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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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	**98-1032470**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of November 1, 2023, 62,956,913 ordinary shares of the registrant, nominal value $0.0001 per share, were outstanding.

JAZZ PHARMACEUTICALS PLC
QUARTERLY REPORT ON FORM 10-Q FOR THE QUARTER ENDED SEPTEMBER 30, 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®, Xywav® (calcium, magnesium, potassium, and sodium oxybates) oral solution, Xyrem® (sodium oxybate) oral solution, Epidiolex® (cannabidiol) oral solution, Epidyolex® (the trade name in Europe and other countries outside the U.S. for Epidiolex), Rylaze® (asparaginase erwinia chrysanthemi (recombinant)-rywn), Enrylaze® (the trade name in Europe and other countries outside the U.S. and Canada for Rylaze), Zepzelca® (lurbinectedin), Defitelio® (defibrotide sodium), Defitelio® (defibrotide), Vyxeos® (daunorubicin and cytarabine) liposome for injection, Vyxeos® liposomal 44 mg/100 mg powder for concentrate for solution for infusion, CombiPlex® 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.

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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,335,690	$ 881,482
Investments	250,000	—
Accounts receivable, net of allowances	627,841	651,493
Inventories	611,827	714,061
Prepaid expenses	109,990	91,912
Other current assets	310,404	267,192
Total current assets	3,245,752	2,606,140
Property, plant and equipment, net	222,476	228,050
Operating lease assets	65,038	73,326
Intangible assets, net	5,417,860	5,794,437
Goodwill	1,705,320	1,692,662
Deferred tax assets, net	464,367	376,247
Deferred financing costs	7,172	9,254
Other non-current assets	76,080	55,139
Total assets	$ 11,204,065	$ 10,835,255
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 109,850	$ 90,758
Accrued liabilities	769,942	803,255
Current portion of long-term debt	604,507	31,000
Income taxes payable	89,026	7,717
Deferred revenue	4	463
Total current liabilities	1,573,329	933,193
Long-term debt, less current portion	5,110,757	5,693,341
Operating lease liabilities, less current portion	61,892	71,838
Deferred tax liabilities, net	841,234	944,337
Other non-current liabilities	127,480	106,812
Commitments and contingencies (Note 9)		
Shareholders' equity:		
Ordinary shares	6	6
Non-voting euro deferred shares	55	55
Capital redemption reserve	473	472
Additional paid-in capital	3,639,940	3,477,124
Accumulated other comprehensive loss	(1,035,399)	(1,125,509)
Retained earnings	884,298	733,586
Total shareholders' equity	3,489,373	3,085,734
Total liabilities and shareholders' equity	$ 11,204,065	$ 10,835,255

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenues:				
Product sales, net	$ 938,398	$ 935,766	$ 2,769,604	$ 2,673,903
Royalties and contract revenues	33,742	4,886	52,665	13,348
Total revenues	972,140	940,652	2,822,269	2,687,251
Operating expenses:				
Cost of product sales (excluding amortization of acquired developed technologies)	102,153	133,661	328,334	373,153
Selling, general and administrative	308,310	358,478	947,071	1,033,764
Research and development	234,402	148,870	633,050	417,898
Intangible asset amortization	154,883	141,232	456,731	461,782
Acquired in-process research and development	—	—	1,000	69,148
Impairment charge	—	133,648	—	133,648
Total operating expenses	799,748	915,889	2,366,186	2,489,393
Income from operations	172,392	24,763	456,083	197,858
Interest expense, net	(71,497)	(80,244)	(219,114)	(214,117)
Foreign exchange loss	(1,377)	(4,649)	(566)	(16,532)
Income (loss) before income tax benefit and equity in loss (gain) of investees	99,518	(60,130)	236,403	(32,791)
Income tax benefit	(47,176)	(43,027)	(86,823)	(58,603)
Equity in loss (gain) of investees	(126)	2,545	2,548	9,148
Net income (loss)	$ 146,820	$ (19,648)	$ 320,678	$ 16,664
Net income (loss) per ordinary share:				
Basic	$ 2.33	$ (0.31)	$ 5.05	$ 0.27
Diluted	$ 2.14	$ (0.31)	$ 4.67	$ 0.26
Weighted-average ordinary shares used in per share calculations - basic	63,114	62,785	63,532	62,365
Weighted-average ordinary shares used in per share calculations - diluted	71,293	62,785	72,866	63,388

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net income (loss)	$ 146,820	$ (19,648)	$ 320,678	$ 16,664
Other comprehensive income (loss):				
Foreign currency translation adjustments	(170,826)	(511,617)	82,952	(1,217,414)
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
Unrealized gain on cash flow hedging activities, net of income tax expense of $1,176, $—, $3,063 and $—, respectively	3,539	—	9,218	—
Gain on cash flow hedging activities reclassified from accumulated other comprehensive income (loss) to interest expense, net of income tax expense of $428, $—, $684 and $—, respectively	(1,289)	—	(2,060)	—
Other comprehensive income (loss)	(168,576)	(511,617)	90,110	(1,217,286)
Total comprehensive income (loss)	$ (21,756)	$ (531,265)	$ 410,788	$ (1,200,622)

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	63,987	$ 6	4,000	$ 55	$ 472	$ 3,511,732	$ (980,230)	$ 803,006	$ 3,335,041
Issuance of ordinary shares in conjunction with exercise of share options	28	—	—	—	—	2,003	—	—	2,003
Issuance of ordinary shares under employee stock purchase plan	81	—	—	—	—	8,863	—	—	8,863
Issuance of ordinary shares in conjunction with vesting of restricted stock units	58	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(4,188)	—	—	(4,188)
Share-based compensation	—	—	—	—	—	61,705	—	—	61,705
Shares repurchased	(756)	—	—	—	1	—	—	(95,595)	(95,594)
Other comprehensive income	—	—	—	—	—	—	113,407	—	113,407
Net income	—	—	—	—	—	—	—	104,438	104,438
Balance at June 30, 2023	63,398	$ 6	4,000	$ 55	$ 473	$ 3,580,115	$ (866,823)	$ 811,849	$ 3,525,675
Issuance of ordinary shares in conjunction with exercise of share options	50	—	—	—	—	5,512	—	—	5,512
Issuance of ordinary shares in conjunction with vesting of restricted stock units	59	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(1,884)	—	—	(1,884)
Share-based compensation	—	—	—	—	—	56,197	—	—	56,197
Shares repurchased	(562)	—	—	—	—	—	—	(74,371)	(74,371)
Other comprehensive loss	—	—	—	—	—	—	(168,576)	—	(168,576)
Net income	—	—	—	—	—	—	—	146,820	146,820
Balance at September 30, 2023	62,945	$ 6	4,000	$ 55	$ 473	$ 3,639,940	$ (1,035,399)	$ 884,298	$ 3,489,373

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, 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	62,244	$ 6	4,000	$ 55	$ 472	$ 3,239,327	$ (590,720)	$ 959,347	$ 3,608,487
Issuance of ordinary shares in conjunction with exercise of share options	194	—	—	—	—	16,640	—	—	16,640
Issuance of ordinary shares under employee stock purchase plan	81	—	—	—	—	8,234	—	—	8,234
Issuance of ordinary shares in conjunction with vesting of restricted stock units	104	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(6,289)	—	—	(6,289)
Share-based compensation	—	—	—	—	—	54,407	—	—	54,407
Shares repurchased	—	—	—	—	—	—	—	(54)	(54)
Other comprehensive loss	—	—	—	—	—	—	(515,309)	—	(515,309)
Net income	—	—	—	—	—	—	—	34,665	34,665
Balance at June 30, 2022	62,623	$ 6	4,000	$ 55	$ 472	$ 3,312,319	$ (1,106,029)	$ 993,958	$ 3,200,781
Issuance of ordinary shares in conjunction with exercise of share options	207	—	—	—	—	21,260	—	—	21,260
Issuance of ordinary shares in conjunction with vesting of restricted stock units	60	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(2,567)	—	—	(2,567)
Share-based compensation	—	—	—	—	—	56,985	—	—	56,985
Other comprehensive loss	—	—	—	—	—	—	(511,617)	—	(511,617)
Net loss	—	—	—	—	—	—	—	(19,648)	(19,648)
Balance at September 30, 2022	62,890	$ 6	4,000	$ 55	$ 472	$ 3,387,997	$ (1,617,646)	$ 974,310	$ 2,745,194

