

**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 March 31, 2023

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
(State or other jurisdiction of
incorporation or organization)

98-1032470
(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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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

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

As of May 3, 2023, 64,004,791 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 MARCH 31, 2023

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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 and other countries outside the U.S. for Epidiolex), 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[®] (asparaginase erwinia chrysanthemi (recombinant)-rywn) and Sativex[®] (nabiximols) oral solution. This Quarterly Report on Form 10-Q 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)

	March 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 1,167,911	\$ 881,482
Accounts receivable, net of allowances	623,938	651,493
Inventories	674,778	714,061
Prepaid expenses	72,779	91,912
Other current assets	245,244	267,192
Total current assets	2,784,650	2,606,140
Property, plant and equipment, net	227,552	228,050
Operating lease assets	75,538	73,326
Intangible assets, net	5,764,209	5,794,437
Goodwill	1,723,444	1,692,662
Deferred tax assets, net	399,097	376,247
Deferred financing costs	8,559	9,254
Other non-current assets	64,076	55,139
Total assets	\$ 11,047,125	\$ 10,835,255
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 125,454	\$ 90,758
Accrued liabilities	712,349	803,255
Current portion of long-term debt	31,000	31,000
Income taxes payable	40,095	7,717
Deferred revenue	4	463
Total current liabilities	908,902	933,193
Long-term debt, less current portion	5,689,662	5,693,341
Operating lease liabilities, less current portion	72,095	71,838
Deferred tax liabilities, net	932,247	944,337
Other non-current liabilities	109,178	106,812
Commitments and contingencies (Note 9)		
Shareholders' equity:		
Ordinary shares	6	6
Non-voting euro deferred shares	55	55
Capital redemption reserve	472	472
Additional paid-in capital	3,511,732	3,477,124
Accumulated other comprehensive loss	(980,230)	(1,125,509)
Retained earnings	803,006	733,586
Total shareholders' equity	3,335,041	3,085,734
Total liabilities and shareholders' equity	\$ 11,047,125	\$ 10,835,255

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

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

	Three Months Ended March 31,	
	2023	2022
Revenues:		
Product sales, net	\$ 884,219	\$ 809,837
Royalties and contract revenues	8,593	3,884
Total revenues	892,812	813,721
Operating expenses:		
Cost of product sales (excluding amortization of acquired developed technologies)	128,644	115,284
Selling, general and administrative	297,917	308,813
Research and development	189,410	129,981
Intangible asset amortization	149,786	172,094
Acquired in-process research and development	1,000	—
Total operating expenses	766,757	726,172
Income from operations	126,055	87,549
Interest expense, net	(74,147)	(70,684)
Foreign exchange gain (loss)	3,193	(10,540)
Income before income tax expense (benefit) and equity in loss of investees	55,101	6,325
Income tax expense (benefit)	(15,324)	536
Equity in loss of investees	1,005	4,142
Net income	\$ 69,420	\$ 1,647
Net income per ordinary share:		
Basic	\$ 1.09	\$ 0.03
Diluted	\$ 1.04	\$ 0.03
Weighted-average ordinary shares used in per share calculations - basic	63,494	61,865
Weighted-average ordinary shares used in per share calculations - diluted	73,771	62,907

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 March 31,	
	2023	2022
Net income	\$ 69,420	\$ 1,647
Other comprehensive income (loss):		
Foreign currency translation adjustments	145,279	(190,488)
Loss on fair value hedging activities reclassified from accumulated other comprehensive income (loss) to foreign exchange gain (loss), net of income tax benefit of \$— and \$43, respectively	—	128
Other comprehensive income (loss)	145,279	(190,360)
Total comprehensive income (loss)	\$ 214,699	\$ (188,713)

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, 2022	63,214	\$ 6	4,000	\$ 55	\$ 472	\$ 3,477,124	\$ (1,125,509)	\$ 733,586	\$ 3,085,734
Issuance of ordinary shares in conjunction with exercise of share options	188	—	—	—	—	21,228	—	—	21,228
Issuance of ordinary shares in conjunction with vesting of restricted stock units	585	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(43,266)	—	—	(43,266)
Share-based compensation	—	—	—	—	—	56,646	—	—	56,646
Other comprehensive income	—	—	—	—	—	—	145,279	—	145,279
Net income	—	—	—	—	—	—	—	69,420	69,420
Balance at March 31, 2023	<u>63,987</u>	<u>\$ 6</u>	<u>4,000</u>	<u>\$ 55</u>	<u>\$ 472</u>	<u>\$ 3,511,732</u>	<u>\$ (980,230)</u>	<u>\$ 803,006</u>	<u>\$ 3,335,041</u>

	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, 2021	61,633	\$ 6	4,000	\$ 55	\$ 472	\$ 3,534,792	\$ (400,360)	\$ 830,226	\$ 3,965,191
Cumulative effect adjustment from adoption of ASU 2020-06	—	—	—	—	—	(333,524)	—	127,474	(206,050)
Issuance of ordinary shares in conjunction with exercise of share options	207	—	—	—	—	21,729	—	—	21,729
Issuance of ordinary shares in conjunction with vesting of restricted stock units	404	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(33,776)	—	—	(33,776)
Share-based compensation	—	—	—	—	—	50,106	—	—	50,106
Other comprehensive loss	—	—	—	—	—	—	(190,360)	—	(190,360)
Net income	—	—	—	—	—	—	—	1,647	1,647
Balance at March 31, 2022	<u>62,244</u>	<u>\$ 6</u>	<u>4,000</u>	<u>\$ 55</u>	<u>\$ 472</u>	<u>\$ 3,239,327</u>	<u>\$ (590,720)</u>	<u>\$ 959,347</u>	<u>\$ 3,608,487</u>

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)

	Three Months Ended March 31,	
	2023	2022
Operating activities		
Net income	\$ 69,420	\$ 1,647
Adjustments to reconcile net income to net cash provided by operating activities:		
Intangible asset amortization	149,786	172,094
Acquisition accounting inventory fair value step-up adjustment	60,458	63,943
Share-based compensation	56,352	50,070
Other non-cash transactions	16,773	(14,701)
Depreciation	7,574	7,617
Non-cash interest expense	4,766	12,168
Provision for losses on accounts receivable and inventory	2,316	2,170
Acquired in-process research and development	1,000	—
Deferred tax benefit	(66,061)	(45,339)
Changes in assets and liabilities:		
Accounts receivable	28,460	(9,723)
Inventories	(6,266)	(24,812)
Prepaid expenses and other current assets	42,032	23,170
Operating lease assets	4,508	3,095
Other non-current assets	(9,541)	979
Accounts payable	34,286	(27,617)
Accrued liabilities	(96,985)	(23,241)
Income taxes payable	25,413	16,767
Deferred revenue	(459)	(523)
Operating lease liabilities, less current portion	(4,959)	(3,915)
Other non-current liabilities	1,835	5,130
Net cash provided by operating activities	320,708	208,979
Investing activities		
Acquired in-process research and development	(1,000)	—
Purchases of property, plant and equipment	(3,822)	(12,292)
Acquisition of intangible assets	—	(25,000)
Net cash used in investing activities	(4,822)	(37,292)
Financing activities		
Proceeds from employee equity incentive and purchase plans	21,228	21,729
Repayments of long-term debt	(7,750)	(258,764)
Payment of employee withholding taxes related to share-based awards	(43,266)	(33,776)
Net cash used in financing activities	(29,788)	(270,811)
Effect of exchange rates on cash and cash equivalents	331	(1,489)
Net increase (decrease) in cash and cash equivalents	286,429	(100,613)
Cash and cash equivalents, at beginning of period	881,482	591,448
Cash and cash equivalents, at end of period	\$ 1,167,911	\$ 490,835

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 strive to identify 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 approved by the U.S. Food and Drug Administration, or FDA, in July 2020 and launched in the U.S. in November 2020 for the treatment of cataplexy or excessive daytime sleepiness, or EDS, in patients with narcolepsy seven years of age and older, and also approved by FDA in August 2021 for the treatment of idiopathic hypersomnia, or IH, in adults and launched in the U.S. in November 2021. Xywav contains 92% less sodium than Xyrem®;
- **Xyrem (sodium oxybate) oral solution**, a product approved by FDA and distributed in the U.S. for the treatment of cataplexy or EDS in patients with narcolepsy seven years of age and older; Jazz also markets Xyrem in Canada for the treatment of cataplexy in patients with narcolepsy. Xyrem is also approved and distributed in the European Union, or EU (EU market authorizations include Northern Ireland), Great Britain and other markets through a licensing agreement; and
- **Epidiolex® (cannabidiol) oral solution**, a product approved by FDA and launched in the U.S. in 2018 by GW Pharmaceuticals plc, or GW, and currently indicated for the treatment of seizures associated with Lennox-Gastaut syndrome, or LGS, Dravet syndrome, or DS, or tuberous sclerosis complex, or TSC, in patients one year of age or older; in the EU and Great Britain (where it is marketed as Epidyolex®) and other markets, it is approved for adjunctive treatment of seizures associated with LGS or DS, in conjunction with clobazam (EU and Great Britain only), in patients 2 years of age and older and for adjunctive treatment of seizures associated with TSC in patients 2 years of age and older (select markets).

Oncology

- **Rylaze® (asparaginase erwinia chrysanthemi (recombinant)-rywn)**, 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 lymphoblastic lymphoma in adults and pediatric patients aged one month or older who have developed hypersensitivity to *E. coli*-derived asparaginase;
- **Zepzelca® (lurbinectedin)**, a product approved by FDA in June 2020 under FDA's accelerated approval pathway 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 received conditional approval in September 2021 for the treatment of adults with Stage III or metastatic SCLC, who have progressed on or after platinum-containing therapy;
- **Defitelio® (defibrotide sodium)**, a product approved in the U.S. and Brazil for the treatment of hepatic veno-occlusive disease, or VOD, with renal or pulmonary dysfunction following hematopoietic stem cell transplantation, or HSCT, and in Japan for the treatment of hepatic sinusoidal obstruction syndrome (hepatic VOD). It is currently approved in the EU, Great Britain and other markets for the treatment of severe hepatic VOD, also known as sinusoidal obstructive syndrome in HSCT therapy. It is indicated in adults and pediatric patients over 1 month of age; and
- **Vyxeos® (daunorubicin and cytarabine) liposome for injection**, a product approved in the U.S., Canada, EU, Great Britain and other markets (marketed as Vyxeos® liposomal in the EU, Great Britain and other markets) for the treatment of adults with newly diagnosed therapy-related acute myeloid leukemia, or t-AML, or AML with myelodysplasia-related changes, or AML-MRC. An expanded indication was granted in the U.S. for the treatment of newly diagnosed t-AML or AML-MRC in pediatric patients aged 1 year and older.

Throughout this Quarterly Report on Form 10-Q, 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 Quarterly Report on Form 10-Q, 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, 2022.

