Notes of $218.8 million in the nine months ended September 30, 2021; compared to
  - Net proceeds from issuance of the 2026 Notes of $981.4 million, partially offset by payments for partial repurchase of the 2021 Notes of $356.2 million and repayment of long-term debt of $25.0 million in the nine months ended September 30, 2020.
- The impact of share repurchases of $146.5 million in the nine months ended September 30, 2020; and
- An increase of $82.8 million in proceeds from employee equity incentive and purchase plans in the nine months ended September 30, 2021.

Contractual Obligations

The table below presents a summary of our contractual obligations as of September 30, 2021 (in thousands):

	Payments Due by Period				
Contractual Obligations (1)	**Total**	**Less than 1 Year**	**1-3 Years**	**3-5 Years**	**More than 5 years**
Term Loan - principal	$ 3,574,708	$ 31,000	$ 62,000	$ 62,000	$ 3,419,708
Term Loan - interest (2)	931,699	144,925	286,130	281,170	219,474
Secured Notes - principal	1,500,000	—	—	—	1,500,000
Secured Notes - interest (3)	492,188	65,625	131,250	131,250	164,063
Exchangeable Senior Notes - principal	1,575,000	—	575,000	1,000,000	—
Exchangeable Senior Notes - interest (4)	125,875	28,625	57,250	40,000	—
Purchase and other obligations (5)	112,113	68,276	31,354	4,548	7,935
Operating lease obligations (6)	127,506	19,591	39,304	31,026	37,585
Finance lease obligations	10,700	877	1,740	1,740	6,343
Total	$ 8,449,789	$ 358,919	$ 1,184,028	$ 1,551,734	$ 5,355,108

(1) This table does not include potential future milestone payments or royalty obligations to third parties under asset purchase, product development, license and other agreements as the timing and likelihood of such milestone payments are not known, and, in the case of royalty obligations, as the amount of such obligations are not estimable. Our contingent obligations to third parties, in the form of development, regulatory and sales-based milestone payments, as of September 30, 2021 included $1,025.0 million across five targets under our strategic collaboration agreement with Codiak, $706.0 million under our license agreement with PharmaMar, $610.0 million under asset purchase and collaboration agreements with Redx, $375.0 million under our asset purchase and exclusive license agreement with SpringWorks Therapeutics, Inc., $260.0 million in connection with our acquisition of Cavion, $165.0 million to Aerial BioPharma LLC and SK Biopharmaceuticals Co. Ltd in connection with our acquisition of the rights to Sunosi, $155.5 million under our license agreement with Ligand and $395.2 million related to other agreements.

(2) As of September 30, 2021, the interest rate on the Dollar Term Loan and Euro Term Loan was 4.00% and 4.34%, respectively.

(3) We used the fixed interest rate of 4.375% on the Secured Notes to estimate interest owed as of September 30, 2021 until the final maturity date of these notes.

(4) We used the fixed interest rates of 1.50% on the 2024 Notes and 2.00% on the 2026 Notes to estimate interest owed as of September 30, 2021 until the respective final maturity dates of these notes.

(5) Consists primarily of noncancelable commitments to our third party manufacturers.

(6) Consists primarily of the minimum lease payments for our office buildings, manufacturing sites and automobile lease payments for our sales force. Operating expenses associated with our leased office buildings are not included in table above.

We do not provide for Irish income taxes on undistributed earnings of our foreign operations that are intended to be indefinitely reinvested in our foreign subsidiaries. In addition, our liability for unrecognized tax benefits has been excluded from the above contractual obligations table as the nature and timing of future payments, if any, cannot be reasonably estimated. We do not anticipate that the amount of our existing liability for unrecognized tax benefits will significantly change in the next twelve months.

Critical Accounting Estimates

To understand our financial statements, it is important to understand our critical accounting estimates. The preparation of our financial statements in conformity with U.S. generally accepted accounting principles requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions are required in determining the amounts to be deducted from gross revenues, in particular estimates of government rebates, which include Medicaid and TRICARE rebates, commercial contracting and estimated product returns. Significant estimates and assumptions are also required to determine whether to capitalize intangible assets, the amortization periods for identifiable intangible assets, the potential impairment of goodwill and other intangible assets and income taxes. Some of these judgments can be subjective and complex, and, consequently, actual results may differ from these estimates. For any given individual estimate or assumption we make, there may also be other estimates or assumptions that are reasonable.

Although we believe our estimates and assumptions are reasonable, they are based upon information available at the time the estimates and assumptions were made.

Our critical accounting policies and significant estimates are detailed in our Annual Report on Form 10-K for the year ended December 31, 2020. Our critical accounting policies and significant estimates have not changed substantially from those previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2020.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which are subject to the "safe harbor" created by those sections. Forward-looking statements are based on our management's current plans, objectives, estimates, expectations and intentions and on information currently available to our management. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expect," "plan," "anticipate," "believe," "estimate," "project," "predict," "propose," "intend," "continue," "potential," "possible," "foreseeable," "likely," "unforeseen" and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance, time frames or achievements to be materially different from any future results, performance, time frames or achievements expressed or implied by the forward-looking statements. We discuss many of these risks, uncertainties and other risk factors in greater detail under Part II, Item 1A of this Quarterly Report on Form 10-Q. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. Also, these forward-looking statements represent our plans, objectives, estimates, expectations and intentions only as of the date of this filing. You should read this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results and the timing of events may be materially different from what we expect. We hereby qualify our forward-looking statements by our cautionary statements. Except as required by law, we undertake no obligation to update or supplement any forward-looking statements publicly, or to update or supplement the reasons that actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk. The primary objectives of our investment policy, in order of priority, are as follows: safety and preservation of principal and diversification of risk; liquidity of investments sufficient to meet cash flow requirements; and competitive yield. Although our investments are subject to market risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or certain types of investment. Our investment policy allows us to maintain a portfolio of cash equivalents and short-term investments in a variety of securities, including U.S. federal government and federal agency securities, corporate bonds or commercial paper issued by U.S. corporations, money market instruments, certain qualifying money market mutual funds, certain repurchase agreements, and tax-exempt obligations of states, agencies and municipalities in the U.S. Our cash equivalents as of September 30, 2021 consisted of time deposits and money market funds which are not subject to significant interest rate risk.

We are exposed to risks associated with changes in interest rates in connection with our term loan borrowings. In May 2021 we entered into a credit agreement, or the Credit Agreement, that provides for (i) a seven-year $3.1 billion term loan B facility, or the Dollar Term Loan, (ii) a seven-year €625 million term loan B facility, or the Euro Term Loan and, together with the Dollar Term Loan, collectively known as the Term Loan and (iii) a five-year $500 million revolving credit facility, or the Revolving Credit Facility. We used the proceeds from the Term Loan (i) to repay in full $575.9 million under that certain credit agreement, dated as of June 18, 2015 (as amended) among the Company, and certain of our other subsidiaries as borrowers, the lenders party thereto and Bank of America, N.A., as administrative agent and collateral agent, or the Existing Credit Agreement, (ii) to fund, in part, the cash consideration payable in connection with the GW Acquisition and (iii) to pay related fees and expenses. There were no borrowings outstanding under the Revolving Credit Facility as of September 30, 2021. In the third quarter of 2021 we made a voluntary prepayment of €208.3 million on the Euro Term Loan. The Dollar Term Loan is subject to a London Inter-Bank Offering Rate, or LIBOR, floor of 0.50%. Based on the outstanding borrowings of $3.6 billion as of September 30, 2021, a hypothetical 1% increase or decrease in interest rates, above the LIBOR floor in the case of Dollar Term Loan borrowings, would increase or decrease net income for the remainder of 2021 by approximately $9 million.

In April 2021, we issued $1.5 billion in aggregate principal amount of 4.375% senior secured notes, due 2029, or the Secured Notes. In 2017, we completed a private placement of $575.0 million aggregate principal amount of 1.50% exchangeable senior notes due 2024, or the 2024 Notes, and in June 2020, we completed a private offering of $1.0 billion aggregate principal amount of 2.00% exchangeable senior notes due 2026, or the 2026 Notes. The 2024 Notes and the 2026 Notes, together with the 1.875% exchangeable senior notes due 2021, or the 2021 Notes, that were repurchased on maturity on August 15, 2021, are collectively known as the Exchangeable Senior Notes.

The Secured Notes, 2024 Notes and 2026 Notes have fixed annual interest rates of 4.375%, 1.50% and 2.00%, respectively, and we, therefore, do not have economic interest rate exposure on the Secured Notes and the Exchangeable Senior Notes. However, the fair values of the Secured Notes and Exchangeable Senior Notes are exposed to interest rate risk. Generally, the fair values of the Secured Notes and the Exchangeable Senior Notes will increase as interest rates fall and decrease as interest rates rise. The fair values of the Exchangeable Senior Notes are also affected by volatility in our ordinary share price. As of September 30, 2021 the fair values of the Secured Notes, 2024 Notes and 2026 Notes were estimated to be approximately $1.6 billion, $583 million and $1.2 billion, respectively.

In July 2017, the Financial Conduct Authority, or FCA, the authority that regulates LIBOR, announced it intended to stop compelling banks to submit rates for the calculation of LIBOR after 2021. In a further update, on November 30, 2020, ICE Benchmark Administration, the administrator of LIBOR, with the support of the U.S. Federal Reserve and FCA, announced plans to consult on ceasing publication of LIBOR on December 31, 2021 for only the one week and two month LIBOR tenors, and on June 30, 2023 for all other LIBOR tenors. While this announcement extends the transition period to June 2023, the U.S. Federal Reserve concurrently issued a statement advising banks to stop new LIBOR issuances by the end of 2021. The Alternative Reference Rates Committee, or ARRC, in the U.S. has proposed that the Secured Overnight Financing Rate, or SOFR, is the rate that represents best practice as the alternative to the U.S. dollar, or USD, LIBOR for use in derivatives and other financial contracts that are currently indexed to USD LIBOR. ARRC has proposed a paced market transition plan to SOFR from USD LIBOR and organizations are currently working on industry wide and company specific transition plans as it relates to derivatives and cash markets exposed to USD LIBOR. We currently have a USD LIBOR cross currency swap which matures in March 2022; as such, the impact of Inter-Bank Offering Rate, or IBOR, reform is not expected to be material.

Foreign Exchange Risk. We have significant operations in Europe as well as in the U.S. The functional currency of each foreign subsidiary is generally the local currency. We are exposed to foreign currency exchange risk as the functional currency financial statements of foreign subsidiaries are translated to U.S. dollars. The assets and liabilities of our foreign subsidiaries having a functional currency other than the U.S. dollar are translated into U.S. dollars at the exchange rate prevailing at the balance sheet date, and at the average exchange rate for the reporting period for revenue and expense accounts. The cumulative foreign currency translation adjustment is recorded as a component of accumulated other comprehensive loss in shareholders' equity. The reported results of our foreign subsidiaries will be influenced by their translation into U.S. dollars by currency movements against the U.S. dollar. Our primary currency translation exposure is related to our subsidiaries that have functional currencies denominated in sterling and euro. A hypothetical 10% strengthening or weakening in the rates used to translate the results of our foreign subsidiaries that have functional currencies denominated in sterling and euro would have increased or decreased net income for the nine months ended September 30, 2021 by approximately $43.0 million and $8.4 million, respectively.

Transactional exposure arises where transactions occur in currencies other than the functional currency. Transactions in foreign currencies are recorded at the exchange rate prevailing at the date of the transaction. The resulting monetary assets and liabilities are translated into the appropriate functional currency at exchange rates prevailing at the balance sheet date and the resulting gains and losses are reported in foreign exchange gain (loss) in the condensed consolidated statements of income (loss). As of September 30, 2021, our primary exposure to transaction risk primarily related to the translation of our Euro Term Loan and sterling and euro-denominated net monetary liabilities, including intercompany loans, held by subsidiaries with a U.S. dollar functional currency.

In order to hedge our exposure to foreign currency exchange risk associated with our Euro Term Loan, we entered into a cross-currency interest rate swap contract in May 2021 with a maturity date of March 31, 2022. The terms of this contract convert the principal repayments and interest payments on our Euro Term Loan into U.S. dollar. As of September 30, 2021, the cross-currency interest rate swap had a notional amount of $502.0 million which is designated for accounting purposes as a fair value hedge. The net liability fair value of the cross currency swap was $20.0 million as of September 30, 2021. The carrying amount of the Euro Term Loan and the fair value of the cross-currency interest rate swap contract will be remeasured with changes in the euro to U.S. dollar foreign exchange rates recognized within foreign exchange gain (loss) in the condensed consolidated statements of income (loss). The impact of a hypothetical increase or decrease in the euro to U.S. dollar exchange rate on the fair value of our cross-currency interest rate swap contract would be offset by a change in the value of the Euro Term Loan.

We have entered into foreign exchange forward contracts to manage the currency risk associated with the translation of our other sterling and euro-denominated net monetary liabilities, including intercompany loans. These foreign exchange

forward contracts are not designated as hedges; gains and losses on these derivative instruments are designed to offset gains and losses on the underlying balance sheet exposures. As of September 30, 2021, we held foreign exchange forward contracts with notional amounts totaling $407.7 million. The net liability fair value of outstanding foreign exchange forward contracts was $9.3 million as of September 30, 2021. Based on our foreign currency exchange rate exposures as of September 30, 2021, a hypothetical 10% adverse fluctuation in exchange rates would decrease the fair value of our foreign exchange forward contracts by approximately $28.1 million as of September 30, 2021. The resulting loss on these forward contracts would be offset by a positive impact on the underlying monetary assets and liabilities.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures. We have carried out an evaluation under the supervision and with the participation of management, including our principal executive officer and principal financial officer, of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on their evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of September 30, 2021.

Limitations on the Effectiveness of Controls. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Accordingly, our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met and, as set forth above, our principal executive officer and principal financial officer have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.

Changes in Internal Control over Financial Reporting. As discussed above, the GW Acquisition closed on May 5, 2021. The GW Acquisition was accounted for using the acquisition method of accounting. The results of operations of the acquired GW business have been included in our results of operations since May 5, 2021, and we are currently in the process of evaluating and integrating GW's historical internal controls over financial reporting with ours.

During the quarter ended September 30, 2021, other than continuing changes to our internal control process resulting from the GW Acquisition as discussed above, there have been no changes to our internal control over financial reporting that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

The information required to be set forth under this Item 1 is incorporated by reference to Note 11, Commitments and Contingencies—Legal Proceedings of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Item 1A. Risk Factors

We have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations. Our business could be harmed by any of these risks. The trading price of our ordinary shares could decline due to any of these risks, and you may lose all or part of your investment. In assessing these risks, you should also refer to the other information contained in this Quarterly Report on Form 10-Q, including our condensed consolidated financial statements and accompanying notes.

Summary Risk Factors

Below is a summary of material factors that make an investment in our ordinary shares speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, immediately follows this risk factor summary. The below risk factor summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. You should consider carefully the risks and uncertainties described below as part of your evaluation of an investment in our ordinary shares.

- Our inability to maintain or increase sales from our oxybate franchise would have a material adverse effect on our business, financial condition, results of operations and growth prospects.
- The introduction of new products in the U.S. market that compete with, or otherwise disrupt the market for, our oxybate products and product candidates would adversely affect sales of our oxybate products and product candidates.
- The distribution and sale of our oxybate products are subject to significant regulatory restrictions, including the requirements of a risk evaluation and mitigation strategy, or REMS, and safety reporting requirements, and these regulatory requirements subject us to risks and uncertainties, any of which could negatively impact sales of Xyrem and Xywav.
- While we expect our oxybate products, Xyrem and Xywav, to remain the largest part of our business, our success also depends on our ability to effectively commercialize other products in our neuroscience and oncology therapeutic areas.
- We face substantial competition from other companies, including companies with larger sales organizations and more experience working with large and diverse product portfolios.
- Adequate coverage and reimbursement from third party payors may not be available for our products and we may be unable to successfully contract for coverage from pharmacy benefit managers and other organizations; conversely, to secure coverage from these organizations, we may be required to pay rebates or other discounts or other restrictions to reimbursement, either of which could diminish our sales or adversely affect our ability to sell our products profitably.
- The pricing of pharmaceutical products has come under increasing scrutiny as part of a global trend toward healthcare cost containment and resulting changes in healthcare law and policy may impact our business in ways that we cannot currently predict, which could have a material adverse effect on our business and financial condition.
- In addition to access, coverage and reimbursement, the commercial success of our products depends upon their market acceptance by physicians, patients, third party payors and the medical community.
- Delays or problems in the supply of our products for sale or for use in clinical trials, loss of our single source suppliers or failure to comply with manufacturing regulations could materially and adversely affect our business, financial condition, results of operations and growth prospects.
- Our future success depends on our ability to successfully develop and obtain and maintain regulatory approvals for our late-stage product candidates and, if approved, to successfully launch and commercialize those product candidates.

- We may not be able to successfully identify and acquire or in-license additional products or product candidates to grow our business, and, even if we are able to do so, we may otherwise fail to realize the anticipated benefits of these transactions.
- Conducting clinical trials is costly and time-consuming, and the outcomes are uncertain. A failure to prove that our product candidates are safe and effective in clinical trials, or to generate data in clinical trials to support expansion of the therapeutic uses for our existing products, could materially and adversely affect our business, financial condition, results of operations and growth prospects.
- We may not realize the anticipated benefits and synergies from the acquisition of GW Pharmaceuticals.
- It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.
- We have incurred and may in the future incur substantial costs as a result of litigation or other proceedings relating to patents, other intellectual property rights and related matters, and we may be unable to protect our rights to, or commercialize, our products.
- Our business is currently adversely affected and could be materially and adversely affected in the future by the evolving effects of the COVID-19 pandemic and related global economic slowdown as a result of the current and potential future impacts on our commercialization efforts, clinical trial activity, research and development activities, supply chain and corporate development activities and other business operations, in addition to the impact of a global economic slowdown.
- Significant disruptions of information technology systems or data security breaches could adversely affect our business.
- We are subject to significant ongoing regulatory obligations and oversight, which may result in significant additional expense and limit our ability to commercialize our products.
- If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.
- We have incurred substantial debt, which could impair our flexibility and access to capital and adversely affect our financial position, and our business would be adversely affected if we are unable to service our debt obligations.
- To continue to grow our business, we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate and grow our business.

Risks Related to Our Lead Products and Product Candidates

Our inability to maintain or increase sales from our oxybate franchise would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Our business has been substantially dependent on Xyrem® (sodium oxybate) oral solution, and our financial results have been significantly influenced by sales of Xyrem. Our future plans assume that Xywav™, our oxybate product launched in November 2020 with 92%, or approximately 1,000 to 1,500 milligrams per day, less sodium than Xyrem, depending on the dose, absence of a sodium warning and dosing titration option, will become the treatment of choice for patients who can benefit from oxybate treatment, current Xyrem patients, and patients who previously were not prescribed Xyrem, including those patients for whom sodium content is a concern. In June 2021, U.S. Food and Drug Administration, or FDA, recognized seven years of Orphan Drug Exclusivity for Xywav stating that Xywav is clinically superior to Xyrem by means of greater safety due to reduced chronic sodium burden. Our ability to successfully commercialize Xywav will depend on, among other things, our ability to maintain adequate coverage and reimbursement for Xywav and acceptance of Xywav by payors, physicians and patients.

Our ability to maintain or increase oxybate product sales and realize the anticipated benefits from our investment in Xywav is subject to a number of additional risks and uncertainties as discussed in greater detail below, including those related to the introduction of authorized generic and generic versions of sodium oxybate and new products for treatment of cataplexy and/or excessive daytime sleepiness, or EDS, in narcolepsy in the U.S. market; the current and potential impacts of the COVID-19 pandemic, including the current and expected future negative impact on demand for our products and the uncertainty with respect to our ability to meet commercial demand in the future; increased pricing pressure from, changes in policies by, or restrictions on reimbursement imposed by, third party payors, including our ability to maintain adequate coverage and reimbursement for Xywav; and challenges to our intellectual property around Xyrem and/or Xywav. While we

expect that our business will continue to be substantially dependent on oxybate product sales from both Xyrem and Xywav, there is no guarantee that we can maintain oxybate sales at or near historical levels, or that oxybate sales will continue to grow. A significant decline in oxybate sales could cause us to reduce our operating expenses or seek to raise additional funds, which would have a material adverse effect on our business, financial condition, results of operations and growth prospects, including on our ability to acquire, in-license or develop new products to grow our business.

The introduction of new products in the U.S. market that compete with, or otherwise disrupt the market for, our oxybate products and product candidates would adversely affect sales of our oxybate products and product candidates.

While Xyrem and Xywav are currently the only products approved by FDA and marketed in the U.S. for the treatment of both cataplexy and EDS in both adult and pediatric patients with narcolepsy, new treatment options for cataplexy and EDS in narcolepsy have launched, and in the future, other products may be launched that are competitive with or disrupt the market for our oxybate products.

For example, in the future, we expect Xyrem and Xywav to face competition from authorized generic and generic versions of sodium oxybate. Nine companies have sent us notices that they had filed abbreviated new drug applications, or ANDAs, seeking approval to market a generic version of Xyrem, and we have filed and settled patent lawsuits with all nine companies. To date, FDA has approved or tentatively approved four of these ANDAs, and we believe that it is likely that FDA will approve or tentatively approve some or all of the others. In our patent litigation settlement with the first filer, West-Ward Pharmaceuticals Corp. (a wholly owned subsidiary of Hikma Pharmaceuticals PLC and now known as Hikma in the U.S.), or Hikma, we granted Hikma the right to sell an authorized generic product, or AG Product, with royalties back to us, in the U.S. beginning on January 1, 2023, or earlier under certain circumstances. Hikma has a right to elect to continue to sell the Hikma AG Product for a total of up to five years. We also granted Hikma a license to launch its own generic sodium oxybate product as early as six months after it has the right to sell the Hikma AG Product, but if it elects to launch its own generic product, Hikma will no longer have the right to sell the Hikma AG Product. In our settlements with Amneal Pharmaceuticals LLC, or Amneal, Lupin Inc., or Lupin, and Par Pharmaceutical, Inc., or Par, we granted each party the right to sell a limited volume of an AG Product in the U.S. beginning on July 1, 2023, or earlier under certain circumstances, and ending on December 31, 2025, with royalties back to us. AG Products will be distributed through the same REMS as Xyrem and Xywav. We also granted each of Amneal, Lupin and Par a license to launch its own generic sodium oxybate product under its ANDA on or after December 31, 2025, or earlier under certain circumstances, including the circumstance where Hikma elects to launch its own generic product. If Amneal, Lupin or Par elects to launch its own generic product under such circumstance, it will no longer have the right to sell an AG Product. In our settlements with each of the other five ANDA filers, we granted each a license to launch its own generic sodium oxybate product under its ANDA on or after December 31, 2025, or earlier under certain circumstances, including circumstances where Hikma launches its own generic sodium oxybate product. The actual timing of the launch of an AG Product or generic sodium oxybate product is uncertain because the launch dates of the AG Products and generic sodium oxybate products under our settlement agreements are subject to acceleration under certain circumstances.

Any ANDA holder launching an AG Product or another generic sodium oxybate product will independently establish the price of the AG Product and/or its own generic sodium oxybate product. Generic competition often results in decreases in the prices at which branded products can be sold. After any introduction of a generic product, whether or not it is an AG Product, a significant percentage of the prescriptions written for Xyrem will likely be filled with the generic product. Certain U.S. state laws allow for, and in some instances in the absence of specific instructions from the prescribing physician mandate, the dispensing of generic products rather than branded products when a generic version is available. This would result in reduction in sales of, and revenue from, Xyrem, although we would continue to receive royalties and other revenue based on sales of an AG Product in accordance with the terms of our settlement agreements.

It is possible that additional companies may file ANDAs seeking to market a generic version of Xyrem which could lead to additional patent litigation or challenges with respect to Xyrem. Such patent litigation or challenges could potentially trigger acceleration of the launch dates in our settlement agreements if, for example, our patents covering Xyrem were invalidated. Alternatively, the launch dates in our settlement agreements could be accelerated if a new ANDA filer were to obtain FDA approval for its sodium oxybate product, and launch its generic product through a generic sodium oxybate REMS before the entry dates specified in our settlement agreements. It is also possible that we could enter into a settlement agreement with a future ANDA filer that would permit such filer to enter the market on or prior to the launch date(s) in our settlement agreements. If a company launches a generic or authorized generic sodium oxybate product in any of these scenarios, except in limited circumstances related to an “at risk” launch, the launch date for Hikma’s AG Product would be accelerated to a date on or prior to the date of such entry, which could lead to acceleration of the other settling ANDA filers’ AG Product and generic sodium oxybate product launch dates as described above.

Another circumstance that could trigger acceleration of Hikma’s launch date for an AG Product, which would also accelerate Amneal, Lupin and Par’s launch dates for their AG Products and ultimately could lead to acceleration of the other settling ANDA filers’ launch dates for their generic sodium oxybate products, is a substantial reduction in Xyrem net sales. Such a reduction could occur under various circumstances, including from our sales of Xywav or if a third party introduces a

product to treat EDS or cataplexy in narcolepsy that leads to a substantial decline in Xyrem net sales. Accordingly, our strategy to drive revenue growth in our key franchises through, among other things, rapid adoption and broad access of Xywav in the U.S. could lead to the acceleration of such launch dates. Other companies may develop a sodium oxybate product for treatment of narcolepsy, using an alternative formulation or a different delivery technology, and seek approval in the U.S. using a new drug application, or NDA, approval pathway under Section 505(b)(2) and referencing the safety and efficacy data for Xyrem. In February 2021, FDA accepted for filing an NDA submitted by Avadel Pharmaceuticals plc, or Avadel, for an extended-release formulation of sodium oxybate which uses its proprietary technology for the treatment of EDS and cataplexy in patients with narcolepsy with a Prescription Drug User Fee Act, or PDUFA, target action date of October 15, 2021. On October 15, 2021, Avadel announced that FDA review is ongoing and FDA will likely not take action in October 2021 and will provide a new target action date. Xyrem may also face increased competition from new branded entrants to treat EDS in narcolepsy such as pitolisant. Other companies have announced that they have product candidates in various phases of development to treat the symptoms of narcolepsy, such as Axsome Therapeutics, Inc.'s reboxetine, and various companies are performing research and development on orexin agonists for the treatment of sleep disorders.

We expect that Xywav for the treatment of both cataplexy and EDS in patients with narcolepsy will face competition similar to that described above for Xyrem, including from generic or authorized generic sodium oxybate products or new branded entrants in narcolepsy notwithstanding FDA recognizing Orphan Drug Exclusivity for Xywav. For example, Lupin filed an ANDA for a generic version of Xywav in June 2021. Additional companies may file ANDAs seeking to market a generic version of Xywav which could lead to additional patent litigation or challenges with respect to Xywav. Moreover, Avadel has announced that it has obtained an orphan drug designation from FDA for its extended-release sodium oxybate formulation. To obtain approval with Orphan Drug Exclusivity, Avadel will have to show clinical superiority to Xyrem and Xywav. We cannot predict the timing or approvability of Avadel's sodium oxybate product candidate or how FDA will evaluate any clinical superiority arguments that either we or Avadel may make, but in any event, we expect to face competition from Avadel, if its product candidate is approved.

Moreover, non-oxybate products intended for the treatment of EDS or cataplexy in narcolepsy, including new market entrants, even if not directly competitive with Xyrem or Xywav, could have the effect of changing treatment regimens and payor or formulary coverage of Xyrem or Xywav in favor of other products, and indirectly materially and adversely affect sales of Xyrem and Xywav. Examples of such new market entrants include our product, Sunosi, and pitolisant, a drug that was approved by FDA in 2019 for the treatment of EDS in adult patients with narcolepsy and approved by FDA in October 2020 pursuant to a complete response resubmission for an adult cataplexy indication in the U.S. Pitolisant has also been approved and marketed in Europe to treat adult patients with narcolepsy, with or without cataplexy, and to treat EDS in obstructive sleep apnea, or OSA. In addition, we are also aware that prescribers often prescribe branded or generic medications for cataplexy, before or instead of prescribing oxybate therapy in Xyrem and Xywav, and that payors often require patients to try such medications before they will cover Xyrem or Xywav, even if they are not approved for this use. Examples of such products are described in "Business—Competition" in Part I, Item 1 of our Annual Report on Form 10-K for the year ended December 31, 2020.

We expect that the approval and launch of an AG Product or other generic version of Xyrem could have a material adverse effect on our sales of Xyrem and Xywav and on our business, financial condition, results of operations and growth prospects. We also expect that sales of Xywav will, and the approval and launch of any other sodium oxybate (including Avadel's extended-release sodium oxybate formulation) or alternative product that treats narcolepsy could, have a material adverse effect on our sales of Xyrem, which could have the additional impact of potentially triggering acceleration of market entry of AG Products or other generic sodium oxybate products under our patent litigation settlement agreements.

The distribution and sale of our oxybate products are subject to significant regulatory restrictions, including the requirements of a REMS and safety reporting requirements, and these regulatory requirements subject us to risks and uncertainties, any of which could negatively impact sales of Xyrem and Xywav.

The active pharmaceutical ingredient, or API, of Xyrem and Xywav, is a form of gamma-hydroxybutyric acid, or GHB, a central nervous system depressant known to be associated with facilitated sexual assault as well as with respiratory depression and other serious side effects. As a result, FDA requires that we maintain a REMS with elements to assure safe use, or ETASU, for Xyrem and Xywav to help ensure that the benefits of the drug in the treatment of cataplexy and EDS in narcolepsy outweigh the serious risks of the drug. The REMS imposes extensive controls and restrictions on the sales and marketing of Xyrem and Xywav that we are responsible for implementing. Any failure to demonstrate our substantial compliance with our REMS obligations, including as a result of business or other interruptions resulting from the evolving effects of the COVID-19 pandemic, or a determination by FDA that the REMS is not meeting its goals, could result in enforcement action by FDA, lead to changes in our REMS obligations, negatively affect sales of Xyrem or Xywav, result in additional costs and expenses for us and/or require us to invest a significant amount of resources, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

FDA has stated that it will evaluate the Xywav and Xyrem REMS on an ongoing basis and will require modifications as may be appropriate. We cannot predict whether FDA will request, seek to require or ultimately require modifications to, or impose additional requirements on, the Xywav and Xyrem REMS, including in connection with the submission of new oxybate products or indications, the introduction of authorized generics, or to accommodate generics, or whether FDA will approve modifications to the Xywav and Xyrem REMS that we consider warranted. Any modifications approved, required or rejected by FDA could change the safety profile of Xywav or Xyrem, and have a significant negative impact in terms of product liability, public acceptance of Xywav or Xyrem as a treatment for cataplexy and EDS in narcolepsy, and prescribers' willingness to prescribe, and patients' willingness to take, Xywav or Xyrem, any of which could have a material adverse effect on our oxybate business. Modifications approved, required or rejected by FDA could also make it more difficult or expensive for us to distribute Xywav or Xyrem, make distribution easier for oxybate competitors, disrupt continuity of care for Xywav or Xyrem patients and/or negatively affect sales of Xywav or Xyrem.

