

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

**FORM 10-K**

**(Mark One)**

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

**For the fiscal year ended December 31, 2024**

**or**

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

**For the transition period from            to**

**Commission File Number: 001-33500**

**JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY**

**(Exact name of registrant as specified in its charter)**

**Ireland**

**(State or other jurisdiction of incorporation or organization)**

**98-1032470**

**(I.R.S. Employer Identification No.)**

**Fifth Floor, Waterloo Exchange  
Waterloo Road, Dublin 4, Ireland D04 E5W7  
011-353-1-634-7800**

**(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)**

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

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

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

**None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements.

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b).

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, as of June 28, 2024, the last business day of the registrant's most recently completed second fiscal quarter, was approximately \$6,413,308,100 based upon the last sale price reported for the registrant's ordinary shares on such date on The Nasdaq Global Select Market. The calculation of the aggregate market value of voting and non-voting common equity excludes 1,655,566 ordinary shares of the registrant held by executive officers, directors and shareholders that the registrant concluded were affiliates of the registrant on that date. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant.

As of February 19, 2025, a total of 60,732,479 ordinary shares, nominal value \$0.0001 per share, of the registrant were outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Certain information required by Part III, Items 10-14 of this Form 10-K is incorporated by reference to the registrant's definitive Proxy Statement for the 2025 Annual General Meeting of Shareholders to be filed with the Securities and Exchange Commission pursuant to Regulation 14A. If such Proxy Statement is not filed within 120 days after the end of the fiscal year covered by this Form 10-K, such information will be included in an amendment to this Form 10-K to be filed within such 120-day period.



**JAZZ PHARMACEUTICALS PLC**  
**2024 ANNUAL REPORT ON FORM 10-K**

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**Defined Terms and Products***Defined terms*

We use several terms in this Form 10-K, including but not limited to those that are finance, regulation and disease-state related as well as names of other companies, which are given below.

<b>Term</b>	<b>Description</b>
2007 Directors Award Plan	2007 Non-Employee Directors Stock Award Plan
2011 Plan	2011 Equity Incentive Plan
2015 Credit Agreement	Credit agreement dated as of June 18, 2015 (as amended) among Jazz Pharmaceuticals plc, and certain of our other subsidiaries as borrowers, the lenders party thereto and Bank of America, N.A., as administrative agent and collateral agent
2024 Notes	1.50% exchangeable senior notes due 2024
2025 Proxy Statement	definitive proxy statement for our 2025 annual general meeting of shareholders
2026 Notes	2.00% exchangeable senior notes due 2026
2030 Notes	3.125% exchangeable senior notes due 2030
340B program	U.S. Public Health Service's 340B program
ADR	administrative dispute resolution
ADS	American Depositary Shares
Aetna	Aetna Inc.
AFL Plan Lawsuit	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
AG	authorized generic
AI	artificial intelligence
Alkem	Alkem Laboratories Ltd.
ALL	acute lymphoblastic leukemia
Amended Credit Agreement	Credit Agreement amended to include the Repricing Amendment No. 1, the Repricing Amendment No. 2 and Amendment No. 3
Amended Revolving Credit Facility	Revolving credit facility amended to increase the Initial Revolving Credit Facility to \$885.0 million and extend the maturity date
Amended Revolving Facility Maturity Date	November 26, 2029
Amendment No. 3	amendment to the Credit Agreement entered into by Jazz Lux in November 2024
AML	acute myeloid leukemia
Amneal	Amneal Pharmaceuticals LLC
ANDA	abbreviated new drug application
API	active pharmaceutical ingredient
Ascent	Ascent Pharmaceuticals, Inc.
ASD	ASD Specialty Healthcare LLC
ASP	average sales price
ASU	Accounting Standards Update
Audit Committee	audit committee of our board of directors
Autifony	Autifony Therapeutics Limited
Avadel	Avadel Pharmaceuticals plc
Axsome	Axsome Therapeutics, Inc.
Azur Merger	the merger of Jazz Pharmaceuticals, Inc. and Azur Pharma in January 2012
Azur Pharma	Azur Pharma Public Limited Company
BCBS	Blue Cross and Blue Shield Association
BCBS Defendants	Roxane Laboratories, Inc., Hikma Pharmaceuticals USA Inc., Eurohealth (USA), Inc., Hikma Pharmaceuticals plc, Amneal Pharmaceuticals LLC, Par Pharmaceutical, Inc., Lupin Ltd., Lupin Pharmaceuticals Inc., and Lupin Inc.

<b>Term</b>	<b>Description</b>
BCBS Lawsuit	On June 17, 2020, a class action lawsuit was filed in the United States District Court for the Northern District of Illinois by BCBS against Company Defendants
Biophore	Biophore Pharma, Inc. and Zenara Pharma Private Ltd.
BLA	Biologics License Application
BPCIA	Biologics Price Competition and Innovation Act
BTC	biliary tract cancers
Cardinal	Cardinal Health, Inc.
CAT	Irish capital acquisitions tax
CBD	cannabidiol
Cencora	Cencora, Inc. (formerly named AmerisourceBergen Corporation)
cGMP	current Good Manufacturing Practices
CIO	Chief Information Officer
CISO	Chief Information Security Officer
City of Providence Defendants	Jazz Pharmaceuticals plc, and Roxane Laboratories, Inc., West-Ward Pharmaceuticals Corp., Hikma Labs Inc., Hikma Pharmaceuticals USA Inc., and Hikma Pharmaceuticals plc
Clinigen	Clinigen Group plc
CMS	U.S. Centers for Medicare & Medicaid Services
Code	U.S. Internal Revenue Code
CODM	chief operating decision maker
COG	Children's Oncology Group
Company Defendants	Jazz Pharmaceuticals plc, Jazz Pharmaceuticals, Inc., and Jazz Pharmaceuticals Ireland Limited
ConcERTos	Employee Resource Teams
COSO framework	Committee of Sponsoring Organizations of the Treadway Commission Internal Control - Integrated Framework (2013)
CREATES	Creating and Restoring Equal Access To Equivalent Samples Act
Credit Agreement	Credit Agreement entered into on May 5, 2021, by and among us, Jazz Lux, and certain of our other subsidiaries, as borrowers, the lenders and issuing banks from time to time party thereto, Bank of America, N.A., as administrative agent and U.S. Bank Trust Company, National Association, as collateral trustee
CSA	Federal Controlled Substances Act
DDI	drug-drug interaction
DEA	U.S. Drug Enforcement Administration
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)
DEI	diversity, equity and inclusion
DOJ	U.S. Department of Justice
Dollar Term Loan	our former seven-year \$3.1 billion term loan B facility under the Credit Agreement
DS	Dravet syndrome
DTC	Depository Trust Company
EC	European Commission
EDS	excessive daytime sleepiness
EEA	European Economic Area
EMA	European Medicines Agency
Epidiolex ANDA Filers	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.
Epidiolex Patent Litigation	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.
ESPP	employee stock purchase plan
ESSDS	Express Scripts Specialty Distribution Services, Inc.

<b>Term</b>	<b>Description</b>
ET	essential tremor
ETASU	elements to assure safe use
EU	European Union
EURIBOR	Euro Inter-Bank Offered Rate
Euro Term Loan	our now repaid seven-year €625.0 million term loan B facility under the Credit Agreement
Exchange Act	Securities Exchange Act of 1934, as amended
Exchangeable Senior Notes	our 2026 Notes and 2030 Notes
Fair value step-up expense	the acquisition accounting inventory fair value step-up expense
FASB	Financial Accounting Standards Board
FCP	Federal Ceiling Price
FCPA	U.S. Foreign Corrupt Practices Act
FDA	U.S. Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
FSS	Federal Supply Schedule pricing program
FTC	Federal Trade Commission
GDPR	EU's General Data Protection Regulation
GEA	gastroesophageal adenocarcinoma
GEHA Lawsuit	Class action lawsuits filed on June 23, 2020 against the Company Defendants and the BCBS Defendants by Government Employees Health Association Inc. in the United States District Court for the Northern District of Illinois
GHB	gamma-hydroxybutyric acid
GMP	Good Manufacturing Practice
GW	GW Pharmaceuticals plc
GW Acquisition	our acquisition of GW Pharmaceuticals plc in May 2021
GW Incentive Plans	GW Pharmaceuticals plc 2008 Long-Term Incentive Plan, GW Pharmaceuticals plc 2017 Long-Term Incentive Plan and GW Pharmaceuticals plc 2020 Long-Term Incentive Plan, each as amended from time to time
Hatch-Waxman Act	Drug Price Competition and Patent Term Restoration Act of 1984
HHS	U.S. Department of Health and Human Services
Hikma	Hikma Pharmaceuticals PLC
HIPAA	Health Insurance Portability and Accountability Act of 1996 and its implementing regulations
HRSA	Health Resources and Services Administration
HSCT	post-hematopoietic stem-cell transplantation
HTA	health technology assessment
IFN $\alpha$	interferon alpha
IH	idiopathic hypersomnia
IM	intramuscular
IND	investigational new drug application
Initial Revolving Credit Facility	our five-year \$500.0 million revolving credit facility under the Credit Agreement entered into in May 2021
Internal Revenue Code	Section 4985 of the Internal Revenue Code of 1986, as amended
InvaGen	InvaGen Pharmaceuticals, Inc., Cipla Ltd., Cipla USA, Inc., and API Pharma Tech LLC
IPR	inter partes review
IPR&D	in-process research and development
IRA	Inflation Reduction Act of 2022
IRS	U.S. Internal Revenue Service
Jazz Investments	Jazz Investments I Limited
Jazz Lux	Jazz Financing Lux S.à.r.l.
Jazz Securities	Jazz Securities Designated Activity Company

<b>Term</b>	<b>Description</b>
KRAS	Kirsten rat sarcoma virus
LBL	lymphoblastic lymphoma
LGS	Lennox-Gastaut syndrome
Ligand	Ligand Pharmaceuticals Incorporated
Lupin	Lupin Inc.
MAA	Marketing Authorization Application
MAPK	mitogen-activated protein kinase
McKesson	McKesson Corporation
MDS	Myelodysplastic Syndrome
MSN	MSN Laboratories Private, Ltd. and MSN Pharmaceuticals, Inc.
NDA	New Drug Application
New Repurchase Program	our share repurchase program announced on July 31, 2024
NHS	U.K. National Health Service
NOL	net operating loss
Non-FAMP	non-federal average manufacturer price
ODE	Orphan Drug Exclusivity in the U.S.
OECD	Organization for Economic Co-operation and Development
OIG	Office of Inspector General of the U.S. Department of Health and Human Services
Old Repurchase Program	our share repurchase program authorized by our board of directors in November 2016
OME	orphan market exclusivity in the EU
Orange Book	FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations"
Otsuka	Otsuka Pharmaceutical Co., Ltd
Padagis	Padagis US LLC
Par	Par Pharmaceutical, Inc.
Patheon	Patheon Pharmaceuticals Inc., together with its affiliates
Patheon Agreement	our Master Manufacturing Services Agreement with Patheon
PBL	Porton Biopharma Limited
PBMs	pharmacy benefit managers
PDUFA	Prescription Drug User Fee Act
Pfenex	Pfenex, Inc.
PharmaMar	Pharma Mar, S.A.
Pillar Two	the OECD framework proposal to implement a two-pillar plan on global tax reform, including a global minimum tax rate of 15% for large multinational corporations on a jurisdiction-by-jurisdiction basis
PRC	People's Republic of China
Protected cell	the cell of a protected cell company, which Jazz invested in in the year ended December 31, 2021
PRSUs	Performance-based restricted stock units
PRV	priority review voucher
PTAB	Patent Trial and Appeal Board of the USPTO
R&D	research and development
R/R	relapsed/refractory
Redx	Redx Pharma plc
REMS	risk evaluation and mitigation strategy
Repricing Amendment No.1	amendment to the Credit Agreement entered into by Jazz Lux in January 2024
Repricing Amendment No.2	amendment to the Credit Agreement entered into by Jazz Lux in July 2024
RFC	Request for Comment
RK Pharma	RK Pharma, Inc., Apicore US LLC, Archis Pharma LLC, Vgyaan Pharmaceuticals LLC

<b>Term</b>	<b>Description</b>
RLD	reference listed drug
Roche	F. Hoffmann-La Roche Ltd
RSUs	restricted stock units
RTOR	Real-Time Oncology Review
sBLA	supplemental Biologics License Application
SCLC	small cell lung cancer
SEC	U.S. Securities and Exchange Commission
Secured Notes	our issued \$1.5 billion in aggregate principal amount of 4.375% senior secured notes, due 2029
Self-Insured Schools Lawsuit	On August 14, 2020, a 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
Siegfried	Siegfried USA, LLC and its European affiliates
Simtra	Simtra Biopharma Solutions
SmPC	Summary of Product Characteristics
sNDA	supplemental New Drug Application
Sumitomo	Sumitomo Pharma Co., Ltd
Sunshine provisions	Physician Payment Sunshine Act
sVOD	severe VOD
T-DXd	trastuzumab deruxtecan
Taro	Taro Pharmaceutical Industries Ltd.
TCA	EU-U.K. Trade and Cooperation Agreement
Term SOFR	U.S. dollar Secured Overnight Financing Rate
Teva	Teva Pharmaceuticals, Inc.
Tranche B-1 Dollar Term Loans	upon entry into the Repricing Amendment No.1, the then outstanding Dollar Term Loan was refinanced into a new tranche of U.S. dollar term loans
Tranche B-2 Dollar Term Loans	upon entry into the Repricing Amendment No.2, the then outstanding Tranche B-1 Dollar Term Loans were refinanced into a new tranche of U.S. dollar term loans
Tricare program	Tricare Retail Pharmacy program
TSC	tuberous sclerosis complex
TSR	total shareholder return
U.K. Bribery Act	U.K. Bribery Act of 2010
U.S. GAAP	U.S. generally accepted accounting principles
UFCW Defendants	Jazz Pharmaceuticals Ireland Ltd., Jazz Pharmaceuticals, Inc., Roxane Laboratories, Inc., Hikma Pharmaceuticals plc, Eurohealth (USA), Inc. and West-Ward Pharmaceuticals Corp.
UFCW Lawsuit	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 the UFCW Defendants
UHS Lawsuit	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.
USPTO	U.S. Patent and Trademark Office
VA	U.S. Department of Veterans Affairs
VOD	veno-occlusive disease
WAC	Wholesale Acquisition Cost
Werewolf	Werewolf Therapeutics, Inc.
WuXi	WuXi Biologics Co., Ltd.

<b>Term</b>	<b>Description</b>
XLp	XL-protein GmbH
Zepzelca ANDA Filers	Sandoz Inc., InvaGen Pharmaceuticals, Inc., CIPLA USA, Inc. CIPLA (EU) Limited, CIPLA Limited, Zydus Lifesciences Global FZE, Zydus Pharmaceuticals (USA) Inc., Zydus Lifesciences Limited, RK Pharma, Inc., Apicore US LLC, Archis Pharma LLC, Vgyaan Pharmaceuticals LLC, MSN Pharmaceuticals Inc., and MSN Laboratories PVT. LTD.
Zymeworks	Zymeworks Inc.

### Products

The brand names of our products, our delivery devices and certain of our product candidates and their associated generic names are given below.

<b>Term</b>	<b>Description</b>
CombiPlex	CombiPlex® (delivery technology platform)
Defitelio	Defitelio® (defibrotide sodium), Defitelio® (defibrotide)
Epidiolex	Epidiolex® (cannabidiol) oral solution, Epidyolex® (the trade name in Europe and other countries outside the U.S. for Epidiolex)
Rylaze	Rylaze® (asparaginase erwinia chrysanthemi (recombinant)-rywn), Enrylaze® (the trade name in Europe and other countries outside the U.S. and Canada for Rylaze)
Sativex	Sativex® (nabiximols) oral solution
Suvecaltamide	Suvecaltamide (JZP385)
Vyxeos	Vyxeos® (daunorubicin and cytarabine) liposome for injection, Vyxeos® liposomal 44 mg/100 mg powder for concentrate for solution for infusion
Xyrem	Xyrem® (sodium oxybate) oral solution
Xywav	Xywav® (calcium, magnesium, potassium, and sodium oxybates) oral solution
Zepzelca	Zepzelca® (lurbinectedin)
Ziihera	Ziihera® (zanidatamab-hrii)

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®, Sativex® (nabiximols) oral solution and Ziihera® (zanidatamab-hrii).

This Annual Report on Form 10-K also includes trademarks, service marks and trade names of other companies. Trademarks, service marks and trade names appearing in this Annual Report on Form 10-K are the property of their respective owners.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

*This Annual Report on Form 10-K 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 beliefs and assumptions 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,” “strive,” “seek,” “designed,” “goal”, “foreseeable,” “likely,” “unforeseen” and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance, time frames or achievements to be materially different from any future results, performance, time frames or achievements expressed or implied by the forward-looking statements. We discuss many of these risks, uncertainties and other factors in greater detail under Risk Factors in Part I, Item 1A of this Annual Report on Form 10-K. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements. In addition, our goals and objectives are aspirational and are not guarantees or promises that such goals and objectives will be met. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this filing. You should read this Annual Report on Form 10-K completely and with the understanding that our actual future results 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 assume no obligation to update our forward-looking statements publicly, or to update 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.*

## SUMMARY RISK FACTORS

Below is a summary of material factors that make an investment in our ordinary shares speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found under “Risk Factors” in Part I, Item 1A of this Annual Report on Form 10-K. The below risk factor summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. You should consider carefully the risks and uncertainties described under “Risk Factors” in Part I, Item 1A of this Annual Report on Form 10-K as part of your evaluation of an investment in our ordinary shares.

- Our inability to maintain revenues 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 has adversely affected and may continue to adversely affect sales of our oxybate products.
- The distribution and sale of our oxybate products are subject to significant regulatory restrictions, including the requirements of a REMS and safety reporting requirements, and these regulatory and safety requirements subject us to risks and uncertainties, any of which could negatively impact sales of Xywav and Xyrem.
- Our inability to maintain or increase sales of Epidiolex/Epidyolex would have a material adverse effect on our business, financial condition, results of operations and growth prospects.
- While we expect Xywav 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 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 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.
- If we fail to attract, retain and motivate members of our executive management team and key personnel, our operations and our future growth may be adversely affected.

#### **NOTE REGARDING COMPANY REFERENCE**

*In this report, unless otherwise indicated or the context otherwise requires, all references to “Jazz Pharmaceuticals,” “Jazz,” “the registrant,” “we,” “us,” and “our” refer to Jazz Pharmaceuticals plc and its consolidated subsidiaries.*

## PART I

### Item 1. Business

#### 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, including leading therapies for sleep disorders and epilepsy, and a growing portfolio of cancer treatments. Our patient-focused and science-driven approach powers pioneering research and development advancements across our robust pipeline of innovative therapeutics in oncology and neuroscience.

Our strategy for growth is rooted in executing commercial launches and ongoing commercialization initiatives, advancing robust R&D programs and delivering impactful clinical results, effectively deploying capital to strengthen the prospects of achieving our short- and long-term goals through strategic corporate development, and delivering strong financial performance. We focus on patient populations with high unmet needs. We seek to 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.

Our lead marketed products, listed below, are approved in countries around the world to improve patient care.

#### Neuroscience

- **Xywav® (calcium, magnesium, potassium, and sodium oxybates) oral solution**, a product approved by FDA in July 2020, and launched in the U.S. in November 2020 for the treatment of cataplexy or EDS in patients seven years of age and older with narcolepsy, and also approved by FDA in August 2021 for the treatment of IH in adults and launched in the U.S. in November 2021. Xywav contains 92% less sodium than Xyrem®. Xywav is also approved in Canada for the treatment of cataplexy in patients with narcolepsy.
- **Epidiolex® (cannabidiol) oral solution**, a product approved by FDA and launched in the U.S. in 2018 by GW and currently indicated for the treatment of seizures associated with LGS, DS, or TSC in patients one year of age or older; in the EU and Great Britain (where it is marketed as Epidyolax®) 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.

#### 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 ALL or LBL 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 granted marketing authorization under the trade name Enrylaze. This therapy is also approved in markets including Great Britain, Canada and Switzerland.
- **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 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.
- **Ziihera® (zanidatamab-hrii)**, a product approved by FDA in November 2024 under FDA's accelerated approval pathway and launched in the U.S. in December 2024 for the treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) BTC, as detected by an FDA-approved test.

In 2024, consistent with our strategy, we continued to focus on research and development activities within our neuroscience and oncology therapeutic areas. For a summary of our ongoing research and development activities, see "Business—Research and Development" in this Part I, Item 1.

## Our Commercialized Products

### Neuroscience

**Our Sleep Products.** We are the leader in the development and commercialization of oxybate therapy for patients with sleep disorders. Xyrem was approved by FDA in 2002, and is indicated for treating cataplexy and EDS in patients seven years of age or older with 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.

**Xywav.** In July 2020, FDA approved Xywav for the treatment of cataplexy and EDS in patients seven years of age and older with narcolepsy. Narcolepsy is a chronic, debilitating neurological disorder characterized by EDS and the inability to regulate sleep-wake cycles normally. 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. Narcolepsy affects an estimated one in 2,000 people in the U.S., with symptoms typically appearing in childhood. There are five primary symptoms of narcolepsy, including EDS, cataplexy, disrupted nighttime sleep, sleep-related hallucinations, and sleep paralysis. While patients with narcolepsy may not experience all five symptoms, EDS, an essential symptom of narcolepsy, is present in all narcolepsy patients and is characterized by chronic, pervasive sleepiness as well as sudden irresistible and overwhelming urges to sleep (inadvertent naps and sleep attacks). Narcolepsy may affect many areas of life, including limiting a patient's education and employment opportunities, and may lead to difficulties at work, school, or in daily life activities like driving, operating machinery or caring for children. Patients with narcolepsy may also suffer from significant medical comorbidities in both adult and pediatric populations, including increased psychiatric comorbidity (including anxiety disorders and mood disorders), intentional self-injury, attempted suicide, suicide-related mortality, other sleep disorders (such as periodic limb movement disorder), cardiovascular disorders (such as hypertension, coronary atherosclerosis, acute myocardial infarction, and congestive heart failure), and metabolic disorders (such as obesity, metabolic syndrome and diabetes).

Cataplexy, the sudden loss of muscle tone with retained consciousness, can be one of the most debilitating symptoms of narcolepsy. Cataplexy is present in approximately 70% of patients with narcolepsy. Cataplexy can range from slight weakness or a drooping of facial muscles to the complete loss of muscle tone resulting in postural collapse. It may also impair a patient's vision or speech. Cataplexy is often triggered by strong emotions such as laughter, anger or surprise. Cataplexy can severely impair a patient's quality of life and ability to function.

Narcolepsy patients, by virtue of their diagnosis, are at increased risk of cardiovascular events and disease, and the impact of sodium on cardiovascular health is well established. There is also extensive scientific evidence that reducing sodium consumption, which is a modifiable risk factor, is associated with clinically meaningful reductions in blood pressure and cardiovascular disease risk. Therefore, we believe that reducing sodium intake compared to currently-marketed high-sodium oxybate products by 92% each day is a significant advancement for these patients. The 92% reduction of sodium translates into a reduction of approximately 1,000 to 1,500 milligrams per day for a patient prescribed high-sodium oxybate, depending on the dose. 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. When patients transition from Xyrem to Xywav, Xywav treatment is initiated at the same dose and regimen (gram for gram) and titrated as needed based on efficacy and tolerability.

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 ODE for Xywav in narcolepsy through July 21, 2027 (which was subsequently extended to January 21, 2028). Nevertheless, 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 and was launched in the U.S. market in June 2023. 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 through August 12, 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), severe sleep inertia, and prolonged and

non-restorative nighttime sleep. Although there are overlapping clinical features with other conditions, including narcolepsy, IH has its own specific diagnostic criteria. IH can significantly affect social, educational and occupational functioning. 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 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. In 2024, net product sales of Xywav were \$1,473.2 million, which represented 39% of our total net product sales for the year.

**Xyrem.** Xyrem was approved in the U.S. for the treatment of cataplexy in patients with narcolepsy in 2002 and was approved for treatment of EDS in patients with narcolepsy in 2005. In October 2018, Xyrem was also approved in the U.S. for the treatment of cataplexy or EDS in pediatric patients seven years of age and older with narcolepsy.

In 2024, net product sales of Xyrem were \$233.8 million, which represented 6% of our total net product sales for the year.

**Xywav and Xyrem REMS.** Our marketing, sales and distribution of Xywav and Xyrem in the U.S. are subject to a REMS, which is required by FDA to mitigate the risks of serious adverse outcomes resulting from inappropriate prescribing, abuse, misuse and diversion of Xywav and Xyrem. The Xywav and Xyrem REMS has the same requirements for both products. Under this REMS, all of the Xywav and Xyrem sold in the U.S. must be dispensed and shipped directly to patients or caregivers through a central pharmacy. Xywav and Xyrem may not be stocked in retail pharmacies. Physicians and patients must complete an enrollment process prior to fulfillment of Xywav and Xyrem prescriptions, and each physician and patient must receive materials concerning the serious risks associated with Xywav and Xyrem before the physician can prescribe, or a patient can receive, the product. The central certified pharmacy must monitor and report instances of patient or prescriber behavior giving rise to a reasonable suspicion of abuse, misuse or diversion of Xywav and Xyrem, and maintains enrollment and prescription monitoring information in a central database. The central pharmacy ships the product directly to the patient (or caregiver) by a courier service.

Since 2002, we have had exclusive agreements with ESSDS, the central pharmacy for Xywav and Xyrem, to distribute Xywav and Xyrem in the U.S. and provide patient support services related to Xyrem. In December 2022, we entered into new agreements with ESSDS with a two-year term and our ability to extend the term for an additional year. Our current agreements with ESSDS, which expire on December 31, 2025, may be terminated by either party at any time without cause on 180 days' prior written notice to the other party.

**Epidiolex.** We acquired Epidiolex (Epidyolex outside the U.S.) in May 2021 as part of our 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 the other approved indications, LGS and DS, to patients one year of age and older. In September 2019, the EC granted marketing authorization under the trade name Epidyolex 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 in 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 for this indication in other markets. Epidiolex/Epidyolex is also approved in markets including Switzerland, Israel, Canada, and Australia. See "Research and Development" below for a discussion of clinical development activities for Epidiolex.

LGS and DS are severe childhood-onset, drug-resistant epilepsy syndromes. LGS and DS affect approximately 35,000-50,000 and approximately 10,000 individuals in the U.S., respectively. TSC is a rare genetic disorder that causes non-malignant tumors to form in many different organs and is a leading cause of genetic epilepsy. TSC affects approximately 50,000 individuals in the U.S. Epidiolex has received ODE to treat seizures associated with LGS and DS through 2025 and TSC through 2027.

Net product sales of Epidiolex/Epidyolex in 2024 were \$972.4 million, which represented 25% of our total net product sales for the year.

### **Oncology**

**Rylaze.** Rylaze was approved by FDA in June 2021 under the RTOR program, and was launched in the U.S. in July 2021, for use as a component of a multi-agent chemotherapeutic regimen for the treatment of ALL, and 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 serum asparaginase activity throughout the entire intended course 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. See “Research and Development” below for a discussion of clinical development activities for Rylaze.

The initial approved recommended dosage of Rylaze was for an IM administration of 25 mg/m<sup>2</sup> every 48 hours. In November 2022, FDA approved an sBLA, for a Monday/Wednesday/Friday 25/25/50 mg/m<sup>2</sup> IM dosing schedule. In September 2023, the EC granted marketing authorization for JZP458 (Rylaze) under the trade name Enrylaze. Enrylaze was approved in Great Britain in January 2024, and is approved in other markets.

In 2024, net product sales of Rylaze were \$410.8 million, which represented 11% of our total net product sales for the year.

**Zepzelca.** 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. Zepzelca is an alkylating drug that binds guanine residues within DNA. This triggers a cascade of events that can affect the activity of DNA binding proteins, including some transcription factors, and DNA repair pathways, resulting in disruption of the cell cycle and eventual cell death. 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.

Our exclusive U.S. development and commercialization rights to Zepzelca were acquired through an exclusive license agreement we entered into with PharmaMar in December 2019. In October 2020, we entered into an amendment to the license agreement with PharmaMar to expand our exclusive license to include rights to develop and commercialize Zepzelca in Canada. The term of the amended license agreement extends on a licensed product-by-licensed product and country-by-country basis until the latest of: (i) expiration of the last PharmaMar patent covering Zepzelca in that country (subject to certain exclusions), (ii) expiration of regulatory exclusivity for Zepzelca in that country and (iii) 12 years after the first commercial sale of Zepzelca in that country. We have the right to terminate the amended license agreement at will upon a specified notice period, and either party can terminate the amended license agreement for the other party's uncured material breach or bankruptcy.

Zepzelca was granted orphan drug designation for adults with metastatic SCLC with disease progression on or after platinum-based chemotherapy by FDA in August 2018. In December 2019, PharmaMar submitted an NDA, to FDA for accelerated approval of Zepzelca for relapsed SCLC based on data from a Phase 2 trial, and in February 2020, FDA accepted the NDA for filing with priority review. In June 2020, FDA granted accelerated approval of Zepzelca for the treatment of adult patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy. Zepzelca is approved based on response rate and duration of response. In collaboration with Roche, we have an ongoing Phase 3 pivotal clinical trial for Zepzelca for use as maintenance therapy in first-line extensive-stage SCLC in combination with Tecentriq® (atezolizumab) following induction therapy with carboplatin, etoposide and Tecentriq. In October 2024, we announced positive top-line results from the trial showing a statistically significant and clinically meaningful benefit for Zepzelca and atezolizumab in combination in the first-line maintenance setting. We plan to submit a sNDA in the first half of 2025 to support approval of this combination in the first-line maintenance setting. In addition, our licensor PharmaMar is conducting 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 maintenance trial of Zepzelca in combination with Tecentriq or the PharmaMar trial could serve to confirm clinical benefit of Zepzelca and support full approval in the U.S. See “Research and Development” below for a discussion of clinical development activities for Zepzelca.

In 2024, net product sales of Zepzelca were \$320.3 million, which represented 8% of our total net product sales for the year.

**Ziihera.** We acquired our exclusive development and commercialization rights to Ziihera in 2022 through a licensing agreement with a subsidiary of Zymeworks providing development and commercialization rights to zanidatamab across all indications in the U.S., Europe, Japan and all other territories except for those Asia/Pacific territories previously licensed by Zymeworks. The term of the license agreement extends on a licensed product-by-licensed product and country-by-country basis until the expiration of the royalty term for such licensed product in such country. We have the right to terminate the license agreement at will upon a specified notice period, and either party can terminate the license agreement for the other party's uncured material breach or bankruptcy.

Ziihera is a bispecific HER2-directed antibody that binds to two extracellular sites on HER2. Binding of zanidatamab-hrii with HER2 results in internalization leading to a reduction of the receptor on the tumor cell surface. In the U.S., Ziihera is indicated for the treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) BTC, as detected by an FDA-approved test. Ziihera was launched in December 2024.

In 2024, net product sales of Ziihera were \$1.1 million, which represented less than 1% of our total net product sales for the year.

***Revenue Diversification***

As part of our objective to build a durable, growing commercial portfolio and reduce business risk by diversifying our revenue sources, we have been actively seeking to expand our commercial portfolio through a combination of launching internally developed therapies and commercial assets or investigational therapies acquired through corporate development. In 2020, 74% of total revenue was generated by one product, the high-sodium oxybate Xyrem. For the year ended December 31, 2024, 11% of total revenue was generated by Xyrem plus high-sodium oxybate AG royalty revenue.

Our lead marketed products, listed below, are approved in countries around the world to improve patient care.

<b>Product</b>	<b>Indications</b>	<b>Initial Approval Date</b>	<b>Markets</b>
<b>NEUROSCIENCE</b>			
Xywav® (calcium, magnesium, potassium, and sodium oxybates)	Treatment of cataplexy or EDS in patients seven years of age and older with narcolepsy.	July 2020	U.S.
	Treatment of IH in adults.	August 2021	U.S.
	Treatment of cataplexy in patients with narcolepsy.	May 2023	Canada
Epidiolex® (cannabidiol)	Treatment of seizures associated with LGS, DS, 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. <sup>1</sup>	September 2019	EU, Great Britain, EEA, Israel, Switzerland, Australia, other markets
	For adjunctive therapy of seizures associated with TSC for patients 2 years of age and older.	April 2021	EU, Great Britain, Israel and Switzerland
Epidiolex® (cannabidiol)	For adjunctive therapy of seizures associated with LGS, DS or TSC for patients 2 years of age and older.	November 2023	Canada
<b>ONCOLOGY</b>			
Rylaze® (asparaginase erwinia chrysanthemi (recombinant)-rywn)	A component of a multi-agent chemotherapeutic regimen for the treatment of ALL 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
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, Great Britain, Switzerland, other markets
Zepzelca® (lurbinectedin)	Treatment of adult patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy.	June 2020	U.S. (licensed from PharmaMar) <sup>2</sup>
	Treatment of adults with Stage III or metastatic SCLC who have progressed on or after platinum-containing therapy.	September 2021	Canada (licensed from PharmaMar) <sup>3</sup>
Ziihera® (zanidatamab-hrii)	Treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) BTC, as detected by an FDA-approved test.	November 2024	U.S. (licensed from Zymeworks) <sup>2</sup>

<sup>1</sup> The clobazam restriction limited to EU and Great Britain

<sup>2</sup> Accelerated approval received from FDA

<sup>3</sup> Conditional approval received from Health Canada

## 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 neuroscience and precision medicines in oncology. We are increasingly leveraging our growing internal research and development function, and we have also entered into collaborations with third parties for the research and development of innovative early-stage product candidates and have supported additional investigator-sponsored trials 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.

### Oncology

**Zanidatamab.** Zanidatamab is a HER2-targeted bispecific antibody that can simultaneously bind two non-overlapping epitopes of HER2, known as biparatopic binding. Zanidatamab is currently being evaluated in multiple clinical trials as a treatment for patients with HER2-expressing cancers. In November 2024, we announced that zanidatamab had been approved by FDA for treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) BTC, as detected by an FDA-approved test. We have an ongoing Phase 3 randomized clinical trial evaluating zanidatamab in combination with chemotherapy plus or minus tislelizumab as a first-line treatment for HER2-expressing GEA, an ongoing Phase 2 trial examining zanidatamab in combination with chemotherapy in first-line patients with HER2-expressing metastatic GEA and an ongoing Phase 3 trial examining zanidatamab in first-line patients with HER2-positive BTC. There are also multiple ongoing clinical trials exploring zanidatamab in breast cancer and other HER2-expressing tumor types.

**Zepzelca.** Our development plan for Zepzelca continues to progress.

In collaboration with Roche, we have an ongoing Phase 3 pivotal clinical trial in use as maintenance therapy in first-line extensive-stage SCLC of Zepzelca in combination with Tecentriq® (atezolizumab). In October 2024, we announced positive top-line results from the trial showing a statistically significant and clinically meaningful benefit for Zepzelca and atezolizumab in combination in the first-line maintenance setting. In addition, our licensor PharmaMar is conducting 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 maintenance trial of Zepzelca in combination with Tecentriq or the PharmaMar trial could serve to confirm clinical benefit of Zepzelca and support full approval in the U.S.

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.

**JZP815.** JZP815 is a pan-RAF kinase inhibitor that targets specific components of the MAPK pathway that, when activated by oncogenic mutations, can be a frequent driver of human cancer. In October 2022, we enrolled our first patient in a Phase 1 study to investigate the safety, dosing, and initial antitumor activity of JZP815 in participants with advanced or metastatic solid tumors harboring alterations in the MAPK pathway.

**JZP898.** JZP898 is a differentiated, conditionally-activated IFN $\alpha$  INDUKINE™ molecule. We acquired rights to JZP898 from Werewolf in 2022 under an exclusive, worldwide, royalty-bearing license to develop, manufacture and commercialize Werewolf's investigational WTX-613, now referred to as JZP898. In November 2023, we enrolled our first patient in a Phase 1 study to investigate the safety, tolerability, pharmacokinetics, immunogenicity and preliminary antitumor activity of JZP898 both as a monotherapy and in combination with pembrolizumab in adults with advanced/metastatic solid tumors.

### Neuroscience

**Epidiolex.** We have an ongoing Phase 3 trial of Epidiolex for LGS, DS and TSC in Japan. In August 2024, we announced top-line results from the trial. The trial did not meet the primary efficacy endpoint of a pre-specified percentage change in indication-associated seizure frequency during the treatment period (up to 16 weeks) compared to baseline in Japanese pediatric patients; however, numeric improvements were observed in the primary and several secondary endpoints. No new safety signals were observed in the trial. We are continuing to collect data in Japanese patients and plan to engage with regulatory authorities in Japan regarding a potential new drug application.

**JZP441.** JZP441 is a potent, highly selective oral orexin-2 receptor agonist with potential application for the treatment of narcolepsy, IH and other sleep disorders. In May 2022, we announced that we had entered into a licensing agreement with Sumitomo to acquire exclusive development and commercialization rights in the U.S., Europe and other territories for DSP-0187, now referred to as JZP441. Sumitomo initiated a Phase 1 trial in Japan in November 2021 to evaluate safety, tolerability and pharmacokinetics of JZP441 in healthy volunteers. In November 2022, we initiated a Phase 1 development

program to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics of JZP441 in sleep-deprived healthy volunteers. In November 2023, we announced that the study achieved proof of concept in healthy volunteers based on the Maintenance of Wakefulness Test and that the program was being paused as we analyzed safety findings related to visual disturbances and cardiovascular effects; no liver toxicity signals were observed. Following additional review of the trial findings and input from FDA, we plan to initiate a small Phase 1b trial of JZP441 in narcolepsy Type 1 patients in 2025. We expect data from this trial will further our understanding of JZP441 and orexin-2 receptor agonism, providing learnings that could inform potential future development efforts.

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 patients with serious sleep disorders.

**Preclinical**

Through third parties, we are also pursuing oncology and neuroscience preclinical and clinical research and development activities under a number of licensing and collaboration agreements, including with:

- XLP for rights to use XLP’s PASylation® technology to extend the plasma half-life of selected asparaginase product candidates;
- Redx for preclinical collaboration activities related to the Ras/Raf/MAP kinase pathway program that we purchased from Redx;
- We are also evaluating the use of our CombiPlex delivery technology platform in a number of therapeutic formulations and combinations in oncology as part of our internal oncology research and development activities; and
- Autifony to collaborate on discovering and developing drug candidates targeting two different ion channel targets associated with neurological disorders.

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:

<b>Product Candidates</b>	<b>Description</b>
<b>ONCOLOGY</b>	
<b>Regulatory Review</b>	
Zanidatamab	Second-line HER2-expressing BTC (under EMA review)
<b>Phase 3</b>	
Zanidatamab	First-line HER2-positive GEA (ongoing trial)
Zanidatamab	First-line HER2-positive BTC (ongoing trial)
Zanidatamab	Previously treated HER2-positive breast cancer in patients whose disease has progressed on previous T-DXd treatment (EmpowHER-BC-303) (ongoing trial)
Zepzelca	First-line maintenance for extensive-stage SCLC in combination with Tecentriq (collaboration with Roche) (ongoing trial) Confirmatory second-line trial (PharmaMar study) (ongoing trial)
Vyxeos	AML 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 (COG cooperative group study) (ongoing trial)
<b>Phase 2</b>	
Zanidatamab	HER2-expressing GEA, BTC or colorectal cancer in combination with standard first-line chemotherapy (ongoing trial)
Zanidatamab	Basket trial including HER2-positive solid tumors (DiscovHER-Pan-206) (ongoing trial)
Vyxeos	High-risk MDS (European Myelodysplastic Syndromes) (cooperative group study) (ongoing trial) Newly diagnosed untreated patients with intermediate- and high-risk AML (cooperative group study) (ongoing trial)
Vyxeos + other approved therapies	R/R AML or hypomethylating agent failure MDS (MD Anderson collaboration study) (ongoing trial) De novo or R/R AML (MD Anderson collaboration study) (ongoing trial)
<b>Phase 2a</b>	

Zanidatamab	Previously treated HER2+ HR+ breast cancer in combination with palbociclib (ongoing trial)
<b>Phase 1b/2</b>	
Zanidatamab	First-line breast cancer and GEA (BeiGene trial) (ongoing trial)
Zanidatamab	HER2-expressing breast cancer in combination with ALX148 (ongoing trial)
<b>Phase 1</b>	
JZP815	Raf and Ras mutant tumors (acquired from Redx) (ongoing trial)
Zanidatamab	Previously treated metastatic HER2-expressing cancers in combination with select antineoplastic therapies (cooperative group study) (ongoing trial)
JZP898	Conditionally-activated IFN $\alpha$ INDUKINE™ molecule in solid tumors (ongoing trial)
Vyxeos	Low intensity dosing for higher risk MDS (MD Anderson collaboration study) (ongoing trial)
<b>Preclinical</b>	
KRAS inhibitor targets	G12D selective and pan-KRAS molecules (acquired from Redx)
Undisclosed targets	Oncology
CombiPlex®	Hematology/oncology exploratory activities
<b>NEUROSCIENCE</b>	
<b>Phase 3</b>	
Epidyolex	LGS, TSC and DS (ongoing trial in Japan)
<b>Phase 1</b>	
JZP324	Oxybate extended-release formulation (planned trial)
JZP441*	Potent, highly selective oral orexin-2 receptor agonist (ongoing trial)
<b>Preclinical</b>	
Undisclosed targets	Sleep Epilepsy Other Neuroscience

\*Also known as DSP-0187 (see discussion above in this section for JZP441)

### Commercialization Activities

We have direct Jazz commercial operations in the U.S., Europe, Australia and Canada and a network of commercial distributors that represent our commercial interests in other key markets across the globe. In the U.S., our products are commercialized through a number of teams, including a team of experienced, trained sales professionals who provide education and promote Xywav, Epidiolex, Zepzelca, Rylaze, Ziihera, Vyxeos and Defitelio to healthcare providers in the appropriate specialties for each product. In addition, we have a team that interacts with payors and institutions to ensure access and coverage for the products, as well as Xyrem, and a team that distributes the products throughout the U.S. healthcare system (wholesalers, pharmacies, hospitals, and community and academic institutions) and provides patient services.

In Canada and in approved markets in Europe and Australia where we commercialize Defitelio and Vyxeos, we have a field force of hematology sales specialists. In markets where these products either are not approved or are unable to be promoted under local regulation, we have medical affairs personnel responsible for responding to medical information requests and for providing information consistent with local treatment protocols with respect to such products. In certain European markets and Australia, we have a sales team and a team of medical science liaisons supporting our commercialization of Epidyolex. In addition, we directly market Xywav, Xyrem and Rylaze in Canada.

Other commercial activities include marketing related services, pricing and access, industry analytics and insights, distribution services and commercial support services. We employ third party vendors, such as advertising agencies, market research firms and suppliers of marketing and other sales support-related services, to assist with our commercial activities. We also provide reimbursement and patient assistance support for our U.S. markets.

We intend to scale the size of our sales force as appropriate to effectively reach our target audience in the specialty markets in which we currently operate. We promote Zepzelca, Rylaze, Vyxeos, Defitelio and Ziihera to many hematology and oncology specialists who operate in the same hospitals and outpatient clinical sites, and we believe that we benefit from

operational synergies from this overlap. Continued growth of our current marketed products and the launch of any future products may require a reevaluation of our field force and support organization in and outside the U.S.

### **High Performance Organization and Human Capital Management**

We are committed to creating a high performing company where the culture embodies our corporate purpose to innovate to transform the lives of patients and reflects our key goals: (1) be a purpose-driven, people-centric, and great place to work and (2) live our core values of Integrity, Collaboration, Passion, Innovation, and Pursuit of Excellence.

*Employee Demographics.* As of December 31, 2024, Jazz employed approximately 2,800 people worldwide, of which approximately 50% were employed in the U.S. and approximately 50% were employed outside the U.S., primarily in the U.K., Ireland and across the EU. As an innovative biopharmaceutical company, we have over 740 employees — representing approximately 27% of our global workforce — supporting our research and development activities. We consider our employee relations to be good.

*Company Culture.* We believe a culture rooted in purpose, centered on people, and focused on performance is key to unlocking our full potential and achieving sustainable success. By prioritizing a people-centric and performance-based approach, we aim to create a workplace where purpose fuels passion, leading to innovative solutions and exceptional business outcomes.

We aim to create an environment where our employees live our core values to unlock the full potential of our people as a key to driving business performance. We are committed to fostering an inclusive environment where all employees feel they belong, which in turn brings a variety of perspectives that drive innovation and business success. We strive to create a workplace culture that fosters the ability of our employees to be their authentic selves and contribute boldly. Our belonging and inclusion strategy includes: (1) cultivating a workforce that reflects unique backgrounds, experiences, and talents and represents the varied perspectives of the patients and customers we serve; (2) investing in talent development and ensuring equal opportunities for all; and (3) creating a culture of inclusion and belonging. As of December 31, 2024,

- 50% of our board of directors and 56% of our executive committee is diverse in terms of gender, ethnicity and/or sexual orientation.
- Women represent 55% of our global workforce and 46% at the leadership level (employees at executive director and above).
- In the U.S., people of color represent 35% of our U.S. workforce and 20% at the leadership level.

We believe an employee population that reflects the communities that we serve and a culture that fosters belonging and inclusion leads to innovation, employee engagement, and strong business performance. We have created various employee resource groups with membership open to all employees consisting of three ConcERTos, and six Affinity Forums representing the wide variety of backgrounds of our employees and providing a platform for broader company engagement and education. Our ConcERTos and Affinity Forums were established as broad self-led teams of employee volunteers with varied backgrounds and perspectives with the aim of connecting Jazz employees with similar visions and interests in inclusive, welcoming, and collaborative settings. As of the end of 2024, 37% of our global workforce were active in at least one of these groups.

While we are proud of what we have accomplished to date, we remain committed to our aspiration of providing an inclusive and high-performing workplace that is supportive of all backgrounds, including among our broader leadership.

*Employee Engagement.* We have a strong employee value proposition anchored in our shared commitment to our purpose to innovate to transform the lives of patients and their families. We believe employee engagement and the power of our employee voices is foundational to employee belonging and strong performance. We have transparent and regular communication channels with our employees consisting of many forms – including all employee meetings, regular communication messages from executive leadership, town halls, top leadership forums, pulse check feedback mechanisms and employee feedback surveys.

Our employee feedback surveys are designed to help us measure overall employee engagement as well as gather insights on other important areas of our employee experience, and we consistently achieve participation rates above 75%. We consistently have high levels of engagement as measured by employees' feelings of connection to our purpose, a sense of belonging, as well as Jazz being considered a good place to work by our employees. We continue to focus on high-performance practices we have deemed critical, such as decision-making, planning and prioritizing work, speaking up and constructive challenge, accountability, and a growth mindset. Our survey informs programs and activities aligned with achieving our corporate objectives and achieving our goal of evolving our operating culture for agility and scalability.

Our Community Beat ConcERTO is made up of employee volunteer teams that promote company culture and create a sense of belonging and camaraderie among our employees. They organize programs and engagement activities on a local level to connect employees with the company strategy and business goals, support local communities, and promote employee health

and well-being initiatives. They play a pivotal role in fostering community within our working model by engaging remote employees and maximizing connection during times together at our sites and offices.

*Growth, Development and Total Rewards.* Our talent strategy focuses on attracting the best talent, recognizing and rewarding the performance of our employees as defined by both what they accomplished and how they accomplished it, and continually developing our talent through new experiences and learning opportunities. We believe there is ample opportunity for growth and development at Jazz and there is not a one size fits all approach to growing our talent. We strive to create the best career experience for all of our employees and encourage them to have regular dialogue with their leadership to create meaningful career development plans.

Our performance management process supports our culture of continual feedback and coaching, and ongoing growth and development through new experiences and learning. We encourage all employees to have an individual development plan to outline learning and growth interests and focus areas.

We leverage digital learning platforms to provide on demand, bite-sized learning to all employees that can be accessed 24/7 on a range of topics from leadership, personal effectiveness and well-being. In addition, we provide a number of self-service learning resources via our intranet site on topics such as High-Performance Teamwork, Decision Making, Hybrid Working, and Digital Skills development. We continue to offer tuition reimbursement in our major markets aimed at growth and career development.

In 2024, we continued to focus on developing the capabilities of our Global Leadership Team (Top 80 leaders) to build leadership excellence, strengthen relationships, and encourage cross functional collaboration in pursuit of our enterprise strategic goals. Our focus in 2024 was on building people manager excellence and behaviors linked to a high-performance culture, e.g., how to create an environment where people feel able to constructively challenge one another.

Our management and leadership teams place significant focus and attention to capability development and succession planning for critical roles. We regularly review talent development and succession plans for each of our functions to successfully maintain business operations and develop a pipeline of talent.

We provide our employees with what we believe to be market competitive and locally relevant compensation and benefits that support our overarching strategy to attract, retain and reward highly talented employees in an extremely competitive and dynamic industry. This includes broad-based participation in our annual incentive plan, which rewards employees based on the company's achievement of pre-established goals (or sales targets in the case of sales incentive plans) as well as performance against their personal objectives and our long-term equity incentive plans, which fosters an ownership culture and provides eligible employees with the opportunity to share in the long-term success they help create.

Fundamental to creating a high performing company is our commitment to building and maintaining a culture of health and wellbeing throughout the organization. We do this by supporting employees and their families through access to a suite of innovative programs that inspire them to focus on their mind, body, finances and work/life balance.

- We provide a robust set of offerings centered on mental and emotional health, including resilience, stress management, mindfulness and managing clinical conditions.
- We offer programs that promote activity, healthy nutrition habits, chronic condition prevention and early detection of more serious disease/illness.
- We offer an enhanced suite of global paid leave and other time-off polices to address the differing needs of our employee population through varying stages of life, including minimum standards for new parent leave (irrespective of gender or how a family is created), family caregiver leave and bereavement leave. We offer a global volunteer day to provide employees time off with full pay to give back to their communities.
- Our Wellbeing Reimbursement Account reimburses employees for a wide array of expenses that support their overall wellbeing, empowering them to choose what is most important to them.
- In 2025, we will hold our first-ever Jazz Wellbeing Week, providing dedicated time off to all employees to focus on wellbeing and self-care.

*Employee Care.* We are committed to providing a great workplace experience where people feel invested in, valued and cared for, and a sense of belonging. We strive to enable our employees to live into our values and support one another while doing everything we can to deliver on our patient mission. Important to this are leader expectations and tools given the rise and complexity of emerging employee demands and needs – including more flexibility to address personal needs, a greater connection to understand the whole person and their lives, and creating supportive and productive work environments for people to thrive. We provide productivity and collaboration tools and resources for employees working remotely, including training and toolkits to help leaders effectively lead and manage remote teams; increased flexibility within work schedules and leave programs to support employees caring for children and others; expanded employees assistance and mindfulness programs

to help employees and their families manage anxiety, stress, and overall wellbeing; and increased investment in resources focused on inclusion and belonging.

Through direct input from employees, external insights and best practices, we developed our flexible working model; expanding the power of intentional collaboration and our ability to more effectively manage our global and highly distributed team workforce. This approach to work, called “Jazz Remix,” aims to provide eligible employees with the greatest flexibility and agility to globally connect, collaborate, innovate and perform.

*Environment, Health and Safety.* Our operations are subject to complex and increasingly stringent environmental, health and safety laws and regulations in the countries where we operate and, in particular, in Ireland, the U.K. and Italy where we have manufacturing facilities. Our manufacturing activities involve the controlled storage, use and disposal of chemicals and solvents. Environmental and health and safety authorities in Ireland, the U.K. and Italy administer laws governing, among other matters, the emission of pollutants into the air (including the workplace), the discharge of pollutants into bodies of water, the storage, use, handling and disposal of hazardous substances, the exposure of persons to hazardous substances, and the general health, safety and welfare of employees and members of the public. In certain cases, such laws, directives and regulations may impose strict liability for pollution of the environment and contamination resulting from spills, disposals or other releases of hazardous substances or waste. Costs, damages and/or fines may result from the presence, investigation and remediation of such contamination at properties currently or formerly owned, leased or operated by us or at off-site locations, including where we have arranged for the disposal of hazardous substances or waste. In addition, we may be subject to third party claims, including for natural resource damages, personal injury and property damage, in connection with such contamination.

We seek to operate our manufacturing facilities in an environmentally responsible way to protect our people, our business, our environment and the local communities in which we operate. In light of the potential impact of our business on the environment, we have adopted a number of internal environmental policies and management systems designed to manage our operations in compliance with applicable laws, directives and regulations on environmental protection and in support of environmental sustainability and local biodiversity. Our environmental policies and management systems include procedures for assessing compliance with applicable environmental laws and regulations and reporting incidents of non-compliance to applicable governmental authorities. For example, we have environmental policies governing our manufacturing facilities in Ireland, the U.K. and Italy, which demonstrate our commitment to environmental sustainability and require us to minimize resource use (e.g., energy and water) and waste generation, optimize the use of raw materials, and undertake continuous improvement in environmental performance, with an emphasis on pollution prevention.

## Competition

The biopharmaceutical industry is highly competitive. Our products compete, and our product candidates may in the future compete, with currently existing therapies, product candidates currently under development by us and others and/or future product candidates, including new chemical entities that may be safer, more effective or more convenient than our products. Any products that we develop may be commercialized in competitive markets, and our competitors, which include large global pharmaceutical companies and small research-based companies and institutions, may succeed in developing products that render our products obsolete or noncompetitive.

With respect to competition we face from generic drugs, certain U.S. state laws allow for, and in some instances in the absence of specific instructions from the prescribing physician mandate, the dispensing of generic products rather than branded products when a generic version is available. Generic competition often results in decreases in the net prices at which branded products can be sold.

In particular, our products and most advanced product candidates face or may face competition as described below:

- *Xywav and Xyrem.* Xywav and Xyrem are approved by FDA and marketed in the U.S. for the treatment of both cataplexy and EDS in both adult and pediatric patients with narcolepsy. We and others have launched products to treat EDS in narcolepsy and may in the future launch products to treat cataplexy in narcolepsy that are competitive with or disrupt the market. Xywav and Xyrem face competition from Avadel’s Lumryz, a branded product for treatment of cataplexy and/or EDS in narcolepsy. Lumryz, a once-nightly dose, high-sodium oxybate, was launched in the U.S. market in June 2023. We and Avadel are engaged in various litigation regarding Lumryz and our oxybate products. We cannot at this time predict the timing or ultimate outcome of the litigation or the impact of the litigation on our sleep products, Xywav and Xyrem. For additional information on litigation involving this matter, see “*FDA Litigation*” and “*Avadel Litigation*” in Note 13, Commitments and Contingencies-Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part IV of this Annual Report on Form 10-K.