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 months ended March 31, 2023 are not necessarily indicative of the results to be expected for the year ending December 31, 2023, 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, 2022, 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.

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 October 2021, the Financial Accounting Standards Board issued ASU 2021-08, “Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities from Contracts with Customers”, or ASU 2021-08, which requires entities to recognize and measure contract assets and contract liabilities acquired in a business combination in accordance with ASC 2014-09, “Revenue from Contracts with Customers (Topic 606)”. The update will generally result in an entity recognizing contract assets and contract liabilities at amounts consistent with those recorded by the acquiree immediately before the acquisition date rather than at fair value. ASU 2021-08 was effective for the Company from January 1, 2023 and we will apply to future business combinations, if any.

Significant Risks and Uncertainties

Historically, 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 Xywav and Xyrem, there is no guarantee that we can maintain oxybate sales at or near historical levels, or that oxybate sales will continue to grow. In this regard, our ability to maintain or increase oxybate product sales 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 IH in adults and adoption in that indication; competition from the recent introduction of an authorized generic, or AG, version of Xyrem and in the future from additional AG versions of high-sodium oxybate and generic versions of high-sodium oxybate and new products, such as Avadel’s recently approved Lumryz, for treatment of cataplexy and/or EDS in narcolepsy in the U.S. market and from other competitors; 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 Xyrem; increased rebates required to maintain access to our products; challenges to our intellectual property around Xywav and/or Xyrem, including

from pending antitrust and intellectual property litigation; and continued acceptance of Xywav and Xyrem by physicians and patients. A significant decline in oxybate product 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.

In addition to risks related specifically to Xywav and Xyrem, we are subject to other challenges and risks related to successfully commercializing a portfolio of oncology products and other neuroscience products, 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 approved or acquired products such as Epidiolex, Rylaze and Zepzelca; obtaining and maintaining adequate coverage and reimbursement for our products; contracting and rebates to pharmacy benefit managers and similar organizations that reduce 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, action by the U.S. Drug Enforcement Agency 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 acquisition of GW will depend, in part, on our ability to realize the anticipated benefits from our and GW's historical businesses. The anticipated benefits to us of the GW Acquisition may not be realized at the expected levels, 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.

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 March 31, 2023, we had foreign exchange forward contracts with notional amounts totaling \$183.2 million. As of March 31, 2023, the outstanding foreign exchange forward contracts had a net asset fair value of \$4.3 million. 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 March 31, 2023 and December 31, 2022, allowances on receivables were not material. As of March 31, 2023, three customers accounted for 73% of gross accounts receivable, Express Scripts Specialty Distribution Services, Inc. and its affiliates, or ESSDS, which accounted for 51% of gross accounts receivable, McKesson Corporation and affiliates, or McKesson, which accounted for 12% of gross accounts receivable and Cardinal Health, Inc., or Cardinal, which accounted for 10% of gross accounts receivable. As of December 31, 2022, three customers accounted for 74% of gross accounts receivable, ESSDS, which accounted for 55% of gross accounts receivable, Cardinal, which accounted for 10% of gross accounts receivable and McKesson, which accounted for 9% 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.

2. Cash and Available-for-Sale Securities

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

	March 31, 2023				
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents
Cash	\$ 424,139	\$ —	\$ —	\$ 424,139	\$ 424,139
Time deposits	180,000	—	—	180,000	180,000
Money market funds	563,772	—	—	563,772	563,772
Totals	\$ 1,167,911	\$ —	\$ —	\$ 1,167,911	\$ 1,167,911

	December 31, 2022				
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents
Cash	\$ 334,018	\$ —	\$ —	\$ 334,018	\$ 334,018
Time deposits	30,000	—	—	30,000	30,000
Money market funds	517,464	—	—	517,464	517,464
Totals	\$ 881,482	\$ —	\$ —	\$ 881,482	\$ 881,482

Cash equivalents 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. Interest income from available-for-sale securities was \$10.6 million and \$0.2 million in the three months ended March 31, 2023 and 2022, respectively.

3. Fair Value Measurement

The following table summarizes, by major security type, our available-for-sale securities and derivative contracts as of March 31, 2023 and December 31, 2022 that were measured at fair value on a recurring basis and were categorized using the fair value hierarchy (in thousands):

	March 31, 2023			December 31, 2022		
	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	\$ 563,772	\$ —	\$ 563,772	\$ 517,464	\$ —	\$ 517,464
Time deposits	—	180,000	180,000	—	30,000	30,000
Foreign exchange forward contracts	—	4,906	4,906	—	17,356	17,356
Totals	\$ 563,772	\$ 184,906	\$ 748,678	\$ 517,464	\$ 47,356	\$ 564,820
Liabilities:						
Foreign exchange forward contracts	—	570	570	—	—	—
Totals	\$ —	\$ 570	\$ 570	\$ —	\$ —	\$ —

As of March 31, 2023, 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 are obtained from various third party data providers and 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 foreign exchange derivatives that are measured at fair value using observable market inputs such as forward rates and based on these inputs, the derivative assets and liabilities are classified within Level 2 of the fair value hierarchy.

There were no transfers between the different levels of the fair value hierarchy in 2023 or 2022.

As of March 31, 2023 and December 31, 2022, the carrying amount of investments measured using the measurement alternative for equity investments without a readily determinable fair value was \$5.5 million. The carrying amount, which is recorded within other non-current assets, is based on the latest observable transaction price.

As of March 31, 2023, the estimated fair values of the 1.50% exchangeable senior notes due 2024, or 2024 Notes, the 2.00% exchangeable senior notes due 2026, or 2026 Notes, which we refer to collectively as the Exchangeable Senior Notes, the 4.375% senior secured notes, due 2029, or the Secured Notes, and the seven-year \$3.1 billion term loan B facility, or the Dollar Term Loan, were approximately \$556 million, \$1.1 billion, \$1.4 billion and \$2.7 billion respectively. The fair values of each of these debt facilities was estimated using quoted market prices obtained from brokers (Level 2).

4. 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 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.

We 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 March 31, 2023 and December 31, 2022, the notional amount of foreign exchange contracts where hedge accounting is not applied was \$183.2 million and \$505.0 million, respectively.

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

	Three Months Ended March 31,	
	2023	2022
Foreign Exchange Forward Contracts:		
Gain (loss) recognized in foreign exchange gain (loss)	\$ 4,275	\$ (21,025)

In order to hedge our exposure to foreign currency exchange risk associated with our seven-year €625.0 million term loan B facility, or the Euro Term Loan, we entered into a cross-currency interest rate swap contract in May 2021, which matured on March 31, 2022, and was de-designated as a fair value hedge. The terms of this contract converted the principal repayments and interest payments on the Euro Term Loan into U.S. dollars. The carrying amount of the Euro Term Loan and the fair value of the cross-currency interest rate swap contract were remeasured on a monthly basis, 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.

The impact on accumulated other comprehensive income (loss) and earnings from the cross-currency interest rate swap contract was as follows (in thousands):

	Three Months Ended March 31, 2022
Cross-Currency Interest Rate Contract:	
Loss reclassified from accumulated other comprehensive income (loss) to foreign exchange loss, net of tax	\$ 128
Loss recognized in foreign exchange loss	2,646

The cash flow effects of our derivative contracts for the three months ended March 31, 2023 and 2022 are included within net cash provided by operating activities in the condensed consolidated statements of cash flows, except for the settlement of notional amounts of the cross-currency swap, which were included in net cash used in financing activities.

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

	Classification	March 31, 2023	December 31, 2022
Assets			
Derivatives not designated as hedging instruments:			
Foreign exchange forward contracts	Other current assets	\$ 4,906	\$ 17,356
Liabilities			
Derivatives not designated as hedging instruments:			
Foreign exchange forward contracts	Accrued liabilities	\$ 570	\$ —

Although we do not offset derivative assets and liabilities within our 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. These provisions were not applicable as of December 31, 2022 since all derivatives were in an asset position. The following table summarizes the potential effect on our condensed consolidated balance sheets of offsetting our foreign exchange forward contracts subject to such provisions as of March 31, 2023 (in thousands):

Description	March 31, 2023					
	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	Gross Amounts Not Offset in the Consolidated Balance Sheet		
				Derivative Financial Instruments	Cash Collateral Received (Pledged)	Net Amount
Derivative assets	\$ 4,906	\$ —	\$ 4,906	\$ (570)	\$ —	\$ 4,336
Derivative liabilities	(570)	—	(570)	570	—	—

5. Inventories

Inventories consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Raw materials	\$ 25,797	\$ 20,786
Work in process	510,634	517,670
Finished goods	138,347	175,605
Total inventories	\$ 674,778	\$ 714,061

As of March 31, 2023 and December 31, 2022 inventories included \$409.1 million and \$457.6 million, respectively, related to the purchase accounting inventory fair value step-up on inventory acquired in the GW Acquisition.

6. Goodwill and Intangible Assets

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

Balance at December 31, 2022	\$ 1,692,662
Foreign exchange	30,782
Balance at March 31, 2023	\$ 1,723,444

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

	March 31, 2023			December 31, 2022			
	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	10.2	\$ 7,639,267	\$ (1,875,058)	\$ 5,764,209	\$ 7,491,994	\$ (1,697,557)	\$ 5,794,437
Manufacturing contracts	—	11,641	(11,641)	—	11,417	(11,417)	—
Trademarks	—	2,881	(2,881)	—	2,876	(2,876)	—
Total finite-lived intangible assets		<u>\$ 7,653,789</u>	<u>\$ (1,889,580)</u>	<u>\$ 5,764,209</u>	<u>\$ 7,506,287</u>	<u>\$ (1,711,850)</u>	<u>\$ 5,794,437</u>

The increase in the gross carrying amount of intangible assets as of March 31, 2023 compared to December 31, 2022 primarily reflects the positive impact of foreign currency translation adjustments due to the strengthening 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 March 31, 2023, 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
2023 (remainder)	\$ 455,456
2024	607,275
2025	607,275
2026	607,275
2027	607,275
Thereafter	2,879,653
Total	<u>\$ 5,764,209</u>

7. Certain Balance Sheet Items

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

	March 31, 2023	December 31, 2022
Manufacturing equipment and machinery	\$ 75,541	\$ 73,580
Land and buildings	69,513	68,935
Construction-in-progress	69,196	67,385
Leasehold improvements	66,228	64,776
Computer software	35,561	34,116
Computer equipment	17,127	16,424
Furniture and fixtures	10,526	10,481
Subtotal	343,692	335,697
Less accumulated depreciation and amortization	(116,140)	(107,647)
Property, plant and equipment, net	<u>\$ 227,552</u>	<u>\$ 228,050</u>

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

	March 31, 2023	December 31, 2022
Deferred charge for income taxes on intercompany profit	\$ 188,028	\$ 176,057
Other	57,216	91,135
Total other current assets	\$ 245,244	\$ 267,192