We depend on outside vendors, including Express Scripts Specialty Distribution Services, Inc., the central certified pharmacy, to distribute Xywav and Xyrem in the U.S., provide patient support services and implement the requirements of the Xywav and Xyrem REMS. If the central pharmacy fails to meet the requirements of the Xywav and Xyrem REMS applicable to the central pharmacy or otherwise does not fulfill its contractual obligations to us, moves to terminate our agreement, refuses or fails to adequately serve patients, or fails to promptly and adequately address operational challenges or challenges in implementing REMS modifications, whether due to business or other interruptions resulting from the evolving effects of the COVID-19 pandemic or otherwise, the fulfillment of Xywav or Xyrem prescriptions and our sales would be adversely affected. If we change to a new central pharmacy, new contracts might be required with government payors and other insurers who pay for Xywav or Xyrem, and the terms of any new contracts could be less favorable to us than current agreements. In addition, any new central pharmacy would need to be registered with the U.S. Drug Enforcement Administration, or DEA, and certified under the REMS and would also need to implement the particular processes, procedures and activities necessary to distribute under the Xywav and Xyrem REMS. Transitioning to a new pharmacy could result in product shortages, which would negatively affect sales of Xywav and Xyrem, result in additional costs and expenses for us and/or take a significant amount of time, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

In its approval of Hikma's ANDA, FDA waived the requirement of a single shared REMS between the brand drug and generic versions, approving Hikma's ANDA with a generic sodium oxybate REMS separate from the Xywav and Xyrem REMS, except for the requirement that the generic sodium oxybate REMS program pharmacies contact the Xywav and Xyrem REMS by phone to verify and report certain information. The generic sodium oxybate REMS was approved with the condition that it be open to all future sponsors of ANDAs or NDAs for sodium oxybate products. A sodium oxybate distribution system that is less restrictive than the Xywav and Xyrem REMS, such as the generic sodium oxybate REMS, which provides that generic sodium oxybate products and potentially new sodium oxybate products approved under a Section 505(b)(2) NDA approval pathway could be distributed through multiple pharmacies, could increase the risks associated with oxybate distribution. Because patients, consumers and others may not differentiate generic sodium oxybate from Xyrem or differentiate between the different REMS programs, any negative outcomes, including risks to the public, caused by or otherwise related to a separate sodium oxybate REMS, could have a significant negative impact in terms of product liability, our reputation and good will, public acceptance of Xywav or Xyrem as a treatment for cataplexy and EDS in narcolepsy, and prescribers' willingness to prescribe, and patients' willingness to take, Xywav or Xyrem, any of which could have a material adverse effect on our oxybate business.

We may face pressure to further modify the Xywav and Xyrem REMS or to license or share intellectual property pertinent to that REMS, including proprietary data required for the safe distribution of sodium oxybate, in connection with FDA's approval of the generic sodium oxybate REMS or another oxybate REMS that may be submitted or approved in the future. Our settlement agreements with ANDA filers do not directly impact FDA's waiver of the single shared system REMS requirement, any other ANDA or NDA filer's ability to develop and implement the generic sodium oxybate REMS for its sodium oxybate product, or our ability to take any action with respect to the safety of the generic sodium oxybate REMS. We cannot predict the outcome or impact on our business of any future action that we may take with respect to FDA's waiver of the single shared system REMS requirement, its approval and tentative approval of generic versions of sodium oxybate or the consequences of distribution of sodium oxybate through the generic sodium oxybate REMS approved by FDA or another separate REMS.

REMS programs have increasingly drawn public scrutiny from the U.S. Congress, the Federal Trade Commission, or FTC, and FDA, with allegations that such programs are used as a means of improperly blocking or delaying competition. In December 2019, as part of the Further Consolidated Appropriations Act of 2020, the U.S. Congress passed legislation known as the Creating and Restoring Equal Access To Equivalent Samples Act, or CREATES. CREATES is intended to prevent companies from using REMS and other restricted distribution programs as a means to deny potential competitors access to product samples that are reasonably necessary to conduct testing in support of an application that references a listed drug or

biologic, and provides such potential competitors a potential private right of action if the innovator fails to timely provide samples upon request. CREATES also grants FDA additional authority regarding approval of generic products with REMS.

It is possible that the FTC, FDA or other governmental authorities could claim that, or launch an investigation into whether, we are using our REMS programs in an anticompetitive manner or have engaged in other anticompetitive practices. The Federal Food, Drug and Cosmetic Act further states that a REMS ETASU shall not be used by an NDA holder to block or delay generic drugs or drugs covered by an application under Section 505(b)(2) from entering the market. In its 2015 letter approving the Xyrem REMS, FDA expressed concern that we were aware that the Xyrem REMS is blocking competition. From June 2020 to October 2021, we were served with a number of class action complaints that included allegations that we had used the Xyrem REMS to delay approval of generic sodium oxybate. In December 2020, these cases were centralized and transferred to the United States District Court for the Northern District of California, where the multidistrict litigation will proceed for the purpose of discovery and pre-trial proceedings. For additional information on these class action complaints, see Note 11, Commitments and Contingencies-Legal Proceedings of the Notes to Consolidated Financial Statements included in this Quarterly Report on Form 10-Q. It is possible that additional lawsuits will be filed against us making similar or related allegations. We cannot predict the outcome of these or potential additional lawsuits; however, if the plaintiffs were to be successful in their claims, they may be entitled to injunctive relief or we may be required to pay significant monetary damages, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Pharmaceutical companies, including their agents and employees, are required to monitor adverse events occurring during the use of their products and report them to FDA. The patient counseling and monitoring requirements of the Xywav and Xyrem REMS provide more extensive information about adverse events experienced by patients taking Xywav and Xyrem, including deaths, than is generally available for other products that are not subject to similar REMS requirements. As required by FDA and other regulatory agencies, the adverse event information that we collect for Xywav and Xyrem is regularly reported to FDA and could result in FDA requiring changes to Xywav and/or Xyrem labeling, including additional warnings or additional boxed warnings, or requiring us to take other actions that could have an adverse effect on patient and prescriber acceptance of Xywav and Xyrem. As required by FDA, Xywav's and Xyrem's current labeling includes a boxed warning regarding the risk of central nervous system depression and misuse and abuse.

Any failure to demonstrate our substantial compliance with the REMS or any other applicable regulatory requirements to the satisfaction of FDA or another regulatory authority could result in such regulatory authorities taking actions in the future which could have a material adverse effect on oxybate product sales and therefore on our business, financial condition, results of operations and growth prospects.

While we expect our oxybate products, Xyrem and Xywav, to remain the largest part of our business, our success also depends on our ability to effectively commercialize other products in our neuroscience and oncology therapeutic areas.

In addition to Xyrem, Xywav and our other neuroscience products and product candidates, we are commercializing a portfolio of products, including our other lead marketed products, Epidiolex, Defitelio, Vyxeos, Rylaze and Zepzelca. An inability to effectively commercialize Epidiolex, Defitelio, Vyxeos, Rylaze and Zepzelca and to maximize their potential where possible through successful research and development activities, whether due to the evolving effects of the COVID-19 pandemic or otherwise, would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Epidiolex

Successful commercialization of Epidiolex/Epidyolex (cannabidiol) is subject to many risks. While we have established our Epidiolex commercial team and have hired our U.S. and European sales forces, we will need to continue to maintain and further develop the teams in order to successfully coordinate the commercialization of Epidiolex. Even if we are successful in maintaining and continuing to develop our Epidiolex commercial team, there are many factors that could cause the commercialization of Epidiolex to be unsuccessful, including a number of factors that are outside our control. The commercial success of Epidiolex depends on the extent to which patients and physicians accept and adopt Epidiolex as a treatment for Lennox-Gastaut syndrome, or LGS, Dravet syndrome and Tuberous Sclerosis Complex, and we do not know whether our or others' estimates in this regard will be accurate. Physicians may not prescribe Epidiolex and patients may be unwilling to use Epidiolex if coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost. Additionally, any negative development for Epidiolex in the market after launch, in clinical development for additional indications, or in regulatory processes in other jurisdictions, may adversely impact the commercial results and potential of Epidiolex. Further, reports from the field indicate that COVID-19 and the lack of access to and limited availability of COVID-19 vaccines, especially for children under 12 years of age, have impacted the willingness of parents of pediatric patients to bring their children to a health care provider office, which can increase the risk of COVID exposure through contact with the healthcare system. We believe these dynamics have negatively impacted new patient starts in the U.S. and Europe. Thus, significant uncertainty remains regarding the commercial potential of Epidiolex.

Sunosi

We obtained approval of Sunosi® (solriamfetol) in the U.S. in 2019, in the European Union, or EU, in January 2020 and subsequently in other countries for the treatment of EDS associated with narcolepsy or OSA. Our ability to realize the anticipated benefits from our investment in Sunosi is subject to a number of risks and uncertainties, including the potential impacts of the continuing COVID-19 pandemic on the successful commercialization in the U.S. and the rolling launch in Europe; market acceptance of Sunosi; our ability, in a competitive retail pharmacy market, to differentiate Sunosi from other products that are prescribed to treat excessive sleepiness in patients with OSA or EDS in patients with narcolepsy; adequate coverage and reimbursement by government programs and other third party payors, including the impact of future coverage decisions by payors; restrictions on permitted promotional activities based on any additional limitations on the labeling for the product that may be required by FDA, or the European Commission, or the EC, or other regulatory authorities; and our ability to satisfy FDA's post-marketing requirements. If we are unable to successfully commercialize Sunosi in the U.S. and EU, or if sales of Sunosi do not reach the levels we expect, our anticipated revenue from Sunosi will be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Defitelio

Our ability to maintain and grow sales and to realize the anticipated benefits from our investment in Defitelio® (defibrotide sodium) is subject to a number of risks and uncertainties, including continued acceptance by hospital pharmacy and therapeutics committees in the U.S., the EU and other countries; the continued availability of favorable pricing and adequate coverage and reimbursement; the limited experience of, and need to educate, physicians in recognizing, diagnosing and treating hepatic veno-occlusive disease, or VOD, particularly in adults; the possibility that physicians recognizing VOD symptoms may not initiate or may delay initiation of treatment while waiting for those symptoms to improve, or may terminate treatment before the end of the recommended dosing schedule; and the limited size of the population of VOD patients who are indicated for treatment with Defitelio (particularly if changes in hematopoietic stem cell transplantation treatment protocols reduce the incidence of VOD diagnosis and demand for Defitelio).

Although we saw a resurgence in demand for Defitelio in the U.S. and outside the U.S. beginning in the end of the second quarter of 2020, due to the evolving effects of the COVID-19 pandemic, the reprioritization of healthcare resources and related delays, postponements or suspensions of certain medical procedures such as stem cell transplants, we continue to expect a negative impact on demand growth trends and utilization of Defitelio compared to historical periods. If sales of Defitelio do not reach the levels we expect, our anticipated revenue from the product would be negatively affected and our business, financial condition, results of operations and growth prospects would be materially adversely affected. In addition, because VOD is an ultra-rare disease, we have experienced inter-quarter variability in our Defitelio sales, which makes Defitelio sales difficult to predict from period to period. As a result, Defitelio sales results or trends in any period may not necessarily be indicative of future performance.

Rylaze

Our ability to realize the anticipated benefits from our investments in Rylaze™ (recombinant *Erwinia* asparaginase) is subject to a number of uncertainties, including our ability to successfully commercialize Rylaze in the U.S. including creating awareness among health care professionals and ensuring physicians are confident in its supply and that patients with acute lymphoblastic leukemia, or ALL, or lymphoblastic lymphoma, or LBL, will be given the appropriate course of therapy based on current FDA approval. In addition, there continues to be the potential of a competitive erwinia product being reintroduced into the marketplace that could create uncertainty in demand and utilization of Rylaze moving forward.

Vyxeos

Our ability to realize the anticipated benefits from our investment in Vyxeos® (daunorubicin and cytarabine) liposome for injection by successfully and sustainably growing sales is subject to a number of risks and uncertainties, including our ability to differentiate Vyxeos from other liposomal chemotherapies and generically available chemotherapy combinations with which physicians and treatment centers are more familiar; acceptance by hospital pharmacy and therapeutics committees in the U.S., the EU and other countries; the increasing complexity of the acute myeloid leukemia, or AML, landscape requiring changes in patient identification and treatment selection, including diagnostic tests and monitoring that clinicians may find challenging to incorporate; the use of new and novel compounds in AML that are either used off-label or are only approved for use in combination with other agents and that have not been tested in combination with Vyxeos; the increasing use of venetoclax, which received full FDA approval in October 2020 for AML treatment; the limited size of the population of high-risk AML patients who may potentially be indicated for treatment with Vyxeos, particularly as a result of the shift of healthcare resources toward less intensive outpatient AML treatments in the U.S. in light of the COVID-19 pandemic which is directly negatively impacting, or delaying, the use of Vyxeos, as well as the suspension of in-person interactions with healthcare professionals due to the COVID-19 pandemic; the availability of adequate coverage, pricing and reimbursement approvals; and competition from new and existing products and potential competition from products in development. Although we saw some recovery in demand for Vyxeos beginning in the end of the second quarter of 2020, due to the ongoing impacts of the COVID-19

pandemic, we continue to expect a negative impact on demand trends for and utilization of Vyxeos compared to historical periods. If sales of Vyxeos do not reach the levels we expect, our anticipated revenue from the product would be negatively affected, which would have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Zepzelca

Our ability to realize the anticipated benefits from our investment in Zepzelca® (lurbinectedin) is subject to a number of risks and uncertainties, including our ability to successfully commercialize Zepzelca in the U.S.; adequate supply of Zepzelca to meet demand; availability of favorable pricing and adequate coverage and reimbursement; the limited experience of, and need to educate, physicians in the use of Zepzelca for the treatment of metastatic small cell lung cancer, or SCLC; the potential for negative trial data read-outs in ongoing or future Zepzelca clinical trials; our and Pharma Mar, S.A., or PharmaMar's, ability to maintain accelerated approval or successfully complete a confirmatory study of Zepzelca; and the impact of the evolving effects of the COVID-19 pandemic on our ability to educate health care providers about Zepzelca in the treatment of relapsed, metastatic SCLC in the U.S.

We face substantial competition from other companies, including companies with larger sales organizations and more experience working with large and diverse product portfolios.

Our products compete, and our product candidates may in the future compete, with currently existing therapies, including generic drugs, product candidates currently under development by us and others and/or future product candidates, including new chemical entities that may be safer or more effective or more convenient than our products. Any products that we develop may be commercialized in competitive markets, and our competitors, which include large global pharmaceutical companies and small research-based companies and institutions, may succeed in developing products that render our products obsolete or noncompetitive. Many of our competitors, particularly large pharmaceutical and life sciences companies, have substantially greater financial, operational and human resources than we do. Smaller or earlier stage companies may also prove to be significant competitors, particularly through focused development programs and collaborative arrangements with large, established companies. In addition, many of our competitors deploy more personnel to market and sell their products than we do, and we compete with other companies to recruit, hire, train and retain pharmaceutical sales and marketing personnel. If our sales force and sales support organization are not appropriately resourced and sized to adequately promote our products, the commercial potential of our current and any future products may be diminished. In any event, the commercial potential of our current products and any future products may be reduced or eliminated if our competitors develop or acquire and commercialize generic or branded products that are safer or more effective, are more convenient or are less expensive than our products. If we are unable to compete successfully, our commercial opportunities will be reduced and our business, results of operations and financial conditions may be materially harmed.

There is a substantial amount of change occurring in the U.S. regarding the use of medical and recreational marijuana products. While federal law prohibits the sale and distribution of most marijuana products not approved or authorized by FDA, 46 states and the District of Columbia have legalized either cannabidiol, or CBD, or marijuana for either recreational or medical use, or both. Under the U.S. Farm Bill, enacted in late 2018, certain extracts and other material derived from cannabis are no longer controlled under the Federal Controlled Substances Act, or CSA. Although the marketing of such products as a food, dietary supplement, or for medical purposes remains subject to FDA requirements, FDA continues to evaluate regulatory pathways to permit CBD in conventional foods and dietary supplements. In addition, Congressional efforts related to legalization of marijuana continue. Although our business is distinct from that of entities marketing FDA-unapproved marijuana and CBD-containing dietary supplement, future legislation or federal government action authorizing the sale, distribution, use, and insurance reimbursement of non-FDA approved marijuana or cannabinoid products could increase competition for and adversely affect our ability to generate sales of Epidiolex and our cannabinoid product candidates.

In addition, Epidiolex and nabiximols compete with product offerings from a variety of companies. FDA approved Zogenix, Inc.'s low-dose fenfluramine, or Fintepla, in Dravet syndrome in June 2020, and Zogenix will submit its supplemental NDA for LGS in 2021. Ovid Therapeutics Inc./Takeda Pharmaceutical Company Limited, Eisai Company Limited, and Marinus Pharmaceuticals, Inc. are developing therapies for treating Developmental and Epileptic Encephalopathies (includes Dravet and LGS). Stiripentol has been approved in Europe for several years to treat Dravet syndrome and was approved in 2018 by FDA. Zynerba Pharmaceuticals, Inc. is developing a topical formulation of CBD, for which it is working with FDA on a path forward on CONNECT-FX data for Zygel in Fragile X syndrome. There are a number of public and private companies in the early stages of developing genetic therapies for the underlying causes of Dravet syndrome, including Stoke Therapeutics, Inc., which has an antisense oligonucleotide, STK-001, in early clinical trials. Other companies, including those with greater resources than us may announce similar plans in the future. In addition, there are non-FDA approved CBD preparations being made available from companies in the medical marijuana industry, which might attempt to compete with Epidiolex. The medical marijuana industry could provide additional competition for nabiximols, if and when it is approved by FDA. If we are unable to compete successfully, our commercial opportunities will be reduced and our business, results of operations and financial conditions may be materially harmed.

For a description of the competition that our lead marketed products and most advanced product candidates face or may face, see the discussion in "Business—Competition" in Part I, Item 1 of our Annual Report on Form 10-K for the year ended December 31, 2020 and the risk factor under the heading "*The introduction of new products in the U.S. market that compete with, or otherwise disrupt the market for, our oxybate products and product candidates would adversely affect sales of our oxybate products and product candidates"* in this Part I, Item 1A. For a description of the competition that Epidiolex faces or may face, see the discussion in "Business—Competition" in Part I, Item 1 of GW's Annual Report on Form 10-K for the year ended December 31, 2020.

Adequate coverage and reimbursement from third party payors may not be available for our products and we may be unable to successfully contract for coverage from pharmacy benefit managers and other organizations; conversely, to secure coverage from these organizations, we may be required to pay rebates or other discounts or other restrictions to reimbursement, either of which could diminish our sales or adversely affect our ability to sell our products profitably.

In both U.S. and non-U.S. markets, our ability to successfully commercialize and achieve market acceptance of our products depends in significant part on adequate financial coverage and reimbursement from third party payors, including governmental payors (such as the Medicare and Medicaid programs in the U.S.), managed care organizations and private health insurers. Without third party payor reimbursement, patients may not be able to obtain or afford prescribed medications. In addition, reimbursement guidelines and incentives provided to prescribing physicians by third party payors may have a significant impact on the prescribing physicians' willingness and ability to prescribe our products. The demand for, and the profitability of, our products could be materially harmed if the Medicaid program, Medicare program, other healthcare programs in the U.S. or elsewhere, or third party commercial payors in the U.S. or elsewhere deny reimbursement for our products, limit the indications for which our products will be reimbursed, or provide reimbursement only on unfavorable terms. In particular, we cannot predict to what extent the evolving effects of the COVID-19 pandemic may disrupt global healthcare systems and access to our products or result in a widespread loss of individual health insurance coverage due to unemployment, a shift from commercial payor coverage to government payor coverage, or an increase in demand for patient assistance and/or free drug programs, any of which could adversely affect net revenue.

As part of the overall trend toward cost containment, third party payors often require prior authorization for, and require reauthorization for continuation of, prescription products or impose step edits, which require prior use of another medication, usually a generic or preferred brand, prior to approving coverage for a new or more expensive product. Such restrictive conditions for reimbursement and an increase in reimbursement-related activities can extend the time required to fill prescriptions and may discourage patients from seeking treatment. We cannot predict actions that third party payors may take, or whether they will limit the access and level of reimbursement for our products or refuse to provide any approvals or coverage. From time to time, third party payors have refused to provide reimbursement for our products, and others may do so in the future.

Third party payors increasingly examine the cost-effectiveness of pharmaceutical products, in addition to their safety and efficacy, when making coverage and reimbursement decisions. We may need to conduct expensive pharmacoeconomic and/or clinical studies in order to demonstrate the cost-effectiveness of our products. If our competitors offer their products at prices that provide purportedly lower treatment costs than our products, or otherwise suggest that their products are safer, more effective or more cost-effective than our products, this may result in a greater level of access for their products relative to our products, which would reduce our sales and harm our results of operations. In some cases, for example, third party payors try to encourage the use of less expensive generic products through their prescription benefit coverage and reimbursement and co-pay policies. Because some of our products compete in a market with both branded and generic products, obtaining and maintaining access and reimbursement coverage for our products may be more challenging than for products that are new chemical entities for which no therapeutic alternatives exist.

Third party pharmacy benefit managers, or PBMs, other similar organizations and payors can limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication, and to exclude drugs from their formularies in favor of competitor drugs or alternative treatments, or place drugs on formulary tiers with higher patient co-pay obligations, and/or to mandate stricter utilization criteria. Formulary exclusion effectively encourages patients and providers to seek alternative treatments, make a complex and time-intensive request for medical exemptions, or pay 100% of the cost of a drug. In addition, in many instances, certain PBMs, other similar organizations and third party payors may exert negotiating leverage by requiring incremental rebates, discounts or other concessions from manufacturers in order to maintain formulary positions, which could continue to result in higher gross to net deductions for affected products. In this regard, we have entered into agreements with PBMs and payor accounts to provide rebates to those entities related to formulary coverage for our products, but we cannot guarantee that we will be able to agree to coverage terms with other PBMs and other third party payors. Payors could decide to exclude our products from formulary coverage lists, impose step edits that require patients to try alternative, including generic, treatments before authorizing payment for our products, limit the types of diagnoses for which coverage will be provided or impose a moratorium on coverage for products while the payor makes a coverage decision. An inability to maintain adequate formulary positions could increase patient cost-

sharing for our products and cause some patients to determine not to use our products. Any delays or unforeseen difficulties in reimbursement approvals could limit patient access, depress therapy adherence rates, and adversely impact our ability to successfully commercialize our products. If we are unsuccessful in maintaining broad coverage for our products, our anticipated revenue from and growth prospects for our products could be negatively affected.

In many countries outside the U.S., procedures to obtain price approvals, coverage and reimbursement can take considerable time after the receipt of marketing authorization. Many European countries periodically review their reimbursement of medicinal products, which could have an adverse impact on reimbursement status. In addition, we expect that legislators, policymakers and healthcare insurance funds in the EU member states will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU member states, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU member states, including those representing the larger markets. The HTA process, which is currently governed by national laws in each EU member state, is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU member states. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU member states, although in June 2021 the Council of the EU and the EU Parliament reached a provisional agreement on the HTA regulation which aims to harmonize the clinical benefit assessment of HTA across the EU. If we are unable to maintain favorable pricing and reimbursement status in EU member states that represent significant markets, our anticipated revenue from and growth prospects for our products in the EU could be negatively affected. For example, the EC granted marketing authorization for Vyxeos in August 2018, for Epidyolex in September 2019 and for Sunosi in January 2020, and, as part of our rolling launches of Vyxeos, Epidyolex and Sunosi in Europe, we are making pricing and reimbursement submissions in European countries. Due to the evolving effects of the COVID-19 pandemic, we currently anticipate delays by certain European regulatory authorities in their pricing and reimbursement reviews. If we experience setbacks or unforeseen difficulties in obtaining favorable pricing and reimbursement decisions, including as a result of regulatory review delays due to the COVID-19 pandemic, planned launches in the affected EU member states would be delayed, which could negatively impact anticipated revenue from and growth prospects for Vyxeos, Epidyolex and/or Sunosi.

The pricing of pharmaceutical products has come under increasing scrutiny as part of a global trend toward healthcare cost containment and resulting changes in healthcare law and policy may impact our business in ways that we cannot currently predict, which could have a material adverse effect on our business and financial condition.

Political, economic and regulatory influences are subjecting the healthcare industry in the U.S. to fundamental changes, particularly given the current atmosphere of mounting criticism of prescription drug costs in the U.S. We expect there will continue to be legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our products profitably, as governmental oversight and scrutiny of biopharmaceutical companies is increasing. For example, we anticipate that the U.S. Congress, state legislatures, and federal and state regulators may adopt or accelerate adoption of new healthcare policies and reforms intended to curb healthcare costs, such as federal and state controls on reimbursement for drugs (including under Medicare, Medicaid and commercial health plans), new or increased requirements to pay prescription drug rebates and penalties to government health care programs, and additional pharmaceutical cost transparency policies that aim to require drug companies to justify their prices through required disclosures.

Legislative and regulatory proposals that have recently been considered include, among other things, proposals to limit the terms of patent litigation settlements with generic sponsors, to define certain conduct around patenting and new product development as unfair competition, to facilitate the importation of drugs into the U.S. from other countries, and to increase manufacturer liability in the Medicare Part D pharmaceutical benefit. Legislative and regulatory proposals to reform the regulation of the pharmaceutical industry and reimbursement for pharmaceutical drugs are continually changing, and all such considerations may adversely affect our business and industry in ways that we cannot accurately predict.

There is also ongoing activity related to health care coverage. The Affordable Care Act substantially changed the way healthcare is financed by both governmental and private insurers. These changes impacted previously existing government healthcare programs and have resulted in the development of new programs, including Medicare payment-for-performance initiatives. Further, the Biden administration and Congress have taken and are expected to continue to take notable steps towards expanding health care coverage beyond the Affordable Care Act, which could have ramifications for the pharmaceutical industry.

If healthcare policies or reforms intended to curb healthcare costs are adopted or if we experience negative publicity with respect to pricing of our products or the pricing of pharmaceutical drugs generally, the prices that we charge for our products may be affected, our commercial opportunity may be limited and/or our revenues from sales of our products may be negatively impacted. We have periodically increased the price of Xyrem, most recently in January 2021, and there is no guarantee that we will make similar price adjustments to Xyrem and Xywav in the future or that price adjustments we have taken or may take in the future will not negatively affect Xyrem or Xywav sales volumes and revenues. We also have made and may in the future make price adjustments on our other products. There is no guarantee that such price adjustments will not negatively affect our reputation and our ability to secure and maintain reimbursement coverage for our products, which could limit the prices that we charge for our products, including Xyrem and Xywav, limit the commercial opportunities for our products and/or negatively impact revenues from sales of our products.

If we become the subject of any future government investigation or U.S. Congressional oversight with respect to drug pricing or other business practices, we could incur significant expense and could be distracted from operation of our business and execution of our strategy. Any such investigation or hearing could also result in reduced market acceptance and demand for our products, could harm our reputation and our ability to market our products in the future, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We expect that legislators, policymakers and healthcare insurance funds in Europe will continue to propose and implement cost-containing measures to keep healthcare costs down; particularly due to the financial strain that the COVID-19 pandemic has placed on their healthcare systems. These measures could include limitations on the prices we will be able to charge for our products or the level of reimbursement available for these products from governmental authorities or third party payors. Further, an increasing number of European and other foreign countries use prices for medicinal products established in other countries as “reference prices” to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

In addition to access, coverage and reimbursement, the commercial success of our products depends upon their market acceptance by physicians, patients, third party payors and the medical community.

If physicians do not prescribe our products, we cannot generate the revenues we anticipate from product sales. Market acceptance of each of our products by physicians, patients, third party payors and the medical community depends on:

- the clinical indications for which a product is approved and any restrictions placed upon the product in connection with its approval, such as a REMS or equivalent obligation imposed in a European or other foreign country, patient registry requirements or labeling restrictions;
- the prevalence of the disease or condition for which the product is approved and its diagnosis;
- the efficacy of the product in regular use;
- the severity of side effects and other risks in relation to the benefits of our products;
- unanticipated serious adverse events;
- acceptance by physicians and patients of each product as a safe and effective treatment;
- availability of sufficient product inventory to meet demand;
- physicians’ decisions relating to treatment practices based on availability of product;
- perceived clinical superiority and/or advantages over alternative treatments;
- overcoming negative publicity surrounding illicit use of
    - GHB or
    - cannabinoid and marijuana products

  and the view of patients, law enforcement agencies, physicians and regulators of our products as being the same or similar to illicit products;
- relative convenience and ease of administration;
- with respect to Xyrem and Xywav, physician and patient assessment of the burdens associated with obtaining or maintaining the certifications required under the Xywav and Xyrem REMS;
- the cost of treatment in relation to alternative treatments, including generic products; and
- the availability of financial or other assistance for patients who are uninsured or underinsured.