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

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

	Nine Months Ended September 30,	
	2023	**2022**
Operating activities		
Net income	$ 320,678	$ 16,664
Adjustments to reconcile net income to net cash provided by operating activities:		
Intangible asset amortization	456,731	461,782
Share-based compensation	173,900	160,438
Acquisition accounting inventory fair value step-up adjustment	119,094	203,189
Other non-cash transactions	54,262	(26,352)
Depreciation	22,764	22,958
Non-cash interest expense	16,255	32,002
Provision for losses on accounts receivable and inventory	7,732	13,066
Acquired in-process research and development	1,000	69,148
Impairment charge	—	133,648
Loss on disposal of a business	—	39,258
Deferred tax benefit	(224,317)	(146,874)
Changes in assets and liabilities:		
Accounts receivable	23,581	(43,868)
Inventories	(12,016)	(50,458)
Prepaid expenses and other current assets	(37,327)	23,801
Operating lease assets	14,423	10,672
Other non-current assets	(20,881)	(4,006)
Accounts payable	17,705	4,188
Accrued liabilities	(76,261)	17,864
Income taxes payable	61,159	(172)
Deferred revenue	(459)	(1,570)
Operating lease liabilities, less current portion	(13,855)	(12,139)
Other non-current liabilities	20,500	6,767
Net cash provided by operating activities	924,668	930,006
Investing activities		
Proceeds from maturity of investments	20,000	—
Acquired in-process research and development	(1,000)	(69,148)
Purchases of property, plant and equipment	(13,860)	(19,668)
Acquisition of investments	(270,000)	(61,036)
Proceeds from sale of a business	—	53,000
Acquisition of intangible assets	—	(25,000)
Net cash used in investing activities	(264,860)	(121,852)
Financing activities		
Proceeds from employee equity incentive and purchase plans	37,606	67,863
Repayments of long-term debt	(23,250)	(574,264)
Payment of employee withholding taxes related to share-based awards	(49,338)	(42,632)
Share repurchases	(169,966)	(54)
Net cash used in financing activities	(204,948)	(549,087)
Effect of exchange rates on cash and cash equivalents	(652)	(11,157)
Net increase in cash and cash equivalents	454,208	247,910
Cash and cash equivalents, at beginning of period	881,482	591,448
Cash and cash equivalents, at end of period	$ 1,335,690	$ 839,358

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. In September 2023, the European Commission, or EC, granted marketing authorization for this therapy under the trade name Enrylaze;
- **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. 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 audited 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 audited consolidated financial statements and include all adjustments, consisting only of normal recurring adjustments, considered necessary for the fair presentation of our financial position and operating results. The results for the three and nine months ended September 30, 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 meaningfully depend on oxybate revenues from both Xywav and Xyrem, there is no guarantee that we can maintain oxybate revenues at or near historical levels, or that oxybate revenues will grow. In this regard, our ability to maintain or increase oxybate revenues and realize the anticipated benefits from our investment in Xywav are subject to a number of risks and uncertainties including, without limitation, those related to the launch of Xywav for the treatment of IH in adults and adoption in that indication; competition from the recent introduction of two authorized generic, or AG, versions of high-sodium oxybate and new products, such as Avadel's Lumryz, for treatment of cataplexy and/or EDS in narcolepsy in the U.S. market, as well as potential future competition from additional AG versions of high-sodium oxybate and from generic versions of high-sodium oxybate 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 revenues 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. Federal Government 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, or the GW Acquisition, will depend, in part, on our ability to realize the anticipated benefits from the combination of 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 September 30, 2023, we had foreign exchange forward contracts with notional amounts totaling $509.9 million. As of September 30, 2023, the outstanding foreign exchange forward contracts had a net liability fair value of $14.6 million. As of September 30, 2023, we had interest rate swap contracts with notional amounts totaling $500 million. These outstanding interest rate swap contracts had an asset fair value of $9.6 million as of September 30, 2023. The counterparties to these contracts are large multinational commercial banks, and we believe the risk of nonperformance is not significant.

We are also subject to credit risk from our accounts receivable related to our product sales. We monitor our exposure within accounts receivable and record a reserve against uncollectible accounts receivable as necessary. We extend credit to pharmaceutical wholesale distributors and specialty pharmaceutical distribution companies, primarily in the U.S., and to other international distributors and hospitals. Customer creditworthiness is monitored and collateral is not required. We monitor economic conditions in certain European countries which may result in variability of the timing of cash receipts and an increase in the average length of time that it takes to collect accounts receivable outstanding. Historically, we have not experienced significant credit losses on our accounts receivable and as of September 30, 2023 and December 31, 2022, allowances on receivables were not material. As of September 30, 2023, five customers accounted for 84% of gross accounts receivable, including Express Scripts Specialty Distribution Services, Inc. and its affiliates, or ESSDS, which accounted for 45% of gross accounts receivable, McKesson Corporation and affiliates, or McKesson, which accounted for 12% of gross accounts receivable and ASD Specialty Healthcare LLC, which accounted for 12% of gross accounts receivable. As of December 31, 2022, five customers accounted for 87% of gross accounts receivable, including ESSDS, which accounted for 55% of gross accounts receivable, Cardinal Health Inc, 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, cash equivalents and investments consisted of the following (in thousands):

	September 30, 2023					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Investments
Cash	$ 366,100	$ —	$ —	$ 366,100	$ 366,100	$ —
Time deposits	560,000	—	—	560,000	310,000	250,000
Money market funds	659,590	—	—	659,590	659,590	—
Totals	$ 1,585,690	$ —	$ —	$ 1,585,690	$ 1,335,690	$ 250,000

	December 31, 2022					
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Investments
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 and investments are considered available-for-sale securities. We use the specific-identification method for calculating realized gains and losses on securities sold and include them in interest expense, net in the condensed consolidated statements of income (loss). Our investment balances represent time deposits with original maturities of greater than three months and less than one year. Interest income from available-for-sale securities was $19.2 million and $44.4 million in the three and nine months ended September 30, 2023, respectively, and $3.5 million and $4.4 million in the three and nine months ended September 30, 2022, respectively.

3. Fair Value Measurement

The following table summarizes, by major security type, our available-for-sale securities and derivative contracts as of September 30, 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):

	September 30, 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	$ 659,590	$ —	$ 659,590	$ 517,464	$ —	$ 517,464
Time deposits	—	560,000	560,000	—	30,000	30,000
Interest rate contracts	—	9,577	9,577	—	—	—
Foreign exchange forward contracts	—	1,331	1,331	—	17,356	17,356
Totals	$ 659,590	$ 570,908	$ 1,230,498	$ 517,464	$ 47,356	$ 564,820
Liabilities:						
Foreign exchange forward contracts	$ —	$ 15,964	$ 15,964	$ —	$ —	$ —
Totals	$ —	$ 15,964	$ 15,964	$ —	$ —	$ —

As of September 30, 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 interest rate and foreign exchange derivatives that are measured at fair value using observable market inputs such as forward rates, interest rates, our own credit risk as well as an evaluation of our counterparties' credit risks. Based on these inputs, the derivative assets and liabilities are classified within Level 2 of the fair value hierarchy.