Accrued liabilities consisted of the following (in thousands):

	March 31, 2023	December 31, 2022
Rebates and other sales deductions	\$ 318,048	\$ 313,176
Employee compensation and benefits	104,914	143,243
Accrued collaboration expenses	39,806	33,205
Accrued facilities expenses	30,158	25,864
Sales return reserve	28,868	26,164
Consulting and professional services	23,406	22,278
Clinical trial accruals	22,182	31,338
Accrued interest	21,481	35,614
Accrued royalties	19,439	57,347
Current portion of lease liabilities	17,232	15,938
Selling and marketing accruals	12,635	18,553
Inventory-related accruals	12,631	8,565
Accrued construction-in-progress	3,327	3,298
Derivative instrument liabilities	570	—
Other	57,652	68,672
Total accrued liabilities	\$ 712,349	\$ 803,255

8. Debt

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

	March 31, 2023	December 31, 2022
2024 Notes	\$ 575,000	\$ 575,000
Unamortized - debt issuance costs	(2,353)	(2,738)
2024 Notes, net	572,647	572,262
2026 Notes	1,000,000	1,000,000
Unamortized - debt issuance costs	(8,391)	(8,932)
2026 Notes, net	991,609	991,068
Secured Notes	1,477,509	1,476,938
Term Loan	2,678,897	2,684,073
Total debt	5,720,662	5,724,341
Less current portion	31,000	31,000
Total long-term debt	\$ 5,689,662	\$ 5,693,341

Exchangeable Senior Notes

The Exchangeable Senior Notes were issued by Jazz Investments I Limited, or the Issuer, a 100%-owned finance subsidiary of Jazz Pharmaceuticals plc. The Exchangeable Senior Notes are senior unsecured obligations of the Issuer and are fully and unconditionally guaranteed on a senior unsecured basis by Jazz Pharmaceuticals plc. No subsidiary of Jazz Pharmaceuticals plc 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 Jazz Pharmaceuticals plc to obtain funds from the Issuer or Jazz Pharmaceuticals plc's other subsidiaries by dividend or loan, or any legal or economic restrictions on the ability of the Issuer or Jazz Pharmaceuticals plc's other subsidiaries to transfer funds to Jazz Pharmaceuticals plc in the form of cash dividends, loans or advances. There is no assurance that in the future such restrictions will not be adopted.

The total liability of the 2026 Notes is reflected net of issuance costs of \$15.3 million which will be amortized over the term of the 2026 Notes. The effective interest rate of the 2026 Notes is 2.26%. During the three months ended March 31, 2023 and 2022, we recognized interest expense of \$5.5 million, of which \$5.0 million related to the contractual coupon rate and \$0.5 million related to the amortization of debt issuance costs.

The total liability of the 2024 Notes is reflected net of issuance costs of \$11.4 million which will be amortized over the term of the 2024 Notes. The effective interest rate of the 2024 Notes is 1.79%. During the three months ended March 31, 2023 and 2022, we recognized interest expense of \$2.5 million, of which \$2.1 million related to the contractual coupon rate and \$0.4 million related to the amortization of debt issuance costs.

Maturities

Scheduled maturities with respect to our long-term debt principal balances outstanding as of March 31, 2023 were as follows (in thousands):

Year Ending December 31,	Scheduled Long-Term Debt Maturities
2023 (remainder)	\$ 23,250
2024	606,000
2025	31,000
2026	1,031,000
2027	31,000
Thereafter	4,098,500
Total	\$ 5,820,750

9. 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 March 31, 2023 and December 31, 2022. 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.

Legal Proceedings

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

Xyrem Class Action

From June 2020 to May 2022, a number of 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, 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 referred to as 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.

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.

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.

On February 17, 2022, Health Care Service Corporation 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.

On May 9, 2022, Aetna Inc., or Aetna, filed a lawsuit in the Superior Court of California for the County of Alameda 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. On December 27, 2022, the Court granted in part and denied in part our motion to dismiss Aetna's complaint. As a result of that ruling, the generic defendants have been dismissed from the case, and certain of Aetna's claims against Jazz have been dismissed. On January 27, 2023, Aetna filed an amended complaint against Jazz. On March 22, 2023, we filed motions to dismiss and to strike portions of the amended complaint. The court has not yet issued a final ruling on these motions.

On April 19, 2023, the Court held a hearing on class certification in the consolidated multi-district litigation referenced above, but has not issued a ruling. A trial date will be set following a ruling on class certification.

On January 13, 2023, Amneal Pharmaceuticals LLC, Lupin Ltd., Lupin Pharmaceuticals, Inc., and Lupin Inc, notified the court that they had reached a settlement-in-principle with the class action plaintiffs. On April 19, 2023, the court held a hearing on a motion for preliminary approval of this proposed settlement, but has not issued a ruling.

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 of New York by James Farrell (hereinafter referred to as the Farrell Lawsuit) and an additional suit was filed in New York state court by Brian Levy (hereinafter referred to as the Levy Lawsuit). In addition to Jazz Pharmaceuticals plc, Jazz Pharmaceuticals U.K. 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 (hereinafter 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.

On June 3, 2022, we filed a motion to dismiss the Ziegler Lawsuit. While the motion to dismiss was pending, in December 2022, the parties participated in a mediation and reached a tentative settlement, which remains subject to court approval. On March 20, 2023, the plaintiffs in the Ziegler Lawsuit filed a motion for preliminary approval of the settlement. The court has not yet issued a decision.

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 Lumryz 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 will not infringe our patents. Avadel filed a motion for partial judgment on the pleadings on its counterclaim that one of our patents should be delisted from the Orange Book. On November 18, 2022, the Court issued an order that we delist the patent from the Orange Book. On November 22, 2022, we filed a notice of appeal to the United States Court of Appeals for the Federal Circuit. The Federal Circuit temporarily stayed the district court's delisting order. On February 24, 2023, the Federal Circuit affirmed the district court's delisting order, lifted the temporary stay, and gave Jazz 14 days to request that FDA delist the patent from the Orange Book. Jazz complied with the Federal Circuit's order and requested delisting on February 28, 2023. On March 3, 2023, we and Avadel stipulated to the dismissal without prejudice of the claims and counterclaims related to infringement and validity of the delisted patent in both this suit and a later-filed suit described below related to the same patent.

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 Lumryz 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 will not infringe our patents.

On November 10, 2021, we filed an additional patent infringement suit against Avadel in the United States District Court for the District of Delaware. The third suit alleges that Avadel's Lumryz 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 will not infringe our patents.

On April 14, 2022, Avadel sued us in the United States District Court for the District of Delaware. Avadel's new suit alleges that we misappropriated trade secrets related to Avadel's once-nightly sodium oxybate development program and breached certain contracts between the parties. Avadel seeks monetary damages, an injunction preventing us from using Avadel's confidential information, and an order directing the United States Patent and Trademark Office to modify the inventorship of one of our oxybate patents. On July 8, 2022, we filed a motion for judgment on the pleadings. On February 2, 2023, the Court held a hearing on our motion. The Court has not yet ruled on the motion.

On June 7, 2022, we received notice from Avadel that it had filed a "paragraph IV certification" regarding one patent listed in the Orange Book for Xyrem. 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. On July 15, 2022, we filed an additional lawsuit against Avadel asserting infringement of that patent. The suit alleges that the filing of Avadel's application for approval of FT218 is an act of infringement, and that Avadel's product

would infringe the patent if launched. The suit seeks an injunction to prevent Avadel from launching a product that would infringe the patent, and an award of damages if Avadel does launch an infringing product. Avadel filed an answer to the complaint and counterclaims asserting that the patent is invalid, that its product would not infringe, and that by listing the patent in the Orange Book, we engaged in unlawful monopolization in violation of the Sherman Act. On December 9, 2022, we filed a motion to dismiss Avadel's counterclaims. The Court has not yet ruled on the motion. As noted above, on March 3, 2023, we and Avadel stipulated to the dismissal without prejudice of the claims and counterclaims related to infringement and validity of the delisted patent.

On July 21, 2022, Avadel filed a lawsuit against FDA in the United States District Court for the District of Columbia, challenging FDA's determination that Avadel was required to file a paragraph IV certification regarding one of our Orange Book listed patents. Avadel filed a motion for preliminary injunction, or in the alternative, summary judgment, seeking relief including a declaration that FDA's decision requiring patent certification was unlawful, an order setting aside that decision, an injunction prohibiting FDA from requiring such certification as a precondition to approval of its application for FT218, and an order requiring FDA to take final action on Avadel's application for approval of FT218 within 14 days of the Court's ruling. On July 27, 2022, we filed a motion to intervene in that case, which the Court granted. The Court held a hearing on the parties' respective motions for summary judgment on October 7, 2022. On November 3, 2022, the Court granted our and FDA's motions for summary judgment and denied Avadel's motion.

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. In July 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 term of the '632 patent. In November 2021, the Court issued a claim construction order. On February 23, 2022, the parties filed a Joint Motion and Stipulation to Enter Final Judgment in favor of GW. On February 25, 2022, the Court granted the parties' motion and entered final judgment in favor of GW. Pursuant to the stipulation, Canopy filed a notice of appeal of the Court's ruling on the disputed term in March 2022.

The United States Court of Appeals for the Federal Circuit held oral argument on Canopy's appeal on April 3, 2023. On April 24, 2023, the Federal Circuit affirmed the district court's entry of judgment in favor of GW, finding that the extraction process used in the manufacture of Epidiolex does not infringe Canopy's patent.

Xywav 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.

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.

In April 2022, we received notice from Lupin that it had filed a paragraph IV certification regarding a newly-issued patent listed in the Orange Book for Xywav. On May 11, 2022, we filed an additional lawsuit against Lupin in the United States District Court for the District of New Jersey alleging that by filing its ANDA, Lupin infringed the newly-issued patent related to a method of treatment when Xywav is administered concomitantly with certain other medications. The suit seeks a permanent injunction to prevent Lupin from introducing a generic version of Xywav that would infringe our patent. On June 22, 2022, the court consolidated the two lawsuits we filed against Lupin. No trial date has been set in the consolidated case.

In November 2022, we received notice from Lupin that it had filed a paragraph IV certification regarding a newly-issued patent listed in the Orange Book for Xywav. On January 19, 2023, we filed an additional lawsuit against Lupin in the United States District Court for the District of New Jersey alleging that by filing its ANDA, Lupin infringed the newly-issued patent referenced in its November 2022 paragraph IV certification, as well as another patent that issued in January 2023. The suit seeks a permanent injunction to prevent Lupin from introducing a generic version of Xywav that would infringe the two patents

in suit. On February 15, 2023, the court consolidated the new lawsuit with the two suits we previously filed against Lupin. No trial date has been set in the consolidated case.

In February 2023, we received notice from Teva Pharmaceuticals, Inc., or Teva, that it had filed with FDA an ANDA for a generic version of Xywav. The notice from Teva included a paragraph IV certification with respect to thirteen of our patents listed in FDA's Orange Book for Xywav on the date of the 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.