Because of our dependence upon market acceptance of our products, any adverse publicity associated with harm to patients or other adverse events resulting from the use or misuse of any of our products or any similar products distributed by other companies, including generic versions of our products, could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Delays or problems in the supply of our products for sale or for use in clinical trials, loss of our single source suppliers or failure to comply with manufacturing regulations could materially and adversely affect our business, financial condition, results of operations and growth prospects.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of process controls required to consistently produce the API and the finished product in sufficient quantities while meeting detailed product specifications on a repeated basis. We and our suppliers may encounter difficulties in production, including difficulties with the supply of manufacturing materials, production costs and yields, process controls, quality control and quality assurance, including testing of stability, impurities and impurity levels and other product specifications by validated test methods, and compliance with strictly enforced U.S., state and non-U.S. regulations. In addition, we and our suppliers are subject to FDA's current Good Manufacturing Practices, or cGMP, requirements, DEA regulations and equivalent rules and regulations prescribed by non-U.S. regulatory authorities. If we or any of our suppliers encounter manufacturing, quality or compliance difficulties with respect to any of our products, whether due to the evolving effects of the COVID-19 pandemic (including as a result of disruptions of global shipping and the transport of products) or otherwise, we may be unable to obtain or maintain regulatory approval or meet commercial demand for such products, which could adversely affect our business, financial condition, results of operations and growth prospects. In addition, we could be subject to enforcement action by regulatory authorities for our failure to comply with cGMP with respect to the products we manufacture in our facilities as well as for our failure to adequately oversee compliance with cGMP by any of our third party suppliers operating under contract. Moreover, failure to comply with applicable legal and regulatory requirements subjects us and our suppliers to possible regulatory action, including restrictions on supply or shutdown, which may adversely affect our or a supplier's ability to supply the ingredients or finished products we need.

We have a manufacturing and development facility in Athlone, Ireland where we manufacture Xyrem and Xywav, a manufacturing plant in Villa Guardia, Italy where we produce the defibrotide drug substance and a commercial manufacturing facility in the U.K. in Kent Science Park, where we produce Epidiolex/Epidyolex and Sativex. We currently do not have our own commercial manufacturing or packaging capability for our other products, product candidates or their APIs. As a result, our ability to develop and supply products in a timely and competitive manner depends primarily on third party suppliers being able to meet our ongoing commercial and clinical trial needs for API, other raw materials, packaging materials and finished products.

In part due to the limited market size for our products and product candidates, we have a single source of supply for most of our marketed products, product candidates and their APIs. Single sourcing puts us at risk of interruption in supply in the event of manufacturing, quality or compliance difficulties. If one of our suppliers fails or refuses to supply us for any reason, it would take a significant amount of time and expense to implement and execute the necessary technology transfer to, and to qualify, a new supplier. FDA and similar international or national regulatory bodies must approve manufacturers of the active and inactive pharmaceutical ingredients and certain packaging materials used in our products. If there are delays in qualifying new suppliers or facilities or a new supplier is unable to meet FDA's or similar international regulatory body's requirements for approval, there could be a shortage of the affected products for the marketplace or for use in clinical studies, or both, which could negatively impact our anticipated revenues and could potentially cause us to breach contractual obligations with customers or to violate local laws requiring us to deliver the product to those in need.

We are responsible for the manufacture and supply of Sativex (nabiximols) to our collaboration partners and for the manufacture and supply of Epidiolex/Epidyolex, nabiximols and other cannabinoid product candidates for commercial use and for use in clinical trials. The manufacturing of Epidiolex/Epidyolex, nabiximols and our product candidates necessitates compliance with GMP and other regulatory requirements in jurisdictions internationally. Our ability to successfully manufacture Epidiolex/Epidyolex, nabiximols and other cannabinoid product candidates involves cultivation of botanical raw material from specific cannabinoid plants, extraction and purification processes, manufacture of finished products and labeling and packaging, which includes product information, tamper evidence and anti-counterfeit features, under tightly controlled processes and procedures. In addition, we must ensure chemical consistency among our batches, including clinical batches and, if approved, marketing batches. Demonstrating such consistency may require typical manufacturing controls as well as clinical data. We must also ensure that our batches conform to complex release specifications. For certain steps in the manufacturing process for nabiximols, we are currently reliant on single manufacturing facilities and no back-up facilities are yet in place. We have a second site at which we can grow the specific cannabinoid plants that produce the CBD used in Epidiolex/Epidyolex, a second site at which we can extract CBD from botanical raw material and a second site at which we can crystallize the purified CBD from the liquid plant extract. Because nabiximols is a complex mixture manufactured from plant materials, and because the release specifications may not be identical in all countries, certain batches may fail release testing and not be able to be commercialized. A number of our product candidates (excluding Epidiolex/Epidyolex) also consist of a complex mixture manufactured from plant materials, and are therefore subject to a similar risk. If we are unable to manufacture Epidiolex/Epidyolex, nabiximols or other product candidates in accordance with regulatory specifications, including GMP, or if there are disruptions in our manufacturing process due to damage, loss or otherwise, or failure to pass regulatory inspections of our manufacturing facilities, we may not be able to meet current demand or supply sufficient product for use in clinical trials, and

this may also harm our ability to commercialize Epidiolex/Epidyolex, nabiximols and our product candidates on a timely or cost-competitive basis, if at all. Our manufacturing program requires significant time and resources and may not be successful, may lead to delays, interruptions to supply or may prove to be more costly than anticipated.

Vyxeos is manufactured by Baxter Oncology GmbH, or Baxter, which is a sole source supplier from a single site location. There have been batch failures due to mechanical, component, raw materials and other issues in the production of Vyxeos, and batches have been produced that have otherwise not been in compliance with applicable specifications. We are continuing to work with Baxter and others to address manufacturing complexities related to Vyxeos. Moreover, the proprietary technology that supports the manufacture of Vyxeos is not easily transferable. Consequently, engaging an alternate manufacturer may be difficult, costly and time-consuming. If we fail to obtain a sufficient supply of Vyxeos in accordance with applicable specifications on a timely basis, our sales of Vyxeos, our future maintenance and potential growth of the market for this product, our ability to conduct ongoing and future clinical trials of Vyxeos, and our business, financial condition, results of operations and growth prospects could be materially adversely affected. In addition, while the APIs in Vyxeos, daunorubicin and cytarabine, are available from a number of suppliers, certain suppliers have received warning letters from FDA. As a result, we have qualified other suppliers for each API, and we provided the qualification data to FDA. If FDA restricts importation of API from either supplier, and we are unable to qualify API from additional suppliers in a timely manner, or at all, our ability to successfully commercialize Vyxeos and generate sales of this product at the level we expect and to conduct ongoing and future clinical trials of Vyxeos could be materially and adversely affected.

Rylaze drug substance is manufactured by AGC Biologics at its facility in Copenhagen, Denmark and the drug product is manufactured and packaged by Patheon at its facility in Greenville, North Carolina. Both sites have ample capacity to support forecast demand and we have secured supply for more than one year's forecast demand. To successfully manufacture Rylaze, the manufacturer must have an adequate master and working cell bank. If we fail to obtain a sufficient supply of Rylaze in accordance with applicable specifications on a timely basis, our sales of Rylaze, our future maintenance and potential growth of the market for this product, our competitive advantage over competing products that have supply constraints, and our business, financial condition, results of operations and growth prospects could be materially adversely affected.

In addition, in order to conduct our ongoing and any future clinical trials of, complete marketing authorization submissions for, and potentially launch our other product candidates, we also need to have sufficient quantities of product manufactured.

Moreover, to obtain approval from FDA or a similar international or national regulatory body of any product candidate, we or our suppliers for that product must obtain approval by the applicable regulatory body to manufacture and supply product, in some cases based on qualification data provided to the applicable body as part of our regulatory submission. Any delay in generating, or failure to generate, data required in connection with submission of the chemistry, manufacturing and controls portions of any regulatory submission could negatively impact our ability to meet our anticipated submission dates, and therefore our anticipated timing for obtaining FDA or similar international or national regulatory body approval, or our ability to obtain regulatory approval at all. In addition, any failure of us or a supplier to obtain approval by the applicable regulatory body to manufacture and supply product or any delay in receiving, or failure to receive, adequate supplies of a product on a timely basis or in accordance with applicable specifications could negatively impact our ability to successfully launch and commercialize products and generate sales of products at the levels we expect.

If the effects of the COVID-19 pandemic become more severe and begin to impact supply of manufacturing materials or essential distribution systems such as general delivery services, or require us or our suppliers to again cease or restrict operations at our respective manufacturing facilities, we could experience disruptions to our supply chain and operations, and associated delays in the manufacturing and supply of our products, which would adversely impact our ability to generate sales of our approved products and our business, financial condition, results of operations and growth prospects would be materially adversely affected. For example, supply chain interruptions and shortage of construction materials could lead to delays and rising costs associated with our planned construction project at our commercial manufacturing facility in the U.K. at Kent Science Park. In addition, energy prices have spiked recently due to global macro-economic issues, which can have a direct impact on CO2 prices and availability. CO2 is a critical raw material for manufacturing our cannabinoid products.

Risks Related to Growth of Our Product Portfolio and Research and Development

Our future success depends on our ability to successfully develop and obtain and maintain regulatory approvals for our late-stage product candidates and, if approved, to successfully launch and commercialize those product candidates.

The testing, manufacturing and marketing of our products require regulatory approvals, including approval from FDA and similar bodies in Europe and other countries. If FDA, the European Medicines Agency, or EMA, or the competent authorities of the EU member states or other European countries determine that our quality, safety or efficacy data do not warrant marketing approval for a product candidate, we could be required to conduct additional clinical trials as a condition to

receiving approval, which could be costly and time-consuming and could delay or preclude the approval of our application. Our inability to obtain and maintain regulatory approval for our product candidates in the U.S. and internationally and to successfully commercialize new products that are approved would prevent us from receiving a return on our investments and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Due to the evolving effects of the COVID-19 pandemic, it is possible that we could experience delays in the timing of marketing application review by regulatory authorities and/or our interactions with regulatory authorities due to limited staffing or working hours of governmental employees, governmental "stay-at-home" orders and travel restrictions with respect to physical inspections if required for regulatory approval, or the diversion of regulatory authority efforts and attention to approval of other therapeutics or other activities related to COVID-19, which could delay anticipated approval decisions and otherwise delay or limit our ability to make planned regulatory submissions or obtain new product approvals. It is possible that we could experience delays in regulatory interactions and review of submissions due to COVID-19 impacts described above, such as with respect to our development pathway for nabiximols.

Even if we receive approval of a product, regulatory authorities may impose significant labeling restrictions or requirements, including limitations on the dosing of the product, requirements around the naming or strength of a product, restrictions on indicated uses for which we may market the product, the imposition of a boxed warning or other warnings and precautions, and/or the requirement for a REMS or equivalent obligation imposed in a European or other foreign country to ensure that the benefits of the drug outweigh the risks. FDA requires a REMS and a boxed warning for Xyrem and Xywav, and similar restrictions could be imposed on other products in the future. Our receipt of approval for narrower indications than sought, restrictions on marketing through a REMS or equivalent obligation imposed in a European or other foreign country, or significant labeling restrictions or requirements in an approved label such as a boxed warning, could have a negative impact on our ability to recoup our research and development costs and to successfully commercialize that product, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Regulatory authorities may also impose post-marketing obligations as part of their approval, which may lead to additional costs and burdens associated with commercialization of the drug, and may pose a risk to maintaining approval of the drug. We are subject to certain post-marketing requirements and commitments in connection with the approval of certain of our products, including Epidiolex, Defitelio, Vyxeos, Sunosi, Rylaze and Zepzelca. These post-marketing requirements and commitments include satisfactorily conducting multiple post-marketing clinical trials and safety studies. For example, FDA granted accelerated approval to Zepzelca for relapsed SCLC based on data from a Phase 2 trial, which approval is contingent upon verification and description of clinical benefit in a post-marketing clinical trial. We and our licensor PharmaMar are committed to further study of lurbinectedin both as a single agent and in combination, and have reached agreement with FDA regarding a confirmatory clinical development program. Our failure to confirm its clinical benefit could result in the withdrawal of approval of Zepzelca, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. With respect to FDA's and EC's approvals of Epidiolex/Epidyolex, we are subject to certain post-marketing requirements. Failure to comply with these post-marketing requirements could result in withdrawal of our marketing approval for Epidiolex/Epidyolex and/or other civil or criminal penalties. In any event, if we are unable to comply with our post-marketing obligations imposed as part of the marketing approvals in the U.S., the EU, or other countries, our approval may be varied, suspended or revoked, product supply may be delayed and our sales of our products could be materially adversely affected.

We are pursuing activities related to the development of additional asparaginase products for patients with ALL or other hematological malignancies. Several of our external research and development collaborations are focused on these efforts, including our agreement with Ligand Pharmaceuticals Incorporated, or Ligand. We developed Rylaze, a recombinant Erwinia asparaginase product for the treatment of patients with ALL and LBL who have hypersensitivity to E. coli-derived asparaginase, under our Ligand agreement. We also have clinical development efforts in a variety of other areas, including those focused on expanding the potential of Defitelio, Epidiolex/Epidyolex, Vyxeos, Sunosi, Rylaze and Xywav, as well as clinical development efforts focused on JZP-385 for the treatment of essential tremor. Because combination regimens and the continual generation of new data have become particularly important in AML, if we are unable to initiate multiple combination studies, safely combine Vyxeos with novel agents, or if efficacy results do not meet clinicians' expectations, our growth prospects could be materially adversely affected. Epidiolex has been administered only to a limited number of patients and in limited populations in clinical trials. While FDA and EC granted approval of Epidiolex/Epidyolex based on the data included in GW's NDA, sNDA and marketing authorization application, we do not know whether the results will be consistent with those resulting from administration of the drug to a large number of patients. New data relating to Epidiolex/Epidyolex, including from adverse event reports and post-marketing studies in the U.S. and Europe, and from other ongoing clinical trials, may result in changes to the product label and/or imposition of a REMS and may adversely affect sales, or result in withdrawal of Epidiolex/Epidyolex from the market. FDA, EMA and regulatory authorities in other jurisdictions may also consider the new data in reviewing Epidiolex/Epidyolex marketing applications for indications other than our approved uses in other jurisdictions, or impose additional post-approval requirements. If any of these actions were to occur, it could result in significant expense and delay or limit our ability to generate sales of Epidiolex/Epidyolex. If we are not successful in the

clinical development of our product candidates, if we are unable to obtain regulatory approval for our product candidates in a timely manner, or at all, or if sales of an approved product do not reach the levels we expect, our anticipated revenue from our product candidates would be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We may not be able to successfully identify and acquire or in-license additional products or product candidates to grow our business, and, even if we are able to do so, we may otherwise fail to realize the anticipated benefits of these transactions.

In addition to continued investment in our research and development pipeline, we intend to grow our business by acquiring or in-licensing, and developing, including with collaboration partners, additional products and product candidates that we believe are highly differentiated and have significant commercial potential. However, we may be unable to identify or consummate suitable acquisition or in-licensing opportunities, and this inability could impair our ability to grow our business. Other companies, many of which may have substantially greater financial, sales and marketing resources, compete with us for these opportunities. Even if appropriate opportunities are available, we may not be able to successfully identify them, or we may not have the financial resources necessary to pursue them.

Even if we are able to successfully identify and acquire, in-license or develop additional products or product candidates, we may not be able to successfully manage the risks associated with integrating any products or product candidates into our portfolio or the risks arising from anticipated and unanticipated problems in connection with an acquisition or in-licensing. Further, while we seek to mitigate risks and liabilities of potential acquisitions and in-licensing transactions through, among other things, due diligence, there may be risks and liabilities that such due diligence efforts fail to discover, that are not disclosed to us, or that we inadequately assess. Any failure in identifying and managing these risks, liabilities and uncertainties effectively, could have a material adverse effect on our business, results of operations and financial condition. In addition, product and product candidate acquisitions, particularly when the acquisition takes the form of a merger or other business consolidation such as our acquisition of GW, have required, and any similar future transactions also will require, significant efforts and expenditures, including with respect to transition and integration activities. We may encounter unexpected difficulties, or incur substantial costs, in connection with potential acquisitions and similar transactions, which include:

- the need to incur substantial debt and/or engage in dilutive issuances of equity securities to pay for acquisitions;
- the potential disruption of our historical core business;
- the strain on, and need to continue to expand, our existing operational, technical, financial and administrative infrastructure;
- the difficulties in integrating acquired products and product candidates into our portfolio;
- the difficulties in assimilating employees and corporate cultures;
- the failure to retain key managers and other personnel;
- the need to write down assets or recognize impairment charges;
- the diversion of our management's attention to integration of operations and corporate and administrative infrastructures; and
- any unanticipated liabilities for activities of or related to the acquired business or its operations, products or product candidates.

As a result of these or other factors, products or product candidates we acquire, or obtain licenses to, may not produce the revenues, earnings or business synergies that we anticipated, acquired or in-licensed product candidates may not result in regulatory approvals, and acquired or licensed products may not perform as expected. Failure to manage effectively our growth through acquisitions or in-licensing transactions could adversely affect our growth prospects, business, results of operations and financial condition.

Conducting clinical trials is costly and time-consuming, and the outcomes are uncertain. A failure to prove that our product candidates are safe and effective in clinical trials, or to generate data in clinical trials to support expansion of the therapeutic uses for our existing products, could materially and adversely affect our business, financial condition, results of operations and growth prospects.

As a condition to regulatory approval, each product candidate must undergo extensive and expensive preclinical studies and clinical trials to demonstrate to a statistically significant degree that the product candidate is safe and effective. The results at any stage of the development process may lack the desired safety, efficacy or pharmacokinetic characteristics. If FDA determines that the safety or efficacy data included in any marketing application we submit do not warrant marketing approval for the affected product or product candidate, we may be required to conduct additional clinical trials, which could be costly and time-consuming. Even if we believe we have successfully completed testing, FDA or any equivalent non-U.S. regulatory agency may determine our data is not sufficiently compelling to warrant marketing approval for the indications sought, if at all, and may require us to engage in additional clinical trials or provide further analysis which may be costly and time-consuming. Any adverse events or other data generated during the course of clinical trials of our product candidates and/or clinical trials

related to additional indications for our commercialized products could result in action by FDA or an equivalent non-U.S. regulatory agency, which may restrict our ability to sell, or adversely affect sales of, currently marketed products, or such events or other data could otherwise have a material adverse effect on a related commercial product, including with respect to its safety profile. Any failure or delay in completing such clinical trials could materially and adversely affect the maintenance and growth of the markets for the related marketed products, which could adversely affect our business, financial condition, results of operations and overall growth prospects.

In addition to issues relating to the results generated in clinical trials, clinical trials can be delayed or halted for a variety of reasons, including:

- direct and indirect impacts of the evolving effects of the COVID-19 pandemic on various aspects and stages of the clinical development process, including the inherent limitations of remote and virtual approaches;
- difficulty identifying, recruiting or enrolling eligible patients, often based on the number of clinical trials, particularly in oncology, with enrollment criteria targeting the same patient population, and in rare diseases with small patient populations;
- difficulty identifying a clinical development pathway, including viable indications and appropriate clinical trial protocol design, particularly where there is no applicable regulatory precedent;
- delays or failures in obtaining regulatory authorization to commence a trial because of safety concerns of regulators relating to our product candidates or similar product candidates of our competitors or failure to follow regulatory guidelines;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel, quarantines or social distancing protocols imposed or recommended by federal or state governments, employers and others in connection with the COVID-19 pandemic;
- delays or failures in obtaining clinical materials and manufacturing sufficient quantities of the product candidate for use in trials;
- delays or failures in reaching agreement on acceptable terms with prospective study sites;
- delays or failures in obtaining approval of our clinical trial protocol from an institutional review board, known as an ethics committee in Europe, to conduct a clinical trial at a prospective study site;
- failure of our clinical trials and clinical investigators, including contract research organizations or other third parties assisting us with clinical trials, to satisfactorily perform their contractual duties, meet expected deadlines and comply with FDA and other regulatory agencies' requirements, including good clinical practices;
- unforeseen safety issues;
- inability to monitor patients adequately during or after treatment;
- difficulty monitoring multiple study sites; or
- insufficient funds to complete the trials.

In some jurisdictions such as the EU, initiating phase 3 clinical trials and clinical trials in the pediatric population is subject to a requirement to obtain approval or a waiver from the competent authorities of the EU Member States and/or the EMA. If we do not obtain such approval our ability to conduct clinical trials and obtain marketing authorizations or approvals may be severely impaired and our business may be adversely impacted.

In light of the evolving effects of the COVID-19 pandemic, we have taken measures to implement remote and virtual approaches, including remote data monitoring where possible, to maintain patient safety and trial continuity and to preserve study integrity. We have seen limited COVID-19-related impact to our mid- and late-stage clinical trial activity, despite delays in initiating trial sites. However, GW had begun to recruit patients for an early-stage clinical trial of Epidiolex in the treatment of Rett syndrome and GW terminated this trial in November 2020 due to severe feasibility challenges arising from COVID-19. We could also see an impact on the ability to supply study drug, report trial results, or interact with regulators, ethics committees or other important agencies due to limitations in regulatory authority employee resources or otherwise. In addition, we rely on contract research organizations or other third parties to assist us with clinical trials, and we cannot guarantee that they will continue to perform their contractual duties in a timely and satisfactory manner as a result of the evolving effects of the COVID-19 pandemic. If these effects become more severe, we could experience significant disruptions to our clinical development timelines, which would adversely affect our business, financial condition, results of operations and growth prospects. In addition, some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as health care providers, may have heightened exposure to COVID-19, may adversely impact our clinical trial operations.

Risks Related to the GW Acquisition

We may not realize the anticipated benefits from the acquisition of GW.

On May 5, 2021, we completed the acquisition of GW. The success of the acquisition will depend, in part, on our ability to realize the anticipated benefits from successfully combining our and GW's historical businesses and the integration of our business practices and operations with GW's so that we can fully realize the anticipated benefits of the acquisition. Epidiolex and the other products and technologies acquired may not be successful or continue to grow at the same rate as when our companies operated independently or they may require significantly greater resources and investments than originally anticipated. Conversely, the liabilities assumed in the transaction could be greater than originally anticipated. In addition, difficulties may arise during the process of combining the operations of our companies that could result in the failure to achieve the synergies or free cash flow that we anticipate, the failure to integrate operations and internal systems, programs and controls, the loss of key employees that may be difficult to replace in the very competitive pharmaceutical field, the failure to harmonize both companies' corporate cultures, and the disruption of each company's ongoing businesses or inconsistencies in standards, controls, procedures and policies that adversely affect our ability to maintain relationships with customers, suppliers, distributors, collaboration partners, clinical trial investigators or managers of our clinical trials. As a result, the anticipated benefits of the acquisition may not be realized fully within the expected timeframe or at all or may take longer to realize or cost more than expected, which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

Risks Related to Our Intellectual Property

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.

Our commercial success depends in part on obtaining, maintaining and defending intellectual property protection for our products and product candidates, including protection of their use and methods of manufacturing and distribution. Our ability to protect our products and product candidates from unauthorized making, using, selling, offering to sell or importation by third parties depends on the extent to which we have rights under valid and enforceable patents or have adequately protected trade secrets that cover these activities.

The degree of protection to be afforded by our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- our patent applications, or those of our licensors or partners, may not result in issued patents;
- others may independently develop similar or therapeutically equivalent products without infringing our patents, or those of our licensors, such as products that are not covered by the claims of our patents, or for which we do not have adequate exclusive rights under our license agreements;
- our issued patents, or those of our licensors or partners, may be held invalid or unenforceable as a result of legal challenges by third parties or may be vulnerable to legal challenges as a result of changes in applicable law;
- our patents covering certain aspects of our products could be delisted from FDA's Orange Book as a result of challenges by third parties before FDA or the courts;
- we or our licensors or partners might not have been the first to invent or file, as appropriate, subject matters covered by our issued patents or pending patent applications or those of our licensors or partners;
- competitors may manufacture products in countries where we have not applied for patent protection or that have a different scope of patent protection or that do not respect our patents; or
- others may be issued patents that prevent the sale of our products or require licensing and the payment of significant fees or royalties.

Patent enforcement generally must be sought on a country-by-country basis, and issues of patent validity and infringement may be judged differently in different countries. Many companies have encountered significant problems in protecting, defending and enforcing intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property rights, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Changes in either the patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property portfolio. Even if we are able to obtain patents covering our products and product candidates, any patent may be challenged, and potentially invalidated or held unenforceable, including through patent litigation or through patent office procedures that permit challenges to patent validity. Patents can also be circumvented, potentially including by FDA approval of an ANDA or Section 505(b)(2) application that avoids infringement of our intellectual property.

In June 2021, we received notice from Lupin that it has filed with FDA an ANDA for a generic version of Xywav. The notice from Lupin included a "paragraph IV certification" with respect to ten of our patents listed in FDA's Orange Book for Xywav on the date of our receipt of the notice. A paragraph IV certification is a certification by a generic applicant that patents covering the branded product are invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the generic product.

On July 28, 2021, we filed a patent infringement suit against Lupin in the United States District Court for the District of New Jersey. The complaint alleges that by filing its ANDA, Lupin has infringed ten of our Orange Book listed patents. We are seeking a permanent injunction to prevent Lupin from introducing a generic version of Xywav that would infringe our patents. As a result of this lawsuit, we expect that a stay of approval of up to 30 months will be imposed by FDA on Lupin's ANDA. In June 2021, FDA recognized seven years of Orphan Drug Exclusivity for Xywav through July 21, 2027. On October 4, 2021, Lupin filed an answer to the complaint and counterclaims asserting that the patents are invalid or not enforceable, and that its product, if approved, will not infringe our patents.

We have settled patent litigation with nine companies seeking to introduce generic versions of Xyrem in the U.S. by granting those companies licenses to launch their generic products (and in certain cases, an authorized generic version of Xyrem) in advance of the expiration of the last of our patents. Notwithstanding our Xyrem patents and settlement agreements, additional third parties may also attempt to introduce generic versions of Xyrem, Xywav or other sodium oxybate products for treatment of cataplexy and/or EDS in narcolepsy that design around our patents or assert that our patents are invalid or otherwise unenforceable. Such third parties could launch a generic or 505(b)(2) product referencing Xyrem before the dates provided in our patents or settlement agreements. For example, we have several method of use patents listed in FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," or the Orange Book, that expire in 2033 that cover treatment methods included in the Xyrem label related to a drug-drug interaction, or DDI, with divalproex sodium. Although FDA has stated, in granting a Citizen Petition we submitted in 2016, that it would not approve any sodium oxybate ANDA referencing Xyrem that does not include the portions of the currently approved Xyrem label related to the DDI patents, we cannot predict whether a future ANDA filer, or a company that files a Section 505(b)(2) application for a drug referencing Xyrem, may pursue regulatory strategies to avoid infringing our DDI patents notwithstanding FDA's response to the Citizen Petition, or whether any such strategy would be successful. Likewise, we cannot predict whether we will be able to maintain the validity of these patents or will otherwise obtain a judicial determination that a generic or other sodium oxybate product, its package insert or the generic sodium oxybate REMS or another separate REMS will infringe any of our patents or, if we prevail in proving infringement, whether a court will grant an injunction that prevents a future ANDA filer or other company introducing a different sodium oxybate product from marketing its product, or instead require that party to pay damages in the form of lost profits or a reasonable royalty.

Since Xyrem's regulatory exclusivity has expired in the EU, we are aware that generic or hybrid generic applications have been approved by various EU regulatory authorities, and additional generic or hybrid generic applications may be submitted and approved. We cannot predict whether our licensee in the EU will be able to enforce our existing European patents against generic or hybrid generic filers in the EU.

We also currently rely on trade secret protection for several of our products, including Defitelio, and product candidates, including nabiximols. Trade secret protection does not protect information or inventions if another party develops that information or invention independently, and establishing that a competitor developed a product through trade secret misappropriation rather than through legitimate means may be difficult to prove. We seek to protect our trade secrets and other unpatented proprietary information in part through confidentiality and invention agreements with our employees, consultants, advisors and partners. Nevertheless, our employees, consultants, advisors and partners may unintentionally or willfully disclose our proprietary information to competitors, and we may not have adequate remedies for such disclosures. Moreover, if a dispute arises with our employees, consultants, advisors or partners over the ownership of rights to inventions, including jointly developed intellectual property, we could lose patent protection or the confidentiality of our proprietary information, and possibly also lose the ability to pursue the development of certain new products or product candidates.

We have incurred and may in the future incur substantial costs as a result of litigation or other proceedings relating to patents, other intellectual property rights and related matters, and we may be unable to protect our rights to, or commercialize, our products.

Our ability, and that of our partners, to commercialize any approved products will depend, in part, on our ability to obtain patents, enforce those patents and operate without infringing the proprietary rights of third parties. If we choose to go to court to stop a third party from infringing our patents, our licensed patents or our partners' patents, that third party has the right to ask the court or an administrative agency to rule that these patents are invalid and/or should not be enforced. These lawsuits and administrative proceedings are expensive and consume time and other resources, and we may not be successful in these proceedings or in stopping infringement. In addition, the inter partes review process, or IPR, under the Leahy-Smith America Invents Act permits any person, whether they are accused of infringing the patent at issue or not, to challenge the validity of

certain patents through a proceeding before the Patent Trial and Appeal Board, or PTAB, of the U.S. Patent and Trademark Office.

There is a risk that a court could decide that our patents or certain claims in our patents are not valid or infringed, and that we do not have the right to stop a third party from using the inventions covered by those claims. In addition, the PTAB may invalidate a patent, as happened with six of our patents covering the Xywav and Xyrem REMS, which were invalidated through the IPR process and delisted from the Orange Book. In addition, even if we prevail in establishing that another product infringes a valid claim of one of our patents, a court may determine that we can be compensated for the infringement in damages, and refuse to issue an injunction. As a result, we may not be entitled to stop another party from infringing our patents for their full term.