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

As of September 30, 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 September 30, 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 were approximately $555 million, $1.0 billion, $1.3 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 and fluctuations in interest rates on our outstanding term loan borrowings. 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 September 30, 2023 and December 31, 2022, the notional amount of foreign exchange contracts where hedge accounting is not applied was $509.9 million and $505.0 million, respectively.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
Foreign Exchange Forward Contracts:	**2023**	**2022**	**2023**	**2022**
Loss recognized in foreign exchange gain (loss)	$ (13,549)	$ (40,331)	$ (8,921)	$ (95,536)

To achieve a desired mix of floating and fixed interest rates on our variable rate debt, we entered into interest rate swap agreements in April 2023 which are effective until April 2026. These agreements hedge contractual term loan interest rates. As of September 30, 2023, the interest rate swap agreements had a notional amount of $500.0 million. As a result of these agreements, the interest rate on a portion of our term loan borrowings is fixed at 3.9086%, plus the borrowing spread, until April 30, 2026.

The impact on accumulated other comprehensive income (loss) and earnings from derivative instruments that qualified as cash flow hedges for the three and nine months ended September 30, 2023 was as follows (in thousands):

Interest Rate Contracts:	**Three Months Ended September 30, 2023**	**Nine Months Ended September 30, 2023**
Gain recognized in accumulated other comprehensive income (loss), net of tax	$ 3,539	$ 9,218
Gain reclassified from accumulated other comprehensive income (loss) to interest expense, net of tax	(1,289)	(2,060)

Assuming no change in USD Secured Overnight Financing Rate based interest rates from market rates as of September 30, 2023, $5.1 million of gains, net of tax, recognized in accumulated other comprehensive income (loss) will be reclassified to earnings over the next 12 months.

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 in March 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 (loss).

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

Cross-Currency Interest Rate Contract:	**Nine Months Ended September 30, 2022**
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 nine months ended September 30, 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	**September 30, 2023**	**December 31, 2022**
Assets			
Derivatives designated as hedging instruments:			
Interest rate contracts	Other current assets	$ 6,896	$ —
	Other non-current assets	2,681	—
Derivatives not designated as hedging instruments:			
Foreign exchange forward contracts	Other current assets	1,331	17,356
Total fair value of derivative asset instruments		$ 10,908	$ 17,356
Liabilities			
Derivatives not designated as hedging instruments:			
Foreign exchange forward contracts	Accrued liabilities	$ 15,964	$ —

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 interest rate and foreign exchange forward contracts subject to such provisions as of September 30, 2023 (in thousands):

	September 30, 2023					
				Gross Amounts Not Offset in the Consolidated Balance Sheet		
Description	**Gross Amounts of Recognized Assets/ Liabilities**	**Gross Amounts Offset in the Consolidated Balance Sheet**	**Net Amounts of Assets/ Liabilities Presented in the Consolidated Balance Sheet**	**Derivative Financial Instruments**	**Cash Collateral Received (Pledged)**	**Net Amount**
Derivative assets	$ 10,908	$ —	$ 10,908	$ (7,702)	$ —	$ 3,206
Derivative liabilities	(15,964)	—	(15,964)	7,702	—	(8,262)

5. Inventories

Inventories consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Raw materials	$ 25,028	$ 20,786
Work in process	457,877	517,670
Finished goods	128,922	175,605
Total inventories	$ 611,827	$ 714,061

As of September 30, 2023 and December 31, 2022 inventories included $348.1 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	12,658
Balance at September 30, 2023	$ 1,705,320

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

	September 30, 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	9.7	$ 7,577,534	$ (2,159,674)	$ 5,417,860	$ 7,491,994	$ (1,697,557)	$ 5,794,437
Manufacturing contracts	—	11,340	(11,340)	—	11,417	(11,417)	—
Trademarks	—	2,874	(2,874)	—	2,876	(2,876)	—
Total finite-lived intangible assets		$ 7,591,748	$ (2,173,888)	$ 5,417,860	$ 7,506,287	$ (1,711,850)	$ 5,794,437

The increase in the gross carrying amount of intangible assets as of September 30, 2023 compared to December 31, 2022 primarily relates to the positive impact of foreign currency translation adjustments due to the strengthening of sterling against the U.S. dollar.

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

Based on finite-lived intangible assets recorded as of September 30, 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)	$ 150,595
2024	602,379
2025	602,379
2026	602,379
2027	602,379
Thereafter	2,857,749
Total	$ 5,417,860

7. Certain Balance Sheet Items

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

	September 30, 2023	December 31, 2022
Manufacturing equipment and machinery	$ 77,865	$ 73,580
Construction-in-progress	73,286	67,385
Land and buildings	69,355	68,935
Leasehold improvements	65,994	64,776
Computer software	36,543	34,116
Computer equipment	14,967	16,424
Furniture and fixtures	9,285	10,481
Subtotal	347,295	335,697
Less accumulated depreciation and amortization	(124,819)	(107,647)
Property, plant and equipment, net	$ 222,476	$ 228,050

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

	September 30, 2023	December 31, 2022
Deferred charge for income taxes on intercompany profit	$ 209,009	$ 176,057
Other	101,395	91,135
Total other current assets	$ 310,404	$ 267,192

Accrued liabilities consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Rebates and other sales deductions	$ 323,000	$ 313,176
Employee compensation and benefits	107,890	143,243
Accrued facilities expenses	52,006	25,864
Clinical trial accruals	45,115	31,338
Accrued royalties	28,336	57,347
Accrued collaboration expenses	23,530	33,205
Accrued interest	22,200	35,614
Sales return reserve	20,150	26,164
Consulting and professional services	18,507	22,278
Current portion of lease liabilities	16,722	15,938
Derivative instrument liabilities	15,964	—
Selling and marketing accruals	14,573	18,553
Inventory-related accruals	10,746	8,565
Accrued construction-in-progress	5,167	3,298
Other	66,036	68,672
Total accrued liabilities	$ 769,942	$ 803,255

8. Debt

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

	September 30, 2023	December 31, 2022
2024 Notes	$ 575,000	$ 575,000
Unamortized - debt issuance costs	(1,493)	(2,738)
2024 Notes, net	573,507	572,262
2026 Notes	1,000,000	1,000,000
Unamortized - debt issuance costs	(7,094)	(8,932)
2026 Notes, net	992,906	991,068
Secured Notes	1,479,238	1,476,938
Term Loan	2,669,613	2,684,073
Total debt	5,715,264	5,724,341
Less current portion [(1)]	604,507	31,000
Total long-term debt	$ 5,110,757	$ 5,693,341

(1) Balance as of September 30, 2023 includes the 2024 Notes since they mature in August 2024.

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 September 30, 2023 and 2022, we recognized interest expense of $5.7 million, of which $5.0 million related to the contractual coupon rate and $0.7 million related to the amortization of debt issuance costs, respectively. During the nine months ended September 30, 2023 and 2022, we recognized interest expense of $16.8 million, of which $15.0 million related to the contractual coupon rate and $1.8 million related to the amortization of debt issuance costs, respectively.

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 September 30, 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, respectively. During the nine months ended September 30, 2023 and 2022, we recognized interest expense of $7.6 million, of which $6.4 million related to the contractual coupon rate and $1.2 million related to the amortization of debt issuance costs, respectively.

Maturities

Scheduled maturities with respect to our long-term debt principal balances outstanding as of September 30, 2023 were as follows (in thousands):

Year Ending December 31,	Scheduled Long-Term Debt Maturities
2023 (remainder)	$ 7,750
2024	606,000
2025	31,000
2026	1,031,000
2027	31,000
Thereafter	4,098,500
Total	$ 5,805,250

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 September 30, 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 Antitrust Litigation

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 April 19, 2023, the Court held a hearing on class certification in the consolidated multi-district litigation referenced above. On May 12, 2023, the Court granted the plaintiffs’ motion and preliminarily certified classes of Xyrem purchasers seeking monetary and injunctive relief. The Court excluded Xywav purchasers from the classes. Trial in this matter is scheduled for October 28, 2024.

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. On May 12, 2023, the Court granted the motion for preliminary approval of the proposed settlement.

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. On June 26, 2023, the Court granted our motions, and granted Aetna leave to further amend its complaint. On August 7, 2023, Aetna filed a motion seeking leave of the Court to file a second amended complaint. That motion was granted on November 3, 2023.