In March 2023, we filed a patent infringement suit against Teva in the United States District Court for the District of New Jersey. The complaint alleges that by filing its ANDA, Teva has infringed thirteen of our Orange Book listed patents. We are seeking a permanent injunction to prevent Teva 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 Teva's ANDA.

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.

In December 2021, GW filed an application contesting the jurisdiction of the Patents Court. On May 3, 2022, the Patents Court denied GW's application. GW has filed papers with the Court of Appeal seeking leave to challenge the Patents Court's decision. The Court of Appeal held a hearing on GW's appeal on October 12, 2022. On November 8, 2022, the Court of Appeal ruled against GW on the jurisdictional challenge, so the case will continue in the Patents Court.

In January 2022, we filed a lawsuit against Otsuka in the Supreme Court of the State of New York, County of New York, seeking a declaration that Otsuka is not entitled to any royalties on sales of Epidiolex under the Research Collaboration and License Agreement.

In February 2023, we reached an agreement with Otsuka to settle all outstanding litigation and disputes between the parties related to Epidiolex royalties. Pursuant to that agreement, Otsuka will assign to GW its rights in certain jointly-owned intellectual property, and GW will pay Otsuka royalties on net sales of Epidiolex from product launch through 2032 and, potentially, on certain future cannabidiol products.

Epidiolex Patent Litigation

In November and December 2022, we received notices from Teva Pharmaceuticals, Inc.; Padagis US LLC; Apotex Inc.; API Pharma Tech LLC and InvaGen Pharmaceuticals, Inc.; Lupin Limited; Taro Pharmaceutical Industries Ltd.; Zenara Pharma Private Limited and Biophore Pharma, Inc.; MSN Laboratories Pvt. Ltd. and MSN Pharmaceuticals, Inc.; Alkem Laboratories Ltd.; and Ascent Pharmaceuticals, Inc. (hereinafter referred to as the "Epidiolex ANDA Filers"), that they have each filed with FDA an ANDA for a generic version of Epidiolex (cannabidiol) oral solution. As of the date of this filing, we are not aware of other ANDA filers. The notices from the Epidiolex ANDA Filers each included a "paragraph IV certification" with respect to certain of our patents listed in FDA's Orange Book for Epidiolex on the date of the receipt of the notice. The listed patents relate generally to the composition and method of use of Epidiolex, and methods of treatment using Epidiolex. 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.

On January 3, 2023, we filed a patent infringement suit against the Epidiolex ANDA Filers in the United States District Court for the District of New Jersey. The complaint alleges that by filing their ANDAs, the Epidiolex ANDA Filers have infringed certain of our Orange Book listed patents, and seeks an order that the effective date of FDA approval of the ANDAs shall be a date no earlier than the expiration of the last to expire of the asserted 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 the Epidiolex ANDA Filers' ANDAs.

From March 2023 through May 2023, we received the Epidiolex ANDA Filers' answers to the complaint. The answers include defenses and counterclaims asserting that the Epidiolex ANDA Filers' products, if launched would not infringe our patents, that our patents are invalid, and in one instance, counterclaims related to allegations of inequitable conduct and improper listing of patents in the Orange Book.

The Court in the Epidiolex Patent Litigation set an initial scheduling conference for June 5, 2023. No other case schedule has been set.

Epidiolex also has Orphan Drug Exclusivity for the treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older through September 28, 2025, and for the treatment of seizures associated

with Lennox-Gastaut syndrome or Dravet syndrome in patients between 1 and 2 years of age and for the treatment of seizures associated with tuberous sclerosis complex through July 31, 2027.

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

MSP Litigation

On April 3, 2023, MSP Recovery Claims, Series LLC, or MSP, filed a class action lawsuit on behalf itself and others similarly situated against Jazz Pharmaceuticals plc, Jazz Pharmaceuticals, Inc., and Jazz Pharmaceuticals Ireland Limited, (collectively, the Company Defendants), Express Scripts, Inc., Express Scripts Holding Company, Express Scripts Specialty Distribution Services, Inc., Curascript, Inc. d/b/a Curascript, S.D., Priority Healthcare Distribution, Inc. d/b/a Curascript SD and Curascript Specialty Distribution SD, Caring Voice Coalition, and Adira Foundation (collectively with the Company Defendants, referred to as the Defendants) in the United States District Court for the Northern District of California. The MSP complaint alleges that the Defendants conspired to increase the price and quantity dispensed of Xyrem and Prialt, in violation of the Racketeer Influenced and Corrupt Organizations Act and several state laws. The allegations relate generally to the conduct at issue in the investigation conducted by the United States Department of Justice from 2016-2019, involving the Company's contributions to certain charitable foundations. MSP seeks monetary damages, restitution, disgorgement, and a declaration that the conduct alleged is unlawful.

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.

10. Shareholders' Equity

Accumulated Other Comprehensive Loss

The components of accumulated other comprehensive loss as of March 31, 2023 and December 31, 2022 were as follows (in thousands):

	Foreign Currency Translation Adjustments	Total Accumulated Other Comprehensive Loss
Balance at December 31, 2022	\$ (1,125,509)	\$ (1,125,509)
Other comprehensive income before reclassifications	145,279	145,279
Balance at March 31, 2023	<u>\$ (980,230)</u>	<u>\$ (980,230)</u>

During the three months ended March 31, 2023, other comprehensive income reflects foreign currency translation adjustments, primarily due to the strengthening of the sterling and the euro against the U.S. dollar.

11. Net Income per Ordinary Share

Basic net income per ordinary share is based on the weighted-average number of ordinary shares outstanding. Diluted net income 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 per ordinary share were computed as follows (in thousands, except per share amounts):

	Three Months Ended March 31,	
	2023	2022
Numerator:		
Net income	\$ 69,420	\$ 1,647
Effect of interest on assumed conversions of Exchangeable Senior Notes, net of tax	6,963	—
Net income for dilutive net income per ordinary share	<u>\$ 76,383</u>	<u>\$ 1,647</u>
Denominator:		
Weighted-average ordinary shares used in per share calculations - basic	63,494	61,865
Dilutive effect of Exchangeable Senior Notes	9,044	—
Dilutive effect of employee equity incentive and purchase plans	1,233	1,042
Weighted-average ordinary shares used in per share calculations - diluted	<u>73,771</u>	<u>62,907</u>
Net income per ordinary share:		
Basic	<u>\$ 1.09</u>	<u>\$ 0.03</u>
Diluted	<u>\$ 1.04</u>	<u>\$ 0.03</u>

Potentially dilutive ordinary shares from our employee equity incentive and purchase plans 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 Performance-based restricted stock units, or PRSUs, and the assumed issuance of ordinary shares under our employee stock purchase plan, or ESPP. Potentially dilutive ordinary shares from the Exchangeable Senior Notes are determined by applying the if-converted method to the assumed issuance of ordinary shares upon exchange of the Exchangeable Senior Notes. The potential issue of ordinary shares upon exchange of the Exchangeable Senior Notes was anti-dilutive and had no impact on diluted net income per ordinary share for the three months ended March 31, 2022.

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

	Three Months Ended March 31,	
	2023	2022
Employee equity incentive and purchase plans	1,072	2,509
Exchangeable Senior Notes	—	9,044

12. Revenues

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

	Three Months Ended March 31,	
	2023	2022
Xywav	\$ 277,761	\$ 186,080
Xyrem	178,130	247,497
Total Oxybate	455,891	433,577
Epidiolex/Epidyolex	188,909	157,893
Sativex	7,098	4,742
Sunosi ¹	—	15,878
Total Neuroscience	651,898	612,090
Rylaze	85,927	54,220
Zepzelca	67,181	59,338
Defitelio/defibrotide	39,079	49,489
Vyxeos	36,700	33,757
Total Oncology	228,887	196,804
Other	3,434	943
Product sales, net	884,219	809,837
High-sodium oxybate AG royalty revenue	2,096	—
Other royalty and contract revenues	6,497	3,884
Total revenues	\$ 892,812	\$ 813,721

(1) Divestiture of Sunosi U.S. was completed in May 2022.

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

	Three Months Ended March 31,	
	2023	2022
United States	\$ 810,116	\$ 740,583
Europe	65,900	61,028
All other	16,796	12,110
Total revenues	\$ 892,812	\$ 813,721

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 March 31,	
	2023	2022
ESSDS	51 %	55 %
McKesson	12 %	12 %
Cardinal	10 %	9 %

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.

13. 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 March 31,	
	2023	2022
Selling, general and administrative	\$ 37,402	\$ 34,785
Research and development	15,492	12,436
Cost of product sales	3,458	2,849
Total share-based compensation expense, pre-tax	56,352	50,070
Income tax benefit from share-based compensation expense	(8,556)	(8,894)
Total share-based compensation expense, net of tax	<u>\$ 47,796</u>	<u>\$ 41,176</u>

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 March 31,	
	2023	2022
RSUs granted (in thousands)	1,571	1,888
Grant date fair value	\$ 146.20	\$ 152.38

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

The Compensation & Management Development Committee of our board of directors, and in the case of our Chief Executive Officer, the independent members 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, December 31, 2024, and December 31, 2025, respectively. 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 total shareholder return, or 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:

	Three Months Ended March 31,	
	2023	2022
PRSUs granted (in thousands)	252	281
Grant date fair value	\$ 158.13	\$ 179.19

As the PRSUs granted in each year 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 recognized expense based on the probable number of awards that will ultimately vest.

As of March 31, 2023, compensation cost not yet recognized related to unvested RSUs, PRSUs, share options and ESPP was \$424.8 million, \$67.4 million, \$6.7 million and \$4.5 million, respectively, which is expected to be recognized over a weighted-average period of 3.0 years, 1.9 years, 1.1 years and 0.9 year, respectively.

14. Income Taxes

Our income tax benefit was \$15.3 million for the three months ended March 31, 2023, compared to an income tax expense of \$0.5 million for the same period in 2022, relating to tax arising on income or losses in Ireland, the U.K., the U.S. and certain other foreign jurisdictions, offset by deductions on subsidiary equity, foreign derived intangible income, or FDII, and patent box benefits. The increase in the income tax benefit resulted primarily from the mix of pre-tax income and losses incurred across tax jurisdictions and increases in our FDII and patent box benefits.

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 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. We file income tax returns in multiple tax jurisdictions, the most significant of which are Ireland, the U.K. and the U.S. (both at the federal level and in various state jurisdictions). For Ireland, we are no longer subject to income tax examinations by taxing authorities for the years prior to 2018. For the U.K., we are no longer subject to income tax examinations 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 2018 and earlier may still be adjusted upon examination by the taxing authorities. Certain of our Luxembourg subsidiaries are currently under examination by the Luxembourg taxing authorities for the years ended December 31, 2017, 2018 and 2019. In October 2022 and in January 2023, we received tax assessment notices from the Luxembourg taxing authorities for all years under examination relating to certain transfer pricing and other adjustments. The notices propose additional Luxembourg income tax of approximately \$24.4 million, translated at the foreign exchange rate as March 31, 2023. We disagree with the proposed assessments and are contesting them vigorously.