Litigation involving patent matters is frequently settled between the parties, rather than continuing to a court ruling, and we have settled patent litigation with all nine Xyrem ANDA filers. The FTC has publicly stated that, in its view, certain types of agreements between branded and generic pharmaceutical companies related to the settlement of patent litigation or the manufacture, marketing and sale of generic versions of branded drugs violate the antitrust laws and has commenced investigations and brought actions against some companies that have entered into such agreements. In particular, the FTC has expressed its intention to take aggressive action to challenge settlements that include an alleged transfer of value from the brand company to the generic company (so-called “pay for delay” patent litigation settlements). The U.S. Congress and state legislatures have also identified pharmaceutical patent litigation settlements as potential impediments to generic competition and have introduced, and in states like California passed, legislation to regulate them. Third party payors have also challenged such settlements on the grounds that they increase drug prices. Because there is currently no precise legal standard with respect to the lawfulness of such settlements, many pharmaceutical companies, including us, have faced extensive litigation over whether patent litigation settlements they have entered into are reasonable and lawful. From June 2020 to October 2021, a number of class action lawsuits were filed on behalf of purported direct and indirect Xyrem purchasers, alleging that the patent litigation settlement agreements we entered with Hikma and other ANDA filers violate state and federal antitrust and consumer protection laws. For additional information on these class action complaints, see Note 11, Commitments and Contingencies-Legal Proceedings of the Notes to Consolidated Financial Statements included in this Quarterly Report on Form 10-Q. It is possible that additional lawsuits will be filed against us making similar or related allegations. We cannot predict the outcome of these or potential additional lawsuits or government actions; however, if the plaintiffs in the class action complaints were to be successful in their claims, they may be entitled to injunctive relief or we may be required to pay significant monetary damages, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Parties to such settlement agreements in the U.S. are required by law to file the agreements with the FTC and the U.S. Department of Justice, or DOJ, for review. Accordingly, we have submitted our patent litigation settlement agreements to the FTC and the DOJ for review. We may receive formal or informal requests from the FTC regarding our ANDA litigation settlements, and there is a risk that the FTC may commence a formal investigation or action against us, which could divert the attention of management and cause us to incur significant costs, regardless of the outcome. Any claim or finding that we or our business partners have failed to comply with applicable laws and regulations could be costly to us and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

A third party may claim that we or our manufacturing or commercialization partners are using inventions covered by the third party’s patent rights, or that we or such partners are infringing, misappropriating or otherwise violating other intellectual property rights, and may go to court to stop us from engaging in our normal operations and activities, including making or selling our products. Such lawsuits are costly and could affect our results of operations and divert the attention of management and development personnel. There is a risk that a court could decide that we or our partners are infringing, misappropriating or otherwise violating third party patent or other intellectual property rights, which could be very costly to us and have a material adverse effect on our business. If we are sued for patent infringement, we would need to demonstrate that our products or methods do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid or unenforceable, which we may not be able to do.

In December 2020, Canopy Growth Corporation, or Canopy, filed a complaint against GW alleging infringement of its patent, U.S. Patent No. 10,870,632. Canopy claims that our extraction process used to produce material used to produce Epidiolex infringes its patent. Canopy seeks a judgment that we have infringed their patent and an award of monetary damages. On July 28, 2021, we filed an answer to the amended complaint, and counterclaims seeking judgment that the ‘632 patent is invalid and that we have not infringed the patent. In October 2021, the court held a claim construction hearing regarding the disputed terms of the ‘632 patent. If we were found to infringe upon a patent or other intellectual property right, or if we failed to obtain or renew a license under a patent or other intellectual property right from a third party, or if a third party that we were licensing technologies from was found to infringe upon a patent or other intellectual property rights of another third party, we may be required to pay damages, including damages of up to three times the damages found or assessed, if the infringement is found to be willful, suspend the manufacture of certain products or reengineer or rebrand our products, if feasible, or we may be unable to enter certain new product markets. Litigation, whether filed by us or against us, can be expensive and time

consuming to defend and divert management's attention and resources. Our competitive position could suffer as a result. In addition, if we have declined or failed to enter into a valid non-disclosure or assignment agreement for any reason, we may not own the invention or our intellectual property, and our products may not be adequately protected.

With respect to our products and product candidates targeting rare indications, relevant regulatory exclusivities such as orphan drug exclusivity or pediatric exclusivity may not be granted or, if granted, may be limited.

The first NDA applicant with an Orphan Drug Designation for a particular active moiety to treat a specific disease or condition that receives FDA approval is usually entitled to a seven-year exclusive marketing period in the U.S. for that drug, for that indication. We rely in part on this Orphan Drug Exclusivity and other regulatory exclusivities to protect Xywav, Epidiolex, Zepzelca, Sunosi, Defitelio (defibrotide), Vyxeos and, potentially, our other products and product candidates from competitors, and we expect to continue relying in part on these regulatory exclusivities in the future. The duration of our regulatory exclusivity period could be impacted by a number of factors, including FDA's later determination that our request for orphan designation was materially defective, that the manufacturer is unable to supply sufficient quantities of the drug, that the extension of the exclusivity period established by the Improving Regulatory Transparency for New Medical Therapies Act does not apply, or the possibility that we are unable to successfully obtain pediatric exclusivity. There is no assurance that we will successfully obtain Orphan Drug Designation for other products or product candidates or other rare diseases or that a product candidate for which we receive Orphan Drug Designation will be approved, or that we will be awarded orphan drug exclusivity upon approval as, for example, FDA may reconsider whether the eligibility criteria for such exclusivity have been met and/or maintained. Moreover, a drug product with an active moiety that is different from that in our drug candidate or, under limited circumstances, the same drug product, may be approved by FDA for the same indication during the period of marketing exclusivity. The limited circumstances include a showing that the second drug is clinically superior to the drug with marketing exclusivity through a demonstration of superior safety or efficacy or that it makes a major contribution to patient care. In addition, if a competitor obtains approval and marketing exclusivity for a drug product with an active moiety that is the same as that in a product candidate we are pursuing for the same indication before us, approval of our product candidate would be blocked during the period of marketing exclusivity unless we could demonstrate that our product candidate is clinically superior to the approved product. In addition, if a competitor obtains approval and marketing exclusivity for a drug product with an active moiety that is the same as that in a product candidate we are pursuing for a different orphan indication, this may negatively impact the market opportunity for our product candidate. There have been legal challenges to aspects of FDA's regulations and policies concerning the exclusivity provisions of the Orphan Drug Act, including whether two drugs are the same drug product, and future challenges could lead to changes that affect the protections potentially afforded our products in ways that are difficult to predict. In a successful legal challenge, a court invalidated FDA's denial of orphan exclusivity to a drug on the grounds that the drug was not proven to be clinically superior to a previously approved product containing the same ingredient for the same orphan use. In response to the decision, FDA released a policy statement stating that the court's decision is limited just to the facts of that particular case and that FDA will continue to require the sponsor of a designated drug that is the "same" as a previously approved drug to demonstrate that its drug is clinically superior to that drug upon approval in order to be eligible for orphan drug exclusivity, or in some cases, to even be eligible for marketing approval. In the future, there is the potential for additional legal challenges to FDA's orphan drug regulations and policies, and it is uncertain how such challenges might affect our business.

In the European Union, if a marketing authorization is granted for a medicinal product that is designated an orphan drug, that product is entitled to ten years of marketing exclusivity. We rely in part on this orphan drug exclusivity and other regulatory exclusivities to protect Epidyolex, Vyxeos, Defitelio, and Sunosi. During the period of marketing exclusivity, subject to limited exceptions, no similar medicinal product may be granted a marketing authorization for the orphan indication. There is no assurance that we will successfully obtain Orphan Drug Designation for future rare indications or orphan exclusivity upon approval of any of our product candidates that have already obtained designation. Even if we obtain orphan exclusivity for any product candidate, the exclusivity period can be reduced to six years if at the end of the fifth year it is established that the orphan designation criteria are no longer met or if it is demonstrated that the orphan drug is sufficiently profitable that market exclusivity is no longer justified. Further, a similar medicinal product may be granted a marketing authorization for the same indication notwithstanding our marketing exclusivity if we are unable to supply sufficient quantities of our product, or if the second product is safer, more effective or otherwise clinically superior to our orphan drug. In addition, if a competitor obtains marketing authorization and orphan exclusivity for a product that is similar to a product candidate we are pursuing for the same indication, approval of our product candidate would be blocked during the period of orphan marketing exclusivity unless we could demonstrate that our product candidate is safer, more effective or otherwise clinically superior to the approved product.

Other Risks Related to Our Business and Industry

Changes in the market for directors and officers liability insurance could make it more difficult and more expensive for us to obtain directors and officers liability insurance, and such insurance coverage may have reduced policy limits and coverage and may not be sufficient to cover our potential liabilities.

Recently, the market for directors and officers liability insurance for biopharmaceuticals and life sciences companies has changed in ways adverse to us. Fewer insurance companies are offering quotes for directors and officers liability coverage, the premiums charged for such policies have generally increased and the terms of such policies have generally become less favorable, and these trends may continue or worsen in the future. In addition, these market conditions are generally presenting more challenges for companies like ours that actively pursue corporate development transactions such as the GW Acquisition and that experience regular share price volatility, including volatility that may be unrelated or disproportionate to our operating performance. As a result, it is currently expensive and may become significantly more expensive for us to maintain directors and officers liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. In any event, there can be no assurance that directors and officers liability insurance will be adequate to cover our potential liabilities or will be generally available to us in the future or, if available, that the cost of such insurance will be commercially justifiable. The increased cost and decreased availability of directors and officers liability insurance could make it more difficult for us to attract and retain qualified persons to serve on our board of directors or as executive officers, and could also make it more difficult and more expensive for us to negotiate and consummate future corporate development transactions, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Our business is currently adversely affected and could be materially and adversely affected in the future by the evolving effects of the COVID-19 pandemic and related global economic slowdown as a result of the current and potential future impacts on our commercialization efforts, clinical trial activity, research and development activities, supply chain and corporate development activities and other business operations, in addition to the impact of a global economic slowdown.

The COVID-19 pandemic continues to have a significant impact on the global healthcare delivery system. Many healthcare systems have had to restructure operations to prioritize caring for COVID-19 patients and limit or cease other activities. The severe burden on healthcare systems caused by this pandemic has impaired the ability to diagnose and treat patients with non-COVID-19 related conditions and impaired the ability of many clinical research sites to start new studies, enroll new patients and monitor patients in clinical trials. Health care provider offices and institutions have experienced workforce disruption, including the inability to hire staff and challenges maintaining appropriate staffing. The lack of access to health care providers has caused, and may continue to cause, delays in appropriate diagnosis, treatment and ongoing care for some patients, which could subsequently impact prescribing and use of our products. The evolving effects of the COVID-19 pandemic and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce, as significant reductions in business related activities have occurred, supply chains have been disrupted, and manufacturing and clinical development activities have been curtailed or suspended.

Continued remote work policies, quarantines, shelter-in-place and similar government orders, shutdowns or other restrictions on the conduct of business operations related to the effects of the COVID-19 pandemic may materially and adversely affect our business, our ability to generate sales of our approved products, our supply chain, regulatory, clinical development and corporate development activities. With respect to our commercialization activities, the evolving effects of the COVID-19 pandemic continue to have a negative impact on demand, new patient starts and treatments for our products, primarily due to the inherent limitations of telemedicine and a reprioritization of healthcare resources toward COVID-19. Due to the nature of the pandemic, we are not able to accurately predict the duration or extent of these impacts on demand for our products. Beginning in March 2020, we transitioned our field-based sales, market access, reimbursement and medical employees out of the field and suspended work-related travel and in-person customer interactions. We utilized technology to continue to engage healthcare professionals and other customers virtually to support patient care. In late June 2020, as clinics and institutions began to allow in-person interactions pursuant to local health authority and government guidelines, our field teams resumed in-person interactions with healthcare professionals and clinics combined with virtual engagement. The level of renewed in-person engagement varies by account, region and country and may be adversely impacted in the future as a result of the continuing impact of the COVID-19 pandemic. The absence of in-person interactions can negatively impact our ability to effectively communicate product benefits to physicians, limiting their awareness and understanding and use of our medicines.

For Xyrem and Xywav, COVID-19 protocols and staffing shortages at sleep labs across the U.S. have resulted in reduced access to sleep testing. Since the end of the first quarter of 2020, we have seen a decline in prescribers' ability to diagnose new narcolepsy patients and a related overall decline in new patients starting on therapy. Although patient persistence and compliance with oxybate therapy have increased during 2020, we continue to expect that delays in obtaining a narcolepsy diagnosis will have a negative impact on new Xyrem and Xywav patient enrollments in future quarters. For Epidiolex/Epidyolex, reports from the field indicate that COVID-19 and the lack of access to and limited availability of COVID-19 vaccines, especially for children under 12 years of age, have impacted the willingness of parents of pediatric patients to bring

their children to a health care provider office, which can increase the risk of COVID exposure through contact with the healthcare system. We believe these dynamics have negatively impacted new patient starts in the U.S. and Europe. For Sunosi, the impact on demand has been primarily related to the reduced ability of our field-based teams to interact with prescribers and patients' inability to meet with health care providers during this time. As a result, we have seen slower than expected growth of Sunosi prescribers and new patient starts in the U.S. We also anticipate that pricing and reimbursement reviews by certain European regulatory authorities may take longer in certain countries due to the pandemic, which could delay our rolling Sunosi launch in those EU member states. In addition, due to the ongoing impacts of the COVID-19 pandemic, we continue to expect a negative impact on demand for and utilization of Defitelio and Vyxeos.

We have also seen an upward trend in demand for patient assistance programs since the end of the first quarter of 2020. In this regard, total revenue bottle volume on a combined basis for Xyrem and Xywav decreased by 1% in the nine months ended September 30, 2021, compared to the same period in 2020 reflecting our continued investment in patient access programs during the launch of Xywav. Depending on the ultimate duration and severity of the COVID-19 pandemic and the extent of a global economic slowdown, widespread unemployment and resulting loss of employer-sponsored insurance coverage or other market dynamics, we may experience an increasing shift from commercial payor coverage to government payor coverage or increasing demand for patient assistance and/or free drug programs, which could continue to adversely affect net product sales.

In addition, the COVID-19 pandemic continues to rapidly evolve and has resulted in significant volatility in the global financial markets. If this volatility persists and deepens, we could experience an inability to access additional capital or our liquidity could otherwise be impacted, which could in the future negatively affect our capacity for certain corporate development transactions or our ability to make other important, opportunistic investments. In addition, the current recession or additional market corrections resulting from the impact of the evolving effects of the COVID-19 pandemic could materially affect our business and the value of our ordinary shares. While we expect these effects to adversely affect our business operations and financial results, the extent of the impact on our ability to generate sales of our approved products, execute on new product launches, our clinical development and regulatory efforts, our corporate development objectives and the value of and market for our ordinary shares, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time. Such developments include continued spread of the Delta variant in the U.S. and other countries and the potential emergence of other SARS-CoV-2 variants that may prove especially contagious or virulent, the ultimate duration and severity of the pandemic, governmental "stay-at-home" orders and travel restrictions, quarantines, social distancing and business closure requirements in the U.S., Ireland and other countries, and the effectiveness of vaccination programs and other actions taken globally to contain and treat the disease. For example, the inability of our workforce to return to office and field-based work and the ongoing stress and reprioritization within the healthcare systems in our key markets may require us to reassess the timing and scope of key business activities for the remainder of 2021, including with respect to our ability to continue the launch momentum for Epidiolex, Sunosi, Xywav, Zepzelca and Rylaze. These effects could materially and adversely affect our business, financial condition, results of operations and growth prospects, as further described in the risks and uncertainties described elsewhere in this ''Risk Factors'' section.

We have substantially expanded our international footprint and operations, and we may expand further in the future, which subjects us to a variety of risks and complexities which, if not effectively managed, could negatively affect our business.

We are headquartered in Dublin, Ireland and have offices in multiple locations, including the U.S., the U.K., Italy and Canada. We may further expand our international operations into other countries in the future, either organically or by acquisition. Conducting our business in multiple countries subjects us to a variety of risks and complexities that may materially and adversely affect our business, results of operations, financial condition and growth prospects, including:

- the diverse regulatory, financial and legal requirements in the countries where we are located or do business, and any changes to those requirements;
- the impact of Brexit on trade relations between the EU and the U.K.;
- challenges inherent in efficiently managing employees in diverse geographies, including the need to adapt systems, policies, benefits and compliance programs to differing labor and employment law and other regulations, as well as maintaining positive interactions with our unionized employees;
- costs of, and liabilities for, our international operations, products or product candidates; and
- public health risks, such as the COVID-19 pandemic and potential related effects on supply chain, travel and employee health and availability.

In addition, there can be no guarantee that we will effectively manage the increasing, global complexity of our business without experiencing operating inefficiencies or control deficiencies. Our failure to do so could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The U.K.'s withdrawal from the EU, commonly referred to as Brexit, could increase our cost of doing business, reduce our gross margins or otherwise negatively impact our business and our financial results.

Brexit will continue to create significant uncertainty concerning the future relationship between the U.K. and the EU, following the U.K. withdrawal from the EU in January 2020. Since a significant portion of the regulatory framework in the U.K. is derived from EU laws, Brexit materially impacts the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the U.K. or the EU. In this regard, in December 2020, the EU and U.K. reached an agreement in principle on the framework for their future relationship, the EU-U.K. Trade and Cooperation Agreement, or TCA. The TCA primarily focuses on ensuring free trade between the EU and the U.K. in relation to goods, including medicinal products. Although the body of the TCA includes general terms which apply to medicinal products, greater detail on sector-specific issues is provided in an Annex to the TCA. The Annex provides a framework for the recognition of Good Manufacturing Practice, or GMP, inspections and for the exchange and acceptance of official GMP documents. The regime does not, however, extended to procedures such as batch release certification. Among the changes that will now occur are that Great Britain (England, Scotland and Wales) will be treated as a "third country," a country that is not a member of the EU and whose citizens do not enjoy the EU right to free movement. Northern Ireland will continue to follow many aspects of the EU regulatory rules, particularly in relation to trade in goods. As part of the TCA, the EU and the U.K. will recognize GMP inspections carried out by the other party and the acceptance of official GMP documents issued by the other party. The TCA also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release. The U.K. has unilaterally agreed to accept EU batch testing and batch release for a period of at least 2 years until January 1, 2023. However, the EU continues to apply EU laws that require batch testing and batch release to take place in the EU territory. This means that medicinal products that are tested and released in the U.K. must be retested and re-released when entering the EU market for commercial use. As it relates to marketing authorizations, Great Britain will have a separate regulatory submission process, approval process and a separate national marketing authorization. Northern Ireland will, however, continue to be covered by the marketing authorizations granted by the EC. For example, the scope of a marketing authorization for a medicinal product granted by the EC or by the competent authorities of EU member states will no longer encompass Great Britain (England, Scotland and Wales). In these circumstances, a separate marketing authorization granted by the U.K. competent authorities will be required to place medicinal products on the market in Great Britain. Northern Ireland will, however, continue to be covered by the marketing authorizations granted by the EC. All of these changes could increase our costs and otherwise adversely affect our business.

We have a commercial manufacturing facility in the U.K. in Kent Science Park, and multiple offices in England. We do not know to what extent, or when, the U.K.'s withdrawal from the EU will impact our business, particularly our ability to conduct international business from a base of operations in the U.K. The U.K. could lose the benefits of global trade agreements negotiated by the EU on behalf of its member states, possibly resulting in increased trade barriers, which could make doing business in Europe more difficult and/or costly. Moreover, in the U.S., tariffs on certain U.S. imports have been imposed, and the EU and other countries have responded with retaliatory tariffs on certain U.S. exports. We cannot predict what effects these and potential additional tariffs will have on our business, including in the context of escalating global trade and political tensions. However, these tariffs and other trade restrictions, whether resulting from the U.K.'s withdrawal from the EU or otherwise, could increase our cost of doing business, reduce our gross margins or otherwise negatively impact our business and our financial results.

Significant disruptions of information technology systems or data security breaches could adversely affect our business.

In the ordinary course of our business, we collect, store, process and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal data. We have also outsourced some of our operations (including parts of our information technology infrastructure) to a number of third party vendors who may have, or could gain, access to our confidential information. In addition, many of those third parties, in turn, subcontract or outsource some of their responsibilities to third parties.

Our information technology systems, and those of our vendors, are large and complex and store large amounts of confidential information. The size and complexity of these systems make them potentially vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third party vendors and/or business partners, or from cyber-attacks by malicious third parties. Attacks of this nature are increasing in frequency, persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, "hacktivists," nation states and others. In addition to the extraction of important information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of our information. Although the aggregate impact on our operations and financial condition has not been material to date, we and our vendors have been the target of events of this nature and expect them to continue.

Significant disruptions of our, our third party vendors' and/or business partners' information technology systems or security breaches, including in our remote work environment as a result of the COVID-19 pandemic, could adversely affect our business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information and personal data), and could result in financial, legal, business and reputational harm to us. Any such event that leads to unauthorized access, use or disclosure of personal data, including personal data regarding our patients or employees, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal data. This could disrupt our business, result in increased costs or loss of revenue, and/or result in significant legal and financial exposure. In addition, security breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may further harm us. Moreover, the prevalent use of mobile devices to access confidential information increases the risk of security breaches. While we have implemented security measures to protect our information technology systems and infrastructure, there can be no assurance that such measures will prevent service interruptions or security breaches that could adversely affect our business. In addition, failure to maintain effective internal accounting controls related to security breaches and cybersecurity in general could impact our ability to produce timely and accurate financial statements and subject us to regulatory scrutiny.

We are subject to significant ongoing regulatory obligations and oversight, which may result in significant additional expense and limit our ability to commercialize our products.

FDA and Equivalent Non-U.S. Regulatory Authorities

Our activities are subject to extensive regulation encompassing the entire life cycle of our products, from research and development activities to marketing approval (including specific post-marketing obligations), manufacturing, labeling, packaging, adverse event and safety reporting, storage, advertising, promotion, sale, pricing and reimbursement, recordkeeping, distribution, importing and exporting. The failure by us or any of our third party partners, including our corporate development and collaboration partners, clinical trial sites, suppliers, distributors and our central pharmacy for Xyrem and Xywav, to comply with applicable requirements could subject us to administrative or judicial sanctions or other negative consequences, such as delays in approval or refusal to approve a product candidate, restrictions on our products, our suppliers, our other partners or us, the withdrawal, suspension or variation of product approval or manufacturing authorizations, untitled letters, warning letters, fines and other monetary penalties, unanticipated expenditures, product recall, withdrawal or seizure, total or partial suspension of production or distribution, interruption of manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, civil penalties and/or criminal prosecution, any of which could result in a significant drop in our revenues from the affected products and harm to our reputation and could have a significant impact on our sales, business and financial condition.

We monitor adverse events resulting from the use of our products, as do the regulatory authorities, and we file periodic reports with the authorities concerning adverse events. The authorities review these events and reports, and if they determine that any events and/or reports indicate a trend or signal, they can require a change in a product label, restrict sales and marketing and/or require conduct or other actions, potentially including variation, withdrawal or suspension of the marketing authorization, any of which could result in reduced market acceptance and demand for our products, could harm our reputation and our ability to market our products in the future, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects. FDA, the competent authorities of the EU member states on behalf of the EMA, and the competent authorities of other European countries, also periodically inspect our records related to safety reporting. The EMA's Pharmacovigilance Risk Assessment Committee may propose to the Committee for Medicinal Products for Human Use that the marketing authorization holder be required to take specific steps or advise that the existing marketing authorization be varied, suspended or revoked. Failure to adequately and promptly correct the observation(s) can result in further regulatory enforcement action, which could include the variation, suspension or withdrawal of marketing authorization or imposition of financial penalties or other enforcement measures.

Defibrotide, Vyxeos, Epidyolex and Sativex are available on a named patient basis or through a compassionate use process in many countries where they are not commercially available. If any such country's regulatory authorities determine that we are promoting such products without proper authorization, we could be found to be in violation of pharmaceutical advertising laws or the regulations permitting sales under named patient programs. In that case, we may be subject to financial or other penalties. Any failure to maintain revenues from sales of products on a named patient basis and/or to generate revenues from commercial sales of these products exceeding historical sales on a named patient basis could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

FDA, the competent authorities of the EU member states and other European countries, and other governmental authorities require advertising and promotional materials to be truthful and not misleading, and products to be marketed only for their approved indications and in accordance with the provisions of the approved label. Regulatory authorities actively investigate allegations of off-label promotion in order to enforce regulations prohibiting these types of activities. A determination that we have promoted an approved product for off-label uses could subject us to significant liability, including

civil and administrative financial penalties and other remedies as well as criminal financial penalties, other sanctions and imprisonment. Even if we are not determined to have engaged in off-label promotion, an allegation that we have engaged in such activities could have a significant impact on our sales, business and financial condition. The U.S. government has also required companies to enter into complex corporate integrity agreements and/or non-prosecution agreements that impose significant reporting and other burdens on the affected companies. Failure to maintain a comprehensive and effective compliance program, and to integrate the operations of acquired businesses into a combined comprehensive and effective compliance program on a timely basis, could subject us to a range of regulatory actions and/or civil or criminal penalties that could affect our ability to commercialize our products and could harm or prevent sales of the affected products, or could substantially increase the costs and expenses of commercializing and marketing our products.

Other Regulatory Authorities

We are also subject to regulation by other regional, national, state and local agencies, including the DEA, the DOJ, the FTC, the United States Department of Commerce, the Office of Inspector General of the U.S. Department of Health and Human Services, or OIG, and other regulatory bodies, as well as similar governmental authorities in those non-U.S. countries in which we commercialize our products.

We are subject to numerous fraud and abuse laws and regulations globally and our sales, marketing, patient support and medical activities may be subject to scrutiny under these laws and regulations. These laws are described in “Business—Government Regulation” in Part I, Item 1 of our Annual Report on Form 10-K for the year ended December 31, 2020, or 2020 10-K. While we maintain a comprehensive compliance program to try to ensure that our practices and the activities of our third-party contractors and employees fall within the scope of available statutory exceptions and regulatory safe harbors whenever possible, and otherwise comply with applicable laws, regulations or guidance, regulators and enforcement agencies may disagree with our assessment or find fault with the conduct of our employees or contractors. In addition, existing regulations are subject to regulatory revision or changes in interpretation by the DOJ or OIG. For example, in November 2020, the U.S. Department of Health and Human Services finalized a previously abandoned proposal to amend the discount safe harbor regulation of the federal anti-kickback statute in a purported effort to create incentives to manufacturers to lower their list prices, and to lower federal program beneficiary out-of-pocket costs. The rule, which is currently slated to take full effect January 1, 2023, revises the discount safe harbor to exclude manufacturer rebates to Medicare Part D plans, either directly or through PBMs, creates a new safe harbor for point-of-sale price reductions that are set in advance and are available to the beneficiary at the point-of-sale, and creates a new safe harbor for service fees paid by manufacturers to PBMs for services rendered to the manufacturer. The effective date of the rule was already delayed by the Biden Administration and legal challenges. It is unclear whether the rule will be further delayed, rewritten, or allowed to go into effect, and if so, what the effect of the rule will be on negotiations of coverage for our products with Medicare Part D plans, or whether the rule will affect our coverage arrangements with commercial insurers. It is also unclear whether the rule will have the intended effect of reducing net prices and beneficiary out-of-pocket costs without also increasing Medicare Part D premiums, which may impact the willingness of Part D plans to cover our products and the price concessions or other terms the plans or their PBMs may seek from us. In addition, in November 2020, the OIG issued a Special Fraud Alert to highlight certain inherent fraud and abuse risks associated with speaker fees, honorariums and expenses paid by pharmaceutical and medical device companies to healthcare professionals participating in company-sponsored events. The Special Fraud Alert sent a clear signal that speaker programs will be subject to potentially heightened enforcement scrutiny.

Many companies have faced government investigations or lawsuits by whistleblowers who bring a *qui tam* action under the False Claims Act on behalf of themselves and the government for a variety of alleged improper marketing activities, including providing free product to customers expecting that the customers would bill federal programs for the product, providing consulting fees, grants, free travel and other benefits to physicians to induce them to prescribe the company’s products, and inflating prices reported to private price publication services, which are used to set drug reimbursement rates under government healthcare programs. In addition, the government and private whistleblowers have pursued False Claims Act cases against pharmaceutical companies for causing false claims to be submitted as a result of the marketing of their products for unapproved uses or violations of the federal anti-kickback statute. If we become the subject of a government False Claims Act or other investigation or whistleblower suit, we could incur substantial legal costs (including settlement costs) and business disruption responding to such investigation or suit, regardless of the outcome.

Public reporting under the Physician Payment Sunshine Act, or Sunshine provisions, and other similar state laws, the requirements of which are discussed in “Business—Government Regulation” in Part I, Item 1 of our 2020 Form 10-K, has resulted in increased scrutiny of the financial relationships between industry, teaching hospitals, physicians and other health care providers. Such scrutiny may negatively impact our ability to engage with physicians and other health care providers on matters of importance to us. In addition, government agencies and private entities may inquire about our marketing practices or pursue other enforcement activities based on the disclosures in those public reports. If the data reflected in our reports are found to be in violation of any of the Sunshine provisions or any other U.S. federal, state or local laws or regulations that may

apply, or if we otherwise fail to comply with the Sunshine provisions or similar requirements of state or local regulators, we may be subject to significant civil, and administrative penalties, damages or fines.

We have various programs to help patients access our products, including patient assistance programs, which include co-pay coupons for certain of our products, assistance to help patients determine their insurance coverage for our products, and a free product program. Co-pay coupon programs for commercially insured patients, including our program for Xyrem, have received negative publicity related to allegations regarding their use to promote branded pharmaceutical products over other less costly alternatives, and some states have imposed restrictions on manufacturer co-pay programs when therapeutic equivalents are available. In September 2014, the OIG issued a Special Advisory Bulletin warning manufacturers that they may be subject to sanctions under the federal Anti-Kickback Statute and other laws if they do not take appropriate steps to exclude Medicare Part D beneficiaries from using co-pay coupons. It is possible that changes in insurer policies regarding co-pay coupons and/or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these patient support programs, which could result in fewer patients using affected products, including Xyrem, and therefore could have a material adverse effect on our sales, business and financial condition.

We have established programs to consider grant applications submitted by independent charitable organizations, including organizations that provide co-pay support to patients who suffer from the diseases treated by our drugs. The OIG has issued guidance for how pharmaceutical manufacturers can lawfully make donations to charitable organizations who provide co-pay assistance to Medicare patients, provided that such organizations, among other things, are *bona fide* charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria, and do not link aid to use of a donor's product. In April 2019, we finalized our civil settlement agreement with the DOJ and OIG and entered into a corporate integrity agreement requiring us to maintain our ongoing corporate compliance program and obligating us to implement or continue, as applicable, a set of defined corporate integrity activities for a period of five years from the effective date of the corporate integrity agreement. These obligations are being extended to the GW legacy organization as part of ongoing integration efforts, and we are working with OIG in that regard. Although we have structured our programs to follow available guidance and the requirements of our corporate integrity agreement, including with regard to our ongoing integration of GW, if we or our vendors or donation recipients are deemed to fail to comply with relevant laws, regulations or evolving government guidance in the operation of these programs, such facts could be used as the basis for an enforcement action against us by the federal government or other enforcement agencies or private litigants, or we could become liable for payment of certain stipulated penalties or could be excluded from participation in federal health care programs, which would have a material adverse effect on our sales, business and financial condition.