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. On July 28, 2023, the Court granted the motion for preliminary approval, which conditionally certified a class for settlement purposes. A hearing on whether final approval should be granted is scheduled for December 11, 2023.

Patent Infringement Litigation

Avadel 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, which the Court denied on July 18, 2023. The denial is not a ruling that Jazz misappropriated Avadel‘s trade secrets or breached any contract. The case will go forward in discovery and the Court instructed the parties to submit a proposed scheduling order.

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. On June 29, 2023, we filed a motion seeking leave to supplement our motion to dismiss, as well as a motion to stay discovery pending resolution of the motion to dismiss. The Court has not yet ruled on these motions. 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 November 1, 2023, the Court held a claim construction hearing relating to disputed terms in the asserted patents. The Court has not yet issued a ruling.

The Court scheduled a trial regarding our patent infringement claims against Avadel for February 26, 2024. No trial date has been set for Avadel’s trade secret misappropriation claims or Avadel’s counterclaims related to unlawful monopolization.

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.

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.

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 against Lupin.

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. On May 23, 2023, Teva 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. No trial date has been set in the case against Teva.

Alkem Patent Litigation

In April 2023, we received notice from Alkem Laboratories Ltd., or Alkem, that it has filed with FDA an ANDA, for a generic version of Xyrem. The notice from Alkem included a paragraph IV certification with respect to six of our patents listed in FDA's Orange Book for Xyrem on the date of our receipt of the notice. The asserted patents relate generally to methods of treatment when Xyrem is administered concomitantly with certain other medications.

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

On October 4, 2023, we entered into a settlement agreement with Alkem that resolves our patent litigation. Under the settlement agreement, we granted Alkem a license to manufacture, market, and sell its generic version of Xyrem on or after December 31, 2025, or earlier under certain circumstances, including circumstances where Hikma launches its own generic sodium oxybate product.

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. On May 25, 2023, we filed a motion to dismiss certain of the counterclaims, which remains pending.

The Court in the Epidiolex Patent Litigation scheduled trial for September 2025.

In June and July 2023, we received notice from certain of the Epidiolex ANDA Filers that they had each filed a paragraph IV certification regarding a newly-issued patent listed in the Orange Book for Epidiolex. On July 21, 2023, we filed an additional lawsuit against all of the Epidiolex ANDA Filers in the United States District Court for the District of New Jersey alleging that, by filing its ANDA, each Epidiolex ANDA Filer infringed the newly-issued patent related to a method of treatment using Epidiolex. The suit seeks an order that the effective date of FDA approval of each Epidiolex ANDA Filer's application shall be a date no earlier than the expiration of the newly-issued patent.

On October 24, 2023, we entered into a settlement agreement with Padagis US LLC, or Padagis, that resolved our patent litigation with Padagis related to Epidiolex. Under the settlement agreement, we granted Padagis a license to manufacture, market, and sell its generic version of Epidiolex on a date that depends on the occurrence of certain other events. The specific terms of the Padagis settlement agreement are confidential.

The settlement with Padagis does not resolve the litigation against the other nine Epidiolex ANDA Filers, which is ongoing. We cannot predict the specific timing or outcome of events in these matters with respect to the remaining defendants or the impact of developments involving any specific parties or patents on other ongoing proceedings with any specific Epidiolex ANDA Filer.

Epidiolex also has ODE for the treatment of seizures associated with LGS or DS in patients 2 years of age and older through September 28, 2025, and for the treatment of seizures associated with LGS or DS in patients between 1 and 2 years of age and for the treatment of seizures associated with TSC 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.

On July 25, 2023, we and certain other defendants filed motions to dismiss MSP's complaint, which remain pending. No trial date has been set for this matter.

FDA Litigation

On June 22, 2023, we filed a complaint in the United States District Court for the District of Columbia seeking a declaration that FDA’s approval on May 1, 2023 of the New Drug Application, or NDA, for Avadel's Lumryz was unlawful. In the complaint, we allege that FDA acted outside its authority under the Orphan Drug Act, when, despite the orphan drug exclusivity, or ODE, protecting Jazz’s low-sodium oxybate product Xywav, FDA approved the Lumryz NDA and granted Lumryz ODE based on FDA’s finding that Lumryz makes a major contribution to patient care and is therefore clinically superior to Xywav and Xyrem. Jazz further alleges that in doing so, FDA failed to follow its own regulations, failed to follow established agency policy without providing a reasoned explanation for the departure, reversed prior decisions by its own staff and experts without a reasoned explanation, and disregarded the relevant scientific literature and data. The complaint, filed pursuant to the Administrative Procedure Act, seeks to have the Court vacate and set aside FDA’s approval of the Lumryz NDA and seeks a declaration that FDA’s approval of the Lumryz NDA was arbitrary, capricious, an abuse of discretion and otherwise not in accordance with law; and that approval of the Lumryz NDA was in excess of FDA’s statutory authority and was made without observance of procedure required by law.

On September 15, 2023, we filed a motion for summary judgment. On October 20, 2023, Avadel and FDA filed cross motions for summary judgment. These motions remain pending and the Court has not set a hearing date.

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

Share Repurchase Program

In November 2016, our board of directors authorized a share repurchase program and as of September 30, 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. The timing and amount of repurchases will depend on a variety of factors, including the price of our ordinary shares, alternative investment opportunities, restrictions under the May 2021 credit agreement, corporate and regulatory requirements and market conditions. The share repurchase program may be modified, suspended or discontinued at any time without prior notice. During the nine months ended September 30, 2023, we spent a total of $170.0 million to purchase 1.3 million of our ordinary shares under the share repurchase program at an average total purchase price, including commissions, of $128.89 per share. All ordinary shares repurchased were canceled. As of September 30, 2023, the remaining amount authorized under the share repurchase program was $261.2 million, exclusive of any brokerage commissions.

Accumulated Other Comprehensive Loss

The components of accumulated other comprehensive loss as of September 30, 2023 and December 31, 2022 were as follows (in thousands):

	Net Unrealized Gain From Hedging Activities	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	9,218	82,952	92,170
Amounts reclassified from accumulated other comprehensive income (loss)	(2,060)	—	(2,060)
Other comprehensive income, net	7,158	82,952	90,110
Balance at September 30, 2023	$ 7,158	$ (1,042,557)	$ (1,035,399)

During the nine months ended September 30, 2023, other comprehensive income primarily reflects foreign currency translation adjustments, primarily due to the strengthening of the sterling against the U.S. dollar.

11. Net Income (Loss) per Ordinary Share

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Numerator:				
Net income (loss)	$ 146,820	$ (19,648)	$ 320,678	$ 16,664
Effect of interest on assumed conversions of Exchangeable Senior Notes, net of tax	5,912	—	19,951	—
Net income (loss) for dilutive net income per ordinary share	$ 152,732	$ (19,648)	$ 340,629	$ 16,664
Denominator:				
Weighted-average ordinary shares used in per share calculations - basic	63,114	62,785	63,532	62,365
Dilutive effect of Exchangeable Senior Notes	7,560	—	8,549	—
Dilutive effect of employee equity incentive and purchase plans	619	—	785	1,023
Weighted-average ordinary shares used in per share calculations - diluted	71,293	62,785	72,866	63,388
Net income (loss) per ordinary share:				
Basic	$ 2.33	$ (0.31)	$ 5.05	$ 0.27
Diluted	$ 2.14	$ (0.31)	$ 4.67	$ 0.26

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. In August 2023, we made an irrevocable election to fix the settlement method for exchanges of the 2024 Notes to a combination of cash and ordinary shares of the Company with a specified cash amount per $1,000 principal amount of the 2024 Notes of $1,000. As a result, the assumed issuance of ordinary shares upon exchange of the 2024 Notes has only been included in the calculation of diluted net income per ordinary share in the three and nine months ended September 30, 2023 up to the date the irrevocable election was made. 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 and nine months ended September 30, 2022.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Employee equity incentive and purchase plans	2,501	2,194	3,091	1,904
Exchangeable Senior Notes	—	9,044	—	9,044