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 I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022, as supplemented by the risks and uncertainties described in "Risk Factors" Item 1A, Risk Factors in Part II of 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 strive to identify new options for patients by actively exploring small molecules and biologics, and through innovative delivery technologies and cannabinoid science.

Our strategy for growth is rooted in executing commercial launches and ongoing commercialization initiatives, advancing robust research and development, or 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. We focus on patient populations with high unmet needs. We identify and develop differentiated therapies for these patients that we expect will be long-lived assets and that we can support with an efficient commercialization model. In addition, we leverage our efficient, scalable operating model and integrated capabilities across our global infrastructure to effectively reach patients around the world.

In January 2022, we announced our Vision 2025, which aims to deliver sustainable growth and enhanced value, driving our continued transformation to an innovative, high-growth global pharmaceutical leader. The three core components of our Vision 2025 focus on commercial execution, pipeline productivity and operational excellence.

Our strategy to deliver sustainable growth and enhanced value is focused on:

- Strong commercial execution to drive diversified revenue growth and address unmet medical needs of our patients across our product portfolio, which focuses on neuroscience and oncology medicines;
- Expanding and advancing our pipeline to achieve a valuable product portfolio of durable, highly differentiated programs;
- Continuing to build a flexible, efficient and productive development engine for targeted therapeutic areas to identify and progress early-, mid- and late-stage assets;
- Identifying and acquiring novel product candidates and approved therapies to complement our existing pipeline and commercial portfolio;
- Investing in an efficient, scalable operating model and differentiated capabilities to enable growth; and
- Unlocking further value through indication expansion and entry into global markets.

In 2023, consistent with our strategy, we are continuing to focus on research and development activities within our neuroscience and oncology therapeutic areas.

Our lead marketed products, listed below, 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.
	Treatment of cataplexy in patients with narcolepsy.	August 2005	Canada
	Treatment of narcolepsy with cataplexy in adult patients, adolescents and children from age of 7 years.	October 2005	European Union, or EU, Great Britain, other markets (through licensing agreement)
Epidiolex® (cannabidiol)	Treatment of seizures associated with Lennox-Gastaut syndrome, or LGS, Dravet syndrome, or DS, or tuberous sclerosis complex, or TSC, in patients 1 year of age and older.	June 2018	U.S.
Epidyolex® (cannabidiol)	For adjunctive therapy of seizures associated with LGS or DS, in conjunction with clobazam, for patients 2 years of age and older.*	September 2019	EU, Great Britain, Israel, Switzerland, Australia and New Zealand
	For adjunctive therapy of seizures associated with TSC for patients 2 years of age and older.	April 2021	EU, Great Britain, Israel and Switzerland
ONCOLOGY			
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.
	A component of a multi-agent chemotherapeutic regimen for the treatment of ALL and LBL, in adults and pediatric patients 1 year or older who have developed hypersensitivity to E. coli-derived asparaginase.	September 2022	Canada

Product	Indications	Initial Approval Date	Markets
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 PharmaMar)**
	Treatment of adults with Stage III or metastatic SCLC who have progressed on or after platinum-containing therapy.	September 2021	Canada (licensed from PharmaMar)***
Defitelio® (defibrotide)	Treatment of severe hepatic veno-occlusive disease, or VOD, also known as sinusoidal obstruction syndrome, or SOS, following hematopoietic stem cell transplantation, or HSCT, therapy.	October 2013	EU, Great Britain, Switzerland, Israel, Australia, South Korea, Saudi Arabia
Defitelio® (defibrotide sodium)	Treatment of adult and pediatric patients with hepatic VOD, also known as SOS, with renal or pulmonary dysfunction following HSCT.	March 2016	U.S., Brazil
Defitelio® (defibrotide sodium)	Treatment of severe hepatic VOD, also known as SOS, following HSCT therapy.	July 2017	Canada
Defitelio® (defibrotide)	Treatment of hepatic sinusoidal obstruction syndrome (hepatic VOD).	June 2019	Japan
Vyxeos® (daunorubicin and cytarabine) liposome for injection	Treatment of newly-diagnosed therapy-related acute myeloid leukemia, or t-AML 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, Great Britain, Switzerland, Israel, Australia, South Korea
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

*The clobazam restriction limited to EU and Great Britain

**Accelerated approval received from U.S. Food and Drug Administration, or FDA

***Conditional approval received from Health Canada

Neuroscience

We are the global leader in the development and commercialization of oxybate therapy for patients with sleep disorders. Xyrem was approved by FDA in 2002 for treating EDS and cataplexy in narcolepsy. In 2020, we received 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. Xywav has become a standard of care for patients with narcolepsy and IH.

Since there is no cure for narcolepsy and long-term disease management is needed, we believe that Xywav represents an important 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 intake, and how the use of Xywav enables them to address what is a modifiable risk factor.

We view the adoption of Xywav in narcolepsy as a positive indication that physicians and patients appreciate the benefits of a low-sodium oxybate option. We continue to see Xywav adoption among existing Xyrem patients, as well as the majority of new-to-oxybate narcolepsy patients.

In June 2021, FDA recognized seven years of Orphan Drug Exclusivity, or ODE, for Xywav in narcolepsy, which extends through July 2027. Lumryz, a fixed-dose, high-sodium oxybate, was approved by FDA on May 1, 2023, for treatment of cataplexy or EDS in adults with narcolepsy. FDA continues to recognize seven years of ODE for Xywav in narcolepsy. In connection with granting ODE for Xywav, 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." FDA has also recognized that the difference in sodium content between Xywav and Lumryz is likely to be clinically meaningful in all patients with narcolepsy and that Xywav is safer than Lumryz in all such patients. Lumryz has the same sodium content as Xyrem. Xywav is the only approved oxybate therapy that does not carry a warning and precaution related to high sodium intake.

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. In January 2022, FDA recognized seven years of ODE for Xywav in IH that extends through August 2028. 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.

We have agreements in place for Xywav with all three major pharmacy benefit managers, or PBMs, in the U.S. To date, we have entered into agreements with various entities and have achieved benefit coverage for Xywav in both narcolepsy and IH indications for approximately 90% of commercial lives.

We have seen strong adoption of Xywav in narcolepsy since its launch in November 2020, and increasing adoption in IH since its launch in November 2021. Exiting the first quarter of 2023, there were approximately 11,050 patients taking Xywav, including approximately 9,050 patients with narcolepsy and approximately 2,000 patients with IH. With respect to Xywav and Xyrem in the aggregate, the average number of active Jazz oxybate patients on therapy was approximately 17,400 in the first quarter of 2023.

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 expanded 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 use as adjunctive therapy of seizures associated with LGS or DS, in conjunction with clobazam, for patients two years of age and older. Epidyolex is now launched in all five key European markets: United Kingdom, Germany, Italy, Spain and France. The clobazam restriction is limited to the EU, and Great Britain. Epidyolex was also approved for adjunctive therapy of seizures associated with TSC for patients 2 years of age and older in the EU in April 2021 and Great Britain in August 2021, and is approved or under review for this indication in other markets. Outside the U.S. and Europe, Epidiolex/Epidyolex is approved in Israel, Switzerland, Australia and New Zealand.

Oncology

Rylaze was approved by FDA in June 2021 under the Real-Time Oncology Review 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 initial approved recommended dosage of Rylaze was for an intramuscular, or IM, administration of 25 mg/m² every 48 hours. In November 2022, FDA approved a supplemental Biologics License Application, or sBLA, for a Monday/Wednesday/Friday, or M/W/F, IM dosing schedule. In April 2022, we submitted a separate sBLA for intravenous, or IV, administration. In February 2023, we received a complete response letter from FDA requesting additional clinical data on the IV administration of Rylaze. There is no impact on the approved product labeling for Rylaze IM administration. We also completed a Marketing Authorization Application, or MAA, submission to the European Medicines Agency, or EMA, in May 2022 for M/W/F and

every 48-hour dosing schedules and IV and IM administration, with potential for approval in 2023. We are also continuing to evaluate patient need in other geographies.

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 continuing to raise awareness of Zepzelca across academic and community cancer centers, and see continued opportunities for 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 an ongoing 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.

Defitelio is the first and only approved treatment 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. Moving forward, we expect changes in chemotherapy regimens and the increasing use of cell therapies to potentially lower the incidence of VOD; additionally, there has been a reduction of prophylactic use of Defitelio in Europe.

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 t-AML, or AML-MRC, in pediatric patients aged one year and older. We have a number of ongoing development activities and continue to expand into new markets internationally. Despite an ongoing trend in the U.S. towards lower-intensity treatments and away from Vyxeos that accelerated due to the COVID-19 pandemic, we continue to see recovery in demand for Vyxeos and expect future demand for appropriate secondary AML patients to remain steady.

Research and Development Progress

Our research and 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 also have active preclinical programs for novel therapies, including precision medicines in hematology and oncology and the GW Cannabinoid Platform. We are increasingly leveraging our growing internal research and development function, and our proprietary GW Cannabinoid Platform, 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 are anticipated to generate additional data related to our products. We also seek out investment opportunities in support of the 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.

Our neuroscience R&D efforts include the initiation in August 2022 of an ongoing pivotal Phase 3 clinical trial of Epidiolex for the treatment of Epilepsy with Myoclonic-Atonic Seizures, or EMAS, also known as Doose syndrome. This trial is evaluating Epidiolex in a fourth childhood-onset epileptic encephalopathy with high unmet need. EMAS is characterized by generalized myoclonic-atic seizures, and this trial is designed to provide the first randomized, controlled clinical data with Epidiolex in this syndrome type. Seizure types including atonic, tonic, clonic, tonic-clonic and partial onset seizures are seen in LGS, DS, and TSC. We enrolled the first patient in a Phase 3 trial of Epidiolex for LGS, DS and TSC in Japan in October 2022.

In December 2021 we initiated Phase 2 clinical trials for suvcaltamide, or JZP385, for essential tremor, or ET, and for JZP150 for post-traumatic stress disorder, or PTSD. Additionally, in November 2022, we initiated a Phase 2 trial of suvcaltamide in patients with Parkinson's disease tremor. These patient populations suffer significant impacts to their quality of life and there are limited current treatment options. We are also pursuing early-stage activities related to the development of JZP324, an extended-release low sodium, oxybate formulation that we believe could provide a clinically meaningful option for narcolepsy patients.