We may also become subject to similar investigations by other state or federal governmental agencies or offices of our patient assistance programs or other business practices, which could result in damages, fines, penalties, exclusion from participation in federal health care programs or other criminal, civil or administrative sanctions or enforcement actions, as well as negative publicity, reduction in demand for, or patient access to, our products and/or reduce coverage of our products, including by federal and state health care programs. If any or all of these events occur, our business, financial condition, results of operations and stock price could be materially and adversely affected.

Our business activities outside of the U.S. are subject to the U.S. Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K. Bribery Act of 2010, or the U.K. Bribery Act. In certain countries, the health care providers who prescribe pharmaceuticals are employed by their government and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers may be subject to regulation under the FCPA, the U.K. Bribery Act and equivalent national laws in other countries. As an example, recently the U.S. Securities and Exchange Commission and the DOJ have increased their FCPA enforcement activities with respect to pharmaceutical companies. Violation of these laws by us or our suppliers and other third party agents for which we may be liable may result in civil or criminal sanctions, which could include monetary fines, criminal penalties, and disgorgement of past profits, which could have a material adverse impact on our business and financial condition.

Outside the U.S., interactions between pharmaceutical companies and physicians are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

We are also subject to federal, state, national and international laws and regulations governing the privacy and security of health related and other personal data we collect and maintain (e.g., Section 5 of the Federal Trade Commission Act, the California Consumer Privacy Act, or CCPA, and the EU's General Data Protection Regulation, or GDPR). These laws and regulations are evolving and subject to interpretation, and may impose limitations on our activities or otherwise adversely affect our business. Because of the remote work policies we implemented due to the COVID-19 pandemic, information that is normally protected, including company confidential information, may be less secure. Cybersecurity and data security threats continue to evolve and raise the risk of an incident that could affect our operations or compromise our business information or

sensitive personal data, including health data. We may also need to collect more extensive health-related information from our employees to manage our workforce. If we or our third party partners fail to comply or are alleged to have failed to comply with applicable data protection and privacy laws and regulations, and related employment rules, or if we were to experience a data breach involving personal data, we could be subject to government enforcement actions or private lawsuits. In addition, our business could be adversely impacted if our ability to transfer personal data outside of the European Economic Area or Switzerland is restricted, which could adversely impact our operating results. For example, in July 2020, the Court of Justice of the European Union, or the Court of Justice, declared the Privacy Shield Decision (Decision 2018/1250) invalid, which could adversely impact our ability to transfer personal data from the EU to the U.S. The Court of Justice further ruled that in order to transfer data outside of the EU, under the existing mechanism known as the Standard Contractual Clauses, or SCCs, the importing country's level of protection must be adequate. In addition, on September 8, 2020 the Federal Data Protection and Information Commissioner, or FDPIC, of Switzerland issued an opinion concluding that the Swiss-U.S. Privacy Shield Framework does not provide an adequate level of protection for data transfers from Switzerland to the United States. The FDPIC found, however, that SCCs may still be legally adequate at an individual level provided that they can pass a risk assessment conducted by the FDPIC. If the level of protection in the U.S. or any other importing country is called into question under the SCCs, this could further impact our ability to transfer data outside of the EU or Switzerland. Furthermore, following the U.K.'s exit from the EU, the U.K. became a third country to the EU in terms of personal data transfers. The EC has adopted an Adequacy Decision concerning the level of personal data protection. However, personal data transfers from the EU to the U.K. may nevertheless be at a greater risk than before because an Adequacy Decision may be suspended.

In addition, numerous other federal, state, national and international laws and regulations govern the privacy and security of the personal data we collect and maintain, including data breach notification laws, state health information and/or genetic privacy laws, federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act, and the CCPA), and laws outside of the United States that may apply to us, such as the GDPR and other country laws. Many of these laws and regimes, across countries but even within the United States, differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Compliance with these laws is difficult, constantly evolving, and time consuming. International regulators, federal regulators, state attorneys general, and plaintiffs' attorneys, including class action attorneys, have been and will likely continue to be active in this space.

In California, the CCPA took effect on January 1, 2020. The CCPA establishes certain requirements for data use and sharing transparency and creates new data privacy rights for California residents. The CCPA and its implementing regulations have already been amended multiple times since their enactment. These laws and regulations are evolving and subject to interpretation, and may impose limitations on our activities or otherwise adversely affect our business. Similarly, there are a number of legislative proposals in the European Union, the United States (at both the federal and state level) as well as in other jurisdictions that could impose new obligations or limitations in areas affecting our business. In addition, some countries are considering or have passed legislation implementing data protection or privacy requirements or requiring local storage and processing of data or similar requirements that could increase the cost and complexity of delivering our services and research activities.

If we or our third party partners fail to comply or are alleged to have failed to comply with these or other applicable data protection and privacy laws and regulations, or if we were to experience a data breach involving personal data, we could be subject to government enforcement actions or private lawsuits. Any associated claims, inquiries, or investigations or other government actions could lead to unfavorable outcomes that have a material impact on our business including through significant penalties or fines, monetary judgments or settlements including criminal and civil liability for us and our officers and directors, increased compliance costs, delays or impediments in the development of new products, negative publicity, increased operating costs, diversion of management time and attention, or other remedies that harm our business, including orders that we modify or cease existing business practices.

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We participate in the Medicaid Drug Rebate program, the 340B program, the U.S. Department of Veterans Affairs, Federal Supply Schedule, or FSS, pricing program, and the Tricare Retail Pharmacy program, and have obligations to report the average sales price for certain of our drugs to the Medicare program. All of these programs are described in more detail under the heading "Business—Pharmaceutical Pricing, Reimbursement by Government and Private Payors and Patient Access" in Part I, Item 1 of our 2020 Form 10-K. For calendar quarters beginning January 1, 2022, manufacturers will need to start reporting the average sales price for drugs under the Medicare program regardless of whether they are enrolled in the Medicaid Drug Rebate Program. Currently, only manufacturers participating in the Medicaid Drug Rebate Program are obligated to do so.

Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts, which can change and evolve over time. In the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are generally obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program and give rise to an obligation to refund entities participating in the 340B program for overcharges during past quarters impacted by a price recalculation.

Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we are found to have made a misrepresentation in the reporting of our average sales price, if we fail to submit the required price data on a timely basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. The Centers for Medicare & Medicaid Services, or CMS, could also decide to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect.

Our failure to comply with our reporting and payment obligations under the Medicaid Drug Rebate program and other governmental programs could negatively impact our financial results. CMS issued a final regulation, which became effective on April 1, 2016, to implement the changes to the Medicaid Drug Rebate program under the Healthcare Reform Act. On December 21, 2020, CMS issued a final regulation that modified prior Medicaid Drug Rebate program regulations to permit reporting multiple best price figures with regard to value-based purchasing arrangements (beginning in 2022); provide definitions for “line extension,” “new formulation,” and related terms, with the practical effect of expanding the scope of drugs considered to be line extensions that are subject to an alternative rebate formula (beginning in 2022); and revise best price and average manufacturer price exclusions of manufacturer-sponsored patient benefit programs, specifically regarding applicability of such exclusions in the context of pharmacy benefit manager “accumulator” programs (beginning in 2023). The pharmaceutical industry has challenged the provisions of the rule applicable to patient benefit programs in court. It is currently unclear whether the Biden administration will delay or suspend implementation of any of the provisions of this rule or whether any other provisions will become subject to judicial challenge. Regulatory and legislative changes, and judicial rulings relating to the Medicaid Drug Rebate program and related policies (including coverage expansion), have increased and will continue to increase our costs and the complexity of compliance, have been and will continue to be time-consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS or another agency challenges the approach we take in our implementation.

The Health Resources and Services Administration, or HRSA, issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities, which became effective on January 1, 2019. Implementation of this regulation could affect our obligations and potential liability under the 340B program in ways we cannot anticipate. We are also required to report the 340B ceiling prices for our covered outpatient drugs to HRSA, which then publishes them to 340B covered entities. Any charge by HRSA that we have violated this regulation or other requirements of the program could negatively impact our financial results. Moreover, HRSA newly established an administrative dispute resolution, or ADR, process under a final regulation effective January 13, 2021, for claims by covered entities that a manufacturer engaged in overcharging, including claims that a manufacturer limited the ability of a covered entity to purchase the manufacturer’s drugs at the 340B ceiling price, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that could be appealed only in federal court. An ADR proceeding could potentially subject us to discovery by covered entities and other onerous procedural requirements and could result in additional liability. HRSA could also decide to terminate a manufacturer’s agreement to participate in the 340B program for a violation of that agreement or other good cause shown, in which case the manufacturer’s covered outpatient drugs may no longer be eligible for federal payment under the Medicaid or Medicare Part B program.

Further, legislation may be introduced that, if passed, would, among other things, further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting, and any additional future changes to the definition of average manufacturer price or the Medicaid rebate amount could affect our 340B ceiling price calculations and negatively impact our results of operations.

We have obligations to report the average sales price for certain of our drugs to the Medicare program. Statutory or regulatory changes or CMS guidance could affect the average sales price calculations for our products and the resulting Medicare payment rate, and could negatively impact our results of operations.

Pursuant to applicable law, knowing provision of false information in connection with price reporting under the U.S. Department of Veterans Affairs, FSS or Tricare Retail Pharmacy, or Tricare, programs can subject a manufacturer to civil

monetary penalties. These program obligations also contain extensive disclosure and certification requirements. If we overcharge the government in connection with our arrangements with FSS or Tricare, we are required to refund the difference to the government. Failure to make necessary disclosures and/or to identify contract overcharges can result in allegations against us under the False Claims Act and other laws and regulations. Unexpected refunds to the government, and responding to a government investigation or enforcement action, would be expensive and time-consuming, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Product liability and product recalls could harm our business.

The development, manufacture, testing, marketing and sale of pharmaceutical products are associated with significant risks of product liability claims or recalls. Side effects or adverse events known or reported to be associated with, or manufacturing defects in, the products sold by us could exacerbate a patient's condition, or could result in serious injury or impairment or even death. This could result in product liability claims against us and/or recalls of one or more of our products. In many countries, including in EU member states, national laws provide for strict (no-fault) liability which applies even where damages are caused both by a defect in a product and by the act or omission of a third party.

Product recalls may be issued at our discretion or at the discretion of our suppliers, government agencies and other entities that have regulatory authority for pharmaceutical sales. Any recall of our products could materially adversely affect our business by rendering us unable to sell that product for some time and by adversely affecting our reputation. A recall could also result in product liability claims by individuals and third party payors. In addition, product liability claims could result in an investigation of the safety or efficacy of our products, our manufacturing processes and facilities, or our marketing programs conducted by FDA, the EC or the competent authorities of the EU member states. Such investigations could also potentially lead to a recall of our products or more serious enforcement actions, limitations on the therapeutic indications for which they may be used, or suspension, variation, or withdrawal of approval. Any such regulatory action by FDA, the EC or the competent authorities of the EU member states could lead to product liability lawsuits as well.

Product liability insurance coverage is expensive, can be difficult to obtain and may not be available in the future on acceptable terms, or at all. Our product liability insurance may not cover all of the future liabilities we might incur in connection with the development, manufacture or sale of our products. A successful claim or claims brought against us in excess of available insurance coverage could subject us to significant liabilities and could have a material adverse effect on our business, financial condition, results of operations and growth prospects. Such claims could also harm our reputation and the reputation of our products, adversely affecting our ability to market our products successfully.

We use hazardous materials in our manufacturing facilities, and any claims relating to the improper handling, storage, release or disposal of these materials could be time-consuming and expensive.

Our operations are subject to complex and increasingly stringent environmental, health and safety laws and regulations in the countries where we operate and, in particular, in Italy, Ireland and the U.K. where we have manufacturing facilities. If an accident or contamination involving pollutants or hazardous substances occurs, an injured party could seek to hold us liable for any damages that result and any liability could exceed the limits or fall outside the coverage of our insurance. We may not be able to maintain insurance with sufficient coverage on acceptable terms, or at all. Costs, damages and/or fines may result from the presence, investigation and remediation of such contamination at properties currently or formerly owned, leased or operated by us or at off-site locations, including where we have arranged for the disposal of hazardous substances or waste. In addition, we may be subject to third party claims, including for natural resource damages, personal injury and property damage, in connection with such contamination.

Risks Related to Controlled Substances

Xyrem, Xywav, Sunosi and nabiximols are controlled substances and certain other cannabis derived product candidates we are developing may be subject to U.S. federal and state controlled substance laws and regulations, and our failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations, could materially and adversely affect our business, results of operations, financial condition and growth prospects.

Xyrem, Xywav, Sunosi, nabiximols and certain other product candidates we are developing contain controlled substances as defined in the CSA. Controlled substances are subject to a number of requirements and restrictions under the CSA and implementing regulations, including certain registration, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. The DEA classifies controlled substances into five schedules: Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse, no currently "accepted medical use" in the U.S., lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the U.S. Pharmaceutical products approved for use in the U.S. which contain a controlled substance are listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II drugs are subject to the strictest controls under the

CSA, including manufacturing and procurement quotas, heightened security requirements and additional criteria for importation. In addition, dispensing of Schedule II drugs is further restricted. For example, they may not be refilled without a new prescription.

Drug products approved by FDA that contain cannabis or cannabis extracts may be controlled substances and will be rescheduled to Schedules II-V after approval, or, like Epidiolex, removed completely from the schedules by operation of other laws.

Individual states have also established controlled substance laws and regulations. Though state-controlled substances laws often mirror federal law, they may separately schedule our products or our product candidates as well. We or our partners may also be required to obtain separate state registrations, permits or licenses in order to be able to manufacture, distribute, administer or prescribe controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

U.S facilities conducting research, manufacturing, distributing, importing or exporting, or dispensing controlled substances must be registered (licensed) to perform these activities and must comply with the security, control, recordkeeping and reporting obligations under the CSA, DEA regulations and corresponding state requirements. DEA and state regulatory bodies conduct periodic inspections of certain registered establishments that handle controlled substances. Obtaining and maintaining the necessary registrations and complying with the regulatory obligations may result in delay of the importation, manufacturing, distribution or clinical research of our commercial products and products candidates. Furthermore, failure to maintain compliance with the CSA and DEA and state regulations by us or any of our contractors, distributors or pharmacies can result in regulatory action that could have a material adverse effect on our business, financial condition and results of operations. DEA and state regulatory bodies may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations. In certain circumstances, violations could lead to criminal penalties.

Schedule I and II substances are subject to DEA's annual manufacturing and procurement quota requirements. The annual quota allocated to us or our contract manufacturers for the active ingredients in our products may not be sufficient to complete clinical trials or meet commercial demand. Consequently, any delay or refusal by the DEA in establishing our, or our contract manufacturers', procurement and/or production quota for controlled substances could delay or stop our clinical trials or product launches, which could have a material adverse effect on our business, results of operations, financial condition and growth prospects.

Nabiximols and other cannabinoid product candidates are currently controlled substances, the use of which may generate public controversy.

Since nabiximols and some of our other product candidates derived from botanical marijuana contain controlled substances, their regulatory approval may generate public controversy. Political and social pressures and adverse publicity could lead to delays in approval of, and increased expenses for, nabiximols and our product candidates. These pressures could also limit or restrict the introduction and marketing of nabiximols and our product candidates. Adverse publicity from cannabis misuse or adverse side effects from cannabis or other cannabinoid products may adversely affect the commercial success or market penetration achievable by nabiximols and our other cannabinoid product candidates. The nature of our business attracts a high level of public and media interest, and in the event of any resultant adverse publicity, our reputation may be harmed.

Our ability to research, develop and commercialize Epidiolex, nabiximols and certain of our product candidates is dependent on our ability to maintain licenses relating to the cultivation, possession and supply of botanical cannabis, a controlled substance.

Our cannabinoid research and manufacturing facilities are located exclusively in the U.K. In the U.K., licenses to cultivate, possess and supply cannabis for medical research are granted by the Home Office on an annual basis. Although the Home Office has renewed our licenses each year since 1998, it may not do so in the future, in which case we may not be in a position to carry on our research and development program in the U.K. In addition, we are required to maintain our existing commercial licenses to cultivate, produce and supply cannabis. However, if the Home Office were not prepared to renew such licenses, we would be unable to manufacture and distribute our products on a commercial basis in the U.K. or beyond. In order to carry out research in countries other than the U.K., similar licenses to those outlined above are required to be issued by the relevant authority in each country. In addition, we will be required to obtain licenses to export from the U.K. and to import into the recipient country. To date, we have obtained necessary import and export licenses to over 30 countries. Although we have an established track record of successfully obtaining such licenses as required, this may change in the future, which could materially and adversely affect our business, results of operations, financial condition and growth prospects.

Controlled substance legislation differs between countries and legislation in certain countries may restrict or limit our ability to sell Epidyolex, nabiximols and certain of our product candidates.

Most countries are parties to the Single Convention on Narcotic Drugs 1961, which governs international trade and domestic control of narcotic substances, including cannabis extracts. Countries may interpret and implement their treaty obligations in a way that creates a legal obstacle to our obtaining regulatory approval for Epidyolex, nabiximols and certain of our other products in those countries. These countries may not be willing or able to amend or otherwise modify their laws and regulations to permit Epidyolex, nabiximols or certain of our other products to be marketed, or achieving such amendments to the laws and regulations may take a prolonged period of time. In the case of countries with similar obstacles, we would be unable to market Epidyolex, nabiximols and certain of our product candidates in countries in the near future or perhaps at all if the laws and regulations in those countries do not change.

Risks Related to Our Financial Condition and Results

We have incurred substantial debt, which could impair our flexibility and access to capital and adversely affect our financial position, and our business would be adversely affected if we are unable to service our debt obligations.

As of September 30, 2021, we had total indebtedness of approximately $6.6 billion. Our substantial indebtedness may:

- limit our ability to use our cash flow or borrow additional funds for working capital, capital expenditures, acquisitions, investments or other general business purposes;
- require us to use a substantial portion of our cash flow from operations to make debt service payments;
- limit our flexibility to plan for, or react to, changes in our business and industry, or our ability to take specified actions to take advantage of certain business opportunities that may be presented to us;
- expose us to the risk of increased interest rates as certain of our borrowings, including borrowings under the credit agreement, are at variable rates of interest;
- result in dilution to our existing shareholders in the event exchanges of our exchangeable senior notes are settled in our ordinary shares;
- place us at a competitive disadvantage compared to our less leveraged competitors; and
- increase our vulnerability to the impact of adverse economic and industry conditions.

If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay investments and capital expenditures, seek additional capital or restructure or refinance our debt. These alternative measures may not be successful and may not permit us to meet our debt service obligations. In the absence of such cash flows and resources, we could face substantial liquidity problems and might be required to dispose of material assets or operations to meet our debt service and other obligations. In addition, if we are unable to repay amounts under our secured credit agreement or senior secured notes, the credit agreement lenders and note holders could proceed against the collateral granted to them to secure that debt, which would seriously harm our business.

Covenants in our credit agreement and indenture governing our senior secured notes restrict our business and operations in many ways and if we do not effectively manage our covenants, our financial conditions and results of operations could be adversely affected.

The credit agreement and the indenture governing our senior secured notes contain various covenants that, among other things, limit our ability and/or our restricted subsidiaries' ability to:

- incur or assume liens or additional debt or provide guarantees in respect of obligations of other persons;
- pay dividends or distributions or redeem or repurchase capital stock;
- prepay, redeem or repurchase certain debt;
- make loans, investments, acquisitions (including certain acquisitions of exclusive licenses) and capital expenditures;
- enter into agreements that restrict distributions from our subsidiaries;
- enter into transactions with affiliates;
- enter into sale and lease-back transactions;
- sell, transfer or exclusively license certain assets, including material intellectual property, and capital stock of our subsidiaries; and
- consolidate or merge with or into, or sell substantially all of our assets to, another person.

If we undergo a change of control triggering event, we would be required to make an offer to purchase all of the senior secured notes at a purchase price in cash equal to 101% of their principal amount, plus accrued and unpaid interest, subject to certain exceptions. If we engage in certain asset sales, we will be required under certain circumstances to make an offer to purchase the senior secured notes at 100% of the principal amount, plus accrued and unpaid interest.

The credit agreement also includes certain financial covenants that require us to maintain a maximum secured leverage ratio and a minimum interest coverage ratio as long as we have drawn funds under the revolving credit facility (or letters of credit in excess of $50 million have been issued and remain undrawn).

As a result of these restrictions, we may be:

- limited in how we conduct our business;
- unable to raise additional debt or equity financing to operate during general economic or business downturns; or
- unable to compete effectively, take advantage of new business opportunities or grow in accordance with our plans.

Our failure to comply with any of the covenants could result in a default under the credit agreement and the indenture governing our senior secured notes, which, if not cured or waived, could result in us having to repay our borrowings before their due dates. Such default may allow the lenders or the note holders to accelerate the related debt and may result in the acceleration of any other debt to which a cross-acceleration or cross-default provision applies. If we are forced to refinance these borrowings on less favorable terms or if we were to experience difficulty in refinancing the debt prior to maturity, our results of operations or financial condition could be materially affected. In addition, an event of default under the credit agreement may permit the lenders to refuse to permit additional borrowings under the revolving credit facility or to terminate all commitments to extend further credit under the revolving credit facility. Furthermore, if we are unable to repay the amounts due and payable under the credit agreement or senior secured notes, the lenders and note holders may be able to proceed against the collateral granted to them to secure that indebtedness. In the event our lenders or note holders accelerate the repayment of such borrowings, we cannot assure you that we will have sufficient assets to repay such indebtedness.

Moreover, our failure to repurchase our senior secured notes or our exchangeable senior notes at a time when the repurchase is required by the indentures governing our senior secured notes and our exchangeable senior notes or to pay any cash payable on future exchanges of our exchangeable senior notes as required by the indenture governing our exchangeable senior notes, would constitute a default under those indentures.

A default under the indentures governing our exchangeable senior notes could also lead to a default under other debt agreements or obligations, including the credit agreement and indenture governing the senior secured notes. Likewise, a default under the credit agreement or senior secured notes could lead to a default under other debt agreements or obligations, including the indentures governing our exchangeable senior notes.

To continue to grow our business, we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate and grow our business.

The scope of our business and operations has grown substantially since 2012, including through a series of business combinations and acquisitions. To continue to grow our business over the longer term, we plan to commit substantial resources to product acquisition and in-licensing, product development, clinical trials of product candidates and expansion of our commercial, development, manufacturing and other operations. Acquisition opportunities that we pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the U.S. and worldwide resulting from the effects of the COVID-19 pandemic. In addition, as a matter of Irish law, when an Irish public limited company issues ordinary shares to new shareholders for cash, the company must first offer those shares on the same or more favorable terms to existing shareholders on a pro-rata basis, unless this statutory pre-emption obligation is dis-applied, or opted-out of, by approval of its shareholders. At our extraordinary general meeting of shareholders in September 2021, our shareholders voted to approve our proposal to dis-apply the statutory pre-emption obligation on terms that are substantially more limited than our general pre-emption opt-out authority that had been in effect prior to August 4, 2021, which could adversely affect our ability to effectively use our unissued share capital to fund in-licensing or acquisition opportunities, or to otherwise raise additional capital for our business. In any event, an inability to borrow or raise additional capital in a timely manner and on attractive terms could prevent us from expanding our business or taking advantage of acquisition opportunities, and could otherwise have a material adverse effect on our business and growth prospects. In addition, if we use a substantial amount of our funds to acquire or in-license products or product candidates, we may not have sufficient additional funds to conduct all of our operations in the manner we would otherwise choose.

We have significant intangible assets and goodwill. Consequently, the future impairment of our intangible assets and goodwill may significantly impact our profitability.

Our intangible assets and goodwill are significant and are subject to an impairment analysis whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Additionally, goodwill and indefinite-lived assets are subject to an impairment test at least annually. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. For example, in the first quarter of 2020, we recorded a $136.1 million asset

impairment charge following the decision to stop enrollment in our Phase 3 clinical study of defibrotide for the prevention of VOD due to a determination that the study is highly unlikely to reach one of its primary endpoints. Our results of operations and financial position in future periods could be negatively impacted should future impairments of intangible assets or goodwill occur.

Our financial results have been and may continue to be adversely affected by foreign currency exchange rate fluctuations.

Because our financial results are reported in U.S. dollars, we are exposed to foreign currency exchange risk as the functional currency financial statements of non-U.S. subsidiaries are translated to U.S. dollars for reporting purposes. To the extent that revenue and expense transactions are not denominated in the functional currency, we are also subject to the risk of transaction losses. For example, because our product sales outside of the U.S. are primarily denominated in the euro, our sales of those products have been and may continue to be adversely affected by fluctuations in foreign currency exchange rates. Given the volatility of exchange rates, as well as our expanding operations, there is no guarantee that we will be able to effectively manage currency transaction and/or translation risks, which could adversely affect our operating results. Although we utilize foreign exchange forward contracts to manage currency risk primarily related to certain intercompany balances denominated in non-functional currencies, our efforts to manage currency risk may not be successful.

Changes in our effective tax rates could adversely affect our business and financial condition, results of operations and growth prospects.

We are incorporated in Ireland and maintain subsidiaries in North America, the U.K. and a number of other foreign jurisdictions. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various jurisdictions where we operate. Our effective tax rate may fluctuate depending on a number of factors, including, but not limited to, the distribution of our profits or losses between the jurisdictions where we operate and changes to or differences in interpretation of tax laws. For example, our income tax provision for the nine months ended September 30, 2021 included an expense of $250.6 million arising on the remeasurement of our U.K. net deferred tax liability, which arose primarily in relation to the GW Acquisition, due to a change in the statutory tax rate in the U.K. following enactment of the U.K. Finance Act 2021.

We are subject to reviews and audits by the U.S. Internal Revenue Services, or IRS, and other taxing authorities from time to time, and the IRS or other taxing authority may challenge our structure, transfer pricing arrangements and tax positions through an audit or lawsuit. Responding to or defending against challenges from taxing authorities could be expensive and consume time and other resources. If we are unsuccessful, we may be required to pay taxes for prior periods, interest, fines or penalties, and may be obligated to pay increased taxes in the future, any of which could require us to reduce our operating expenses, decrease efforts in support of our products or seek to raise additional funds. Any of these actions could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

The IRS may not agree with the conclusion that we should be treated as a foreign corporation for U.S. federal tax purposes.

Although we are incorporated in Ireland, the IRS may assert that we should be treated as a U.S. corporation (and, therefore, a U.S. tax resident) for U.S. federal tax purposes pursuant to Section 7874 of the U.S. Internal Revenue Code, or the Code. For U.S. federal tax purposes, a corporation generally is considered a tax resident in the jurisdiction of its organization or incorporation. Because we are an Irish incorporated entity, we would be classified as a foreign corporation (and, therefore, a non-U.S. tax resident) under these rules. Section 7874 of the Code provides an exception under which a foreign incorporated entity may, in certain circumstances, be treated as a U.S. corporation for U.S. federal tax purposes. Because we indirectly acquired all of Jazz Pharmaceuticals, Inc.'s assets through the acquisition of the shares of Jazz Pharmaceuticals, Inc. common stock when the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma Public Limited Company were combined in a merger transaction in January 2012, or the Azur Merger, the IRS could assert that we should be treated as a U.S. corporation for U.S. federal tax purposes under Section 7874. The IRS continues to scrutinize transactions that are potentially subject to Section 7874, and has issued several sets of final and temporary regulations under Section 7874 since 2012. We do not expect these regulations to affect the U.S. tax consequences of the Azur Merger. Nevertheless, new statutory and/or regulatory provisions under Section 7874 of the Code or otherwise could be enacted that could adversely affect our status as a foreign corporation for U.S. federal tax purposes, and any such provisions could have prospective or retroactive application to us, our shareholders, Jazz Pharmaceuticals, Inc. and/or the Azur Merger.

Our affiliates' ability to use their net operating losses and carryforward tax losses to offset potential taxable income is limited under applicable law and could be subject to further limitations if we do not generate taxable income in a timely manner or if certain "ownership change" provisions of applicable law result in further limitations.

Following certain acquisitions of a U.S. corporation by a foreign corporation, Section 7874 of the Code can limit the ability of the acquired U.S. corporation and its U.S. affiliates to use U.S. tax attributes such as net operating losses, or NOLs, to offset U.S. taxable income resulting from certain transactions. Our U.S. affiliates have a significant amount of NOLs. As a result of Section 7874 of the Code, after the Azur Merger, our U.S. affiliates have not been able and will continue to be unable, for a period of time, to utilize their U.S. tax attributes to offset their U.S. taxable income, if any, resulting from certain taxable

transactions. While we expect to be able to fully utilize our U.S. affiliates' U.S. NOLs before they expire, as a result of this limitation, it may take our U.S. affiliates longer to use their NOLs.

Our ability to use these NOLs to offset potential future taxable income and related income taxes that would otherwise be due also depends on our ability to generate future income that is taxable in the U.S. before the NOLs expire. We cannot predict with certainty when, or whether, our U.S. affiliates will generate sufficient taxable income to use all of the NOLs. In addition, the use of NOLs to offset potential future taxable income and related income taxes that would otherwise be due is subject to limitations under the "ownership change" provisions of Sections 382 and 383 of the Code and similar state provisions. Additionally, U.K. carryforward tax losses may become subject to limitations in the event of certain changes in the ownership interest of significant shareholders where there is also a major change in the nature of conduct of a trade or business within a specified period of time. These limitations may cause us to lose or forfeit additional NOLs or carryforward tax losses before we can use these attributes. Subsequent ownership changes and changes to the U.S. federal or state or U.K. tax rules with respect to the use of NOLs and carryforward tax losses may further affect our ability to use these losses in future years.

Changes to tax laws relating to multinational corporations could adversely affect us.