12. Revenues

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Xywav	$ 331,633	$ 255,936	$ 935,958	$ 677,041
Xyrem	125,110	256,039	463,009	772,957
Epidiolex/Epidyolex	213,711	196,218	604,846	529,400
Sativex	4,627	3,220	14,531	12,104
Sunosi[1]	—	—	—	28,844
Total Neuroscience	675,081	711,413	2,018,344	2,020,346
Rylaze	104,859	73,513	292,479	200,687
Zepzelca	77,994	70,320	215,523	197,943
Defitelio/defibrotide	47,730	49,452	132,917	153,637
Vyxeos	29,827	30,067	100,583	97,714
Total Oncology	260,410	223,352	741,502	649,981
Other	2,907	1,001	9,758	3,576
Product sales, net	938,398	935,766	2,769,604	2,673,903
High-sodium oxybate AG royalty revenue	28,921	—	36,531	—
Other royalty and contract revenues	4,821	4,886	16,134	13,348
Total revenues	$ 972,140	$ 940,652	$ 2,822,269	$ 2,687,251

(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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
United States	$ 884,579	$ 867,835	$ 2,579,401	$ 2,466,758
Europe	68,971	60,024	194,198	181,831
All other	18,590	12,793	48,670	38,662
Total revenues	$ 972,140	$ 940,652	$ 2,822,269	$ 2,687,251

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
ESSDS	47 %	57 %	49 %	56 %
McKesson	12 %	10 %	11 %	11 %

Financing and payment

Our payment terms vary by the type and location of our customer but payment is generally required in a term ranging from 30 to 65 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Selling, general and administrative	$ 35,268	$ 37,435	$ 113,155	$ 108,453
Research and development	16,635	16,000	49,346	43,338
Cost of product sales	4,212	3,246	11,399	8,647
Total share-based compensation expense, pre-tax	56,115	56,681	173,900	160,438
Income tax benefit from share-based compensation expense	(9,792)	(10,715)	(29,533)	(30,632)
Total share-based compensation expense, net of tax	$ 46,323	$ 45,966	$ 144,367	$ 129,806

Restricted Stock Units

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
RSUs granted (in thousands)	91	64	1,728	2,014
Grant date fair value	$ 134.33	$ 153.75	$ 145.05	$ 152.45

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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
PRSUs granted (in thousands)	13	2	270	287
Grant date fair value	$ 142.65	$ 176.58	$ 157.01	$ 179.10

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 September 30, 2023, compensation cost not yet recognized related to unvested RSUs, PRSUs, ESPP and share options was $351.8 million, $44.1 million, $6.0 million and $3.3 million, respectively, which is expected to be recognized over a weighted-average period of 2.6 years, 1.4 years, 1.1 years and 0.7 years, respectively.

14. Income Taxes

Our income tax benefit was $47.2 million and $86.8 million for the three and nine months ended September 30, 2023, compared to an income tax benefit of $43.0 million and $58.6 million for the same periods 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 and patent box benefits. Our effective tax rate was (47.4)% and (36.7)% for the three and nine months ended September 30, 2023 compared to effective tax rates of 71.6% and 178.7% for the same periods of 2022. The increase in the income tax benefit for the three and nine months ended September 30, 2023, resulted primarily from the mix of pre-tax income and losses across tax jurisdictions partially offset by the impairment of our acquired in-process research and development asset in 2022. We do not provide for Irish income taxes on undistributed earnings of our foreign operations that are intended to be indefinitely reinvested in our foreign subsidiaries.

Our net deferred tax liability is primarily related to acquired intangible assets, and is net of deferred tax assets related to U.S. federal and state tax credits, U.S. federal and state and foreign net operating loss carryforwards and other temporary differences. We maintain a valuation allowance against certain 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 $23.7 million, translated at the foreign exchange rate as September 30, 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 disclosed in Part II, Item 1A of our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2023. 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 portfolio of durable, highly differentiated products;
- 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.
	Treatment of cataplexy in patients with narcolepsy.	May 2023	Canada
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, EEA**, 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.
Rylaze® (crisantaspase recombinant)	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
Enrylaze® (recombinant crisantaspase)	A component of a multi-agent chemotherapeutic regimen for the treatment of ALL and LBL in adult and pediatric patients (1 month and older) who have developed hypersensitivity or silent inactivation to E. coli-derived asparaginase.	September 2023	EU
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, EEA**, 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.
Defitelio® (defibrotide sodium)	Treatment of severe hepatic VOD, also known as SOS, following HSCT therapy.	July 2017	Canada, Brazil
Defitelio® (defibrotide)	Treatment of haptic SOS (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 with myelodysplasia-related changes, or AML-MRC, in adults and pediatric patients one year and older.	August 2017	U.S.
Vyxeos® liposomal 44 mg/100 mg powder for concentrate for solution for infusion	Treatment of adults with newly-diagnosed t-AML or AML-MRC.	August 2018	EU, 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

**European Economic Area

***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.

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 the 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 remains 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 third quarter of 2023, there were approximately 12,050 patients taking Xywav, including approximately 9,500 patients with narcolepsy and approximately 2,550 patients with IH.

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, or EC, 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 25/25/50 mg/m^2, 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. In September 2023, the EC granted marketing authorization for JZP458 under the trade name Enrylaze.

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. In collaboration with F. Hoffmann-La Roche Ltd., or 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 severe VOD, or sVOD, 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, while HSCT procedures are gradually returning to pre-pandemic numbers, we expect changes in chemotherapy regimens and the increasing use of cell therapies to potentially lower the incidence of sVOD; 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. With ongoing trends in the U.S. towards lower-intensity treatments and away from intensive chemotherapy regimens for AML, we note increasing competition from other therapeutic options as we continue to educate providers on the clinical benefits of Vyxeos in appropriate patients.

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 an ongoing Phase 3 clinical trial of Epidyolex for the treatment of LGS, DS, and TSC in Japan. We have discontinued the Phase 3 clinical trial of Epidiolex in Epilepsy with Myoclonic-Atonic Seizures based on recruitment challenges.

In December 2021 we initiated Phase 2 clinical trials for suvecaltamide, 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 suvecaltamide 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. In September 2023, the EC granted marketing authorization for JZP458 under the trade name Enrylaze.

Our development plan for Zepzelca continues to progress. 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 addition, we have an ongoing 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. We plan to initiate a rolling BLA submission for zanidatamab this year for accelerated approval in second-line biliary tract cancers, or BTC.

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 IFNα, 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 immuno-oncology. We have received clearance from FDA on the Investigational New Drug application for JZP898 and expect to initiate a Phase 1 clinical trial in 2023.

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

Product Candidates	Description
NEUROSCIENCE	
Phase 3	
Epidyolex	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)
Phase 1	
JZP324	Oxybate extended-release formulation (planned trial)
JZP441*	Potent, highly selective oral orexin-2 receptor agonist (ongoing trial)
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
Phase 3	
Zanidatamab	HER2-positive gastroesophageal adenocarcinoma, or GEA (ongoing trial)
Zepzelca	First-line extensive stage SCLC in combination with Tecentriq (collaboration with Roche) (ongoing trial) Confirmatory Study (PharmaMar study) (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 BTC (ongoing trial) (pivotal trial)
Phase 2	
Zanidatamab	HER2-expressing GEA, BTC or colorectal cancer in combination with standard first-line chemotherapy (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 + other approved therapies	R/R AML or hypomethylating agent failure MDS (MD Anderson collaboration study) (ongoing trial) De novo or relapsed/refractory, or R/R, AML (MD Anderson collaboration study) (ongoing trial)
Phase 2a	
Zanidatamab	Previously treated HER2+HR+ breast cancer in combination with palbociclib (ongoing trial)
Phase 1b/2	
Zanidatamab	First-line breast cancer and GEA (BeiGene trial) (ongoing trial)

Product Candidates	Description
Zanidatamab	HER2-expressing breast cancer in combination with ALX148 (ongoing trial)
Phase 1	
JZP815	Raf and Ras mutant tumors (acquired from Redx Pharma plc, or Redx) (ongoing trial)
Zanidatamab	Previously treated metastatic HER2-expressing cancers in combination with select antineoplastic therapies (ongoing trial)
JZP341 (long-acting *Erwinia* asparaginase)	Solid tumors (licensed from Ligand Pharmaceuticals Incorporated, or Ligand) (ongoing trial)
Vyxeos	Low intensity dosing for higher risk MDS (MD Anderson collaboration study) (ongoing trial)
Preclinical	
CombiPlex®	Hematology/oncology exploratory activities
JZP898	Conditionally-activated IFNα INDUKINE™ molecule
Undisclosed target	Ras/Raf/MAP kinase pathway (collaboration with Redx)
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 maintaining an increasingly agile and adaptable commercialization engine and strengthening our customer-focused market expertise across patients, providers and payors. We are continuously refining our approach to engaging our customers by strengthening alignment and integration across functions and across regions. This includes an 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 have increased the frequency of in-person interactions as medical congresses and healthcare practices have resumed in-person activities.