In May 2022, we announced that we had entered into a licensing agreement with Sumitomo Pharma Co., Ltd, or Sumitomo, to acquire exclusive development and commercialization rights in the United States, Europe and other territories for JZP441, also known as DSP-0187, a potent, highly selective oral orexin-2 receptor agonist with potential application for the treatment of narcolepsy, IH and other sleep disorders. In November 2022, the first participant was enrolled in a Phase 1 development program to assess the safety, tolerability, pharmacokinetics and pharmacodynamics of JZP441 in sleep-deprived healthy volunteers. Under the terms of the agreement, we made an upfront payment of \$50 million to Sumitomo, and Sumitomo is eligible to receive development, regulatory and commercial milestone payments of up to \$1.09 billion. If approved, Sumitomo is eligible to receive a tiered, low double-digit royalty on Jazz's net sales of JZP441.

Within our oncology R&D program, in November 2022, FDA approved an sBLA for Rylaze, with a M/W/F IM dosing schedule. In April 2022, we submitted a separate sBLA for IV administration. In February 2023, we received a complete response letter from FDA requesting additional clinical data on the IV administration of Rylaze. There is no impact on the approved product labeling for Rylaze IM administration. We completed a MAA submission to the EMA in May 2022 for M/W/F and every 48-hour dosing schedules and IV and IM administration.

We are executing a robust development plan 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. In December 2021, our licensor Pharma Mar, S.A., or PharmaMar, initiated a confirmatory trial in second-line SCLC. This is a three-arm trial comparing Zepzelca as either monotherapy or in combination with irinotecan to investigator's choice of irinotecan or topotecan. Data from either the first-line trial of Zepzelca in combination with Tecentriq or the PharmaMar trial could serve to confirm clinical benefit of Zepzelca and secure full approval in the U.S.

In 2022, we initiated a Phase 2 basket trial to explore Zepzelca monotherapy in patients with select advanced or metastatic solid tumors. Cohorts include advanced urothelial cancer, poorly differentiated neuroendocrine carcinomas, or PD-NECs, and homologous recombination deficient, or 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 SCLC who progress on or after prior platinum-containing chemotherapy.

In October 2022, we announced an exclusive licensing and collaboration agreement with Zymeworks Inc., or Zymeworks, providing us the right to acquire development and commercialization rights to Zymeworks' zanidatamab across all indications in the United States, Europe, Japan and all other territories except for those Asia/Pacific territories previously licensed by Zymeworks. In December 2022, we exercised the option to continue with the exclusive development and commercialization rights to zanidatamab. Zanidatamab is a bispecific antibody that can simultaneously bind two non-overlapping epitopes of HER2, known as biparatopic binding. Under the terms of the agreement, Zymeworks received an upfront payment of \$50.0 million, and following the exercise of our option to continue the collaboration, a second, one-time payment of \$325 million. Zymeworks is also eligible to receive regulatory and commercial milestone payments of up to \$1.4 billion, for total potential payments of \$1.76 billion. Pending approval, Zymeworks is eligible to receive tiered royalties between 10% and 20% on our net sales. On April 25, 2023, Jazz and Zymeworks entered into a Stock and Asset Purchase Agreement to, among other things, transfer to Jazz certain assets, contracts and employees associated with the development of zanidatamab.

In June 2022, we announced the FDA had cleared our Investigational New Drug application for JZP815 and in October 2022, we enrolled the first patient in a Phase 1 trial. JZP815 is an investigational stage pan-RAF kinase inhibitor that targets specific components of the mitogen-activated protein kinase pathway that, when activated by oncogenic mutations, can be a frequent driver of human cancer.

In April 2022, we announced that we had entered into a licensing and collaboration agreement with Werewolf Therapeutics, Inc., or Werewolf, to acquire exclusive global development and commercialization rights to Werewolf's investigational WTX-613, now referred to as JZP898. JZP898 is a differentiated, conditionally-activated interferon alpha, or IFN α , INDUKINE™ molecule. Under the terms of the agreement, we made an upfront payment of \$15.0 million to Werewolf, and Werewolf is eligible to receive development, regulatory and commercial milestone payments of up to \$1.26 billion. If approved, Werewolf is eligible to receive a tiered, mid-single-digit percentage royalty on net sales of JZP898. This transaction underscores our commitment to enhancing our pipeline to deliver novel oncology therapies to patients, and also provides us with an opportunity to expand into immunology.

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:

<u>Product Candidates</u>	<u>Description</u>
NEUROSCIENCE	
Phase 3	
Epidiolex	EMAS, also known as Doose syndrome (ongoing trial) LGS, TSC and DS (ongoing trial in Japan)
Phase 2b	
Suvecaltamide (JZP385)	ET (ongoing trial)
Phase 2	
Suvecaltamide (JZP385)	Parkinson's disease tremor (ongoing trial)
JZP150	PTSD (ongoing trial)
JZP541	Irritability associated with autism spectrum disorder, or ASD (planned trial)

Product Candidates	Description
Additional cannabinoids	ASD (ongoing trial)
Phase 1	
JZP324	Oxybate extended-release formulation (planned trial)
JZP441*	Potent, highly selective oral orexin-2 receptor agonist (ongoing trials in Japan and the U.S.)
Additional cannabinoids	Neuropsychiatry targets (ongoing trial)
Preclinical	
Undisclosed targets	Neuroscience Cannabinoids
ONCOLOGY	
Regulatory Review	
Rylaze	ALL/LBL FDA approval in June 2021; approval for M/W/F IM dosing schedule in November 2022; submitted an sBLA for IV administration in April 2022; received complete response letter from FDA requesting additional data on IV administration in February 2023; submitted MAA to EMA in May 2022
Phase 3	
Zepzelca	First-line extensive stage SCLC in combination with Tecentriq (collaboration with Roche) (ongoing trial) Confirmatory Study (PharmaMar study) (ongoing trial)
Zanidatamab	HER2-positive gastroesophageal adenocarcinoma, or GEA (ongoing trial)
Vyxeos	AML or high-risk Myelodysplastic Syndrome, or MDS (AML18) (cooperative group studies) (ongoing trial) Newly diagnosed adults with standard- and high-risk AML (AML Study Group cooperative group study) (ongoing trial) Newly diagnosed pediatric patients with AML (Children's Oncology Group cooperative group study) (ongoing trial)
Pivotal Phase 2	
Zanidatamab	Previously treated, advanced HER2-expressing biliary tract cancer, or BTC (ongoing trial) (pivotal trial)
Phase 2	
Zepzelca	Basket trial including urothelial cancer, PD-NECs, and HRD cancers (ongoing trial)
Vyxeos	High-risk MDS (European Myelodysplastic Syndromes) (cooperative group study) (ongoing trial) Newly diagnosed untreated patients with high-risk AML (cooperative group study) (planned trial)
Vyxeos + venetoclax	De novo or relapsed/refractory, or R/R, AML (MD Anderson collaboration study) (ongoing trial)
Zanidatamab	HER2-expressing GEA, BTC or colorectal cancer in combination with standard first-line chemotherapy (ongoing trial)
Phase 2a	
Zanidatamab	Previously treated HER2+HR+ breast cancer in combination with palbociclib
Phase 1b/2	
Zanidatamab	First-line breast cancer and GEA (BeiGene trial) (ongoing trial)
Zanidatamab	HER2-expressing breast cancer in combination with ALX148 (ongoing trial)
Vyxeos + other approved therapies	First-line, fit AML (ongoing trial) Low intensity therapy for first-line, unfit AML (ongoing trial)
Phase 1	
Vyxeos	Low intensity dosing for higher risk MDS (MD Anderson collaboration study) (ongoing trial)
Vyxeos + other approved therapies	R/R AML or hypomethylating agent failure MDS (MD Anderson collaboration study) (ongoing trial)
JZP815	Raf and Ras mutant tumors (acquired from Redx Pharma plc, or Redx) (ongoing trial)

Product Candidates	Description
Zanidatamab	In previously treated metastatic HER2-expressing cancers in combination with select antineoplastic therapies (ongoing trial)
JZP341 (long-acting <i>Erwinia</i> asparaginase)	Solid tumors (licensed from Ligand Pharmaceuticals Incorporated, or Ligand) (ongoing trial)
Preclinical	
CombiPlex®	Hematology/oncology exploratory activities
JZP898	Conditionally-activated IFN α INDUKINE™ molecule
Undisclosed target	Ras/Raf/MAP kinase pathway (collaboration with Redx) Oncology
Undisclosed targets	Oncology

*Also known as DSP-0187

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 reaching our key audiences through both in-person and virtual initiatives. This includes maintaining a virtual presence at scientific congresses, when appropriate, designed to ensure we can continue to provide promotional and non-promotional interactions and supporting 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. In most geographies, our teams are increasing 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.

Other Challenges, Risks and Trends Related to Our Business

Historically, our business has been substantially dependent on Xyrem and our financial results have been significantly influenced by sales of Xyrem. Our operating plan assumes that Xywav, with 92% lower sodium compared to Xyrem, depending on the dose, absence of a sodium warning and dosing titration option, will remain the treatment of choice for patients who can benefit from oxybate treatment. In June 2021, FDA recognized seven years of ODE for Xywav in narcolepsy through July 21, 2027 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, 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 payor coverage and reimbursement for Xywav and acceptance of Xywav by physicians and patients, including of Xywav for the treatment of IH 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.

Xywav and Xyrem also face increased competition from new branded products for treatment of cataplexy and/or EDS in narcolepsy, such as Avadel's recently approved Lumryz, in the U.S. market.

In addition, in January 2023 our oxybate products began to face competition from an authorized generic, or AG, version of high-sodium oxybate pursuant to a settlement agreement we entered into with an abbreviated new drug application, or ANDA, filer, and, in the future, we expect our oxybate products to face competition from additional AG versions of high-sodium oxybate and from generic versions of high-sodium oxybate pursuant to settlement agreements we entered into with multiple ANDA filers. Generic competition can decrease the prices at which Xywav and Xyrem are sold and the number of prescriptions written for Xywav and Xyrem. 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, or similar organizations 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 or similar organizations and payors to ensure patient access has and will likely continue to result in higher gross to net deductions.

Our financial condition, results of operations and growth prospects are also dependent on our ability to maintain or increase sales of Epidiolex/Epidyolex in the U.S. and Europe, which is subject to many risks and there is no guarantee that we

will be able to continue to successfully commercialize Epidiolex/Epidyolex for its approved indications. The commercial success of Epidiolex/Epidyolex depends on the extent to which patients and physicians accept and adopt Epidiolex/Epidyolex as a treatment for seizures associated with 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/Epidyolex if coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost. Additionally, any negative development for Epidiolex/Epidyolex in the market, in clinical development for additional indications, or in regulatory processes in other jurisdictions, may adversely impact the commercial results and potential of Epidiolex/Epidyolex. Moreover, we expect that Epidiolex will face competition from generic products in the future. For example, in November and December 2022, we received notices from ten ANDA filers that they have each filed with FDA an ANDA for a generic version of Epidiolex. 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. Thus, significant uncertainty remains regarding the commercial potential of Epidiolex/Epidyolex.