In addition, since January 2023 our oxybate products have faced competition from AG high-sodium oxybate pursuant to a settlement agreement we entered into with an ANDA filer, and since July 2023, an additional AG version of

high-sodium oxybate from a volume-limited ANDA filer. Collectively, these AG versions of high-sodium oxybate have negatively impacted and are expected to continue to negatively impact Xyrem and Xywav sales for patients with narcolepsy. Specifically, a wholly owned subsidiary of Hikma launched its AG version of high-sodium oxybate in January 2023 and Amneal launched its AG version of high-sodium oxybate in July 2023. Hikma has elected to continue to sell the Hikma AG product, with royalties to be paid 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; the royalty rate was fixed for the second half of 2023. There was also a substantial increase in the royalty rate beginning in January 2024, which will remain fixed for the duration of the agreement's term. For a description of generic versions of sodium oxybate and/or new products for the treatment of cataplexy and/or EDS that currently compete or could in the future compete with, or otherwise disrupt the market for, Xywav and Xyrem, as well as a description of our settlement agreements with ANDA filers, see the risk factor under the heading *“The introduction of new products in the U.S. market that compete with, or otherwise disrupt the market for, our oxybate products has adversely affected and may continue to adversely affect sales of our oxybate products”* in Part I, Item 1A of this Annual Report on Form 10-K.

In addition, Xywav and Xyrem may face competition in the future from other new sodium oxybate formulations for treatment of narcolepsy. Also, in the future we expect competition from generic versions of sodium oxybate. For example, we received notices in June 2021 and February 2023, that Lupin and Teva, respectively, filed ANDAs for generic versions of Xywav. On October 13, 2023, Lupin announced that it has received tentative approval for its application to market a generic version of Xywav.

Non-oxybate products intended for the treatment of EDS or cataplexy in narcolepsy or IH (Xywav is the first and only FDA-approved therapy to treat IH), including new market entrants, even if not directly competitive with Xywav or Xyrem, could have the effect of changing treatment regimens and payor or formulary coverage of Xywav or Xyrem in favor of other products, and indirectly materially and adversely affect sales of Xywav and Xyrem. Xywav and Xyrem face competition from Sunosi, which we sold to Axsome in 2022. Xywav and Xyrem may face increased competition from new branded entrants to treat EDS or cataplexy in narcolepsy such as pitolisant, which has been approved by FDA for the treatment of both cataplexy and EDS in adult patients with narcolepsy. Harmony Biosciences has announced a phase 3 study for pitolisant for IH after receiving a refusal to file from FDA in February 2025. Other companies have announced that they have product candidates in various phases of development to treat the symptoms of narcolepsy, such as Axsome's reboxetine, and various companies are performing research on orexin agonists for the treatment of sleep disorders, including Takeda Pharmaceutical Company Limited, Merck & Co., Inc., Eisai Co., Ltd., Centessa Pharmaceuticals plc and Alkermes plc.

In addition, we are also aware that prescribers often prescribe branded or generic medications for cataplexy and IH before prescribing or instead of prescribing oxybate therapy, and that payors often require patients to try such medications before they will cover Xywav or Xyrem, even if they are not approved for this use. For example, prescribers often treat mild cataplexy with drugs that have not been approved by FDA for this indication, including tricyclic antidepressants and selective serotonin reuptake inhibitors or selective norepinephrine reuptake inhibitors. We are also aware that branded or generic stimulants may be prescribed off-label for treatment of EDS in narcolepsy. Wake-promoting agents modafinil and armodafinil, including both branded and generic equivalents, are approved for the treatment of EDS in narcolepsy and other conditions, and may be used in conjunction with or instead of Xywav or Xyrem.

- *Epidiolex*. Patients in the U.S. suffering from seizures associated with DS, LGS or TSC are treated with a variety of FDA-approved products, including clobazam, clonazepam, valproate, lamotrigine, levetiracetam, rufinamide, topiramate, ethosuximide, and zonisamide. FDA approved Zogenix, Inc.'s low-dose fenfluramine in DS in June 2020, and for LGS in March 2022. In March 2022, UCB S.A. announced that it had completed its acquisition of Zogenix. FDA approved Marinus Pharmaceuticals, Inc.'s ganaxolone for the treatment of seizures associated with cyclin-dependent kinase-like 5 deficiency disorder in March 2022. Ovid Therapeutics Inc./Takeda Pharmaceutical Company Limited, Eisai Company Limited and H Lundbeck A/S are developing therapies for treating Developmental and Epileptic Encephalopathies (includes DS and LGS). Stiripentol has been approved in Europe for several years to treat DS and was approved in 2018 by FDA. Harmony Biosciences is developing a topical formulation of CBD for which it is working with FDA on a path forward on CONNECT-FX data for Zygel in Fragile X syndrome. There are a number of public and private companies in various stages of developing genetic therapies for DS, including Stoke Therapeutics, Inc., which has an antisense oligonucleotide, STK-001, in clinical trials.

In addition, there are non-FDA approved CBD preparations being made available from companies in the medical marijuana industry, which might attempt to compete with Epidiolex. While federal law prohibits the sale and distribution of most marijuana products not approved or authorized by FDA, the vast majority of states and the

District of Columbia have legalized either CBD or marijuana for either recreational or medical use, or both. Under the U.S. Farm Bill, enacted in late 2018, certain extracts and other material derived from cannabis are no longer controlled under the CSA. However, the marketing of such products as a food, dietary supplement, or for medical purposes remains subject to FDA requirements. With respect to the marketing of CBD as a food or dietary supplement, in January 2023 FDA concluded that the existing regulatory frameworks for foods and supplements were not appropriate for CBD products and denied three citizen petitions that had asked the agency to conduct rulemaking to allow the marketing of CBD products as dietary supplements. In addition, Congressional efforts related to legalization of marijuana continue. Although our business is distinct from that of entities marketing FDA-unapproved marijuana and CBD-containing dietary supplements, future legislation or federal government action authorizing the sale, distribution, use, and insurance reimbursement of non-FDA approved marijuana or CBD products could increase competition for and adversely affect our ability to generate sales of Epidiolex and our cannabinoid product candidates.

We are aware of exploratory research into the effects of tetrahydrocannabinol, often referred to as THC, and CBD drug formulations; discovery research within the pharmaceutical industry into synthetic agonists and antagonists of CB1 and CB2 receptors; companies that supply synthetic cannabinoids and cannabis extracts to researchers for pre-clinical and clinical investigation; and various companies that cultivate cannabis plants with a view to supplying herbal cannabis or nonpharmaceutical cannabis-based formulations to patients. These activities have not been approved by FDA but may in the future compete with our products.

Moreover, we expect that Epidiolex will face competition from generic products in the future. In November and December 2022, we received notices from various ANDA filers that they have each filed with FDA an ANDA for a generic version of Epidiolex (cannabidiol) oral solution. In January 2023, we filed patent infringement suits against these ANDA filers. For a description of this litigation, see “*Epidiolex Patent Litigation*” in Note 13, Commitments and Contingencies-Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part IV of this Annual Report on Form 10-K. As a result of these lawsuits, we expect that a stay of approval of up to 30 months will be imposed by FDA on these ANDA filers.

- *Zepzelca*. Zepzelca faces competition from topotecan, which is also an approved treatment in second line SCLC in the U.S., as well as other regimens for relapsed SCLC currently recommended in compendia guidelines, including rechallenge with first line platinum chemotherapy. There are also a number of products and immunotherapies for the treatment of second line SCLC in various phases of development, including Amgen Inc.’s tarlatamab, which was approved for use in the U.S. in May 2024. Moreover, we expect that Zepzelca will face competition from generic products in the future. In July and August 2024, we received notices from various ANDA filers that they have each filed with FDA an ANDA for a generic version of Zepzelca (lurbinectedin). In September 2024, we filed patent infringement suits against these ANDA filers. For a description of this litigation, see “*Zepzelca Patent Litigation*” in Note 13, Commitments and Contingencies-Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part IV of this Annual Report on Form 10-K. As a result of these lawsuits, we expect that a stay of approval of up to 30 months will be imposed by FDA on these ANDA filers.
- *Rylaze*. Rylaze may face competition from Erwinaze in the future. Erwinaze was previously approved and commercialized by us as a treatment for ALL patients with hypersensitivity to *E. coli*-derived asparaginase. In April 2020, PBL granted Clinigen a global license for Erwinaze. However, in December 2021, Clinigen announced that FDA issued a complete response letter to PBL’s BLA for Erwinaze, indicating that the BLA cannot be approved in its current form. Outside of the U.S., Enrylaze faces competition from Erwinaze. Rylaze may also face competition from other companies who have developed or are developing new treatments for ALL. In addition, some new asparaginase treatments could reduce the rate of hypersensitivity in patients with ALL, and new treatment protocols are being developed and approved for ALL that may not include asparaginase-containing regimens, including some for the treatment of relapsed or refractory ALL patients.
- *Vyxeos*. With respect to Vyxeos, there are a number of alternative established therapies in AML. A key consideration in the treatment of AML patients is the patient’s suitability for chemotherapy. The AML patient population studied in the Vyxeos Phase 3 clinical trial supporting our NDA included 60-75 year old fit patients, or those deemed able to tolerate intensive induction chemotherapy. Prior to Vyxeos, the most widely recognized option for the treatment of newly-diagnosed t-AML and AML-MRC in fit patients was cytarabine in combination with daunorubicin, known as 7+3, which is still used today in this population, along with other intensive chemotherapy regimens, particularly in patients under the age of 60. Also, since Vyxeos was approved, several other products have been approved by FDA or are in development as treatment options for newly diagnosed AML patients eligible for intensive chemotherapy, such as targeted agents (e.g. midostaurin, enasidenib and ivosidenib), immunotherapies (e.g., gemtuzumab, ozogamicin and chimeric antigen receptor T-cell therapy), and agents disrupting leukemia cell survival (e.g., glasdegib). We are also aware of the increasing use of venetoclax combined with either a hypomethylating

agent or low-dose cytarabine, a treatment approved by FDA in newly diagnosed AML patients who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy. 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.

- *Defitelio*. Defitelio is the first and only approved treatment for patients with VOD, sVOD, or VOD with renal or pulmonary dysfunction following HSCT by regulatory authorities in the U.S., Europe, Japan and other markets. Utilization of Defitelio is in part driven by evolving treatment practices in HSCT. While there is currently no direct competition to Defitelio to treat severe VOD, changes in the types of conditioning regimens used as part of HSCT may affect the incidence of VOD diagnosis and demand for Defitelio. In December 2024, FDA accepted an ANDA for a generic version of Defitelio (defibrotide sodium). We have yet to receive notice of this ANDA filing.
- *Ziihera*. Ziihera faces competition from generic chemotherapies, including cisplatin/gemcitabine rechallenge, and other HER2 directed therapies, including Enhertu and trastuzumab.

An important part of our corporate strategy is to build a diversified product pipeline, including by acquiring or in-licensing and developing, or partnering to license and develop, additional products and product candidates that we believe are highly differentiated and have significant commercial potential. Our ability to continue to grow our product portfolio requires that we compete successfully with other pharmaceutical companies, many of which may have substantially greater financial sales and marketing resources, to acquire or in-license products and product candidates.

## Customers

In the U.S., Xywav and Xyrem are sold to one certified specialty pharmacy, ESSDS, that ships Xywav and Xyrem directly to patients. Also in the U.S., Epidiolex is sold to specialty pharmacies, wholesalers and specialty distributors. Defitelio is sold to hospital customers through subsidiary specialty distributors of McKesson. Zepzelca, Rylaze, Vyxeos and Ziihera are sold to customers through subsidiary specialty distributors of McKesson, Cencora, and Cardinal. We have distribution services agreements made in the ordinary course of business with McKesson, Cencora and Cardinal and a pharmacy services agreement with ESSDS. For more information regarding our relationship with ESSDS, see “Business—Our Commercialized Products—Xywav and Xyrem REMS” in this Part I, Item 1. Purchases are made on a purchase order basis.

In certain countries in Europe, Defitelio and Vyxeos are sold pursuant to marketing authorizations. We distribute these products through Durbin PLC, a U.K.-based wholesaler and distributor, and O&M Movianto Nederland BV, our centralized European logistics services provider, to hospitals and local wholesalers in Europe where we market these products directly and, in other markets in Europe and elsewhere where we do not market these products directly, to local distributors and wholesalers. In certain countries in Europe, Epidyolex is sold pursuant to marketing authorizations. We distribute Epidyolex through a variety of wholesalers and distributors. In countries where there is no marketing authorization, Epidyolex is available pursuant to named patient programs, temporary use authorizations or similar authorizations in accordance with local regulations controlling the medical use of unapproved products.

We commercialize and distribute Xyrem in Canada for the treatment of cataplexy in patients with narcolepsy. Xyrem is also sold in certain countries outside the U.S. and Canada by UCB under the UCB license. In July 2024, the parties agreed to terminate the UCB license. UCB has up to two years from the execution of the termination agreement to withdraw the marketing authorization for Xyrem in all applicable territories.

## Manufacturing

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

### Marketed Products

*Xywav*. Xywav is manufactured at our Athlone facility. Xywav, like Xyrem, is a Schedule III controlled substance in the U.S. The API of Xywav are the calcium, magnesium, potassium and sodium salts of gamma-hydroxybutyric acid (as gamma-hydroxybutyric acid is the API for Xyrem), which are Schedule I controlled substances in the U.S. As a result, Xywav and Xyrem are subject to regulation by the DEA under the CSA, and its manufacturing and distribution are highly restricted. Quotas from the DEA are required in order to manufacture or procure calcium, magnesium, potassium and sodium salts of gamma-hydroxybutyric acid in the U.S. For information related to DEA quota requirements, see “Business—Government

Regulation—Other Post-Approval Pharmaceutical Product Regulation—Controlled Substance Regulations” in this Part I, Item 1.

*Xyrem*. Xyrem is manufactured by us in our Athlone facility and by Patheon under the Patheon Agreement entered into with Patheon in 2015. We manufacture Xyrem in our Athlone facility for most of our U.S. commercial supply and rely on Patheon to supply Xyrem for other markets, though we are not required to purchase Xyrem exclusively from Patheon. The current term of the Patheon Agreement will expire in December 2026, subject to further automatic two-yearly extensions if Patheon is then providing manufacturing services for any product, unless either party provides prior notice of termination. In addition, we may terminate the Patheon Agreement for any reason upon 12 months’ prior written notice.

Siegfried supply sodium oxybate, the API of Xyrem, to Patheon and our Athlone facility. Although Siegfried has been our only supplier of sodium oxybate since 2012, we have the right to purchase a portion of our worldwide requirements of sodium oxybate from other suppliers. The agreement with Siegfried expires in April 2027, subject to automatic three-year extensions until either party provides advance notice of its intent to terminate the agreement. During the term of the agreement and, under certain circumstances for 18 months after the agreement terminates, Siegfried is not permitted to manufacture sodium oxybate for any other company.

*Epidiolex*. Epidiolex/Epidyolex is manufactured by us in our Kent Science Park facility in the U.K. Epidiolex is a pharmaceutical formulation comprising highly purified plant-derived CBD. We cultivate our cannabinoid plants in the U.K. under highly controlled and standardized conditions.

*Zepzelca*. Zepzelca is manufactured by Simtra. The current term of the agreement with Simtra will expire in December 2025 and will then be subject to automatic two-year extensions, unless either party provides advance notice of its intent to terminate the agreement. PharmaMar retains manufacturing rights for the API for U.S. and Canadian commercial supply of Zepzelca.

*Rylaze*. Rylaze is currently manufactured by Patheon, and the API of Rylaze is manufactured by AGC Biologics A/S. The initial term of the agreement with Patheon will expire in December 2025 and will then be subject to automatic two-year extensions, unless either party provides advance notice of its intent to terminate the agreement. The initial term of the agreement with AGC Biologics A/S will expire in October 2026 and will then be subject to automatic three-year extensions, unless either party provides advance notice of its intent to terminate the agreement.

*Vyxeos*. Vyxeos is manufactured by Simtra, which is a sole source supplier from a single site location, using our CombiPlex technology platform. CombiPlex products represent formulations with increased manufacturing complexities associated with producing drug delivery vehicles encapsulating two or more drugs that are maintained at a fixed ratio and, in the case of Vyxeos, two drugs that are co-encapsulated in a freeze-dried liposomal format. Our manufacturing agreement with Simtra expires in August 2025, subject to automatic three-year renewal terms, unless either party provides advance notice of its intent to terminate the agreement. While other contract manufacturers may be able to produce Vyxeos, the proprietary technology that supports the manufacture of Vyxeos is not easily transferable. The marketing authorization in the EU for Vyxeos also requires us to comply with certain manufacturing-related post-approval commitments.

*Defitelio*. We are our own sole supplier of, and we believe that we are currently the sole worldwide producer of, defibrotide API. We manufacture defibrotide API from porcine DNA in a single facility located in Villa Guardia, Italy. Patheon currently processes defibrotide API into its finished vial form under a specific product agreement entered into under a separate agreement with Patheon. Patheon is the sole provider of our commercial and clinical supply of Defitelio; however, we are not required to purchase Defitelio exclusively from Patheon. If Patheon does not or is not able to supply us with Defitelio for any reason, it may take time and resources to implement and execute the necessary technology transfer to another processor, and such delay could negatively impact our anticipated revenues from Defitelio and could potentially cause us to breach contractual obligations with customers or to violate local laws requiring us to deliver the product to those in need.

*Ziihera*. Ziihera is manufactured by WuXi Biologics (Hong Kong) Limited at their manufacturing site in WuXi, China. The initial term of the agreement with WuXi will expire in March 2029 and will then be subject to automatic three year extensions, unless either party provides advance notice of its intent to terminate the agreement. We have the right to appoint an alternate contract manufacturer at our discretion.

#### **Product Candidates**

For discussion of the challenges we face with respect to supply of our products and product candidates, see the risk factor under the heading “*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*” in Part I, Item 1A of this Annual Report on Form 10-K.

## Patents and Proprietary Rights

We actively seek to patent, or to acquire or obtain licenses to third party patents, to protect our products and product candidates and related inventions and improvements that we consider important to our business. We own a portfolio of U.S. and ex-U.S. patents and patent applications and have licensed rights to a number of issued patents and patent applications. Our owned and licensed patents and patent applications cover or relate to our products and product candidates, including certain formulations, used to treat particular conditions, distribution methods and methods of administration, drug delivery technologies and delivery profiles and methods of making and use. Patents extend for varying periods according to the date of the patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The patent laws of ex-U.S. countries differ from those in U.S., and the degree of protection afforded by ex-U.S. patents may be different from the protection offered by U.S. patents. In addition to patents, our products and product candidates are in some instances protected by various regulatory exclusivities. For a description of those exclusivities and their regulatory background, see “Business—Government Regulation—Marketing Exclusivity—The Hatch-Waxman Act” in this Part I, Item 1.

The patents, patent applications and regulatory exclusivities that relate to our marketed products include:

- *Xywav*. We have 15 U.S. patents that relate to Xywav. These patents expire from 2033 to 2041. In addition, we have patent applications that relate to Xywav for use in additional indications that would, if issued, expire between 2040 and 2041. Xywav has been granted ODE by FDA to treat narcolepsy through January 2028 (inclusive of six months of pediatric exclusivity) and to treat IH through August 2028. Some of our Xywav patents have been subject to patent litigation with the companies who filed ANDAs seeking to market a generic version of Xywav. For example, we received notices in June 2021 and February 2023, that Lupin and Teva, respectively, filed ANDAs for generic versions of Xywav. For additional information on litigation involving these matters, see Note 13, Commitments and Contingencies-Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part IV of this Annual Report on Form 10-K.
- *Xyrem*. We currently have seven issued patents in the U.S. relating to Xyrem listed in the Orange Book. Our patents relate to a DDI between Xyrem and divalproex sodium. In October 2018, due to FDA’s grant of pediatric exclusivity, an additional six months was added to the original expiration dates of all of our Orange Book-listed patents that existed at that time. As a result, our Orange Book-listed patents have periods of exclusivity between December 2022 (with an additional six months for pediatric exclusivity) and September 2033. Some of our Xyrem patents have been subject to patent litigation with the companies who filed ANDAs seeking to market a generic version of Xyrem, including challenge through the IPR procedures of the PTAB. The PTAB dismissed some of the IPR petitions. However, in July 2018, the United States Court of Appeals for the Federal Circuit upheld on appeal PTAB decisions finding that six patents associated with the Xywav and Xyrem REMS and three claims of a seventh REMS patent were unpatentable. As a result, we will not be able to enforce patents or claims that the PTAB found unpatentable. Although we have settled all patent litigation against the ten companies that filed ANDAs, additional companies may challenge our U.S. patents for Xyrem in the future. For a description of our Xyrem settlements, see the risk factor under the heading “The introduction of new products in the U.S. market that compete with, or otherwise disrupt the market for, our oxybate products has adversely affected and may continue to adversely affect sales of our oxybate products” in Part I, Item 1A of this Annual Report on Form 10-K. For additional information on litigation involving our Orange Book-listed patents, see “*Avadel Litigation*” in Note 13, Commitments and Contingencies-Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part IV of this Annual Report on Form 10-K.

The European Patent Office issued a method of administration patent relating to the DDI between Xyrem and divalproex sodium that expires in 2034.

- *Epidiolex*. Our patent portfolio relating to the use of CBD in the treatment of epileptic encephalopathies includes 32 issued U.S. patents listed in the Orange Book. These patents claim the use of CBD for the treatment of convulsive, drop and atonic seizures associated with both LGS and DS, an oral composition of CBD, as well as the use of CBD in combination with clobazam, and the teaching that dose adjustment may be needed when concomitantly prescribed. The patents currently listed in the Orange Book will expire between 2035 and 2041. We have filed corresponding patent applications in many jurisdictions worldwide, including Europe, U.K., Canada, Japan, Mexico, Australia and New Zealand. The USPTO has granted two patents based on data that demonstrates that Epidiolex provides a benefit over synthetic CBD in an animal model of epilepsy, which will expire in 2039 and which are listed in the Orange Book. Epidiolex has received ODE to treat seizures associated with LGS and DS through 2025 and TSC through 2027. Some of our Epidiolex patents have been subject to patent litigation with the companies who filed ANDAs seeking to market a generic version of Epidiolex. In November and December 2022, ten companies sent us notices that they had filed ANDAs seeking approval to market a generic version of Epidiolex. For additional information on litigation involving these matters, see Note 13, Commitments and Contingencies-Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part IV of this Annual Report on Form 10-K.

- *Zepzelca*. In December 2019, we entered into an exclusive license agreement with PharmaMar pursuant to which we obtained exclusive U.S. development and commercialization rights to Zepzelca. In October 2020, we entered into the amended license agreement which expanded our exclusive license to include rights to develop and commercialize Zepzelca in Canada. We have a portfolio of in-licensed U.S. and Canadian patents for lurbinectedin relating to compositions, methods of use, and processes. For example, one Orange Book listed U.S. patent (expiring in 2029, with granted patent term extension) covers a genus of compounds, including lurbinectedin, and use in treating various cancers. A request for extension (CSP) has also been filed in Canada. Zepzelca has also been granted ODE for the treatment of adults with metastatic SCLC with disease progression on or after platinum-based chemotherapy until 2027 and new chemical entity exclusivity until 2025 in the U.S. In July and August 2024, we received notices from various ANDA filers that they have each filed with FDA an ANDA for a generic version of Zepzelca (lurbinectedin). In September 2024, we filed patent infringement suits against these ANDA filers. For a description of this litigation, see “*Zepzelca Patent Litigation*” in Note 13, Commitments and Contingencies-Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part IV of this Annual Report on Form 10-K. As a result of these lawsuits, we expect that a stay of approval of up to 30 months will be imposed by FDA on these ANDA filers.
- *Rylaze*. In 2016, we obtained worldwide rights from Pfenex, including Pfenex’s patent rights relating to Rylaze, to develop and commercialize multiple early-stage hematology product candidates, including a license to two U.S. process patents relating to Rylaze, with respective expirations in 2026 and 2038. Pfenex has been acquired by Ligand. Rylaze has been granted orphan drug designation for the treatment of patients with ALL or LBL. We have two patent application families relating to dosing regimens. One covers the dosing regimen (25mg/m<sup>2</sup> intramuscularly every 48 hours), while the other covers various dosing regimens of interest. If issued, these would expire in 2040 and 2042, respectively. Another patent application relating to formulations of asparaginase would expire in 2042, if issued.
- *Vyxeos*. We have a portfolio of U.S. and ex-U.S. patents and patent applications for Vyxeos and the CombiPlex technology platform relating to various compositions and methods of making and use. These include seven U.S. patents covering Vyxeos compositions and methods of use expiring between 2025 and 2032 and two U.S. patents covering CombiPlex (which also cover Vyxeos) expiring in January 2027. These patents are listed in the Orange Book. FDA granted Vyxeos ODE for the treatment of adults with newly-diagnosed t-AML or AML-MRC, which expired in August 2024. In March 2021, FDA approved an expanded label for Vyxeos for the treatment of t-AML or AML-MRC in pediatric patients 1 year and older. In addition, Vyxeos was granted OME by the EC until August 2028, ten years from its EC approval for the treatment of adults with newly-diagnosed t-AML or AML-MRC. Vyxeos was approved by Health Canada for treatment of adults with newly diagnosed t-AML or AML-MRC in April 2021. Vyxeos was approved in March 2024 in Japan and designated as an orphan drug.
- *Defitelio*. The unique process of deriving defibrotide from porcine DNA is extensive and uses both chemical and biological processes that rely on complex characterization methods. We have U.S. and non-U.S. patents and patent applications relating to various compositions, methods of use and methods of characterization, with the issued patents expiring at various times between 2021 and 2035. Three U.S. patents are listed in the Orange Book. In December 2024, FDA accepted an ANDA for a generic version of Defitelio (defibrotide sodium). We have yet to receive notice of this ANDA filing. Defibrotide has also been granted orphan drug designation by the Korean Ministry of Food and Drug Safety to treat and prevent VOD, by the Commonwealth of Australia-Department of Health for the treatment of VOD and by the EC for the prevention of acute Graft-versus-Host Disease. We acquired the rights to defibrotide for the treatment and prevention of VOD in North America, Central America and South America from Sigma-Tau Pharmaceuticals, Inc. in 2014.
- *Ziihera*. In 2022, we obtained a license from Zymeworks BC Inc., which included rights to a portfolio of U.S. and ex-U.S. patents and patent applications, including compositions and methods of using Ziihera. The portfolio contains a U.S. composition of matter patent relating to Ziihera, which expires in 2034 (excluding any adjustments or extensions).

The patents and/or patent applications that relate to our product candidates include:

- *JZP815*. Through a collaboration agreement and an asset purchase agreement with Redx in 2019, we acquired a portfolio of U.S. and ex-U.S. patents and patent applications, including rights relating to compositions and methods of using JZP815. The portfolio contains a U.S. composition of matter patent relating to JZP815, which expires in 2035 (excluding any adjustments or extensions).
- *JZP898*. Through a license agreement with Werewolf in 2022, we obtained a license to a portfolio of U.S. and ex-U.S. patents and patent applications, including rights relating to compositions and methods of using JZP898. The portfolio contains a U.S. composition of matter patent relating to JZP898, which, if granted, expires in 2040 (excluding any adjustments or extensions).

- *Suvecaltamide (JZP385)*. Through the acquisition of Cavion in 2019, we obtained a portfolio of U.S. and ex-U.S. patents and patent applications, including rights relating to compositions and methods of using suvecaltamide. The portfolio includes a U.S. composition of matter patent relating to suvecaltamide, which expires in 2027, but which may be extended to 2032 depending on regulatory approval. A U.S. patent to the treatment of ET may provide supplemental protection to 2039.
- *JZP441*. Through a license agreement with Sumitomo in 2022, we obtained a license to a portfolio of U.S. and ex-U.S. patents and patent applications, including rights relating to compositions and methods of using JZP441. The portfolio contains a U.S. composition of matter patent relating to JZP441, which expires in 2040 (excluding any adjustments or extensions).

In addition, we have rights to a number of trademarks and service marks, and pending trademark and service mark applications, in the U.S. and elsewhere in the world to further protect the proprietary position of our products. For a discussion of the challenges we face in obtaining or maintaining patent and/or trade secret protection, see the risk factors under the heading “Risks Related to Our Intellectual Property” in Part I, Item 1A of this Annual Report on Form 10-K.

## **Government Regulation**

As a global pharmaceutical company, our activities are subject to extensive regulation in the U.S., Europe and other countries where we do business. Regulatory requirements encompass the entire life cycle of pharmaceutical products, from research and development activities to marketing approval, manufacturing, labeling, packaging, adverse event and safety reporting, storage, advertising, promotion, sale, pricing and reimbursement, recordkeeping, distribution, importing and exporting. Regulations differ from country to country and are constantly evolving.

### ***Testing and Approval of Pharmaceutical Products***

We are not permitted to market a product in a country until we receive approval from the relevant regulatory authority, such as FDA in the U.S. and the EC or the competent authorities of the EU member states. An application for marketing approval must contain information generated by the applicant, also called a sponsor, demonstrating the quality, safety and efficacy of the product candidate, including data from preclinical and clinical trials, proposed product packaging and labeling and information pertaining to product formulation and the manufacture and analytical testing of the API and the finished product.

In the U.S., FDA reviews and, if warranted, approves applications for marketing approval. The process for obtaining marketing approval in the U.S. for a drug or biologic product candidate generally includes:

- conducting preclinical laboratory and animal testing and submitting the results to FDA in an IND application requesting approval to test the product candidate in human clinical trials;
- conducting adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate in the desired indication;
- submitting an NDA, sNDA, BLA or sBLA as appropriate, to FDA seeking approval for a specific indication; and
- completing inspections by FDA of the facilities where the product candidate is manufactured, analyzed and stored to demonstrate compliance with cGMP, and any requested FDA audits of the clinical trial sites that generated the data supporting the application.

Human clinical trials conducted before approval of a product generally proceed in three sequential phases, although the phases may overlap. In Phase 1, the initial introduction of the product candidate in humans, the product candidate is typically tested to assess metabolism, pharmacokinetics, pharmacological actions and tolerability, including side effects associated with increasing doses. Phase 2 usually involves clinical trials in a limited patient population to determine the effectiveness of the product candidate for a particular indication or indications, dosage tolerance and optimum dosage and to identify common adverse effects and safety risks. If a product candidate demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2, Phase 3 clinical trials are undertaken to obtain additional information about clinical efficacy and safety in a larger number of patients. Clinical trials must be conducted in accordance with specific protocols, as well as FDA requirements related to conducting the trials and recording and reporting the results, commonly referred to as good clinical practices, to ensure that the resulting data are credible and accurate and that the trial participants are adequately protected. FDA enforces good clinical practices through periodic inspections of trial sponsors, clinical investigators and trial sites.

Once an NDA, sNDA, BLA or sBLA has been compiled and submitted, FDA performs an initial review before it accepts the application for filing. FDA may refuse to file an application and/or request additional information before acceptance. Once accepted for filing, FDA begins an in-depth review of the application. Under the current goals and policies agreed to by FDA under the PDUFA for a new molecular entity, FDA has ten months from the filing decision in which to complete its initial

review of a standard application and respond to the applicant, and six months from the filing decision for a priority application. FDA does not always meet its PDUFA goal dates, and in certain circumstances, the PDUFA goal date may be extended.

FDA also has various programs, including Fast Track, Priority Review, Breakthrough Therapy and Accelerated Approval (Subpart H and E), RTOR pilot program, that are intended to expedite the process for reviewing certain applications and/or provide for approval on the basis of surrogate endpoints or restricted distribution. Generally, products may be eligible for one or more of these programs if they are intended for serious or life-threatening diseases or conditions, have potential to address unmet medical needs, or may provide meaningful benefit over existing treatments. For example, FDA granted Vyxeos Breakthrough Therapy and Fast Track designations and granted Priority Review with respect to our NDA for Vyxeos for the treatment of t-AML and AML-MRC that was approved in August 2017. In addition, a PRV may be used to obtain priority review by FDA for one of our future regulatory submissions. We used the PRV we acquired in May 2018 to obtain priority review for our Xywav sNDA for the treatment of IH, which was approved by FDA in August 2021. In June 2020, FDA granted Accelerated Approval to Zepzelca for relapsed SCLC. In December 2020, we initiated the submission of a BLA for Rylaze for ALL under the RTOR pilot program, which was approved by FDA in June 2021.

During its review of an application, FDA evaluates whether the product demonstrates the required level of safety and efficacy for the indication for which approval is sought and conducts the inspections and audits described above. FDA may also refer an application to an advisory committee, typically a panel of clinicians, for review, evaluation and a non-binding recommendation as to whether the application should be approved. When FDA completes its evaluation, it issues either an approval letter or a complete response letter. A complete response letter generally outlines what FDA considers to be the deficiencies in the application and may indicate that substantial additional testing or information is required prior to FDA approval of the product. If and when identified deficiencies have been addressed to FDA's satisfaction after a review of the resubmission of the application FDA will issue an approval letter.

Even if a product is approved, the approval may be subject to limitations based on FDA's interpretation of the data submitted in the application. For example, as a condition of approval, FDA may require the sponsor to agree to certain post-marketing requirements, such as conducting Phase 4, or post-approval, clinical trials to gain additional safety data or to document a clinical benefit in the case of products approved under Accelerated Approval regulations. FDA's approval of the NDA for Defitelio included a number of post-marketing commitments and requirements, including the requirement that we conduct a clinical trial to analyze the safety of defibrotide versus best supportive care in the prevention of VOD in adult and pediatric patients. For its approval of Vyxeos, FDA required that we conduct a safety study to characterize infusion-related reactions in patients treated with Vyxeos and a clinical trial to determine dosing to minimize toxicity in patients with moderate and severe renal impairment. Further, FDA granted Accelerated Approval to Zepzelca for relapsed SCLC based on data from a Phase 2 trial, which approval is contingent upon verification and description of clinical benefit in a post-marketing clinical trial.

In addition, if FDA determines that a REMS is necessary to ensure that the benefits of the product outweigh the risks, a sponsor may be required to include a proposed REMS (either as part of the application or after approval), which may include a patient package insert or a medication guide to provide information to consumers about the product's risks and benefits; a plan for communication to healthcare providers; or conditions on the product's prescribing or distribution referred to as elements to assure safe use. Xywav and Xyrem are required to have a REMS. For more discussion regarding the Xywav and Xyrem REMS, see the risk factors under the headings "*The distribution and sale of our oxybate products are subject to significant regulatory restrictions, including the requirements of a REMS, and these regulatory requirements subject us to risks and uncertainties, any of which could negatively impact sales of Xywav and Xyrem*" and "Risks Related to Our Intellectual Property" in Part I, Item 1A of this Annual Report on Form 10-K.

The EU and many individual countries have regulatory structures similar to the U.S. for conducting preclinical and clinical testing and applying for marketing approval or authorization, although specifics may vary widely from country to country. Clinical trials in the EU must be conducted in accordance with the requirements of the EU Clinical Trials Regulation and applicable good clinical practice standards. In the EU, there are several procedures for requesting marketing authorization which can be more efficient than applying for authorization on a country-by-country basis. There is a "centralized" procedure allowing submission of a single marketing authorization application to EMA. If EMA issues a positive opinion, the EC will grant a centralized marketing authorization that is valid in all EU member states and three of the four European Free Trade Association countries (Iceland, Liechtenstein and Norway). The centralized procedure is mandatory for certain medicinal products, including orphan medicinal products and biotechnology-derived medicinal products, and optional for others. There is also a "decentralized" procedure allowing companies to file identical applications to several EU member states simultaneously for product candidates that have not yet been authorized in any EU member state and a "mutual recognition" procedure allowing companies that have a product already authorized in one EU member state to apply for that authorization to be recognized by the competent authorities in other EU member states. The U.K.'s withdrawal from the EU on January 31, 2020, commonly referred to as Brexit, has created uncertainty concerning the future relationship between the U.K. and the EU. Among the changes that have had a direct impact are that Great Britain (England, Scotland and Wales) is now treated as a third country. To mitigate the immediate impact of this in December 2020, the EU and U.K. reached an agreement in principle on

the framework for their future relationship, the EU-U.K. TCA. With regard to EU regulations, Northern Ireland continues to follow the EU regulatory rules. As part of the TCA, the EU and the U.K. recognize GMP, inspections carried out by the other party and the acceptance of official GMP documents issued by the other party. The TCA also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release. The U.K. has unilaterally agreed to accept EU batch testing and batch release; there is a list of approved countries for import into Great Britain, currently including EU and EEA countries, which require no import testing or U.K. “qualified person” release certification. However, the EU continues to apply EU laws that require batch testing and batch release to take place in the EU territory. This means that medicinal products that are tested and released in the U.K. must be retested and re-released when entering the EU market for commercial use. As regards marketing authorizations, Great Britain has introduced a separate regulatory submission process, approval process and a separate national marketing authorization. Northern Ireland, however, continues to be covered by the marketing authorizations granted by the EC.

The maximum timeframe for the evaluation of an application in the EU under the centralized procedure is 210 days, subject to certain exceptions and clock stops. An initial marketing authorization granted in the EU is valid for five years, with renewal subject to re-evaluation of the risk-benefit profile of the product. Once renewed, the authorization is usually valid for an unlimited period unless the national competent authority or the EC decides on justified grounds to proceed with one additional five-year renewal.

In the EU, if an applicant can demonstrate that comprehensive data on the efficacy and safety of the product under normal conditions of use cannot be provided due to certain specified objective and verifiable reasons, products may be granted marketing authorization “under exceptional circumstances.” A marketing authorization granted under exceptional circumstances is valid for five years, subject to an annual reassessment of conditions imposed by the EC. The marketing authorization in the EU for Defitelio was granted under exceptional circumstances because it was not possible to obtain complete information about the product due to the rarity of the disease and because ethical considerations prevented conducting a study directly comparing Defitelio with best supportive care or a placebo. As a result, the marketing authorization requires us to comply with a number of post-marketing obligations, including obligations relating to the manufacture of the drug substance and finished product, the submission of data concerning patients treated with the product collected through a third-party patient registry and the establishment of a multi-center, multinational and prospective observational patient registry to investigate the long-term safety, health outcomes and patterns of utilization of Defitelio during normal use. We are in the process of conducting the post-authorization study in the EU to provide further data on long-term safety, health outcomes and patterns of utilization of Defitelio in normal use.

Similar to the use of REMS in the U.S. to ensure that the benefits of a product outweigh its risks, in the EU and other countries we are required and may, in the future in relation to new products, be required to agree to post-marketing obligations or conditions in the marketing authorization for our products, to include a patient package insert or a medication guide to provide information to consumers about the product’s risks and benefits, to implement a plan for communication to healthcare providers, and to impose restrictions on the product’s distribution. For example, the marketing authorization in the EU for Vyxeos requires us to comply with certain manufacturing-related post-approval commitments.

After approval, certain changes to the approved product, such as adding new indications, making certain manufacturing changes, modifying a REMS, or making certain additional labeling claims, are subject to further regulatory review and approval. Obtaining approval for a new indication generally requires that additional clinical studies be conducted to demonstrate that the product is safe and effective for the new intended use. Such regulatory reviews can result in denial or modification of the planned changes, or requirements to conduct additional tests or evaluations that can substantially delay or increase the cost of the planned changes.

### ***Manufacture of Pharmaceutical Products***

The manufacturing process for pharmaceutical products is highly regulated, and regulators may shut down manufacturing facilities that they believe do not comply with regulations. We and the third party suppliers of our products are subject to cGMP, which are extensive regulations governing manufacturing processes, stability testing, recordkeeping and quality standards as defined by FDA, the EC, EMA, competent authorities of EU member states and other regulatory authorities. FDA also periodically inspects manufacturing facilities and the sponsor’s and manufacturer’s records related to manufacturing, and assesses compliance with cGMP. Following such inspections, FDA may issue notices on Form FDA 483 and warning letters. In addition to Form FDA 483 notices and warning letters, failure to comply with the statutory and regulatory requirements may result in suspension of manufacturing, product seizure, withdrawal of the product from the market, administrative, civil and criminal penalties, among other enforcement remedies both in the U.S. and in non-U.S. countries.

In the EU, a manufacturing authorization is required to manufacture medicinal products, and the manufacturing authorization holder must comply with various requirements set out in applicable EU laws, regulations and guidance. These requirements include compliance with EU cGMP standards when manufacturing products and their APIs, including APIs

manufactured outside of the EU with the intention of importing them into the EU. In addition to inspection reports, manufacturers and marketing authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in cases of non-compliance with the EU or EU member states' requirements applicable to manufacturing.

### ***Sales and Marketing of Pharmaceutical Products***

#### *Advertising and Promotional Activities*

FDA regulates advertising and promotional activities for products in the U.S., requiring advertising, promotional materials and labeling to be truthful and not misleading, and products to be marketed only for their approved indications and in accordance with the provisions of the approved label. FDA actively investigates allegations of off-label promotion in order to enforce regulations prohibiting these types of activities. FDA routinely issues informal and more formal communications such as untitled letters or warning letters interpreting its authority over these matters. While such communications may not be considered final agency decisions, many companies may decide not to contest the agency's interpretations so as to avoid disputes with FDA, even if they believe the claims they were making to be truthful, not misleading and otherwise lawful.

In the EU, the advertising and promotion of our products are subject to laws governing promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's SmPC as approved by the competent authorities in connection with a marketing authorization approval. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. Other applicable laws at the EU level and in the individual EU member states also apply to the advertising and promotion of medicinal products, including laws that prohibit the direct-to-consumer advertising of prescription-only medicinal products and further limit or restrict the advertising and promotion of our products to the general public and to health care professionals. Violations of the rules governing the promotion of medicinal products in the EU could be penalized by administrative measures, fines and imprisonment.

#### *Fraud and Abuse*

We are also subject to numerous fraud and abuse laws and regulations globally. In the U.S., there are a variety of federal and state laws restricting certain marketing practices in the pharmaceutical industry pertaining to healthcare fraud and abuse, including anti-kickback laws and false claims laws. Our sales, marketing, patient support and medical activities may be subject to scrutiny under these laws. The U.S. federal healthcare program Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving anything of value to induce (or in return for) the referral of business, including the purchase, recommendation or prescription of a particular drug reimbursable under Medicare, Medicaid or other federally financed healthcare programs. The statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and patients, prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common manufacturer business arrangements and activities from prosecution and administrative sanction, the exemptions and safe harbors are drawn narrowly and are subject to regulatory revision or changes in interpretation by the DOJ and the OIG. Practices or arrangements that involve remuneration may be subject to scrutiny if they do not qualify for an exemption or safe harbor. For example, in November 2020, the OIG issued a Special Fraud Alert to highlight certain inherent risks of remuneration related to speaker programs sponsored by drug and device companies, which may not in all circumstances qualify under either safe harbor or statutory exception protection. The Special Fraud Alert sent a clear signal that speaker programs will be subject to potentially heightened enforcement scrutiny, in particular for those programs with certain characteristics identified as risk factors by OIG, including meals exceeding modest value or where alcohol is made available; lack of substantive or new content presented; programs held at venues not conducive to the exchange of educational information; repeat attendees or attendees without a legitimate business interest; sales or marketing influence on speaker selection; and excessive speaker compensation. Violations of the federal Anti-Kickback Statute may be established without providing specific intent to violate the statute, and may be punishable by civil, criminal, and administrative fines and penalties, damages, imprisonment, and/or exclusion from participation in federal healthcare programs.

The federal civil False Claims Act prohibits, among other things, any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of federal funds, or knowingly making, or causing to be made, a false record or statement to get a false claim paid. A claim resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim. The False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of themselves and the federal government alleging violations of the statute and to share in any monetary recovery. Violations of the False Claims Act may result in significant financial penalties (including mandatory penalties on a per claim or statement basis), treble damages and exclusion from participation in federal health care programs.

Pharmaceutical companies are subject to other federal false claim and statements laws, some of which extend to non-government health benefit programs. For example, the healthcare fraud provisions under HIPAA impose criminal liability for,

among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program, including private third party payors, or falsifying or covering up a material fact or making any materially false or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Violations of HIPAA fraud provisions may result in criminal, civil and administrative penalties, fines and damages, including exclusion from participation in federal healthcare programs.

The majority of individual states also have statutes or regulations similar to the federal Anti-Kickback Statute and the False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Other states restrict whether and when pharmaceutical companies may provide meals to health care professionals or engage in other marketing-related activities, and certain states and cities require identification or licensing of sales representatives.

### ***Other Post-Approval Pharmaceutical Product Regulation***

#### *Safety Reporting/Pharmacovigilance*

FDA, EMA and other governmental authorities track information on side effects and adverse events reported during clinical studies and after marketing approval. We are required to file periodic safety update reports with the authorities concerning adverse events. If, upon review, an authority determines that any events and/or reports indicate a trend or signal, they can require a change in a product label, restrict sales and marketing, require post-approval safety studies, require a labor intensive collection of data regarding the risks and benefits of marketed products and ongoing assessments of those risks and benefits and/or require or conduct other actions, potentially including withdrawal or suspension of the product from the market. For example, if EMA has concerns that the risk-benefit profile of a product has changed, it can, following an investigation procedure, adopt an opinion advising that the existing marketing authorization for the product be varied or suspended and requiring the marketing authorization holder to conduct post-authorization safety studies. The opinion is then submitted for approval by the EC. Also, from time to time, FDA issues drug safety communications on its adverse event reporting system based on its review of reported adverse events.

FDA and the competent authorities of the EU member states on behalf of EMA also periodically inspect our records related to safety reporting. Following such inspections, FDA may issue notices on FDA Form 483 and warning letters that could cause us to modify certain activities. An FDA Form 483 notice, if issued, can list conditions FDA investigators believe may have violated relevant FDA regulations or guidance. Failure to adequately and promptly correct the observation(s) can result in a warning letter or other regulatory enforcement action. Similarly, EMA's Pharmacovigilance Risk Assessment Committee may propose to the Committee for Medicinal Products for Human Use that the marketing authorization holder be required to take specific steps. Non-compliance can lead to the variation, suspension or withdrawal of marketing authorization or imposition of financial penalties or other enforcement measures.

#### *Sunshine Act and Transparency Laws*

The Sunshine provisions require tracking of payments and transfers of value to physicians and teaching hospitals and ownership interests held by physicians and their families, and reporting to the federal government and public disclosure of these data. Since 2022, reporting has been required of information regarding payments and transfers of value provided to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, and certified nurse-midwives. A number of states now require pharmaceutical companies to report expenses relating to the marketing and promotion of pharmaceutical products and to report gifts and payments to healthcare providers in the states. Government agencies and private entities may inquire about our marketing practices or pursue other enforcement activities based on the disclosures in those public reports.

Outside the U.S., interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products, which is prohibited in the EU, is governed by the national anti-bribery laws of the EU member states, as described below in "Business—Government Regulation—Anti-Corruption Legislation" in this Part I, Item 1. Violation of these laws could result in substantial fines and imprisonment. Certain EU member states, or industry codes of conduct, require that payments made to physicians be publicly disclosed. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her competent professional organization, and/or the competent authorities of the individual EU member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

#### *Controlled Substance Regulations*

A drug product approved by FDA may be subject to scheduling as a controlled substance under the CSA depending on the drug's potential for abuse. Controlled substances that are pharmaceutical products are subject to a high degree of regulation under the CSA, which establishes, among other things, certain registration, manufacturing quotas, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. The DEA classifies controlled substances into five

schedules. Schedule I substances have a high potential for abuse, have no currently “accepted medical use” in the U.S., lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the U.S. Pharmaceutical products approved for use in the U.S. may be classified as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse. The API of Xywav and Xyrem, oxybate salts, are regulated by the DEA as Schedule I controlled substances, and Xywav and Xyrem drug products are regulated as Schedule III controlled substances. Certain product candidates we are developing contain controlled substances as defined in the CSA. Drug products approved by FDA that contain cannabis or cannabis extracts may be controlled substances and will be rescheduled to Schedules II-V after approval or, like Epidiolex, removed completely from the schedules by operation of other laws.

The DEA limits the quantity of certain Schedule I and II controlled substances that may be manufactured and procured in the U.S. in any given calendar year through a quota system and, as a result, quotas from the DEA are required in order to manufacture and procure oxybate salts in the U.S. Accordingly, we require DEA quotas for Siegfried, our U.S. based sodium oxybate supplier, to manufacture sodium oxybate and for Patheon, our U.S.-based Xyrem supplier, to procure sodium oxybate from Siegfried in order to manufacture and supply us with Xyrem drug product. We also require DEA quotas for Patheon to manufacture and procure the API of Xywav oxybate salt. Xywav and Xyrem manufactured at our plant in Ireland enter the U.S. as Schedule III drugs and therefore do not require a DEA manufacturing or procurement quota.

As Schedule III drugs, Xywav and Xyrem are also subject to DEA and state regulations relating to the importation, manufacturing, storage, distribution and physician prescription procedures, including limitations on prescription refills. In addition, the third parties who perform our clinical and commercial manufacturing, distribution, dispensing and clinical studies for Xywav and Xyrem are required to maintain necessary DEA registrations and state licenses. The DEA periodically inspects facilities for compliance with its rules and regulations.

#### *Other Regulations*

There are many other requirements and restrictions in the U.S. and elsewhere imposed on pharmaceutical companies and their activities, including those related to the posting of information relating to clinical studies and their outcomes, the export and importation of products, required authorizations for distributors, the identification or licensing of sales representatives, restrictions on the ability of manufacturers to offer co-pay support to patients for certain prescription drugs, implementation of required compliance programs or marketing codes of conduct, protection of the environment, taxation and work safety. Non-compliance with such requirements may result in civil, criminal or administrative sanctions.

#### *Anti-Corruption Legislation*

Our business activities outside of the U.S. are subject to the FCPA, and similar anti-bribery or anti-corruption laws, regulations, industry self-regulation codes of conduct and physicians’ codes of professional conduct or rules of other countries in which we operate, including the U.K. Bribery Act. The FCPA and similar anti-corruption laws in other countries generally prohibit the offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to U.S. or non-U.S. government officials in order to improperly influence any act or decision, secure an improper advantage, or obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the company and to devise and maintain an adequate system of internal accounting controls. The U.K. Bribery Act prohibits giving, offering, or promising bribes to any person, including U.K. and non-U.K. government officials and private persons, as well as requesting, agreeing to receive, or accepting bribes from any person. In addition, under the U.K. Bribery Act, companies that carry on a business or part of a business in the U.K. may be held liable for bribes given, offered or promised to any person, including U.K. and non-U.K. government officials and private persons in any country, by employees and persons associated with the company in order to obtain or retain business or a business advantage for the company. Liability is strict, with no element of a corrupt state of mind, but a defense of having in place adequate procedures designed to prevent bribery is available under the U.K. Bribery Act and certain other laws; under the FCPA, it might be considered as a mitigating factor.

As described above, our business is heavily regulated and therefore involves significant interaction with government officials in many countries. Additionally, in certain countries, the health care providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers may be subject to the FCPA, the U.K. Bribery Act and similar laws. Recently the SEC, and the DOJ have increased their FCPA enforcement activities with respect to pharmaceutical companies. In addition, under the Dodd-Frank Wall Street Reform and Consumer Protection Act, private individuals who report to the SEC original information that leads to successful enforcement actions may be eligible for a monetary award. We engage in ongoing efforts designed to ensure our compliance with these laws, including conducting due diligence of our business partners, requiring training of our employees on FCPA requirements, and implementing and maintaining policies, procedures, and internal controls to ensure compliance with the FCPA and similar laws. However, there is no certainty that all employees and third party business partners (including our distributors, wholesalers, agents, contractors, and other partners) will comply with anti-bribery laws. In

particular, we do not control the actions of our suppliers and other third party agents, although we may be liable for their actions. Violation of these laws may result in civil or criminal sanctions, which could include monetary fines, criminal penalties, disgorgement of past profits, and could cause disruption to our business, including through procurement bans or similar administrative actions. It is possible that an adverse outcome in an FCPA action could materially affect our consolidated results of operations, liquidity, and financial position and result in parallel civil litigation such as securities class actions and shareholder derivative suits.

### ***Data Protection and Privacy***

We are subject to data protection and privacy laws and regulations globally, which restrict the processing of personal data. The legislative and regulatory landscape for privacy and data security continues to evolve with an increased attention in countries globally that could potentially affect our business. In particular, we are subject to the EU General Data Protection Regulation, which imposes penalties up to 4% of annual global revenue, the California Consumer Privacy Act of 2018, as amended by the California Consumer Privacy Rights Act, and numerous other federal, state, national and international laws and regulations that govern the privacy and security of the personal data we collect and maintain. These laws and regulations applicable to our business, increase potential enforcement and litigation activity. In order to manage these evolving risks, we have adopted a global privacy program that governs the processing of personal data across our business.

### ***Marketing Exclusivity***

#### *The Hatch-Waxman Act*

The marketing approval process described above for the U.S. is premised on the applicant being the owner of, or having obtained a right of reference to, all of the data required to prove the safety and effectiveness of a drug product. This type of marketing application, sometimes referred to as a “full” or “stand-alone” NDA, is governed by Section 505(b)(1) of the FDCA. A Section 505(b)(1) NDA contains full reports of investigations of safety and effectiveness, which includes the results of preclinical and clinical trials, together with detailed information on the manufacture and composition of the product, in addition to other information. As an alternative, the Hatch-Waxman Act provides two abbreviated approval pathways for certain drug products.

The first path, under Section 505(b)(2) of the FDCA, usually is used for the approval of a product that is similar, but not identical, to a previously-approved brand-name product, referred to as the RLD. Under this path, the applicant is permitted to rely to some degree on FDA’s finding that the RLD is safe and effective and must submit its own product-specific data on safety and effectiveness only to the extent necessary to bridge the differences between the products. The second abbreviated path established under the Hatch-Waxman Act is for the approval of generic drugs. Section 505(j) of the FDCA permits the submission of an ANDA for a generic version of an approved, brand-name drug. Generally, an ANDA must contain data and information showing that the proposed generic product and the RLD (i) have the same active ingredient, in the same strength and dosage form, to be delivered via the same route of administration, (ii) are intended for the same uses, and (iii) are bioequivalent. This data and information are provided instead of data and information independently demonstrating the proposed generic product’s safety and effectiveness.