The U.S. Congress, the EU, the Organization for Economic Co-operation and Development, or OECD, and other government agencies in jurisdictions where we and our affiliates do business have had an extended focus on issues related to the taxation of multinational corporations. One example is the OECD's initiative in the area of "base erosion and profit shifting," or BEPS. Many countries have implemented or begun to implement legislation and other guidance to align their international tax rules with the OECD's BEPS recommendations. In addition, the OECD has been working on an extension of the BEPS project, referred to as BEPS 2.0, focusing on (1) global profit allocation and (2) a global minimum tax rate. In particular, the OECD has released a framework proposal reflecting the agreement of over 130 jurisdictions, including Ireland, for a global minimum tax rate of 15% for large multinational corporations on a jurisdiction-by-jurisdiction basis by 2023. As a result of the focus on the taxation of multinational corporations, the tax laws in Ireland, the U.S. and other countries in which we and our affiliates do business could change on a prospective or retroactive basis, and any such changes could adversely affect us.

Further, the Biden administration and current Congress continue to consider changes in U.S. tax laws. In April 2021, the Biden administration released the Made in America Tax Plan, which includes significant modifications to key provisions of the existing U.S. corporate income tax regime, including an increase in the U.S. corporate income tax rate and an increase in the tax rate on certain earnings of controlled foreign corporations. In May 2021, the Biden Administration released its fiscal year 2022 budget recommendation which includes proposals to increase the corporate tax rates and make other changes to existing tax laws. These changes, if enacted, could adversely impact our tax provision, cash tax liability and effective tax rate. At this stage, it is not possible to predict which, if any, proposals the U.S. Congress will accept, reject or modify and whether any proposals will be enacted into law.

A substantial portion of our indebtedness bears interest at variable interest rates based on USD LIBOR and certain of our financial contracts are also indexed to USD LIBOR. Changes in the method of determining LIBOR, or the replacement of LIBOR with an alternative reference rate, may adversely affect interest rates on our current or future indebtedness and may otherwise adversely affect our financial condition and results of operations.

In July 2017, the Financial Conduct Authority, the authority that regulates the London Inter-bank Offered Rate, or LIBOR, announced that it intended to stop compelling banks to submit rates for the calculation of LIBOR after 2021. We have certain financial contracts, including the credit agreement and our derivative instruments, that are indexed to USD LIBOR. Changes in the method of determining LIBOR, or the replacement of LIBOR with an alternative reference rate, may adversely affect interest rates on our current or future indebtedness. Any transition process may involve, among other things, increased volatility or illiquidity in markets for instruments that rely on LIBOR, reductions in the value of certain instruments or the effectiveness of related transactions such as hedges, increased borrowing costs, uncertainty under applicable documentation, or difficult and costly consent processes. In addition, we have certain financial contracts, including the credit agreement and our derivative instruments, that are indexed to Euro Inter-bank Offered Rate, or EURIBOR (which is based on the average interest rates at which a large panel of European banks borrow funds from one another). There is no indication at this time that EURIBOR will cease to be published in the near future. However, the transition away from LIBOR, and also potentially EURIBOR, may result in increased expenses, may impair our ability to refinance our indebtedness or hedge our exposure to floating rate instruments, or may result in difficulties, complications or delays in connection with future financing efforts, any of which could adversely affect our financial condition and results of operations.

Risks Related to Our Ordinary Shares

The market price of our ordinary shares has been volatile and is likely to continue to be volatile in the future, and the value of your investment could decline significantly.

The stock market in general, including the market for life sciences companies, has experienced extreme price and trading volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies, which has resulted in decreased market prices, notwithstanding the lack of a fundamental change in the underlying business models of those companies. Worsening economic conditions and other adverse effects or developments may negatively affect the market price of our ordinary shares, regardless of our actual operating performance. The market price for our ordinary shares is likely to continue to be volatile and subject to significant price and volume fluctuations in response to market, industry and other factors, including the risk factors described in this “Risk Factors” section.

Our share price may be dependent upon the valuations and recommendations of the analysts who cover our business. If our results do not meet these analysts’ forecasts, the expectations of our investors or the financial guidance we provide to investors in any period, the market price of our ordinary shares could decline. Our ability to meet analysts’ forecasts, investors’ expectations and our financial guidance is substantially dependent on our ability to maintain or increase sales of our marketed products.

In addition, the market price of our ordinary shares may decline if the effects of our acquisition of GW and other strategic transactions on our financial or operating results are not consistent with the expectations of financial analysts or investors. The market price of our ordinary shares could also be affected by possible sales of our ordinary shares by holders of our exchangeable senior notes who may view our exchangeable senior notes as a more attractive means of equity participation in our company and by hedging or arbitrage trading activity involving our ordinary shares by the holders of our exchangeable senior notes.

We are subject to Irish law, which differs from the laws in effect in the U.S. and may afford less protection to holders of our securities.

It may not be possible to enforce court judgments obtained in the U.S. against us in Ireland based on the civil liability provisions of the U.S. federal or state securities laws. In addition, there is some uncertainty as to whether the courts of Ireland would recognize or enforce judgments of U.S. courts obtained against us or our directors or officers based on the civil liability provisions of the U.S. federal or state securities laws or hear actions against us or those persons based on those laws. We have been advised that the U.S. currently does not have a treaty with Ireland providing for the reciprocal recognition and enforcement of judgments in civil and commercial matters. Therefore, a final judgment for the payment of money rendered by any U.S. federal or state court based on civil liability, whether or not based solely on U.S. federal or state securities laws, would not automatically be enforceable in Ireland.

As an Irish company, we are governed by the Irish Companies Act 2014, which differs in some material respects from laws generally applicable to U.S. corporations and shareholders, including, among others, differences relating to interested director and officer transactions, mergers, amalgamations and acquisitions, takeovers and shareholder lawsuits. The duties of directors and officers of an Irish company are generally owed to the company only. Shareholders of Irish companies generally do not have a personal right of action against directors or officers of the company and may exercise such rights of action on behalf of the company only in limited circumstances. Accordingly, holders of our securities may have more difficulty protecting their interests than would holders of securities of a corporation incorporated in a U.S. jurisdiction.

Our articles of association, Irish law, our credit agreement and the indentures governing our senior secured notes and exchangeable senior notes contain provisions that could delay or prevent a takeover of us by a third party.

Our articles of association could delay, defer or prevent a third party from acquiring us, despite the possible benefit to our shareholders, or otherwise adversely affect the price of our ordinary shares. In addition to our articles of association, several mandatory provisions of Irish law could prevent or delay an acquisition of us. We are also subject to various provisions of Irish law relating to mandatory bids, voluntary bids, requirements to make a cash offer and minimum price requirements, as well as substantial acquisition rules and rules requiring the disclosure of interests in our shares in certain circumstances. Furthermore, our credit agreement limits our ability to enter into certain fundamental changes, and the indentures governing our senior secured notes and exchangeable senior notes require us to offer to repurchase such notes for cash if we undergo certain fundamental changes. Additionally, in certain circumstances, the indentures governing our exchangeable senior notes require us to increase the exchange rate for a holder of our exchangeable senior notes in connection with a fundamental change. A takeover of us may trigger a default under the credit agreement or the requirement that we offer to purchase our senior secured notes or exchangeable senior notes and/or increase the exchange rate applicable to our exchangeable senior notes, which could make it more costly for a potential acquirer to engage in a business combination transaction with us.

These provisions, whether alone or together, may discourage potential takeover attempts, discourage bids for our ordinary shares at a premium over the market price or adversely affect the market price of, and the voting and other rights of the holders

of, our ordinary shares. These provisions, whether alone or together, could also discourage proxy contests and make it more difficult for our shareholders to elect directors other than the candidates nominated by our board.

Future sales and issuances of our ordinary shares, securities convertible into our ordinary shares or rights to purchase ordinary shares or convertible securities could result in additional dilution of the percentage ownership of our shareholders and could cause our share price to decline.

We expect to continue to opportunistically seek access to additional capital to license or acquire additional products, product candidates or companies to expand our operations or for general corporate purposes. To the extent we raise additional capital by issuing equity securities or securities convertible into or exchangeable for ordinary shares, our shareholders may experience substantial dilution. We may sell ordinary shares, and we may sell convertible or exchangeable securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell such ordinary shares, convertible or exchangeable securities or other equity securities in subsequent transactions, existing shareholders may be materially diluted.

We have never declared or paid dividends on our capital stock and we do not anticipate paying dividends in the foreseeable future.

We do not currently plan to pay cash dividends in the foreseeable future. Any future determination as to the payment of dividends will, subject to Irish legal requirements, be at the sole discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, compliance with the terms of the credit agreement and the indenture governing our senior secured notes, and other factors our board of directors deems relevant. Accordingly, holders of our ordinary shares must rely on increases in the trading price of their shares for returns on their investment in the foreseeable future. In addition, in the event that we pay a dividend on our ordinary shares, in certain circumstances, as an Irish tax resident company, some shareholders may be subject to withholding tax, which could adversely affect the price of our ordinary shares.

General Risk Factors

If we fail to attract, retain and motivate key personnel or to retain the members of our executive management team, our operations and our future growth may be adversely affected.

Our success and our ability to grow depend in part on our continued ability to attract, retain and motivate highly qualified personnel, including our executive management team. We do not carry “key person” insurance. The loss of services and institutional knowledge of one or more additional members of our executive management team or other key personnel could delay or prevent the successful completion of some of our vital activities and may negatively impact our operations and future growth. In addition, changes in our organization as a result of executive management transition may have a disruptive impact on our ability to implement our strategy. Until we integrate new personnel, and unless they are able to succeed in their positions, we may be unable to successfully manage and grow our business. In any event, if we are unable to attract, retain and motivate quality individuals, or if there are delays, or if we do not successfully manage personnel and executive management transitions, our business, financial condition, results of operations and growth prospects could be adversely affected.

Our business and operations could be negatively affected if we become subject to shareholder activism or hostile bids, which could cause us to incur significant expense, hinder execution of our business strategy and impact our stock price.

Shareholder activism, which takes many forms and arises in a variety of situations, has been increasingly prevalent. Recent stock price declines due to the evolving effects of the COVID-19 may also increase our vulnerability to unsolicited approaches. If we become the subject of certain forms of shareholder activism, such as proxy contests or hostile bids, the attention of our management and our board of directors may be diverted from execution of our strategy. Such shareholder activism could give rise to perceived uncertainties as to our future strategy, adversely affect our relationships with business partners and make it more difficult to attract and retain qualified personnel. Also, we may incur substantial costs, including significant legal fees and other expenses, related to activist shareholder matters. Our stock price could be subject to significant fluctuation or otherwise be adversely affected by the events, risks and uncertainties of any shareholder activism.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Issuer Purchases of Equity Securities

In November 2016, our board of directors authorized a share repurchase program and as of September 30, 2021 had authorized the repurchase of ordinary shares having an aggregate purchase price of up to $1.5 billion, exclusive of any brokerage commissions. Under this program, which has no expiration date, we may repurchase ordinary shares from time to time on the open market. During the three and nine months ended September 30, 2021, we did not repurchase any of our ordinary shares. As of September 30, 2021, the remaining amount authorized under the share repurchase program was $431.2 million.

Under our share repurchase program, we are authorized to repurchase shares from time to time through open market repurchases. Such repurchases may be pursuant to Rule 10b-18 or Rule 10b5-1 agreements as determined by our management and in accordance with the requirements of the Securities and Exchange Commission.

Item 6. Exhibits

Exhibit Number	Description of Document
2.1	Agreement and Plan of Merger and Reorganization, dated as of September 19, 2011, by and among Azur Pharma Limited (now Jazz Pharmaceuticals plc), Jaguar Merger Sub Inc., Jazz Pharmaceuticals, Inc. and Seamus Mulligan, solely in his capacity as the Indemnitors' Representative (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals, Inc.'s Current Report on Form 8-K (File No. 001-33500) filed with the SEC on September 19, 2011).
2.2	Letter Agreement, dated as of January 17, 2012, by and among Jazz Pharmaceuticals plc, Jaguar Merger Sub Inc., Jazz Pharmaceuticals, Inc. and Seamus Mulligan, solely in his capacity as the Indemnitors' Representative (incorporated by reference to Exhibit 2.2 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).
2.3	Agreement and Plan of Merger, dated as of April 26, 2012, by and among Jazz Pharmaceuticals plc, Jewel Merger Sub Inc., EUSA Pharma Inc., and Essex Woodlands Health Ventures, Inc., Mayflower L.P., and Bryan Morton, in their capacity as the representatives of the equity holders of EUSA Pharma Inc. (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-33500), as filed with the SEC on April 27, 2012).
2.4	Assignment, dated as of June 11, 2012, by and among Jazz Pharmaceuticals plc and Jazz Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.1B in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-33500), as filed with the SEC on June 12, 2012).
2.5	Tender Offer Agreement, dated December 19, 2013, by and among Jazz Pharmaceuticals Public Limited Company, Jazz Pharmaceuticals Italy S.r.l. and Gentium S.p.A. (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K/A (File No. 001-33500), as filed with the SEC on December 20, 2013).
2.6†	Asset Purchase Agreement, dated January 13, 2014, by and among Jazz Pharmaceuticals International III Limited, Aerial BioPharma, LLC and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-33500), as filed with the SEC on January 13, 2014).
2.7†	Assignment Agreement, dated July 1, 2014, by and among Jazz Pharmaceuticals International II Limited, Sigma-Tau Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and Gentium S.p.A. (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-33500), as filed with the SEC on August 5, 2014).
2.8	Amended and Restated Agreement for the Acquisition of the Topaz Portfolio Business of Jazz Pharmaceuticals plc, dated March 20, 2015, between Jazz Pharmaceuticals plc and Essex Bidco Limited (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-33500), as filed with the SEC on March 23, 2015).
2.9	Agreement and Plan of Merger, dated as of May 27, 2016, by and among Jazz Pharmaceuticals plc, Plex Merger Sub, Inc., and Celator Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-33500), as filed with the SEC on May 31, 2016).
2.10‡	Transaction Agreement, dated as of February 3, 2021, by and among Jazz Pharmaceuticals UK Holdings Limited, Jazz Pharmaceuticals Public Limited Company and GW Pharmaceuticals PLC (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-33500), as filed with the SEC on February 4, 2021).
3.1	Amended and Restated Memorandum and Articles of Association of Jazz Pharmaceuticals plc, as amended on August 4, 2016 (incorporated herein by reference to Exhibit 3.1 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2016, as filed with the SEC on August 9, 2016).
4.1	Reference is made to Exhibit 3.1.
4.2A	Indenture, dated as of August 13, 2014, by and among Jazz Pharmaceuticals plc, Jazz Investments I Limited and U.S. Bank National Association (incorporated herein by reference to Exhibit 4.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-33500), as filed with the SEC on August 13, 2014).
4.2B	Form of 1.875% Exchangeable Senior Note due 2021 (incorporated herein by reference to Exhibit 4.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-33500), as filed with the SEC on August 13, 2014).
4.3A	Indenture, dated as of August 23, 2017, among Jazz Pharmaceuticals Public Limited Company, Jazz Investments I Limited and U.S. Bank National Association (incorporated herein by reference to Exhibit 4.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-033500), as filed with the SEC on August 23, 2017).
4.3B	Form of 1.50% Exchangeable Senior Note due 2024 (incorporated herein by reference to Exhibit 4.2 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-033500), as filed with the SEC on August 23, 2017).

4.4A	Indenture, dated as of June 11, 2020 among Jazz Pharmaceuticals Public Limited Company, Jazz Investments I Limited and U.S. Bank National Association (incorporated herein by reference to Exhibit 4.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-033500), as filed with the SEC on June 11, 2020).
4.4B	Form of 2.000% Exchangeable Senior Note due 2026 (incorporated herein by reference to Exhibit 4.2 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-033500), as filed with the SEC on June 11, 2020).
4.5A	Indenture, dated as of April 29, 2021, among Jazz Securities Designated Activity Company, the guarantors party thereto, U.S. Bank National Association, as trustee and acknowledged by U.S. Bank National Association, as collateral trustee. (incorporated herein by reference to Exhibit 4.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-033500), as filed with the SEC on April 29, 2021).
4.5B	Form of 4.375% Senior Notes due 2029 (incorporated herein by reference to Exhibit 4.2 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-033500), as filed with the SEC on April 29, 2021).
4.5C	First Supplemental Indenture, dated as of July 21, 2021, among GW Pharmaceuticals Limited, GW Global Services (International) Limited, GW Pharma Limited, GW Research Limited, GW UK Services Limited and Greenwich Biosciences, Inc., Jazz Securities Designated Activity Company, and U.S. Bank National Association, as trustee under the Indenture, dated as of April 29, 2021.
10.1+	Form of Non-U.S. Restricted Stock Unit Award Grant Notice and Form of Non-U.S. Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2011 Equity Incentive Plan.
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.
32.1*	Certifications of Chief Executive Officer and Chief 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 - The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

+ Indicates management contract or compensatory plan.

† Confidential treatment has been granted for portions of this exhibit. Omitted portions have been filed separately with the SEC.

‡ Certain portions of this exhibit have been omitted pursuant to Item 601(b)(2) of Regulation S-K.

* The certification attached as Exhibit 32.1 accompanies this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

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.

Date: November 9, 2021

JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY
(Registrant)

/s/ Bruce C. Cozadd

Bruce C. Cozadd

Chairman and Chief Executive Officer and Director
(Principal Executive Officer)

/s/ Renée Galá

Renée Galá

Executive Vice President and Chief Financial Officer
(Principal Financial Officer)

/s/ Patricia Carr

Patricia Carr

Senior Vice President, Chief Accounting Officer
(Principal Accounting Officer)

Exhibit 10.1

Jazz Pharmaceuticals plc
2011 Equity Incentive Plan
Non-U.S. Restricted Stock Unit Award Grant Notice

Jazz Pharmaceuticals plc (the "***Company***"), pursuant to its 2011 Equity Incentive Plan (the "***Plan***"), hereby awards to Participant the number of restricted stock units ("***RSUs***") specified and on the terms set forth below (the "***Award***"). The Award is subject to all of the terms and conditions as set forth in this Non-U.S. Restricted Stock Unit Award Grant Notice (the "***Grant Notice***") and in the Non-U.S. Restricted Stock Unit Award Agreement, including any country-specific Appendix (the "***Agreement***"), and the Plan, both of which are attached hereto and incorporated herein in their entirety.

Participant:	_____
RSU #:	_____
Date of Grant:	_____
Vesting Commencement Date:	_____
Number of RSUs Subject to Award:	_____
Consideration:	Participant's Services (payment of par value of newly issued shares)

Vesting Schedule: Subject to Sections 2 and 11 of the Agreement, the Ordinary Shares subject to this Award will vest as follows: 1/4th of the Ordinary Shares subject to this Award will vest on each of the first, second, third and fourth anniversaries of the Vesting Commencement Date.

Issuance Schedule: One Ordinary Share will be issuable for each RSU which vests at the time set forth in Section 6 of the Agreement.

Additional Terms/Acknowledgements: The undersigned Participant acknowledges receipt of, and understands and agrees to, this Grant Notice, the Agreement and the Plan. Participant further acknowledges that as of the Date of Grant, this Grant Notice, the Agreement and the Plan set forth the entire understanding between Participant and the Company regarding the Award and supersede all prior oral and written agreements on that subject, with the exception of: (i) any employment or severance arrangement that would provide for vesting acceleration of the Award upon the terms and conditions set forth therein and (ii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law. By accepting this Award, Participant consents to receive Plan documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

Jazz Pharmaceuticals plc

By: _____
Signature

Title:

Date:

Participant

_____
Signature

Date: _____

Attachments: Non-U.S. Restricted Stock Unit Award Agreement, 2011 Equity Incentive Plan

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Attachment I

Non-U.S. Restricted Stock Unit Award Agreement

Jazz Pharmaceuticals plc
2011 Equity Incentive Plan

Non-U.S. Restricted Stock Unit Award Agreement

Pursuant to your Non-U.S. Restricted Stock Unit Award Grant Notice (the "***Grant Notice***") and this Non-U.S. Restricted Stock Unit Award Agreement, including any country-specific Appendix (the "***Agreement***"), and in consideration of your services, Jazz Pharmaceuticals plc (the "***Company***") has awarded you a Restricted Stock Unit Award (the "***Award***") under its 2011 Equity Incentive Plan (the "***Plan***") for the number of restricted stock units (the "***RSUs***") indicated in your Grant Notice. The Award is granted to you effective as of the date of grant set forth in the Grant Notice (the "***Date of Grant***"). Except as otherwise explicitly provided in the Grant Notice or this Agreement, in the event of any conflict between the terms in the Grant Notice or this Agreement and the Plan, the terms of the Plan shall control. Capitalized terms not explicitly defined in the Grant Notice or this Agreement but defined in the Plan shall have the same definitions as in the Plan.

The details of your Award, in addition to those set forth in the Grant Notice and the Plan, are as follows.

1. Grant of the Award. This Award represents your right to be issued on a future date the number of Ordinary Shares that is equal to the number of RSUs indicated in the Grant Notice. As of the Date of Grant, the Company will credit to a bookkeeping account maintained by the Company for your benefit (the "***Account***") the number of RSUs subject to the Award. This Award was granted in consideration of your services to the Company or one of its Affiliates. Except as otherwise provided herein, you will not be required to make any payment to the Company (other than services to the Company or its Affiliates) with respect to your receipt of the Award, the vesting of the RSUs or the delivery of the Ordinary Shares to be issued in respect of the Award; *provided, however*, that to the extent that any Ordinary Shares issued upon settlement of your Award are newly issued Ordinary Shares, a payment must be received by the Company of an amount equal to the par value of such number of newly issued Ordinary Shares (rounded up to the nearest whole cent) in cash, by check, bank draft or money order payable to the Company.

2. Vesting. Subject to Section 11 and the limitations contained herein, your Award will vest, if at all, in accordance with the vesting schedule provided in the Grant Notice, provided that vesting will cease upon the termination of your Continuous Service, except as otherwise set forth below in this Section 2. Upon such termination of your Continuous Service, the RSUs credited to the Account that were not vested on the date of such termination will be forfeited at no cost to the Company and you will have no further right, title or interest in such RSUs or the

Ordinary Shares to be issued in respect of such portion of the Award, except as otherwise directed by the Compensation & Management Development Committee of the Board (or its successor following a Change in Control) (the "***Committee***"), *provided*, that:

(a) Termination of Continuous Service due to Death. If your Continuous Service terminates due to your death, the vesting of the RSUs subject to this Award shall be accelerated in full, effective as of the date of such termination (or as soon as administratively practicable thereafter, but no later than 60 days following such termination).

(b) Termination of Continuous Service due to Disability. If your Continuous Service terminates due to your Disability, your unvested RSUs will continue to vest pursuant to the original Vesting Schedule as provided in the Grant Notice.

(c) Termination of Continuous Service due to Retirement. If, on or after the first anniversary of the Date of Grant, your Continuous Service terminates due to your Regular Retirement or your Long-Service Retirement (each as defined below, and together, "***Retirement***"), then provided that (i) you have given the Company at least four months advance written notice of your intention to terminate your Continuous Service and (ii) you execute and deliver a non-solicitation agreement satisfactory to the Company that will apply for a period of 12 months after your termination date (the "***Non-Solicitation Agreement***"), then the RSUs will be treated as follows:

(1) In the case of your Regular Retirement, a pro-rata portion of each unvested tranche of your RSUs will continue to vest pursuant to the original Vesting Schedule as provided in the Grant Notice. For each such unvested tranche of the RSUs, such pro-rata portion shall be determined by reference to the number of RSUs in such unvested tranche of the Award multiplied by the ratio of (x) the number of calendar days that have elapsed from the Vesting Commencement Date through the date of your termination of Continuous Service divided by (y) the total number of calendar days in such vesting tranche (which, for clarity, shall be equal to the number of calendar days that have elapsed from the Vesting Commencement Date through the vesting date for such tranche), and rounded down to the nearest whole RSU. For purposes of the foregoing, "***Regular Retirement***" means your voluntary termination of Continuous Service, unless circumstances exist at the time of such termination that would constitute Cause, following: (a) your completion of five years of Continuous Service and (b) your attainment of age 55.

(2) In the case of your Long-Service Retirement, all of your unvested RSUs will continue to vest pursuant to the original Vesting Schedule as provided in the Grant Notice. For purposes of the Award, "***Long-Service Retirement***" means your voluntary termination of Continuous Service, unless circumstances exist at the time of such termination that would constitute Cause, following: (a) your completion of 10 years of Continuous Service and (b) your attainment of age 55.

For avoidance of doubt, in the event of your Retirement, if you fail to comply with the conditions in this Section 2(c), including compliance with the Non-Solicitation Agreement for a period of 12 months after your termination date, you will forfeit all unvested RSUs.

3. Number of RSUs and Ordinary Shares.

(a) The number of RSUs subject to your Award may be adjusted from time to time for Capitalization Adjustments, as provided in the Plan.

(b) Any additional RSUs that become subject to the Award pursuant to this Section 3 shall be subject, in a manner determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of delivery as applicable to the other RSUs covered by your Award.

(c) Notwithstanding the provisions of this Section 3, no fractional Ordinary Shares or rights for fractional Ordinary Shares shall be created pursuant to this Section 3. The Board shall, in its discretion, determine an equivalent benefit for any fractional Ordinary Shares or fractional Ordinary Shares that might be created by the adjustments referred to in this Section 3.

4. Securities Law Compliance. You may not be issued any Ordinary Shares in respect of your Award unless either (a) the Ordinary Shares are registered under the Securities Act; or (b) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Your Award also must comply with other applicable laws and regulations governing the Award, and you will not receive such Ordinary Shares if the Company determines that such receipt would not be in material compliance with such laws and regulations. The Company shall not be liable if Ordinary Shares cannot be issued to you as a consequence of the Company's determination that the issuance of Ordinary Shares does not comply with applicable laws and regulations governing the Award.

5. Transfer Restrictions. Your Award is not transferable, except by will or by the laws of descent and distribution. In addition to any other limitation on transfer created by applicable securities laws, you agree not to assign, hypothecate, donate, encumber or otherwise dispose of any interest in any of the Ordinary Shares subject to the Award until the Ordinary Shares are issued to you in accordance with Section 6 of this Agreement. After the Ordinary Shares have been issued to you, you are free to assign, hypothecate, donate, encumber or otherwise dispose of any interest in such Ordinary Shares provided that any such actions are in compliance with the provisions herein (including the country-specific Appendix hereto) and applicable securities laws.

6. Date of Issuance.

(a) To the extent your Award is exempt from application of Section 409A of the Code and any state or foreign law of similar effect (collectively "***Section 409A***"), the Company will deliver to you a number of Ordinary Shares equal to the number of vested RSUs subject to your Award, including any additional RSUs received pursuant to Section 3 above that relate to those vested RSUs, on the applicable vesting date(s). However, if a scheduled delivery date falls on a date that is not a U.S. business day, such delivery date shall instead fall on the next following U.S. business day. Notwithstanding the foregoing, in the event that (i) you are subject to the Company's Policy Regarding Stock Trading by Executive Officers, Directors and Other

Designated Employees (or any successor policy) (the "***Policy***"), the Company's Policy Against Trading on the Basis of Inside Information, or you are otherwise prohibited from selling Ordinary Shares in the open market and any Ordinary Shares covered by your Award are scheduled to be delivered on a day (the "***Original Distribution Date***") that does not occur during an open "window period" applicable to you or a day on which you are permitted to sell Ordinary Shares pursuant to a written plan that meets the requirements of Rule 10b5-1 under the Exchange Act, as determined by the Company in accordance with the Policy, or does not occur on a date when you are otherwise permitted to sell Ordinary Shares in the open market, and (ii) the Company elects not to satisfy any Tax-Related Items (defined below) by withholding Ordinary Shares from your distribution, then such Ordinary Shares shall not be delivered on such Original Distribution Date and shall instead be delivered on the first U.S. business day of the next occurring open "window period" applicable to you pursuant to the Policy (regardless of whether you are still providing Continuous Service at such time) or the next U.S. business day when you are not prohibited from selling Ordinary Shares in the open market, but if you are a U.S. taxpayer, in no event later than the fifteenth (15th) day of the third calendar month of the calendar year following the calendar year in which the Ordinary Shares covered by the Award are no longer subject to a "substantial risk of forfeiture" within the meaning of Treasury Regulations Section 1.409A-1(d). Delivery of the Ordinary Shares pursuant to the provisions of this Section 6(a) is intended to comply with the requirements for the short-term deferral exemption available under Treasury Regulations Section 1.409A-1(b)(4) and shall be construed and administered in such manner. The form of such delivery of the Ordinary Shares (*e.g.*, a share certificate or electronic entry evidencing such Ordinary Shares) shall be determined by the Company.

(b) The provisions of this Section 6(b) are intended to apply to the extent you are a U.S. taxpayer and your Award is subject to Section 409A (including, but not limited to, because you are party to a severance arrangement or other agreement between you and the Company (or are eligible for benefits under a severance arrangement, plan or policy maintained by the Company), if any, that provides for acceleration of vesting of your Award upon your termination of employment or separation from service (as such term is defined in Section 409A(a)(2)(A)(i) of the Code (and without regard to any alternative definition thereunder)) ("***Separation from Service***") and such severance benefit does not satisfy the requirements for an exemption from application of Section 409A provided under Treasury Regulations Section 1.409A-1(b)(4) or 1.409A-1(b)(9) ("***Non-Exempt Severance Arrangement***")). If you are not a U.S. taxpayer, this Section 6(b) shall not apply to you. To the extent you are a U.S. taxpayer and your Award is subject to and not exempt from application of Section 409A, the following provisions in this Section 6(b) shall supersede anything to the contrary in Section 6(a).

(i) If your Award vests in the ordinary course during your Continuous Service in accordance with the original Vesting Schedule provided in the Grant Notice, without vesting under the terms of a Non-Exempt Severance Arrangement or pursuant to Section 2(a), 2(b), 2(c) or 11(a) of this Agreement, in no event will the Ordinary Shares be issued in respect of your Award any later than the 60th day that follows the applicable vesting date.