In addition to our neuroscience products and product candidates, we are commercializing a portfolio of oncology products, including Rylaze, Zepzelca, Defitelio and Vyxeos. An inability to effectively commercialize Rylaze, Zepzelca, Defitelio and Vyxeos 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.

A key aspect of our growth strategy is our continued investment in our evolving and expanding R&D 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 R&D 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.

The success of the GW Acquisition will depend, in part, on our ability to realize the anticipated benefits from our and GW's historical businesses. Nonetheless, Epidiolex and the other products and technologies acquired may not be successful or continue to grow at the same rate as if our companies operated independently or they may require significantly greater resources and investments than originally anticipated. For example, in the third quarter of 2022, we recorded a \$133.6 million asset impairment charge as a result of the decision to discontinue the nabiximols program. As a result, the anticipated benefits of the GW Acquisition may not be realized at the expected level, 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 new 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. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 into law, which, among other things, requires the U.S. Department of Health and Human Services Secretary to negotiate, with respect to Medicare units and subject to a specified cap, the price of a set number of certain high Medicare spend drugs and biologics per year starting in 2026, penalizes manufacturers of certain Medicare Parts B and D drugs for price increases above inflation, and makes several changes to the Medicare Part D benefit, including a limit on annual out-of-pocket costs, and a change in manufacturer liability under the program, that could negatively affect our business and financial condition. In addition, under the Medicaid Drug Rebate Program, rebates owed by manufacturers are currently capped at 100 percent of average manufacturer price, but, effective January 1, 2024, this cap will be lifted, which could adversely affect our rebate liability. 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 our current products 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 such products 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 and the U.S. Drug Enforcement

Administration will make a scheduling determination. U.S. or foreign regulatory agencies may request additional information regarding the abuse potential of our products which 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, delay the approval and/or delay the launch of that product.

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. Government investigations 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, could cause us to incur significant monetary charges to resolve these matters and could distract us from the operation of our business and execution of our strategy. For example, in July 2022, we received a subpoena from the U.S. Attorney's Office for the District of Massachusetts requesting documents related to Xyrem and U.S. Patent No. 8,772,306 ("Method of Administration of Gamma Hydroxybutyrate with Monocarboxylate Transporters"), product labeling changes for Xyrem, communications with FDA and the U.S. Patent and Trademark Office, pricing of Xyrem, and other related documents. We may also become subject to similar investigations by other state or federal governmental agencies. The investigation by the U.S. Attorney's Office and any additional investigations or litigation related to the subject matter of this investigation may result in damages, fines, penalties, financial charges to resolve the matter or administrative sanctions against us, negative publicity or other negative actions that could harm our reputation, reduce demand for Xyrem and/or reduce coverage of Xyrem, including by federal health care programs and state health care programs. In addition, from June 2020 to May 2022, a number of 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 lawsuits and other legal matters, see Note 9, Commitments and Contingencies-Legal Proceedings of the Notes to Condensed Consolidated Financial Statements, included in Part I 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; however, if the plaintiffs were to be successful in their claims against us, they may be entitled to injunctive relief or we may be required to pay significant monetary damages. Moreover, we are, and expect to continue to be, the subject of various claims, legal proceedings, and government investigations apart from those set forth above that have arisen in the ordinary course of business that have not yet been fully resolved and that could adversely affect our business and the execution of our strategy. Any of the foregoing risks and uncertainties could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

All of these risks and uncertainties are discussed in greater detail, along with other risks and uncertainties, in "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022, as supplemented by the risks and uncertainties described in "Risk Factors" Item 1A. Risk Factors in Part II 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 March 31,		Increase/ (Decrease)
	2023	2022	
Product sales, net	\$ 884,219	\$ 809,837	9 %
Royalties and contract revenues	8,593	3,884	121 %
Cost of product sales (excluding amortization of acquired developed technologies)	128,644	115,284	12 %
Selling, general and administrative	297,917	308,813	(4)%
Research and development	189,410	129,981	46 %
Intangible asset amortization	149,786	172,094	(13)%
Acquired in-process research and development	1,000	—	N/A(1)
Interest expense, net	74,147	70,684	5 %
Foreign exchange loss (gain)	(3,193)	10,540	N/A(1)
Income tax expense (benefit)	(15,324)	536	N/A(1)
Equity in loss of investees	1,005	4,142	(76)%

(1) 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 March 31,		Increase/ (Decrease)
	2023	2022	
Xywav	\$ 277,761	\$ 186,080	49 %
Xyrem	178,130	247,497	(28)%
Total Oxybate	455,891	433,577	5 %
Epidiolex/Epidyolex	188,909	157,893	20 %
Sativex	7,098	4,742	50 %
Sunosi	—	15,878	N/A(1)
Total Neuroscience	651,898	612,090	7 %
Rylaze	85,927	54,220	58 %
Zepzelca	67,181	59,338	13 %
Defitelio/defibrotide	39,079	49,489	(21)%
Vyxeos	36,700	33,757	9 %
Total Oncology	228,887	196,804	16 %
Other	3,434	943	264 %
Product sales, net	884,219	809,837	9 %
High-sodium oxybate AG royalty revenue	2,096	—	N/A(2)
Other royalty and contract revenues	6,497	3,884	67 %
Total revenues	\$ 892,812	\$ 813,721	10 %

(1) Divestiture of Sunosi U.S. was completed in May 2022

(2) Comparison to prior period not meaningful

Product Sales, Net

Total oxybate product sales increased by \$22.3 million in the three months ended March 31, 2023, compared to the same period in 2022. Average active oxybate patients on therapy were approximately 17,400 in the first quarter of 2023, an increase of approximately 5% compared to the same period in 2022. Xywav product sales increased in the three months ended March 31, 2023 compared to the same period in 2022, primarily due to a 43% increase in sales volumes. We continue to see Xywav adoption among existing Xyrem patients, as well as the majority of new-to-oxybate narcolepsy patients, driven by educational initiatives around the benefit of lowering sodium intake. In addition, Xywav product sales were positively impacted by Xywav for IH as we see continued growth of new prescribers. Xyrem product sales decreased in the three months ended March 31, 2023 compared to the same period in 2022, primarily due to a decrease in sales volume of 31%, reflecting the continued adoption of Xywav by existing Xyrem patients and the launch of a high-sodium oxybate AG in January 2023, partially offset by a higher average selling price. Price increases were instituted in January 2022 and January 2023. Epidiolex/Epidyolex product sales increased by \$31.0 million in the three months ended March 31, 2023 compared to the same period in 2022, primarily due to an increase in commercial sales volumes of 24%.

Rylaze product sales in the three months ended March 31, 2023 increased compared to the same period in 2022, primarily due to higher sales volumes reflecting the significant unmet patient need for a high-quality, reliable supply of Erwinia asparaginase for patients with ALL. Zepzelca product sales in the three months ended March 31, 2023 increased compared to the same period in 2022, primarily due to higher sales volumes and a higher average selling price, partially offset by higher gross to net deductions. Price increases were instituted in January 2022, July 2022 and January 2023. Defitelio/defibrotide product sales in the three months ended March 31, 2023 decreased compared to the same period in 2022, primarily due to a decrease in sales volumes, partially offset by a higher average selling price. Price increases were instituted in January 2022, July 2022 and January 2023. Vyxeos product sales in the three months ended March 31, 2023 increased compared to the same period in 2022, primarily due to higher sales volumes and a higher average selling price, partially offset by higher gross to net deductions. Price increases were instituted in January 2022, July 2022 and January 2023.

We expect total product sales will increase in 2023 over 2022, primarily due to an increase in product sales of Xywav due to continuing growth in IH and as patients continue to transition to Xywav from Xyrem, expected growth in Epidiolex and our

oncology products, primarily Rylaze and Zepzelca, offset by the continued decline in Xyrem due to strong Xywav adoption and availability of high-sodium oxybate AG and branded fixed-dose, high-sodium oxybate.

Royalties and Contract Revenues

Royalties and contract revenues increased in the three months ended March 31, 2023 compared to the same period in 2022 primarily due to royalty revenue received from Hikma Pharmaceuticals plc on net sales of their high-sodium oxybate AG and higher contract revenues resulting from the achievement of a sales-based milestone. We expect royalties and contract revenues to increase in 2023 compared to 2022 primarily due to increased royalty revenues arising from the launch of a high-sodium oxybate AG.

Cost of Product Sales

Cost of product sales increased in the three months ended March 31, 2023 compared to the same period in 2022 primarily due to changes in product mix. Gross margin as a percentage of net product sales of 85.5% was in line with the same period in 2022. We expect our cost of product sales to decrease in 2023 compared to 2022 primarily driven by a reduction in the acquisition accounting inventory fair value step-up expense.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased in the three months ended March 31, 2023 compared to the same period in 2022, primarily due to transaction and integration expenses related to the acquisition of GW of \$9.6 million and Sunosi related spend incurred in the three months ended March 31, 2022, partially offset by increased investment in our priority programs.

We expect selling, general and administrative expenses in 2023 to decrease compared to 2022, primarily due to the removal of costs relating to the Sunosi business following its disposal, together with synergies realized following the GW Acquisition, continued disciplined approach in our capital allocation and our focus on operational efficiencies.

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 March 31,	
	2023	2022
Clinical studies and outside services	\$ 106,345	\$ 56,429
Personnel expenses	60,391	55,301
Other	22,674	18,251
Total	\$ 189,410	\$ 129,981

Research and development expenses increased by \$59.4 million in the three months ended March 31, 2023, compared to the same period in 2022. Clinical studies and outside services costs increased in the three months ended March 31, 2023, compared to the same period in 2022, primarily due to the inclusion of costs related to zanidatamab, as well as, JZP815, JZP898 and JZP441, offset by a decrease in costs related to JZP458.

For 2023, we expect that our research and development expenses will continue to increase from previous levels as we prepare for anticipated data read-outs from clinical trials, initiate and undertake additional clinical trials and related development work primarily relating to zanidatamab and JZP441 and additional spend on new product candidates acquired.

Intangible Asset Amortization

Intangible asset amortization decreased by \$22.3 million in the three months ended March 31, 2023, compared to the same period in 2022, primarily due to the inclusion of amortization relating to the Sunosi intangible asset in the three months ended March 31, 2022 and the positive movements in foreign exchange rates. Intangible asset amortization for 2023 is expected to be in line with 2022.

Interest Expense, Net

Interest expense, net in the three months ended March 31, 2023 increased by \$3.5 million, compared to the same period in 2022, primarily driven by higher interest rates on our outstanding term loan borrowings, partially offset by the inclusion of interest expense on the now repaid seven-year €625.0 million term loan B facility, or the Euro Term Loan, in the three months ended March 31, 2022 and higher interest income on investments in the three months ended March 31, 2023. We expect interest expense, net for 2023 to increase compared to 2022 primarily due to higher interest rates on our term loan borrowings.