The Hatch-Waxman Act requires an ANDA or a Section 505(b)(2) NDA applicant to certify that there are no patents listed for that product in the Orange Book, or that for each Orange Book-listed patent either the listed patent has expired, the listed patent will expire on a particular date and approval is sought after patent expiration, or the listed patent is invalid or will not be infringed by the manufacture, use or sale of the new product. A certification that approval is sought after patent expiration is called a “Paragraph III Certification.” A certification that the new product will not infringe the RLD’s Orange Book-listed patents, or that such patents are invalid, is called a “Paragraph IV Certification.” If a relevant patent covers an approved method of use, an ANDA or Section 505(b)(2) NDA applicant can also file a statement, called, in the case of an ANDA, a “section viii statement,” that the application does not seek approval of the method of use covered by the listed patent. With such a statement, the applicant must “carve out” the protected method of use (typically an indication and related material) from the proposed product’s labeling. If the applicant makes a Paragraph III Certification, the ANDA or the Section 505(b)(2) NDA will not be approved until the listed patents claiming the RLD have expired.

If the applicant has provided a Paragraph IV Certification to FDA, the applicant must also send a notice of that certification to the NDA holder and the relevant patent holders once FDA accepts the ANDA or the Section 505(b)(2) NDA for filing. The NDA and patent holders then have 45 days to initiate a patent infringement lawsuit. Filing the lawsuit triggers an automatic stay on FDA’s approval of the ANDA or the Section 505(b)(2) NDA until the earliest of 30 months after the NDA holder’s receipt of the notice of Paragraph IV Certification, expiration of the patent, certain settlements of the lawsuit, or a decision in the infringement case that is favorable to the applicant. FDA may issue tentative approval of an application if the application meets all conditions for approval but cannot receive effective approval because the 30-month stay or another period of regulatory exclusivity has not expired. If an ANDA or Section 505(b)(2) NDA is approved before conclusion of any relevant patent litigation, the applicant can choose to launch the product, but does so “at risk” of being liable for damages, and potentially treble damages, if the RLD sponsor or patent holder ultimately prevails in patent litigation.

Under the Hatch-Waxman Act, newly approved drugs and indications may benefit from statutory periods of non-patent marketing exclusivity that can potentially delay review or approval of an ANDA or Section 505(b)(2) application. For example, the Hatch-Waxman Act provides five-year marketing exclusivity to the first applicant to gain approval of an NDA for a new chemical entity, meaning a drug containing an active moiety that FDA has not previously approved. During this period, FDA cannot accept for review an ANDA or a Section 505(b)(2) NDA for a product containing the same moiety, except that an application containing a Paragraph IV Certification may be submitted after four years, which may trigger the litigation and stay described above. The Hatch-Waxman Act also provides three years of marketing exclusivity with the approval of an NDA, including a Section 505(b)(2) NDA, for a product containing a previously-approved moiety but that incorporates a change (such as a new indication, dosage form or strength) from an approved product with the same moiety, if the change required clinical data from new investigations that were conducted or sponsored by the applicant. This three-year exclusivity does not preclude submission of the ANDA or Section 505(b)(2) NDA for such a product, but prevents FDA from giving final approval to such product.

The Hatch-Waxman Act also permits a patent term extension of up to five years (but not beyond 14 years from the date of approval) for an NDA, including a Section 505(b)(2) NDA, that is approved for a product that contains an active ingredient that has not previously been approved. The extension, which compensates for patent term lost during product development and FDA regulatory review process, is generally equal to the sum of one-half the time between the effective date of an IND application and the submission date of an NDA, and all of the time between the submission date of an NDA and the approval of that application. It is available for only one patent for a given product, and it must be a patent that claims the product or a method of using or manufacturing the product. The USPTO, in consultation with FDA, reviews and approves applications for patent term extension.

In the EU, innovative medicinal products that are subject to marketing authorization on the basis of a full dossier qualify for eight years' data exclusivity upon marketing authorization and an additional two years' market exclusivity. Data exclusivity prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced. However, the generic product or biosimilar products cannot be marketed in the EU for a further two years thereafter. The overall ten-year period may be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. In April 2023, the European Commission proposed the "Pharmaceutical Package", which aims to revise and replace existing pharmaceutical legislation to enhance the availability, accessibility, and affordability of medicinal products across the EU. This package includes a proposal for a new directive and a new regulation that would replace the current pharmaceutical legislation in the EU. Among others, the standard data protection period is proposed to decrease from eight to six years but would allow extensions of up to 12 years if specific conditions are met. As of January 2025, the legislative process is ongoing. Once an agreement is reached between the Council and the European Parliament, the legislation will be formally adopted and published. Its adoption is likely to occur in 2026, with implementation following thereafter.

#### *Orphan Drug and Other Exclusivities*

Some jurisdictions, including the U.S., may designate drugs or biologics for relatively small patient populations as orphan drugs. FDA grants orphan drug designation to drugs or biologics intended to treat a rare disease or condition, which is one that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals, but for which there is no reasonable expectation that the cost of developing the product and making it available in the U.S. for the disease or condition will be recovered from U.S. sales of the product. Orphan drug designation does not shorten the duration of the regulatory review process or lower the approval standards, but can provide important benefits, including consultation with FDA. If a product is approved for its orphan designated use, it may be entitled to ODE, which blocks FDA from approving for seven years any other application for a product that is the same drug for the same indication. If there is a previously-approved product that is the same drug for the same indication, orphan drug designation requires the sponsor to provide a plausible hypothesis of clinical superiority over the approved product, whereas ODE requires the sponsor to actually demonstrate clinical superiority. Clinical superiority can be established by way of greater efficacy, greater safety, or making a major contribution to patient care. Additionally, a later product can be approved if the sponsor holding ODE consents, or cannot adequately supply the market. ODE does not prevent approval of another sponsor's application for different indications or uses of the same drug, or for different drugs for the same indication. Defibrotide was granted ODE by FDA to treat and prevent VOD until March 2023. Vyxeos was granted ODE by FDA for the treatment of AML until August 2024. Epidiolex has received ODE to treat seizures associated with LGS and DS through 2025 and TSC through 2027. In June 2021, FDA, recognized seven years of ODE for Xywav stating that Xywav is clinically superior to Xyrem by means of greater safety due to reduced chronic sodium burden. Xywav has been granted ODE by FDA to treat narcolepsy through January 2027 and to treat IH through August 2028. Rylaze has been granted ODE for the treatment of patients with ALL or LBL until 2028.

Biologic products approved under a BLA are subject to the BPCIA, which authorizes an abbreviated approval pathway for a biological product that is “biosimilar” to an already approved biologic, or reference product. The BPCIA provides periods of exclusivity that protect a reference product from competition by biosimilars. FDA may not accept a biosimilar application for review until four years after the date of first licensure of the reference product, and the biosimilar cannot be licensed until 12 years after the reference product was first licensed.

Under certain circumstances, the exclusivity periods applicable to drugs and biologics and the patent-related protections applicable to drugs may be eligible for a six-month extension if the sponsor submits pediatric data that fairly respond to a written request from FDA for such data. This exclusivity may be granted even if the data does not support a pediatric indication. We consider seeking pediatric exclusivity for our products whenever appropriate. For example, in response to a written request from FDA, we conducted a Phase 3 clinical trial to assess the safety and efficacy of Xyrem in children and adolescents aged seven to 17 who have narcolepsy with cataplexy, and submitted study results in a supplement to the Xyrem NDA, seeking approval for this indication. In October 2018, FDA approved the sNDA and notified us that we had been granted pediatric exclusivity, extending by six months the preclusive effect of our Orange Book-listed patents for Xyrem, as well as the three-year regulatory exclusivity period granted to the Xyrem pediatric indication because of the clinical studies that were necessary for approval of the sNDA.

In the EU, orphan designation may be granted to products that can be used to treat life-threatening diseases or chronically debilitating conditions with an incidence of no more than five in 10,000 people or that, for economic reasons, would be unlikely to be developed without incentives. Orphan designated medicinal products are entitled to a range of benefits during the development and regulatory review process and ten years of OME in all EU member states upon approval. As in the U.S., a similar medicinal product with the same orphan indication may be approved, notwithstanding OME, if the exclusivity holder gives consent or if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities. Marketing authorization may also be granted to a similar medicinal product with the same orphan indication if the similar product is deemed safer, more effective or otherwise clinically superior to the original orphan medicinal product. The period of OME granted in relation to the original orphan medicinal product may, in addition, be reduced to six years if it can be demonstrated, on the basis of available evidence, that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity. Defibrotide was granted orphan drug designation by the EC for the treatment of VOD and prevention of GvHD until October 2023, by the Korean Ministry of Food and Drug Safety to treat and prevent VOD, and by the Commonwealth of Australia-Department of Health for the treatment of VOD. Vyxeos has been granted OME by the EC until August 2028. Epidyolex has been granted OME for use as adjunct therapy of seizures associated with DS and LGS until September 2029, and for use as adjunctive therapy of seizures associated with TSC until April 2031.

## **Pharmaceutical Pricing, Reimbursement by Government and Private Payors and Patient Access**

### ***Pricing and Reimbursement***

Successful commercialization of our products depends in significant part on adequate financial coverage and reimbursement from third party payors, including governmental payors (such as the Medicaid and Medicare programs in the U.S.), managed care organizations and private health insurers. Third party payors decide which drugs will be reimbursed and establish reimbursement and co-pay levels and conditions for reimbursement. Third party payors are increasingly challenging the prices charged for medical products and services by examining their cost effectiveness, as demonstrated in pharmacoeconomic and/or clinical studies, in addition to their safety and efficacy. In some cases, for example, third party payors try to encourage the use of less expensive products, when available, through their prescription benefits coverage and reimbursement, co-pay and prior authorization policies. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third party payors may require prior approval before covering a specific product, or may require patients and health care providers to try other covered products first. Third party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication. For certain categories of products, third party payors, principally through contracted PBMs negotiate rebates with drug manufacturers for inclusion of products on their formularies in specific positions or coverage criteria. Beginning in the third quarter of 2019, we have been entering into agreements with certain PBMs or similar organizations to provide rebates for our products where coverage was provided and products were listed in certain formulary positions, among other conditions.

Medicaid is a joint federal and state program that is administered by the states for low-income and disabled beneficiaries. Medicare is a federal program that is administered by the federal government covering individuals age 65 and over as well as those with certain disabilities. Medicare Part B pays physicians who administer our products. Under the Medicaid Drug Rebate Program, as a condition of having federal funds made available to the states for our drugs under Medicaid and Medicare Part B, we are required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries and paid for by a state Medicaid program. Medicaid rebates are based on pricing data we report on a monthly and quarterly basis to the CMS, the federal agency that administers Medicare and Medicaid, including the Medicaid Drug Rebate Program. These data include the average manufacturer price and, in the case of innovator products, the best price

for each drug which, in general, represents the lowest price available from the manufacturer to any entity in the U.S. in any pricing structure, calculated to include all applicable sales and associated rebates, discounts and other price concessions. If we become aware that our reporting for a prior quarter was incorrect, or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data originally were due. We are required to provide ASP information for certain of our products to CMS on a quarterly basis. The ASP is calculated based on a statutorily defined formula as well as regulations and interpretations of the statute by CMS. This information may be used to compute Medicare payment rates, with rates for Medicare Part B drugs outside the hospital outpatient setting and in the hospital outpatient setting consisting of ASP plus a specified percentage.

Federal law requires that any company that participates in the Medicaid Drug Rebate Program also participate in the 340B program, in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program, which is administered by the HRSA requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered drugs used in an outpatient setting. These 340B covered entities include certain qualifying community health clinics, a variety of entities that receive health services grants from the Public Health Service, and multiple categories of hospitals, including children's hospitals, critical access hospitals, free standing cancer hospitals and hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the average manufacturer price and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate Program, and in general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B ceiling price calculation and discount requirement. A regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities became effective on January 1, 2019. We also are required to report our 340B ceiling prices to HRSA on a quarterly basis and HRSA then publishes them to 340B covered entities. In addition, legislation may be introduced that, if passed, would further expand the 340B program to additional covered entities or would require participating manufacturers to agree to provide 340B discounted pricing on drugs used in an inpatient setting.

A provision in The American Rescue Plan Act of 2021 eliminated, effective January 2024, the statutory cap on rebates drug manufacturers are required to pay under the Medicaid Drug Rebate Program. The elimination of the cap on rebates means that manufacturer discounts to Medicaid may rise beginning in 2024 and, in certain circumstances, rebates could exceed the amount that state Medicaid programs pay for the drug. This policy change will have the greatest impact on drugs whose prices have reached the 100 percent Average Manufacturer Price rebate cap. Further, the Inflation Reduction Act of 2022 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, which could negatively affect our business and financial condition.

Effective January 2023, a provision of the Infrastructure Investment and Jobs Act requires a manufacturer of single source drugs or biologicals in single-use packages or single dose containers to pay a refund on discarded amounts of drug under Medicare Part B where the discarded amount exceeds an applicable threshold.

In order to be eligible to have our products paid for with federal funds under the Medicaid and Medicare Part B programs and purchased by certain federal agencies and grantees, we also participate in the VA FSS pricing program. Under this program, we are obligated to make our products available for procurement on an FSS contract under which we must comply with standard government terms and conditions and charge a price to certain federal agencies that is no higher than the statutory FCP. The FCP is based on the Non-FAMP, which we calculate and report to the VA on a quarterly and annual basis. We also participate in the Tricare program, under which we pay quarterly rebates on utilization of innovator products that are dispensed through the Tricare Retail Pharmacy network to Tricare beneficiaries. The rebates are calculated as the difference between the annual Non-FAMP and FCP. Pricing and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts, which can change and evolve over time.

In addition, in the U.S., drug pricing by pharmaceutical companies is currently, and is expected to continue to be, under close scrutiny, including with respect to companies that have increased the price of products after acquiring those products from other companies. There are numerous ongoing efforts at the federal and state level seeking to indirectly or directly regulate drug prices to reduce overall healthcare costs using tools such as price ceilings, value-based pricing and increased transparency and disclosure obligations. Numerous states have passed or are considering legislation that requires or purports to require companies to report pricing information, including proprietary pricing information. For example, in 2017, California adopted a prescription drug price transparency state bill requiring advance notice of and an explanation for price increases of certain drugs that exceed a specified threshold. Additionally, some individual states have begun establishing Prescription Drug Affordability Boards to review high-cost drugs and, in some cases, set upper payment limits. Similar bills have been previously introduced at the federal level and additional legislation could be introduced in the near future.

Similar to what is occurring in the U.S., political, economic and regulatory developments outside of the U.S. are also subjecting the healthcare industry to fundamental changes and challenges. Pressure by governments and other stakeholders on prices and reimbursement levels continue to exist. In various EU member states, we expect to be subject to continuous cost-cutting measures, such as voluntary and temporary sales rebates, lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative. HTA of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU member states, including countries representing major markets. The HTA process, which is governed by the national laws of these countries, is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. HTA generally compares attributes of individual medicinal products, as compared with other treatment options available on the market. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU member states. In December 2021, the EC adopted a HTA regulation intended to boost cooperation among EU member states in assessing health technologies, including new medicinal products. The HTA regulation entered into application in January 2025 and provides that EU member states must use common HTA tools, methodologies, and procedures across the EU. However, individual EU member states continue to be responsible for drawing conclusions on the overall value of a new health technology for their healthcare system, and pricing and reimbursement decisions.

In the EU, our products are marketed through various channels and within different legal frameworks. The making available or placing on the EU market of unauthorized medicinal products is generally prohibited. However, the competent authorities of the EU member states may exceptionally and temporarily allow and reimburse the supply of such unauthorized products, either on a named patient basis or through a compassionate use process, to individual patients or a group of patients with a chronically or seriously debilitating disease or whose disease is considered to be life-threatening, and who cannot be treated satisfactorily by an authorized medicinal product. Such reimbursement may no longer be available if authorization for named patient or compassionate use programs expire or is terminated or if marketing authorization is granted for the product. In some EU member states, authorization and reimbursement policies may also delay commercialization of our products, or may adversely affect our ability to sell our products on a profitable basis. After initial price and reimbursement approvals, reductions in prices and changes in reimbursement levels can be triggered by multiple factors, including reference pricing systems and publication of discounts by third party payors or authorities in other countries. In the EU, prices can be reduced further by parallel distribution and parallel trade, or arbitrage between low-priced and high-priced EU member states.

For more information, including with respect to recent legal developments regarding the Medicaid Drug Rebate Program, Medicare Part B, and the 340B program, see the risk factors under the headings *“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 group purchasing organizations, which could diminish our sales or affect our ability to sell our products profitably; conversely, to secure coverage from these organizations, we may be required to pay rebates or other discounts or other restrictions to reimbursement that could diminish our sales,” “The pricing of pharmaceutical products has come under increasing scrutiny as part of a global trend toward healthcare cost containment and resulting changes in healthcare law and policy may impact our business in ways that we cannot currently predict, which could have a material adverse effect on our business and financial condition” and “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”* in Part I, Item 1A of this Annual Report on Form 10-K.

#### ***Patient Copay Assistance and Free Product Programs***

We have various patient programs to help patients access and pay for our products, including co-pay coupons for certain products, services that help patients determine their insurance coverage for our products, and a free product program. We also make grants to independent charitable foundations that help financially needy patients with their premium, and co-pay and co-insurance obligations. There has been enhanced scrutiny of company-sponsored patient assistance programs, including co-pay assistance programs and donations to third-party charities that provide such assistance, as well as reimbursement support offerings.

The OIG has established guidelines for pharmaceutical manufacturers who make donations to charitable organizations providing co-pay assistance to Medicare patients. Such donations are unlikely to run afoul of the anti-kickback laws provided that the organizations receiving donations, among other things, are *bona fide* charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria, and do not link aid to use of a donor’s product. In 2016 and 2017, we received subpoenas from the U.S. Attorney’s Office for the District of Massachusetts requesting documents related to our support of charitable organizations that provide financial assistance to Medicare patients. In April 2019, we finalized our civil settlement agreement with the DOJ and OIG, and entered into a corporate integrity agreement requiring us to maintain our ongoing corporate compliance program and obligating us to

implement or continue, as applicable, a set of defined corporate integrity activities to ensure compliance with OIG's policies around charitable contributions for a period of five years from the effective date of the corporate integrity agreement. As of August 2024, we have fulfilled the terms and OIG closed out our corporate integrity agreement.

### **About Jazz Pharmaceuticals plc**

Jazz Pharmaceuticals plc was formed under the laws of Ireland (registered number 399192) as a private limited liability company in March 2005 under the name Azur Pharma Limited and was subsequently re-registered as a public limited company under the name Azur Pharma Public Limited Company in October 2011. On January 18, 2012, the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma were combined in a merger transaction, in connection with which Azur Pharma was re-named Jazz Pharmaceuticals plc and we became the parent company of and successor to Jazz Pharmaceuticals, Inc.

Our predecessor, Jazz Pharmaceuticals, Inc., was incorporated in California in March 2003 and was reincorporated in Delaware in January 2004.

### **Available Information**

The mailing address of our headquarters is Fifth Floor, Waterloo Exchange, Waterloo Road, Dublin 4, Ireland, and our telephone number at that location is 353-1-634-7800. Our website is [www.jazzpharmaceuticals.com](http://www.jazzpharmaceuticals.com).

We file or furnish pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as applicable, our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, amendments to those reports, proxy statements and other information electronically with the SEC. Through a link on our website, we make copies of our periodic and current reports, amendments to those reports, proxy statements and other information available, free of charge, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Information found on, or accessible through, our website is not a part of, and is not incorporated into, this Annual Report on Form 10-K.

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

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

#### **Risks Related to Our Lead Products and Product Candidates**

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

Historically, our business was substantially dependent on Xyrem, and our financial results were significantly influenced by sales of Xyrem. Our current operating plan assumes that Xywav, with 92% lower sodium compared to high-sodium oxybates (depending on the dose) and absence of a sodium warning, will remain the #1 branded oxybate treatment for narcolepsy; the position it held based on revenue in the fourth quarter of 2024. While we expect that our business will continue to be meaningfully dependent on oxybate revenues, there is no guarantee that oxybate revenues will remain at current levels. In this regard, our ability to maintain oxybate revenues and realize the anticipated benefits from our investment in Xywav are subject to a number of risks and uncertainties as discussed in greater detail below, including: those related to the commercialization of Xywav for the treatment of IH in adults and adoption in that indication; competition from the introduction of AG versions of high-sodium oxybate and branded products, such as Avadel's once-nightly dose, high-sodium oxybate branded product Lumryz, for treatment of cataplexy and/or EDS in adults with narcolepsy in the U.S. market, as well as potential future competition from additional AG and 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 Xyrem and/or Xywav, including from pending antitrust and intellectual property litigation; and continued acceptance of Xywav and Xyrem by physicians and patients. In addition, a wholly owned subsidiary of Hikma launched its AG version of high-sodium oxybate in January 2023 and Amneal launched its AG version of high-sodium oxybate in July 2023. For a discussion of risks associated with maintaining the AG royalty revenue from these AG products, see the risk factor below titled "*The introduction of new products in the U.S. market that compete with, or otherwise disrupt the market for, our oxybate products has adversely affected and may continue to adversely affect sales of our oxybate products.*" We have seen a negative impact and expect to see a further negative impact on our oxybate revenues as a result of these AG products and Avadel's Lumryz and any generic products and new branded products. A substantial decline in oxybate revenues could cause us to reduce our operating expenses or seek to raise additional

funds and would have a material adverse effect on our business, financial condition, results of operations and growth prospects, including on our ability to acquire, in-license or develop new products to grow our business.

***The introduction of new products in the U.S. market that compete with, or otherwise disrupt the market for, our oxybate products has adversely affected and may continue to adversely affect sales of our oxybate products.***

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

Ten companies have sent us notices that they had filed ANDAs seeking approval to market a generic version of Xyrem. We filed patent lawsuits against all ten companies and have settled with all ten of the companies. To date, FDA has approved or tentatively approved four of these ANDAs, and we believe that it is likely that FDA will approve or tentatively approve some or all of the others. Pursuant to our patent litigation settlement with the first filer, Hikma launched its AG version of high-sodium oxybate in the U.S. beginning on January 1, 2023. Accordingly, beginning in January 2023, Xywav and Xyrem face competition from an AG version of high-sodium oxybate. We also granted Hikma a license to launch its own generic high-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 our settlements with Amneal, Lupin, and 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 to be paid to us. Amneal launched its AG version of high-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 are 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 high-sodium oxybate product under its ANDA on or after December 31, 2025, or earlier under certain circumstances, including the circumstance where Hikma elects to launch its own generic product. If Amneal, Lupin or Par elects to launch its own generic product under such circumstance, it will no longer have the right to sell an AG product. In our settlements with each of six other ANDA filers, we granted each a license to launch its own generic high-sodium oxybate product under its ANDA on or after December 31, 2025, or earlier under certain circumstances, including circumstances where Hikma launches its own generic high-sodium oxybate product. It is possible that additional companies may file ANDAs seeking to market a generic version of Xyrem which could lead to additional patent litigation or challenges with respect to Xyrem and/or additional competition for our oxybate products.

Any ANDA holder launching an AG product or another generic high-sodium oxybate product will independently establish the price of the AG product and/or its own generic high-sodium oxybate product and determine the types of discounts or rebates they will offer parties that purchase or pay for the product. Generic competition often results in decreases in the net prices at which branded products can be sold. A component of drug pricing is the manufacturer's list price for a drug to wholesalers or direct purchasers in the U.S. (without discounts, rebates or other reductions) referred to as the WAC. In this regard, Hikma and Amneal launched their AG products in 2023 at a WAC that was less than 15% lower than the WAC for Xyrem. After any introduction of a generic product, whether or not it is an AG product, a significant percentage of the prescriptions written for Xyrem have been, and will likely continue to be, filled with the generic product. Certain U.S. state laws allow for, and in some instances in the absence of specific instructions from the prescribing physician mandate, the dispensing of generic products rather than branded products when a generic version is available. This has resulted in reduced sales of, and revenue from, Xyrem. We continue to receive royalties and other revenue based on sales of AG products in accordance with the terms of our settlement agreements.

Other companies may develop sodium oxybate products for the treatment of narcolepsy, using an alternative formulation or a different delivery technology, and seek approval in the U.S. using an NDA approval pathway under Section 505(b)(2) and referencing the safety and efficacy data for Xyrem. For example, we face competition from branded products for treatment of cataplexy and/or EDS in narcolepsy, such as Avadel's Lumryz. On May 1, 2023, Avadel announced that it had received FDA approval and ODE through May 1, 2030 for Lumryz, a fixed-dose, high-sodium oxybate which uses its proprietary technology for the treatment of EDS and cataplexy in patients with narcolepsy. For additional information on litigation involving this matter, see "FDA Litigation" in Note 13, Commitments and Contingencies-Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part IV of this Annual Report on Form 10-K. Xyrem and Xywav also face increased competition from other branded entrants to treat EDS in narcolepsy such as pitolisant and Sunosi. Other companies have announced that they have product candidates in various phases of development to treat the symptoms of narcolepsy, such as Axsome's reboxetine, and various companies are performing research and development on orexin agonists for the treatment of sleep disorders.

We expect that Xywav for the treatment of both cataplexy and EDS in patients with narcolepsy will continue to face competition from generic or AG high-sodium oxybate products or branded entrants in narcolepsy, such as Avadel's Lumryz, notwithstanding FDA recognizing ODE for Xywav. For example, we received notices in June 2021 and February 2023, that Lupin and Teva, respectively, filed ANDAs for generic versions of Xywav. On October 13, 2023, Lupin announced that it has received tentative approval for its application to market a generic version of Xywav. We have filed patent infringement suits against these ANDA filers. For additional information see "Xywav Patent Litigation" in Note 13, Commitments and

Contingencies—Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part IV of this Annual Report on Form 10-K. Additional companies may file ANDAs seeking to market a generic version of Xywav which could lead to additional patent litigation or challenges with respect to Xywav and/or additional competition.

Moreover, generic or AG high-sodium oxybate products or branded high-sodium oxybate entrants in narcolepsy, such as Avadel's Lumryz, as well as non-oxybate products intended for the treatment of EDS or cataplexy in narcolepsy or IH including new market entrants, even if not directly competitive with Xywav or Xyrem, have had and may continue to have the effect of changing treatment regimens and payor or formulary coverage of Xywav or Xyrem in favor of other products, and indirectly adversely affect sales of Xywav and Xyrem. Examples of such new market entrants of non-oxybate products include pitolisant, a drug that was approved by FDA in 2019 for the treatment of EDS in adult patients with narcolepsy and approved by FDA in 2020 for an adult cataplexy indication in the U.S. Pitolisant has also been approved and marketed in Europe to treat adult patients with narcolepsy, with or without cataplexy, and to treat EDS in obstructive sleep apnea. Harmony Biosciences has announced a phase 3 study for pitolisant for IH after receiving a refusal to file from FDA in February 2025. In addition, we are also aware that prescribers often prescribe branded or generic medications for cataplexy and IH, before or instead of prescribing oxybate therapy including Xywav and Xyrem, and that payors often require patients to try such medications before they will cover Xywav or Xyrem, even if they are not approved for this use. Examples of such products are described in "Business—Competition" in Part I, Item 1 of this Annual Report on Form 10-K.

We expect that the approval and launch of AG products or other generic versions of Xyrem or Xywav and the approval and launch of any other sodium oxybate product, such as Avadel's Lumryz, or alternative product that treats narcolepsy will continue to have a negative impact on, and could have a material adverse effect on, our sales of Xywav and Xyrem and on our business, financial condition, results of operations and growth prospects.

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

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

FDA continues to evaluate the Xywav and Xyrem REMS on an ongoing basis and has required, and may in the future require, modifications to the Xywav and Xyrem REMS. In 2023, FDA requested certain modifications to the Xywav and Xyrem REMS, which FDA approved in January 2024 as part of additional modifications to the REMS that we requested. We cannot predict whether FDA will request, seek to require or ultimately require additional modifications to, or impose additional requirements on, the Xywav and Xyrem REMS, including in connection with the submission of new oxybate products or indications, the introduction of AGs, or to accommodate generics, or whether FDA will approve modifications to the Xywav and Xyrem REMS that we consider warranted. Any modifications approved, required or rejected by FDA could change the safety profile of Xywav or Xyrem, and have a significant negative impact in terms of product liability, public acceptance of Xywav or Xyrem as a treatment for cataplexy and EDS in narcolepsy or Xywav as a treatment for IH, and prescribers' willingness to prescribe, and patients' willingness to take, Xywav or Xyrem, any of which could have a material adverse effect on our business. Modifications approved, required or rejected by FDA could also make it more difficult or expensive for us to distribute Xywav or Xyrem, make distribution easier for oxybate competitors, disrupt continuity of care for Xywav or Xyrem patients and/or negatively affect sales of Xywav or Xyrem.

We depend on outside vendors, including ESSDS, the central certified pharmacy, to distribute Xywav and Xyrem in the U.S., provide patient support services and implement the requirements of the Xywav and Xyrem REMS. If the central pharmacy fails to meet the requirements of the Xywav and Xyrem REMS applicable to the central pharmacy or otherwise does not fulfill its contractual obligations to us, moves to terminate our agreement, refuses or fails to adequately serve patients, or fails to promptly and adequately address operational challenges or challenges in implementing REMS modifications, the fulfillment of Xywav or Xyrem prescriptions and our sales would be adversely affected. If we change to a new central pharmacy, new contracts might be required with government payors and other insurers who pay for Xywav or Xyrem, and the terms of any new contracts could be less favorable to us than current agreements. In addition, any new central pharmacy would need to be registered with the DEA, and certified under the REMS and would also need to implement the particular processes, procedures and activities necessary to distribute under the Xywav and Xyrem REMS. Transitioning to a new pharmacy could result in product shortages, which would negatively affect sales of Xywav and Xyrem, result in additional costs and expenses

for us and/or take a significant amount of time, any of which could materially and adversely affect our business, financial condition, results of operations and growth prospects.

In its approval of Hikma's ANDA, FDA waived the requirement of a single shared REMS with the Xywav and Xyrem REMS, approving Hikma's ANDA with a generic high-sodium oxybate REMS separate from the Xywav and Xyrem REMS, except for the requirement that the high-sodium oxybate REMS program pharmacies contact the Xywav and Xyrem REMS by phone to verify and report certain information. The generic high-sodium oxybate REMS was approved with the condition that it be open to all future sponsors of ANDAs or NDAs for high-sodium oxybate products. In its approval of Avadel's high-sodium oxybate product, FDA also approved a separate REMS for that product, also with a requirement that the pharmacies in the Avadel-sponsored REMS contact the Xywav and Xyrem REMS to verify and report certain information. Administration of multiple sodium oxybate REMS systems could increase the risks associated with oxybate distribution, could make it more difficult or expensive for us to distribute Xywav and Xyrem and disrupt patient access to Xywav or Xyrem. Because patients, consumers and others may not differentiate other high-sodium oxybate products from our sodium oxybate products or differentiate between the different REMS programs, any negative outcomes, including risks to the public, caused by or otherwise related to a separate high-sodium oxybate REMS, could have a significant negative impact in terms of product liability, our reputation and good will, public acceptance of Xywav or Xyrem as a treatment for cataplexy and EDS in narcolepsy or Xywav for the treatment of IH, and prescribers' willingness to prescribe, and patients' willingness to take, Xywav or Xyrem, any of which could have a material adverse effect on our business.

We may face pressure to further modify the Xywav and Xyrem REMS, including sharing data, which may be proprietary, required for the safe distribution of sodium oxybate, in connection with FDA's approval of the generic sodium oxybate REMS or another oxybate REMS that has been approved or may be submitted or approved in the future. We cannot predict the outcome or impact on our business of any future action that we may take with respect to FDA's waiver of the single shared system REMS requirement, its approval and tentative approval of generic versions of sodium oxybate or the consequences of distribution of sodium oxybate through the generic sodium oxybate REMS approved by FDA or another separate REMS.

REMS programs have increasingly drawn public scrutiny from the U.S. Congress, the FTC, the USPTO, and FDA, with allegations that such programs are used as a means of improperly blocking or delaying competition. In December 2019, as part of the Further Consolidated Appropriations Act of 2020, the U.S. Congress passed legislation known as the CREATES. CREATES is intended to prevent companies from using REMS and other restricted distribution programs as a means to deny potential competitors access to product samples that are reasonably necessary to conduct testing in support of an application that references a listed drug or biologic, and provides such potential competitors a potential private right of action if the innovator fails to timely provide samples upon request. CREATES also grants FDA additional authority regarding generic products with REMS. A further example of continued interest in REMS oversight came from the USPTO in collaboration with FDA in November 2022, when they published an RFC in the Federal Register that asked, "What policy considerations or concerns should the USPTO and FDA explore in relation to the patenting of REMS associated with certain FDA-approved products?" The comments for this RFC closed on February 6, 2023.

It is possible that the FTC, FDA or other governmental authorities could claim that, or launch an investigation into whether, we are using our REMS programs in an anticompetitive manner or have engaged in other anticompetitive practices, whether under CREATES or otherwise. The Federal Food, Drug and Cosmetic Act further states that a REMS ETASU shall not be used by an NDA holder to block or delay generic drugs or drugs covered by an application under Section 505(b)(2) from entering the market. In its 2015 letter approving the Xyrem REMS, FDA expressed concern that we were aware that the Xyrem REMS is blocking competition. From June 2020 to May 2022, we were served with a number of lawsuits that included allegations that we had used the Xyrem REMS to delay approval of generic high-sodium oxybate. In December 2020, these cases were centralized and transferred to the United States District Court for the Northern District of California, where the multidistrict litigation will proceed for the purpose of discovery and pre-trial proceedings. For additional information on these lawsuits, see "*Xyrem Antitrust Litigation*" (and for other litigation involving our listing of our REMS patent in FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations," or Orange Book, see "*Avadel Litigation*") in Note 13, Commitments and Contingencies—Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part IV of this Annual Report on Form 10-K. It is possible that additional lawsuits will be filed against us making similar or related allegations or that governmental authorities could commence an investigation. We cannot predict the outcome of these or potential additional lawsuits; however, if the plaintiffs were to be successful in their claims, they may be entitled to injunctive relief or we may be required to pay significant monetary damages, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Pharmaceutical companies, including their agents and employees, are required to monitor adverse events occurring during the use of their products and report them to FDA. The patient counseling and monitoring requirements of the Xywav and Xyrem REMS provide more extensive information about adverse events experienced by patients taking Xywav and Xyrem, including deaths, than is generally available for other products that are not subject to similar REMS requirements. As required by FDA and other regulatory agencies, the adverse event information that we collect for Xywav and Xyrem is regularly

reported to FDA and could result in FDA requiring changes to Xywav and/or Xyrem labeling, including additional warnings or additional boxed warnings, or requiring us to take other actions that could have an adverse effect on patient and prescriber acceptance of Xywav and Xyrem. As required by FDA, Xywav's and Xyrem's current labeling includes a boxed warning regarding the risk of central nervous system depression and misuse and abuse.

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

***Our inability to maintain or increase sales of Epidiolex/Epidyolex would have a material adverse effect on our business, financial condition, results of operations and growth prospects.***

Our ability to maintain or increase sales of Epidiolex/Epidyolex (cannabidiol) is subject to many risks. There are many factors that could cause the commercialization of Epidiolex to be unsuccessful, including a number of factors that are outside our control. The commercial success of Epidiolex depends on the extent to which patients and physicians accept and adopt Epidiolex as a treatment for 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 if coverage is not provided or reimbursement is inadequate to cover a significant portion of the cost. Additionally, any negative development for Epidiolex in the market, in clinical development for additional indications, or in regulatory processes in other jurisdictions, may adversely impact the commercial results and potential of Epidiolex. In the future, we expect Epidiolex to face competition from generic cannabinoids. In November and December 2022, we received notices from various ANDA filers that they have each filed with FDA an ANDA for a generic version of Epidiolex (cannabidiol) oral solution. In January 2023, we filed patent infringement suits against these ANDA filers. For additional information see "*Epidiolex Patent Litigation*" in Note 13, Commitments and Contingencies—Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part IV of this Annual Report on Form 10-K. Additional companies may file ANDAs seeking to market a generic version of Epidiolex which could lead to additional patent litigation or challenges with respect to Epidiolex.

***While we expect Xywav 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.***

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

Our ability to realize the anticipated benefits from our investment in Zepzelca is subject to a number of risks and uncertainties, including: our ability to successfully commercialize Zepzelca in the U.S. and Canada; adequate supply of Zepzelca to meet demand; availability of favorable treatment pathway designations pricing and adequate coverage and reimbursement; the potential for negative trial data read-outs in ongoing or future Zepzelca clinical trials; our and PharmaMar's, ability to maintain accelerated approval or successfully complete a confirmatory study of Zepzelca; competition from a newly approved product for the treatment of extensive-stage metastatic SCLC; and patients' access to lung cancer screening, diagnosis and treatment. In July and August 2024, we received notices from Zepzelca ANDA filers. On September 11, 2024, we and PharmaMar filed a patent infringement suit against the Zepzelca ANDA Filers in the United States District Court for the District of New Jersey. For additional information see "*Zepzelca Patent Litigation*" in Note 13, Commitments and Contingencies—Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part IV of this Annual Report on Form 10-K. Additional companies may file ANDAs seeking to market a generic version of Zepzelca which could lead to additional patent litigation or challenges with respect to Zepzelca.

Our ability to realize the anticipated benefits from our investments in Rylaze is subject to a number of uncertainties, including our ability to successfully commercialize Rylaze including creating awareness among health care professionals and ensuring that patients with ALL or LBL will be given the appropriate course of therapy and dosing regimen based on the currently approved label. Our ability to realize the anticipated benefits from our investments in Ziihera is subject to a number of uncertainties, including our ability to successfully commercialize Ziihera in BTC and clinical development of potential future indications in HER2+ solid tumors.

***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.***

Our products compete, and our product candidates may in the future compete, with currently existing therapies, including other branded products, AG and other generic products, product candidates currently under development by us and others and/or future product candidates, including new molecular and chemical entities that may be safer or more effective or more

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

For a description of the competition that our lead marketed products and most advanced product candidates face or may face, see the discussion in “Business—Competition” in Part I, Item 1 of this Annual Report on Form 10-K and the risk factor under the heading “*The introduction of new products in the U.S. market that compete with, or otherwise disrupt the market for, our oxybate products has adversely affected and may continue to adversely affect sales of our oxybate products*” in this Part I, Item 1A.

***Recent executive and judicial changes and flux in the regulatory landscape creates uncertainty for us and our industry.***

The current administration is pursuing policies to reduce regulations and expenditures across government including at HHS, FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions may include directives to reduce agency workforce, rescinding a Biden administration executive order tasking the Center for Medicare & Medicaid Innovation to consider new payment and healthcare models to limit drug spending and eliminating the Biden administration’s executive order that directed HHS to establish an AI task force and develop a strategic plan. Additionally, in its June 2024 decision in *Loper Bright*, the U.S. Supreme Court overturned the longstanding *Chevron* doctrine, under which courts were required to give deference to regulatory agencies’ reasonable interpretations of ambiguous federal statutes. The *Loper Bright* decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by FDA. Finally, Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA. We cannot predict which additional measures may be adopted or the impact of current and additional measures on the marketing, pricing and demand for our products, which could have a material adverse effect on our business, financial condition and results of operations.

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

In both U.S. and non-U.S. markets, our ability to successfully commercialize and achieve market acceptance of our products depends in significant part on adequate financial coverage and reimbursement from third party payors, including governmental payors (such as the Medicare and Medicaid programs in the U.S.), managed care organizations and private health insurers. Without third party payor reimbursement, patients may not be able to obtain or afford prescribed medications. In addition, reimbursement guidelines and incentives provided to prescribing physicians by third party payors may have a significant impact on the prescribing physicians’ willingness and ability to prescribe our products. The demand for, and the profitability of, our products could be materially harmed if state Medicaid programs, the Medicare program, other healthcare programs in the U.S. or elsewhere, or third party commercial payors in the U.S. or elsewhere, deny reimbursement for our products, limit the indications for which our products will be reimbursed, or provide reimbursement only on unfavorable terms.

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

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

Third party PBMs, other similar organizations and payors can limit coverage to specific products on an approved list, or formulary, which might: not include all of the approved products for a particular indication, exclude drugs from their formularies in favor of competitor drugs or alternative treatments, place drugs on formulary tiers with higher patient co-pay obligations, and/or mandate stricter utilization criteria. Formulary exclusion effectively encourages patients and providers to seek alternative treatments, make a complex and time-intensive request for medical exemptions, or pay 100% of the cost of a drug. In addition, in many instances, certain PBMs, other similar organizations and third party payors may exert negotiating leverage by requiring incremental rebates, discounts or other concessions from manufacturers in order to maintain formulary positions, which could continue to result in higher gross to net deductions for affected products. The market for PBM services has become highly concentrated and vertically integrated, giving these entities further leverage in negotiating rebates, discounts or other concessions. In this regard, we have entered into agreements with PBMs and payor accounts to provide rebates to those entities related to formulary coverage for our products, but we cannot guarantee that we will be able to agree to coverage terms with other PBMs and other third party payors. Payors could decide to exclude our products from formulary coverage lists, impose step edits that require patients to try alternative, including generic, treatments before authorizing payment for our products, limit the types of diagnoses for which coverage will be provided or impose a moratorium on coverage for products while the payor makes a coverage decision. An inability to maintain adequate formulary positions could increase patient cost-sharing for our products and cause some patients to determine not to use our products. Any delays or unforeseen difficulties in reimbursement approvals could limit patient access, depress therapy adherence rates, and adversely impact our ability to successfully commercialize our products. In addition, PBMs and other third-party payors could implement alternative funding programs that could have an impact on product revenue. If we are unsuccessful in maintaining broad coverage for our products, our anticipated revenue from and growth prospects for our products could be negatively affected.

In many countries outside the U.S., procedures to obtain price approvals, coverage and reimbursement can take considerable time after the receipt of marketing authorization. Many European countries periodically review their reimbursement of medicinal products, which could have an adverse impact on reimbursement status. In addition, we expect that legislators, policymakers and healthcare insurance funds in the EU member states will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some EU member states, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. HTA of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU member states, including those representing the larger markets. The HTA process, which is currently governed by national laws in each EU member state, is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU member states. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU member states. In January 2025, the EU HTA regulation entered into application. This regulation aims to harmonize the clinical benefit assessment of HTA across the EU. Under this regulation, EU member states must use common HTA tools, methodologies, and procedures across the EU. However, individual member states remain responsible for determining the overall value of a new health technology within their healthcare systems, as well as making pricing and reimbursement decisions. If we are unable to maintain favorable pricing and reimbursement status in EU member states that represent significant markets, our anticipated revenue from and growth prospects for our products in the EU could be negatively affected. For example, the EC granted marketing authorization for Enrylaze in September 2023, and, as part of our rolling launch of Enrylaze in Europe, we are making pricing and reimbursement submissions in European countries. If we experience setbacks or unforeseen difficulties in obtaining favorable pricing and reimbursement decisions, including as a result of regulatory review delays, planned launches in the affected EU member states would be delayed, which could negatively impact anticipated revenue from and growth prospects for Enrylaze.

***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 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.***

Political, economic and regulatory influences are subjecting the healthcare industry in the U.S. to fundamental changes, particularly given the current atmosphere of mounting criticism of prescription drug costs in the U.S. We expect there will continue to be legislative and regulatory proposals to change the healthcare system in ways that could impact our ability to sell our products profitably, as governmental oversight and scrutiny of biopharmaceutical companies is increasing. For example, we anticipate that the U.S. Congress, state legislatures, and federal and state regulators may adopt or accelerate adoption of new healthcare policies and reforms intended to curb healthcare costs, such as federal and state controls on reimbursement for drugs (including under Medicare, Medicaid and commercial health plans), new or increased requirements to pay prescription drug rebates and penalties to government health care programs, and additional pharmaceutical cost transparency policies that aim to require drug companies to justify their prices through required disclosures. This includes efforts by individual states in the U.S. to pass legislation and implement regulations designed to control pharmaceutical and biological product pricing, including by establishing Prescription Drug Affordability Boards (or similar entities) to review high-cost drugs and, in some cases, set upper payment limits and implementing marketing cost disclosure and transparency measures. Further, the IRA, 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, which could negatively affect our business and financial condition. The CMS has issued final guidance implementing the Drug Price Negotiation Program in which it finalized certain policies governing the selection of drugs for negotiation. Among other things, CMS finalized definitions of “qualifying single source drug” and “marketed” that, especially if they persist, could further disincentivize innovation. In addition, under the Medicaid Drug Rebate Program, rebates owed by manufacturers are no longer subject to a cap on the rebate amount effective January 1, 2024, which may adversely affect our rebate liability.

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

There is also ongoing activity related to health care coverage. The Affordable Care Act substantially changed the way healthcare is financed by both governmental and private insurers. These changes impacted previously existing government healthcare programs and have resulted in the development of new programs, including Medicare payment-for-performance initiatives. Further, federal and state policy makers have taken and may continue to try to take steps regarding health care coverage beyond the Affordable Care Act, which could have ramifications for the pharmaceutical industry. Additional legislative changes, regulatory changes, or guidance could be adopted, which may impact the marketing approvals and reimbursement for our products and product candidates. For example, there has been increasing legislative, regulatory, and enforcement interest in the U.S. with respect to drug pricing practices. There have been several Congressional inquiries and proposed and enacted federal and state legislation and regulatory initiatives designed to, among other things, bring more transparency to product pricing, evaluate the relationship between pricing and manufacturer patient programs, and reform government healthcare program reimbursement methodologies for drug products beyond the changes enacted by the IRA.

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. We have periodically increased the price of our products, including Xywav and Xyrem most recently in January 2025, and there is no guarantee that we will make similar price adjustments to our products in the future or that price adjustments we have taken or may take in the future will not negatively affect our sales volumes and revenues. There is no guarantee that such price adjustments will not negatively affect our reputation and our ability to secure and maintain reimbursement coverage for our products, which could limit the prices that we charge for our products, limit the commercial opportunities for our products and/or negatively impact revenues from sales of our products.

Government investigations or U.S. Congressional oversight with respect to drug pricing or our other business practices could cause us to incur significant expense and could distract us from the operation of our business and execution of our strategy. Any such investigation or hearing could also result in reduced market acceptance and demand for our products, could harm our reputation and our ability to market our products in the future, and could have a material adverse effect on our

business, financial condition, results of operations and growth prospects. For more information, see the risk factor under the heading “*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*” in Part I, Item 1A of this Annual Report on Form 10-K.

We expect that legislators, policymakers and healthcare insurance funds in Europe and other international markets will continue to propose and implement cost-containing measures to keep healthcare costs down. These measures could include limitations on the prices we will be able to charge for our products or the level of reimbursement available for these products from governmental authorities or third party payors as well as clawbacks and revenue caps. For example, in the U.K., the cap on NHS spending on branded medicines agreed between the U.K. government and industry for 2019 to 2023 has remained unaltered despite higher than expected growth in NHS use of branded medicines, resulting in significant increases to the industry level revenue clawback rate payable on sales of branded medicines to the NHS. In the EU, a trend in some EU member states is for medicinal products to be reimbursed based on competitor products and not in relation with the value or the cost of the product. On April 26, 2023, the EC adopted proposals for a new Directive and a new Regulation, which revise and replace the existing EU general pharmaceutical legislation. This proposal includes increased transparency on research and development costs or public contributions to these costs with a view to strengthen the negotiating position of national competent authorities of the EU member states responsible for pricing and reimbursement, as well as reinforced cooperation with these authorities on pricing and reimbursement matters. On April 10, 2024, the European Parliament adopted its position on the proposals, whose legislative processes are expected to continue in 2025. Further, an increasing number of European and other foreign countries use prices for medicinal products established in other countries as “reference prices” to help determine the price of the product in their own territory. Consequently, a downward trend in prices of medicinal products in some countries could contribute to similar downward trends elsewhere.

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

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

- the clinical indications for which a product is approved and any restrictions placed upon the product in connection with its approval, such as a REMS or equivalent obligation imposed in a European or other foreign country, patient registry requirements or labeling restrictions;
- the prevalence of the disease or condition for which the product is approved and its diagnosis;
- the efficacy of the product in regular use;
- the severity of side effects and other risks in relation to the benefits of our products;
- unanticipated serious adverse events;
- acceptance by physicians and patients of each product as a safe and effective treatment;
- availability of sufficient product inventory to meet demand;
- physicians’ decisions relating to treatment practices based on availability of product;
- perceived clinical superiority and/or advantages over alternative treatments;
- overcoming negative publicity surrounding illicit use of
  - GHB or
  - CBD and marijuana productsand the view of patients, law enforcement agencies, physicians and regulators of our products as being the same or similar to illicit products;
- relative convenience and ease of administration;
- with respect to Xywav and Xyrem, physician and patient assessment of the burdens associated with obtaining or maintaining the certifications required under the Xywav and Xyrem REMS;
- the cost of treatment in relation to alternative treatments, including generic products; and
- the availability of financial or other assistance for patients who are uninsured or underinsured.

Because of our dependence upon market acceptance of our products, any adverse publicity associated with harm to patients or other adverse events resulting from the use or misuse of any of our products or any similar products distributed by

other companies, including generic versions of our products, could materially and adversely affect our business, financial condition, results of operations and growth prospects.

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

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

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

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

We are responsible for the manufacture and supply of Epidiolex/Epidyolex for commercial use and for use in clinical trials. The manufacturing of Epidiolex/Epidyolex necessitates compliance with GMP, and other regulatory requirements in jurisdictions internationally. Our ability to successfully manufacture Epidiolex/Epidyolex involves cultivation of botanical raw material from specific cannabinoid plants, extraction and purification processes, manufacture of finished products and labeling and packaging, which includes product information, tamper evidence and anti-counterfeit features, under tightly controlled processes and procedures. In addition, we must ensure chemical consistency among our batches, including clinical batches and, if approved, marketing batches. Demonstrating such consistency may require typical manufacturing controls as well as clinical data. We must also ensure that our batches conform to complex release specifications. We have a second site at which we can grow the specific cannabinoid plants that produce the CBD used in Epidiolex/Epidyolex and a second site at which we can crystallize the purified CBD from the liquid plant extract. If we are unable to manufacture Epidiolex/Epidyolex in accordance with regulatory specifications, including GMP, or if there are disruptions in our manufacturing process due to damage, loss or otherwise, or failure to pass regulatory inspections of our manufacturing facilities, we may not be able to meet current demand or supply sufficient product for use in clinical trials, and this may also harm our ability to commercialize Epidiolex/Epidyolex on a timely or cost-competitive basis, if at all. Our manufacturing program requires significant time and resources and may not be successful, may lead to delays, interruptions to supply or may prove to be more costly than anticipated.

Vyxeos is manufactured by Simtra, which is a sole source supplier from a single site location. Moreover, the proprietary technology that supports the manufacture of Vyxeos is not easily transferable. Consequently, engaging an alternate manufacturer may be difficult, costly and time-consuming. If we fail to obtain a sufficient supply of Vyxeos in accordance with applicable specifications on a timely basis, our sales of Vyxeos, our future maintenance and potential growth of the market for this product, our ability to conduct ongoing and future clinical trials of Vyxeos, and our business, financial condition, results of operations and growth prospects could be materially adversely affected.

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

We currently rely on WuXi, a company based in the PRC, as the sole supplier of Ziihera. Accordingly, there is a risk that supplies of Ziihera may be significantly delayed by, or may become unavailable as a result of, manufacturing, equipment, process, regulatory or business-related issues affecting that company. We may also face additional manufacturing and supply-chain risks due to the regulatory and political structure of the PRC, or as a result of the international relationship between the PRC and the U.S., including but not limited to potential trade restrictions, sanctions, other regulatory requirements, or proposed legislation imposed by the U.S. government, which could restrict or even prohibit our ability to work with WuXi. For example, the House of Representatives of the prior Congress (the 118<sup>th</sup> Congress) passed the BIOSECURE Act, which proposed targeting U.S. government contracts, grants and loans for entities that use biotechnology equipment or services from certain named Chinese biotechnology companies, including WuXi, and potentially other biotechnology companies designated in the future. The language of the proposed BIOSECURE Act would, among other things, prohibit U.S. federal agencies from entering into or renewing any contract with any entity that uses biotechnology equipment or services produced or provided by a “biotechnology company of concern.” The version of the bill passed by the prior House of Representatives included a “grandfathering” provision, which provided that the BIOSECURE Act’s prohibitions would not apply to pre-existing contracts and agreements entered into prior to the legislation’s effective date until 2032. The BIOSECURE Act did not become law in the 118<sup>th</sup> Congress. It is unclear whether the current Congress (the 119<sup>th</sup> Congress) will introduce the BIOSECURE Act or similar legislation in this congressional session and, if so, how the scope, prohibitions, or designated biotechnology companies of concern may differ from the version of the BIOSECURE Act passed by the House in the prior 118<sup>th</sup> Congress. Although to date there has been no impact on our ability to obtain supply of Ziihera, there can be no assurance that operations would not be impacted in the future with a negative impact on Ziihera supply.

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

***Global trade issues and changes in and uncertainties with respect to trade policies and export regulations, including import and export license requirements, trade sanctions, tariffs and international trade disputes, could adversely impact our business and operations, and reduce the competitiveness of our products and services relative to local and global competitors.***

There is inherent risk, based on the complex relationships among the U.S. and the countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments and persons targeted by U.S. sanctions. The U.S. and other countries have imposed and may continue to impose new trade restrictions and export regulations, have levied tariffs and taxes on certain goods, and could significantly increase tariffs on a broad array of goods. For example, on February 1, 2025, President Donald Trump signed executive orders imposing a 25% tariff on certain imports

from Mexico and Canada, and a 10% tariff on certain imports from China, which were to take effect on February 4, 2025. A 30-day pause was granted to Mexico and Canada. However, these newly proposed and imposed tariffs have resulted in retaliatory tariffs, and threats thereof, against U.S. goods. The ultimate impact of these potential and actual tariffs on our business and financial condition is unknown. In addition, ongoing changes in U.S. and foreign government trade policies, including potential modifications to existing trade agreements, could introduce additional uncertainty. Trade restrictions and export regulations, or increases in tariffs (including tariffs on imports from Europe) and additional taxes, including any retaliatory measures, can negatively impact end-user demand, increase our supply chain complexity and our manufacturing costs, decrease margins, reduce the competitiveness of our products, or restrict our ability to sell products, provide services or purchase necessary equipment and supplies, any or all of which could have a material and adverse effect on our business, results of operations, or financial condition and, given the nature of our products, relocating the manufacturing supply can be a complex, costly and time-consuming process making it difficult to react quickly to a changing environment.