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 high-sodium oxybates, 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 meaningfully depend on oxybate revenues, there is no guarantee that we can maintain oxybate revenues at or near historical levels, or that oxybate revenues will grow in future periods.

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 face competition from a branded product for treatment of cataplexy and/or EDS in narcolepsy. Avadel's Lumryz was launched in the U.S. market in June 2023. On June 22, 2023, we filed a complaint in the United States District Court for the District of Columbia seeking a declaration that FDA's approval of the New Drug Application, or NDA, for Avadel's Lumryz was unlawful. In the complaint, we allege that FDA acted outside its authority under the Orphan Drug Act, when, despite ODE protecting Jazz's low-sodium oxybate product Xywav, FDA approved the Lumryz NDA and granted Lumryz ODE based on FDA's finding that Lumryz makes a major contribution to patient care and is therefore clinically superior to Xywav and Xyrem.

In addition, in January 2023 our oxybate products began to face competition from an 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 July 2023, an additional AG version of high-sodium oxybate entered the market, which has negatively impacted and is expected to continue to negatively impact Xyrem sales and could impact Xywav sales. Specifically, a wholly owned subsidiary of Hikma Pharmaceuticals PLC, or Hikma, launched its AG version of sodium oxybate in January 2023 and Amneal Pharmaceuticals LLC, or Amneal, launched its AG version of sodium oxybate in July 2023. Hikma has elected to continue to sell the Hikma AG product, with royalties back to us, for a total of up to four years beginning in January 2024, which election may be terminated by Hikma in accordance with the notice provisions in the agreements between the parties. We have the right to receive a meaningful royalty from Hikma on net sales of the Hikma AG product, with the royalty rate fixed for the second half of 2023. There will also be a substantial increase in the royalty rate beginning in January 2024, which will remain fixed for the duration of the agreement's term. We are also paid for supply of the Hikma AG product and reimbursed by Hikma for a portion of the services costs associated with the operation of the Xywav and Xyrem risk evaluation and mitigation strategy, or REMS, and distribution of the Hikma AG product. We also granted Hikma a license to launch its own generic sodium oxybate 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 addition, Hikma would need to set up its own REMS, which must be open to any other company seeking to commercialize a sodium oxybate product. In our settlements with 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. Amneal launched its AG version of sodium oxybate in July 2023. At this time, Amneal has rights to sell a low-single-digit percentage of historical Xyrem sales over each 6-month sales period. At this time, Lupin and Par have elected not to launch an AG product. AG products will be distributed through the same REMS, as Xywav and Xyrem. We also granted each of Amneal, Lupin and Par a license to launch its own generic sodium oxybate product under its ANDA on or after December 31, 2025, or earlier under certain circumstances, including the circumstance where Hikma elects to launch its own generic product. If Amneal, Lupin or Par elects to launch its own generic product under such circumstance, it will no longer have the right to sell an AG product. In addition, any company commercializing a generic version of high-sodium oxybate would need to establish its own REMS, or join an existing REMS operated by another company.

In the future, we expect our oxybate products to face competition 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. In addition, 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 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. Moreover, generic or AG high-sodium oxybate products or branded high-sodium oxybate entrants in narcolepsy, such as Avadel’s Lumryz, have had and may continue to have the effect of changing payor or formulary coverage of Xywav or Xyrem in favor of other products, and indirectly adversely affect sales of Xywav and Xyrem.

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 the combination of 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 biologicals 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 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, Item 1 of this Quarterly Report on Form 10-Q. It is possible that additional lawsuits will be filed against us making similar or related allegations. We cannot predict the outcome of these or potential additional lawsuits; 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.

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 Part II, Item 1A of our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2023.

Results of Operations

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

	Three Months Ended September 30,		Increase/	Nine Months Ended September 30,		Increase/
	2023	2022	(Decrease)	2023	2022	(Decrease)
Product sales, net	$ 938,398	$ 935,766	— %	$ 2,769,604	$ 2,673,903	4 %
Royalties and contract revenues	33,742	4,886	N/A(1)	52,665	13,348	N/A(1)
Cost of product sales (excluding amortization of acquired developed technologies)	102,153	133,661	(24)%	328,334	373,153	(12)%
Selling, general and administrative	308,310	358,478	(14)%	947,071	1,033,764	(8)%
Research and development	234,402	148,870	57 %	633,050	417,898	51 %
Intangible asset amortization	154,883	141,232	10 %	456,731	461,782	(1)%
Acquired in-process research and development	—	—	—	1,000	69,148	(99)%
Impairment charge	—	133,648	N/A(1)	—	133,648	N/A(1)
Interest expense, net	71,497	80,244	(11)%	219,114	214,117	2 %
Foreign exchange loss	1,377	4,649	(70)%	566	16,532	(97)%
Income tax benefit	(47,176)	(43,027)	10 %	(86,823)	(58,603)	48 %
Equity in loss (gain) of investees	(126)	2,545	(105)%	2,548	9,148	(72)%

(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 September 30,		Increase/	Nine Months Ended September 30,		Increase/
	2023	2022	(Decrease)	2023	2022	(Decrease)
Xywav	$ 331,633	$ 255,936	30 %	$ 935,958	$ 677,041	38 %
Xyrem	125,110	256,039	(51)%	463,009	772,957	(40)%
Epidiolex/Epidyolex	213,711	196,218	9 %	604,846	529,400	14 %
Sativex	4,627	3,220	44 %	14,531	12,104	20 %
Sunosi	—	—	—	—	28,844	N/A(1)
Total Neuroscience	675,081	711,413	(5)%	2,018,344	2,020,346	— %
Rylaze	104,859	73,513	43 %	292,479	200,687	46 %
Zepzelca	77,994	70,320	11 %	215,523	197,943	9 %
Defitelio/defibrotide	47,730	49,452	(3)%	132,917	153,637	(13)%
Vyxeos	29,827	30,067	(1)%	100,583	97,714	3 %
Total Oncology	260,410	223,352	17 %	741,502	649,981	14 %
Other	2,907	1,001	190 %	9,758	3,576	173 %
Product sales, net	938,398	935,766	— %	2,769,604	2,673,903	4 %
High-sodium oxybate AG royalty revenue	28,921	—	N/A(2)	36,531	—	N/A(2)
Other royalty and contract revenues	4,821	4,886	(1)%	16,134	13,348	21 %
Total revenues	$ 972,140	$ 940,652	3 %	$ 2,822,269	$ 2,687,251	5 %

(1) Divestiture of Sunosi U.S. was completed in May 2022
(2) Comparison to prior period not meaningful

Product Sales, Net

Xywav product sales increased in the three and nine months ended September 30, 2023 compared to the same periods in 2022, primarily due to increased sales volumes of 24% and 33% in the respective periods and, to a lesser extent, a higher selling price. We continue to see strong Xywav adoption 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. Exiting the quarter there were 9,500 narcolepsy patients taking Xywav for narcolepsy and 2,550 taking Xywav for IH, an increase of approximately 18% and 76%, respectively, compared to the same period in 2022. Xyrem product sales decreased in the three and nine months ended September 30, 2023 compared to the same periods in 2022, primarily due to decreased sales volumes of 57% and 45% in the respective periods, reflecting the strong adoption of Xywav by existing Xyrem patients and the availability of high-sodium oxybate competition, partially offset by a higher selling price. Epidiolex/Epidyolex product sales increased in the three and nine months ended September 30, 2023 compared to the same periods in 2022, respectively, primarily due to increased sales volumes of 10% and 15% in the respective periods due to increased demand and expansion in European markets.