Foreign Exchange Loss (Gain)

The foreign exchange loss (gain) 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 Expense (Benefit)

Our income tax benefit was \$15.3 million for the three months ended March 31, 2023, compared to an income tax expense of \$0.5 million for the same period in 2022, relating to tax arising on income or losses in Ireland, the U.K., the U.S. and certain other foreign jurisdictions, offset by deductions on subsidiary equity, Foreign Derived Intangible Income, or FDII, and patent box benefits. The increase in the income tax benefit resulted primarily from the mix of pre-tax income and losses incurred across tax jurisdictions and increases in our FDII and patent box benefits. 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.

Liquidity and Capital Resources

As of March 31, 2023, we had cash and cash equivalents of \$1,167.9 million, borrowing availability under our revolving credit facility of \$500.0 million and long-term debt principal balance of \$5.8 billion. Our long-term debt included \$2.8 billion aggregate principal amount of the seven-year \$3.1 billion in aggregate term loan B facility, or the Dollar Term Loan, \$1.5 billion in aggregate principal amount of 4.375% senior secured notes, due 2029, or the Secured Notes, \$1.0 billion principal amount on our 2.00% exchangeable senior notes due 2026 and \$575.0 million principal amount on our 1.50% exchangeable senior notes due 2024. We generated cash flows from operations of \$320.7 million during the three months ended March 31, 2023, 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.

Since the closing of the acquisition of GW in May 2021, we have made voluntary repayments of €625.0 million, or \$753.0 million, relating to the Euro Term Loan and voluntary and mandatory repayments of \$300.0 million and \$54.3 million, respectively, relating to the Dollar Term Loan.

For a more detailed description of our debt arrangements, including information relating to our scheduled maturities with respect to our long-term debt, see Note 8, 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 "Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2022 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 balance, 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 "Risk Factors" under the heading "Risks

Related to our Lead Products and Product Candidates” in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022, as supplemented by the risks described in “Risk Factors” 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 Part II, Item 1A of this Quarterly Report on Form 10-Q, as well as those factors set forth in “Risk Factors” under the heading “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” in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022.

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. We regularly evaluate the performance of our products and product candidates to ensure fit within our portfolio and support efficient allocation of capital. 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, our ability to raise additional capital may be adversely impacted by worsening global economic conditions, with disruptions to, and volatility in, the credit and financial markets in the U.S. and worldwide resulting from the effects of inflationary pressures, the COVID-19 pandemic and otherwise. If these conditions persist and deepen, 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, under Irish law we must have authority from our shareholders to issue any ordinary shares, including ordinary shares that are part of our authorized but unissued share capital. Moreover, 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 annual general meeting of shareholders in July 2022, 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. This current pre-emption opt-out authority is due to expire in January 2024. If we are unable to obtain further pre-emption authorities from our shareholders in the future, or otherwise continue to be limited by the terms of new pre-emption authorities approved by our shareholders in the future, our ability to use our unissued share capital to fund in-licensing, acquisition or other business opportunities, or to otherwise raise capital, could be adversely affected. 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.

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

	Three Months Ended March 31,	
	2023	2022
Net cash provided by operating activities	\$ 320,708	\$ 208,979
Net cash used in investing activities	(4,822)	(37,292)
Net cash used in financing activities	(29,788)	(270,811)
Effect of exchange rates on cash and cash equivalents	331	(1,489)
Net increase (decrease) in cash and cash equivalents	\$ 286,429	\$ (100,613)

Operating activities

Net cash provided by operating activities increased by \$111.7 million in the three months ended March 31, 2023 compared to the same period in 2022, primarily due to an increase in net cash inflow related to changes in operating assets and liabilities.

Investing activities

Net cash used in investing activities decreased by \$32.5 million in the three months ended March 31, 2023 compared to the same period in 2022, primarily due to a \$25.0 million milestone payment to PharmaMar in relation to our first sales-based milestone for Zepzelca in the three months ended March 31, 2022.

Financing activities

Net cash used in financing activities decreased by \$241.0 million in the three months ended March 31, 2023 compared to the same period in 2022, primarily due to repayments of long-term debt of \$7.8 million in the three months ended March 31, 2023, compared to \$258.8 million in the three months ended March 31, 2022.

Debt

The summary of our outstanding indebtedness and scheduled maturities with respect to our long-term debt principal balances is included in Note 8, Debt, of the Notes to Condensed Consolidated Financial Statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q. During the three months ended March 31, 2023, there were no changes to the credit agreement and our other financing arrangements, as set forth in Note 12, Debt, of the Notes to Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2022.

Contractual Obligations

During the three months ended March 31, 2023, there were no material changes to our contractual obligations as set forth in Part II, Item 7 “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2022.

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 and also with respect to the acquisition and valuation of intangibles 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, 2022. 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, 2022.

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. These known and unknown risks, uncertainties and other factors include, without limitation:

- 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 and safety requirements subject us to risks and uncertainties, any of which could negatively impact sales of Xywav and Xyrem.
- While we expect our oxybate products and Epidiolex/Epidyolex to remain our largest products, our success also depends on our ability to effectively commercialize our other existing products and potential future products.
- We face substantial competition from other companies, including companies with larger sales organizations and more experience working with large and diverse product portfolios, and competition from generic drugs.
- 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, including recently enacted changes to Medicare, 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.
- 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.
- 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 subject us to civil or criminal proceedings, investigations, or penalties and 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.

Additional discussion of the risks, uncertainties and other factors described above, as well as other risks material to our business, can be found under "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022, as supplemented by the risks and uncertainties described in "Risk Factors" Item 1A. Risk Factors in Part II 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

During the three months ended March 31, 2023, there were no material changes to our market risk disclosures as set forth in Part II, Item 7A “Quantitative and Qualitative Disclosures About Market Risk” in our Annual Report on Form 10-K for the year ended December 31, 2022.

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) and 15d-15(e) of the Exchange Act) 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 March 31, 2023.

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. During the quarter ended March 31, 2023, there were 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 9, 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

Below we are providing, in supplemental form, changes to our risk factors from those previously disclosed in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022. Our risk factors disclosed in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022 provide additional discussion regarding these supplemental risks and we encourage you to read and carefully consider all of the risk factors disclosed in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022, together with the below, for a more complete understanding of the risks and uncertainties material to 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.

New treatment options for cataplexy and EDS in narcolepsy have been commercially launched, and in the future, other products may be launched that are competitive with or disrupt the market for our oxybate products.

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, the U.S. Food and Drug Administration, or 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. Pursuant to our patent litigation settlement with the first filer, a wholly owned subsidiary of Hikma Pharmaceuticals PLC, or Hikma, Hikma launched an authorized generic product, or AG Product, in the U.S. beginning on January 1, 2023. Accordingly, beginning in January 2023, Xywav and Xyrem face competition from an authorized generic version of high-sodium oxybate and in the future, we expect to compete with other authorized generic and generic versions of high-sodium oxybate. Hikma has a right to elect to continue to sell the Hikma AG Product, with royalties back to us, for a total of up to five years. We will receive a meaningful royalty from Hikma on net sales of the Hikma AG Product, with the royalty rate increasing during the initial six-month term based on increased net sales of the Hikma AG Product; if Hikma elects to extend the term for the remainder of the first year, the rate will become fixed. There will also be a substantial increase in the royalty rate should the term be extended beyond one year. We will also be paid for supply of the Hikma AG Product and will be reimbursed by Hikma for a portion of the services costs associated with the operation of the Xywav and Xyrem REMS and distribution of the Hikma AG Product. We also granted Hikma a license to launch its own generic high-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 and ending on December 31, 2025, with royalties back to us. AG Products will be distributed through the same risk evaluation and mitigation strategy, or REMS, as Xywav and Xyrem. We also granted each of Amneal, Lupin and Par a license to launch its own generic high-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 high-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 high-sodium oxybate product. 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.

Any ANDA holder launching an AG Product or another generic high-sodium oxybate product will independently establish the price of the AG Product and/or its own generic high-sodium oxybate product and determine the types of discounts or rebates they will offer parties that purchase or pay for the product. Generic competition often results in decreases in the net prices at which branded products can be sold. A component of drug pricing is the manufacturer's list price for a drug to wholesalers or direct purchasers in the U.S. (without discounts, rebates or other reductions) referred to as the Wholesale Acquisition Cost, or WAC. In this regard, Hikma launched the Hikma AG Product at a WAC that was less than 15% lower than the WAC for Xyrem. 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.

Other companies may develop high-sodium oxybate products 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. For example, on May 1, 2023, Avadel announced that it had received approval and orphan drug exclusivity through May 1, 2030 for Lumryz, a fixed-dose, high-sodium oxybate which uses its proprietary technology for the treatment of EDS and cataplexy in patients with narcolepsy, and we expect to begin to face competition from Avadel in the coming months. For additional information on litigation involving this matter, see “*Avadel Patent Litigation*” in Note 9, Commitments and Contingencies-Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part I of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023. Xyrem and Xywav also face increased competition from other 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 continue to face competition from generic or authorized generic high-sodium oxybate products or new branded entrants in narcolepsy such as Avadel’s recently approved Lumryz notwithstanding FDA recognizing Orphan Drug Exclusivity for Xywav. For example, we received notice in June 2021 that Lupin filed an ANDA for a generic version of Xywav. 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, non-oxybate products intended for the treatment of EDS or cataplexy in narcolepsy or idiopathic hypersomnia, or IH, including new market entrants, even if not directly competitive with Xywav or Xyrem, could have the effect of changing treatment regimens and payor or formulary coverage of Xywav or Xyrem in favor of other products, and indirectly materially and adversely affect sales of Xywav and Xyrem. Examples of such new market entrants include 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 2020 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. Pitolisant is also in late stage development for the treatment of IH. In addition, we are also aware that prescribers often prescribe branded or generic medications for cataplexy, before or instead of prescribing oxybate therapy in Xywav and Xyrem, and that payors often require patients to try such medications before they will cover Xywav or Xyrem, 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, 2022.

We expect that the approval and launch of the Hikma AG Product, another AG Product or other generic version of Xyrem and the approval and launch of any other high-sodium oxybate product (including Avadel’s recently approved Lumryz) or alternative product that treats narcolepsy could have a material adverse effect on our sales of Xywav and Xyrem and on our business, financial condition, results of operations and growth prospects.

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 March 31, 2023 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 months ended March 31, 2023, we did not repurchase any of our ordinary shares. As of March 31, 2023, 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‡	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 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).
4.2B	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).
4.2C	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.
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)

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

Portions of this document (indicated by “[*]”) have been omitted pursuant to Item 601(b)(10) of Regulations S-K because they are both not material and are the type that the Company treats as private and confidential.

* 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: May 10, 2023

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)

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: May 10, 2023

By:

/s/ Renée Galá

Renée Galá
Executive Vice President and Chief Financial Officer

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 March 31, 2023, 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: May 10, 2023

/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

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- (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.