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

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

The testing, manufacturing and marketing of our products require regulatory approvals, including approval from FDA and similar bodies in Europe and other countries. If FDA, EMA, the EC or the competent authorities of the EU member states or other European countries determine that our quality, safety or efficacy data do not warrant marketing approval for a product candidate, we could be required to conduct additional clinical trials as a condition to receiving approval, which could be costly and time-consuming and could delay or preclude the approval of our application. Our inability to obtain and maintain regulatory approval for our product candidates in the U.S. and internationally and to successfully commercialize new products that are approved would prevent us from receiving a return on our investments and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

Regulatory authorities may also impose post-marketing obligations as part of their approval, which may lead to additional costs and burdens associated with commercialization of the product and may pose a risk to maintaining approval of the product. We are subject to certain post-marketing requirements and commitments in connection with the approval of certain of our products, including Epidiolex/Epidyolex, Defitelio, Vyxeos, Rylaze, Zepzelca and Ziihera. These post-marketing requirements and commitments include satisfactorily conducting multiple post-marketing trials and safety studies. Failure to comply with these post-marketing requirements could result in withdrawal of our marketing approvals for the applicable product and/or other civil or criminal penalties. If a product is approved under accelerated approval, continued approval may be contingent upon verification and description of clinical benefit in a confirmatory trial. For example, FDA granted accelerated approval to Zepzelca for relapsed SCLC based on data from a Phase 2 trial, which approval is contingent upon verification and description of clinical benefit in a post-marketing clinical trial. While we and our licensor PharmaMar have reached agreement with FDA regarding a confirmatory clinical development program, our inability to confirm its clinical benefit in the second-line treatment setting for SCLC could result in the withdrawal of approval of Zepzelca, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In addition, FDA granted accelerated approval to Ziihera for previously treated, unresectable or metastatic HER2-positive BTC based on data from a Phase 2 trial. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. While a Phase 3 confirmatory trial is ongoing to evaluate zanidatamab in combination with standard-of-care therapy versus standard-of-care therapy alone in the first-line setting for patients with HER2-positive BTC, our inability to confirm its clinical benefit in the first-line setting for patients with HER2-positive BTC could result in the withdrawal of approval of Ziihera, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. In any event, if we are unable to comply with our post-marketing obligations imposed as part of the marketing approvals in the U.S., the EU, or other countries, our approval may be varied, suspended or revoked, product supply may be delayed and our sales of our products could be materially adversely affected.

Any new data relating to Epidiolex/Epidyolex, including from adverse event reports and post-marketing studies in the U.S. and Europe, and from other ongoing clinical trials, may result in changes to the product label and/or imposition of a REMS

and may adversely affect sales, or result in withdrawal of Epidiolex/Epidyolex from the market. FDA, EMA and regulatory authorities in other jurisdictions may also consider the new data in reviewing Epidiolex/Epidyolex marketing applications for indications beyond its currently approved uses or impose additional post-approval requirements. If any of these actions were to occur, it could result in significant expense and delay or limit our ability to generate sales of Epidiolex/Epidyolex.

If we are not successful in the clinical development of our product candidates, if we are unable to obtain regulatory approval for our product candidates in a timely manner, or at all, or if sales of an approved product do not reach the levels we expect, in each case including as a result of any executive or judicial actions as described under “—Recent executive and judicial changes and flux in the regulatory landscape creates uncertainty for us and our industry,” our anticipated revenue from our product candidates would be negatively affected, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

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

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

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

As a result of these or other factors, products or product candidates we acquire, or obtain licenses to, may not produce the revenues, earnings or business synergies that we anticipated, may not result in regulatory approvals, and may not perform as expected. For example, in May 2021, we made a substantial investment in Epidiolex and certain other products and technologies acquired in our acquisition of GW. The total consideration paid by us for the entire issued share capital of GW was \$7.2 billion. The success of our acquisition of GW will depend, in part, on our ability to realize the anticipated benefits from the acquisition, which benefits 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. In this regard, 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 that we acquired as part of our acquisition of GW. In any event, failure to manage effectively our growth through acquisitions or in-licensing transactions could adversely affect our growth prospects, business, results of operations and financial condition.

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

As a condition to regulatory approval, each product candidate must undergo extensive and expensive preclinical studies and clinical trials to demonstrate that the product candidate is safe and effective. The results at any stage of the development process may lack the desired safety, efficacy or pharmacokinetic characteristics. If FDA or any equivalent non-U.S. regulatory agency determines that the safety or efficacy data included in any marketing application we submit do not warrant marketing approval for the affected product or product candidate, we may be required to conduct additional preclinical studies or clinical trials, which could be challenging to perform, costly and time-consuming. Even if we believe we have successfully completed testing, FDA or any equivalent non-U.S. regulatory agency may determine our data is not sufficiently compelling to warrant marketing approval for the indication(s) sought, if at all, and may require us to engage in additional clinical trials or provide further analysis which may be costly and time-consuming. Any adverse events or other data generated during the course of clinical trials of our product candidates and/or clinical trials related to additional indications for our commercialized products could result in action by FDA, or an equivalent non-U.S. regulatory agency, which may restrict our ability to sell, or adversely affect sales of, currently marketed products, or such events or other data could otherwise have a material adverse effect on a related commercial product, including with respect to its safety profile. Any failure or delay in completing such clinical trials could materially and adversely affect the maintenance and growth of the markets for the related marketed products, which could adversely affect our business, financial condition, results of operations and overall growth prospects.

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

- difficulty identifying, recruiting or enrolling eligible patients, often based on the number of clinical trials, particularly with enrollment criteria targeting the same patient population, and in rare diseases with small patient populations;
- difficulty identifying a clinical development pathway, including viable indications and appropriate clinical trial protocol design, particularly where there is no applicable regulatory precedent;
- delays or failures in obtaining regulatory authorization to commence a trial because of safety concerns of regulators relating to our product candidates or similar product candidates of our competitors or failure to follow regulatory guidelines;
- delays or failures in obtaining clinical materials and manufacturing sufficient quantities of the product candidate for use in trials;
- delays or failures in reaching agreement on acceptable terms with prospective study sites;
- delays or failures in obtaining approval of our clinical trial protocol from an institutional review board, or similar bodies in other jurisdictions, such as an ethics committee in Europe, to conduct a clinical trial at a prospective study site;
- failure of our clinical trials and clinical investigators, including contract research organizations or other third parties assisting us with clinical trials, to satisfactorily perform their contractual duties, meet expected deadlines and comply with FDA and other regulatory agencies' requirements, including good clinical practices;
- unforeseen safety issues;
- inability to monitor patients adequately during or after treatment;
- difficulty monitoring multiple study sites; or
- insufficient funds to complete the trials.

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

## Risks Related to Our Intellectual Property

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

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

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

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

Patent enforcement generally must be sought on a country-by-country basis, and patent validity and infringement may be judged differently in different countries. The legal systems of certain countries, particularly certain developing countries, may lack maturity or consistency when it comes to the enforcement of patents and other intellectual property rights, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business.

Changes in either the patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property portfolio. Any patent may be challenged, and potentially invalidated or held unenforceable, including through patent litigation or through administrative procedures that permit challenges to patent validity. Patents can also be designed around by an ANDA or Section 505(b)(2) NDA that avoids infringement of our intellectual property.

In June 2021, we received notice from Lupin that it has filed with FDA an ANDA for a generic version of Xywav. The notice from Lupin included a "paragraph IV certification" with respect to ten of our patents listed in FDA's Orange Book for Xywav on the date of our receipt of the notice. A paragraph IV certification is a certification by a generic applicant that patents covering the branded product are invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the generic product. 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. In February 2023, we received notice from Teva that it had filed an ANDA seeking approval to market a generic version of Xywav, which notice included a paragraph IV certification with respect to certain of our patents listed in FDA's Orange Book for Xywav. For additional information on litigation involving these matters, see Note 13, Commitments and Contingencies—Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part IV of this Annual Report on Form 10-K.

We have settled patent litigation with each of the ten companies seeking to introduce generic versions of Xyrem in the U.S. by granting those companies licenses to launch their generic products (and in certain cases, an AG version of Xyrem) in advance of the expiration of the last of our patents. Notwithstanding our Xyrem patents and settlement agreements, additional third parties may also attempt to introduce generic versions of Xyrem, Xywav or other sodium oxybate products for treatment of cataplexy and/or EDS in narcolepsy that design around our patents or assert that our patents are invalid or otherwise unenforceable. Such third parties could launch a generic or 505(b)(2) product referencing Xyrem before the dates provided in our patents or settlement agreements. For example, we have several methods of use patents listed in the Orange Book, that expire in 2033 that cover treatment methods included in the Xyrem label related to a DDI with divalproex sodium. Although FDA has stated, in granting a Citizen Petition we submitted in 2016, that it would not approve any sodium oxybate ANDA referencing Xyrem that does not include the portions of the currently approved Xyrem label related to the DDI patents, we

cannot predict whether a future ANDA filer, or a company that files a Section 505(b)(2) application for a drug referencing Xyrem, may pursue regulatory strategies to avoid infringing our DDI patents notwithstanding FDA's response to the Citizen Petition, or whether any such strategy would be successful. Likewise, we cannot predict whether we will be able to maintain the validity of these patents or will otherwise obtain a judicial determination that a generic or other sodium oxybate product, its package insert or the generic sodium oxybate REMS or another separate REMS will infringe any of our patents or, if we prevail in proving infringement, whether a court will grant an injunction that prevents a future ANDA filer or other company introducing a different sodium oxybate product from marketing its product, or instead require that party to pay damages in the form of lost profits or a reasonable royalty.

Since Xyrem's regulatory exclusivity has expired in the EU, we are aware that generic or hybrid generic applications have been approved by various EU regulatory authorities, and additional generic or hybrid generic applications may be submitted and approved.

Additionally, in November and December 2022, ten companies sent us notices that they had filed ANDAs seeking approval to market a generic version of Epidiolex, which notices 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 applicable notice. On January 3, 2023, we filed a patent infringement suit against the ten Epidiolex ANDA filers in the United States District Court for the District of New Jersey. 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. For additional information on litigation involving this matter, see "*Epidiolex Patent Litigation*" in Note 13, Commitments and Contingencies—Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part IV of this Annual Report on Form 10-K.

On May 13, 2021, we filed a patent infringement suit against Avadel and several of its corporate affiliates in the United States District Court for the District of Delaware. The suit alleges that Avadel's product candidate FT218 will infringe five of our patents related to controlled release formulations of oxybate and the safe and effective distribution of oxybate. In March 2024, the jury upheld the validity of both of our asserted patents and awarded us damages for infringement for past sales of Lumryz in the U.S. For additional information on litigation involving this matter, see "*Avadel Litigation*" in Note 13, Commitments and Contingencies—Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part IV of this Annual Report on Form 10-K.

In July and August 2024, Zepzelca ANDA filers sent us notices that they had filed ANDAs seeking approval to market a generic version of Zepzelca (lurbinectedin), which notices each included a paragraph IV certification with respect to our Orange Book listed patent for Zepzelca on the date of the receipt of the applicable notice. In September 2024, we filed patent infringement suits against these ANDA filers. For additional information on litigation involving this matter, see "*Zepzelca Patent Litigation*" in Note 13, Commitments and Contingencies—Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part IV of this Annual Report on Form 10-K.

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

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

Our ability, and that of our partners, to successfully commercialize any approved products will depend, in part, on our ability to obtain patents, enforce those patents and operate without infringing the proprietary rights of third parties. If we choose to go to court to stop a third party from infringing our patents, our licensed patents or our partners' patents, that third party has the right to ask the court or an administrative agency to rule that these patents are invalid and/or should not be enforced. These lawsuits and administrative proceedings are expensive and consume time and other resources, and we may not be successful in these proceedings or in stopping infringement. In addition, the IPR or a post-grant review process under the

Leahy-Smith America Invents Act permits any person, whether they are accused of infringing the patent at issue or not, to challenge the validity of certain patents through a proceeding before the PTAB of the USPTO.

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

Litigation involving patent matters is frequently settled between the parties, rather than continuing to a court ruling. The FTC has publicly stated that, in its view, certain types of agreements between branded and generic pharmaceutical companies related to the settlement of patent litigation or the manufacture, marketing and sale of generic versions of branded drugs violate the antitrust laws and has commenced investigations and brought actions against some companies that have entered into such agreements. In particular, the FTC has expressed its intention to take aggressive action to challenge settlements that include an alleged transfer of value from the brand company to the generic company (so-called “pay for delay” patent litigation settlements). The U.S. Congress and state legislatures have also identified pharmaceutical patent litigation settlements as potential impediments to generic competition and have introduced, and in states like California passed, legislation to regulate them. Third party payors have also challenged such settlements on the grounds that they increase drug prices. Because there is currently no precise legal standard with respect to the lawfulness of such settlements, many pharmaceutical companies, including us, have faced extensive litigation over whether patent litigation settlements they have entered into are reasonable and lawful. From June 2020 to May 2022, several lawsuits were filed on behalf of purported direct and indirect Xyrem purchasers, alleging that the patent litigation settlement agreements we entered with Hikma and other ANDA filers violate state and federal antitrust and consumer protection laws. For additional information on these lawsuits, see "*Xyrem Antitrust Litigation*" in Note 13, Commitments and Contingencies—Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part IV of this Annual Report on Form 10-K. 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 in the class action complaints were to be successful in their claims, they may be entitled to injunctive relief or we may be required to pay significant monetary damages, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

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

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

If we were found to infringe upon a patent or other intellectual property right, if we failed to obtain or renew a license under a patent or other intellectual property right from a third party, or if a third party that we were licensing technologies from was found to infringe upon a patent or other intellectual property rights of another third party, we may be required to pay damages, including damages of up to three times the damages found or assessed, if the infringement is found to be willful, suspend the manufacture of certain products or reengineer or rebrand our products, if feasible, or we may be unable to enter certain new product markets. In addition, if we have declined or failed to enter into a valid assignment agreement for any reason, we may not own the invention or our intellectual property, and our products may not be adequately protected.

Litigation, whether filed by us or against us, can be expensive and time consuming to defend and divert management’s attention and resources. Our competitive position could suffer as a result. 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 NDA for Avadel’s drug Lumryz was unlawful. On September 15, 2023, we filed a motion for summary judgment. On October 20, 2023, Avadel and FDA filed cross motions for summary judgment. Oral argument on these motions was held on May 10, 2024, and

on October 30, 2024, the District Court issued an order denying our motion for summary judgment and granting Avadel's and FDA's cross-motions for summary judgment. We have appealed the matter to the United States Court of Appeals for the District of Columbia Circuit. We cannot predict the timing or ultimate outcome of this litigation or the impact of this litigation on our business, including any potential adverse consequences to, among other things, our reputation, relationships with governmental or regulatory authorities, including FDA. For additional information, see "*FDA Litigation*" in Note 13, Commitments and Contingencies—Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part IV of this Annual Report on Form 10-K.

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

The first NDA applicant with an orphan drug designation for a particular active moiety to treat a specific disease or condition that receives FDA approval is usually entitled to a seven-year exclusive marketing period in the U.S. for that drug, for that indication. We rely in part on this ODE and other regulatory exclusivities to protect Xywav, Epidiolex, Zepzelca, Zihera and, potentially, our other products and product candidates from competitors, and we expect to continue relying in part on these regulatory exclusivities in the future. The duration of our regulatory exclusivity period could be impacted by a number of factors, including FDA's later determination that our request for orphan designation was materially defective, that the manufacturer is unable to supply sufficient quantities of the drug, that the extension of the exclusivity period established by the Improving Regulatory Transparency for New Medical Therapies Act does not apply, or the possibility that we are unable to successfully obtain pediatric exclusivity. There is no assurance that we will successfully obtain orphan drug designation for other products or product candidates or other rare diseases or that a product candidate for which we receive orphan drug designation will be approved, or that we will be awarded ODE upon approval as, for example, FDA may reconsider whether the eligibility criteria for such exclusivity have been met and/or maintained. Moreover, a drug product with an active moiety that is different from that in our drug candidate or, under limited circumstances, the same drug product, may be approved by FDA for the same indication during the period of marketing exclusivity. According to FDA, the limited circumstances include a showing that the second drug is clinically superior to the drug with marketing exclusivity through a demonstration of superior safety or efficacy or that it makes a major contribution to patient care. For example, even though FDA granted seven-year ODE to Xywav, FDA also approved Lumryz and granted Lumryz seven-year 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, if a competitor obtains approval and marketing exclusivity for a drug product with an active moiety that is the same as that in a product candidate we are pursuing for the same indication before us, approval of our product candidate would be blocked during the period of marketing exclusivity unless we could demonstrate that our product candidate is clinically superior to the approved product. In addition, if a competitor obtains approval and marketing exclusivity for a drug product with an active moiety that is the same as that in a product candidate we are pursuing for a different orphan indication, this may negatively impact the market opportunity for our product candidate. There have been legal challenges, including from us, to aspects of FDA's regulations and policies concerning the exclusivity provisions of the Orphan Drug Act, including whether two drugs are the same drug product, and our and future challenges could lead to changes that affect the protections potentially afforded our products in ways that are difficult to predict. In this regard, we have filed a complaint in the United States District Court for the District of Columbia seeking a declaration that FDA's approval of Lumryz was unlawful and allege that FDA acted outside its authority under the Orphan Drug Act, when, despite the ODE protecting Xywav, FDA approved Lumryz and granted Lumryz seven-year ODE. However, legal challenges like this are inherently uncertain and there can be no guarantee that the United States District Court for the District of Columbia will agree with our interpretation of applicable laws and regulations or will otherwise agree with any or all of the allegations included in our complaint, or that we will otherwise prevail in this litigation. We also cannot predict what other adverse consequences to, among other things, our reputation, our relationship with FDA or other governmental or regulatory authorities or the protections afforded our products could result from our decision to proceed with this litigation or the ultimate outcome thereof. Moreover, in the future, there is the potential for legislative changes or additional legal challenges to FDA's orphan drug regulations and policies, and it is uncertain how such challenges might affect our business.

In the EU, if a marketing authorization is granted for a medicinal product designated an orphan drug, that product is currently entitled to ten years of marketing exclusivity. We rely in part on this orphan drug exclusivity and other regulatory exclusivities to protect Epidiolex and Vyxeos. During the period of marketing exclusivity, subject to limited exceptions, no similar medicinal product may be granted a marketing authorization for the orphan indication. There is no assurance that we will successfully obtain orphan drug designation for future rare indications or orphan exclusivity upon approval of any of our product candidates that have already obtained designation. On April 26, 2023, the EC published proposals for a new package of pharmaceutical legislation that would replace the current Medicines Directive and the existing medicinal product regulation (including the pediatric and orphan regulations). If enacted, the proposal could impact our ability to secure orphan designation for future products, and would impact the scope and duration of market and orphan exclusivities in the EU. Further, a similar medicinal product may be granted a marketing authorization for the same indication notwithstanding our marketing exclusivity if we are unable to supply sufficient quantities of our product, or if the second product is safer, more effective or otherwise clinically superior to our orphan drug. In addition, if a competitor obtains marketing authorization and orphan exclusivity for a

product that is similar to a product candidate we are pursuing for the same indication, approval of our product candidate would be blocked during the period of orphan marketing exclusivity unless we could demonstrate that our product candidate is safer, more effective or otherwise clinically superior to the approved product.

### **Other Risks Related to Our Business and Industry**

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

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

- the diverse regulatory, financial and legal requirements in the countries where we are located or do business, and any changes to those requirements;
- challenges inherent in efficiently managing employees and commercial partners in diverse geographies, including the need to adapt systems, policies, benefits and compliance programs to differing labor and employment law and other regulations, as well as maintaining positive interactions with our unionized employees;
- costs of, and liabilities for, our international operations, including clinical trials, products or product candidates;
- additional exposure to foreign currency exchange risk from non-U.S. operations;
- political and economic instability, such as the instability caused by Russia's invasion of Ukraine;
- escalating trade tensions; and
- public health risks and potential related effects on supply chain, travel and employee health and availability.

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

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

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

Our information technology systems, and those of our vendors, are large and complex and store large amounts of sensitive data. We and the third parties upon which we rely face a variety of evolving threats that could impact the availability of our sensitive data and information technology systems and cause security incidents from inadvertent or intentional actions by our employees, third party vendors and/or business partners, or from cyber-attacks and malicious third parties.

Threats of this nature are prevalent, are increasing in frequency, persistence, sophistication and intensity, are being conducted by sophisticated and organized groups and individuals, are increasingly difficult to detect, and come from a variety of sources and with a wide range of motives (including, but not limited to, industrial espionage) and expertise, including organized criminal groups, "hacktivists," traditional computer "hackers," threat actors, personnel (such as through theft or misuse), nation states, nation-state-supported actors, and others.

In addition to the extraction of important information, such threats could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering, malicious code, credential harvesting, personnel misconduct or error, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, and other threats that affect service reliability and threaten the confidentiality, integrity and availability of our information technology systems and sensitive data. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, or otherwise experience significant disruptions of our, our third party vendors' and/or business partners' information technology systems or security breaches, including in our remote work environment, such occurrence could adversely affect our

business operations and/or result in the loss, misappropriation, and/or unauthorized access, use or disclosure of, or the prevention of access to, sensitive data, and could result in adverse consequences to us such as government enforcement actions, additional reporting requirements and/or oversight, restrictions on processing sensitive data, litigation, indemnification obligations, negative publicity, reputational harm, monetary fund diversions, diversion of management attention, interruptions in our operations, financial loss, and other similar harms. Any such event that leads to unauthorized access, use or disclosure of personal data, including personal data regarding our patients or employees, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, notify relevant stakeholders, subject us to mandatory corrective action, require us to verify the correctness of database contents and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal data. This could disrupt our business, result in increased costs or loss of revenue, and/or result in significant legal and financial exposure. In addition, security breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may further harm us.

While we have implemented security measures to protect our information technology systems and infrastructure and sensitive data, there can be no assurance that such measures will be effective or prevent service interruptions or security breaches that could adversely affect our business. We may expend significant resources to implement and maintain security measures to try to protect against security incidents. In addition, failure to maintain effective internal accounting controls related to security breaches and cybersecurity in general could impact our ability to produce timely and accurate financial statements and subject us to regulatory scrutiny.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive data about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

***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.***

#### *FDA and Equivalent Non-U.S. Regulatory Authorities*

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

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

Rylaze and Epidyolex are available on a named patient basis or through a compassionate use process in many countries where they are not commercially available. If any such country's regulatory authorities determine that we are promoting such products without proper authorization, we could be found to be in violation of pharmaceutical advertising laws or the regulations permitting sales under named patient programs. In that case, we may be subject to financial or other penalties. Any failure to maintain revenues from sales of products on a named patient basis and/or to generate revenues from commercial sales

of these products exceeding historical sales on a named patient basis could have an adverse effect on our business, financial condition, results of operations and growth prospects.

FDA, the competent authorities of the EU member states and other European countries, and other governmental authorities require advertising and promotional materials to be truthful and not misleading, and products to be marketed only for their approved indications and in accordance with the provisions of the approved label. Regulatory authorities actively investigate allegations of off-label promotion in order to enforce regulations prohibiting these types of activities. A determination that we have promoted an approved product for off-label uses could subject us to significant liability, including civil and administrative financial penalties and other remedies as well as criminal financial penalties, other sanctions and imprisonment. Even if we are not determined to have engaged in off-label promotion, an allegation that we have engaged in such activities could have a significant impact on our sales, business and financial condition. The U.S. government has also required companies to enter into complex corporate integrity agreements and/or non-prosecution agreements that impose significant reporting and other burdens on the affected companies. Failure to maintain a comprehensive and effective compliance program, and to integrate the operations of acquired businesses into a combined comprehensive and effective compliance program on a timely basis, could subject us to a range of regulatory actions and/or civil or criminal penalties that could affect our ability to commercialize our products and could harm or prevent sales of the affected products, or could substantially increase the costs and expenses of commercializing and marketing our products.

#### *Other Regulatory Authorities*

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

We are subject to numerous fraud and abuse laws and regulations globally and our sales, marketing, patient support and medical activities may be subject to scrutiny under these laws and regulations. These laws are described in “Business—Government Regulation” in Part I, Item 1 of this Annual Report on Form 10-K. While we maintain a comprehensive compliance program to try to ensure that our practices and the activities of our third party contractors and employees fall within the scope of available statutory exceptions and regulatory safe harbors whenever possible, and otherwise comply with applicable laws, regulations or guidance, regulators and enforcement agencies may disagree with our assessment or find fault with the conduct of our employees or contractors. In addition, existing regulations are subject to regulatory revision or changes in interpretation by the DOJ or OIG. For example, in November 2020, the OIG issued a Special Fraud Alert to highlight certain inherent risks of remuneration related to speaker programs sponsored by drug and medical device companies, which may not in all circumstances qualify under either safe harbor or statutory exception protection. The Special Fraud Alert sent a clear signal that speaker programs will be subject to potentially heightened enforcement scrutiny, in particular for those programs with certain characteristics identified as risk factors by OIG.

Many companies have faced government investigations or lawsuits by whistleblowers who bring a *qui tam* action under the False Claims Act on behalf of themselves and the government for a variety of alleged improper marketing activities, including providing free product to customers expecting that the customers would bill federal programs for the product, providing consulting fees, grants, free travel and other benefits to physicians to induce them to prescribe the company’s products, and inflating prices reported to private price publication services, which are used to set drug reimbursement rates under government healthcare programs. For example, we are subject to a *qui tam* whistleblower lawsuit originally filed under seal on May 27, 2021. For additional information see “*Qui tam matter*” in Note 13, Commitments and Contingencies—Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part IV of this Annual Report on Form 10-K. In addition, the government and private whistleblowers have pursued False Claims Act cases against pharmaceutical companies for causing false claims to be submitted as a result of the marketing of their products for unapproved uses or violations of the federal anti-kickback statute. If we become the subject of a government False Claims Act or other investigation or whistleblower suit, we could incur substantial legal costs (including settlement costs) and business disruption responding to such investigation or suit, regardless of the outcome.

Any investigations or litigation may result in damages, fines, penalties or administrative sanctions against us, negative publicity or other negative actions that could harm our reputation, reduce demand for our products and/or reduce coverage of our products, including by federal health care programs and state health care programs. If any or all of these events occur, our business and stock price could be materially and adversely affected.

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

of the Sunshine provisions or any other U.S. federal, state or local laws or regulations that may apply, or if we otherwise fail to comply with the Sunshine provisions or similar requirements of state or local regulators, we may be subject to significant civil, and administrative penalties, damages or fines.

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

We have established programs to consider grant applications submitted by independent charitable organizations, including organizations that provide co-pay support to patients who suffer from the diseases treated by our drugs. The OIG has issued guidance for how pharmaceutical manufacturers can lawfully make donations to charitable organizations who provide co-pay assistance to Medicare patients, provided that such organizations, among other things, are *bona fide* charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria, and do not link aid to use of a donor's product. As of August 2024, we have fulfilled the terms and OIG closed out our corporate integrity agreement that required us to maintain our ongoing corporate compliance program. Although we are continuing to implement our corporate compliance program and have structured our programs to follow available guidance, if we or our vendors or donation recipients are deemed to fail to comply with relevant laws, regulations or evolving government guidance in the operation of these programs, such facts could be used as the basis for an enforcement action against us by the federal government or other enforcement agencies or private litigants, or we could become liable for payment of certain stipulated penalties or could be excluded from participation in federal health care programs, which would have a material adverse effect on our sales, business and financial condition.

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

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

We are also subject to federal, state, national and international laws and regulations governing the privacy and security of health-related and other personal data we collect and maintain, including, but not limited to, Section 5 of the Federal Trade Commission Act, the Health Breach Notification Rule, HIPAA, the California Consumer Privacy Act, as amended by California Privacy Rights Act, as well as other similar state privacy laws, and the EU's and U.K.'s GDPR. The GDPR, for example, imposes restrictions on the processing (e.g., collection, use and disclosure) of personal data in the EU and the U.K. and also imposes strict restrictions on the transfer of personal data out of the EU to the U.S. The GDPR imposes penalties of up to 20 million Euros or up to 4% of annual global revenue. HIPAA imposes privacy and security obligations on covered entity health care providers, health plans, and health care clearinghouses, as well as their "business associates" – certain persons or covered entities that create, receive, maintain, or transmit protected health information in connection with providing a specified service or performing a function for or on behalf of a covered entity. Although we are not directly subject to HIPAA, we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly receive individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA. The FTC also sets expectations for failing to take appropriate steps to keep consumers' personal information secure or failing to provide a level of security commensurate to promises made to an individual about the security of their personal information (such as in a privacy notice); such failures may constitute unfair or deceptive acts or practices in violation of Section 5(a) of the Federal Trade Commission Act. Compliance with these laws requires a flexible privacy framework and substantial resources, and compliance efforts will likely be an increasing and substantial cost in the future.

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

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

We participate in the Medicaid Drug Rebate Program, the 340B program, the U.S. Department of Veterans Affairs' FSS pricing program, and Tricare program, and have obligations to report the average sales price for certain of our drugs to the Medicare program. All of these programs are described in more detail under the heading "Business—Pharmaceutical Pricing, Reimbursement by Government and Private Payors and Patient Access" in Part I, Item 1 of our Annual Report on Form 10-K for the year ended December 31, 2024. Manufacturers are required to report the average sales price for drugs under the Medicare program regardless of whether they are enrolled in the Medicaid Drug Rebate Program. In addition, manufacturers must pay refunds to Medicare for single source drugs or biologicals, or biosimilar biological products, reimbursed under Medicare Part B and packaged in single-dose containers or single-use packages for units of discarded drug reimbursed by Medicare Part B in excess of 10 percent of total allowed charges under Medicare Part B for that drug. Statutory or regulatory changes or guidance from CMS could affect the average sales price calculations for our products and the resulting Medicare payment rate and could negatively impact our results of operations. Further, the IRA established a Medicare Part B inflation rebate scheme, under which, generally speaking, manufacturers will owe rebates if the average sales price of a Part B drug increases faster than the pace of inflation. Failure to timely pay a Part B inflation rebate is subject to a civil monetary penalty.

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

Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we are found to have made a misrepresentation in the reporting of our average sales price, if we fail to submit the required price data on a timely basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. CMS could also decide to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. We cannot be certain that our submissions will not be found by CMS to be incomplete or incorrect. Moreover, failure to pay refunds for units of discarded drug under the discarded drug refund program could subject us to civil monetary penalties of 125 percent of the refund amount.

Our failure to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program and other governmental programs could negatively impact our financial results. CMS issued a final rule that modified prior Medicaid Drug Rebate Program regulations to permit reporting multiple best price figures with regard to value-based purchasing arrangements; and to provide definitions for "line extension," "new formulation," and related terms, with the practical effect of expanding the scope of drugs considered to be line extensions that are subject to an alternative rebate formula. While the regulatory modifications that purported to affect the applicability of the best price and average manufacturer price exclusions of manufacturer-sponsored patient benefit programs, in the context of PBM "accumulator" programs were invalidated by a court and rescinded, such programs may continue to negatively affect us in other ways. Our failure to comply with these price reporting and rebate payment options could negatively impact our financial results. In addition, on September 26, 2024, CMS finalized a rule modifying the regulations implementing the Medicaid Drug Rebate Program in ways that could increase the costs and complexity of compliance and that could increase manufacturer rebate liability, given that the final rule clarified certain aspects of the definition of covered outpatient drugs subject to these rebates, which could expand the number of units of drugs that qualify for this definition, among other changes. Regulatory and legislative changes, and judicial rulings relating to the Medicaid Drug Rebate Program and related policies (including coverage expansion), have increased and will continue to

increase our costs and the complexity of compliance, have been and will continue to be time-consuming to implement, and could have a material adverse effect on our results of operations, particularly if CMS or another agency challenges the approach we take in our implementation. Rebates are no longer subject to a cap on the rebate amount, which negatively impacts our rebate liability.

The HRSA issued a final regulation regarding the calculation of the 340B ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities. Implementation of this regulation could affect our obligations and potential liability under the 340B program in ways we cannot anticipate. We are also required to report the 340B ceiling prices for our covered outpatient drugs to HRSA, which then publishes them to 340B covered entities. If we are found to have knowingly and intentionally charged 340B covered entities more than the statutorily mandated ceiling price, we could be subject to significant civil monetary penalties and/or such failure also could be grounds for HRSA to terminate our agreement to participate in the 340B program, in which case our covered outpatient drugs would no longer be eligible for federal payment under the Medicaid or Medicare Part B program, which would have a material adverse effect on our business, financial condition, results of operations and growth prospects, including our ability to acquire, in-license or develop new products to grow our business. Moreover, HRSA established an ADR process under a final regulation for claims by covered entities that a manufacturer engaged in overcharging, including claims that a manufacturer limited the ability of a covered entity to purchase the manufacturer's drugs at the 340B ceiling price, and by manufacturers that a covered entity violated the prohibitions against diversion or duplicate discounts. Such claims are to be resolved through an ADR panel of government officials rendering a decision that may be appealed to a federal court. An ADR proceeding could potentially subject us to discovery by covered entities and other onerous procedural requirements and could result in additional liability. Additionally, HRSA issued a final rule that changes aspects of the ADR process effective June 2024, which could negatively affect us. In addition, HRSA could decide to terminate a manufacturer's agreement to participate in the 340B program for a violation of that agreement or other good cause shown, in which case the manufacturer's covered outpatient drugs may no longer be eligible for federal payment under the Medicaid or Medicare Part B program.

Further, legislation may be introduced at the state or Federal level that, if passed, would, among other things, modify the requirements of the 340B program.

Medicare Part D generally provides coverage to enrolled Medicare patients for self-administered drugs (*i.e.*, drugs that are not administered by a physician). Medicare Part D is administered by private prescription drug plans approved by the U.S. government and, subject to detailed program rules and government oversight, each drug plan establishes its own Medicare Part D formulary for prescription drug coverage and pricing, which the drug plan may modify from time to time. The prescription drug plans negotiate pricing with manufacturers and pharmacies and may condition formulary placement on the availability of manufacturer discounts. In addition, manufacturers, including us, were required through December 31, 2024 to provide to CMS a 70% discount on brand name prescription drugs utilized by Medicare Part D beneficiaries when those beneficiaries are in the coverage gap phase of the Part D benefit design. Civil monetary penalties could be due if we fail to offer discounts to beneficiaries under the Medicare Part D coverage gap discount program. The IRA sunsets the coverage gap discount program starting in 2025 and replaces it with a new manufacturer discount program, under which manufacturers are, in general, to provide a 10% discount on a covered Part D drug where a beneficiary is in the initial phase of Part D coverage and a 20% discount where a beneficiary is in the catastrophic phase of Part D coverage. Failure to pay a discount under this new program will be subject to a civil monetary penalty. In addition, the IRA established a Medicare Part D inflation rebate scheme, under which, generally speaking, manufacturers will owe additional rebates if the average manufacturer price of a Part D drug increases faster than the pace of inflation. Failure to timely pay a Part D inflation rebate is subject to a civil monetary penalty.

The IRA also creates a drug price negotiation program under which the prices for Medicare units of certain high Medicare spend drugs and biologicals without generic or biosimilar competition will be capped by reference to, among other things, a specified non-federal average manufacturer price starting in 2026. Failure to comply with requirements under the drug price negotiation program is subject to an excise tax and/or a civil monetary penalty. This or any other legislative change could impact the market conditions for our products. We further expect continued scrutiny on government price reporting from Congress, agencies, and other bodies.

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

***Product liability and product recalls could harm our business.***

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

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

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

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

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

**Risks Related to Controlled Substances**

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

Xyrem and Xywav and certain product candidates we are developing contain controlled substances as defined by state law and the federal CSA. Controlled substances are subject to a number of requirements and restrictions under the CSA and implementing regulations, including certain registration, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. The DEA classifies controlled substances into five schedules: Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse, no currently "accepted medical use" in the U.S., lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the U.S. Pharmaceutical products approved for use in the U.S. which contain a controlled substance are listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, heightened security requirements and additional criteria for importation. In addition, dispensing of Schedule II drugs is subject to additional requirements. For example, they may not be refilled without a new prescription.

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

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

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

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

***Our ability to research, develop and commercialize Epidiolex/Epidyolex is dependent on our ability to maintain licenses relating to the cultivation, possession and supply of botanical cannabis, a controlled substance.***

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

***Controlled substance legislation differs between countries and legislation in certain countries may restrict or limit our ability to sell Epidyolex.***

Most countries are parties to the Single Convention on Narcotic Drugs 1961, which governs international trade and domestic control of narcotic substances, including cannabis extracts. Countries may interpret and implement their treaty obligations in a way that creates a legal obstacle to our obtaining regulatory approval for Epidyolex in those countries. These countries may not be willing or able to amend or otherwise modify their laws and regulations to permit Epidyolex to be marketed, or achieving such amendments to the laws and regulations may take a prolonged period of time.

#### **Risks Related to Our Financial Condition and Results**

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

As of December 31, 2024, we had total indebtedness of approximately \$6.2 billion. Our substantial indebtedness may:

- limit our ability to use our cash flow or borrow additional funds for working capital, capital expenditures, acquisitions, investments or other general business purposes;
- require us to use a substantial portion of our cash flow from operations to make debt service payments;
- limit our flexibility to plan for, or react to, changes in our business and industry, or our ability to take specified actions to take advantage of certain business opportunities that may be presented to us;

- expose us to the risk of increased interest rates as certain of our borrowings, including a portion of borrowings under the Amended Credit Agreement, are at variable rates of interest;
- result in dilution to our existing shareholders to the extent that the remainder, if any, of the exchange obligation in excess of our Exchangeable Senior Notes are settled in our ordinary shares upon exchange;
- place us at a competitive disadvantage compared to our less leveraged competitors; and
- increase our vulnerability to the impact of adverse economic and industry conditions.

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

***Covenants in the Amended Credit Agreement and indenture governing our Secured Notes restrict our business and operations in many ways and if we do not effectively manage our covenants, our financial conditions and results of operations could be adversely affected.***

The Amended Credit Agreement and the indenture governing our Secured Notes contain various covenants that, among other things, limit our ability and/or our restricted subsidiaries' ability to:

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

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

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

As a result of these restrictions, we may be:

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

Our failure to comply with any of the covenants could result in a default under the Amended Credit Agreement and the indenture governing our Secured Notes, which, if not cured or waived, could result in us having to repay our borrowings before their due dates. Such default may allow the lenders or the note holders to accelerate the related debt and may result in the acceleration of any other debt to which a cross-acceleration or cross-default provision applies. If we are forced to refinance these borrowings on less favorable terms or if we were to experience difficulty in refinancing the debt prior to maturity, our results of operations or financial condition could be materially affected. In addition, an event of default under the Amended Credit Agreement may permit the lenders to refuse to permit additional borrowings under the Amended Revolving Credit Facility or to terminate all commitments to extend further credit under the Amended Revolving Credit Facility. Furthermore, if we are unable to repay the amounts due and payable under the Amended Credit Agreement or the Secured Notes, as the case

may be, the lenders and note holders thereof may be able to proceed against the collateral granted to them to secure that indebtedness. In the event our lenders or note holders, as the case may be, accelerate the repayment of such borrowings, we cannot assure you that we will have sufficient assets to repay such indebtedness.

A default under the indentures governing our Exchangeable Senior Notes could also lead to a default under other debt agreements or obligations, including the Amended Credit Agreement and indenture governing the Secured Notes. Likewise, a default under the Amended Credit Agreement or the Secured Notes could lead to a default under other debt agreements or obligations, including the indentures governing our Exchangeable Senior Notes.

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

The scope of our business and operations has grown substantially, including through a series of business combinations and acquisitions. To continue to grow our business over the longer term, we plan to commit substantial resources to product acquisition and in-licensing, product development, clinical trials of product candidates and expansion of our commercial, development, manufacturing and other operations. Acquisition opportunities that we pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. Our ability to raise additional capital may be adversely impacted by worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the U.S. and worldwide resulting from the effects of inflationary pressures, potential future bank failures or otherwise. 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, and we currently have such authorization. Moreover, as a matter of Irish law, when an Irish public limited company issues ordinary shares to new shareholders for cash, the company must first offer those shares on the same or more favorable terms to existing shareholders on a pro-rata basis, unless this statutory pre-emption obligation is dis-applied, or opted-out of, by approval of its shareholders. At our annual general meeting of shareholders in July 2024, our shareholders voted to approve our proposal to dis-apply the statutory pre-emption obligation. This current pre-emption opt-out authority is due to expire in January 2026. 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.

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

Our intangible assets and goodwill are significant and are subject to an impairment analysis whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Additionally, goodwill and indefinite-lived assets are subject to an impairment test at least annually. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. For example, in the third quarter of 2022, we recorded a \$133.6 million asset impairment charge as a result of the decision to discontinue our nabiximols program. Our results of operations and financial position in future periods could be negatively impacted should future impairments of intangible assets or goodwill occur.

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

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

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

We are incorporated in Ireland and maintain subsidiaries in North America, the U.K. and a number of other foreign jurisdictions. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various jurisdictions where we operate. Our effective tax rate may fluctuate depending on a number of factors, including, but not limited to, the

distribution of our profits or losses between the jurisdictions where we operate and changes to or differences in interpretation of tax laws. For example, our income tax expense for the year ended December 31, 2021, included an expense of \$259.9 million arising on the remeasurement of our U.K. net deferred tax liability, which arose primarily in relation to the GW Acquisition, due to a change in the statutory tax rate in the U.K. following enactment of the U.K. Finance Act 2021.

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

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

The U.S. Congress, the EU, the OECD, and other government agencies in jurisdictions where we and our affiliates do business have had an extended focus on issues related to the taxation of multinational corporations. As a result of the focus on the taxation of multinational corporations, the tax laws in Ireland, the U.S. and other countries in which we and our affiliates do business could change on a prospective or retroactive basis, and any such changes could adversely affect us.

One example is the OECD's initiative in the area of "base erosion and profit shifting." In October 2021, the OECD released Pillar Two. In December 2022, the EU agreed to implement this global minimum tax rate for EU member states by the start of 2024. In accordance with the EU directive, Ireland adopted legislation implementing Pillar Two on December 18, 2023, with effect from the start of 2024. Other jurisdictions in which we do business have also adopted legislation implementing Pillar Two. Pillar Two legislation could have an adverse impact on our effective tax rate, tax liabilities, and cash tax.

Further, the IRA, among other things, introduced new tax provisions, including a 15% corporate alternative minimum tax for certain large corporations, and a one percent excise tax on certain share repurchases by publicly traded corporations, including certain repurchases by specified domestic affiliates of publicly traded foreign corporations. These provisions became effective in 2023. The IRS has issued limited guidance on the corporate alternative minimum tax, the excise tax and the other tax provisions in the IRA, and much of this guidance has yet to be finalized. Final guidance under the IRA could adversely affect our tax provision, cash tax liability and effective tax rate.

The U.S. and other jurisdictions in which we operate continue to consider other changes in tax laws and regulations that apply to multinationals, including proposed legislation and guidance with respect to research and development expenditures and other guidance under the 2017 Tax Cuts and Jobs Act. The new presidential administration has included as part of its agenda a potential reform of U.S. tax laws, the details of which have not yet emerged. In addition, certain of the provisions in the 2017 Tax Cuts and Jobs Act will change or expire on December 31, 2025 unless Congress takes action to extend these provisions in their current form. In particular, a significant portion of our income taxable in the U.S. qualifies for preferential treatment as foreign-derived intangible income. Beginning in 2026, the effective tax rate for foreign-derived intangible income will increase from 13% to 16%. If U.S. tax rates increase and/or the foreign-derived intangible income deduction is reduced or eliminated, our tax provision, cash tax liability and effective tax rate would be adversely affected.

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

Although we are incorporated in Ireland, the IRS may assert that we should be treated as a U.S. corporation (and, therefore, a U.S. tax resident) for U.S. federal tax purposes pursuant to Section 7874 of the Code. For U.S. federal tax purposes, a corporation generally is considered a tax resident in the jurisdiction of its organization or incorporation. Because we are an Irish incorporated entity, we would be classified as a foreign corporation (and, therefore, a non-U.S. tax resident) under these rules. Section 7874 of the Code provides an exception under which a foreign incorporated entity may, in certain circumstances, be treated as a U.S. corporation for U.S. federal tax purposes. Because we indirectly acquired all of Jazz Pharmaceuticals, Inc.'s assets through the acquisition of the shares of Jazz Pharmaceuticals, Inc. common stock when the businesses of Jazz Pharmaceuticals, Inc. and Azur Pharma Public Limited Company were combined in the Azur Merger, the IRS could assert that we should be treated as a U.S. corporation for U.S. federal tax purposes under Section 7874. Moreover, new statutory and/or regulatory provisions under Section 7874 of the Code or otherwise could be enacted that could adversely affect our status as a foreign corporation for U.S. federal tax purposes, and any such provisions could have prospective or retroactive application to us, our shareholders, Jazz Pharmaceuticals, Inc. and/or the Azur Merger.

***Our ability to use NOLs and carryforward tax losses to offset potential taxable income is limited under applicable law and could be subject to further limitations if we do not generate taxable income in a timely manner or if certain “ownership change” provisions of applicable law result in further limitations.***

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

#### **Risks Related to Our Ordinary Shares**

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

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

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

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

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

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

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

***Our articles of association, Irish law, the Amended Credit Agreement and the indentures governing our Secured Notes and Exchangeable Senior Notes contain provisions that could delay or prevent a takeover of us by a third party.***

Our articles of association could delay, defer or prevent a third party from acquiring us, despite the possible benefit to our shareholders, or otherwise adversely affect the price of our ordinary shares. In addition to our articles of association, several mandatory provisions of Irish law could prevent or delay an acquisition of us. We are also subject to various provisions of Irish law relating to mandatory bids, voluntary bids, requirements to make a cash offer and minimum price requirements, as well as substantial acquisition rules and rules requiring the disclosure of interests in our shares in certain circumstances. Furthermore, a takeover of us may trigger a default under the Amended Credit Agreement or the requirement that we offer to purchase our Secured Notes or Exchangeable Senior Notes and/or increase the exchange rate applicable to our Exchangeable Senior Notes, which could make it more costly for a potential acquirer to engage in a business combination transaction with us.

These provisions, whether alone or together, may discourage potential takeover attempts, discourage bids for our ordinary shares at a premium over the market price or adversely affect the market price of, and the voting and other rights of the holders of, our ordinary shares. These provisions, whether alone or together, could also discourage proxy contests and make it more difficult for our shareholders to elect directors other than the candidates nominated by our board.

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

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

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

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

#### **General Risk Factors**

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

Our success and our ability to grow depend in part on our continued ability to attract, retain and motivate highly qualified personnel, including our executive management team. In addition, changes we make to our current and future work environments may not meet the needs or expectations of our employees or may be perceived as less favorable compared to other companies' policies, which could negatively impact our ability to hire and retain qualified personnel, whether in a remote or in-office environment. In December 2024, our Chief Executive Officer notified us of his intent to retire from his role as Chief Executive Officer upon the selection and appointment of our next Chief Executive Officer, and to continue serving as Chairperson of the Board of Directors. Moreover, the loss of services and institutional knowledge of one or more additional members of our executive management team or other key personnel could delay or prevent the successful completion of some of our vital activities and may negatively impact our operations and future growth. We do not carry "key person" insurance. In addition, changes in our organization as a result of executive management transition may have a disruptive impact on our ability to implement our strategy. Until we integrate new personnel, and unless they are able to succeed in their positions, we may be unable to successfully manage and grow our business. In any event, if we are unable to attract, retain and motivate quality individuals, or if there are delays, or if we do not successfully manage personnel and executive management transitions, our business, financial condition, results of operations and growth prospects could be adversely affected.

***Anti-diversity, equity and inclusion initiatives could expose us to the risk of litigation or investigations, resulting in injunctions, penalties, or reputational harm.***

We have talent management efforts designed to build and maintain an inclusive environment with diverse thought, backgrounds, experiences and skillsets throughout our organization. However, there has been increasing scrutiny on corporate DEI initiatives, including from activists and policymakers challenging how such initiatives comply with civil rights protections. For example, the U.S. President recently issued an executive order opposing DEI initiatives in the private sector. Such anti-DEI initiatives and scrutiny could expose us to the risk of litigation or investigations, resulting in injunctions, penalties, or reputational harm. In addition, if we become unable to (or are perceived not to) successfully implement certain of our workforce initiatives, including in keeping with current or potential future laws or interpretations thereof, our ability to recruit, attract and retain talent may be adversely impacted.

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

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

#### **Item 1B. Unresolved Staff Comments**

There are no material unresolved written comments that were received from the SEC staff 180 days or more before the end of our 2024 fiscal year relating to our periodic or current reports under the Securities Exchange Act of 1934, as amended.

#### **Item 1C. Cybersecurity**

##### ***Risk management and strategy***

We have implemented and maintain an information security program designed to identify, assess, and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data including intellectual property, clinical trial participant and patient-related data, and confidential information that is proprietary, strategic or competitive in nature, or collectively, Information Systems and Data.

Our cybersecurity threat risk management processes include the following, among others:

- Our information security department identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment and risk profile using various methods including, for example, manual methods and automated tools, conducting scans of the threat environment, conducting threat assessments, performing vulnerability assessments, use of external intelligence feeds, and through third-party-conducted red/blue team testing and tabletop incident response exercises.
- Depending on the environment, we implement and maintain various technical, physical and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: information security policies and standards governing access control, network and device security, encryption standards, incident response plans, disaster recovery plans, risk management, vulnerability detection and management and security awareness training requirements as well as security tools such as firewalls, malware protection tools, secure authentication tools, centralized logging and monitoring tools, threat intelligence tools, and data protection tools.
- Our overall risk assessment and management processes address cybersecurity threats that may have a material impact on our business. Our information security department maintains a risk register of individual risks from cybersecurity threats. Our CISO and CIO periodically review the area of cybersecurity risk management within our overall enterprise risk management program and work with our executive director of internal audit and enterprise risk management to incorporate the aggregate risks from the cybersecurity threat risk register into the overall enterprise risk management program risk register. In addition, our CISO and CIO report significant increases to our threat profile to the Information Security Governance Committee (described below).

- We use third parties, including professional services, incident response and managed security firms (including some that we have on a pre-paid retainer basis), to assist us from time to time to identify, assess, and manage cybersecurity risks, perform threat assessments relating to our Information Systems and Data by reviewing our business and industry vertical threat profiles and applying those to the overall threat landscape, perform penetration tests, conduct cybersecurity readiness exercises, assess program maturity, and to assist in the event of a cyber security incident.
- We have third-party vendor management processes designed to help us identify, assess and manage risks from cybersecurity threats to our Information Systems and Data that may arise out of our use of third-party vendors across our business, including, among others, application providers, hosting companies, contract research organizations, contract manufacturing organizations, distributors, and supply chain resources. Depending on the nature of the services and the service provider, our vendor management processes may include assessment of the cybersecurity practices of such vendors and contractually imposing obligations on the provider.

For a description of the risks from cybersecurity threats that may materially affect us and how those risks may affect us see “*Significant disruptions of information technology systems or data security breaches could adversely affect our business*” under Part I, Item 1A. Risk Factors in this Annual Report on Form 10-K.

#### **Governance**

- Our board of directors addresses our cybersecurity risk management as part of its general oversight function. The Audit Committee helps oversee our cybersecurity risk management processes, including oversight of risks from cybersecurity threats.
- The Information Governance Security Committee and the Audit Committee receive various reports from CISO and CIO. The CISO (or its designee) reports to the Audit Committee on cybersecurity risk on at least a quarterly basis. Written reports and presentation materials regarding cybersecurity risk provided to the Audit Committee are made available to the board of directors and they can discuss the materials and cybersecurity risk with the Audit Committee members. The Internal Audit team oversees internal controls implemented by us under our information security program.
- Our information security program is implemented and maintained by certain of our management, including the CISO, CIO and other members of our Information Security Governance Committee (Chief Legal Officer, Chief Financial Officer, and Chief Privacy Officer).
- The Information Security Governance Committee helps assess and manage our cybersecurity risks and monitor the effectiveness of our information security program and risk management. Management, including those serving on our Information Security Governance Committee, is responsible for hiring appropriate cybersecurity personnel, helping to integrate cybersecurity considerations into our overall risk management strategy, providing appropriate resources for cybersecurity risk management, and communicating key priorities to relevant personnel. Our cybersecurity incident response plan includes processes designed to escalate certain cybersecurity incidents that caused a significant impact to us to members of the Information Security Governance Committee, and certain members of executive management depending on the circumstances. In addition, our incident response plan includes reporting to the Audit Committee for certain cybersecurity incidents, including those that have potentially had a material impact to us.

**Item 2. Properties**

Our corporate headquarters are located in Dublin, Ireland, and our U.S. operations are located in Palo Alto, California, Carlsbad, California and Philadelphia, Pennsylvania. In addition to our owned manufacturing and development facilities and our leased administrative, manufacturing and development facilities, we also have dedicated growing facilities operated by contract partners. The following table contains information about our significant properties as of December 31, 2024:

Type	Location	Approximate Square Feet	Lease / Contract Expiration Date
Administrative office	Dublin, Ireland	45,000	2036
Administrative office	Palo Alto, United States	99,000	2025
Administrative office	Philadelphia, United States	60,000	2029
Administrative office	Carlsbad, United States	43,000	2028
Administrative office	Oxford, United Kingdom	26,000	2025
Administrative office	Cambridge, United Kingdom	22,000	2030-2031
Administrative office and laboratory	Vancouver, Canada	15,000	2029
Administrative office	London, United Kingdom	13,000	2034
Administrative office and laboratory	Villa Guardia (Como), Italy	34,000	2029
Manufacturing and development	Athlone, Ireland	58,000	Owned
Manufacturing and development	Southern United Kingdom	136,000	2026-2036
Manufacturing and development	Villa Guardia (Como), Italy	45,000	Owned
Growing facility	Eastern United Kingdom	1,960,000	2026
Growing facility	Northern United Kingdom	915,000	2025
Growing facility	Southern United Kingdom	165,000	2028
Growing facility under construction	Southern United Kingdom	370,000	2035

In addition, we have offices in Japan, Australia, France and elsewhere in Europe.

On October 11, 2024, a new lease agreement was entered into for premises located at 3000 El Camino Real, Palo Alto, California, with an area of 27,000 square feet, with occupancy expected by July 1, 2025. The lease expires in 2035.

We believe that our existing properties are in good condition and suitable for the conduct of our business. As we continue to expand our operations, we may need to lease additional or alternative facilities.

**Item 3. Legal Proceedings**

The information required to be set forth under this Item 3 is incorporated by reference to Note 13, Commitments and Contingencies—Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part IV of this Annual Report on Form 10-K.

**Item 4. Mine Safety Disclosures.**

Not applicable.

## PART II

### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

#### Market Information

Our ordinary shares trade on The Nasdaq Global Select Market under the trading symbol "JAZZ."

#### Holders of Ordinary Shares

As of February 19, 2025, there were 882 holders of record of our ordinary shares. Because almost all of our ordinary shares are held by brokers, nominees and other institutions on behalf of shareholders, we are unable to estimate the total number of shareholders represented by these record holders.