(ii) If vesting of your Award accelerates under the terms of a Non-Exempt Severance Arrangement in connection with your Separation from Service, and such vesting acceleration provisions were in effect as of the Date of Grant of your Award and, therefore, are part of the terms of your Award as of the Date of Grant, then the Ordinary Shares will be earlier issued in respect of your Award upon your Separation from Service in accordance with the terms of the Non-Exempt Severance Arrangement, but in no event later than the 60th day that follows the date of your Separation from Service. For clarity, if such Non-Exempt Severance Arrangement is the Jazz Pharmaceuticals plc Amended and Restated Executive Change in Control and Severance Benefit Plan (the "***CIC Plan***"), such Ordinary Shares will be issued on the 60th day following the date of your Covered Termination (as defined in the CIC Plan) (which, for clarity, must be a Separation from Service). However, if at the time the Ordinary Shares would otherwise be issued you are subject to the distribution limitations contained in Section 409A applicable to "specified employees," as defined in Section 409A(a)(2)(B)(i) of the Code, such Ordinary Shares shall not be issued before the date that is six (6) months following the date of your Separation from Service, or, if earlier, the date of your death that occurs within such six (6) month period.

(iii) If vesting of your Award accelerates upon your termination of Continuous Service due to your death under Section 2(a) of this Agreement, then the Ordinary Shares will be issued in respect of your Award to your beneficiary (if any) or to the personal representative of your estate by the 60th day that follows the date of your death.

(iv) If your Award continues to vest pursuant to the original Vesting Schedule as provided in the Grant Notice upon your termination of Continuous Service due to your Disability under Section 2(b) or Retirement under Section 2(c) of this Agreement, then in no event will the Ordinary Shares be issued in respect of your Award any later than the 60th day that follows the applicable vesting date.

(v) If vesting of your Award accelerates upon your Involuntary Termination Without Cause under Section 11(a) of this Agreement, then the Ordinary Shares will be issued in respect of your Award on the 60th day that follows the date of your Involuntary Termination Without Cause (which, for clarity, must be a Separation from Service). However, if at the time the Ordinary Shares would otherwise be issued you are subject to the distribution limitations contained in Section 409A applicable to "specified employees," as defined in Section 409A(a)(2)(B)(i) of the Code, such Ordinary Shares shall not be issued before the date that is six (6) months following the date of your Separation from Service, or, if earlier, the date of your death that occurs within such six (6) month period.

(vi) If vesting of your Award accelerates under the terms of a Non-Exempt Severance Arrangement in connection with your Separation from Service, and such vesting acceleration provisions were not in effect as of the Date of Grant of the Award and, therefore, are not a part of the terms of your Award on the Date of Grant, then such acceleration of vesting of your Award shall not accelerate the issuance date of the Ordinary Shares in respect of your Award, but such Ordinary Shares shall instead be issued on the same schedule as set forth in Section 6(b)(i) of this Agreement as if they had vested in the ordinary course during your

Continuous Service in accordance with the original Vesting Schedule provided in the Grant Notice (without vesting under the terms of a Non-Exempt Severance Arrangement or pursuant to Section 2(a), 2(b), 2(c) or 11(a) of this Agreement), notwithstanding the vesting acceleration of the Award. Such issuance schedule is intended to satisfy the requirements of payment on a specified date or pursuant to a fixed schedule, as provided under Treasury Regulations Section 1.409A-3(a)(4).

(c) If you are a U.S. taxpayer and your Award is subject to and not exempt from Section 409A (a "***Non-Exempt Award***"), then the provisions in this Section 6(c) shall apply and supersede anything to the contrary that may be set forth in the Plan, the Grant Notice or in any other section of this Agreement with respect to the permitted treatment of your Non-Exempt Award:

(i) Any exercise by the Board of discretion to accelerate the vesting of your Non-Exempt Award shall not result in any acceleration of the scheduled issuance dates for the Ordinary Shares in respect of the Non-Exempt Award unless earlier issuance of the Ordinary Shares upon the applicable vesting dates would be in compliance with the requirements of Section 409A.

(ii) The Company explicitly reserves the right to (A) earlier settle your Non-Exempt Award to the extent permitted and in compliance with the requirements of Section 409A, including pursuant to any of the exemptions available in Treasury Regulations Section 1.409A-3(j)(4)(i), and (B) provide that you will receive a cash settlement equal to the Fair Market Value of the Ordinary Shares that would otherwise be issued to you, if applicable and in compliance with the requirements of Section 409A.

(iii) To the extent the terms of your Non-Exempt Award provide that it will be settled upon a Change in Control or Corporate Transaction, to the extent it is required for compliance with the requirements of Section 409A, the Change in Control or Corporate Transaction event triggering settlement must also constitute a change in the ownership or effective control of the Company, or in the ownership of a substantial portion of the Company's assets, each as determined under Section 409A(a)(2)(A)(v) of the Code and Treasury Regulations Section 1.409A-3(i)(5) (a "***409A Change of Control***"). To the extent the terms of your Non-Exempt Award provide that it will be settled upon a termination of employment or termination of Continuous Service, to the extent it is required for compliance with the requirements of Section 409A, the termination event triggering settlement must also constitute a Separation from Service. However, if at the time the Ordinary Shares would otherwise be issued to you in connection with your Separation from Service, you are subject to the distribution limitations contained in Section 409A applicable to "specified employees," as defined in Section 409A(a)(2)(B)(i) of the Code, such Ordinary Shares shall not be issued before the date that is six (6) months following the date of your Separation from Service, or, if earlier, the date of your death that occurs within such six (6) month period.

(iv) The provisions in this Agreement for delivery of the Ordinary Shares in respect of the Non-Exempt Award are intended to comply with the requirements of Section 409A so that the delivery of the Ordinary Shares to you in respect of your Non-Exempt

Award will not trigger the additional tax imposed under Section 409A, and any ambiguities herein will be so interpreted.

7. Dividends. You shall receive no benefit or adjustment to your Award with respect to any cash dividend, share dividend or other distribution that does not result from a Capitalization Adjustment as provided in the Plan; *provided, however*, that this sentence shall not apply with respect to any Ordinary Shares that are delivered to you in connection with your Award after such Ordinary Shares have been delivered to you.

8. Restrictive Legends. The Ordinary Shares issued in respect of your Award shall be endorsed with appropriate legends determined by the Company.

9. Award Not a Service Contract.

(a) Nothing in this Agreement (including, but not limited to, the vesting of your Award pursuant to the schedule set forth in Section 2 herein or the issuance of the Ordinary Shares in respect of your Award), the Plan or any covenant of good faith and fair dealing that may be found implicit in this Agreement or the Plan shall: (i) confer upon you any right to continue in the employ of, or affiliation with, the Company or an Affiliate; (ii) constitute any promise or commitment by the Company or an Affiliate regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of employment or affiliation; (iii) confer any right or benefit under this Agreement or the Plan unless such right or benefit has specifically accrued under the terms of this Agreement or Plan; or (iv) deprive the Company or its Affiliates, as applicable, of the right to terminate you without regard to any future vesting opportunity that you may have.

(b) By accepting this Award, you acknowledge and agree that the right to continue vesting in the Award pursuant to the schedule set forth in Section 2 is earned only by providing Continuous Service (not through the act of being hired, being granted this Award or any other award or benefit) and that the Company has the right to reorganize, sell, spin-out or otherwise restructure one or more of its businesses or Affiliates at any time or from time to time, as it deems appropriate (a "reorganization"). You further acknowledge and agree that such a reorganization could result in the termination of your Continuous Service, or the termination of Affiliate status of your employer and the loss of benefits available to you under this Agreement, including but not limited to, the termination of the right to continue vesting in the Award. You further acknowledge and agree that this Agreement, the Plan, the transactions contemplated hereunder and the vesting schedule set forth herein or any covenant of good faith and fair dealing that may be found implicit in any of them do not constitute an express or implied promise of continued engagement as an employee or consultant for the term of this Agreement, for any period, or at all, and shall not interfere in any way with your right or the right of the Company or its Affiliate, as applicable, to terminate your Continuous Service at any time.

10. Tax Withholding Obligations.

(a) On or before the time you receive a distribution of the Ordinary Shares subject to your Award, or at any time thereafter as requested by the Company, you hereby

authorize the Company or, if different, your employer (the "***Employer***") to withhold from the Ordinary Shares issuable to you an amount sufficient to satisfy any income tax, social insurance, payroll tax, fringe benefits tax, payment on account or other tax-related items which arise in connection with your Award ("***Tax-Related Items***"), where the Fair Market Value of the Ordinary Shares is measured as of the date the Ordinary Shares are issued pursuant to Section 6. Further, to the extent that any obligation to withhold Tax-Related Items arises prior to distribution of the Ordinary Shares, the Company may cause the RSUs to vest and be deemed payable for the purpose of satisfying such obligation by withholding of Ordinary Shares as provided for above, where the Fair Market Value of the Ordinary Shares is measured as of such deemed RSU payment date, provided that (i) to avoid a prohibited acceleration under Section 409A, the number of RSUs so vested and deemed payable will not exceed the number necessary to satisfy the liability for Tax-Related Items; and (ii) if you are subject to Section 16 of the Exchange Act, withholding in Ordinary Shares pursuant to the foregoing will either be approved in advance by the Committee or solely at your election, provided that, for clarity, you will not have any discretion with respect to whether any RSUs will vest pursuant to this Section 10(a).

(b) Additionally, the Company or the Employer may, in its sole discretion, satisfy all or any portion of the Tax-Related Items obligation relating to your Award by any of the following means or by a combination of such means: (i) withholding from any compensation otherwise payable to you by the Company or your Employer; (ii) causing you to tender a cash payment; or (iii) permitting or requiring you to enter into a "same day sale" commitment with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a "***FINRA Dealer***") whereby you irrevocably elect to sell a portion of the Ordinary Shares to be delivered in connection with your Award to satisfy the Tax-Related Items and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the Tax-Related Items directly to the Company and/or its Affiliates. Notwithstanding the foregoing, if you are subject to Section 16 of the Exchange Act, the alternative withholding methods set forth in this Section 10(b) shall not apply to you other than with respect to any withholding obligation for Tax-Related Items that arises prior to the distribution of the Ordinary Shares.

(c) Depending on the withholding method, the Company may withhold or account for Tax-Related Items by considering applicable minimum statutory withholding amounts or other applicable withholding rates, including maximum applicable rates, in which case you will receive a refund of any over-withheld amount in cash and will have no entitlement to the Ordinary Share equivalent. If the obligation for Tax-Related Items is satisfied by withholding from Ordinary Shares otherwise issuable to you, for tax purposes, you are deemed to have been issued the full number of Ordinary Shares subject to the vested RSUs, notwithstanding that a number of the Ordinary Shares is held back solely for the purpose of paying the Tax-Related Items. Furthermore, you acknowledge that the Company and/or your Employer make no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of the Award grant, including, but not limited to, the grant or vesting of the RSUs, the subsequent sale of Ordinary Shares acquired pursuant to such vesting and the receipt of any dividends, and do not commit to and are under no obligation to structure the terms of the grant or any aspect of the Award to reduce or eliminate your liability for Tax-Related Items or achieve any particular tax result. You further acknowledge that if you become subject to tax in

more than one jurisdiction between the Date of Grant and the date of any relevant taxable event, the Company and/or your Employer (or former employer, as applicable) may be required to withhold or account for Tax-Related Items in more than one jurisdiction.

(d) Unless the Tax-Related Items withholding obligations of the Company and/or the Employer are satisfied, the Company and/or the Employer shall have no obligation to deliver to you any Ordinary Shares.

(e) In the event that the amount of the Company's and/or the Employer's withholding obligation was greater than the amount withheld by the Company and/or the Employer, you agree to indemnify and hold the Company harmless from any failure by the Company and/or the Employer to withhold the proper amount.

11. Change in Control.

(a) If your Continuous Service terminates either within twelve (12) months following or one (1) month prior to the effective date of a Change in Control due to an Involuntary Termination Without Cause, the vesting of the RSUs subject to this Award shall be accelerated in full, effective as of the date of such Involuntary Termination Without Cause (or as soon as administratively practicable thereafter, but no later than 60 days following such Involuntary Termination Without Cause). In order to give effect to the intent of this provision, in the event of your Involuntary Termination Without Cause, notwithstanding anything to the contrary set forth in the Plan or Section 2 of this Agreement, in no event will any portion of this Award be forfeited or terminate any earlier than 60 days following such termination date.

(b) For purposes of this Agreement, "***Involuntary Termination Without Cause***" means the involuntary termination of your Continuous Service for reasons other than death, Disability, or Cause. For this purpose, "Cause" means the occurrence of any of the following events that has a material negative impact on the business or reputation of the Company or an Affiliate: (i) your conviction for any criminal offence (other than an offence under any road traffic legislation for which a fine or non-custodial penalty is imposed) or any offence under any regulation or legislation relating to insider dealing, fraud or dishonesty; (ii) your attempted commission of, or participation in, a fraud or act of dishonesty against the Company or an Affiliate; (iii) your intentional, material violation of any contract or agreement between you and the Company or an Affiliate, or of any statutory duty owed to the Company or an Affiliate; (iv) your unauthorized use or disclosure of the Company's or an Affiliate's confidential information or trade secrets; or (v) your gross misconduct. The determination that a termination of your Continuous Service is either for Cause or without Cause shall be made by the Company in its sole discretion. Any determination by the Company that your Continuous Service was terminated with or without Cause for the purposes of this Agreement shall have no effect upon any determination of the rights or obligations of the Company or an Affiliate or you for any other purpose.

(c) Notwithstanding anything in the Agreement or the CIC Plan to the contrary, if you otherwise become entitled to vesting of this Award under more than one of the Special Vesting Provisions, only the Special Vesting Provision that would provide you with the

most favorable vesting benefit will be deemed to be applicable to this Award and any other Special Vesting Provision will be deemed to be inapplicable to this Award. For purposes of the Agreement, "***Special Vesting Provisions***" means Sections 2(a), 2(b), 2(c) and 11(a) of the Agreement, and Section 4(c) of the CIC Plan.

12. Parachute Payments.

(a) If you are a U.S. taxpayer and any payment or benefit you would receive from the Company or otherwise in connection with a Change in Control or other similar transaction ("***Payment***") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "***Excise Tax***"), then such Payment shall be equal to the Reduced Amount. The "Reduced Amount" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax, or (y) the largest portion, up to and including the total, of the Payment, whichever amount ((x) or (y)), after taking into account all applicable federal, state, foreign and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in your receipt, on an after-tax basis, of the greater amount of the Payment notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting "parachute payments" is necessary so that the Payment equals the Reduced Amount, reduction shall occur in the manner that results in the greatest economic benefit for you.

(b) The independent registered public accounting firm engaged by the Company for general audit purposes as of the day prior to the effective date of the event described in Section 280G(b)(2)(A)(i) of the Code shall perform the foregoing calculations. If the independent registered public accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting such Change in Control or similar transaction, the Company shall appoint a nationally recognized independent registered public accounting firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such independent registered public accounting firm required to be made hereunder.

(c) The independent registered public accounting firm engaged to make the determinations hereunder shall provide its calculations, together with detailed supporting documentation, to the Company and you within thirty (30) calendar days after the date on which your right to a Payment is triggered (if requested at that time by the Company or you) or such other time as reasonably requested by the Company or you. Any good faith determinations of the independent registered public accounting firm made hereunder shall be final, binding and conclusive upon the Company and you.

13. Unsecured Obligation. Your Award is unfunded, and as a holder of a vested Award, you shall be considered an unsecured creditor of the Company with respect to the Company's obligation, if any, to issue Ordinary Shares pursuant to this Agreement. You shall not have voting or any other rights as a shareholder of the Company with respect to the Ordinary Shares to be issued pursuant to this Agreement until such Ordinary Shares are issued to you pursuant to Section 6 of this Agreement. Upon such issuance, you will obtain full voting and

other rights as a shareholder of the Company. Nothing contained in this Agreement, and no action taken pursuant to its provisions, shall create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

14. Other Documents. You hereby acknowledge receipt or the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act, which includes the Plan prospectus. In addition, you acknowledge receipt of the Company's policy permitting officers and directors to sell Ordinary Shares only during certain "window" periods and the Company's insider trading policy, in effect from time to time.

15. Nature of Grant. In accepting the grant, you acknowledge, understand and agree that:

(a) the Plan is established voluntarily by the Company, it is discretionary in nature and it may be modified, amended, suspended or terminated by the Company at any time, to the extent permitted by the Plan;

(b) the Award grant is voluntary and occasional and does not create any contractual or other right to receive future grants of RSUs, or benefits in lieu of RSUs, even if RSUs have been granted in the past;

(c) all decisions with respect to future grants of RSUs or other grants, if any, will be at the sole discretion of the Company;

(d) you are voluntarily participating in the Plan;

(e) the RSUs and the Ordinary Shares subject to the RSUs, and the income and value of same, are not intended to replace any pension rights or compensation;

(f) the RSUs and the Ordinary Shares subject to the RSUs, and the income and value of same, are not part of normal or expected compensation for any purpose, including, without limitation, calculating any severance, resignation, termination, redundancy, dismissal, end-of-service payments, bonuses, long-service awards, pension or retirement or welfare benefits or similar payments;

(g) the future value of the underlying Ordinary Shares is unknown, indeterminable and cannot be predicted with certainty;

(h) no claim or entitlement to compensation or damages shall arise from forfeiture of the Award resulting from the termination of your Continuous Service (for any reason whatsoever, whether or not later found to be invalid or in breach of employment laws in the jurisdiction where you are providing Continuous Service or the terms of your employment agreement, if any), and in consideration of the Award, you agree not to institute any claim against the Company, any Affiliate or the Employer;

(i) unless otherwise agreed with the Company, the RSUs and the Ordinary Shares subject to the RSUs, and the income and value of same, are not granted as consideration

for, or in connection with, the service you may provide as a director of the Company or any Affiliate;

(j) unless otherwise provided in the Plan or by the Company in its discretion, the Award and the benefits evidenced by this Agreement do not create any entitlement to have the Award or any such benefits transferred to, or assumed by, another company nor to be exchanged, cashed out or substituted for, in connection with any corporate transaction affecting the Ordinary Shares; and

(k) neither the Company, the Employer nor any Affiliate shall be liable for any foreign exchange rate fluctuation between your local currency and the United States Dollar that may affect the value of the Award or of any amounts due to you pursuant to the settlement of the Award or the subsequent sale of any Ordinary Shares acquired upon settlement.

16. No Advice Regarding Grant. The Company is not providing any tax, legal or financial advice, nor is the Company making any recommendations regarding your participation in the Plan, or your acquisition or sale of the underlying Ordinary Shares. You are hereby advised to consult with your own personal tax, legal and financial advisors regarding your participation in the Plan before taking any action related to the Plan.

17. Data Privacy. The Employer, the Company and any Affiliate may collect, use, process, transfer or disclose your Personal Information for the purpose of implementing, administering and managing your participation in the Plan, in accordance with the Jazz Pharmaceuticals Employee Data Privacy Notice you have previously received. (Please contact Human Resources if you would like to receive another copy of this notice.) For example, your Personal Information may be directly or indirectly transferred to E*TRADE or any other third party stock plan service provider as may be selected by the Company, and any other third parties assisting the Company with the implementation, administration and management of the Plan.

18. Governing Law and Venue. The Award and the provisions of this Agreement are governed by, and subject to, the laws of the State of Delaware, without regard to the conflict of law provisions.

For purposes of any action, lawsuit or other proceedings brought to enforce this Agreement, relating to it, or arising from it, the parties hereby submit to and consent to the sole and exclusive jurisdiction of the courts of Santa Clara County, California, or the federal courts for the United States for the Northern District of California, and no other courts, where this grant is made and/or to be performed.

19. Language. If you have received this Agreement or any other document related to the Plan translated into a language other than English and if the meaning of the translated version is different than the English version, the English version will control.

20. Appendix. Notwithstanding any provisions in this Agreement, the Award shall be subject to any special terms and conditions set forth in any Appendix to this Agreement for your country. Moreover, if you relocate to one of the countries included in the Appendix, the

special terms and conditions for such country will apply to you, to the extent the Company determines that the application of such terms and conditions is necessary or advisable for legal or administrative reasons. The Appendix constitutes part of this Agreement.

21. Notices; Electronic Delivery. Any notices provided for in your Award or the Plan shall be given in writing (including electronically) and shall be deemed effectively given upon receipt or, in the case of notices delivered by the Company to you, fourteen (14) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. Notwithstanding the foregoing, the Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this Award by electronic means or to request your consent to participate in the Plan by electronic means. By accepting this Award you consent to receive such documents by electronic delivery and, if requested, to agree to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

22. Miscellaneous.

(a) All covenants and agreements hereunder shall inure to the benefit of, and be enforceable by the Company's successors and assigns, if any. Your rights and obligations under your Award may only be assigned with the prior written consent of the Company.

(b) You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your Award.

(c) You acknowledge and agree that you have reviewed your Award in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your Award, and fully understand all provisions of your Award.

(d) All obligations of the Company under the Plan and this Agreement shall be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

(e) The Committee shall have complete and absolute discretion to make the determinations called for under this Agreement, and all such determinations shall be binding on you and on any person who claims all or any part of your Award on your behalf as well as on the Company.

23. Insider Trading / Market Abuse Laws. You may be subject to insider trading restrictions and/or market abuse laws based on the exchange on which the Ordinary Shares are listed and in applicable jurisdictions including the United States and your country or your broker's country, if different, which may affect your ability to accept, acquire, sell or otherwise dispose of Ordinary Shares, rights to Ordinary Shares (e.g., RSUs) or rights linked to the value of Ordinary Shares under the Plan during such times as you are considered to have "inside information" regarding the Company (as defined by the laws in the applicable jurisdictions).

Local insider trading laws and regulations may prohibit the cancellation or amendment of orders you placed before you possessed inside information. Furthermore, you could be prohibited from (a) disclosing the inside information to any third party and (b) "tipping" third parties or causing them otherwise to buy or sell securities (third parties include fellow employees). Any restrictions under these laws or regulations are separate from and in addition to any restrictions that may be imposed under the Company's insider trading policy as may be in effect from time to time. You acknowledge that it is your responsibility to comply with any applicable restrictions, and you should speak to your personal advisor on this matter.

24. Foreign Asset/Account, Exchange Control and Tax Reporting. You may be subject to foreign asset/account, exchange control and/or tax reporting requirements as a result of the acquisition, holding and/or transfer of Ordinary Shares or cash (including dividends and the proceeds arising from the sale of Ordinary Shares) derived from your participation in the Plan, to and/or from a brokerage/bank account or legal entity located outside your country. The applicable laws of your country may require that you report such accounts, assets, the balances therein, the value thereof and/or the transactions related thereto to the applicable authorities in such country. You acknowledge that you are responsible for ensuring compliance with any applicable foreign asset/account, exchange control and tax reporting requirements and should consult your personal legal advisor on this matter.

25. Governing Plan Document. Your Award is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Award, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. Except as expressly provided in this Agreement, in the event of any conflict between the provisions of your Award and those of the Plan, the provisions of the Plan shall control. In addition, your Award (and any compensation paid or Ordinary Shares issued under your Award) is subject to recoupment in accordance with the Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law.

26. Severability. If all or any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

27. Amendment. Notwithstanding anything in the Plan to the contrary, the Board reserves the right to change, by written notice to you, the provisions of this Agreement in any way it may deem necessary or advisable for legal or administrative reasons, and to require you to sign any additional agreements or undertakings that may be necessary to accomplish the foregoing.

28. Headings. The headings of the Sections in this Agreement are inserted for convenience only and shall not be deemed to constitute a part of this Agreement or to affect the meaning of this Agreement.

29. Waiver. You acknowledge that a waiver by the Company of breach of any provision of this Agreement shall not operate or be construed as a waiver of any other provision of this Agreement, or of any subsequent breach by you or any other Participant.

* * * * *

By signing the Non-U.S. Restricted Stock Unit Award Grant Notice to which this Non-U.S. Restricted Stock Unit Award Agreement is attached, you shall be deemed to have signed and agreed to the terms and conditions of this Non-U.S. Restricted Stock Unit Award Agreement.

* * * * *

APPENDIX

TO THE

NON-U.S. RESTRICTED STOCK UNIT AWARD AGREEMENT

Terms and Conditions

This Appendix contains additional terms and conditions that govern the Award granted under the Plan to you if you reside and/or work in one of the countries listed below. Certain capitalized terms used but not defined in this Appendix have the meanings set forth in the Plan and/or the Agreement.

If you are a citizen or resident of a country other than the one in which you are currently working, transfer employment and/or residency after the RSUs are granted, or are considered a resident of another country for local law purposes, the information contained herein may not be applicable to you, and the Company shall, in its discretion, determine to what extent the terms and conditions contained herein shall apply to you.

Notifications

This Appendix contains information regarding exchange controls and certain other issues of which you should be aware with respect to participation in the Plan. The information is based on the securities, exchange control, and other laws in effect in the respective countries as of January 2021. Such laws are often complex and change frequently. As a result, the Company strongly recommends that you not rely on the information in this Appendix as the only source of information relating to the consequences of your participation in the Plan because the information may be out of date at the time you vest in the RSUs or sell Ordinary Shares acquired pursuant thereto.

The information contained herein is general in nature and may not apply to your particular situation, and the Company is not in a position to assure you of a particular result. Accordingly, you are advised to seek appropriate professional advice as to how the relevant laws in your country may apply to your situation.

AUSTRALIA

Terms and Conditions

Australia Offer Document. The RSUs are intended to comply with the provisions of the Corporations Act 2001, Australia Securities and Investments Commission ("***ASIC***") Regulatory Guide 49 and ASIC Class Order 14/1000. Additional details are set forth in the Offer Document below.

Notifications

Tax Information. Subdivision 83A-C of the Income Tax Assessment Act 1997 (the "***Act***") applies to the RSUs granted in accordance with the terms and conditions of the Grant Notice, the Plan and the Agreement (subject to the requirements of the Act).

Exchange Control Notification. Exchange control reporting is required for cash transactions exceeding AUD 10,000 and international fund transfers. If an Australian bank is assisting you with the transaction, the bank will file the report on your behalf. If there is no Australian bank involved with the transfer, you will be required to file the report.

OFFER OF RESTRICTED STOCK UNITS
TO AUSTRALIAN RESIDENT EMPLOYEES

Jazz Pharmaceuticals plc
2011 Equity Incentive Plan

Offer. We are pleased to provide you with this offer to participate in the Plan. This offer sets out information regarding the grant of RSUs to Australian resident employees of the Company and its Affiliates ("***Australian Participants***"). This information is provided by the Company to ensure compliance with the Australian Securities and Investments Commission ("***ASIC***") Class Order 14/1000 and the relevant provisions of the *Corporations Act 2001*.

In addition to the information set out in the Agreement, Australian Participants are also being provided with copies of the following documents, which are available on the Company's internal website (https://jazzpharma.sharepoint.com/sites/EmployeeResources/SitePages/Stock-Plan-Services-Australia.aspx):

(a) the Plan;

(b) the Plan Prospectus; and

(c) Employee Tax Supplement for Australia.

(collectively, the "***Additional Documents***").

The Additional Documents provide further information to help Australian Participants make an informed investment decision about participating in the Plan. Neither the Plan nor the Plan Prospectus is a prospectus for purposes of the *Corporations Act 2001*.

Australian Participants should not rely upon any oral statements made in relation to this offer. Australian Participants should rely only upon the statements contained in the Agreement and the Additional Documents when considering participation in the Plan.

Securities Law Notification. Investment in Ordinary Shares involves a degree of risk. Australian Participants should monitor their participation and consider all risk factors relevant to the acquisition of Ordinary Shares under the Plan as set forth below and in the Additional Documents.

The information herein is general information only. It is not advice or information that takes into account Australian Participants' objectives, financial situations or needs.

Australian Participants should consider obtaining their own financial product advice from a person who is licensed by ASIC to give such advice.

Additional Risk Factors for Australian Participants. Australian Participants should have regard to risk factors relevant to investment in securities generally and, in particular, to the holding of Ordinary Shares. For example, the price at which Ordinary Shares are quoted on the Nasdaq may increase or decrease due to a number of factors. There is no guarantee that the price of the Ordinary Shares will increase. Factors which may affect the price of Ordinary Shares include fluctuations in the domestic and international market for listed stocks, general economic conditions, including interest rates, inflation rates, commodity and oil prices, changes to government fiscal, monetary or regulatory policies, legislation or regulation, the nature of the markets in which the Company operates and general operational and business risks.

More information about potential factors that could affect the Company's business and financial results are included in the Company's most recent Annual Report on Form 10-K and the Company's Quarterly Report on Form 10-Q, available upon request. In addition, Australian Participants should be aware that the Australian dollar equivalent of the value of Ordinary Shares acquired at vesting/settlement will be affected by the US$/A$ exchange rate. Participation in the Plan involves certain risks related to fluctuations in this rate of exchange.

Common Stock in a U.S. Corporation. Common stock of a U.S. corporation is analogous to ordinary shares of an Australian corporation. Each holder of common stock is entitled to one vote for every Ordinary Share held in the Company.

Dividends may be paid on the Ordinary Shares out of any funds of the Company legally available for dividends at the discretion of the Board.

The Ordinary Shares are currently traded on the Nasdaq Global Select Market (the "***Nasdaq***") in the United States of America under the symbol "JAZZ."

The Ordinary Shares are not liable to any further calls for payment of capital or for other assessment by the Company and have no sinking fund provisions, pre-emptive rights, conversion rights or redemption provisions.

Ascertaining the Market Price of Shares. Australian Participants may ascertain the current or historical market price of the Ordinary Shares as traded on the Nasdaq at http://www.nasdaq.com under the symbol "JAZZ." The Australian dollar equivalent of that price can be obtained at: http://www.rba.gov.au/statistics/frequency/exchange-rates.html.

This will not be a prediction of what the market price per Ordinary Share will be when the RSUs vest or settle or of the applicable exchange rate on the actual date of vesting or settlement.

AUSTRIA

Notifications

Exchange Control Notification. If you hold Ordinary Shares acquired under the Plan outside of Austria, you must submit a report to the Austrian National Bank. An exemption applies if the value of the Ordinary Shares as of any given quarter does not meet or exceed €30,000,000 or if the value of the Ordinary Shares in any given year as of December 31 does not meet or exceed €5,000,000. If the former threshold is exceeded, quarterly obligations are imposed, whereas if the latter threshold is exceeded, annual reports must be given. The annual reporting date is December 31 and the deadline for filing the annual report is March 31 of the following year.

A separate reporting requirement applies when you sell Ordinary Shares acquired under the Plan or receive a dividend. In that case, there may be exchange control obligations if the cash proceeds are held outside of Austria. If the transaction volume of all accounts abroad meets or exceeds €10,000,000, the movements and balances of all accounts must be reported monthly, as of the last day of the month, on or before the 15th day of the following month, on the prescribed form (*Meldungen SI-Forderungen und/oder SI-Verpflichtungen*).