Rylaze product sales increased in the three and nine months ended September 30, 2023 compared to the same periods in 2022, primarily due to increased sales volumes of 43% and 42% in the respective periods and, to a lesser extent, a higher selling price, offset by higher gross to net deductions. The increased volumes reflect the significant unmet patient need for a high-quality, reliable supply of Erwinia asparaginase for patients with ALL. Zepzelca product sales increased in the three and nine months ended September 30, 2023 compared to the same periods in 2022, primarily due to increased sales volumes and a higher selling price, offset by higher gross to net deductions. Defitelio/defibrotide product sales decreased in the three and nine months ended September 30, 2023 compared to the same periods in 2022, primarily due to a decrease in sales volumes, partially offset by a higher average selling price. Vyxeos product sales in the three months ended September 30, 2023 were in line with the same period in 2022, as higher gross to net deductions and to a lesser extent, a decrease in sales volumes, were offset by a higher average selling price and the positive impact of foreign exchange rates. Vyxeos product sales increased in the nine months ended September 30, 2023 compared to the same period in 2022, primarily due to a higher average selling price and an increase in sales volumes, partially offset by higher gross to net deductions.

We expect total product sales will increase in 2023 over 2022. The increase is primarily due to higher product sales of Xywav due to continuing growth of new prescribers in IH, transition of narcolepsy patients to Xywav from Xyrem and adoption of Xywav by oxybate-naïve patients, 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 competition.

Royalties and Contract Revenues

Royalties and contract revenues increased in the three and nine months ended September 30, 2023 compared to the same periods in 2022, primarily due to royalty revenue received from Hikma on net sales of their high-sodium oxybate AG. We expect royalties and contract revenues to increase in 2023 compared to 2022, primarily due to increased royalty revenues arising from the launch of high-sodium oxybate AGs.

Cost of Product Sales

Cost of product sales decreased in the three and nine months ended September 30, 2023 compared to the same periods in 2022, primarily due to a reduction in the acquisition accounting inventory fair value step-up expense, or fair value step-up expense, offset by changes in product mix. Gross margin as a percentage of net product sales was 89.1% and 88.1% for the three and nine months ended September 30, 2023 compared to 85.7% and 86.0% for the same periods in 2022. We expect our cost of product sales to decrease in 2023 compared to 2022 primarily driven by a reduction in the fair value step-up expense.

Selling, General and Administrative Expenses

Selling, general and administrative expenses decreased in the three months ended September 30, 2023 compared to the same period in 2022, primarily due to the inclusion of restructuring costs of $22.2 million and program termination costs of $21.2 million in the three months ended September 30, 2022, and a reduction in compensation related expenses. Selling, general and administrative expenses decreased in the nine months ended September 30, 2023 compared to the same period in 2022, primarily due to the inclusion of costs related to the disposal of Sunosi of $49.5 million, restructuring costs of $22.2 million and transaction and integration expenses related to the acquisition of GW of $21.1 million in the nine months ended September 30, 2022, together with a decrease in compensation related expenses, partially offset by higher litigation related expenses in the 2023 period.

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Clinical studies and outside services	$ 140,036	$ 57,115	$ 366,659	$ 170,694
Personnel expenses	65,945	59,123	192,435	170,728
Milestone expense	5,000	752	5,500	6,252
Restructuring expenses	—	11,891	—	11,891
Other	23,421	19,989	68,456	58,333
Total	$ 234,402	$ 148,870	$ 633,050	$ 417,898

Research and development expenses increased by $85.5 million and $215.2 million, respectively, in the three and nine months ended September 30, 2023, compared to the same periods in 2022. Clinical studies and outside services costs increased in the three and nine months ended September 30, 2023, compared to the same periods in 2022, primarily due to the inclusion of costs related to zanidatamab, and, to a lesser extent, JZP441, JZP385 and JZP150, partially offset by a decrease in costs related to JZP458. Personnel expenses increased in the three and nine months ended September 30, 2023, compared to the same periods in 2022, primarily due to increased headcount in support of our development programs.

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.

Intangible Asset Amortization

Intangible asset amortization increased in the three months ended September 30, 2023, compared to the same period in 2022, primarily due to the impact of foreign currency translation adjustments. Intangible asset amortization for the nine months ended September 30, 2023 was in line with the same period in 2022. Intangible asset amortization for 2023 is expected to be in line with 2022.

Acquired In-Process Research and Development

Acquired in-process research and development, or IPR&D, expense in the nine months ended September 30, 2022 primarily related to the upfront payments made in connection with our licensing agreements with Sumitomo and Werewolf of $50.0 million and $15.0 million, respectively.

Impairment charge

In the three and nine months ended September 30, 2022, we recorded an IPR&D asset impairment charge of $133.8 million as a result of the decision to discontinue our nabiximols program.

Interest Expense, Net

Interest expense, net decreased by $8.7 million in the three months ended September 30, 2023, compared to the same period in 2022, primarily driven by higher interest income on investments, offset by higher interest rates on our outstanding term loan borrowings. Interest expense, net increased by $5.0 million in the nine months ended September 30, 2023, compared to the same period in 2022, primarily driven by higher interest rates on our outstanding term loan borrowings, partially offset by higher interest income on investments and 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 nine months ended September 30, 2022. We expect interest expense, net for 2023 to increase compared to 2022 primarily due to higher interest rates on our term loan borrowings, offset by higher interest income on investments.

Foreign Exchange Loss

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

Income Tax Benefit

Our income tax benefit was $47.2 million and $86.8 million for the three and nine months ended September 30, 2023, compared to an income tax benefit of $43.0 million and $58.6 million for the same periods 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 and patent box benefits. Our effective tax rate was (47.4)% and (36.7)% for the three and nine months ended September 30, 2023 compared to effective tax rates of 71.6% and 178.7% for the same periods of 2022. The increase in the income tax benefit for the three and nine months ended September 30, 2023, resulted primarily from the mix of pre-tax income and losses across tax jurisdictions partially offset by the impairment of our acquired IPR&D asset in 2022. 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 September 30, 2023, we had cash, cash equivalents and investments of $1.6 billion, borrowing availability under our five-year $500.0 million revolving credit facility, or the Revolving Credit Facility, of $500.0 million and long-term debt principal balance of $5.8 billion. Our long-term debt included $2.7 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, or 2024 Notes. We generated cash flows from operations of $924.7 million during the nine months ended September 30, 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 fully repaid our Euro Term Loan €625.0 million, or $753.0 million and made voluntary and mandatory repayments of $300.0 million and $69.8 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, cash equivalents and investments balances, 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 has adversely affected and may continue to adversely affect sales of our oxybate products and product candidates” in Part II, Item 1A of our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2023, 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, recent and potential future bank failures 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 August 2023, 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 February 2025. 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 our credit agreement, or the Credit Agreement, that provides for (i) the Dollar Term Loan, (ii) the Euro Term Loan and, together with the Dollar Term Loan, collectively known as the Term Loan and (iii) the Revolving Credit Facility, and the indenture for the Secured Notes for certain financings.