#### Dividends

Under Irish law, dividends may only be paid, and share repurchases and redemptions must generally be funded only out of, "distributable reserves." In addition, the terms of the Amended Credit Agreement restrict our ability to make certain restricted payments, including dividends and other distributions by us in respect of our ordinary shares, subject to, among other exceptions, (1) a general exception for dividends and other restricted payments not to exceed in the aggregate the greater of \$350 million and 3.5% of consolidated total assets (as defined in the Amended Credit Agreement) when made, (2) an exception that allows for dividends and other restricted payments equal to an amount tied to our financial performance, so long as no default or event of default shall have occurred and is continuing under the Amended Credit Agreement and the total net leverage ratio (as defined in in the Amended Credit Agreement) on a pro forma basis does not exceed 5:1, and (3) an exception that allows for additional dividends and other restricted payments, so long as no default or event of default shall have occurred and is continuing under the Amended Credit Agreement and the total net leverage ratio (as defined in our Amended Credit Agreement) on a pro forma basis is not greater than 4:1. Any future determination as to the payment of dividends will, subject to Irish legal requirements, be at the sole discretion of our board of directors and will depend on our consolidated financial condition, results of operations, capital requirements, compliance with the terms of the Amended Credit Agreement or other future borrowing arrangements, and other factors our board of directors deems relevant.

#### Irish Law Matters

As we are an Irish incorporated company, the following matters of Irish law are relevant to the holders of our ordinary shares.

##### *Irish Restrictions on Import and Export of Capital*

Except as indicated below, there are no restrictions on non-residents of Ireland dealing in Irish domestic securities, which includes ordinary shares of Irish companies. Dividends and redemption proceeds also continue to be freely transferable to non-resident holders of such securities. It is an offense under Irish law (pursuant to various statutory instruments) to transfer funds or make funds or economic resources available, directly or indirectly to any person or entity in contravention of Irish, EU or United Nations sanctions or to otherwise contravene Irish, EU or United Nations sanctions. Any transfer of, or payment in respect of, securities involving a person or entity that is currently the subject of Irish, EU or United Nations sanctions or any person or entity controlled by any of the foregoing, or any person acting on behalf of the foregoing, may be subject to restrictions pursuant to such sanctions as implemented into Irish law. The Financial Transfers Act, 1992 gives power to the Minister for Finance of Ireland to restrict financial transfers between Ireland and other countries and persons. Financial transfers are broadly defined and include all transfers that would be movements of capital or payments within the meaning of the treaties governing the member states of the EU. The acquisition or disposal of interests in shares issued by an Irish incorporated company and associated payments falls within this definition. In addition, dividends or payments on redemption or purchase of shares and payments on a liquidation of an Irish incorporated company would fall within this definition. The 1992 Act and underlying EU regulations prohibit financial transfers with certain persons and entities listed in the EU Consolidated Financial Sanctions List and United Nations Security Council Consolidated List, without the prior permission of the Central Bank of Ireland.

Any transfer of, or payment in respect of, a share or interest in a share involving the government of any country that is currently the subject of United Nations sanctions, any person or body controlled by any of the foregoing, or by any person acting on behalf of the foregoing, may be subject to restrictions pursuant to such sanctions as implemented into Irish law.

##### *Irish Taxes Applicable to U.S. Holders*

*Irish Tax on Dividends.* While we have no current plans to pay dividends, dividends on our ordinary shares would generally be subject to Irish Dividend Withholding Tax at the standard rate (currently 25%), unless an exemption applies.

*Irish Tax on Capital Gains.* A shareholder who (i) is neither resident nor ordinarily resident in Ireland for Irish tax purposes and (ii) does not use or hold, and did not acquire, our ordinary shares in connection with a trade or business carried on by such shareholder in Ireland through a branch or agency generally should not be subject to Irish tax on capital gains on a disposal of our ordinary shares.

A shareholder who is an individual and who is temporarily not resident in Ireland may, under Irish anti-avoidance legislation, still be liable for Irish tax on capital gains on any chargeable gain realized upon the disposal of our ordinary shares during the period in which such individual is a non-resident.

*Capital Acquisitions Tax.* Irish CAT is comprised principally of gift tax and inheritance tax. CAT could apply to a gift or inheritance of our ordinary shares irrespective of the place of residence, ordinary residence or domicile of the parties. This is because our ordinary shares are regarded as property situated in Ireland as our share register must be held in Ireland. The person who receives the gift or inheritance has primary liability for CAT.

CAT is levied at a rate of 33% above certain tax-free thresholds. The appropriate tax-free threshold is dependent upon (i) the relationship between the donor and the donee and (ii) the aggregation of the values of previous gifts and inheritances received by the donee from persons within the same category of relationship for CAT purposes. Gifts and inheritances passing between spouses are exempt from CAT. Our shareholders should consult their own tax advisers as to any tax consequences of holding our ordinary shares, including whether CAT is creditable or deductible in computing any domestic tax liabilities.

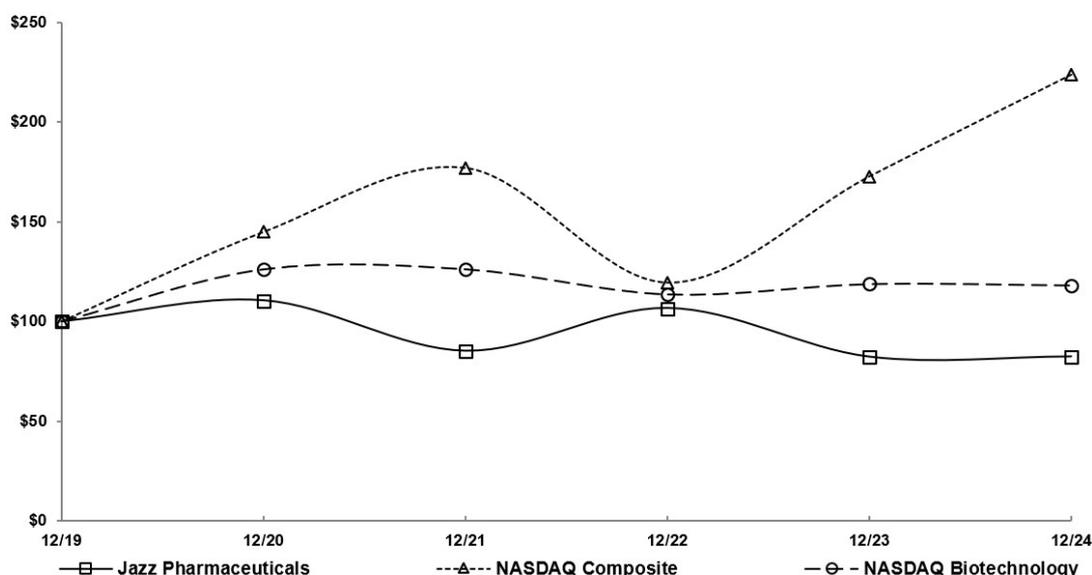
*Stamp Duty.* Irish stamp duty (if any) may become payable in respect of ordinary share transfers. However, a transfer of our ordinary shares from a seller who holds shares through DTC to a buyer who holds the acquired shares through DTC will not be subject to Irish stamp duty. A transfer of our ordinary shares (i) by a seller who holds ordinary shares outside of DTC to any buyer or (ii) by a seller who holds the ordinary shares through DTC to a buyer who holds the acquired ordinary shares outside of DTC, may be subject to Irish stamp duty (currently at the rate of 1% of the price paid or the market value of the ordinary shares acquired, if greater). The person accountable for payment of stamp duty is the buyer or, in the case of a transfer by way of a gift or for less than market value, all parties to the transfer.

A shareholder who holds ordinary shares outside of DTC may transfer those ordinary shares into DTC without giving rise to Irish stamp duty provided that the shareholder would be the beneficial owner of the related book-entry interest in those ordinary shares recorded in the systems of DTC (and in exactly the same proportions) as a result of the transfer and at the time of the transfer into DTC there is no sale of those book-entry interests to a third party being contemplated by the shareholder. Similarly, a shareholder who holds ordinary shares through DTC may transfer those ordinary shares out of DTC without giving rise to Irish stamp duty provided that the shareholder would be the beneficial owner of the ordinary shares (and in exactly the same proportions) as a result of the transfer, and at the time of the transfer out of DTC there is no sale of those ordinary shares to a third party being contemplated by the shareholder. In order for the share registrar to be satisfied as to the application of this Irish stamp duty treatment where relevant, the shareholder must confirm to us that the shareholder would be the beneficial owner of the related book-entry interest in those ordinary shares recorded in the systems of DTC (and in exactly the same proportions) (or vice-versa) as a result of the transfer and there is no agreement being contemplated for the sale of the related book-entry interest or the ordinary shares or an interest in the ordinary shares, as the case may be, by the shareholder to a third party.

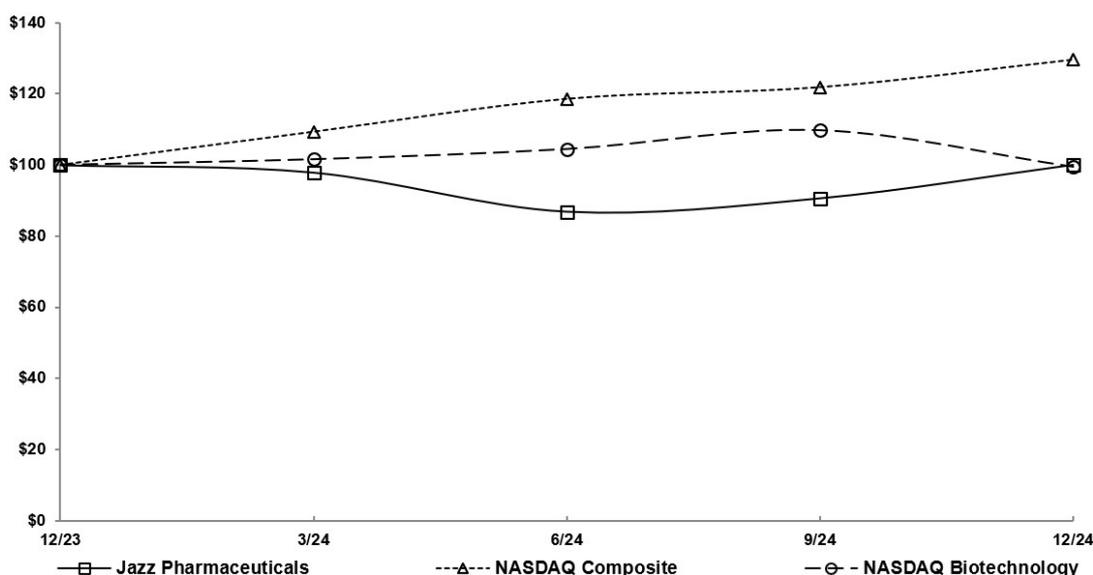
**Performance Measurement Comparison (1)**

The following graphs show the total shareholder return on the last day of each year of an investment of \$100 in cash as if made on December 31, 2019 and on the last day of each quarter of an investment of \$100 in cash as if made on December 31, 2023, respectively, in (i) our ordinary shares; (ii) the Nasdaq Composite Index; and (iii) the Nasdaq Biotechnology Index through December 31, 2024. The shareholder return shown in the graphs below are not necessarily indicative of future performance, and we do not make or endorse any predictions as to future shareholder returns.

**COMPARISON OF FIVE YEAR CUMULATIVE TOTAL RETURN (2)**



**COMPARISON OF ONE YEAR CUMULATIVE TOTAL RETURN (2)**



- (1) This section is not “soliciting material,” is not deemed “filed” with the SEC and is not to be incorporated by reference into any of our filings under the Exchange Act, whether made before or after the date hereof and irrespective of any general incorporation language in any such filing.
- (2) Information used in the graph was obtained from Research Data Group, Inc.

**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 December 31, 2024:

	Total Number of Shares Purchased (1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (2)	Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs (3)
October 1 - October 31, 2024	—	\$ —	—	\$ 349,999,951
November 1 - November 30, 2024	—	\$ —	—	\$ 349,999,951
December 1 - December 31, 2024	—	\$ —	—	\$ 349,999,951
Total	—	\$ —	—	

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. No ordinary shares were otherwise repurchased during the three-month period ended December 31, 2024.
2. On July 31, 2024, we announced that our board of directors had authorized the use of up to \$500.0 million to repurchase our ordinary shares under the New Repurchase Program. Under the New Repurchase Program, which has no expiration date, we may repurchase ordinary shares from time to time by any methods and/or structures permitted by applicable law. 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 outstanding credit agreement and the indenture for our Secured Notes, corporate and regulatory requirements and market conditions. The New Repurchase Program may be modified, suspended or discontinued at any time without our prior notice. The ordinary shares reported in the table above were purchased pursuant to the New Repurchase Program. The New Repurchase Program replaces and supersedes the share repurchase program authorized by our board of directors in November 2016, which, as of July 25, 2024, the date it was replaced and superseded by the New Repurchase Program, had authorized the repurchase of ordinary shares having an aggregate purchase price of up to \$1.5 billion, exclusive of any brokerage commissions. On July 25, 2024, the amount remaining authorized for repurchase under the Old Repurchase Program was \$47,475, exclusive of any brokerage commissions, which amount is included in the \$500.0 million authorized for repurchase under the New Repurchase Program.
3. 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 the New Repurchase Program, exclusive of any brokerage commissions.

**Item 6. Reserved****Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations**

*The purpose of the Management Discussion and Analysis is to present information that management believes is relevant to promote an understanding of our results of operations and cash flows for the fiscal year ended December 31, 2024 and our financial condition as of December 31, 2024 and should be read in conjunction with the consolidated financial statements and notes to consolidated financial statements included elsewhere in this Annual Report on Form 10-K. 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 impact or could impact our business. In particular, we encourage you to review the risks and uncertainties described in “Risk Factors” in Part I, Item 1A in this Annual Report on Form 10-K. 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 beginning of this Annual Report. These statements, like all statements in this report, speak only as of the date of this Annual Report on Form 10-K (unless another date is indicated), and we undertake no obligation to update or revise these statements in light of future developments. 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 beginning of this Annual Report. These statements, like all statements in this report, speak only as of the date of this Annual Report on Form 10-K (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, including leading therapies for sleep disorders and epilepsy, and a growing portfolio of cancer treatments. Our patient-focused and science-driven approach powers pioneering research and development advancements across our robust pipeline of innovative therapeutics in oncology and neuroscience.

Our strategy for growth is rooted in executing commercial launches and ongoing commercialization initiatives, advancing robust R&D programs and delivering impactful clinical results, effectively deploying capital to strengthen the prospects of achieving our short- and long-term goals through strategic corporate development, and delivering strong financial performance. We focus on patient populations with high unmet needs. We seek to 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.

Our strategy to deliver sustainable growth and enhanced value continues to be 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 2024, consistent with our strategy, we continued to focus on research and development activities within our neuroscience and oncology therapeutic areas. For a summary of our ongoing research and development activities, see “Business—Research and Development” in Part I, Item 1 of this Annual Report on Form 10-K.

Our lead marketed products, listed below, are approved in countries around the world to improve patient care.

<b>Product</b>	<b>Indications</b>	<b>Initial Approval Date</b>	<b>Markets</b>
<b>NEUROSCIENCE</b>			
Xywav® (calcium, magnesium, potassium, and sodium oxybates)	Treatment of cataplexy or EDS in patients seven years of age and older with narcolepsy.	July 2020	U.S.
	Treatment of IH in adults.	August 2021	U.S.
	Treatment of cataplexy in patients with narcolepsy.	May 2023	Canada
Epidiolex® (cannabidiol)	Treatment of seizures associated with LGS, DS, 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. <sup>1</sup>	September 2019	EU, Great Britain, EEA, Israel, Switzerland, Australia, other markets
	For adjunctive therapy of seizures associated with TSC for patients 2 years of age and older.	April 2021	EU, Great Britain, Israel and Switzerland
Epidiolex® (cannabidiol)	For adjunctive therapy of seizures associated with LGS, DS or TSC for patients 2 years of age and older.	November 2023	Canada
<b>ONCOLOGY</b>			

<b>Product</b>	<b>Indications</b>	<b>Initial Approval Date</b>	<b>Markets</b>
Rylaze® (asparaginase erwinia chrysanthemi (recombinant)-rywn)	A component of a multi-agent chemotherapeutic regimen for the treatment of ALL, and 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
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, Great Britain, Switzerland, oth markets
Zepzelca® (lurbinectedin)	Treatment of adult patients with metastatic SCLC, with disease progression on or after platinum-based chemotherapy.	June 2020	U.S. (licensed from PharmaMar) <sup>2</sup>
	Treatment of adults with Stage III or metastatic SCLC who have progressed on or after platinum-containing therapy.	September 2021	Canada (licensed from PharmaMar)
Ziihera® (zanidatamab-hrii)	Treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) BTC, as detected by an FDA-approved test.	November 2024	U.S. (licensed from Zymeworks) <sup>2</sup>

<sup>1</sup>The clobazam restriction limited to EU and Great Britain

<sup>2</sup> Accelerated approval received from FDA

<sup>3</sup> 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, and is indicated for treating cataplexy and EDS in patients seven years of age or older with 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 for cardiovascular morbidity. 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 ODE for Xywav in narcolepsy. ODE extends through January 2028. Nevertheless, 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 and was launched in the U.S. market by Avadel. FDA continues to recognize seven years of ODE for Xywav in narcolepsy. In connection with granting ODE, FDA stated that "Xywav is clinically superior to Xyrem by means of greater safety because Xywav provides a greatly reduced chronic sodium burden compared to Xyrem." FDA's summary also stated that "the differences in the sodium content of the two products at the recommended doses will be clinically meaningful in reducing cardiovascular morbidity in a substantial proportion of patients for whom the drug is indicated." 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 in November 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), severe sleep inertia, and prolonged and non-restorative nighttime sleep. 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 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 2024, there were approximately 14,150 patients taking Xywav, including approximately 10,250 patients with narcolepsy and approximately 3,900 patients with IH.

We acquired Epidiolex (Epidyolex outside the U.S.) in May 2021 as part of 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 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. The clobazam restriction is limited to the EU and Great Britain. Epidyolex is now launched in all five key European markets: United Kingdom, Germany, Italy, Spain and France. 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, Canada, Australia, New Zealand and Taiwan.

### ***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 approved in the U.S. that maintains a clinically meaningful level of asparaginase activity throughout the entire course 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 IM administration of 25 mg/m<sup>2</sup> every 48 hours. In November 2022, FDA approved an sBLA for a Monday/Wednesday/Friday 25/25/50 mg/m<sup>2</sup> IM dosing schedule. In September 2023, the EC granted marketing authorization for JZP458 under the trade name Enrylaze. This product has also been approved in Great Britain, Canada and Switzerland.

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 Roche, we have an ongoing Phase 3 pivotal clinical trial of Zepzelca for use as maintenance therapy in first-line extensive-stage SCLC in combination with Tecentriq® (atezolizumab) following induction therapy with carboplatin, etoposide and Tecentriq. In October 2024, we announced positive top-line results from the trial showing a statistically significant and clinically meaningful benefit for Zepzelca and atezolizumab in combination in the first-line maintenance setting. We plan to submit an sNDA in the first half of 2025 to support this combination in the first-line maintenance setting.

We acquired exclusive development and commercialization rights to Ziihera in 2022 through an exclusive licensing agreement with a subsidiary of Zymeworks providing development and commercialization rights to zanidatamab across all indications in the U.S., Europe, Japan and all other territories except for those Asia/Pacific territories previously licensed by Zymeworks. The term of the license agreement extends on a licensed product-by-licensed product and country-by-country basis until the expiration of the royalty term for such licensed product in such country. We have the right to terminate the amended license agreement at will upon a specified notice period, and either party can terminate the amended license agreement for the other party's uncured material breach or bankruptcy.

Ziihera is a bispecific HER2-directed antibody that binds to two extracellular sites on HER2. Binding of zanidatamab-hrii with HER2 results in internalization leading to a reduction of the receptor on the tumor cell surface. In the U.S., Ziihera

was approved by FDA in November 2024 and is indicated for the treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) BTC, as detected by an FDA-approved test.

Defitelio is the first and only approved treatment for patients with VOD, sVOD, or VOD with renal or pulmonary dysfunction following HSCT by regulatory authorities in the U.S., Europe, Japan and other markets. Utilization of Defitelio is in part driven by evolving treatment practices in HSCT, and we are continuing to educate healthcare professionals on the clinical profile of Defitelio and its role in treating VOD and/or severe VOD following HSCT.

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 continue to expand into new markets internationally as the product receives approvals and reimbursement in relevant markets. In the U.S., with ongoing trends towards lower-intensity treatments and away from intensive chemotherapy regimens for AML, we have seen increasing competition from other therapeutic options.

### ***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 neuroscience and precision medicines in oncology. We are increasingly leveraging our growing internal research and development function, and we have also entered into collaborations with third parties for the research and development of innovative early-stage product candidates and have supported additional investigator-sponsored trials 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.

Within our oncology R&D program, in October 2022, we announced an exclusive licensing and collaboration agreement with Zymeworks providing us the right to acquire development and commercialization rights to Zymeworks' zanidatamab across all indications in the U.S., 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. 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 \$325.0 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. Zymeworks is eligible to receive tiered royalties between 10% and 20% on our net sales. Zanidatamab is a bispecific HER2-directed antibody that binds to two extracellular sites on HER2. Zanidatamab is currently being evaluated in multiple clinical trials as a treatment for patients with HER2-expressing cancers. Following positive data from a pivotal Phase 2 clinical trial evaluating zanidatamab monotherapy in patients with previously treated advanced or metastatic HER2-amplified BTC, we completed a BLA submission in second-line BTC in March 2024. In May 2024, FDA granted Priority Review of the BLA; we received FDA approval for this BLA in November 2024. EMA has validated our MAA for zanidatamab in second-line BTC; we anticipate a response to our MAA in 2025. In addition, we have an ongoing Phase 3 randomized clinical trial evaluating zanidatamab in combination with chemotherapy plus or minus tislelizumab as a first-line treatment for HER2-expressing GEA, an ongoing Phase 2 trial examining zanidatamab in combination with chemotherapy in first-line patients with HER2-expressing metastatic GEA and an ongoing Phase 3 trial examining zanidatamab in first-line patients with HER2-positive BTC. In July 2024, we announced the initiation of the Phase 3 EmpowHER-BC-303 to evaluate zanidatamab plus chemotherapy or trastuzumab plus chemotherapy in patients with HER2-positive breast cancer whose disease has progressed on previous T-DXd treatment. There are also multiple ongoing clinical trials exploring zanidatamab in breast cancer and other HER2-expressing tumor types.

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 for use as maintenance therapy in first-line extensive-stage SCLC. In October 2024, we announced positive top-line results from the trial showing a statistically significant and clinically meaningful benefit for Zepzelca and atezolizumab in combination in the first-line maintenance setting. We plan to submit an sNDA in the first half of 2025 to support this combination in the first-line maintenance setting. In December 2021, our licensor PharmaMar initiated a confirmatory trial in second-line SCLC. This ongoing three-arm trial is 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. Preliminary findings from this study presented at the 2024 World Conference on Lung Cancer demonstrated Zepzelca provided clinical

benefit when administered as second-line SCLC therapy. The safety and tolerability profile observed in this study was consistent with prior findings, with no new safety signals reported.

In June 2022, we announced 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 to acquire exclusive global development and commercialization rights to Werewolf's investigational WTX-613, now referred to as JZP898. 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. JZP898 is a differentiated, conditionally-activated IFN $\alpha$  INDUKINE™ molecule. We initiated a Phase 1 clinical trial of JZP898 in late 2023.

Our neuroscience R&D efforts include an ongoing Phase 3 trial of Epidyolex for LGS, DS and TSC in Japan. In August 2024, we announced top-line results from the trial. The trial did not meet the primary efficacy endpoint of a pre-specified percentage change in indication-associated seizure frequency during the treatment period (up to 16 weeks) compared to baseline in Japanese pediatric patients; however, numeric improvements were observed in the primary and several secondary endpoints. No new safety signals were observed in the trial. We are continuing to collect data in Japanese patients and plan to engage with regulatory authorities in Japan regarding a potential new drug application.

In December 2021, we initiated a Phase 2 clinical trial for suvcaltamide (JZP385), for ET. Additionally, in November 2022, we initiated a Phase 2 trial of suvcaltamide in patients with Parkinson's disease tremor. In June 2024, we announced the ET trial did not achieve statistical significance on the primary and key secondary endpoint for the 30 mg dose. In January 2025, we announced that consistent with the results from the ET trial, results from the Parkinson's disease tremor trial did not show statistical significance on the primary and key secondary endpoint. Based on these results, we will not continue the ET or PDT development program. We are exploring options for the suvcaltamide program. 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 to acquire exclusive development and commercialization rights in the U.S., 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. Under the terms of the agreement, we made an upfront payment of \$50.0 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 our net sales of JZP441. In November 2023, we announced that we achieved initial proof-of-concept in our Phase 1 clinical trial program in healthy volunteers as demonstrated by the Maintenance of Wakefulness Test (MWT). At that time, we also noted the program was being paused as we analyzed safety findings related to visual disturbances and cardiovascular effects; no liver toxicity signals were observed. Following additional review of the trial findings and input from FDA, we plan to initiate a small Phase 1b trial of JZP441 in narcolepsy Type 1 patients in 2025. We expect data from this trial will further our understanding of JZP441 and orexin-2 receptor agonism, providing learnings that could inform future development efforts.

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:

<b>Product Candidates</b>	<b>Description</b>
<b>ONCOLOGY</b>	
<b>Regulatory</b>	
Zanidatamab	Second-line HER2-expressing BTC (under EMA review)
<b>Phase 3</b>	
Zanidatamab	First-line HER2-positive GEA (ongoing trial)
Zanidatamab	First-line HER2-positive BTC (ongoing trial)
Zanidatamab	Previously treated HER2-positive breast cancer in patients whose disease has progressed on previous T-DXd treatment (EmpowHER-BC-303) (ongoing trial)

Zepzelca	First-line extensive-stage SCLC in combination with Tecentriq (collaboration with Roche) (ongoing trial) Confirmatory second-line trial (PharmaMar study) (ongoing trial)
Vyxeos	AML or high-risk 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 (COG cooperative group study) (ongoing trial)
<b>Phase 2</b>	
Zanidatamab	HER2-expressing GEA, BTC or colorectal cancer in combination with standard first-line chemotherapy (ongoing trial)
Zanidatamab	Basket trial including HER2-positive solid tumors (DiscovHER-Pan-206) (ongoing trial)
Vyxeos	High-risk MDS (European Myelodysplastic Syndromes) (cooperative group study) (ongoing trial) Newly diagnosed untreated patients with intermediate- and high-risk AML (cooperative group study) (ongoing trial)
Vyxeos + other approved therapies	R/R AML or hypomethylating agent failure MDS (MD Anderson collaboration study) (ongoing trial) De novo or R/R AML (MD Anderson collaboration study) (ongoing trial)
<b>Phase 2a</b>	
Zanidatamab	Previously treated HER2+ HR+ breast cancer in combination with palbociclib (ongoing trial)
<b>Phase 1b/2</b>	
Zanidatamab	First-line breast cancer and GEA (BeiGene trial) (ongoing trial)
Zanidatamab	HER2-expressing breast cancer in combination with ALX148 (ongoing trial)
<b>Phase 1</b>	
JZP815	Raf and Ras mutant tumors (acquired from Redx) (ongoing trial)
Zanidatamab	Previously treated metastatic HER2-expressing cancers in combination with select antineoplastic therapies (cooperative group study) (ongoing trial)
JZP898	Conditionally-activated IFN $\alpha$ INDUKINE™ molecule in solid tumors (ongoing trial)
Vyxeos	Low intensity dosing for higher risk MDS (MD Anderson collaboration study) (ongoing trial)
<b>Preclinical</b>	
KRAS inhibitor targets	G12D selective and pan-KRAS molecules (acquired from Redx)
Undisclosed targets	Oncology
CombiPlex®	Hematology/oncology exploratory activities
<b>NEUROSCIENCE</b>	
<b>Phase 3</b>	
Epidyolex	LGS, TSC and DS (ongoing trial in Japan)
<b>Phase 1</b>	
JZP324	Oxybate extended-release formulation (planned trial)
JZP441*	Potent, highly selective oral orexin-2 receptor agonist (ongoing trial)
<b>Preclinical</b>	
Undisclosed targets	Sleep Epilepsy Other Neuroscience

\*Also known as DSP-0187

### ***2024 Highlights and Recent Developments***

#### **Regulatory Submissions, Approvals and Commercial Launches**

- Following positive data from a Phase 2b clinical trial evaluating zanidatamab monotherapy in patients with previously treated advanced or metastatic HER2-amplified BTC, completed a BLA submission in second-line BTC in March 2024. This BLA received Priority Review, and zanidatamab was approved by FDA under the trade name Ziihera in November 2024.
- Launched Ziihera in the U.S. for treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) BTC, as detected by an FDA-approved test, in December 2024.
- Based on results from the Phase 2b second-line BTC trial, Ziihera was incorporated into NCCN and ESMO guidelines for BTC treatment.
- Submitted MAA to EMA for zanidatamab in second-line BTC; EMA validated the MAA.
- Reimbursement for Epidyolex was secured in Switzerland, Czech Republic, Estonia, Iceland, Poland and Slovakia for DS, LGS and TSC and in Taiwan for DS and TSC.

#### **Research & Development**

- Initiated zanidatamab Phase 3 EmpowHER-BC-303 trial in previously treated HER2-positive breast cancer patients whose disease has progressed on previous T-DXd treatment.
- Initiated zanidatamab Phase 2 DiscovHER-Pan-206 trial to evaluate HER2-positive solid tumors.
- Announced positive top-line findings from the Phase 3 IMforte trial, showing statistically significant and clinically meaningful benefits for Zepzelca and atezolizumab in combination in first-line maintenance therapy for extensive-stage SCLC.
- Reported findings from two Phase 2 trials of suvecaltamide in ET and PDT; these trials did not achieve statistical significance compared to placebo on the primary or key secondary endpoints.
- Reported top-line results from an ongoing Phase 3 trial of Epidyolex for LGS, DS and TSC in Japan. While the trial did not meet the primary efficacy endpoint, numeric improvements were observed in the primary and several secondary endpoints.

#### ***Challenges, Risks and Trends Related to Our Business***

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 #1 branded oxybate treatment for narcolepsy; the position it held based on revenue in the fourth quarter of 2024. In June 2021, FDA recognized seven years of ODE for Xywav in narcolepsy through July 21, 2027 (which was subsequently extended to January 21, 2028), 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 oxybate revenues will remain at current levels.

Our ability to successfully commercialize Xywav depends 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 and patient success, we are focused on facilitating payor coverage for Xywav and providing robust patient copay and savings programs.

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 NDA for Avadel's Lumryz was unlawful. In the complaint, we alleged that FDA acted outside its authority under the Orphan Drug Act, when, despite ODE protecting 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. On September 15, 2023, we filed a motion for summary judgment. On October 20, 2023, Avadel and FDA filed cross motions for summary judgment. Oral argument on these motions was held on May 10, 2024, and on October 30, 2024, the District Court issued an order denying our motion for summary judgment and granting Avadel's and FDA's cross-motions for summary judgment. We have appealed the matter to the United States Court of Appeals for the District of Columbia Circuit. We cannot at this time predict the timing or ultimate outcome of this litigation or the impact of this litigation on our business.

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 ANDA filer. In July 2023, a volume-limited ANDA filer launched an AG version of high-sodium oxybate. These AG products have negatively impacted and are expected to continue to negatively impact Xyrem and Xywav sales for patients with narcolepsy. Specifically, a wholly owned subsidiary of Hikma launched its AG version of sodium oxybate in January 2023 and Amneal launched its AG version of sodium oxybate in July 2023. Hikma has elected to continue to sell the Hikma AG product, with royalties to be paid 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; the royalty rate was fixed for the second half of 2023. There was 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 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 (or join an existing REMS operated by another company), which must be open to any other company seeking to commercialize a sodium oxybate product. In our settlements with Amneal, Lupin, and 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 to be paid to us. Amneal launched its AG version of high-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 continue to face competition from generic versions of high-sodium oxybate pursuant to settlement agreements we entered into with multiple ANDA filers. In addition, we received notices in June 2021 and February 2023, that Lupin and Teva, respectively, filed ANDAs for generic versions of Xywav. On October 13, 2023, Lupin announced that it has received tentative approval for its application to market a generic version of Xywav. Generic competition can decrease the net prices at which branded products, such as Xywav and Xyrem are sold, as can competition from other branded products. 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 may continue to result in decreased net prices for some of our products. 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.

In any event, we expect that the approval and launch of AG products or other generic versions of Xyrem or Xywav and the approval and launch of any other sodium oxybate product, such as Avadel's Lumryz, or alternative product that treats narcolepsy will continue to have a negative impact on, and could have a material adverse effect on, our sales of Xywav and Xyrem and on our business, financial condition, results of operations and growth prospects.

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

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.

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, the Inflation Reduction Act of 2022 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 no longer subject to a cap on the rebate amount, 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. 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 13, Commitments and Contingencies-Legal Proceedings of the Notes to Consolidated Financial Statements, included in Part IV of this Annual Report on Form 10-K. 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.

## Results of Operations

The following table presents our revenues and expenses for the years ended December 31, 2024, 2023 and 2022 (in thousands except percentages):

	2024	Change	2023	Change	2022
Product sales, net	\$ 3,821,164	2 %	\$ 3,736,943	3 %	\$ 3,641,429
Royalties and contract revenues	247,786	155 %	97,261	442 %	17,945
Cost of product sales (excluding amortization of acquired developed technologies)	445,713	2 %	435,577	(19)%	540,517
Selling, general and administrative	1,385,294	3 %	1,343,105	(5)%	1,416,967
Research and development	884,000	4 %	849,658	44 %	590,453
Intangible asset amortization	627,313	3 %	608,284	2 %	599,169
Intangible asset impairment charge	—	— %	—	N/A(1)	133,648
Acquired in-process research and development	10,000	(47)%	19,000	(96)%	444,148
Interest expense, net	238,097	(18)%	289,438	— %	288,242
Foreign exchange (gain) loss	8,182	193 %	(8,787)	(146)%	19,014
Income tax benefit	(91,429)	(24)%	(119,912)	(24)%	(158,645)
Equity in loss of investees	1,660	(45)%	3,009	N/A(1)	9,921

(1) Comparison to prior period is not meaningful.

## Revenues

The following table presents product sales, royalties and contract revenues, and total revenues for the years ended December 31, 2024, 2023 and 2022 (in thousands except percentages):

	2024	Change	2023	Change	2022
Xywav	\$ 1,473,202	16 %	\$ 1,272,977	33 %	\$ 958,425
Xyrem	233,816	(59)%	569,730	(44)%	1,020,453
Epidiolex/Epidyolex	972,423	15 %	845,468	15 %	736,398
Sativex	18,877	(4)%	19,668	17 %	16,825
Sunosi <sup>2</sup>	—	— %	—	N/A(1)	28,844
Total Neuroscience	2,698,318	— %	2,707,843	(2)%	2,760,945
Rylaze/Enrylaze	410,846	4 %	394,226	40 %	281,659
Zepzelca	320,318	11 %	289,533	7 %	269,912
Defitelio/defibrotide	216,565	18 %	184,000	(5)%	194,290
Vyxeos	162,595	10 %	147,495	15 %	127,980
Ziihera	1,051	N/A(1)	—	— %	—
Total Oncology	1,111,375	9 %	1,015,254	16 %	873,841
Other	11,471	(17)%	13,846	108 %	6,643
Product sales, net	3,821,164	2 %	3,736,943	3 %	3,641,429
High-sodium oxybate AG royalty revenue	217,575	187 %	75,918	N/A(1)	—
Other royalty and contract revenues	30,211	42 %	21,343	19 %	17,945
Total revenues	\$ 4,068,950	6 %	\$ 3,834,204	5 %	\$ 3,659,374

(1) Comparison to prior period is not meaningful.

(2) Net product sales of Sunosi U.S. are included until the date of divestment to Axsome of May 9, 2022.

## Product Sales, Net

Xywav product sales increased in 2024 compared to 2023, primarily due to increased sales volumes of 16% and, to a lesser extent, a higher selling price, offset by higher gross to net deductions. We continue to see Xywav adoption in patients

with narcolepsy driven by educational initiatives around efficacy and the benefit of lowering sodium intake. In addition, Xywav product sales were positively impacted by adoption in IH; Xywav is the only oxybate therapy approved to treat IH and we see continued growth of new prescribers. Exiting 2024, there were 10,250 patients taking Xywav for narcolepsy and 3,900 taking Xywav for IH, an increase of approximately 8% and 41%, respectively, compared to 2023. Xywav product sales increased in 2023 compared to 2022, primarily due to increased sales volumes of 28% and, to a lesser extent, a higher selling price. Xyrem product sales decreased in 2024 compared to 2023, primarily due to decreased sales volumes of 57%, due to high-sodium oxybate competition and the adoption of Xywav by existing Xyrem patients and higher gross to net deductions, partially offset by a higher selling price. Xyrem product sales decreased in 2023 compared to 2022, primarily due to decreased sales volumes of 49%, reflecting the adoption of Xywav by existing Xyrem patients and the impact of high-sodium oxybate competition, offset by a higher selling price and lower gross to net deductions. Epidiolex/Epidyolex product sales increased by 15% in 2024 compared to 2023, primarily due to increased sales volumes of 12% due to increased demand, and, to a lesser extent, geographic expansion and a higher average selling price. Epidiolex/Epidyolex product sales increased by 15% in 2023 compared to 2022, primarily due to increased sales volumes of 15% due to increased demand and expansion in European markets and, to a lesser extent, a higher average selling price, partially offset by higher gross to net deductions.

Rylaze/Enrylaze product sales increased in 2024 compared to 2023, primarily due to a higher average selling price, partially offset by higher gross to net deductions. Rylaze sales volumes in 2024 have been negatively impacted due to an update to the COG pediatric treatment protocols for ALL, which impacts the timing of asparaginase administration. While this had a temporary negative impact on Rylaze product sales in the latter part of 2024, we do not expect it will affect ongoing demand and we still expect our product sales to normalize by early 2025. Rylaze remains the only therapy available to patients in the U.S. who have a hypersensitivity reaction to E. coli-derived asparaginase. Rylaze product sales increased in 2023 compared to 2022, primarily due to increased sales volumes of 37% and, to a lesser extent, a higher selling price, offset by higher gross to net deductions. The increased sales volumes reflected the significant unmet patient need for a high-quality, reliable supply of Erwinia asparaginase for patients with ALL. Zepzelca product sales increased by 11% in 2024 compared to 2023, primarily due to increased sales volumes and a higher selling price, offset by higher gross to net deductions. Zepzelca product sales increased by 7% in 2023 compared to 2022, primarily due to a higher selling price and increased sales volumes, offset by higher gross to net deductions. Defitelio/defibrotide product sales increased by 18% in 2024 compared to 2023, primarily due to increased sales volumes, and to a lesser extent, a higher average selling price. Defitelio/defibrotide product sales decreased by 5% in 2023 compared to 2022, primarily due to a decrease in sales volumes, partially offset by a higher selling price. Vyxeos product sales increased by 10% in 2024 compared to 2023, primarily due to increased sales volumes, partially offset by a lower average selling price due to regional mix. Vyxeos product sales increased by 15% in 2023 compared to 2022, primarily due to increased sales volumes and to a lesser extent, a higher selling price, partially offset by higher gross to net deductions.

We expect product sales, net will increase in 2025 over 2024, primarily driven by growth across our commercial portfolio, offset by a decrease in sales of Xyrem due to the impact of high-sodium oxybate competition.

#### *Royalties and Contract Revenues*

Royalties and contract revenues increased in 2024 compared to 2023 and in 2023 compared to 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 2025 compared to 2024, primarily due to increased royalty revenues arising from net sales of high-sodium oxybate AG.

#### *Cost of Product Sales*

Cost of product sales increased in 2024 compared to 2023, due to increased inventory provisions and changes in product mix, offset by a decrease in the fair value step-up expense, of \$16.4 million. Cost of product sales decreased in 2023 compared to 2022, primarily due to a reduction in the fair value step-up expense of \$121.9 million and the impact of an expense for past royalties recorded in 2022 in connection with a settlement agreement with Otsuka, partially offset by changes in product mix. Gross margin as a percentage of net product sales was 88.3% in both 2024 and 2023 and 85.2% in 2022. The increase in our gross margin percentage in 2023 compared to 2022 was primarily due to the decrease in the fair value step-up expense in 2023 and the impact of the Otsuka royalty expense in 2022.

We expect our cost of product sales to increase in 2025 compared to 2024, primarily driven by changes in product mix.

#### *Selling, General and Administrative Expenses*

Selling, general and administrative expenses increased in 2024 compared to 2023, primarily due to increased compensation-related expenses of \$72.6 million, primarily driven by higher headcount and increased investment in sales and marketing of \$19.3 million, in support of our commercial portfolio and increased litigation costs of \$13.6 million, partially offset by costs relating to the impairment of facility assets of \$61.7 million and program terminations of \$23.5 million incurred in 2023. Selling, general and administrative expenses decreased in 2023 compared to 2022, primarily due to the loss on

disposal of Sunosi of \$40.8 million, restructuring costs of \$22.1 million and GW related integration costs of \$21.1 million incurred in 2022, together with a reduction in costs related to program terminations of \$19.1 million and in compensation related expenses, partially offset by an impairment of facility assets of \$61.7 million in 2023. We expect selling, general and administrative expenses in 2025 to increase compared to 2024, primarily due to investment in our commercial portfolio, including the launch of Ziibera, along with increased compensation-related expenses.

#### *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):

	Year Ended December 31,		
	2024	2023	2022
Clinical studies and outside services	\$ 510,941	\$ 501,181	\$ 270,008
Personnel expenses	290,856	258,303	223,603
Milestone expense	2,500	5,500	6,250
Restructuring expenses	—	—	10,284
Other	79,703	84,674	80,308
Total	<u>\$ 884,000</u>	<u>\$ 849,658</u>	<u>\$ 590,453</u>

Research and development expenses increased by \$34.3 million in 2024 compared to 2023. Clinical studies and outside services costs increased in 2024 compared to 2023, primarily due to the addition of costs related to clinical programs for zanidatamab, partially offset by a reduction in costs related to JZP150 (post-traumatic stress disorder) and JZP385. Personnel expenses increased by \$32.6 million in 2024 compared to 2023, primarily due to increased compensation related expenses in support of our development programs. Research and development expenses increased by \$259.2 million in 2023 compared to 2022. Clinical studies and outside services costs increased in 2023 compared to 2022, primarily due to the addition of costs related to clinical programs for zanidatamab, and, to a lesser extent, JZP385 and JZP441, partially offset by a reduction in costs related to JZP458 (Rylaze). Personnel expenses increased by \$34.7 million in 2023 compared to 2022, primarily due to increased headcount in support of our development programs. Milestone expenses of \$5.5 million in 2023 primarily related to a milestone expense of \$5.0 million under our collaboration and license agreement with Werewolf. Milestone expenses of \$6.3 million in 2022 primarily related to a milestone expense of \$5.0 million made under our asset purchase and collaboration agreements with Redx. We incurred restructuring costs of \$10.3 million in 2022.

For 2025, we expect that our research and development expenses will decrease compared to 2024, primarily driven by a reduction in clinical studies and outside services costs relating to JZP385 and continued portfolio prioritization.

#### *Intangible Asset Amortization*

Intangible asset amortization increased by \$19.0 million in 2024 compared to 2023, primarily due to the foreign exchange impact on our sterling-denominated intangible assets. Intangible asset amortization for 2023 was in line with 2022. Intangible asset amortization in 2025 is expected to be broadly in line with 2024.

#### *Acquired In-Process Research and Development*

Acquired IPR&D expense in 2024 related to the upfront payment made in connection with our asset purchase agreement with Redx, of \$10.0 million. Acquired IPR&D expense in 2023 primarily related to the upfront payment made in connection with our licensing and collaboration agreement with Autifony of \$18.0 million. Acquired IPR&D expense in 2022 primarily related to the upfront payments made in connection with our licensing and collaboration agreements with Zymeworks and Werewolf of \$375.0 million and \$15.0 million, respectively, and our licensing agreement with Sumitomo of \$50.0 million.

### *Intangible Asset Impairment Charge*

In 2022, we recorded an acquired IPR&D asset impairment charge of \$133.6 million as a result of the decision to discontinue our nabiximols program.

### *Interest Expense, Net*

Interest expense, net decreased by \$51.3 million in 2024 compared to 2023, primarily due to higher interest income on investments driven by our increased deposits and higher interest rates and lower interest expense on the Tranche B-2 Dollar Term Loans following the 2024 repricings described under “Liquidity and Capital Resources—Credit Agreement” below, offset by the inclusion of interest expense on our 2030 Notes. Interest expense, net increased by \$1.2 million in 2023 compared to 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 Euro Term Loan, in 2022.

We expect interest expense, net to decrease in 2025 compared to 2024 primarily due to lower interest expense following the voluntary repayment of \$750.0 million on our Tranche B-2 Dollar Term Loans in January 2025, partially offset by lower interest income and interest expense on the 2030 Notes. For further information on this please refer to Liquidity and Capital Resources.

### *Foreign Exchange (Gain) Loss*

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

### *Income Tax Benefit*

Our income tax benefit was \$91.4 million, \$119.9 million and \$158.6 million in 2024, 2023 and 2022, respectively, 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, patent box benefits, foreign derived intangible income benefits and originating tax credits. Our income tax benefit in 2024 decreased compared to 2023 primarily due to the change in income mix across jurisdictions, partially offset by patent box benefits. Our income tax benefit in 2023 decreased compared to 2022 primarily due to pretax losses from payments for acquired IPR&D made in 2022 and the impact of the 2022 impairment of our acquired IPR&D asset as a result of the decision to discontinue our nabiximols program, partially offset by the change in income mix across jurisdictions.

### *Equity in Loss of Investees*

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

### **Liquidity and Capital Resources**

As of December 31, 2024, we had cash, cash equivalents and investments of \$3.0 billion, borrowing available under our Amended Revolving Credit Facility of \$885.0 million and a long-term debt principal balance of \$6.2 billion. Our long-term debt included \$2.7 billion aggregate principal amount of the Tranche B-2 Dollar Term Loans, \$1.5 billion in aggregate principal amount of the Secured Notes, \$1.0 billion principal amount of the 2026 Notes and \$1.0 billion principal amount of the 2030 Notes. During 2024, 2023 and 2022, we generated cash flows from operations of \$1.4 billion, \$1.1 billion and \$1.3 billion, respectively, and we expect to continue to generate positive cash flow from operations which we expect 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. With respect to our Tranche B-2 Dollar Term Loans, we have made voluntary repayments of \$1.1 billion, \$300.0 million in September 2022 and \$750.0 million in January 2025, along with mandatory repayments of \$108.5 million. In August 2024, we repaid the \$575.0 million aggregate principal amount of our 2024 Notes.

We have a significant amount of debt outstanding on a consolidated basis. 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 11, Debt, of the Notes to Consolidated Financial Statements, included in Part IV of this Annual Report on Form 10-K. This substantial level of debt could have important consequences to our business, including, but not limited to the factors set forth in in Part I, Item 1A “Risk Factors” of this Annual Report on Form 10-K 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 Amended 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” in Part I, Item 1A of this Annual Report on Form 10-K under the headings “Risks Related to our Lead Products and Product Candidates” and *“To continue to grow our business, we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate and grow our business.”* Our assumptions may prove to be wrong or other factors may adversely affect our business, and as a result we could exhaust or significantly decrease our available cash resources, and we may not be able to generate sufficient cash to service our debt obligations which could, among other things, force us to raise additional funds and/or force us to reduce our expenses, either of which could have a material adverse effect on our business.

To continue to grow our business over the longer term, we plan to commit substantial resources to product acquisition and in-licensing, product development, clinical trials of product candidates and expansion of our commercial, development, manufacturing and other operations. In this regard, we have evaluated and expect to continue to evaluate a wide array of strategic transactions as part of our strategy to acquire or in-license and develop additional products and product candidates. Acquisition opportunities that we pursue could materially affect our liquidity and capital resources and may require us to incur additional indebtedness, seek equity capital or both. 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 and the recent disruptions to, and volatility in, the credit and financial markets in the U.S. and worldwide resulting from the effects of inflationary pressures, potential future bank failures, or otherwise. Accordingly, 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, and we currently have such authorization. Moreover, as a matter of Irish law, when an Irish public limited company issues ordinary shares to new shareholders for cash, the company must first offer those shares on the same or more favorable terms to existing shareholders on a pro rata basis, unless this statutory pre-emption obligation is dis-applied, or opted-out of, by approval of its shareholders. At our annual general meeting of shareholders in July 2024, our shareholders voted to approve our proposal to dis-apply the statutory pre-emption obligation. This current pre-emption opt-out authority is due to expire in January 2026. 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, including at the time we are required to make repurchases of the 2026 Notes, the 2030 Notes and/or the Secured Notes, are required to repay outstanding amounts under the Amended Credit Agreement, or pay cash upon exchange of the 2026 Notes or the 2030 Notes, could likewise be adversely affected. In any event, an inability to borrow or raise additional capital in a timely manner and on attractive terms could prevent us from expanding our business or taking advantage of acquisition opportunities and could otherwise have a material adverse effect on our business and growth prospects. In addition, if we use a substantial amount of our funds to acquire or in-license products or product candidates, we may not have sufficient additional funds to conduct all of our operations in the manner we would otherwise choose. Furthermore, any equity financing would be dilutive to our shareholders, and could require the consent of the lenders under the Amended Credit Agreement that provides for (i) the Tranche B-2 Dollar Term Loans and Amended Revolving Credit Facility, and the indenture for the Secured Notes for certain financings.

In July 2024, our board of directors authorized the New Repurchase Program. Under the New Repurchase Program, which has no expiration date, we may repurchase ordinary shares from time to time by any methods and/or structures permitted by applicable law. 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 Amended Credit Agreement and the indenture for our Secured Notes, corporate and regulatory requirements and market conditions. The New Repurchase Program may be modified, suspended or discontinued at any time without our prior notice. The New Repurchase Program replaces and supersedes the Old Repurchase Program. In 2024, we spent a total of \$311.4 million to purchase 2.8 million of our ordinary shares under the repurchase programs at an average total purchase price, including commissions, of \$110.06 per share. The repurchases in 2024 included a total of \$150.0 million to repurchase 1.4 million of our ordinary shares, all under the New Repurchase Program, at a purchase price, including commissions, of \$109.32 per share and \$161.4 million to repurchase 1.5 million of our ordinary shares, all under the Old Repurchase Program, at a purchase price, including commissions, of \$110.75 per share. The repurchases made under the New Repurchase Program in 2024 were effected in privately negotiated transactions with or through one of the initial purchasers of the 2030 Notes concurrently with the pricing of the offering of the 2030 Notes. In 2023, we spent a total of \$269.8 million to purchase 2.1 million of our ordinary shares under the Old Repurchase Program at an average total purchase price, including commissions, of \$126.65 per share. All ordinary shares repurchased were cancelled. As of December 31, 2024, the remaining amount authorized for repurchases under the New Repurchase Program was \$350.0 million, exclusive of any brokerage commissions.

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

	Year Ended December 31,		
	2024	2023	2022
Net cash provided by operating activities	\$ 1,395,908	\$ 1,092,007	\$ 1,271,977
Net cash used in investing activities	(508,195)	(163,062)	(446,230)
Net cash provided by (used in) financing activities	20,516	(305,254)	(529,491)
Effect of exchange rates on cash and cash equivalents	(1,675)	1,137	(6,222)
Net increase in cash and cash equivalents	\$ 906,554	\$ 624,828	\$ 290,034

#### *Operating activities*

Net cash provided by operating activities increased by \$303.9 million in 2024 compared to 2023, primarily due to cash received from increased sales of our products, decreased prepaid income taxes and the timing of payment of accrued expenses.

Net cash provided by operating activities decreased by \$180.0 million in 2023 compared to 2022, primarily due to an increase in research and development expenses primarily related to zanidatamab, increased prepaid income taxes and increased interest expense on our outstanding term loan borrowings.

#### *Investing activities*

Net cash used in investing activities increased by \$345.1 million in 2024 compared to 2023, primarily due to the following:

- \$340.0 million net increase in the acquisition of investments, driven by time deposits; and
- \$14.1 million increase in purchases of property, plant and equipment; offset by
- \$9.0 million decrease in upfront payments for acquired IPR&D driven by the \$18.0 million payment to Autifony in 2023, partially offset by the \$10.0 million payment to Redx in 2024.

Net cash used in investing activities decreased by \$283.2 million in 2023 compared to 2022, primarily due to the following:

- \$425.1 million decrease in upfront payments for acquired IPR&D primarily driven by the \$375.0 million, \$50.0 million and \$15.0 million payments to Zymeworks, Sumitomo and Werewolf, respectively, in 2022, partially offset by the \$18.0 million payment to Autifony in 2023; offset by
- \$119.1 million net increase in the acquisition of investments, primarily time deposits; and
- \$53.0 million upfront payment from Axsome in 2022 relating to the Sunosi U.S. disposition.

### *Financing activities*

Net cash provided by (used in) financing activities increased by \$325.8 million in 2024 compared to 2023, primarily due to:

- An increase of \$405.8 million in debt financing due to net proceeds from issuance of the 2030 Notes of \$980.8 million, offset by the repayment of the 2024 Notes of \$575.0 million; partially offset by
- An increase of \$41.7 million in share repurchases; and
- A decrease of \$25.8 million in proceeds from employee equity incentive and purchase plans.

Net cash used in financing activities decreased by \$224.2 million in 2023 compared to 2022, primarily due to:

- Repayments of long-term debt of \$31.0 million in 2023, compared to \$582.0 million in 2022; offset by
- Share repurchases of \$269.8 million in 2023; and
- A decrease of \$51.6 million in proceeds from employee equity incentive and purchase plans.

### **Credit Agreement**

On May 5, 2021, Jazz Pharmaceuticals plc, Jazz Lux, and certain of our other subsidiaries, as borrowers, or, collectively with Jazz Pharmaceuticals plc and Jazz Lux, the “Borrowers”, entered into the Credit Agreement. The Credit Agreement initially provided for (i) the Dollar Term Loan, which was drawn by Jazz Lux on the closing date thereof in U.S. dollars (ii) the Euro Term Loan, which was drawn by Jazz Lux on the closing date thereof in Euros and (iii) the Initial Revolving Credit Facility.