BELGIUM

Notifications

Foreign Asset / Account Reporting. Belgian residents are required to report any securities held (*e.g.*, Ordinary Shares) or bank accounts (including brokerage accounts) opened and maintained outside of Belgium on their annual tax returns. Belgian residents are also required to complete a separate report, providing the Central Contact Point of the National Bank of Belgium with details regarding any such account, including the account number, the name of the bank in which such account is held and the country in which such account is located the first time they report the foreign security and/or bank account on their annual tax returns. The forms to complete this report are available on the website of the National Bank of Belgium, www.nbb.be, under *Kredietcentrales / Centrales des crédits* caption. You should consult your personal tax advisor to ensure compliance with applicable reporting obligations.

CANADA

Terms and Conditions

Settlement of RSUs. Notwithstanding any discretion contained in Section 6(b)(iii) of the Plan, the grant of RSUs does not provide any right for you to receive a cash payment; the RSUs are payable in Ordinary Shares only.

Involuntary Termination Terms. Except as otherwise provided in the Agreement, in the event of involuntary termination of your Continuous Service (regardless of the reason for such termination and whether or not later found to be invalid, unlawful or in breach of employment laws in the jurisdiction where you are providing Continuous Service or the terms of your

employment agreement, if any), except as otherwise set forth in the Agreement, vesting will terminate as of the date that is the earlier of: (1) the date you receive notice of termination of employment from the Employer, or (2) the date you are no longer actively rendering services, regardless of any notice period or period of pay in lieu of such notice required under local law (including, but not limited to, statutory law, regulatory law, and/or common law); the Board or the chief executive officer of the Company or an Affiliate, as applicable, shall have the exclusive discretion to determine when you are no longer actively employed or rendering services for purposes of the RSUs (including whether you may still be considered to be providing services while on a leave of absence). If, notwithstanding the foregoing, applicable employment legislation explicitly requires continued vesting during a statutory notice period, your right to vest in the RSUs, if any, will terminate effective as of the last date of the minimum statutory notice period, but you will not earn or be entitled to pro-rated vesting if the vesting date falls after the end of your statutory notice period, nor will you be entitled to any compensation for lost vesting.

The following provisions apply if Participant resides in Quebec:

Consent to Receive Information in English. The parties acknowledge that it is their express wish that the Agreement, as well as all documents, notices and legal proceedings entered into, given or instituted pursuant hereto or relating directly or indirectly hereto, be drawn up in English.

Consentement Pour Recevoir Des Informations en Anglais. *Les parties reconnaissent avoir exigé la rédaction en anglais de la convention, ainsi que de tous documents, avis et procédures judiciaires, exécutés, donnés ou intentés en vertu de, ou liés directement ou indirectement à, la présente convention.*

Notifications

Securities Law Notification. You will not be permitted to sell or otherwise dispose of the Ordinary Shares acquired under the Plan within Canada. You will be permitted to sell or dispose of any Ordinary Shares only if such sale or disposal takes place outside of Canada through the facilities of the stock exchange on which the Ordinary Shares are traded (*i.e.*, Nasdaq).

Foreign Asset / Account Reporting. Canadian residents are required to report any foreign specified property (including unvested RSUs and Ordinary Shares) annually on Form T1135 (Foreign Income Verification Statement) if the total cost of the foreign specified property exceeds C$100,000 at any time during the year. The form must be filed by April 30th of the following year. RSUs must be reported - generally at a nil cost - if the C$100,000 cost threshold is exceeded because of other foreign specified property. When Ordinary Shares are acquired, their cost generally is the adjusted cost base ("***ACB***") of the Ordinary Shares. The ACB would ordinarily equal the fair market value of the Ordinary Shares at the time of acquisition, but if other shares are also owned, this ACB may have to be averaged with the ACB of the other shares. You should consult your personal tax advisor to ensure compliance with applicable reporting obligations.

DENMARK

Notifications

Special Notice for Employees in Denmark. A Special Notice for Employees in Denmark, Employer Statement pursuant to the Danish Act on Stock Options, as amended effective January 1, 2019, will be provided to you under separate cover.

FINLAND

There are no country-specific provisions.

FRANCE

Terms and Conditions

Language Consent. By accepting the grant, you confirm that you have read and understood the documents relating to the grant (the Plan and the Agreement, including this Appendix) which were provided in the English language. You accept the terms of these documents accordingly.

Consentement Relatif à la Langue Utilisée. *En acceptant l'attribution, vous confirmez avoir lu et compris les documents relatifs à l'attribution (le Plan et le Contrat, y compris cette Annexe) qui ont été communiqués en langue anglaise. Vous acceptez les termes de ces documents en connaissance de cause.*

Notifications

Foreign Asset / Account Reporting. If you hold Ordinary Shares outside of France or maintain a foreign bank account, you are required to report such to the French tax authorities when filing your annual tax return.

GERMANY

Notifications

Exchange Control Notification. Cross-border payments in excess of €12,500 must be reported monthly to the German Federal Bank (*Bundesbank*). Effective from September 2013, the report must be filed electronically. The form of report (*Allgemeines Meldeportal Statistik*) can be accessed via the *Bundesbank's* website (www.bundesbank.de) and is available in both German and English. You are responsible for satisfying the reporting obligations.

Foreign Asset / Account Reporting. If your acquisition of Ordinary Shares leads to a so-called qualified participation at any point during the calendar year, you may need to report the acquisition when you file your tax return for the relevant year. A qualified participation is attained if (i) you own 1% or more of the Company and the value of Ordinary Shares acquired exceeds €150,000 or (ii) you hold Company common stock exceeding 10% of the Company's total common stock.

IRELAND

Terms and Conditions

Vesting and Issuance. The following supplements Sections 2 and 6 of the Agreement, provided you are not a U.S. taxpayer:

Notwithstanding the vesting schedule provided in the Grant Notice and Section 6 (a) of the Agreement, (i) if any vesting date set forth in the Grant Notice ("***Vesting Date***") falls on a date when the Company determines that you are not permitted to sell Ordinary Shares in the open market for any reason, including under the Company's Policy Regarding Stock Trading by Executive Officers, Directors and Other Designated Employees (or any successor policy) or the Company's Policy Against Trading on the Basis of Inside Information (or any successor policy), and (ii) the Company elects not to satisfy any Tax-Related Items (defined in Section 10) by withholding Ordinary Shares, then such Vesting Date shall instead be the later of the next U.S. business day of the next occurring open "window period" applicable to you or the next U.S. business day when the Company determines that you are not prohibited from selling Ordinary Shares in the open market (such later date, the "***Actual Vesting Date***").

Notwithstanding the foregoing and Section 2 of the Agreement, if your Continuous Service terminates between the Vesting Date and the Actual Vesting Date, then the vesting of the Ordinary Shares subject to the Award originally scheduled to vest on the Vesting Date will cease and not vest upon termination of your Continuous Service, unless your Continuous Service terminates for a reason other than Cause, in which case they will instead vest in full on the first U.S. business day following the termination of your Continuous Service.

Notifications

Director Notification Obligation. If you are a director, shadow director or secretary of the Company or an Irish Affiliate, you must notify the Company or the Irish Affiliate in writing if you receive or dispose of an interest exceeding 1% of the Company (*e.g.*, RSUs, Ordinary Shares), or become aware of the event giving rise to the notification requirement, or if you become a director or secretary if such an interest exceeding 1% of the Company exists at the time. This notification requirement also applies with respect to the interests of a spouse or minor children (whose interests will be attributed to the director, shadow director or secretary, as applicable).

ITALY

Terms and Conditions

Tax Withholding Obligations. The following provisions replace Section 10 of the Agreement:

10. Tax Withholding Obligations.

(a) On or before the time you receive a distribution of the Ordinary Shares subject to your Award, or at any time thereafter as requested by the Company, you hereby authorize the Company or, if different, your employer (the "***Employer***") to withhold from the Ordinary Shares issuable to you an amount sufficient to satisfy any income tax, social insurance, payroll tax, fringe benefits tax, payment on account or other tax-related items which arise in connection with your Award ("***Tax-Related Items***"). Additionally, the Company or the Employer may, in its sole discretion, satisfy all or any portion of the Tax-Related Items obligation relating to your Award by any of the following means or by a combination of such means: (i) withholding from any compensation otherwise payable to you by the Company or your Employer; (ii) causing you to tender a cash payment; or (iii) permitting or requiring you to enter into a "same day sale" commitment with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a "***FINRA Dealer***") whereby you irrevocably elect to sell a portion of the Ordinary Shares to be delivered in connection with your Award to satisfy the Tax-Related Items and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the Tax-Related Items directly to the Company and/or its Affiliates. Depending on the withholding method, the Company may withhold or account for Tax-Related Items by considering applicable minimum statutory withholding amounts or other applicable withholding rates, including maximum applicable rates, in which case you will receive a refund of any over-withheld amount in cash and will have no entitlement to the Ordinary Share equivalent. If the obligation for Tax-Related Items is satisfied by withholding from Ordinary Shares otherwise issuable to you, for tax purposes, you are deemed to have been issued the full number of Ordinary Shares subject to the vested RSUs, notwithstanding that a number of the Ordinary Shares are held back solely for the purpose of paying the Tax-Related Items. Furthermore, you acknowledge that the Company and/or your Employer make no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of the Award grant, including, but not limited to, the grant or vesting of the RSUs, the subsequent sale of Ordinary Shares acquired pursuant to such vesting and the receipt of any dividends, and do not commit to and are under no obligation to structure the terms of the grant or any aspect of the Award to reduce or eliminate your liability for Tax-Related Items or achieve any particular tax result. You further acknowledge that if you become subject to tax in more than one jurisdiction between the Date of Grant and the date of any relevant taxable event, the Company and/or your Employer (or former employer, as applicable) may be required to withhold or account for Tax-Related Items in more than one jurisdiction.

(b) Unless the tax withholding obligations of the Company and/or the Employer are satisfied, the Company and/or the Employer shall have no obligation to deliver to you any Ordinary Shares.

(c) In the event the Company's and/or the Employer's obligation to withhold arises prior to the delivery to you of Ordinary Shares or it is determined after the delivery of Ordinary Shares to you that the amount of the Company's and/or the Employer's withholding obligation was greater than the amount withheld by the Company and/or the Employer, you agree to indemnify and hold the Company harmless from any failure by the Company and/or the Employer to withhold the proper amount.

Acknowledgement. You acknowledge that you have read and specifically and expressly approve the following sections of the Agreement: Section 10 - Tax Withholding Obligations; Section 15 - Nature of Grant; Section 17 - Data Privacy; Section 18 - Governing Law and Venue; Section 19 - Language; Section 21- Notices; Electronic Delivery; and Section 26 - Severability.

Notifications

Foreign Asset / Account Reporting. Italian residents who, at any time during the fiscal year, hold foreign financial assets (including Ordinary Shares) which may generate income taxable in Italy are required to report these assets on their annual tax returns (UNICO Form, RW Schedule) for the year during which the assets are held, or on a special form if no tax return is due. These reporting obligations will also apply to Italian residents who are the beneficial owners of foreign financial assets under Italian money laundering provisions. You are responsible for complying with this reporting obligation and should speak with your personal legal advisor in this regard.

NETHERLANDS

There are no country-specific provisions.

NORWAY

There are no country-specific provisions.

POLAND

Notifications

Exchange Control Notification. Polish residents are required to file quarterly reports to the National Bank of Poland with information on transactions and balances regarding their rights to Ordinary Shares (such as RSUs) and Ordinary Shares if the total value (calculated individually or together with other assets and liabilities possessed abroad) exceeds PLN 7 million.

Polish residents also are required to transfer funds through a bank account in Poland if the transferred amount in any single transaction exceeds a specified threshold (currently €15,000, unless the transfer of funds is considered to be connected with the business activity of an entrepreneur, in which case a lower threshold may apply). Polish residents are required to retain documents connected with foreign exchange transactions for a period of five years from the date the exchange transaction was made.

PORTUGAL

Terms and Conditions

Language Consent. You hereby expressly declare that you have full knowledge of the English language and have read, understood and fully accepted and agreed with the terms and conditions established in the Plan and the Agreement.

Conhecimento da Lingua. Por meio do presente, eu declaro expressamente que tem pleno conhecimento da língua inglesa e que li, compreendi e livremente aceitei e concordei com os termos e condições estabelecidas no Plano e no Acordo.

Notifications

Exchange Control Notification. If you acquire Ordinary Shares under the Plan and hold the Ordinary Shares with a U.S. broker that is not a Portuguese financial intermediary, you may need to file a report with the Portuguese Central Bank. If the Ordinary Shares are held by a Portuguese financial intermediary, it will file the report for you.

SPAIN

Terms and Conditions

Tax Withholding Obligations. The following provisions replace Section 10 of the Agreement:

10. Tax Withholding Obligations.

(a) On or before the time you receive a distribution of the Ordinary Shares subject to your Award, or at any time thereafter as requested by the Company, you hereby authorize the Company or, if different, your employer (the "***Employer***") to withhold from the Ordinary Shares issuable to you an amount sufficient to satisfy any income tax, social insurance, payroll tax, fringe benefits tax, payment on account or other tax-related items which arise in connection with your Award ("***Tax-Related Items***"), where the Fair Market Value of the Ordinary Shares is measured as of the date the Ordinary Shares are issued pursuant to Section 6. Additionally, the Company or the Employer may, in its sole discretion, satisfy all or any portion of the Tax-Related Items obligation relating to your Award by any of the following means or by a combination of such means: (i) withholding from any compensation otherwise payable to you by the Company or your Employer; (ii) causing you to tender a cash payment; or (iii) permitting or requiring you to enter into a "same day sale" commitment with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a "***FINRA Dealer***") whereby you irrevocably elect to sell a portion of the Ordinary Shares to be delivered in connection with your Award to satisfy the Tax-Related Items and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the Tax-Related Items directly to the Company and/or its Affiliates. Depending on the withholding method, the Company may withhold or account for Tax-Related Items by considering applicable minimum statutory withholding amounts or other applicable withholding rates, including maximum applicable rates, in which case you will receive a refund of any over-withheld amount in cash and will have no entitlement to the Ordinary Share equivalent. If the obligation for Tax-Related Items is satisfied by withholding from Ordinary Shares otherwise issuable to you, for tax purposes, you are deemed to have been issued a cash bonus in the amount of the Ordinary Shares that are held back for the purpose of paying the Tax-Related Items and compensation in kind corresponding to the number of Ordinary Shares issued to you. Furthermore, you acknowledge that the Company and/or your Employer make no representations or undertakings regarding the treatment of any Tax-Related Items in connection with any aspect of the Award grant, including, but not limited to, the grant or

vesting of the RSUs, the subsequent sale of Ordinary Shares acquired pursuant to such vesting and the receipt of any dividends, and do not commit to and are under no obligation to structure the terms of the grant or any aspect of the Award to reduce or eliminate your liability for Tax-Related Items or achieve any particular tax result. You further acknowledge that if you become subject to tax in more than one jurisdiction between the Date of Grant and the date of any relevant taxable event, the Company and/or your Employer (or former employer, as applicable) may be required to withhold or account for Tax-Related Items in more than one jurisdiction.

(b) Unless the tax withholding obligations of the Company and/or the Employer are satisfied, the Company and/or the Employer shall have no obligation to deliver to you any Ordinary Shares.

(c) In the event the Company's and/or the Employer's obligation to withhold arises prior to the delivery to you of Ordinary Shares or it is determined after the delivery of Ordinary Shares to you that the amount of the Company's and/or the Employer's withholding obligation was greater than the amount withheld by the Company and/or the Employer, you agree to indemnify and hold the Company harmless from any failure by the Company and/or the Employer to withhold the proper amount.

Nature of Grant. This provision supplements Section 15 of the Agreement:

In accepting the RSUs, you consent to participate in the Plan and acknowledge having received and read a copy of the Plan.

You understand that the Company has unilaterally, gratuitously and discretionally decided to grant the RSUs under the Plan to individuals who may be employees of the Employer, the Company or any Affiliate throughout the world. The decision is a limited decision that is entered into upon the express assumption and condition that any grant will not bind the Company or any Affiliate except as set forth in the Plan or Agreement. Consequently, you understand that the RSUs are granted on the assumption and condition that such RSUs and any Ordinary Shares acquired upon vesting of the RSUs shall not become a part of any employment contract (either with the Employer or the Company or any Affiliate) and shall not be considered a mandatory benefit, salary for any purpose (including severance compensation) or any other right whatsoever. In addition, you understand that the RSUs would not be granted but for the assumptions and conditions referred to above; thus, you acknowledge and freely accept that should any or all of the assumptions be mistaken or should any of the conditions not be met for any reason, then the grant of the RSUs shall be null and void.

Further, the vesting of the RSUs is expressly conditioned on your Continuous Service, such that if your service or employment terminates for any reason whatsoever, the RSUs will cease to vest immediately effective on the date of termination of your service or employment unless otherwise expressly set forth in the Agreement. This will be the case, for example, even if you (1) are considered to be unfairly dismissed without good cause; (2) are dismissed for disciplinary or objective reasons or due to a collective dismissal; (3) terminate service or employment due to a change of work location, duties or any other employment or contractual condition; (4) terminate service or employment due to the Company's or any Affiliate's unilateral breach of contract; or

(5) are terminated from service or employment for any other reason whatsoever. Consequently, upon your termination of service or employment for any of the above reasons, you will automatically lose any rights to the RSUs that were unvested on the date of termination.

Notifications

Securities Law Notification. The RSUs described in the Plan and the Agreement, including this Appendix, do not qualify under Spanish regulations as securities. No "offer of securities to the public," as defined under Spanish law, has taken place or will take place in the Spanish territory. The Plan and the Agreement, including this Appendix, have not been nor will they be registered with the Comisión Nacional del Mercado de Valores (Spanish Securities Exchange Commission), and they do not constitute a public offering prospectus.

Exchange Control Notification. The acquisition, ownership and sale of Ordinary Shares under the Plan must be declared for statistical purposes to the Spanish Dirección General de Comercio e Inversiones (the "***DGCI***"), the Bureau for Commerce and Investments, which is a department of the Ministry of Economy and Competitiveness. Generally, the declaration must be made each January for Ordinary Shares owned as of December 31 of the prior year; however, if the amount of Ordinary Shares acquired or sold exceeds a specific threshold or if you hold 10% or more of the share capital of the Company or such other amount that would entitle you to join the Company's board of directors, the declaration must be filed also within one month of the acquisition or sale, as applicable.

Foreign Asset / Account Reporting. Spanish residents are required to declare electronically to the Bank of Spain any securities accounts (including brokerage accounts held abroad), as well as the Ordinary Shares held in such accounts if the value of the transactions during the prior tax year or the balances in such accounts as of December 31 of the prior tax year exceed €1,000,000. More frequent reporting is required if such transaction value or account balance exceeds €100,000,000.

In addition, you may be subject to certain tax reporting requirements with respect to assets or rights that you hold outside of Spain, including bank accounts, securities and real estate if the aggregate value for particular category of assets exceeds €50,000 as of December 31 each year. Ordinary Shares acquired under the Plan or other equity programs offered by the Company constitute securities for purposes of this requirement, but unvested awards (*e.g.*, RSUs, etc.) are not considered assets or rights for purposes of this reporting requirement. If applicable, you must report the assets on Form 720 by no later than March 31 following the end of the relevant year. After the rights and/or assets are initially reported, the reporting obligation will apply only if the value of previously-reported rights or assets increases by more than €20,000 as of each subsequent December 31 or if you sell or otherwise dispose of previously-reported rights or assets. You should consult with your personal advisor to determine your obligations in this respect.

SWEDEN

Terms and Conditions

Tax Withholding Obligations. The following provisions supplements Section 10 of the Agreement:

Without limiting the Company's and the Employer's authority to satisfy their withholding obligations for Tax-Related Items as set forth in Section 10 of the Agreement, in accepting the RSUs, you authorize the Company and/or the Employer to sell or withhold Ordinary Shares otherwise deliverable to you upon vesting to satisfy Tax-Related Items, regardless of whether the Company and/or the Employer have an obligation to withhold such Tax-Related Items.

SWITZERLAND

Notifications

Securities Law Notification. Neither this document nor any other materials relating to the RSUs (i) constitutes a prospectus according to articles 35 et seq. of the Swiss Federal Act on Financial Services ("***FinSA***"), (ii) may be publicly distributed or otherwise made available in Switzerland to any person other than an employee of the Company, or (iii) has been or will be filed with, approved or supervised by any Swiss reviewing body according to article 51 of FinSA or any Swiss regulatory authority (in particular, the Swiss Financial Market Supervisory Authority (FINMA)).

UNITED KINGDOM

Terms and Conditions

Tax Withholding Obligations. This provision supplements Section 10 of the Agreement:

Without limitation to Section 10 of the Agreement, you agree that you are liable for all Tax-Related Items and hereby covenant to pay all such Tax-Related Items as and when requested by the Company or the Employer or by Her Majesty's Revenue and Customs ("***HMRC***") (or any other tax authority or any other relevant authority). You also agree to indemnify and keep indemnified the Company and the Employer against any taxes that they are required to pay or withhold or have paid or will pay on your behalf to HMRC (or any other tax authority or any other relevant authority).

Notwithstanding the foregoing, if you are a director or executive officer of the Company (within the meaning of Section 13(k) of the Exchange Act), the terms of the immediately foregoing provision will not apply. In such case, if the amount of any income tax due is not collected from or paid by you within 90 days of the end of the UK tax year in which an event giving rise to the indemnification described above occurs, the amount of any uncollected income tax may constitute a benefit to you on which additional income tax and national insurance contributions ("***NICs***") may be payable. You will be responsible for reporting and paying any income tax due on this additional benefit directly to HMRC under the self-assessment regime and for reimbursing the Employer for the value of any employee NICs due on this additional benefit, which the Company or the Employer may recover from you at any time thereafter by any of the means referred to in Section 10 of the Agreement.

Joint Election for Transfer of Liability for Employer National Insurance Contributions. As a condition of participation in the Plan and the vesting of the RSUs, you agree to accept any liability for secondary Class 1 NICs that may be payable by the Company, the Employer or any Affiliate in connection with the RSUs and any event giving rise to Tax-Related Items (the "***Employer NICs***"). Without prejudice to the foregoing, you agree to execute a joint election with the Company, the form of such joint election (the "Joint Election") having been approved formally by HMRC, and any other required consent or election prior to vesting of the RSUs. You further agree to execute such other joint elections as may be required between you and any successor to the Company, the Employer or any Affiliate. You further agree that the Company, the Employer or any Affiliate may collect the Employer NICs from you by any of the means set forth in Section 10 of the Agreement.

If you do not enter into a Joint Election prior to the vesting of the RSUs, you will not be entitled to vest in the RSUs without any liability to the Company, the Employer or any Affiliate.

JAZZ PHARMACEUTICALS PLC

2011 EQUITY INCENTIVE PLAN

ELECTION TO TRANSFER THE EMPLOYER'S SECONDARY CLASS 1 NATIONAL INSURANCE LIABILITY TO THE EMPLOYEE

This Election is between:

A. The individual who has received this Election (the "**Employee**"), who is employed by one of the employing companies listed in the attached schedule (the "**Employer**") and who is eligible to receive stock options and/or restricted stock units (together, the "**Awards**") pursuant to the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (the "**Plan**"), and

B. Jazz Pharmaceuticals plc, Fourth Floor, Connaught House, 1 Burlington Road, Dublin 4, Ireland (the "**Company**"), which may grant Awards under the Plan and is entering into this Election on behalf of the Employer.

1. Introduction

1.1 This Election relates to all Awards granted to the Employee under the Plan on or after January 18, 2012 up to the termination date of the Plan.

1.2 In this Election the following words and phrases have the following meanings:

(a) "**Chargeable Event**" means, in relation to the Awards:

(i) the acquisition of securities pursuant to the Awards (within section 477(3)(a) of ITEPA);

(ii) the assignment (if applicable) or release of the Awards in return for consideration (within section 477(3)(b) of ITEPA);

(iii) the receipt of a benefit in connection with the Awards, other than a benefit within (i) or (ii) above (within section 477(3)(c) of ITEPA);

(iv) post-acquisition charges relating to the Awards and/or ordinary shares of the Company acquired pursuant to the Awards (within section 427 of ITEPA); and/or

(v) post-acquisition charges relating to the Awards and/or ordinary shares of the Company acquired pursuant to the Awards (within section 439 of ITEPA).

(b) "**ITEPA**" means the Income Tax (Earnings and Pensions) Act 2003.

(c) "**SSCBA**" means the Social Security Contributions and Benefits Act 1992.

1.3 This Election relates to the Employer's secondary Class 1 National Insurance Contributions (the "**Employer's Liability**") which may arise on the occurrence of a Chargeable Event in respect of the Awards pursuant to section 4(4)(a) and/or paragraph 3B(1A) of Schedule 1 of the SSCBA.

1.4 This Election does not apply in relation to any liability, or any part of any liability, arising as a result of regulations being given retrospective effect by virtue of section 4B(2) of either the SSCBA, or the Social Security Contributions and Benefits (Northern Ireland) Act 1992.

1.5 This Election does not apply to the extent that it relates to relevant employment income which is employment income of the earner by virtue of Chapter 3A of Part VII of ITEPA (employment income: securities with artificially depressed market value).

2. The Election

The Employee and the Company jointly elect that the entire liability of the Employer to pay the Employer's Liability on the Chargeable Event is hereby transferred to the Employee. The Employee understands that, by signing the award grant notice, he or she will become personally liable for the Employer's Liability covered by this Election. This Election is made in accordance with paragraph 3B(1) of Schedule 1 of the SSCBA.

3. Payment of the Employer's Liability

3.1 The Employee hereby authorises the Company and/or the Employer to collect the Employer's Liability from the Employee at any time after the Chargeable Event:

(i) by deduction from salary or any other payment payable to the Employee at any time on or after the date of the Chargeable Event; and/or

(ii) directly from the Employee by payment in cash or cleared funds; and/or

(iii) by arranging, on behalf of the Employee, for the sale of some of the securities which the Employee is entitled to receive in respect of the Awards, the proceeds from which must be delivered to the Employer in sufficient time for payment to be made to Her Majesty's Revenue & Customs ("**HMRC**") by the due date; and/or

(iv) where the proceeds of the gain are to be made through a third party, the Employee will authorize that party to withhold an amount from the payment or to sell some of the securities which the Employee is entitled to receive in respect of the Award,

such amount to be paid in sufficient time to enable the Company and/or the Employer to make payment to HMRC by the due date; and/or

(v) by any other means specified in the applicable Award agreement entered into between the Employee and the Company.

3.2 The Company hereby reserves for itself and the Employer the right to withhold the transfer of any securities to the Employee in respect of the Awards until full payment of the Employer's Liability is received.

3.3 The Company agrees to procure the remittance by the Employer of the Employer's Liability to HMRC on behalf of the Employee within 14 days after the end of the UK tax month during which the Chargeable Event occurs (or within 17 days after the end of the UK tax month during which the Chargeable Event occurs if payments are made electronically).

4. Duration of Election

4.1 The Employee and the Company agree to be bound by the terms of this Election regardless of whether the Employee is transferred abroad or is not employed by the Employer on the date on which the Employer's Liability becomes due.

4.2 Any reference to the Company and/or the Employer shall include that entity's successors in title and assigns as permitted in accordance with the terms of the Plan and relevant award agreement. This Election will continue in effect in respect of any awards which replace the Awards in circumstances where section 483 of ITEPA applies.

4.3 This Election will continue in effect until the earliest of the following:

(i) the date on which the Employee and the Company agree in writing that it should cease to have effect;

(ii) the date on which the Company serves written notice on the Employee terminating its effect;

(iii) the date on which HMRC withdraws approval of this Election; or

(iv) the date on which, after due payment of the Employer's Liability in respect of the entirety of the Awards to which this Election relates or could relate, the Election ceases to have effect in accordance with its own terms.

SCHEDULE OF EMPLOYER COMPANIES

The following are employer companies to which this Election may apply:

Employer Company:	Jazz Pharmaceuticals UK Limited
Registered Office:	Wing B, Building 5700 Spires House John Smith Drive - Oxford Business Park South, Oxford OX4 2RW, United Kingdom
Company Registration Number:	4555273
Corporation Tax Reference:	452/76424 00934
Corporation Tax Address:	HM Revenue & Customs CT Operations (Large & Complex Specialist) 16 North Government Buildings Ty Glas, Llanishen Cardiff, CF14 5 FP
PAYE Reference:	120/WZ72892

Attachment II

Jazz Pharmaceuticals plc
2011 Equity Incentive Plan

Exhibit 31.1

CERTIFICATION

I, Bruce C. Cozadd, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Jazz Pharmaceuticals public limited company;

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 (the registrant's fourth fiscal quarter in the case of an annual report) 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 audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: November 9, 2021

By: /s/ Bruce C. Cozadd

Bruce C. Cozadd
Chairman and Chief Executive Officer and Director

Exhibit 31.2

CERTIFICATION

I, Renée Galá, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Jazz Pharmaceuticals public limited company;

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 (the registrant's fourth fiscal quarter in the case of an annual report) 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 audit committee of the registrant's board of directors (or persons performing the equivalent functions):

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

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

Date: November 9, 2021

By: /s/ Renée Galá

Renée Galá
Executive Vice President and Chief Financial Officer

Exhibit 32.1

CERTIFICATION[(1)]

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. Section 1350), Bruce C. Cozadd, Chief Executive Officer of Jazz Pharmaceuticals public limited company (the "Company"), and Renée Galá, Executive Vice President and Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Quarterly Report on Form 10-Q for the period ended September 30, 2021, to which this Certification is attached as Exhibit 32.1 (the "Periodic Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

Date: November 9, 2021

/s/ Bruce C. Cozadd

Bruce C. Cozadd
Chairman and Chief Executive Officer and Director

/s/ Renée Galá

Renée Galá
Executive Vice President and Chief Financial Officer

(1) This certification accompanies the Quarterly Report on Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Jazz Pharmaceuticals public limited company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing. A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to Jazz Pharmaceuticals public limited company and will be retained by Jazz Pharmaceuticals public limited company and furnished to the Securities and Exchange Commission or its staff upon request.