In November 2016, our board of directors authorized a share repurchase program and as of September 30, 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. The timing and amount of repurchases will depend on a variety of factors, including the price of our ordinary shares, alternative investment opportunities, restrictions under the Credit Agreement, corporate and regulatory requirements and market conditions. The share repurchase program may be modified, suspended or discontinued at any time without prior notice. During the nine months ended September 30, 2023, we spent a total of $170.0 million to purchase 1.3 million of our ordinary shares under the share repurchase program at an average total purchase price, including commissions, of $128.89 per share. All ordinary shares repurchased were canceled. As of September 30, 2023, the remaining amount authorized under the share repurchase program was $261.2 million, exclusive of any brokerage commissions.

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

	Nine Months Ended September 30,	
	2023	**2022**
Net cash provided by operating activities	$ 924,668	$ 930,006
Net cash used in investing activities	(264,860)	(121,852)
Net cash used in financing activities	(204,948)	(549,087)
Effect of exchange rates on cash and cash equivalents	(652)	(11,157)
Net increase in cash and cash equivalents	$ 454,208	$ 247,910

Operating activities

Net cash provided by operating activities in the nine months ended September 30, 2023 was broadly in line with the same period in 2022.

Investing activities

Net cash used in investing activities increased by $143.0 million in the nine months ended September 30, 2023 compared to the same period in 2022, primarily due to the following:

- $189.0 million net increase in the acquisition of investments, driven by time deposits;
- $53.0 million upfront payment from Axsome relating to the Sunosi U.S. disposition in the nine months ended September 30, 2022; partially offset by
- $69.1 million in upfront payments for acquired IPR&D primarily driven by the $50.0 million and $15.0 million payments to Sumitomo and Werewolf, respectively, in connection with our licensing agreements in the nine months ended September 30, 2022;
- $25.0 million milestone payment to PharmaMar in relation to our first sales-based milestone for Zepzelca in the nine months ended September 30, 2022.

Financing activities

Net cash used in financing activities decreased by $344.1 million in the nine months ended September 30, 2023 compared to the same period in 2022, primarily due to:

- Repayments of long-term debt of $23.3 million in the nine months ended September 30, 2023, compared to $574.3 million in the nine months ended September 30, 2022; partially offset by
- Share repurchases of $170.0 million in the nine months ended September 30, 2023.

Debt

In August 2023, we made an irrevocable election to fix the settlement method for exchanges of the 2024 Notes to a combination of cash and ordinary shares of the Company with a specified cash amount per $1,000 principal amount of the 2024 Notes of $1,000. As a result, for the 2024 Notes exchanged subsequent to such notice, an exchanging noteholder will receive (i) up to $1,000 in cash per $1,000 principal amount of the 2024 Notes and (ii) ordinary shares of the Company, together with cash in lieu of any fractional shares, for any exchange consideration in excess of $1,000 per $1,000 principal amount of the 2024 Notes. 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 nine months ended September 30, 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 nine months ended September 30, 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 has adversely affected and may continue to 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 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 Part II, Item 1A in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2023.

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 nine months ended September 30, 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 interim 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 interim principal financial officer concluded that our disclosure controls and procedures were effective as of September 30, 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 interim 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 September 30, 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

There have been no material changes to the risk factors as previously disclosed in Part I, Item 1A in our Annual Report on Form 10-K for the year ended December 31, 2022 as supplemented by the risks and uncertainties disclosed in Part II, Item 1A in our Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2023.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchases of Equity Securities

Issuer Purchases of Equity Securities

The following table summarizes purchases of our ordinary shares made by or on behalf of us or any of our "affiliated purchasers" as defined in Rule 10b-18(a)(3) under the Securities Exchange Act of 1934, as amended, during each fiscal month during the three-month period ended September 30, 2023:

	Total Number of Shares Purchased (1)	Average Price Paid per Share (2)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (3)	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs (4)
July 1 - July 31, 2023	278,471	$ 123.62	278,471	$ 301,164,979
August 1 - August 31, 2023	34,870	$ 143.20	34,870	$ 296,171,748
September 1 - September 30, 2023	248,852	$ 140.45	248,852	$ 261,226,226
Total	562,193	$ 132.29	562,193	

1. This table does not include ordinary shares that we withheld in order to satisfy tax withholding requirements in connection with the vesting and release of restricted stock units. All the ordinary shares reported in this column were purchase pursuant to our publicly announced share repurchase program.
2. Average price paid per ordinary share includes brokerage commissions.
3. The ordinary shares reported in the table above were purchased pursuant to our publicly announced share repurchase program. On November 8, 2016, we announced that our board of directors had authorized the use of up to $300 million to repurchase our ordinary shares. In November 2018, December 2018, and October 2019, our board of directors increased the existing share repurchase program authorization by $320.0 million, $400.0 million, and $500.0 million respectively thereby increasing the total amount authorized for repurchase 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. 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. The timing and amount of repurchases will depend on a variety of factors, including the price of our ordinary shares, alternative investment opportunities, restrictions under our credit agreement, corporate and regulatory requirements and market conditions. The share repurchase program may be modified, suspended or discontinued at any time without prior notice.
4. The dollar amount shown represents, as of the end of each period, the approximate dollar value of ordinary shares that may yet be purchased under our publicly announced share repurchase program, exclusive of any brokerage commissions. The timing and amount of repurchases will depend on a variety of factors, including the price of our ordinary shares, alternative investment opportunities, restrictions under our credit agreement, corporate and regulatory requirements and market conditions, and may be modified, suspended or otherwise discontinued at any time without prior notice.

Insider Trading Arrangements

The following is a summary of the material terms of the contracts, instructions or written plans for the purchase or sale of the Company's securities adopted or terminated by our officers (as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended) and directors during the quarter ended September 30, 2023:

		Type of Trading Arrangement			
Name and Position	**Date**	**Action**	**Rule 10b5-1***	**Expiration Date**	**Total Ordinary Shares to be Sold**
Bruce C. Cozadd, Chairman and Chief Executive Officer	August 14, 2023	Adoption	X	October 31, 2024	145,484
Robert Iannone, Executive Vice President Global Head of Research and Development	August 18, 2023	Modification	X	March 8, 2024	3,507

* Contract, instruction or written plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Securities Exchange Act of 1934, as amended.

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.
4.2	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).
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 Interim Principal 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 Interim Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document - 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.

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: November 8, 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/ Patricia Carr

Patricia Carr
Senior Vice President, Chief Accounting Officer
(Principal Accounting Officer and Interim Principal Financial Officer)

Exhibit 31.1

CERTIFICATION

I, Bruce C. Cozadd, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Jazz Pharmaceuticals public limited company;

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

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

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

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

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

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

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

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

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

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

Date: November 8, 2023

By: /s/ Bruce C. Cozadd

Bruce C. Cozadd
Chairman and Chief Executive Officer and Director

Exhibit 31.2

CERTIFICATION

I, Patricia Carr, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Jazz Pharmaceuticals public limited company;

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

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

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

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

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

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

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

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

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

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

Date: November 8, 2023

By: /s/ Patricia Carr

Patricia Carr
Senior Vice President, Chief Accounting Officer
(Principal Accounting Officer and Interim Principal Financial Officer)

Exhibit 32.1

CERTIFICATION[(1)]

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. Section 1350), Bruce C. Cozadd, Chief Executive Officer of Jazz Pharmaceuticals public limited company (the “Company”), and Patricia Carr, Senior Vice President, Chief Accounting Officer and Interim Principal Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company’s Quarterly Report on Form 10-Q for the period ended September 30, 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: November 8, 2023

/s/ Bruce C. Cozadd

Bruce C. Cozadd
Chairman and Chief Executive Officer and Director (Principal Executive Officer)

/s/ Patricia Carr

Patricia Carr
Senior Vice President, Chief Accounting Officer
(Principal Accounting Officer and Interim Principal Financial Officer)

(1) This certification accompanies the Quarterly Report on Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Jazz Pharmaceuticals public limited company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing. A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to Jazz Pharmaceuticals public limited company and will be retained by Jazz Pharmaceuticals public limited company and furnished to the Securities and Exchange Commission or its staff upon request.