In January 2024, Jazz Lux entered into the Repricing Amendment No.1, to the Credit Agreement. Upon entry into the Repricing Amendment No.1, certain existing lenders converted a portion of the outstanding Dollar Term Loan into the Tranche B-1 Dollar Term Loans, and Jazz Lux borrowed \$201.9 million aggregate principal amount of additional Tranche B-1 Dollar Term Loans, the proceeds of which were used to repay the portion of the outstanding Dollar Term Loan that was not converted.

In July 2024, Jazz Lux entered into the Repricing Amendment No. 2, to the Credit Agreement, as amended by the Repricing Amendment No. 1. Upon entry into the Repricing Amendment No. 2, certain existing lenders converted a portion of the outstanding Tranche B-1 Dollar Term Loans into the Tranche B-2 Dollar Term Loans, and Jazz Lux borrowed \$289.6 million aggregate principal amount of additional Tranche B-2 Dollar Term Loans, the proceeds of which were used to repay the portion of the outstanding Tranche B-1 Dollar Term Loans that were not converted.

The Tranche B-2 Dollar Term Loans are a separate class of term loans under the Credit Agreement, as amended by Repricing Amendment No. 1 and Repricing Amendment No. 2, with the same material terms (including with respect to maturity, prepayment, security, covenants and events of default) as the previously outstanding Tranche B-1 Dollar Term Loans and the initial Dollar Term Loan incurred on May 5, 2021, with the interest rate amended as described below and the credit spread adjustment removed. The principal amount of Tranche B-1 Dollar Term Loans outstanding immediately prior to the Repricing Amendment No. 2 and the outstanding principal amount of Tranche B-2 Dollar Term Loans immediately following the Repricing Amendment No.2, each totaled \$2.7 billion.

The Tranche B-2 Dollar Term Loans bear interest at a rate equal to either (a) Term SOFR, or (b) the prime lending rate, in each case, plus an applicable margin. The applicable margin for the Tranche B-2 Dollar Term Loans is 2.25% (in the case of Term SOFR borrowings) and 1.25% (in the case of borrowings at the prime lending rate), a decrease, in each case, of 75 basis points from the applicable margin on the Tranche B-1 Dollar Term Loans. The Tranche B-2 Dollar Term Loans are subject to a Term SOFR floor of 0.50%. As of December 31, 2024, the interest rate and effective interest rate on the Tranche B-2 Dollar Term Loans were 6.61% and 8.27%, respectively.

In November 2024, we entered into Amendment No. 3 to the Credit Agreement, as amended by the Repricing Amendment No. 1 and Repricing Amendment No. 2, to increase the Initial Revolving Credit Facility from \$500.0 million to \$885.0 million and extend the maturity date from May 5, 2026 to the Amended Revolving Facility Maturity Date, provided that:

- if, as of any date from March 16, 2026 to the 2026 Notes Springing Maturity Date, (x) any 2026 Maturity Indebtedness remains outstanding and (y) the aggregate amount of unrestricted cash of Jazz Pharmaceuticals plc and its subsidiaries is less than an amount equal to 125% of the aggregate principal amount of 2026 Maturity Indebtedness outstanding, then the maturity date for the Amended Revolving Credit Facility will be shortened to the 2026 Notes Springing Maturity Date;
- if, as of February 4, 2028, (x) more than \$500,000,000 of the Term Loan Indebtedness remains outstanding and (y) the maturity date of such Term Loan Indebtedness is not later than the date that is 91 days after the Amended

Revolving Facility Maturity Date, then the maturity date for the Amended Revolving Credit Facility will be shortened to February 4, 2028; and

- if, as of the Senior Notes Springing Maturity Date, (x) more than \$500,000,000 of the Senior Note Indebtedness remains outstanding and (y) the maturity date with respect to such Senior Note Indebtedness is not later than the date that is 91 days after the Amended Revolving Facility Maturity Date, then the maturity date for the Amended Revolving Credit Facility will be shortened to October 16, 2028.

Initially, the applicable margin for the loans under the Amended Revolving Credit Facility will be 2.00% (in the case of Term SOFR borrowings) and 1.00% (in the case of borrowings at the prime lending rate). Thereafter, the applicable margin for the Amended Revolving Credit Facility ranges from 1.75% to 2.75% (in the case of Term SOFR borrowings) and 0.75% to 1.75% (in the case of borrowings at the prime lending rate), depending on our first lien secured net leverage ratio level, and any loans under the Amended Revolving Credit Facility are subject to a Term SOFR floor of 0.00%. The Amended Revolving Credit Facility has a commitment fee payable on the undrawn amount ranging from 0.25% to 0.45% per annum based upon our first lien secured net leverage ratio. As of December 31, 2024, we had an undrawn Amended Revolving Credit Facility totaling \$885.0 million.

## **2029 Senior Secured Notes**

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

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

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

Some or all of the Secured Notes, may be redeemed at any time and from time to time at a specified redemption prices, plus accrued and unpaid interest, if any, to, but excluding, to the redemption date. In addition, Jazz Securities may redeem all but not part of the Secured Notes at its option at any time in connection with certain tax-related events at a price equal to 100% of the principal amount of the Secured Notes to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date.

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

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

As of December 31, 2024, the interest rate and effective interest rate on the Secured Notes were 4.375% and 4.64%, respectively.

## **Exchangeable Senior Notes**

*2030 Notes.* In September 2024, Jazz Investments, our wholly owned subsidiary, completed a private placement of \$1.0 billion principal amount of the 2030 Notes.

Interest on the 2030 Notes is payable semi-annually in cash in arrears on March 15 and September 15 of each year, beginning on March 15, 2025, at a rate of 3.125% per year. In certain circumstances, we may be required to pay additional amounts as a result of any applicable tax withholding or deductions required in respect of payments on the 2030 Notes. The 2030 Notes mature on September 15, 2030, unless earlier exchanged, redeemed or repurchased.

The holders of the 2030 Notes have the ability to require us to repurchase all or a portion of their 2030 Notes for cash at a fundamental change repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date in the event we undergo a fundamental change (as defined in the indenture related to the 2030 Notes), such as specified change of control transactions, our liquidation or

dissolution or the delisting of our ordinary shares from any of The New York Stock Exchange, The Nasdaq Global Market, The Nasdaq Global Select Market or The Nasdaq Capital Market (or any of their respective successors).

Additionally, the terms and covenants in the indenture related to the 2030 Notes include certain events of default after which the 2030 Notes may be due and payable immediately.

Prior to September 15, 2030, we may redeem the 2030 Notes, in whole but not in part, in connection with certain tax-related events. We also may redeem the 2030 Notes on or after September 20, 2027 and prior to June 15, 2030, in whole or in part (subject to the partial redemption limitation described in the indenture related to the 2030 Notes), if the last reported sale price per ordinary share has been at least 130% of the exchange price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption at a redemption price equal to 100% of the principal amount of the notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

The 2030 Notes are exchangeable at an initial exchange rate of 6.5339 ordinary shares per \$1,000 principal amount of 2030 Notes, which is equivalent to an initial exchange price of approximately \$153.05 per ordinary share. Upon exchange of the 2030 Notes, we will pay cash up to the aggregate principal amount of the 2030 Notes to be exchanged and pay or deliver, as the case may be, cash, ordinary shares or a combination of cash and ordinary shares, at our election, in respect of the remainder, if any, of our exchange obligation in excess of the aggregate principal amount of the 2030 Notes being exchanged. The exchange rate is subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain make-whole fundamental changes (as defined in the indenture related to the 2030 Notes) that occur prior to the maturity date or upon our issuance of a notice of redemption, we will, in certain circumstances, increase the exchange rate for a holder who elects to exchange its 2030 Notes in connection with that make-whole fundamental change or exchange its 2030 Notes called (or deemed called) for redemption during the related redemption period. Prior to June 15, 2030, the 2030 Notes will be exchangeable only upon satisfaction of certain conditions and during certain periods, and thereafter, at any time until the close of business on the second scheduled trading day immediately preceding the maturity date.

*2026 Notes.* In June 2020, Jazz Investments completed a private placement of \$1.0 billion principal amount of the 2026 Notes. We used a portion of the net proceeds from this offering to repurchase for cash \$332.9 million aggregate principal amount of the 1.875% exchangeable senior notes due 2021, through privately-negotiated transactions concurrently with the offering of the 2026 Notes. Interest on the 2026 Notes is payable semi-annually in cash in arrears on June 15 and December 15 of each year, beginning on December 15, 2020, at a rate of 2.00% per year. In certain circumstances, we may be required to pay additional amounts as a result of any applicable tax withholding or deductions required in respect of payments on the 2026 Notes. The 2026 Notes mature on June 15, 2026, unless earlier exchanged, repurchased or redeemed.

The holders of the 2026 Notes have the ability to require us to repurchase all or a portion of their 2026 Notes for cash in the event we undergo certain fundamental changes, such as specified change of control transactions, our liquidation or dissolution or the delisting of our ordinary shares from any of The New York Stock Exchange, The Nasdaq Global Market, The Nasdaq Global Select Market or The Nasdaq Capital Market (or any of their respective successors). Additionally, the terms and covenants in the indenture related to the 2026 Notes include certain events of default after which the 2026 Notes may be due and payable immediately. Prior to June 15, 2026, we may redeem the 2026 Notes, in whole but not in part, subject to compliance with certain conditions, if we have, or on the next interest payment date would, become obligated to pay to the holder of any 2026 Notes additional amounts as a result of certain tax-related events. We also may redeem the 2026 Notes prior to March 15, 2026, in whole or in part, if the last reported sale price per ordinary share has been at least 130% of the exchange price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which we provide the notice of redemption.

The 2026 Notes are exchangeable at an initial exchange rate of 6.4182 ordinary shares per \$1,000 principal amount of 2026 Notes, which is equivalent to an initial exchange price of approximately \$155.81 per ordinary share. On July 22, 2024, we irrevocably elected to fix the settlement method for exchange of the 2026 Notes to a combination of cash and ordinary shares of Jazz Pharmaceuticals plc with a specified cash amount per \$1,000 principal amount of 2026 Notes exchanged equal to or in excess of \$1,000. As a result, for any 2026 Notes exchanged subsequent to such notice, an exchanging holder will receive (i) up to \$1,000 in cash per \$1,000 principal amount of 2026 Notes exchanged and (ii) cash, ordinary shares, or any combination thereof, at our election, in respect of the remainder, if any, of its exchange obligation in excess of \$1,000 per \$1,000 principal amount of 2026 Notes exchanged. The exchange rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain make-whole fundamental changes occurring prior to the maturity date of the 2026 Notes or upon our issuance of a notice of redemption, we will in certain circumstances increase the exchange rate for holders of the 2026 Notes who elect to exchange their 2026 Notes in connection with that make-whole fundamental change or during the related redemption period. Prior to March 15, 2026, the 2026 Notes will be exchangeable only upon satisfaction of certain conditions and during certain periods, and thereafter, at any time until the close of business on the second scheduled trading day immediately preceding the maturity date.

*2024 Notes.* In 2017, Jazz Investments completed a private placement of \$575.0 million principal amount of 2024 Notes. We used the net proceeds from this offering to repay \$500.0 million in outstanding loans under the Initial Revolving Credit Facility and to pay related fees and expenses. We used the remainder of the net proceeds for general corporate purposes. Interest on the 2024 Notes was payable semi-annually in cash in arrears on February 15 and August 15 of each year, beginning on February 15, 2018, at a rate of 1.50% per year. The 2024 Notes were exchangeable at an initial exchange rate of 4.5659 ordinary shares per \$1,000 principal amount of 2024 Notes, which was equivalent to an initial exchange price of approximately \$219.02 per ordinary share.

On August 15, 2024, the maturity date for the 2024 Notes, we repaid the \$575.0 million aggregate principal amount, plus accrued and unpaid interest thereon.

### **Contractual Obligations**

Our primary contractual obligations relate to our outstanding indebtedness, as described above. We also have obligations under lease agreements and third-party manufacturing agreements. For information relating to our scheduled maturities with respect to our long-term debt and our lease liabilities see Note 11 Debt and Note 12 Leases, respectively, and for information relating to our noncancelable purchase commitments due within one year see Note 13 Commitments and Contingencies, included in the Notes to Consolidated Financial Statements, included in Part IV of this Annual Report on Form 10-K. Our long-term noncancelable purchase commitments were \$31.7 million at December 31, 2024, primarily related to agreements with third party manufactures.

We also have potential future milestone payments or royalty obligations to third parties under asset purchase, product development, license and other agreements as the timing and likelihood of such milestone payments are not known, and, in the case of royalty obligations, as the amount of such obligations are not estimable. Our contingent obligations to third parties, in the form of development, regulatory and sales-based milestone payments, as of December 31, 2024 included \$1,362.5 million under our license and collaboration agreement with Zymeworks, \$1,255.0 million under our global license and collaboration agreement with Werewolf, \$1,090.0 million under our license agreement with Sumitomo, \$1,065.0 million under our asset purchase agreements with Redx, \$752.5 million under our license and collaboration agreement with Autifony, \$581.0 million under our amended license agreement with PharmaMar, \$375.0 million under the asset purchase and exclusive license agreement with SpringWorks Therapeutics, Inc., \$260.0 million in connection with our acquisition of Cavion, \$155.5 million under our license agreement with Ligand, and \$492.4 million related to other agreements.

### **Critical Accounting Policies and Significant Estimates**

A critical accounting policy is one that is both important to the portrayal of our financial condition and results of operations and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. While our significant accounting policies are described in more detail in Note 2, Summary of Significant Accounting Policies, of the Notes to Consolidated Financial Statements included in Part IV of this Annual Report on Form 10-K, we believe the following accounting estimates and policies to be critical.

#### ***Revenue Recognition***

Revenues are recognized when control of the promised goods or services is transferred to our customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services.

##### *Product Sales, Net*

Product sales revenue is recognized when control has transferred to the customer, which occurs at a point in time, which is typically on delivery to the customer or, in the case of products that are subject to consignment agreements, when the customer removes product from our consigned inventory location for shipment directly to a patient.

##### *Items Deducted from Gross Product Sales.*

Revenues from sales of products are recorded net of government rebates and rebates under managed care plans and commercial payor contracts, estimated allowances for sales returns, government chargebacks, prompt payment discounts, patient coupon programs, and specialty distributor and wholesaler fees. Calculating certain of these items involves estimates and judgments based on sales or invoice data, contractual terms, historical utilization rates, new information regarding changes in applicable regulations and guidelines that would impact the amount of the actual rebates, our expectations regarding future utilization rates and channel inventory data. We review the adequacy of our provisions for sales deductions on a quarterly basis. Amounts accrued for sales deductions are adjusted when trends or significant events indicate that adjustment is appropriate and to reflect actual experience. The most significant items deducted from gross product sales where we exercise judgment are rebates, sales returns and chargebacks.

The following table presents the activity and ending balances for our sales-related accruals and allowances (in thousands):

	Rebates Payable	Sales Returns Reserve	Chargebacks	Discounts and Distributor Fees	Total
Balance at December 31, 2021	\$ 195,715	\$ 15,814	\$ 11,389	\$ 21,808	\$ 244,726
Provision, net	630,295	13,222	135,854	186,609	965,980
Payments/credits	(528,209)	(2,872)	(132,622)	(190,062)	(853,765)
Balance at December 31, 2022	297,801	26,164	14,621	18,355	356,941
Provision, net	651,209	2,485	185,886	179,688	1,019,268
Payments/credits	(640,566)	(8,214)	(185,575)	(174,814)	(1,009,169)
Balance at December 31, 2023	308,444	20,435	14,932	23,229	367,040
Provision, net	820,865	15,883	212,389	189,071	1,238,208
Payments/credits	(810,782)	(9,890)	(214,896)	(174,067)	(1,209,635)
Balance at December 31, 2024	\$ 318,527	\$ 26,428	\$ 12,425	\$ 38,233	\$ 395,613

Total items deducted from gross product sales were \$1,238.2 million, \$1,019.3 million and \$966.0 million, or 24.5%, 21.4% and 21.0% as a percentage of gross product sales, in 2024, 2023 and 2022, respectively. Included in these amounts are immaterial adjustments related to prior-year sales due to changes in estimates.

#### *Rebates*

We are subject to rebates on sales made under governmental managed-care pricing programs and commercial payor contracts in the U.S. The largest of these rebates is associated with sales covered by commercial payor contracts and Epidiolex Medicaid. We participate in state government-managed Medicaid programs as well as certain other qualifying federal and state government programs under the terms of which discounts and rebates are provided to participating government entities. We offer rebates and discounts to managed health care organizations and commercial payors in the U.S. In estimating our provisions for rebates, we consider relevant statutes with respect to governmental pricing programs and contractual sales terms with managed-care providers, commercial payors and group purchasing organizations. We estimate the rebate provision based on historical utilization rates, historical payment experience, new information regarding changes in regulations and guidelines that would impact the amount of the actual rebates, our expectations regarding future utilization rates and channel inventory data obtained from our major distributors in accordance with our inventory management agreements. Estimating these rebates is complex, in part due to the time delay between the date of sale and the actual settlement of the liability. We believe that the methodology we use to estimate rebates on product sales made under governmental managed-care pricing programs and commercial payor contracts is reasonable and appropriate given current facts and circumstances. However, estimates may vary from actual experience.

Rebates were \$820.9 million, \$651.2 million and \$630.3 million, or 16.2%, 13.7% and 13.7% as a percentage of gross product sales, in 2024, 2023 and 2022, respectively. Rebates as a percentage of gross product sales in 2024 increased compared to 2023, primarily due to higher rebate rates with commercial payors. Rebates as a percentage of gross product sales in 2023 were in line with 2022. Rebates as a percentage of gross product sales are expected to increase in 2025 compared to 2024, primarily due to higher rebate rates in commercial payor contracts.

#### *Sales returns*

For certain products, we allow customers to return product within a specified period before and after the applicable expiration date and issue credits which may be applied against existing or future invoices. We account for sales returns as a reduction in net revenue at the time a sale is recognized by establishing an accrual in an amount equal to the estimated value of products expected to be returned. The sales return accrual is estimated principally based on historical experience, the level and estimated shelf life of inventory in the distribution channel, our return policy and expected market events including generic competition.

Sales returns were \$15.9 million, \$2.5 million and \$13.2 million, or 0.3%, 0.1% and 0.3% as a percentage of gross product sales in 2024, 2023 and 2022, respectively. Sales returns as a percentage of gross product sales are not expected to change materially in 2025 compared to 2024.

#### *Chargebacks*

We participate in chargeback programs with a number of entities, principally Federal Supply Schedule, Group Purchasing Organizations, and other public parties, under which pricing on products below wholesalers' list prices is provided to participating entities. These entities purchase product through wholesalers at the contract price and the wholesalers charge back to us the difference between their acquisition cost and the lower negotiated price. We record the difference as allowances

against accounts receivable. We determine our estimate of the chargebacks provision primarily based on historical experience on a product and program basis, current contract prices under the chargeback programs and channel inventory data.

Chargebacks were \$212.4 million, \$185.9 million and \$135.9 million, or 4.2%, 3.9% and 2.9% as a percentage of gross product sales in 2024, 2023 and 2022, respectively. Chargebacks as a percentage of gross product sales increased in 2024 compared to 2023, primarily due to higher chargeback utilization. Chargebacks as a percentage of gross product sales increased in 2023 compared to 2022, primarily due to higher chargeback utilization. Chargebacks as a percentage of gross product sales are not expected to change materially in 2025 compared to 2024.

#### *Discounts and distributor fees*

Discounts and distributor fees comprise prompt payment discounts, patient coupon programs and specialty distributor and wholesaler fees. We offer customers a cash discount on gross product sales as an incentive for prompt payment. We estimate provisions for prompt pay discounts based on contractual sales terms with customers and historical payment experience. To help patients afford our products, we have various programs to assist them, including patient assistance programs, a free product voucher program and co-pay coupon programs for certain products. We estimate provisions for these programs primarily based on expected program utilization, adjusted as necessary to reflect our actual experience on a product and program basis. Specialty distributor and wholesaler fees comprise fees for distribution of our products. We estimate provisions for distributor and wholesaler fees primarily based on sales volumes and contractual terms with our distributors.

Discounts and distributor fees were \$189.1 million, \$179.7 million and \$186.6 million, or 3.7%, 3.8% and 4.1% as a percentage of gross product sales in 2024, 2023 and 2022, respectively. Discounts and distributor fees as a percentage of gross product sales in 2024 were in line with 2023. Discounts and distributor fees as a percentage of gross product sales in 2023 were broadly in line with 2022. Discounts and distributor fees as a percentage of gross product sales are not expected to change materially in 2025 compared to 2024.

#### *Acquisitions and Valuation of Intangibles*

We make certain judgments to determine whether transactions should be accounted for as acquisitions of assets or as business combinations. If it is determined that substantially all of the fair value of gross assets acquired in a transaction is concentrated in a single asset (or a group of similar assets), the transaction is treated as an acquisition of assets. We evaluate the inputs, processes, and outputs associated with the acquired set of activities. If the assets in a transaction include an input and a substantive process that together significantly contribute to the ability to create outputs, the transaction is treated as an acquisition of a business.

We account for business combinations using the acquisition method of accounting, which requires that assets acquired and liabilities assumed generally be recorded at their fair values as of the acquisition date. Goodwill represents the excess of the acquisition consideration over the fair value of assets acquired and liabilities assumed. We test goodwill for impairment annually in October and when events or changes in circumstances indicate that the carrying value may not be recoverable. We have determined that we operate in a single segment and have a single reporting unit associated with the development and commercialization of pharmaceutical products. In performing the annual impairment test, the fair value of the reporting unit is compared to its corresponding carrying value, including goodwill. If the carrying value exceeds the fair value of the reporting unit an impairment loss will be recognized for the amount by which the reporting unit's carrying amount exceeds its fair value, not to exceed the carrying amount of goodwill. We have determined the fair value of our single reporting unit to be equal to our market capitalization, as determined by our traded share price, plus a control premium. The control premium used was based on a review of such premiums identified in recent acquisitions of companies of similar size and in similar industries. We performed our annual goodwill impairment test in October 2024 and concluded that goodwill was not impaired as the fair value of the reporting unit significantly exceeded its carrying amount, including goodwill. As of December 31, 2024, we had \$1.7 billion of goodwill resulting from acquisitions accounted for as business combinations.

In transactions accounted for as acquisitions of assets, no goodwill is recorded and contingent consideration such as payments upon achievement of various developmental, regulatory and commercial milestones generally is not recognized at the acquisition date. In an asset acquisition, upfront payments allocated to IPR&D projects at the acquisition date are expensed unless there is an alternative future use. In addition, product development milestones are expensed upon achievement.

#### *Valuation of Intangible Assets*

We have acquired, and expect to continue to acquire, intangible assets through asset acquisitions or business combinations. When significant identifiable intangible assets are acquired, we engage an independent third party valuation firm to assist in determining the fair values of these assets as of the acquisition date. Discounted cash flow models are typically used in these valuations, which require the use of significant estimates and assumptions, including but not limited to:

- estimating the timing of and expected costs to complete the in-process projects;
- projecting regulatory approvals;

- estimating future cash flows including revenues and operating profits resulting from completed products and in-process projects; and
- developing appropriate discount rates and probability rates by project.

We believe the fair values that we assign to the intangible assets acquired are based upon reasonable estimates and assumptions given available facts and circumstances as of the acquisition dates. No assurance can be given, however, that the underlying assumptions used to estimate expected cash flows will transpire as estimated. In addition, we are required to estimate the period of time over which to amortize the intangible assets, which requires significant judgment.

#### *Impairment of Intangible Assets*

Finite-lived intangible assets consist primarily of purchased developed technology and are amortized on a straight-line basis over their estimated useful lives, which range from seven to sixteen years. The estimated useful lives associated with intangible assets are consistent with the estimated lives of the products and may be modified when circumstances warrant. Intangible assets with finite lives are reviewed for impairment whenever events or circumstances indicate that the carrying value of an asset may not be recoverable. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. Factors that we consider in deciding when to perform an impairment review include significant under-performance of a product in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in our use of the assets. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than its carrying amount. Estimating future cash flows related to an intangible asset involves estimates and assumptions. If our assumptions are not correct, there could be an impairment loss or, in the case of a change in the estimated useful life of the asset, a change in amortization expense.

IPR&D is not amortized but is tested for impairment annually or when events or circumstances indicate that the fair value may be below the carrying value of the asset. If the carrying value of the assets is not expected to be recovered, the assets are written down to their estimated fair values.

As of December 31, 2024, we had \$4.8 billion of finite-lived intangible assets, of which \$3.3 billion related to the Epidiolex intangible asset which we acquired in the GW Acquisition and \$1.0 billion related to the Vyxeos intangible asset which we acquired in the Celator Acquisition. As part of our annual impairment assessment, we reviewed these intangible assets as of December 31, 2024 and determined the carrying value is recoverable. Cash flow models used in our assessment are based on our commercial experience to date and require the use of significant estimates, which include, but are not limited to, patient-related assumptions, including patient population and segmentation, patient growth and treatment rates, and long-range pricing expectations.

We did not recognize an impairment charge related to our intangible assets in 2024 or 2023. In 2022, we recorded an acquired IPR&D asset impairment charge of \$133.6 million as a result of the decision to discontinue our nabiximols program.

Please refer to Note 9, Goodwill and Intangible Assets, of the Notes to Consolidated Financial Statements included in Part IV of this Annual Report on Form 10-K, for further information about our intangible assets and the remaining useful lives of our finite-lived intangible assets as of December 31, 2024.

#### *Income Taxes*

We use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial statement carrying amount and the tax basis of assets and liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. We provide a valuation allowance when it is more-likely-than-not that deferred tax assets will not be realized.

Our most significant tax jurisdictions are Ireland, the U.K. and the U.S. Certain estimates are required in determining our expense for income taxes. Some of these estimates are based on management's interpretations of jurisdiction-specific tax laws or regulations and the likelihood of settlement related to tax audit issues. Various internal and external factors may have favorable or unfavorable effects on our future effective income tax rate. These factors include, but are not limited to, changes in tax laws, regulations and/or rates, changing interpretations of existing tax laws or regulations, changes in estimates of prior years' items, the impact of accounting for share-based compensation, changes in our international organization, likelihood of settlement, and changes in overall levels of income before taxes.

Realization of our deferred tax assets is dependent upon the generation of future taxable income, the amount and timing of which are uncertain. In evaluating our ability to recover our deferred tax assets, we consider all available positive and negative evidence, including cumulative income in recent fiscal years, our forecast of future taxable income exclusive of certain reversing temporary differences and significant risks and uncertainties related to our business. In determining future taxable income, we are responsible for assumptions utilized including the amount of state, federal and international pre-tax operating income, the reversal of certain temporary differences and the implementation of feasible and prudent tax planning strategies.

These assumptions require significant judgment about the forecasts of future taxable income in applicable tax jurisdictions, which are based on our commercial experience to date and are consistent with the plans and estimates that we are using to manage our underlying business.

We maintain a valuation allowance against certain other deferred tax assets where realizability is not certain. We periodically evaluate the likelihood of the realization of deferred tax assets and reduce the carrying amount of these deferred tax assets by a valuation allowance to the extent we believe a portion will not be realized. This determination depends on a variety of factors, some of which are subjective, including our recent cumulative earnings experience by taxing jurisdiction, expectations of future taxable income, carryforward periods available to us for tax reporting purposes, various income tax strategies and other relevant factors. If we determine that the deferred tax assets are not realizable in a future period, we would record material changes to income tax expense in that period.

We have also provided for unrecognized tax benefits that we believe are not more-likely-than-not to be sustained upon examination by tax authorities. The evaluation of unrecognized tax benefits is based on factors that include, but are not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, new audit activity and changes in facts or circumstances related to a tax position. We evaluate unrecognized tax benefits on a quarterly basis and adjust the level of the liability to reflect any subsequent changes in the relevant facts surrounding the uncertain positions. Our liabilities for unrecognized tax benefits can be relieved only if the contingency becomes legally extinguished through either payment to the taxing authority or the expiration of the statute of limitations, the recognition of the benefits associated with the position meet the more-likely-than-not threshold or the liability becomes effectively settled through the examination process. We consider matters to be effectively settled once the taxing authority has completed all of its required or expected examination procedures, including all appeals and administrative reviews. We also accrue for potential interest and penalties related to unrecognized tax benefits in income tax expense.

### **Recent Accounting Pronouncements**

For a discussion of recent accounting pronouncements, please see Note 2, Summary of Significant Accounting Policies, of the Notes to Consolidated Financial Statements included in Part IV of this Annual Report on Form 10-K.

### **Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

*Interest Rate Risk.* The primary objectives of our investment policy, in order of priority, are as follows: safety and preservation of principal and diversification of risk; liquidity of investments sufficient to meet cash flow requirements; and competitive yield. Although our investments are subject to market risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or certain types of investment. Our investment policy allows us to maintain a portfolio of cash equivalents and short-term investments in a variety of securities, including U.S. federal government and federal agency securities, corporate bonds or commercial paper issued by U.S. corporations, money market instruments, certain qualifying money market mutual funds, certain repurchase agreements, and tax-exempt obligations of states, agencies and municipalities in the U.S. Our cash equivalents and investments as of December 31, 2024 consisted of money market funds and time deposits which are not subject to significant interest rate risk.

We are exposed to risks associated with changes in interest rates in connection with our term loan borrowings. In May 2021 we entered into the Credit Agreement which provided for (i) the Dollar Term Loan, (ii) the Euro Term Loan and (iii) the Initial Revolving Credit Facility. In January 2024, we entered into the Repricing Amendment No.1 to the Credit Agreement. Upon entry into the Repricing Amendment No.1, certain existing lenders converted a portion of the outstanding Dollar Term Loan into the Tranche B-1 Dollar Term Loans and we borrowed \$201.9 million aggregate principal amount of additional Tranche B-1 Dollar Term Loans, the proceeds of which were used to repay the portion of the outstanding Dollar Term Loan that was not converted. In July 2024, we entered into the Repricing Amendment No. 2 to the Credit Agreement, as amended by the Repricing Amendment No.1. Upon entry into the Repricing Amendment No. 2, certain existing lenders converted a portion of the outstanding Tranche B-1 Dollar Term Loans into the Tranche B-2 Dollar Term Loans and we borrowed \$289.6 million aggregate principal amount of additional Tranche B-2 Dollar Term Loans, the proceeds of which were used to repay the portion of the outstanding Tranche B-1 Dollar Term Loans that were not converted. In November 2024, we entered into Amendment No. 3 to the Credit Agreement, as amended by the Repricing Amendment No.1 and Repricing Amendment No.2, to increase the Initial Revolving Credit Facility from \$500.0 million to \$885.0 million and extend the maturity date from May 5, 2026 to November 26, 2029.

There were no borrowings outstanding under the Amended Revolving Credit Facility or the Euro Term Loan as of December 31, 2024. Tranche B-2 Dollar Term Loans borrowings of \$2.7 billion were outstanding as of December 31, 2024 and subject to an either (a) Term SOFR, or (b) the prime lending rate, in each case, plus an applicable margin. The applicable margin for the Tranche B-2 Dollar Term Loans is 2.25% (in the case of Term SOFR borrowings) and 1.25% (in the case of borrowings at the prime lending rate). To achieve a desired mix of floating and fixed interest rates on our Tranche B-2 Dollar

Term Loans, we entered into interest rate swap agreements in April 2023. The interest rate swap agreements have a notional amount of \$500.0 million and are effective until April 2026. 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 net asset fair value of outstanding interest rate swap contracts was \$1.0 million as of December 31, 2024. The impact of a hypothetical increase or decrease in interest rates on the fair value of the interest rate swap contracts would be offset by a change in the value of the underlying liability. If interest rates were to increase or decrease by 1%, interest expense for 2025 would increase or decrease by approximately \$15.5 million, based on the unhedged portion of our outstanding variable rate borrowings.

In September 2024, we completed a private placement of \$1.0 billion aggregate principal amount of the 2030 Notes. In April 2021, we issued \$1.5 billion in aggregate principal amount of the Secured Notes. In June 2020, we completed a private placement of \$1.0 billion aggregate principal amount of the 2026 Notes.

The 2030 Notes, the Secured Notes and the 2026 Notes have fixed annual interest rates of 3.125%, 4.375% and 2.000%, respectively, and we therefore do not have economic interest rate exposure on the 2030 Notes, the Secured Notes and the 2026 Notes. However, the fair values of the 2030 Notes, the Secured Notes and the 2026 Notes are exposed to interest rate risk. Generally, the fair values of the 2030 Notes, the Secured Notes and the 2026 Notes will increase as interest rates fall and decrease as interest rates rise. The fair values of the 2030 Notes and the 2026 Notes are also affected by volatility in our ordinary share price. As of December 31, 2024, the fair values of the 2030 Notes, the Secured Notes and the 2026 Notes were estimated to be \$1.1 billion, \$1.4 billion and \$1.0 billion, respectively.

*Foreign Currency Exchange Rate Risk.* We have significant operations in Europe as well as in the U.S. The functional currency of each foreign subsidiary is generally the local currency. We are exposed to foreign currency exchange risk as the functional currency financial statements of foreign subsidiaries are translated to U.S. dollars. The assets and liabilities of our foreign subsidiaries having a functional currency other than the U.S. dollar are translated into U.S. dollars at the exchange rate prevailing at the balance sheet date, and at the average exchange rate for the reporting period for revenue and expense accounts. The cumulative foreign currency translation adjustment is recorded as a component of accumulated other comprehensive loss in shareholders' equity. The reported results of our foreign subsidiaries will be influenced by their translation into U.S. dollars by currency movements against the U.S. dollar. Our primary currency translation exposure is related to our subsidiaries that have functional currencies denominated in sterling and euro. A hypothetical 10% strengthening or weakening in the rates used to translate the results of our foreign subsidiaries that have functional currencies denominated in sterling and euro would have increased or decreased net income for the year ended December 31, 2024 by approximately \$78.0 million and \$3.3 million, respectively.

Transactional exposure arises where transactions occur in currencies other than the functional currency. Transactions in foreign currencies are recorded at the exchange rate prevailing at the date of the transaction. The resulting monetary assets and liabilities are translated into the appropriate functional currency at exchange rates prevailing at the balance sheet date and the resulting gains and losses are reported in foreign exchange gain (loss) in the consolidated statements of income (loss). As of December 31, 2024, our exposure to transaction risk primarily related to sterling and euro denominated net monetary liabilities, including intercompany loans, held by subsidiaries with a U.S. dollar functional currency. We have entered into foreign exchange forward contracts to manage this currency risk. These foreign exchange forward contracts are not designated as hedges; gains and losses on these derivative instruments are designed to offset gains and losses on the underlying balance sheet exposures. As of December 31, 2024, we held foreign exchange forward contracts with notional amounts totaling \$461.2 million. The net liability fair value of outstanding foreign exchange forward contracts was \$7.9 million as of December 31, 2024. Based on our foreign currency exchange rate exposures as of December 31, 2024, a hypothetical 10% adverse fluctuation in exchange rates would decrease the fair value of our foreign exchange forward contracts by approximately \$6.9 million. The resulting loss on these forward contracts would be offset by a positive impact on the underlying monetary assets and liabilities.

**Item 8. Financial Statements and Supplementary Data**

Our consolidated financial statements as listed below are included in this Annual Report on Form 10-K as pages F-1 through F-51.

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<b>Jazz Pharmaceuticals plc</b>	
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**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

Not applicable.

**Item 9A. Controls and Procedures**

*Evaluation of Disclosure Controls and Procedures.* We have carried out an evaluation under the supervision and with the participation of management, including our principal executive officer and principal financial officer, of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) of the Exchange Act) as of the end of the period covered by this Annual Report on Form 10-K. Based on their evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2024.

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

*Changes in Internal Control over Financial Reporting.* During the quarter ended December 31, 2024, 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.

*Management's Report on Internal Control over Financial Reporting.* The following report is provided by management in respect of our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) of the Exchange Act):

1. Our management is responsible for establishing and maintaining adequate internal control over financial reporting.
2. Our management used the COSO framework to evaluate the effectiveness of internal control over financial reporting. Management believes that the COSO framework is a suitable framework for its evaluation of financial reporting because it is free from bias, permits reasonably consistent qualitative and quantitative measurements of our internal control over financial reporting, is sufficiently complete so that those relevant factors that would alter a conclusion about the effectiveness of our internal control over financial reporting are not omitted and is relevant to an evaluation of internal control over financial reporting.
3. Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2024 and has concluded that such internal control over financial reporting was effective. There were no material weaknesses in internal control over financial reporting identified by management.
4. KPMG, our independent registered public accounting firm, has audited the consolidated financial statements of Jazz Pharmaceuticals plc as of and for the year ended December 31, 2024, included herein, and has issued an audit report on our internal control over financial reporting, which is included below.

## Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors  
Jazz Pharmaceuticals plc:

### *Opinion on Internal Control Over Financial Reporting*

We have audited Jazz Pharmaceuticals plc and subsidiaries' (the Company) internal control over financial reporting as of December 31, 2024, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2024 and 2023, the related consolidated statements of income (loss), comprehensive income (loss), shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2024, and the related notes and financial statement schedules at item 15(a)2 (collectively, 'the consolidated financial statements'), and our report dated February 26, 2025 expressed an unqualified opinion on those consolidated financial statements.

### *Basis for Opinion*

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Managements Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

### *Definition and Limitations of Internal Control Over Financial Reporting*

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ KPMG

Dublin, Ireland  
February 26, 2025

**Item 9B. Other Information****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 December 31, 2024:

Name and Position	Date	Action	Rule 10b5-1*	Expiration Date	Total Ordinary Shares to be Sold
Robert Iannone	December 6, 2024	Termination <sup>(1)</sup>	X	March 7, 2025	10,681
Robert Iannone Executive Vice President, Global Head of Research and Development, Chief Medical Officer	December 6, 2024	Adoption <sup>(1)</sup>	X	December 6, 2025	12,625

(1) Represents the modification, as described in Rule 10b5-1(c)(1)(iv) under the Exchange Act, of a written plan initially adopted on March 7, 2024 that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act.

\* 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 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections**

Not applicable.

**PART III**

Certain information required by Part III is omitted from this Annual Report on Form 10-K and incorporated by reference to our 2025 Proxy Statement, to be filed pursuant to Regulation 14A of the Exchange Act. If our 2025 Proxy Statement is not filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, the omitted information will be included in an amendment to this Annual Report on Form 10-K filed not later than the end of such 120-day period.

**Item 10. Directors, Executive Officers and Corporate Governance**

The information required by this item is to be included in our 2025 Proxy Statement as follows and is incorporated by reference:

- The information relating to our directors and nominees for director is to be included in the section entitled "Proposal 1—Election of Directors;"
- The information relating to our executive officers is to be included in the section entitled "Executive Officers;"
- The information relating to our Audit Committee, audit committee financial expert, procedures by which shareholders may recommend nominees to our board of directors and our insider trading policies and procedures is to be included in the section entitled "Corporate Governance and Board Matters;" and
- If required, the information regarding compliance with Section 16(a) of the Exchange Act is to be included in the section entitled "Delinquent Section 16(a) Reports."

Such information is incorporated herein by reference to our 2025 Proxy Statement, provided that if the 2025 Proxy Statement is not filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, the omitted information will be included in an amendment to this Annual Report on Form 10-K filed not later than the end of such 120-day period.

Our Code of Conduct applies to all of our employees, directors and officers, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and those of our

subsidiaries. The Code of Conduct is available on our website at [www.jazzpharmaceuticals.com](http://www.jazzpharmaceuticals.com) under the section entitled “Our Purpose” under “Ethical Standards.” We intend to satisfy the disclosure requirements under Item 5.05 of the SEC Form 8-K regarding an amendment to, or waiver from, a provision of our Code of Conduct by posting such information on our website at the website address and location specified above.

**Item 11. Executive Compensation**

The information required by this item is to be included in our 2025 Proxy Statement under the sections entitled “Executive Compensation,” “Director Compensation,” “Corporate Governance and Board Matters—Compensation Committee Interlocks and Insider Participation” and “Corporate Governance and Board Matters—Compensation Committee Report” and is incorporated herein by reference, provided that if the 2024 Proxy Statement is not filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, the omitted information will be included in an amendment to this Annual Report on Form 10-K filed not later than the end of such 120-day period.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The information required by this item with respect to equity compensation plans is to be included in our 2025 Proxy Statement under the section entitled “Equity Compensation Plan Information” and the information required by this item with respect to security ownership of certain beneficial owners and management is to be included in our 2025 Proxy Statement under the section entitled “Security Ownership of Certain Beneficial Owners and Management” and in each case is incorporated herein by reference, provided that if the 2025 Proxy Statement is not filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, the omitted information will be included in an amendment to this Annual Report on Form 10-K filed not later than the end of such 120-day period.

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

The information required by this item is to be included in our 2025 Proxy Statement under the sections entitled “Certain Relationships and Related Party Transactions” and “Corporate Governance and Board Matters—Independence of the Board of Directors” and is incorporated herein by reference, provided that if the 2025 Proxy Statement is not filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, the omitted information will be included in an amendment to this Annual Report on Form 10-K filed not later than the end of such 120-day period.

**Item 14. Principal Accountant Fees and Services**

The information required by this item is to be included in our 2025 Proxy Statement under the section entitled “Proposal 2—On a Non-Binding Advisory Basis, Ratify Appointment of Independent Registered Accounting Firm and, On a Binding Basis, Authorize the Board of Directors, Acting Through the Audit Committee, to Determine the Independent Auditors’ Remuneration” and is incorporated herein by reference, provided that if the 2025 Proxy Statement is not filed within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, the omitted information will be included in an amendment to this Annual Report on Form 10-K filed not later than the end of such 120-day period.

**PART IV**

**Item 15. Exhibits and Financial Statement Schedules**

*(a) The following documents are filed as part of this Annual Report on Form 10-K:*

*1. Financial Statements:*

See Consolidated Financial Statements in Part II, Item 8 of this Annual Report on Form 10-K.

*2. Financial Statement Schedules:*

The following financial statement schedule of Jazz Pharmaceuticals plc is filed as part of this Annual Report on Form 10-K on page F-51 and should be read in conjunction with the consolidated financial statements of Jazz Pharmaceuticals plc.

Schedule II: Valuation and Qualifying Accounts

All other schedules are omitted because they are not applicable, not required under the instructions, or the requested information is shown in the consolidated financial statements or related notes thereto.

(b) Exhibits—The following exhibits are included herein or incorporated herein by reference:

<b>Exhibit Number</b>	<b>Description of Document</b>
2.1	<a href="#">Agreement and Plan of Merger and Reorganization, dated as of September 19, 2011, by and among Azur Pharma Limited (now Jazz Pharmaceuticals plc), Jaguar Merger Sub Inc., Jazz Pharmaceuticals, Inc. and Seamus Mulligan, solely in his capacity as the Indemnitors' Representative (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals, Inc.'s Current Report on Form 8-K (File No. 001-33500) filed with the SEC on September 19, 2011).</a>
2.2	<a href="#">Agreement and Plan of Merger, dated as of May 27, 2016, by and among Jazz Pharmaceuticals plc, Plex Merger Sub, Inc., and Celator Pharmaceuticals, Inc. (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-33500), as filed with the SEC on May 31, 2016).</a>
2.3‡	<a href="#">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).</a>
2.4#	<a href="#">License and Collaboration Agreement, dated October 18, 2022, between Jazz Pharmaceuticals Ireland Limited and Zymeworks BC Inc. (incorporated herein by reference to Exhibit 2.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-033500), as filed with the SEC on December 5, 2022).</a>
3.1	<a href="#">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).</a>
4.1	<a href="#">Reference is made to Exhibit 3.1.</a>
4.2A	<a href="#">Investor Rights Agreement, dated July 7, 2009 by and between Jazz Pharmaceuticals, Inc. and the other parties named therein (incorporated herein by reference to Exhibit 10.88 in Jazz Pharmaceuticals, Inc.'s Current Report on Form 8-K (File No. 001-33500), as filed with the SEC on July 7, 2009).</a>
4.2B	<a href="#">Assignment, Assumption and Amendment Agreement, dated as of January 18, 2012, by and among Jazz Pharmaceuticals, Inc., Jazz Pharmaceuticals plc and the other parties named therein (incorporated herein by reference to Exhibit 4.7B in the Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals, Inc. with the SEC on February 28, 2012).</a>
4.3A	<a href="#">Indenture, dated as of August 23, 2017, among Jazz Pharmaceuticals Public Limited Company, Jazz Investments I Limited and U.S. Bank National Association (incorporated herein by reference to Exhibit 4.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-33500), as filed with the SEC on August 23, 2017).</a>
4.3B	<a href="#">Form of 1.50% Exchangeable Senior Note due 2024 (incorporated herein by reference to Exhibit 4.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-33500), as filed with the SEC on August 23, 2017).</a>
4.4A	<a href="#">Indenture, dated as of June 11, 2020 among Jazz Pharmaceuticals Public Limited Company, Jazz Investments I Limited and U.S. Bank National Association (incorporated herein by reference to Exhibit 4.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-033500), as filed with the SEC on June 11, 2020).</a>
4.4B	<a href="#">Form of 2.000% Exchangeable Senior Note due 2026 (incorporated herein by reference to Exhibit 4.2 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-033500), as filed with the SEC on June 11, 2020).</a>
4.5A	<a href="#">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).</a>
4.5B	<a href="#">Form of 4.375% Senior Notes due 2029 (incorporated herein by reference to Exhibit 4.2 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-033500), as filed with the SEC on April 29, 2021).</a>

4.5C	<a href="#">First Supplemental Indenture, dated as of July 21, 2021, among GW Pharmaceuticals Limited, GW Global Services (International) Limited, GW Pharma Limited, GW Research Limited, GW UK Services Limited and Greenwich Biosciences, Inc., Jazz Securities Designated Activity Company, and U.S. Bank National Association, as trustee under the Indenture, dated as of April 29, 2021 (incorporated herein by reference to Exhibit 4.5C in Jazz Pharmaceuticals, plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2021, as filed with the SEC on August 3, 2021).</a>
4.5D	<a href="#">Indenture, dated as of September 6, 2024 among Jazz Pharmaceuticals Public Limited Company, Jazz Investments I Limited and U.S. Bank Trust Company, National Association (incorporated herein by reference to Exhibit 4.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-033500), as filed with the SEC on September 6, 2024).</a>
4.5E	<a href="#">Form of 3.125% Exchangeable Senior Note due 2030 (incorporated herein by reference to Exhibit 4.2 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-033500), as filed with the SEC on September 6, 2024).</a>
4.6	<a href="#">Description of Share Capital.</a>
10.1A	<a href="#">Credit Agreement, dated as of May 5, 2021, by and among Jazz Pharmaceuticals Public Limited Company, the other borrowers from time to time party thereto, the lenders and issuing banks from time to time party thereto, Bank of America, N.A., as administrative agent, and U.S. Bank National Association, as collateral trustee (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-033500), as filed with the SEC on May 5, 2021).</a>
10.1B	<a href="#">Conforming Changes Amendment, dated as of June 7, 2023, entered into by Bank of America, N.A. as administrative agent to Credit Agreement, dated as of May 5, 2021, by and among Jazz Pharmaceuticals Public Limited Company, the other borrowers from time to time party thereto, the lenders and issuing banks from time to time party thereto, Bank of America, N.A., as administrative agent, and U.S. Bank National Association, as collateral trustee (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals, plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2023, as filed with the SEC on August 9, 2023).</a>
10.1C	<a href="#">Amendment No. 1, dated as of January 19, 2024, by and among Jazz Pharmaceuticals Public Limited Company, the other borrowers from time to time party thereto, the lenders and issuing banks from time to time party thereto, Bank of America, N.A., as administrative agent, and U.S. Bank Trust Company, National Association, as collateral trustee, (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-033500), as filed with the SEC on January 25, 2024).</a>
10.1D	<a href="#">Amendment No. 2, dated as of January 19, 2024, by and among Jazz Pharmaceuticals Public Limited Company, the other borrowers party thereto, the guarantors party thereto, the lenders party thereto, Bank of America, N.A., as administrative agent, and U.S. Bank Trust Company, National Association, (as successor in interest to U.S. Bank National Association), as collateral trustee (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-033500), as filed with the SEC on July 22, 2024).</a>
10.2	<a href="#">Amendment No. 3, dated as of November 26, 2024, by and among Jazz Pharmaceuticals Public Limited Company, the other borrowers party thereto, the guarantors party thereto, the lenders and issuing banks party thereto, Bank of America, N.A., as administrative agent, and U.S. Bank Trust Company, National Association (as successor in interest to U.S. Bank National Association), as collateral trustee (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-033500), as filed with the SEC on November 26, 2024).</a>
10.3#	<a href="#">Settlement Agreement, dated as of April 5, 2017, by and between Jazz Pharmaceuticals, Inc. and Jazz Pharmaceuticals Ireland Limited, and Roxane Laboratories, Inc., West-Ward Pharmaceuticals Corp., Eurohealth (USA), Inc., and Hikma Pharmaceuticals PLC (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2022, as filed with the SEC on November 9, 2022).</a>
10.4†	<a href="#">Supply Agreement, dated as of April 1, 2010, by and between Jazz Pharmaceuticals, Inc. and Siegfried (USA) Inc. (incorporated herein by reference to Exhibit 10.54 in Jazz Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2010, as filed with the SEC on May 6, 2010).</a>
10.5‡	<a href="#">Master Manufacturing Services Agreement, dated as of October 1, 2015, by and between Jazz Pharmaceuticals Ireland Limited and Patheon Pharmaceuticals Inc. (incorporated herein by reference to Exhibit 10.8 in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2020, as filed with the SEC on February 23, 2021).</a>
10.6‡	<a href="#">Contract Manufacturing Agreement, dated as of January 20, 2020, by and between Jazz Pharmaceuticals Ireland Limited and Siegfried AG (incorporated herein by reference to Exhibit 10.10 in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2019, as filed with the SEC on February 25, 2020).</a>

10.7#	<a href="#">Pharmacy Master Services Agreement, dated as of December 1, 2022, by and between Jazz Pharmaceuticals, Inc. and Express Scripts Specialty Distribution Services, Inc. (incorporated herein by reference to Exhibit 10.8# in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2022, as filed with the SEC on March 1, 2023).</a>
10.8A‡	<a href="#">Amended and Restated License Agreement, dated as of October 14, 2020, between Pharma Mar, S.A. and Jazz Pharmaceuticals Ireland Limited (incorporated herein by reference to Exhibit 10.12 in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2020, as filed with the SEC on February 23, 2021).</a>
10.8B‡	<a href="#">Amendment No. 1, dated as of May 6, 2021, to Amended and Restated License Agreement, dated as of October 14, 2020, between Pharma Mar, S.A. and Jazz Pharmaceuticals Ireland Limited (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals, plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2021, as filed with the SEC on August 3, 2021).</a>
10.9	<a href="#">Lease, dated May 8, 2012, by and between John Ronan and Castle Cove Property Developments Limited and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2012, as filed with the SEC on August 7, 2012).</a>
10.10+	<a href="#">Form of Indemnification Agreement between Jazz Pharmaceuticals plc and its officers and directors (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's Current Report on Form 8-K (File No. 001-33500), as filed with the SEC on January 18, 2012).</a>
10.11+	<a href="#">Offer Letter from Jazz Pharmaceuticals, Inc. to Robert Iannone dated as of April 11, 2019 (incorporated herein by reference to Exhibit 10.4 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2019, as filed with the SEC on August 6, 2019).</a>
10.12A+	<a href="#">Employment Agreement, dated as of May 16, 2012 by and between Patricia Carr and Jazz Pharmaceuticals plc (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2019, as filed with the SEC on November 5, 2019).</a>
10.12B+	<a href="#">Change in Control Severance Terms, dated as of May 15, 2016, by and between Jazz Pharmaceuticals Ireland Ltd. and Patricia Carr (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2019, as filed with the SEC on November 5, 2019).</a>
10.12C+	<a href="#">Change in Control Stock Award Acceleration Agreement, dated as of May 15, 2016 by and between Jazz Pharmaceuticals plc and Patricia Carr (incorporated herein by reference to Exhibit 10.3 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2019, as filed with the SEC on November 5, 2019).</a>
10.13+	<a href="#">Offer Letter, dated as of July 5, 2019 by and between Jazz Pharmaceuticals, Inc. and Neena M. Patil (incorporated herein by reference to Exhibit 10.4 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2019, as filed with the SEC on November 5, 2019).</a>
10.14A+	<a href="#">Employment Contract, dated as of December 14, 2019, by and between Jazz Pharmaceuticals UK Limited and Samantha Pearce (incorporated herein by reference to Exhibit 10.28A in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2019, as filed with the SEC on February 25, 2020).</a>
10.14B+	<a href="#">Equity Award Letter, dated as of December 9, 2019, by and between Jazz Pharmaceuticals UK Limited and Samantha Pearce (incorporated herein by reference to Exhibit 10.28B in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2019, as filed with the SEC on February 25, 2020).</a>
10.14C+	<a href="#">Amendment to Employment Contract, dated as of April 21, 2020, by and between Jazz Pharmaceuticals UK Limited and Samantha Pearce (incorporated herein by reference to Exhibit 10.4 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2020, as filed with the SEC on May 5, 2020).</a>
10.14D+	<a href="#">Offer Letter from Jazz Pharmaceuticals, Inc. to Samantha Pearce (incorporated herein by reference to Exhibit 10.4 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2024, as filed with the SEC on August 1, 2024).</a>
10.15+	<a href="#">Offer Letter, dated as of February 23, 2020, by and between Jazz Pharmaceuticals, Inc. and Renée Galá (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2020, as filed with the SEC on May 5, 2020).</a>

10.16A+	<a href="#">Offer Letter, dated as of April 4, 2023, by and between Jazz Pharmaceuticals Ireland and Liz Henderson (incorporated herein by reference to Exhibit 10.17A in the Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2023, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals Inc. with the SEC on February 28, 2024).</a>
10.16B+	<a href="#">New Hire Equity Letter, dated as of April 4, 2023, from Jazz Pharmaceuticals to Liz Henderson (incorporated herein by reference to Exhibit 10.17B in the Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2023, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals Inc. with the SEC on February 28, 2024).</a>
10.17A+	<a href="#">Offer Letter, dated as of January 30, 2024, by and between Jazz Pharmaceuticals, Inc. and Philip Johnson (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2024, as filed with the SEC on May 2, 2024).</a>
10.17B+	<a href="#">Sign-On Bonus Repayment Agreement, dated as of February 25, 2024, by and between Jazz Pharmaceuticals, Inc. and Philip Johnson.</a>
10.18A+	<a href="#">Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 99.1 in Jazz Pharmaceuticals plc's registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).</a>
10.18B+	<a href="#">Jazz Pharmaceuticals plc 2011 Equity Incentive Plan Sub-Plan Governing Awards to Participants in the Republic of Ireland (incorporated herein by reference to Exhibit 10.39B in the Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2011, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals Inc. with the SEC on February 28, 2012).</a>
10.18C+	<a href="#">Jazz Pharmaceuticals plc 2011 Equity Incentive Plan - Form of U.S. Option Grant Notice and Form of U.S. Option Agreement (approved July 31, 2013) (incorporated herein by reference to Exhibit 10.3 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2013, as filed with the SEC on November 5, 2013).</a>
10.18D+	<a href="#">Jazz Pharmaceuticals plc 2011 Equity Incentive Plan - Form of Non-U.S. Option Grant Notice and Form of Non-U.S. Option Agreement (approved July 31, 2013) (incorporated herein by reference to Exhibit 10.5 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2013, as filed with the SEC on November 5, 2013).</a>
10.18E+	<a href="#">Jazz Pharmaceuticals plc 2011 Equity Incentive Plan - Form of Non-U.S. Option Grant Notice and Form of Non-U.S. Option Agreement (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2016, as filed with the SEC on May 10, 2016).</a>
10.18F+	<a href="#">Amended and Restated 2011 Equity Incentive Plan (approved August 4, 2016) (incorporated herein by reference to Exhibit 10.8 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).</a>
10.18G+	<a href="#">Amended and Restated 2011 Equity Incentive Plan (approved November 3, 2016) (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2016, as filed with the SEC on November 8, 2016).</a>
10.18H+	<a href="#">Amended and Restated 2011 Equity Incentive Plan (approved November 2, 2022) (incorporated herein by reference to Exhibit 10.26Q+ in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2022, as filed with the SEC on March 1, 2023).</a>
10.18I+	<a href="#">Amended and Restated 2011 Equity Incentive Plan (approved November 1, 2023) (incorporated herein by reference to Exhibit 10.18I in the Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2023, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals Inc. with the SEC on February 28, 2024).</a>
10.18J+	<a href="#">Form of U.S. Option Grant Notice and Form of U.S. Option Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.7 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2016, as filed with the SEC on November 8, 2016).</a>
10.18K+	<a href="#">Form of U.S. Restricted Stock Unit Award Grant Notice and Form of U.S. Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.6 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2016, as filed with the SEC on November 8, 2016).</a>

10.18L+	<a href="#">Form of Non-U.S. Option Grant Notice and Non-U.S. Option Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2018, as filed with the SEC on August 7, 2018).</a>
10.18M+	<a href="#">Form of Non-U.S. Option Grant Notice and Non-U.S. Option Agreement under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.4 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2019, as filed with the SEC on May 7, 2019).</a>
10.18N+	<a href="#">Form of Non-U.S. Restricted Stock Unit Award Grant Notice and Non-U.S. Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.5 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2019, as filed with the SEC on May 7, 2019).</a>
10.18O+	<a href="#">Form of U.S. Restricted Stock Unit Award Grant Notice and Form of U.S. Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.8 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2021, as filed with the SEC on August 3, 2021).</a>
10.18P+	<a href="#">Form of Non-U.S. Restricted Stock Unit Award Grant Notice and Form of Non-U.S. Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.9 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2021, as filed with the SEC on August 3, 2021).</a>
10.18Q+	<a href="#">Form of Non-U.S. Restricted Stock Unit Award Grant Notice and Form of Non-U.S. Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.1 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2021, as filed with the SEC on November 9, 2021).</a>
10.18R+	<a href="#">Form of U.S. Performance Restricted Stock Unit Award Grant Notice and Form of U.S. Performance Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.6 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2021, as filed with the SEC on August 3, 2021).</a>
10.18S+	<a href="#">Form of Non-U.S. Performance Restricted Stock Unit Award Grant Notice and Form of Non-U.S. Performance Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2011 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.7 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2021, as filed with the SEC on August 3, 2021).</a>
10.19A+	<a href="#">Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Option Plan (incorporated herein by reference to Exhibit 99.4 in Jazz Pharmaceuticals plc's registration statement on Form S-8 (File No. 333-179075), as filed with the SEC on January 18, 2012).</a>
10.19B+	<a href="#">Form of Non-U.S. Option Grant Notice and Form of Non-U.S. Option Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Option Plan (incorporated herein by reference to Exhibit 10.30B in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2012, as filed with the SEC on February 26, 2013).</a>
10.19C+	<a href="#">Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Option Plan - Form of Non-U.S. Option Grant Notice and Form of Non-U.S. Option Agreement (approved August 1, 2013) (incorporated herein by reference to Exhibit 10.7 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2013, as filed with the SEC on November 5, 2013).</a>
10.19D+	<a href="#">Amended and Restated 2007 Non-Employee Directors Stock Award Plan (approved August 4, 2016) (incorporated herein by reference to Exhibit 10.9 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).</a>
10.19E+	<a href="#">Amended and Restated 2007 Non-Employee Directors Stock Award Plan (approved November 3, 2016) (incorporated herein by reference to Exhibit 10.3 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2016, as filed with the SEC on November 8, 2016).</a>
10.19F+	<a href="#">Amended and Restated 2007 Non-Employee Directors Stock Award Plan (approved July 30, 2020) (incorporated herein by reference to Exhibit 10.3 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2020, as filed with the SEC on August 4, 2020).</a>

10.19G+	<a href="#">Amended and Restated 2007 Non-Employee Directors Stock Award Plan (approved July 30, 2020) (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2024, as filed with the SEC on May 2, 2024).</a>
10.19H+	<a href="#">Form of Non-U.S. Option Grant Notice and Form of Non-U.S. Option Agreement under the Jazz Pharmaceuticals plc Amended and Restated Non-Employee Directors 2007 Stock Award Plan (incorporated herein by reference to Exhibit 10.5 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2016, as filed with the SEC on November 8, 2016).</a>
10.19I+	<a href="#">Form of Non-U.S. Option Grant Notice and Non-U.S. Option Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Award Plan (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2018, as filed with the SEC on November 6, 2018).</a>
10.19J+	<a href="#">Form of Non-U.S. Option Grant Notice and Non-U.S. Option Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Award Plan (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2019, as filed with the SEC on May 7, 2019).</a>
10.19K+	<a href="#">Form of Non-U.S. Option Grant Notice and Non-U.S. Option Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Award Plan (incorporated herein by reference to Exhibit 10.2 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2020, as filed with the SEC on November 2, 2020).</a>
10.19L+	<a href="#">Form of Non-U.S. Restricted Stock Unit Award Grant Notice and Non-U.S. Restricted Stock Unit Award Agreement under the Jazz Pharmaceuticals plc Amended and Restated 2007 Non-Employee Directors Stock Award Plan (incorporated herein by reference to Exhibit 10.3 in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended September 30, 2020, as filed with the SEC on November 2, 2020).</a>
10.20A+	<a href="#">Amended and Restated GW Pharmaceuticals plc 2020 Long-Term Incentive Plan ((incorporated herein by reference to Exhibit 10.20A in the Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2023, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals Inc. with the SEC on February 28, 2024).</a>
10.20B+	<a href="#">Form of Restricted Stock Unit Award Agreement under the GW Pharmaceuticals plc 2020 Long-Term Incentive Plan (incorporated herein by reference to Exhibit 10.10B in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2021, as filed with the SEC on August 3, 2021).</a>
10.20C+	<a href="#">Form of Replacement Stock Option Award Agreement under the GW Pharmaceuticals plc 2020 Long-Term Incentive Plan (incorporated herein by reference to Exhibit 10.10C in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2021, as filed with the SEC on August 3, 2021).</a>
10.20D+	<a href="#">Form of Replacement Restricted Stock Unit Award Agreement under the GW Pharmaceuticals plc 2020 Long-Term Incentive Plan (incorporated herein by reference to Exhibit 10.10D in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2021, as filed with the SEC on August 3, 2021).</a>
10.21A+	<a href="#">Jazz Pharmaceuticals plc 2007 Employee Stock Purchase Plan, as amended and restated (incorporated herein by reference to Exhibit 10.31A in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2012, as filed with the SEC on February 26, 2013).</a>
10.21B+	<a href="#">Amended and Restated 2007 Employee Stock Purchase Plan (approved November 2, 2022). (incorporated herein by reference to Exhibit 10.30B+ in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2022, as filed with the SEC on March 1, 2023).</a>
10.21C+	<a href="#">Amended and Restated 2007 Employee Stock Purchase Plan (approved November 1, 2023) (incorporated herein by reference to Exhibit 10.21C in the Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2023, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals Inc. with the SEC on February 28, 2024).</a>
10.21D+	<a href="#">Jazz Pharmaceuticals plc 2007 Employee Stock Purchase Plan Sub-Plan Governing Purchase Rights to Participants in the Republic of Ireland (incorporated herein by reference to Exhibit 10.14C in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended March 31, 2012, as filed with the SEC on May 8, 2012).</a>

10.22A+	<a href="#">Jazz Pharmaceuticals plc Cash Bonus Plan for U.S. Affiliates (approved October 30, 2019) (incorporated herein by reference to Exhibit 10.34C in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2019, as filed with the SEC on February 25, 2020).</a>
10.22B+	<a href="#">Jazz Pharmaceuticals Cash Bonus Plan (Ireland and Other Specified Affiliates) (Calendar Year 2020) (incorporated herein by reference to Exhibit 10.34D in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2019, as filed with the SEC on February 25, 2020).</a>
10.22C+	<a href="#">Jazz Pharmaceuticals plc Cash Bonus Plan for U.S. Affiliates (approved October 30, 2020) (incorporated herein by reference to Exhibit 10.33C in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2020, as filed with the SEC on February 23, 2021).</a>
10.22D+	<a href="#">Jazz Pharmaceuticals Cash Bonus Plan (Ireland and Other Specified Affiliates) (Calendar Year 2021) (incorporated herein by reference to Exhibit 10.33D in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2020, as filed with the SEC on February 23, 2021).</a>
10.22E+	<a href="#">Jazz Pharmaceuticals plc Global Cash Bonus Plan (approved November, 2021) (incorporated herein by reference to Exhibit 10.34E+ in Jazz Pharmaceuticals plc's Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2021, as filed with the SEC on March 1, 2022).</a>
10.23+	<a href="#">Amended and Restated Executive Change in Control and Severance Benefit Plan, dated as of May 3, 2023 (incorporated herein by reference to Exhibit 10.2+ in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2023, as filed with the SEC on August 9, 2023).</a>
10.24+	<a href="#">Amended and Restated Non-Employee Director Compensation Policy (approved May 4, 2023) (incorporated herein by reference to Exhibit 10.3+ in Jazz Pharmaceuticals plc's Quarterly Report on Form 10-Q (File No. 001-33500) for the period ended June 30, 2023, as filed with the SEC on August 9, 2023).</a>
19.1	<a href="#">Jazz Pharmaceuticals plc Insider Trading Policy</a>
21.1	<a href="#">Subsidiaries of Jazz Pharmaceuticals plc</a>
23.1	<a href="#">Consent of KPMG, Independent Registered Public Accounting Firm</a>
24.1	<a href="#">Power of Attorney (included on the signature page hereto)</a>
31.1	<a href="#">Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.</a>
31.2	<a href="#">Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.</a>
32.1*	<a href="#">Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
97.1	<a href="#">Jazz Pharmaceuticals plc Policy for Recoupment of Incentive Compensation (incorporated herein by reference to Exhibit 97.1 in the Annual Report on Form 10-K (File No. 001-33500) for the period ended December 31, 2023, as filed by Jazz Pharmaceuticals plc on behalf of and as successor to Jazz Pharmaceuticals Inc. with the SEC on February 28, 2024).</a>
101.INS	XBRL Instance Document - The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

+ Indicates management contract or compensatory plan.

† Confidential treatment has been granted for portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

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

- # Portions of this document have been omitted pursuant to Item 601(b)(10) of Regulations S-K because they are both not material and are the type that the Company treats as private and confidential.
- \* The certifications attached as Exhibit 32.1 accompany this Annual Report on Form 10-K 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.

**Item 16. Form 10-K Summary**

None.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) 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: February 26, 2025

**Jazz Pharmaceuticals public limited company**  
(Registrant)

/s/ BRUCE C. COZADD

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

/s/ PHILIP L. JOHNSON

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**Philip L. Johnson**  
**Executive Vice President and Chief Financial Officer**  
**(Principal Financial Officer)**

/s/ PATRICIA CARR

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**Patricia Carr**  
**Senior Vice President, Chief Accounting Officer**  
**(Principal Accounting Officer)**

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Bruce C. Cozadd, Philip L. Johnson, Neena M. Patil and Patricia Carr, and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution for him or her, and in his or her name in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, and any of them, his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, the following persons on behalf of the registrant and in the capacities and on the dates indicated have signed this report below:

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ BRUCE C. COZADD</u> <b>Bruce C. Cozadd</b>	Chairman, Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	February 26, 2025
<u>/s/ PHILIP L. JOHNSON</u> <b>Philip L. Johnson</b>	Executive Vice President and Chief Financial Officer <i>(Principal Financial Officer)</i>	February 26, 2025
<u>/s/ PATRICIA CARR</u> <b>Patricia Carr</b>	Senior Vice President, Chief Accounting Officer <i>(Principal Accounting Officer)</i>	February 26, 2025
<u>/s/ JENNIFER E. COOK</u> <b>Jennifer E. Cook</b>	Director	February 26, 2025
<u>/s/ PATRICK G. ENRIGHT</u> <b>Patrick G. Enright</b>	Director	February 26, 2025
<u>/s/ LAURA HAMILL</u> <b>Laura Hamill</b>	Director	February 26, 2025
<u>/s/ PATRICK KENNEDY</u> <b>Patrick Kennedy</b>	Director	February 26, 2025
<u>/s/ HEATHER ANN MCSHARRY</u> <b>Heather Ann McSharry</b>	Director	February 26, 2025
<u>/s/ SEAMUS C. MULLIGAN</u> <b>Seamus C. Mulligan</b>	Director	February 26, 2025
<u>/s/ KENNETH W. O'KEEFE</u> <b>Kenneth W. O'Keefe</b>	Director	February 26, 2025
<u>/s/ ANNE O'RIORDAN</u> <b>Anne O'Riordan</b>	Director	February 26, 2025
<u>/s/ NORBERT G. RIEDEL, PH.D.</u> <b>Norbert G. Riedel, Ph.D.</b>	Director	February 26, 2025
<u>/s/ MARK D. SMITH, M.D.</u> <b>Mark D. Smith, M.D.</b>	Director	February 26, 2025
<u>/s/ RICK E WINNINGHAM</u> <b>Rick E Winningham</b>	Director	February 26, 2025

## Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors  
Jazz Pharmaceuticals plc:

### *Opinion on the Consolidated Financial Statements*

We have audited the accompanying consolidated balance sheets of Jazz Pharmaceuticals Plc and subsidiaries (the Company) as of December 31, 2024 and 2023, the related consolidated statements of income (loss), comprehensive income (loss), stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2024 and the related notes and financial statement schedules at item 15(a)2 (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission", and our report dated February 26, 2025 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

### *Basis for Opinion*

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these (consolidated) financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

### *Critical Audit Matters*

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

### *Assessment of Epidiolex Medicaid Rebate Accrual*

As discussed in Note 2 to the consolidated financial statements, sales made under governmental and managed-care pricing programs and commercial payor contracts in the U.S. are subject to rebates and requires significant judgment in determining the sales utilization percentage used in calculating the Epidiolex Medicaid rebate accrual. As discussed in Note 10 to the consolidated financial statements, the Company reported rebates and other sales deductions of \$342,717 thousands, which included rebates related to the Epidiolex Medicate rebate program in the U.S..

We identified the assessment of the Epidiolex Medicaid rebate accrual as a critical audit matter. Significant and complex auditor judgment was required to assess the Epidiolex Medicaid rebate accrual, specifically due to the significant judgment required in determining the sales utilization percentage used in the calculation of the Epidiolex Medicaid rebate accrual amount.

The following are the primary procedures we performed to address this critical audit matter.

- We evaluated the design and tested the operating effectiveness of certain internal controls related to the assessment of Epidiolex Medicaid rebate accrual.

- We compared the Company's historical Epidiolex Medicaid rebate accrual amount to the actual claims received to assess the Company's ability to accurately forecast.
- We assessed the assumption for reasonableness by comparing it against a sales utilization percentage range that was independently developed based on historical utilization rates.

/s/ KPMG

We have served as the Company's auditor since 2012.

Dublin, Ireland  
February 26, 2025

**JAZZ PHARMACEUTICALS PLC**  
**CONSOLIDATED BALANCE SHEETS**  
(In thousands, except per share amounts)

	December 31,	
	2024	2023
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 2,412,864	\$ 1,506,310
Investments	580,000	120,000
Accounts receivable, net of allowances of \$32,691 and \$21,136 at December 31, 2024 and 2023, respectively	716,765	705,794
Inventories	480,445	597,039
Prepaid expenses	177,411	185,476
Other current assets	261,543	320,809
Total current assets	4,629,028	3,435,428
Property, plant and equipment, net	173,413	169,646
Operating lease assets	53,582	65,340
Intangible assets, net	4,755,695	5,418,039
Goodwill	1,716,323	1,753,130
Deferred tax assets, net	560,245	477,834
Deferred financing costs	9,489	6,478
Other non-current assets	114,482	67,464
Total assets	<u>\$ 12,012,257</u>	<u>\$ 11,393,359</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 77,869	\$ 102,750
Accrued liabilities	910,947	793,914
Current portion of long-term debt	31,000	604,954
Income taxes payable	18,757	35,074
Total current liabilities	1,038,573	1,536,692
Long-term debt, less current portion	6,077,640	5,107,988
Operating lease liabilities, less current portion	38,938	59,225
Deferred tax liabilities, net	676,736	847,706
Other non-current liabilities	86,614	104,751
Commitments and contingencies (Note 13)		
Shareholders' equity:		
Ordinary shares, nominal value \$0.0001 per share; 300,000 shares authorized; 60,631 and 62,255 shares issued and outstanding at December 31, 2024 and 2023, respectively	6	6
Non-voting euro deferred shares, €0.01 par value per share; 4,000 shares authorized, issued and outstanding at both December 31, 2024 and 2023	55	55
Capital redemption reserve	473	473
Additional paid-in capital	3,913,542	3,699,954
Accumulated other comprehensive loss	(947,667)	(842,147)
Retained earnings	1,127,347	878,656
Total shareholders' equity	<u>4,093,756</u>	<u>3,736,997</u>
Total liabilities and shareholders' equity	<u>\$ 12,012,257</u>	<u>\$ 11,393,359</u>

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

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

	Year Ended December 31,		
	2024	2023	2022
<b>Revenues:</b>			
Product sales, net	\$ 3,821,164	\$ 3,736,943	\$ 3,641,429
Royalties and contract revenues	247,786	97,261	17,945
Total revenues	4,068,950	3,834,204	3,659,374
<b>Operating expenses:</b>			
Cost of product sales (excluding amortization of acquired developed technologies)	445,713	435,577	540,517
Selling, general and administrative	1,385,294	1,343,105	1,416,967
Research and development	884,000	849,658	590,453
Intangible asset amortization	627,313	608,284	599,169
Acquired in-process research and development	10,000	19,000	444,148
Intangible asset impairment charge	—	—	133,648
Total operating expenses	3,352,320	3,255,624	3,724,902
Income (loss) from operations	716,630	578,580	(65,528)
Interest expense, net	(238,097)	(289,438)	(288,242)
Foreign exchange gain (loss)	(8,182)	8,787	(19,014)
Income (loss) before income tax benefit and equity in loss of investees	470,351	297,929	(372,784)
Income tax benefit	(91,429)	(119,912)	(158,645)
Equity in loss of investees	1,660	3,009	9,921
Net income (loss)	<u>\$ 560,120</u>	<u>\$ 414,832</u>	<u>\$ (224,060)</u>
<b>Net income (loss) per ordinary share:</b>			
Basic	<u>\$ 9.06</u>	<u>\$ 6.55</u>	<u>\$ (3.58)</u>
Diluted	<u>\$ 8.65</u>	<u>\$ 6.10</u>	<u>\$ (3.58)</u>
Weighted-average ordinary shares used in per share calculations - basic	<u>61,838</u>	<u>63,291</u>	<u>62,539</u>
Weighted-average ordinary shares used in per share calculations - diluted	<u>66,007</u>	<u>72,066</u>	<u>62,539</u>

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

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

	Year Ended December 31,		
	2024	2023	2022
Net income (loss)	\$ 560,120	\$ 414,832	\$ (224,060)
Other comprehensive income (loss):			
Foreign currency translation adjustments	(106,025)	283,127	(725,277)
Loss on fair value hedging activities reclassified from accumulated other comprehensive 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 \$1,760, \$1,215 and \$—, respectively	5,298	3,658	—
Gain on cash flow hedging activities reclassified from accumulated other comprehensive loss to interest expense, net of income tax expense of \$1,593, \$1,137 and \$—, respectively	(4,793)	(3,423)	—
Other comprehensive income (loss)	(105,520)	283,362	(725,149)
Total comprehensive income (loss)	\$ 454,600	\$ 698,194	\$ (949,209)

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

**JAZZ PHARMACEUTICALS PLC**  
**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY—(Continued)**  
(In thousands)

	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					
<b>Balance at December 31, 2023</b>	62,255	\$ 6	4,000	\$ 55	\$ 473	\$ 3,699,954	\$ (842,147)	\$ 878,656	\$ 3,736,997
Issuance of ordinary shares in conjunction with exercise of share options	22	—	—	—	—	1,629	—	—	1,629
Issuance of ordinary shares under employee stock purchase plan	212	—	—	—	—	19,018	—	—	19,018
Issuance of ordinary shares in conjunction with vesting of restricted stock units	892	—	—	—	—	—	—	—	—
Issuance of ordinary shares in conjunction with vesting of performance-based restricted stock units	80	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(57,753)	—	—	(57,753)
Share-based compensation	—	—	—	—	—	250,694	—	—	250,694
Shares repurchased	(2,830)	—	—	—	—	—	—	(311,429)	(311,429)
Other comprehensive loss	—	—	—	—	—	—	(105,520)	—	(105,520)
Net income	—	—	—	—	—	—	—	560,120	560,120
<b>Balance at December 31, 2024</b>	<u>60,631</u>	<u>\$ 6</u>	<u>4,000</u>	<u>\$ 55</u>	<u>\$ 473</u>	<u>\$ 3,913,542</u>	<u>\$ (947,667)</u>	<u>\$ 1,127,347</u>	<u>\$ 4,093,756</u>

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

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

	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					
<b>Balance at December 31, 2021</b>	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	832	—	—	—	—	82,897	—	—	82,897
Issuance of ordinary shares under employee stock purchase plan	139	—	—	—	—	15,123	—	—	15,123
Issuance of ordinary shares in conjunction with vesting of restricted stock units	610	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(45,443)	—	—	(45,443)
Share-based compensation	—	—	—	—	—	223,279	—	—	223,279
Shares repurchased	—	—	—	—	—	—	—	(54)	(54)
Other comprehensive loss	—	—	—	—	—	—	(725,149)	—	(725,149)
Net loss	—	—	—	—	—	—	—	(224,060)	(224,060)
<b>Balance at December 31, 2022</b>	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	280	—	—	—	—	30,189	—	—	30,189
Issuance of ordinary shares under employee stock purchase plan	156	—	—	—	—	16,270	—	—	16,270
Issuance of ordinary shares in conjunction with vesting of restricted stock units	735	—	—	—	—	—	—	—	—
Shares withheld for payment of employee's withholding tax liability	—	—	—	—	—	(50,952)	—	—	(50,952)
Share-based compensation	—	—	—	—	—	227,323	—	—	227,323
Shares repurchased	(2,130)	—	—	—	1	—	—	(269,762)	(269,761)
Other comprehensive income	—	—	—	—	—	—	283,362	—	283,362
Net income	—	—	—	—	—	—	—	414,832	414,832
<b>Balance at December 31, 2023</b>	62,255	6	4,000	55	473	3,699,954	(842,147)	878,656	3,736,997

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

	Year Ended December 31,		
	2024	2023	2022
<b>Operating activities</b>			
Net income (loss)	\$ 560,120	\$ 414,832	\$ (224,060)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:			
Intangible asset amortization	627,313	608,284	599,169
Share-based compensation	248,045	226,841	221,996
Acquisition accounting inventory fair value step-up adjustment	135,014	151,446	273,392
Depreciation	32,754	30,412	30,302
Provision for losses on accounts receivable and inventory	27,758	11,113	14,537
Non-cash interest expense	21,973	22,378	37,973
Acquired in-process research and development	10,000	19,000	444,148
Deferred tax benefit	(208,327)	(260,217)	(292,251)
Impairment of property, plant and equipment	—	61,014	—
Intangible asset impairment charge	—	—	133,648
Loss on disposal of a business	—	—	37,704
Other non-cash transactions	17,978	11,343	(14,486)
Changes in assets and liabilities:			
Accounts receivable	(21,115)	(51,883)	(90,135)
Inventories	(45,542)	(13,420)	(49,642)
Prepaid expenses and other current assets	10,574	(126,179)	35,788
Operating lease assets	17,111	14,948	14,769
Other non-current assets	(49,820)	(15,884)	(24,038)
Accounts payable	(20,073)	9,603	(11,225)
Accrued liabilities	86,159	(23,245)	165,991
Income taxes payable	(14,742)	25,220	(1,692)
Deferred revenue	—	(463)	(2,093)
Operating lease liabilities, less current portion	(24,741)	(16,965)	(16,422)
Other non-current liabilities	(14,531)	(6,171)	(11,396)
Net cash provided by operating activities	1,395,908	1,092,007	1,271,977
<b>Investing activities</b>			
Acquisition of investments	(1,305,125)	(390,100)	(61,036)
Purchases of property, plant and equipment	(38,070)	(23,962)	(29,046)
Acquired in-process research and development	(10,000)	(19,000)	(444,148)
Proceeds from maturity of investments	845,000	270,000	60,000
Acquisition of intangible assets	—	—	(25,000)
Proceeds from sale of a business	—	—	53,000
Net cash used in investing activities	(508,195)	(163,062)	(446,230)
<b>Financing activities</b>			
Net proceeds from issuance of 2030 Notes	980,767	—	—
Proceeds from employee equity incentive and purchase plans	20,647	46,459	98,020
Payment of debt modification costs	(5,716)	—	—
Repayments of long-term debt	(31,000)	(31,000)	(582,014)
Payment of employee withholding taxes related to share-based awards	(57,753)	(50,952)	(45,443)
Share repurchases	(311,429)	(269,761)	(54)
Repayment of 2024 Notes	(575,000)	—	—
Net cash provided by (used in) financing activities	20,516	(305,254)	(529,491)
Effect of exchange rates on cash and cash equivalents	(1,675)	1,137	(6,222)
Net increase in cash and cash equivalents	906,554	624,828	290,034
Cash and cash equivalents, at beginning of period	1,506,310	881,482	591,448
Cash and cash equivalents, at end of period	\$ 2,412,864	\$ 1,506,310	\$ 881,482

**JAZZ PHARMACEUTICALS PLC**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS—(Continued)**  
**(In thousands)**

	Year Ended December 31,		
	2024	2023	2022
Supplemental disclosure of cash flow information:			
Cash paid for interest	\$ 314,822	\$ 333,112	\$ 270,671
Cash paid for income taxes, net of refunds	114,907	177,880	94,681

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

## JAZZ PHARMACEUTICALS PLC

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. Organization and Description of Business

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, including leading therapies for sleep disorders and epilepsy, and a growing portfolio of cancer treatments. Our patient-focused and science-driven approach powers pioneering research and development advancements across our robust pipeline of innovative therapeutics in oncology and neuroscience.

Our lead marketed products, listed below, are approved in countries around the world to improve patient care.

##### Neuroscience

- **Xywav® (calcium, magnesium, potassium, and sodium oxybates) oral solution**, a product approved by FDA in July 2020, and launched in the U.S. in November 2020 for the treatment of cataplexy or EDS in patients seven years of age and older with narcolepsy, and also approved by FDA in August 2021 for the treatment of IH in adults and launched in the U.S. in November 2021. Xywav contains 92% less sodium than Xyrem®. Xywav is also approved in Canada for the treatment of cataplexy in patients with narcolepsy.
- **Epidiolex® (cannabidiol) oral solution**, a product approved by FDA and launched in the U.S. in 2018 by GW and currently indicated for the treatment of seizures associated with LGS, DS, 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.

##### 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 ALL or LBL 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 granted marketing authorization under the trade name Enrylaze. This therapy is also approved in markets including Great Britain, Canada and Switzerland.
- **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 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.
- **Ziihera® (zanidatamab-hrii)**, a product approved by FDA in November 2024 under FDA's accelerated approval pathway and launched in the U.S. in December 2024 for the treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) BTC, as detected by an FDA-approved test.

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

#### 2. Summary of Significant Accounting Policies

##### Basis of Presentation

The consolidated financial statements have been prepared in accordance with U.S. GAAP, and include the accounts of Jazz Pharmaceuticals plc and our subsidiaries. Intercompany transactions and balances have been eliminated. Our consolidated financial statements include the results of operations of businesses we have acquired from the date of each acquisition for the applicable reporting periods.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)*****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 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 November 2023, the FASB issued ASU 2023-07, “Segment Reporting (Topic 280) - Improvements to Reportable Segment Disclosures”, which requires enhanced disclosures about significant segment expenses. The amendments are effective retrospectively to all prior periods presented in the financial statements, for fiscal years beginning after December 15, 2023. The new guidance has not had a material impact on our financial statement disclosures.

***Significant Risks and Uncertainties***

We expect that our business will continue to meaningfully depend on oxybate revenues; however, there is no guarantee that oxybate revenues will remain at current levels. In this regard, our ability to maintain 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 commercialization of Xywav for the treatment of IH in adults and adoption in that indication; competition from the introduction of two AG versions of high-sodium oxybate and a branded fixed-dose, high-sodium oxybate, 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; 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 and 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 products such as Epidiolex, Rylaze, Zepzelca and Ziihera; 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; our ability to realize the anticipated benefits of acquired or in-licensed products or product candidates, such as Epidiolex and Ziihera, at the expected levels, with the expected costs and within the expected timeframe; 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.

***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.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

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 December 31, 2024 and 2023, we had foreign exchange forward contracts with notional amounts totaling \$461.2 million and \$511.7 million, respectively. As of December 31, 2024 and 2023, the outstanding foreign exchange forward contracts had a net liability fair value of \$7.9 million and a net asset fair value of \$17.4 million, respectively. As of December 31, 2024 and 2023, we had interest rate swap contracts with notional amounts totaling \$500.0 million. As of December 31, 2024 and 2023, these outstanding interest rate swap contracts had a net asset fair value of \$1.0 million and \$0.4 million, respectively. 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 December 31, 2024, allowances on receivables were not material. As of December 31, 2024, five customers accounted for 80% of gross accounts receivable, including ESSDS, which accounted for 39% of gross accounts receivable, ASD, which accounted for 15% of gross accounts receivable and McKesson, which accounted for 13% of gross accounts receivable. As of December 31, 2023, five customers accounted for 79% of gross accounts receivable, including ESSDS, which accounted for 41% of gross accounts receivable, ASD, which accounted for 13% of gross accounts receivable and McKesson, which accounted for 11% of gross accounts receivable.

We depend on single source suppliers for most of our products, product candidates and their 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.

***Business Acquisitions***

Our consolidated financial statements include the results of operations of an acquired business from the date of acquisition. We account for acquired businesses using the acquisition method of accounting. The acquisition method of accounting for acquired businesses requires, among other things, that assets acquired, liabilities assumed and any noncontrolling interests in the acquired business be recognized at their estimated fair values as of the acquisition date, with limited exceptions, and that the fair value of acquired IPR&D, be recorded on the balance sheet. Also, transaction costs are expensed as incurred. Any excess of the acquisition consideration over the assigned values of the net assets acquired is recorded as goodwill. Contingent consideration is included within the acquisition cost and is recognized at its fair value on the acquisition date. A liability resulting from contingent consideration is remeasured to fair value at each reporting date until the contingency is resolved and changes in fair value are recognized in earnings.

***Cash Equivalents and Investments***

We consider all highly liquid investments, readily convertible to cash, that mature within three months or less from date of purchase to be cash equivalents.

Investments consist of time deposits with initial maturities of greater than three months. Collectively, cash equivalents and investments are considered available-for-sale and are recorded at fair value. Unrealized gains and losses, net of tax, are recorded in accumulated other comprehensive loss in shareholders' equity. We use the specific-identification method for calculating realized gains and losses on securities sold. Realized gains and losses and declines in value judged to be other than temporary on investments are included in interest expense, net in the consolidated statements of income (loss).

***Derivative Instruments and Hedging Activities***

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

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

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

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

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

***Inventories***

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

We capitalize inventory costs associated with our products prior to regulatory approval when, based on management's judgment, future commercialization is considered probable and the future economic benefit is expected to be realized; otherwise, such costs are expensed as research and development. The determination to capitalize inventory costs is based on various factors, including status and expectations of the regulatory approval process, any known safety or efficacy concerns, potential labeling restrictions, and any other impediments to obtaining regulatory approval. We had no pre-approval inventory on our consolidated balance sheet as of December 31, 2024 or 2023.

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

***Property, Plant and Equipment***

Property, plant and equipment are stated at cost, less accumulated depreciation. Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Estimated useful lives are as follows:

Buildings	40 years
Manufacturing equipment and machinery	4-20 years
Computer software and equipment	3-7 years
Furniture and fixtures	5 years

Leasehold improvements are amortized over the shorter of the noncancelable term of our leases or their economic useful lives. Maintenance and repairs are expensed as incurred.

***Leases***

We determine if an arrangement is a lease at inception. Leases are classified at lease commencement as either operating leases or finance leases. Operating leases are included in operating lease assets, accrued liabilities, and operating lease liabilities on our consolidated balance sheets. Finance lease assets are included in property, plant and equipment, net, and finance lease liabilities are included in accrued liabilities and other non-current liabilities in our consolidated balance sheets. Lease assets and lease liabilities are recognized based on the present value of the future minimum lease payments over the lease term at commencement date. In determining the net present value of lease payments, we use our incremental borrowing rate based on the information available at the lease commencement date. The lease asset also includes any lease payments made, reduced by lease incentives and increased by initial direct costs incurred. Our lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise that option. Operating lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. Finance lease expense is recognized as depreciation expense of property, plant and equipment and interest expense on finance lease liabilities.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

We have lease agreements with lease and non-lease components, which are generally accounted for separately. For vehicle leases we account for the lease and non-lease components as a single lease component.

We have elected the short-term lease exemption and, therefore, do not recognize a lease asset or corresponding liability for lease arrangements with an original term of 12 months or less. Rent expense under short-term leases is recognized on a straight-line basis over the lease term.

***Goodwill***

Goodwill represents the excess of the acquisition consideration over the fair value of assets acquired and liabilities assumed. We have determined that we operate in a single segment and have a single reporting unit associated with the development and commercialization of pharmaceutical products. In performing the annual impairment test, the fair value of the reporting unit is compared to its corresponding carrying value, including goodwill. If the carrying value exceeds the fair value of the reporting unit an impairment loss will be recognized for the amount by which the reporting unit's carrying amount exceeds its fair value, not to exceed the carrying amount of goodwill. We test goodwill for impairment annually in October and when events or changes in circumstances indicate that the carrying value may not be recoverable.

***Acquired In-Process Research and Development***

The initial costs of rights to IPR&D projects acquired in an asset acquisition are expensed as IPR&D unless the project has an alternative future use. The fair value of IPR&D projects acquired in a business combination are capitalized and accounted for as indefinite-lived intangible assets until the underlying project receives regulatory approval, at which point the intangible asset will be accounted for as a finite-lived intangible asset, or discontinued, at which point the intangible asset will be written off. Development costs incurred after an acquisition are expensed as incurred.

***Intangible Assets***

Intangible assets with finite useful lives consist primarily of purchased developed technology and are amortized on a straight-line basis over their estimated useful lives, which range from seven to sixteen years. The estimated useful lives associated with finite-lived intangible assets are consistent with the estimated lives of the associated products and may be modified when circumstances warrant. Such assets are reviewed for impairment when events or circumstances indicate that the carrying value of an asset may not be recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset and its eventual disposition are less than its carrying amount. The amount of any impairment is measured as the difference between the carrying amount and the fair value of the impaired asset.

***Revenue Recognition***

Our revenue is comprised of product sales, net and royalties and contract revenues. Revenues are recognized when control of the promised goods or services is transferred to our customers, in an amount that reflects the consideration we expect to be entitled to in exchange for those goods or services. Prior to recognizing revenue, we make estimates of the transaction price, including variable consideration that is subject to a constraint. Amounts of variable consideration are included in the transaction price to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

***Product Sales, Net***

Product sales revenue is recognized when control has transferred to the customer, which occurs at a point in time, which is typically on delivery to the customer or, in the case of products that are subject to consignment agreements, when the customer removes product from our consigned inventory location for shipment directly to a patient.

***Reserves for Variable Consideration***

Revenues from sales of products are recorded at the net sales price, which includes estimates of variable consideration for which reserves are established and which relate to returns, specialty distributor fees, wholesaler fees, prompt payment discounts, government rebates, government chargebacks, coupon programs and rebates under managed care plans and commercial payor contracts. Calculating certain of these reserves involves estimates and judgments and we determine their expected value based on sales or invoice data, contractual terms, historical utilization rates, new information regarding changes in these programs' regulations and guidelines that would impact the amount of the actual rebates, our expectations regarding future utilization rates for these programs and channel inventory data. These reserves reflect our best estimates of the amount of consideration to which we are entitled based on the terms of the contract. A large portion of the reserve relates to rebates where there is significant judgment, in particular in the determination of the sales utilization percentage used to calculate the Epidiolex Medicaid rebate accrual. The amount of variable consideration that is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

the cumulative revenue recognized will not occur in a future period. We reassess our reserves for variable consideration at each reporting date. Historically, adjustments to estimates for these reserves have not been material.

Reserves for returns, specialty distributor fees, wholesaler fees, government rebates, coupon programs and rebates under managed care plans and commercial payor contracts are included within current liabilities in our consolidated balance sheets. Reserves for government chargebacks and prompt payment discounts are shown as a reduction in accounts receivable.

***Royalties and Contract Revenues***

We enter into out-licensing agreements under which we license certain rights to our products or product candidates to third parties. If a licensing arrangement includes multiple goods or services, we consider whether the license is distinct. If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue from non-refundable, upfront fees allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. If the license to our intellectual property is determined not to be distinct, it is combined with other goods or services into a combined performance obligation. We consider whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from non-refundable, upfront fees. We evaluate the measure of progress each reporting date and, if necessary, adjust the measure of performance and related revenue recognition.

At the inception of each arrangement that includes development milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or that of the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we re-evaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price.

For arrangements that include sales-based royalties and milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties and sales-based milestones relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty or sales-based milestone has been allocated has been satisfied (or partially satisfied).

***Cost of Product Sales***

Cost of product sales includes manufacturing and distribution costs, the cost of drug substance, royalties due to third parties on product sales, product liability and cargo insurance, FDA user fees, freight, shipping, handling and storage costs and salaries and related costs of employees involved with production. Excluded from cost of product sales shown on the consolidated statements of income (loss) is amortization of acquired developed technology of \$627.3 million, \$608.3 million and \$599.2 million in 2024, 2023 and 2022, respectively.

***Research and Development***

Research and development expenses consist primarily of costs related to clinical studies and outside services, personnel expenses, and other research and development costs, including milestone payments incurred prior to regulatory approval of products. Clinical study and outside services costs relate primarily to services performed by clinical research organizations, clinical studies performed at clinical sites, 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. Research and development costs are expensed as incurred. For product candidates that have not been approved by FDA, inventory used in clinical trials is expensed at the time of production and recorded as research and development expense. For products that have been approved by FDA, inventory used in clinical trials is expensed at the time the inventory is packaged for the trial.

***Advertising Expenses***

We expense the costs of advertising, including promotional expenses, as incurred. Advertising expenses were \$107.4 million, \$92.2 million and \$108.8 million in 2024, 2023 and 2022, respectively.

***Income Taxes***

We use the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial statement carrying amount and the tax basis of assets and

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

liabilities and are measured using enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is provided to reduce deferred tax assets to the amount that is more-likely-than-not to be realized. We recognize the benefits of a tax position if it is more-likely-than-not of being sustained. A recognized tax benefit is then measured as the largest amount of tax benefit that is greater than fifty percent likely of being realized upon settlement. Interest and penalties related to income taxes are included in income tax expense and classified with the related liability on the consolidated balance sheets.

***Foreign Currency***

Our functional and reporting currency is the U.S. dollar. The assets and liabilities of our subsidiaries that have a functional currency other than the U.S. dollar are translated into U.S. dollars at the exchange rate prevailing at the balance sheet date with the results of operations of subsidiaries translated at the weighted average exchange rate for the reporting period. The cumulative foreign currency translation adjustment is recorded as a component of accumulated other comprehensive income (loss) in shareholders' equity.

Transactions in foreign currencies are translated into the functional currency of the relevant subsidiary at the weighted average exchange rate for the reporting period. Any monetary assets and liabilities arising from these transactions are translated into the relevant functional currency at exchange rates prevailing at the balance sheet date or on settlement. Resulting gains and losses are recorded in foreign exchange gain (loss) in our consolidated statements of income (loss).

***Deferred Financing Costs***

Deferred financing costs are reported at cost, less accumulated amortization and are presented in the consolidated balance sheets as a direct deduction from the carrying value of the associated debt, with the exception of deferred financing costs associated with revolving-debt arrangements which are presented as assets. The related amortization expense is included in interest expense, net in our consolidated statements of income (loss).

***Contingencies***

From time to time, we may become involved in claims and other legal matters arising in the ordinary course of business. We record accruals for loss contingencies to the extent that we conclude that it is probable that a liability has been incurred and the amount of the related loss can be reasonably estimated. Legal fees and other expenses related to litigation are expensed as incurred and included in selling, general and administrative expenses.

***Share-Based Compensation***

We account for compensation cost for all share-based awards at fair value on the date of grant. The fair value is recognized as expense over the service period, net of estimated forfeitures, using the straight-line method. The estimation of share-based awards that will ultimately vest requires judgment, and, to the extent actual results or updated estimates differ from current estimates, such amounts will be recorded as a cumulative adjustment in the period estimates are revised. We primarily consider historical experience when estimating expected forfeitures.

***Performance-Based Restricted Stock Unit Awards***

PRSUs awarded to employees vest upon the achievement of certain performance criteria at the end of a specified performance period. For PRSUs granted prior to 2024, the amount of shares awarded will be subject to adjustment based on the application of a TSR modifier. For PRSUs granted in 2024, the relative TSR modifier represents one of the performance metrics. The estimated fair value of these PRSUs is based on a Monte Carlo simulation model. Compensation expense for PRSUs is recognized from the date the Company determines the performance criteria probable of being achieved to the date the award, or relevant portion of the award, is expected to vest. Cumulative adjustments are recorded on a quarterly basis to reflect subsequent changes to the estimated outcome of the performance criteria until the date results are determined.

***Variable Interest Entity***

In 2021, we invested in a protected cell as part of our directors' and officers' liability risk financing strategy. Based on our control and the structure of the protected cell, we concluded that Jazz is the primary beneficiary of the protected cell and is required to consolidate the protected cell. There was no insurance premium payable to the protected cell for the years ended December 31, 2024 and 2023 and it was immaterial for the year ended December 31, 2022. The protected cell's assets and liabilities as of December 31, 2024 and 2023 were immaterial.

***Recent Accounting Pronouncements***

In December 2023, the FASB issued ASU 2023-09, "Income Taxes (Topic 740) - Improvements to Income Tax Disclosures", which requires enhanced income tax disclosures providing greater disaggregation of information in the

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

Company's effective tax rate reconciliation and disaggregates income taxes paid by jurisdiction. The amendments are effective on a prospective basis, with the option to apply it retrospectively, for fiscal years beginning after December 15, 2024. We are currently evaluating the impact of adopting this new accounting guidance.

In November 2024, the FASB issued ASU 2024-03, "Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-04) - Disaggregation of Income Statement Expenses", which requires additional disclosure in the notes to the financial statements of the nature of certain expenses included in the income statement. The amendments are effective on a prospective basis, with the option to apply it retrospectively, for fiscal years beginning after December 15, 2026. We are currently evaluating the impact of adopting this new accounting guidance.

**3. Collaborations and Disposition*****License Agreements***

In February 2024, we entered into a definitive asset purchase agreement with Redx to acquire global rights to a KRAS inhibitor program. Under the terms of the agreement, we made an upfront payment of \$10.0 million to Redx which was recorded as acquired IPR&D expense in our consolidated statements of income (loss) for the year ended December 31, 2024. Redx is eligible to receive development and commercial milestone payments of up to \$870.0 million and, if a product is approved, a tiered, mid-single-digit percentage royalty on net sales of that product.

In November 2023, we entered into an exclusive licensing and collaboration agreement with Autifony to discover and develop drug candidates targeting two different ion channel targets associated with neurological disorders. Under the terms of the agreement, we made an upfront payment of \$18.0 million to Autifony, which was recorded as acquired IPR&D expense in our consolidated statements of income (loss) for the year ended December 31, 2023. Autifony is eligible to receive development and commercial milestone payments of up to \$752.5 million and, if a product is approved, a tiered, mid-single-digit percentage royalty on net sales of that product.

In October 2022, we entered into an exclusive licensing and collaboration agreement with 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 our decision to continue the collaboration after the readout of the top-line clinical data from HERIZON-BTC-01, a second, one-time payment of \$325.0 million. We recorded the \$375.0 million as acquired IPR&D expense in our consolidated statements of income (loss) for the year ended December 31, 2022. In November 2024, we announced FDA accelerated approval of Ziihera for the treatment of adults with previously treated, unresectable or metastatic HER2-positive biliary tract cancer, triggering a regulatory milestone payment of \$25.0 million, which was capitalized as an intangible asset on our consolidated balance sheet. Zymeworks is also eligible to receive regulatory and commercial milestone payments of up to \$1.4 billion, for total potential payments of \$1.8 billion, as well as incremental tiered royalties on future net sales of Ziihera ranging from 10% to 20%.

In May 2022, we entered into a licensing agreement with Sumitomo to acquire exclusive development and commercialization rights in the U.S., Europe and other territories for DSP-0187, now referred to as JZP441. JZP441 is a potent, highly selective oral orexin-2 receptor agonist with potential application for the treatment of narcolepsy, IH and other sleep disorders. Under the terms of the agreement, we made an upfront payment of \$50.0 million to Sumitomo, which was recorded as acquired IPR&D expense in our consolidated statements of income (loss) for the year ended December 31, 2022. Sumitomo is eligible to receive development, regulatory and commercial milestone payments of up to \$1.09 billion and, if JZP441 is approved, a tiered, low double-digit royalty on Jazz's net sales of JZP441.

In April 2022, we entered into a licensing and collaboration agreement with 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 (IFN $\alpha$ ) INDUKINE™ molecule. We made an upfront payment of \$15.0 million to Werewolf in 2022, which was recorded as acquired IPR&D expense in our consolidated statements of income (loss) for the year ended December 31, 2022, and a milestone payment of \$5.0 million in September 2023 which was recorded within research and development expense in our consolidated statements of income (loss) for the year ended December 31, 2023. Werewolf is eligible to receive further development, regulatory and commercial milestone payments of up to \$1.26 billion and, if JZP898 is approved, a tiered, mid-single-digit percentage royalty on net sales of JZP898.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**
**Sunosi Disposition**

In March 2022, we entered into a definitive agreement to divest Sunosi to Axsome. In May 2022, we completed the U.S. divestiture and in November 2022, the ex-U.S. divestiture was completed. Under the terms of the sale agreement, Axsome received the rights to Sunosi in all of the existing territories available to us. We received an upfront payment of \$53.0 million, and have the right to receive a high single-digit royalty on Axsome's U.S. net sales of Sunosi in current indications and a mid-single-digit royalty on Axsome's U.S. net sales of Sunosi in future indications.

Upon closing, we recognized a loss on disposal of \$40.8 million within selling, general and administrative expenses in our consolidated statements of income (loss) in the year ended December 31, 2022. We are accounting for the contingent consideration in the form of the future royalty as it is earned.

We determined that the disposal of Sunosi did not qualify for reporting as a discontinued operation since it did not represent a strategic shift that has or will have a major effect on our operations and financial results.

**4. Cash and Available-for-Sale Securities**

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

December 31, 2024						
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Investments
Cash	\$ 948,894	\$ —	\$ —	\$ 948,894	\$ 948,894	\$ —
Time deposits	790,000	—	—	790,000	210,000	580,000
Money market funds	1,253,970	—	—	1,253,970	1,253,970	—
Totals	<u>\$ 2,992,864</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2,992,864</u>	<u>\$ 2,412,864</u>	<u>\$ 580,000</u>

December 31, 2023						
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value	Cash and Cash Equivalents	Investments
Cash	\$ 437,724	\$ —	\$ —	\$ 437,724	\$ 437,724	\$ —
Time deposits	420,000	—	—	420,000	300,000	120,000
Money market funds	768,586	—	—	768,586	768,586	—
Totals	<u>\$ 1,626,310</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,626,310</u>	<u>\$ 1,506,310</u>	<u>\$ 120,000</u>

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 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 \$106.3 million, \$65.1 million and \$11.5 million in 2024, 2023 and 2022, respectively.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**
**5. Fair Value Measurement**

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

	December 31, 2024			December 31, 2023		
	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
<b>Assets:</b>						
Available-for-sale securities:						
Money market funds	\$ 1,253,970	\$ —	\$ 1,253,970	\$ 768,586	\$ —	\$ 768,586
Time deposits	—	790,000	790,000	—	420,000	420,000
Foreign exchange forward contracts	—	2,250	2,250	—	18,035	18,035
Interest rate contracts	—	991	991	—	3,784	3,784
<b>Totals</b>	<b>\$ 1,253,970</b>	<b>\$ 793,241</b>	<b>\$ 2,047,211</b>	<b>\$ 768,586</b>	<b>\$ 441,819</b>	<b>\$ 1,210,405</b>
<b>Liabilities:</b>						
Foreign exchange forward contracts	\$ —	\$ 10,198	\$ 10,198	\$ —	\$ 681	\$ 681
Interest rate contracts	—	—	—	—	3,410	3,410
<b>Totals</b>	<b>\$ —</b>	<b>\$ 10,198</b>	<b>\$ 10,198</b>	<b>\$ —</b>	<b>\$ 4,091</b>	<b>\$ 4,091</b>

As of December 31, 2024 and 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 2024 or in 2023.

As of December 31, 2024 and 2023, the carrying amount of investments measured using the measurement alternative for equity investments without a readily determinable fair value was \$4.3 million and \$4.7 million, respectively. The carrying amount, which is recorded within other non-current assets, is based on the latest observable transaction price.

As of December 31, 2024, the estimated fair values of the 2026 Notes, the 2030 Notes, the Secured Notes and the Tranche B-2 Dollar Term Loans were \$1.0 billion, \$1.1 billion, \$1.4 billion and \$2.7 billion, respectively. The fair values of each of these debt facilities was estimated using quoted market prices obtained from brokers (Level 2).

**6. 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 December 31, 2024 and 2023,

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

the notional amount of foreign exchange contracts where hedge accounting was not applied was \$461.2 million and \$511.7 million, respectively.

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

<b>Foreign Exchange Forward Contracts:</b>	<b>Year Ended December 31,</b>		
	<b>2024</b>	<b>2023</b>	<b>2022</b>
Gain (loss) recognized in foreign exchange gain (loss)	\$ (14,444)	\$ 13,543	\$ (58,755)

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 December 31, 2024, 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 loss and earnings from derivative instruments that qualified as cash flow hedges was as follows (in thousands):

<b>Interest Rate Contracts:</b>	<b>Year Ended December 31,</b>	
	<b>2024</b>	<b>2023</b>
Gain recognized in accumulated other comprehensive loss, net of tax	\$ 5,298	\$ 3,658
Gain reclassified from accumulated other comprehensive loss to interest expense, net of tax	(4,793)	(3,423)

Assuming no change in the Term SOFR based interest rates from market rates as of December 31, 2024, \$0.7 million of gains, net of tax, recognized in accumulated other comprehensive 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 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 consolidated statements of income (loss).

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

<b>Cross-Currency Interest Rate Contract:</b>	<b>Year Ended December 31,</b>	
	<b>2022</b>	
Loss reclassified from accumulated other comprehensive 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 are included within net cash provided by operating activities in the 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.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

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

	December 31, 2024			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
<b>Derivatives designated as hedging instruments:</b>				
Interest rate contracts	Other current assets	\$ 959	Accrued liabilities	\$ —
	Other non-current assets	32	Other non-current liabilities	—
<b>Derivatives not designated as hedging instruments:</b>				
Foreign exchange forward contracts	Other current assets	2,250	Accrued liabilities	10,198
Total fair value of derivative instruments		<u>\$ 3,241</u>		<u>\$ 10,198</u>

	December 31, 2023			
	Asset Derivatives		Liability Derivatives	
	Balance Sheet Location	Fair Value	Balance Sheet Location	Fair Value
<b>Derivatives designated as hedging instruments:</b>				
Interest rate contracts	Other current assets	\$ 3,784	Accrued liabilities	\$ —
	Other non-current assets	—	Other non-current liabilities	3,410
<b>Derivatives not designated as hedging instruments:</b>				
Foreign exchange forward contracts	Other current assets	18,035	Accrued liabilities	681
Total fair value of derivative instruments		<u>\$ 21,819</u>		<u>\$ 4,091</u>

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. The following table summarizes the potential effect on our consolidated balance sheets of offsetting our interest rate and foreign exchange forward contracts subject to such provisions (in thousands):

Description	December 31, 2024					
	Gross Amounts of Recognized Assets/ Liabilities	Gross Amounts Offset in the Consolidated Balance Sheet	Net Amounts of Assets/ Liabilities Presented in the Consolidated Balance Sheet	Gross Amounts Not Offset in the Consolidated Balance Sheet		
				Derivative Financial Instruments	Cash Collateral Received (Pledged)	Net Amount
Derivative assets	\$ 3,241	\$ —	\$ 3,241	\$ (2,910)	\$ —	\$ 331
Derivative liabilities	(10,198)	—	(10,198)	2,910	—	(7,288)

Description	December 31, 2023					
	Gross Amounts of Recognized Assets/ Liabilities	Gross Amounts Offset in the Consolidated Balance Sheet	Net Amounts of Assets/ Liabilities Presented in the Consolidated Balance Sheet	Gross Amounts Not Offset in the Consolidated Balance Sheet		
				Derivative Financial Instruments	Cash Collateral Received (Pledged)	Net Amount
Derivative assets	\$ 21,819	\$ —	\$ 21,819	\$ (4,091)	\$ —	\$ 17,728
Derivative liabilities	(4,091)	—	(4,091)	4,091	—	—

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

**7. Inventories**

Inventories consisted of the following (in thousands):

	December 31,	
	2024	2023
Raw materials	\$ 20,161	\$ 25,595
Work in process	311,752	431,732
Finished goods	148,532	139,712
Total inventories	<u>\$ 480,445</u>	<u>\$ 597,039</u>

As of December 31, 2024 and 2023, inventories included \$191.2 million and \$328.0 million, respectively, related to the purchase accounting inventory fair value step-up on inventory acquired as part of our GW Acquisition.

**8. Property, Plant and Equipment**

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

	December 31,	
	2024	2023
Manufacturing equipment and machinery	\$ 87,451	\$ 82,897
Land and buildings	71,902	70,912
Leasehold improvements	70,201	67,722
Computer software	42,635	38,134
Construction-in-progress	34,493	18,661
Computer equipment	20,137	15,398
Furniture and fixtures	8,551	9,273
Subtotal	<u>335,370</u>	<u>302,997</u>
Less accumulated depreciation and amortization	<u>(161,957)</u>	<u>(133,351)</u>
Property, plant and equipment, net	<u>\$ 173,413</u>	<u>\$ 169,646</u>

Depreciation and amortization expense on property, plant and equipment amounted to \$32.8 million, \$30.4 million and \$30.3 million for the years ended December 31, 2024, 2023 and 2022, respectively.

**9. Goodwill and Intangible Assets**

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

Balance at December 31, 2023	\$ 1,753,130
Foreign exchange	(36,807)
Balance at December 31, 2024	<u>\$ 1,716,323</u>

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

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

	December 31, 2024			December 31, 2023			
	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	7.8	\$ 7,699,423	\$ (2,943,728)	\$ 4,755,695	\$ 7,785,495	\$ (2,367,456)	\$ 5,418,039
Manufacturing contracts	—	11,121	(11,121)	—	11,828	(11,828)	—
Trademarks	—	2,868	(2,868)	—	2,886	(2,886)	—
Total finite-lived intangible assets		<u>\$ 7,713,412</u>	<u>\$ (2,957,717)</u>	<u>\$ 4,755,695</u>	<u>\$ 7,800,209</u>	<u>\$ (2,382,170)</u>	<u>\$ 5,418,039</u>

The decrease in the gross carrying amount of intangible assets as of December 31, 2024 compared to December 31, 2023 primarily relates to the negative impact of foreign currency translation adjustments due to the weakening of sterling and euro against the U.S. dollar.

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

Based on finite-lived intangible assets recorded as of December 31, 2024, and assuming the underlying assets will not be impaired and that we will not change the expected lives of any other assets, future amortization expenses were estimated as follows (in thousands):

<u>Year Ending December 31,</u>	<u>Estimated Amortization Expense</u>
2025	\$ 618,043
2026	618,043
2027	618,043
2028	616,711
2029	614,977
Thereafter	1,669,878
Total	<u>\$ 4,755,695</u>

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**
**10. Accrued Liabilities**

Accrued liabilities consisted of the following (in thousands):

	December 31,	
	2024	2023
Rebates and other sales deductions	\$ 342,717	\$ 325,711
Employee compensation and benefits	153,133	121,209
Clinical trial accruals	49,962	44,757
Accrued interest	41,626	36,443
Accrued royalties	36,802	30,706
Accrued milestones	27,500	—
Selling and marketing accruals	26,981	14,743
Sales return reserve	26,428	20,435
Consulting and professional services	26,221	19,538
Inventory-related accruals	25,509	13,977
Accrued development expenses	23,099	15,431
Accrued collaboration expenses	18,005	10,158
Current portion of lease liabilities	14,779	19,447
Derivative instrument liabilities	10,198	681
Accrued construction-in-progress	10,061	5,141
Accrued facilities expenses	6,107	55,455
Other	71,819	60,082
Total accrued liabilities	<u>\$ 910,947</u>	<u>\$ 793,914</u>

**11. Debt**

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

	December 31,	
	2024	2023
2024 Notes	\$ —	\$ 575,000
Unamortized - debt issuance costs	—	(1,046)
2024 Notes, net	—	573,954
2026 Notes	1,000,000	1,000,000
Unamortized - debt issuance costs	(3,747)	(6,400)
2026 Notes, net	996,253	993,600
2030 Notes	1,000,000	—
Unamortized - debt issuance costs	(19,135)	—
2030 Notes, net	980,865	—
Secured Notes	1,483,841	1,480,214
Term Loan	2,647,681	2,665,174
Total debt	6,108,640	5,712,942
Less current portion <sup>(1)</sup>	31,000	604,954
Total long-term debt	<u>\$ 6,077,640</u>	<u>\$ 5,107,988</u>

(1) Balance as of December 31, 2023 includes the 2024 Notes as they matured in August 2024.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)*****Credit Agreement***

On May 5, 2021, Jazz Pharmaceuticals plc, Jazz Lux, and certain of our other subsidiaries, as borrowers, or, collectively with Jazz Pharmaceuticals plc and Jazz Lux, the “Borrowers”, entered into the Credit Agreement. The Credit Agreement initially provided for (i) the Dollar Term Loan, which was drawn by Jazz Lux on the closing date thereof in U.S. dollars (ii) the Euro Term Loan, which was drawn by Jazz Lux on the closing date thereof in Euros and (iii) the Initial Revolving Credit Facility.

We used the proceeds from the Dollar Term Loan (i) to repay in full \$575.9 million under the 2015 Credit Agreement, (ii) to fund, in part, the cash consideration payable in connection with the GW Acquisition and (iii) to pay related fees and expenses. Upon the repayment in full of loans under the 2015 Credit Agreement, it was terminated and all guarantees and liens thereunder were released.

In 2021, we made voluntary prepayments on the Euro Term Loan totaling €416.7 million, or \$502.0 million, and in March 2022 we repaid the remaining outstanding principal of €208.3 million, or \$251.0 million. The Euro Term Loan bore interest at the EURIBOR plus an applicable margin. During the term of the Euro Term Loan, the interest rate and effective interest rate were 4.43% and 4.93%, respectively.

In January 2024, Jazz Lux entered into the Repricing Amendment No. 1 to the Credit Agreement. Upon entry into the Repricing Amendment No. 1, certain existing lenders converted a portion of the outstanding Dollar Term Loan into the Tranche B-1 Dollar Term Loans, and Jazz Lux borrowed \$201.9 million aggregate principal amount of additional Tranche B-1 Dollar Term Loans, the proceeds of which were used to repay the portion of the outstanding Dollar Term Loan that was not converted.

In July 2024, Jazz Lux entered into the Repricing Amendment No. 2 to the Credit Agreement, as amended by the Repricing Amendment No. 1. Upon entry into Repricing Amendment No. 2, certain existing lenders converted a portion of the outstanding Tranche B-1 Dollar Term Loans into the Tranche B-2 Dollar Term Loans, and Jazz Lux borrowed \$289.6 million aggregate principal amount of additional Tranche B-2 Dollar Term Loans, the proceeds of which were used to repay the portion of the outstanding Tranche B-1 Dollar Term Loans that were not converted.

The Tranche B-2 Dollar Term Loans are a separate class of term loans under the Credit Agreement, as amended by Repricing Amendment No. 1 and Repricing Amendment No. 2, with the same material terms (including with respect to maturity, prepayment, security, covenants and events of default) as the previously outstanding Tranche B-1 Dollar Term Loans and the initial Dollar Term Loan incurred on May 5, 2021, with the interest rate amended as described below and the credit spread adjustment removed. The principal amount of Tranche B-1 Dollar Term Loans outstanding immediately prior to the Repricing Amendment No. 2 and the outstanding principal amount of Tranche B-2 Dollar Term Loans immediately following the Repricing Amendment No.2, each totaled \$2.7 billion.

The Tranche B-2 Dollar Term Loans bear interest at a rate equal to either (a) Term SOFR or (b) the prime lending rate, in each case, plus an applicable margin. The applicable margin for the Tranche B-2 Dollar Term Loans is 2.25% (in the case of Term SOFR borrowings) and 1.25% (in the case of borrowings at the prime lending rate), a decrease, in each case, of 75 basis points from the applicable margin on the Tranche B-1 Dollar Term Loans. The Tranche B-2 Dollar Term Loans are subject to a Term SOFR floor of 0.50%. As of December 31, 2024, the interest rate and effective interest rate on the Tranche B-2 Dollar Term Loans were 6.61% and 8.27%, respectively.

In November 2024, we entered into Amendment No. 3 to the Credit Agreement, as amended by the Repricing Amendment No. 1 and Repricing Amendment No. 2, to increase the Initial Revolving Credit Facility from \$500.0 million to \$885.0 million and extend the maturity date, or Amended Revolving Credit Facility, from May 5, 2026 to November 26, 2029 (such date, the “Amended Revolving Facility Maturity Date”), provided that:

- if, as of any date from March 16, 2026 to the maturity date of the 2026 Notes (any such date, the “2026 Notes Springing Maturity Date”), (x) any 2026 Notes (or any permitted refinancing indebtedness in respect thereof with a maturity date that is not later than the date that is 91 days after the Amended Revolving Facility Maturity Date) (any such indebtedness, the “2026 Maturity Indebtedness”) remain outstanding and (y) the aggregate amount of unrestricted cash of Jazz Pharmaceuticals plc and its subsidiaries is less than an amount equal to 125% of the aggregate principal amount of 2026 Maturity Indebtedness outstanding, then the maturity date for the Amended Revolving Credit Facility will be shortened to the 2026 Notes Springing Maturity Date;
- if, as of February 4, 2028, (x) more than \$500,000,000 of the Tranche B-2 Dollar Term Loans under the Amended Credit Agreement (and any extended term loans, refinancing term loans, refinancing notes and permitted refinancing indebtedness, in each case, in respect thereof) (any such indebtedness, the “Term Loan Indebtedness”) remains outstanding and (y) the maturity date of such Term Loan Indebtedness is not later than the date that is 91 days after

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

the Amended Revolving Facility Maturity Date, then the maturity date for the Amended Revolving Credit Facility will be shortened to February 4, 2028; and

- if, as of October 16, 2028 (such date, the “Senior Notes Springing Maturity Date”), (x) more than \$500,000,000 of the Secured Notes (and permitted refinancing indebtedness in respect thereof) (any such indebtedness, the “Senior Note Indebtedness”) remains outstanding and (y) the maturity date with respect to such Senior Note Indebtedness is not later than the date that is 91 days after the Amended Revolving Facility Maturity Date, then the maturity date for the Amended Revolving Credit Facility will be shortened to October 16, 2028.

Initially, the applicable margin for the loans under the Amended Revolving Credit Facility will be 2.00% (in the case of Term SOFR borrowings) and 1.00% (in the case of borrowings at the prime lending rate). Thereafter, the applicable margin for the Amended Revolving Credit Facility ranges from 1.75% to 2.75% (in the case of Term SOFR borrowings) and 0.75% to 1.75% (in the case of borrowings at the prime lending rate), depending on our first lien secured net leverage ratio level, and any loans under the Amended Revolving Credit Facility are subject to a Term SOFR floor of 0.00%. The Amended Revolving Credit Facility has a commitment fee payable on the undrawn amount ranging from 0.25% to 0.45% per annum based upon our first lien secured net leverage ratio. As of December 31, 2024, we had an undrawn Amended Revolving Credit Facility totaling \$885.0 million.

We may make voluntary prepayments at any time without payment of a premium or penalty, subject to certain exceptions, and are required to make certain mandatory prepayments of outstanding indebtedness under the Amended Credit Agreement in certain circumstances. Principal repayments of the Dollar Term Loan, which were due quarterly, began in September 2021 and were equal to 1.0% per annum of the original principal amount of \$3.1 billion with any remaining balance payable on the maturity date. In September 2022, we made a voluntary repayment on the Dollar Term Loan totaling \$300.0 million. In January 2025, we made a voluntary repayment on the Tranche B-2 Dollar Term Loans totaling \$750.0 million. The Tranche B-2 Dollar Term Loans will amortize in quarterly installments equal to 0.286294791% of the initial aggregate principal amount thereof, with the remaining balance payable on May 5, 2028.

Our obligations under the Amended Credit Agreement and any hedging or cash management obligations entered into with any lender thereunder are guaranteed by Jazz Pharmaceuticals plc, the other borrowers, and each of the Jazz Pharmaceuticals plc’s other existing or subsequently acquired or organized direct and indirect subsidiaries (subject to certain exceptions), or the Guarantors. We refer to the Borrowers and the Guarantors collectively as the “Loan Parties.”

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

The Amended Credit Agreement contains customary representations and warranties and customary affirmative and negative covenants applicable to Jazz Pharmaceuticals plc and its restricted subsidiaries, including, among other things, restrictions on indebtedness, liens, investments, mergers, dispositions, prepayment of junior indebtedness and dividends and other distributions. The Amended Credit Agreement contains financial covenants that require Jazz Pharmaceuticals plc and its restricted subsidiaries to (a) not exceed a maximum first lien secured net leverage ratio and (b) not fall below a minimum interest coverage ratio, provided that such covenants apply only to the Amended Revolving Credit Facility and are applicable only if amounts are drawn (or non-cash collateralized letters of credit in excess of \$50.0 million are outstanding) under the Amended Revolving Credit Facility. The Amended Credit Agreement also contains customary events of default relating to, among other things, failure to make payments, breach of covenants and breach of representations.

**2029 Senior Secured Notes**

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

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

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

Some or all of the Secured Notes, may be redeemed at any time and from time to time at a specified redemption prices, plus accrued and unpaid interest, if any, to, but excluding, to the redemption date. In addition, Jazz Securities may redeem all

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

but not part of the Secured Notes at its option at any time in connection with certain tax-related events at a price equal to 100% of the principal amount of the Secured Notes to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date.

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

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

As of December 31, 2024, the interest rate and effective interest rate on the Secured Notes were 4.375% and 4.64%, respectively.

**2030 Notes**

In September 2024, Jazz Investments, a wholly owned subsidiary of Jazz Pharmaceuticals plc, completed a private placement of \$1.0 billion principal amount of the 2030 Notes.

Interest on the 2030 Notes is payable semi-annually in cash in arrears on March 15 and September 15 of each year, beginning on March 15, 2025, at a rate of 3.125% per year. In certain circumstances, we may be required to pay additional amounts as a result of any applicable tax withholding or deductions required in respect of payments on the 2030 Notes. The 2030 Notes mature on September 15, 2030, unless earlier exchanged, redeemed or repurchased.

The holders of the 2030 Notes have the ability to require us to repurchase all or a portion of their 2030 Notes for cash at a fundamental change repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus accrued and unpaid interest to, but excluding, the fundamental change repurchase date in the event we undergo a fundamental change (as defined in the indenture related to the 2030 Notes), such as specified change of control transactions, our liquidation or dissolution or the delisting of our ordinary shares from any of The New York Stock Exchange, The Nasdaq Global Market, The Nasdaq Global Select Market or The Nasdaq Capital Market (or any of their respective successors).

Additionally, the terms and covenants in the indenture related to the 2030 Notes include certain events of default after which the 2030 Notes may be due and payable immediately.

Prior to September 15, 2030, we may redeem the 2030 Notes, in whole but not in part, in connection with certain tax-related events. We also may redeem the 2030 Notes on or after September 20, 2027 and prior to June 15, 2030, in whole or in part (subject to the partial redemption limitation described in the indenture related to the 2030 Notes), if the last reported sale price per ordinary share has been at least 130% of the exchange price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which we provide notice of redemption at a redemption price equal to 100% of the principal amount of the notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date.

The 2030 Notes are exchangeable at an initial exchange rate of 6.5339 ordinary shares per \$1,000 principal amount of 2030 Notes, which is equivalent to an initial exchange price of approximately \$153.05 per ordinary share. Upon exchange of the 2030 Notes, we will pay cash up to the aggregate principal amount of the 2030 Notes to be exchanged and pay or deliver, as the case may be, cash, ordinary shares or a combination of cash and ordinary shares, at our election, in respect of the remainder, if any, of our exchange obligation in excess of the aggregate principal amount of the 2030 Notes being exchanged. The exchange rate is subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain make-whole fundamental changes (as defined in the indenture related to the 2030 Notes) that occur prior to the maturity date or upon our issuance of a notice of redemption, we will, in certain circumstances, increase the exchange rate for a holder who elects to exchange its 2030 Notes in connection with that make-whole fundamental change or exchange its 2030 Notes called (or deemed called) for redemption during the related redemption period. Prior to June 15, 2030, the 2030 Notes will be exchangeable only upon satisfaction of certain conditions and during certain periods, and thereafter, at any time until the close of business on the second scheduled trading day immediately preceding the maturity date.

As of December 31, 2024, the "if converted value" did not exceed the principal amount of the 2030 Notes.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

The total liability is reflected net of issuance costs of \$19.2 million which will be amortized over the term of the 2030 Notes. We have determined the expected life of the 2030 Notes to be equal to the original six-year term. The effective interest rate of the 2030 Notes is 3.47%.

**2026 Notes**

In 2020 we completed a private placement of \$1.0 billion principal amount of the 2026 Notes. We used a portion of the net proceeds from this offering to repurchase for cash \$332.9 million aggregate principal amount of the 1.875% exchangeable senior notes due 2021, through privately-negotiated transactions concurrently with the offering of the 2026 Notes. Interest on the 2026 Notes is payable semi-annually in cash in arrears on June 15 and December 15 of each year, beginning on December 15, 2020, at a rate of 2.00% per year. In certain circumstances, we may be required to pay additional amounts as a result of any applicable tax withholding or deductions required in respect of payments on the 2026 Notes. The 2026 Notes mature on June 15, 2026, unless earlier exchanged, repurchased or redeemed.

The holders of the 2026 Notes have the ability to require us to repurchase all or a portion of their 2026 Notes for cash in the event we undergo certain fundamental changes, such as specified change of control transactions, our liquidation or dissolution or the delisting of our ordinary shares from any of The New York Stock Exchange, The Nasdaq Global Market, The Nasdaq Global Select Market or The Nasdaq Capital Market (or any of their respective successors). Additionally, the terms and covenants in the indenture related to the 2026 Notes include certain events of default after which the 2026 Notes may be due and payable immediately. Prior to June 15, 2026, we may redeem the 2026 Notes, in whole but not in part, subject to compliance with certain conditions, if we have, or on the next interest payment date would, become obligated to pay to the holder of any 2026 Notes additional amounts as a result of certain tax-related events. We also may redeem the 2026 Notes prior to March 15, 2026, in whole or in part, if the last reported sale price per ordinary share has been at least 130% of the exchange price then in effect for at least 20 trading days (whether or not consecutive) during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which we provide the notice of redemption.

The 2026 Notes are exchangeable at an initial exchange rate of 6.4182 ordinary shares per \$1,000 principal amount of 2026 Notes, which is equivalent to an initial exchange price of approximately \$155.81 per ordinary share. On July 22, 2024, we irrevocably elected to fix the settlement method for exchanges of the 2026 Notes to a combination of cash and ordinary shares of Jazz Pharmaceuticals plc with a specified cash amount per \$1,000 principal amount of 2026 Notes exchanged equal to or in excess of \$1,000. As a result, for any 2026 Notes exchanged subsequent to such notice, an exchanging holder will receive (i) up to \$1,000 in cash per \$1,000 principal amount of 2026 Notes exchanged and (ii) cash, ordinary shares, or any combination thereof, at our election, in respect of the remainder, if any, of its exchange obligation in excess of \$1,000 per \$1,000 principal amount of 2026 Notes exchanged. The exchange rate will be subject to adjustment in some events but will not be adjusted for any accrued and unpaid interest. In addition, following certain make-whole fundamental changes occurring prior to the maturity date of the 2026 Notes or upon our issuance of a notice of redemption, we will in certain circumstances increase the exchange rate for holders of the 2026 Notes who elect to exchange their 2026 Notes in connection with that make-whole fundamental change or during the related redemption period. Prior to March 15, 2026, the 2026 Notes will be exchangeable only upon satisfaction of certain conditions and during certain periods, and thereafter, at any time until the close of business on the second scheduled trading day immediately preceding the maturity date.

As of December 31, 2024 and 2023, the “if converted value” did not exceed the principal amount of the 2026 Notes.

The total liability is reflected net of issuance costs of \$15.3 million which will be amortized over the term of the 2026 Notes. We have determined the expected life of the 2026 Notes to be equal to the original six-year term. The effective interest rate of the 2026 Notes is 2.26%.

**2024 Notes**

In 2017, we completed a private placement of \$575.0 million principal amount of 2024 Notes. We used the net proceeds from this offering to repay \$500.0 million in outstanding loans under the Initial Revolving Credit Facility and to pay related fees and expenses. We used the remainder of the net proceeds for general corporate purposes. Interest on the 2024 Notes was payable semi-annually in cash in arrears on February 15 and August 15 of each year, beginning on February 15, 2018, at a rate of 1.50% per year. The 2024 Notes were exchangeable at an initial exchange rate of 4.5659 ordinary shares per \$1,000 principal amount of 2024 Notes, which was equivalent to an initial exchange price of approximately \$219.02 per ordinary share.

On August 15, 2024, the maturity date for the 2024 Notes, we repaid the \$575.0 million aggregate principal amount, plus accrued and unpaid interest thereon.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

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.

For the year ended December 31, 2024, we recognized \$40.0 million, in interest expense, net, of which \$35.3 million related to the contractual coupon rate and \$4.7 million related the amortization of the debt issuance costs on the 2024 Notes and the Exchangeable Senior Notes. For the years ended December 31, 2023 and 2022, we recognized \$32.8 million in interest expense, net, of which \$28.6 million related to the contractual coupon rate and \$4.2 million related to the amortization of the debt issuance costs.

Scheduled maturities with respect to our long-term debt are as follows (in thousands):

<b>Year Ending December 31,</b>	<b>Scheduled Long-Term Debt Maturities</b>
2025	\$ 31,000
2026	1,031,000
2027	31,000
2028	2,598,500
2029	1,500,000
Thereafter	1,000,000
<b>Total</b>	<b>\$ 6,191,500</b>

**12. Leases**

We have noncancelable leases for our buildings and growing facilities and we are obligated to make payments under noncancelable operating leases for automobiles used by our sales force.

The components of the lease expense for the years ended December 31, 2024, 2023 and 2022 were as follows (in thousands):

<b>Lease Cost</b>	<b>Year Ended December 31,</b>		
	<b>2024</b>	<b>2023</b>	<b>2022</b>
Operating lease cost	\$ 22,209	\$ 19,394	\$ 19,670
Short-term lease cost	7,441	6,290	5,088
Variable lease cost	789	81	5
Sublease income	(472)	(22)	—
<b>Finance Lease Cost</b>			
Interest on lease liabilities	442	377	429
Amortization of leased asset	413	481	472
<b>Net lease cost</b>	<b>\$ 30,822</b>	<b>\$ 26,601</b>	<b>\$ 25,664</b>

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

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

Leases	Classification	December 31,	
		2024	2023
<b>Assets</b>			
Operating lease assets	Operating lease assets	\$ 53,582	\$ 65,340
Finance lease assets	Property, plant and equipment	3,917	4,450
Total lease assets		<u>\$ 57,499</u>	<u>\$ 69,790</u>
<b>Liabilities</b>			
Current			
Operating lease liabilities	Accrued liabilities	\$ 14,331	\$ 19,019
Finance lease liabilities	Accrued liabilities	448	428
Non-current			
Operating lease liabilities	Operating lease liabilities, less current portion	38,938	59,225
Finance lease liabilities	Other non-current liabilities	4,561	5,039
Total lease liabilities		<u>\$ 58,278</u>	<u>\$ 83,711</u>

Lease Term and Discount Rate	December 31,	
	2024	2023
Weighted-average remaining lease term (years)		
Operating leases	4.3	5.1
Finance leases	10.4	11.2
Weighted-average discount rate		
Operating leases	6.6 %	5.4 %
Finance leases	7.6 %	7.5 %

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

	Year Ended December 31,		
	2024	2023	2022
Cash paid for amounts included in the measurement of lease liabilities:			
Operating cash outflows from operating leases	\$ 33,632	\$ 20,646	\$ 20,544
Operating cash outflows from finance leases	830	835	806
Financing cash outflows from finance leases	442	377	429
Non-cash operating activities:			
Operating lease assets obtained in exchange for new operating lease liabilities	\$ 25,819	\$ 9,953	\$ 4,312
De-recognition of operating lease asset on lease assignment / termination	19,877	4,169	—
De-recognition of operating lease liability on lease assignment / termination	21,297	4,457	—

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

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

Year Ending December 31,	Operating Leases	Finance Leases
2025	\$ 16,574	\$ 837
2026	12,596	811
2027	10,314	758
2028	9,020	601
2029	6,036	601
Thereafter	8,344	3,717
Total lease payments	62,884	7,325
Less imputed interest	(9,615)	(2,316)
Present value of lease liabilities	<u>\$ 53,269</u>	<u>\$ 5,009</u>

On October 11, 2024, we entered into a new lease agreement for premises located at 3000 El Camino Real, Palo Alto, California, with occupancy expected by July 1, 2025. The lease will be recognized on the lease commencement date with the lease ending in 2035.

**13. 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 December 31, 2024 and December 31, 2023. No assurances can be given that the covering insurers will not attempt to dispute the validity, applicability, or amount of coverage without expensive litigation against these insurers, in which case we may incur substantial liabilities as a result of these indemnification obligations.

***Other Commitments***

As of December 31, 2024, we had \$46.3 million of noncancelable purchase commitments due within one year, primarily related to agreements with third party manufacturers.

***Legal Proceedings***

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

***Xyrem 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 ANDAs 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 BCBS against the Company Defendants. The BCBS Lawsuit also 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.

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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 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 UFCW Defendants.

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. The AFL Plan Lawsuit also names Roxane Laboratories Inc., West-Ward Pharmaceuticals Corp., Hikma Labs Inc., Hikma Pharmaceuticals plc, Amneal Pharmaceuticals LLC, Par Pharmaceutical, 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.

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. 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. On April 26, 2024, we,

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

Hikma, and the plaintiffs filed motions for summary judgment. The Court held oral argument on these motions on July 19, 2024. On August 26, 2024, the Court issued a decision granting in part and denying in part the parties' motions for summary judgment. Certain administrative service organization plaintiffs filed a motion for reconsideration of a portion of the Court's summary judgment ruling. On December 16, 2024, the Court denied the motion for reconsideration. On January 15, 2025, Aetna, Inc., which is not a party to the consolidated multi-district litigation, filed a notice of appeal of the order denying reconsideration.

On June 13, 2024, we filed a motion to decertify the class. On June 28, 2024, the plaintiffs filed a motion to amend the definition of the certified class. The Court held oral argument on these motions on August 22, 2024. On October 18, 2024, the Court issued a decision denying our motion to decertify the class and granting the plaintiffs' motion to amend the class definition. On November 1, 2024, we filed a petition with the United States Court of Appeals for the Ninth Circuit seeking leave to appeal the Court's decision amending the class definition. On January 29, 2025, the Ninth Circuit denied our petition for permission to appeal. Trial in this matter has been rescheduled for May 19, 2025.

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 January 11, 2024, the Court held a hearing on the motion for final approval of the proposed settlement. The Court deferred ruling and scheduled a further hearing for final approval of the proposed settlement on April 17, 2024. During February and March 2024, the parties notified the Court of settlements between certain non-class action plaintiffs and each of Amneal and Lupin, and the Court dismissed those plaintiffs' claims against the applicable parties. On April 17, 2024, the Court issued an order granting the motion for final approval of the settlement between the class action plaintiffs, Amneal, and Lupin.

On December 11, 2023, Blue Cross and Blue Shield of Florida, Inc. and Health Options, Inc. filed a lawsuit in the United States District Court for the Middle District of Florida against the Company Defendants, Hikma Pharmaceuticals plc, Hikma Pharmaceuticals USA Inc., Hikma Labs, Inc., and Eurohealth (USA), Inc., raising similar allegations. On January 23, 2024, the Blue Cross Florida case was transferred to the United States District Court for the Northern District of California and consolidated with the above referenced multidistrict litigation for pretrial purposes.

On May 9, 2022, 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 November 17, 2023, Aetna filed its second amended complaint. On February 2, 2024, we filed our answer to the second amended complaint and Hikma filed a motion to quash service. The Court scheduled a hearing on Hikma's motion for December 4, 2024. The Court has not set a further schedule in this case.

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.

*Patent Infringement Litigation**Avadel Litigation*

On May 13, 2021, we filed a patent infringement suit against 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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

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 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. 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. On December 15, 2023, the Court issued a written opinion and order resolving the parties' remaining claim construction disputes. On November 20, 2023, we and Avadel each filed motions for summary judgment. On February 14, 2024, the Court issued a written opinion and order denying both parties' motions for summary judgment.

Trial regarding our patent infringement claims against Avadel began on February 26, 2024, and concluded on March 4, 2024, with the jury finding both of our asserted patents valid, and awarding us damages for infringement for Avadel's past sales of Lumryz. On April 12, 2024, we filed a motion for a permanent injunction and ongoing royalties. On August 27, 2024, the Court granted our motion for an injunction in part, and requested additional briefing about ongoing royalties. The issued injunction prevents Avadel from seeking FDA approval or marketing Lumryz for the treatment of idiopathic hypersomnia or other indications not already a part of Lumryz's product labeling as of March 4, 2024, and enjoins Avadel from infringing in any way Claim 24 of our '782 patent by making, using or selling Lumryz through and including the February 2036 expiration date of the '782 patent, subject to certain exclusions including, among other things (i) for the treatment of narcolepsy, (ii) for the treatment of patients who have been prescribed Lumryz as of the effective date of the

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

injunction conditioned on the payment of an amount to be determined and (iii) in clinical trials and studies ongoing as of the effective date of the injunction. The Court also granted our motion for an ongoing royalty for any future sale of Lumryz to patients with narcolepsy at a rate to be determined based upon further briefing by the parties on the appropriate ongoing rate above 3.5%. Avadel is appealing this injunction to the United States Court of Appeals for the Federal Circuit. The Federal Circuit held oral argument on this appeal on February 7, 2025, but has not yet issued a decision. Avadel filed a motion with the district court for a stay of the injunction pending appeal, which the district court denied. Avadel also filed a motion to stay the injunction pending appeal with the Federal Circuit, which the Federal Circuit granted to the limited extent that the injunction enjoins initiating new clinical trials or studies and denied in all other respects.

The Court scheduled a trial regarding Avadel's counterclaims for unlawful monopolization for November 3, 2025 and a trial regarding Avadel's trade secret misappropriation claims for December 15, 2025. On March 13, 2024 and March 19, 2024, we filed motions to stay Avadel's unlawful monopolization counterclaim and trade secret claims, respectively, pending resolution of post-trial motions and potential appeals in the patent infringement suit. On May 24, 2024, the Court denied the motion to stay the unlawful monopolization counterclaim and the previously-filed motion to dismiss the same. On June 7, 2024, we filed a motion for reargument or, in the alternative, to certify the decision for interlocutory appeal. That motion remains pending and no hearing date has been set. The Court stayed Avadel's trade secret misappropriation claims pending appeal of the injunction in the related patent matter. We filed a further motion to stay the unlawful monopolization counterclaims, which remains pending.

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.

From December 2024 through February 2025, Avadel filed a series of patent infringement suits against us in the United States District Court for the District of Delaware. The suits allege that Jazz's sales of Xywav infringe on certain newly-issued Avadel patents, and Avadel seeks an award of monetary damages. We have not yet responded to these lawsuits.

*Xywav Patent Litigation*

In June 2021, we received notice from Lupin, that it has filed with FDA an ANDA, for a generic version of Xywav. The notice from Lupin included a paragraph IV certification with respect to ten of our patents listed in FDA's Orange Book for Xywav on the date of our receipt of the notice. 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

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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 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.

On December 15, 2023, based on a stipulation between all parties, the Court consolidated the Lupin lawsuits and the Teva lawsuit for all purposes. No trial date has been set in the consolidated case.

In July 2024, we received notices from Lupin and Teva that they had each filed a paragraph IV certification regarding a newly-issued patent listed in the Orange Book for Xywav. On August 27, 2024, we filed an additional lawsuit in the United States District Court for the District of New Jersey against each of Lupin and Teva, alleging that, by filing its ANDA, each party infringed the newly-issued patent related to a method of treatment using Xywav. The suits seek orders that the effective date of FDA approval of each defendant's application shall be a date no earlier than the expiration of the newly-issued patent.

*Epidiolex Patent Litigation*

In November and December 2022, we received notices from 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. On January 11, 2024, the Court issued an order granting in part and denying in part our motion to dismiss. On September 20, 2024, the Court held a claim construction hearing relating to disputed terms in the asserted patents. The Court has not yet issued a decision on the claim construction disputes.

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.

In September and October 2023, we received notice from certain of the Epidiolex ANDA Filers that they had each filed a paragraph IV certification regarding one or more newly-issued patents listed in the Orange Book for Epidiolex. On December 15, 2023, we filed an additional lawsuit against seven of the original Epidiolex ANDA Filers with whom we have not previously settled. We filed this lawsuit 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 patents related to methods of treatment using

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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 patents.

In March and April 2024, we received notice from certain of the Epidiolex ANDA Filers that they had each filed a paragraph IV certification regarding one or more newly-issued patents listed in the Orange Book for Epidiolex. On July 3, 2024, we filed an additional lawsuit against six of the original Epidiolex ANDA Filers with whom we had not previously settled. We filed this lawsuit 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 patents related to methods 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 patents.

From October 2023 through January 2025, we entered into settlement agreements with each of the Epidiolex ANDA Filers that resolved our patent litigation with them related to Epidiolex. Under the settlement agreements, we granted each of the Epidiolex ANDA Filers a license to manufacture, market, and sell its own generic version of Epidiolex beginning in the very late 2030s, or earlier under certain circumstances, including but not limited to the launch of another generic Epidiolex product or a final decision that all unexpired claims of the Epidiolex patents are not infringed, or are invalid and/or unenforceable.

*Zepzelca Patent Litigation*

In July and August 2024, we received notices from the Zepzelca ANDA Filers that they have each filed with FDA an ANDA for a generic version of Zepzelca (lurbinectedin). As of the date of this filing, we are not aware of other ANDA filers. The notices from the Zepzelca ANDA Filers each included a paragraph IV certification with respect to a patent listed in the Orange Book for Zepzelca on the date of the receipt of the notice. The listed patent relates to the drug substance, drug product and approved use of Zepzelca. Jazz is the exclusive licensee to this Zepzelca patent pursuant to an agreement with PharmaMar. A paragraph IV certification is a certification by a generic applicant that alleges that the patent covering the branded product is invalid, unenforceable, and/or will not be infringed by the manufacture, use or sale of the generic product.

On September 11, 2024, we and PharmaMar filed a patent infringement suit against the Zepzelca ANDA Filers in the United States District Court for the District of New Jersey. The complaint alleges that by filing their ANDAs, the Zepzelca ANDA Filers have infringed the Orange Book listed patent for Zepzelca, 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 asserted patent.

In December 2024, we received the Zepzelca ANDA Filers' answers to the complaint. The answers include defenses and counterclaims asserting that the Zepzelca ANDA Filers' products, if launched, would not infringe our patents and that our patents are invalid. No trial date has been set in this matter.

On September 12, 2024, we and PharmaMar filed a patent infringement suit against RK Pharma, in the United States District Court for the District of Delaware. The complaint alleges that by filing its ANDA, RK Pharma has infringed the Orange Book listed patent for Zepzelca, and seeks an order that the effective date of FDA approval of RK Pharma's ANDA shall be no earlier than the expiration of the asserted patent. On November 13, 2024, we voluntarily dismissed this action against RK Pharma in the United States District Court for the District of Delaware. RK Pharma remains a defendant in the litigation referenced above in the United States District Court for the District of New Jersey.

*MSP Litigation*

On April 3, 2023, MSP filed a class action lawsuit on behalf itself and others similarly situated against 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 the Court granted on December 12, 2023. On January 5, 2024, the MSP filed an amended complaint. On February 20, 2024, we filed a motion to dismiss MSP's amended complaint. The Court scheduled a hearing on the motion for June 13, 2024. On June 21, 2024, the Court cancelled the hearing. On July 22, 2024, the Court granted the motion. The Court set a deadline of August 12, 2024, to file a second amended complaint. On August 12, 2024, MSP voluntarily dismissed its complaint.

*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 NDA for Avadel's Lumryz was unlawful. In the complaint, we alleged that FDA acted outside its authority under the Orphan Drug Act, when, despite ODE protecting Jazz's low-sodium oxybate

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

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 alleged 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, asked the Court to vacate and set aside FDA's approval of the Lumryz NDA and sought 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. Oral argument on these motions was held on May 10, 2024 and on October 30, 2024, the District Court issued an order denying Jazz's motion for summary judgment and granting Avadel's and FDA's cross-motions for summary judgment. Jazz respectfully disagrees with the Court's decision and is appealing the matter to the United States Court of Appeals for the District of Columbia Circuit. We filed our opening appeal brief on January 31, 2025. No argument date has been set.

*Qui tam matter*

In July 2022, we received a subpoena from the USAO 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 USPTO, pricing of Xyrem, and other related documents. On July 18, 2024, the United States District Court for the District of Massachusetts unsealed a qui tam whistleblower lawsuit underlying the USAO's subpoena, captioned 1:21-cv-10891-PBS and originally filed under seal on May 27, 2021. The public docket in this matter indicates that on May 24 and June 7, 2024, respectively, the United States and a number of states named in the whistleblower complaint declined to intervene in this matter. As such, private whistleblower litigation will proceed in the United States District Court for the District of Massachusetts. The Court set a deadline of September 1, 2024, for the plaintiff to file an amended complaint, and December 2, 2024, for us to file a motion to dismiss the amended complaint. The plaintiff filed the amended complaint on September 1, 2024. We filed our motion to dismiss on December 2, 2024. The Court scheduled a hearing on the motion to dismiss for April 2, 2025.

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.

**14. Shareholders' Equity***Share Repurchase Program*

In July 2024, our board of directors authorized the New Repurchase Program, to repurchase ordinary shares having an aggregate purchase price of \$500.0 million, exclusive of any brokerage commissions. Under the New Repurchase Program, which has no expiration date, we may repurchase ordinary shares from time to time by any methods and/or structures permitted by applicable law. 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 Amended Credit Agreement and the indenture for our Secured Notes, corporate and regulatory requirements and market conditions. The New Repurchase Program may be modified, suspended or discontinued at any time without our prior notice. The New Repurchase Program replaces and supersedes the Old Repurchase Program, a share repurchase program to repurchase ordinary shares having an aggregate purchase price of \$1.5 billion, exclusive of any brokerage commissions. In 2024, we spent a total of \$150.0 million to repurchase 1.4 million of our ordinary shares, all under the New Repurchase Program, at a purchase price, including commissions, of \$109.32 per share and \$161.4 million to repurchase 1.5 million of our ordinary shares, all under the Old Repurchase Program, at a purchase price, including commissions, of \$110.75 per share. The repurchases made under the New Share Repurchase Program in 2024 were effected in privately negotiated transactions with or through one of the initial purchasers of the 2030 Notes concurrently with the pricing of the offering of the 2030 Notes. In 2023, we spent a total of \$269.8 million to purchase 2.1 million of our ordinary shares under the Old Repurchase Program at an average total purchase price, including commissions, of \$126.65 per share. All ordinary shares repurchased were cancelled. As of December 31, 2024, the remaining amount authorized for repurchases under the New Repurchase Program was \$350.0 million, exclusive of any brokerage commissions.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**
**Authorized But Unissued Ordinary Shares**

We had reserved the following shares of authorized but unissued ordinary shares (in thousands):

	December 31,	
	2024	2023
2011 Equity Incentive Plan	22,056	22,855
2007 Employee Stock Purchase Plan	3,701	3,913
GW Incentive Plans	1,408	1,570
Amended and Restated 2007 Non-Employee Directors Stock Award Plan	677	714
<b>Total</b>	<b>27,842</b>	<b>29,052</b>

**Dividends**

In 2024 and 2023, we did not declare or pay cash dividends on our common equity. Under Irish law, dividends may only be paid, and share repurchases and redemptions must generally be funded only out of, “distributable reserves.” In addition, the terms of the Amended Credit Agreement restrict our ability to make certain restricted payments, including dividends and other distributions by us in respect of our ordinary shares, subject to, among other exceptions, (1) a general exception for dividends and other restricted payments not to exceed in the aggregate the greater of \$350 million and 3.5% of consolidated total assets (as defined in the Amended Credit Agreement) when made, and (2) an exception that allows for dividends and other restricted payments equal to an amount tied to our financial performance, so long as no default or event of default shall have occurred and is continuing under the Amended Credit Agreement and the total net leverage ratio (as defined in the Amended Credit Agreement) on a pro forma basis does not exceed 5:1, and (3) an exception that allows for additional dividends and other restricted payments, so long as no default or event of default shall have occurred and is continuing under the Amended Credit Agreement and the total net total leverage ratio (as defined in the Amended Credit Agreement) on a pro forma basis is not greater than 4:1. Any future determination as to the payment of dividends will, subject to Irish legal requirements, be at the sole discretion of our board of directors and will depend on our consolidated financial condition, results of operations, capital requirements, compliance with the terms of the Amended Credit Agreement or other future borrowing arrangements, and other factors our board of directors deems relevant.

**15. Comprehensive Income (Loss)**

Comprehensive income (loss) includes net income (loss) and all changes in shareholders’ equity during a period, except for those changes resulting from investments by shareholders or distributions to shareholders.

**Accumulated Other Comprehensive Loss**

The components of accumulated other comprehensive loss as of December 31, 2024 and 2023 were as follows (in thousands):

	Net Unrealized Gain From Hedging Activities	Foreign Currency Translation Adjustments	Total Accumulated Other Comprehensive Loss
Balance at December 31, 2023	\$ 235	\$ (842,382)	\$ (842,147)
Other comprehensive income (loss) before reclassifications	5,298	(106,025)	(100,727)
Amounts reclassified from accumulated other comprehensive loss	(4,793)	—	(4,793)
Other comprehensive income (loss), net	505	(106,025)	(105,520)
<b>Balance at December 31, 2024</b>	<b>\$ 740</b>	<b>\$ (948,407)</b>	<b>\$ (947,667)</b>

In 2024, other comprehensive income (loss) primarily reflects foreign currency translation adjustments due to the weakening of sterling and the euro against the U.S. dollar.

**16. 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.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

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

	Year Ended December 31,		
	2024	2023	2022
<b>Numerator:</b>			
Net income (loss)	\$ 560,120	\$ 414,832	\$ (224,060)
Effect of interest on assumed conversions of the 2026 Notes and the 2024 Notes, net of tax	10,762	24,876	—
Net income (loss) for dilutive net income (loss) per ordinary share	<u>\$ 570,882</u>	<u>\$ 439,708</u>	<u>\$ (224,060)</u>
<b>Denominator:</b>			
Weighted-average ordinary shares used in per share calculations - basic	61,838	63,291	62,539
Dilutive effect of the 2026 Notes and the 2024 Notes	3,540	8,016	—
Dilutive effect of employee equity incentive and purchase plans	629	759	—
Weighted-average ordinary shares used in per share calculations - diluted	<u>66,007</u>	<u>72,066</u>	<u>62,539</u>
<b>Net income (loss) per ordinary share:</b>			
Basic	<u>\$ 9.06</u>	<u>\$ 6.55</u>	<u>\$ (3.58)</u>
Diluted	<u>\$ 8.65</u>	<u>\$ 6.10</u>	<u>\$ (3.58)</u>

Potentially dilutive ordinary shares from our employee equity incentive and purchase plans are determined by applying the treasury stock method to the assumed vesting of outstanding RSUs and PRSUs, the assumed exercise of share options and the assumed issuance of ordinary shares under our ESPP.

On January 1, 2022, we adopted ASU No. 2020-06, “Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity” on a modified retrospective basis, which requires the use of the if-converted method to calculate potentially dilutive ordinary shares for convertible instruments.

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 of the election, an exchanging holder will receive (i) up to \$1,000 in cash per \$1,000 principal amount of 2024 Notes exchanged and (ii) cash, ordinary shares, or any combination thereof, at our election, in respect of the remainder, if any, of its exchange obligation in excess of \$1,000 per \$1,000 principal amount of 2024 Notes exchanged. 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 2023 up to the date the irrevocable election was made.

In July 2024, we irrevocably elected to fix the settlement method for exchanges of the 2026 Notes to a combination of cash and ordinary shares of Jazz Pharmaceuticals plc with a specified cash amount per \$1,000 principal amount of 2026 Notes exchanged equal to or in excess of \$1,000. As a result of the election, an exchanging holder will receive (i) up to \$1,000 in cash per \$1,000 principal amount of 2026 Notes exchanged and (ii) cash, ordinary shares, or any combination thereof, at our election, in respect of the remainder, if any, of its exchange obligation in excess of \$1,000 per \$1,000 principal amount of 2026 Notes exchanged. As a result, the assumed issuance of ordinary shares upon exchange of the 2026 Notes has only been included in the calculation of diluted net income per ordinary share in 2024, up to the date the irrevocable election was made.

The potential issue of ordinary shares upon exchange of the 2026 Notes and the 2024 Notes was anti-dilutive and had no impact on diluted net loss per ordinary share for 2022.

For the 2030 Notes, we are required to settle the principal amount in cash and have the option to settle the conversion feature for the amount above the conversion price, or the conversion spread, in cash, ordinary shares or a combination of cash and ordinary shares. The conversion spread will have a dilutive impact on diluted net income per ordinary share when the average market price of our ordinary shares for a given period exceeds the conversion price of the 2030 Notes. For the year ended December 31, 2024, the 2030 Notes have been excluded from the computation of diluted net income per ordinary share, as the effect would be anti-dilutive since the conversion price of the 2030 Notes exceeded the average market price of our ordinary shares for the year ended December 31, 2024.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

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

	Year Ended December 31,		
	2024	2023	2022
Employee equity incentive and purchase plans	4,074	2,973	2,751
2026 Notes and 2024 Notes	—	—	9,044

**17. Segment and Other Information**

Our operating segment is reported in a manner consistent with the internal reporting provided to the 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. The CODM assesses performance and decides how to allocate resources for the segment based on net income (loss) and measure of segment assets which is reported on the Consolidated Statements of Income (Loss) and Consolidated Balance Sheet.

The following table presents total long-lived assets by location (in thousands):

	December 31,	
	2024	2023
Ireland	\$ 85,703	\$ 68,201
United Kingdom	77,741	80,293
United States	33,724	59,440
Italy	21,931	20,942
Other	7,896	6,110
Total long-lived assets (1)	<u>\$ 226,995</u>	<u>\$ 234,986</u>

(1) Long-lived assets consist of property, plant and equipment and operating lease assets.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**
**18. Revenues**

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

	Year Ended December 31,		
	2024	2023	2022
Xywav	\$ 1,473,202	\$ 1,272,977	\$ 958,425
Xyrem	233,816	569,730	1,020,453
Epidiolex/Epidyolex	972,423	845,468	736,398
Sativex	18,877	19,668	16,825
Sunosi <sup>1</sup>	—	—	28,844
Total Neuroscience	2,698,318	2,707,843	2,760,945
Rylaze/Enrylaze	410,846	394,226	281,659
Zepzelca	320,318	289,533	269,912
Defitelio/defibrotide	216,565	184,000	194,290
Vyxeos	162,595	147,495	127,980
Ziihera	1,051	—	—
Total Oncology	1,111,375	1,015,254	873,841
Other	11,471	13,846	6,643
Product sales, net	3,821,164	3,736,943	3,641,429
High-sodium oxybate AG royalty revenue	217,575	75,918	—
Other royalty and contract revenues	30,211	21,343	17,945
<b>Total revenues</b>	<b>\$ 4,068,950</b>	<b>\$ 3,834,204</b>	<b>\$ 3,659,374</b>

(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):

	Year Ended December 31,		
	2024	2023	2022
United States	\$ 3,660,109	\$ 3,489,977	\$ 3,370,379
Europe	312,706	269,243	239,638
All other	96,135	74,984	49,357
<b>Total revenues</b>	<b>\$ 4,068,950</b>	<b>\$ 3,834,204</b>	<b>\$ 3,659,374</b>

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

	Year Ended December 31,		
	2024	2023	2022
ESSDS	42 %	48 %	56 %
McKesson	12 %	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.

**19. Share-Based Compensation**
***GW Incentive Plans***

On May 5, 2021, Jazz Pharmaceuticals plc acquired the entire issued share capital of GW. In connection with the GW Acquisition, we assumed the GW Incentive Plans. The terms of the GW Incentive Plans provide for the grant of stock options, stock appreciation rights, RSUs, other stock awards, and performance awards that may be settled in cash, shares, or other

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

property. Ordinary shares granted to employees in exchange for GW ADS, in connection with the GW Acquisition, vest ratably over service periods of two years, while all post-acquisition grants vest ratably over service periods of four years and expire no more than 10 years after the date of grant. As of December 31, 2024, a total of 1,864,475 of our ordinary shares had been authorized for issuance under the GW Incentive Plans.

***2011 Equity Incentive Plan***

In connection with the Azur Merger, Jazz Pharmaceuticals, Inc.'s board of directors adopted the 2011 Plan in October 2011, and its stockholders approved the 2011 Plan at the special meeting of the stockholders held in December 2011. The 2011 Plan became effective immediately before the consummation of the Azur Merger and was assumed and adopted by us upon the consummation of the Azur Merger. The terms of the 2011 Plan provide for the grant of stock options, stock appreciation rights, RSUs, other stock awards, and performance awards that may be settled in cash, shares, or other property. All outstanding grants under the 2011 Plan were granted to employees and vest ratably over service periods of four years and expire no more than 10 years after the date of grant. As of December 31, 2024, a total of 34,836,988 of our ordinary shares had been authorized for issuance under the 2011 Plan.

***2007 Employee Stock Purchase Plan***

In 2007, Jazz Pharmaceuticals, Inc.'s employees became eligible to participate in the ESPP. The ESPP was amended and restated by Jazz Pharmaceuticals, Inc.'s board of directors in October 2011 and approved by its stockholders in December 2011. The amended and restated ESPP became effective immediately prior to the effective time of the Azur Merger and was assumed by us upon the consummation of the Azur Merger. The amended and restated ESPP allows our eligible employee participants (including employees of any parent or subsidiary company if our board of directors designates such company as eligible to participate) to purchase our ordinary shares at a discount of 15% through payroll deductions. The ESPP consists of a fixed offering period of 24 months with four purchase periods within each offering period. The number of shares available for issuance under our ESPP during any six-month purchase period is 175,000 shares. As of December 31, 2024, a total of 7,029,250 of our ordinary shares had been authorized for issuance under the ESPP.

***Amended and Restated 2007 Non-Employee Directors Stock Award Plan***

The Amended and Restated 2007 Directors Award Plan, which was initially adopted by the Jazz Pharmaceuticals, Inc. board of directors and approved by the Jazz Pharmaceuticals, Inc. stockholders in connection with its initial public offering, was continued and assumed by us upon the consummation of the Azur Merger. Until October 2011, the 2007 Directors Award Plan provided for the automatic grant of stock options to purchase shares of Jazz Pharmaceuticals, Inc.'s common stock to its non-employee directors initially at the time any individual first became a non-employee director, which vest over three years, and then annually over their period of service on its board of directors, which vest over one year. On October 24, 2011, Jazz Pharmaceuticals, Inc.'s board of directors amended the 2007 Directors Award Plan to eliminate all future initial and annual automatic grants so that future automatic grants would not be made that would be subject to the excise tax imposed by the Internal Revenue Code in connection with the Azur Merger. Accordingly, all future stock option grants under the 2007 Directors Award Plan will be at the discretion of our board of directors. Since the Azur Merger, all of the new grants under the 2007 Directors Award Plan were granted to non-employee directors and vest ratably over service periods of one to three years and expire no more than 10 years after the date of grant. In August 2016, our shareholders approved our proposal to expand the types of stock awards that may be granted to our non-employee directors under the 2007 Directors Award Plan and eliminate the final automatic share reserve increase under the 2007 Directors Award Plan that was scheduled to occur on January 1, 2017. In July 2020, our shareholders approved our proposal to increase the number of ordinary shares authorized for issuance under the 2007 Directors Award Plan by 500,000 shares. As of December 31, 2024, a total of 1,403,938 of our ordinary shares had been authorized for issuance under the 2007 Directors Award Plan.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**
**Share-Based Compensation**

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

	Year Ended December 31,		
	2024	2023	2022
Selling, general and administrative	\$ 158,570	\$ 146,942	\$ 151,986
Research and development	74,673	64,847	57,522
Cost of product sales	14,802	15,052	12,488
Total share-based compensation expense, pre-tax	248,045	226,841	221,996
Income tax benefit from share-based compensation expense	(40,552)	(40,015)	(41,058)
Total share-based compensation expense, net of tax	<u>\$ 207,493</u>	<u>\$ 186,826</u>	<u>\$ 180,938</u>

We recognized income tax benefits related to share option exercises of \$0.3 million, \$1.9 million and \$8.0 million in 2024, 2023 and 2022, respectively.

**Restricted Stock Units**

In 2024, 2023 and 2022, we granted RSUs covering an equal number of our ordinary shares to employees with a weighted-average grant date fair value of \$118.41, \$144.65 and \$152.08, respectively. The fair value of RSUs is determined on the date of grant based on the market price of our ordinary shares as of that date. The fair value of RSUs is recognized as an expense ratably over the vesting period of four years. In 2024, 2023 and 2022, 1,341,000, 1,094,000 and 910,000 RSUs were released, respectively, with 892,000, 735,000 and 610,000 ordinary shares issued, respectively, and 449,000, 359,000 and 300,000 ordinary shares withheld for tax purposes, respectively. The total fair value of shares vested was \$156.0 million, \$155.5 million and \$138.1 million during 2024, 2023 and 2022, respectively.

As of December 31, 2024, total compensation cost not yet recognized related to unvested RSUs was \$308.9 million, which is expected to be recognized over a weighted-average period of 2.4 years.

The following table summarizes information as of December 31, 2024 and activity during 2024 related to our RSUs:

	Number of RSUs (In thousands)	Weighted-Average Grant-Date Fair Value	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (In thousands)
Outstanding at January 1, 2024	3,563	\$ 148.79		
RSUs granted	2,260	118.41		
RSUs released	(1,341)	147.14		
RSUs forfeited	(449)	137.25		
Outstanding at December 31, 2024	<u>4,033</u>	\$ 133.60	1.3	\$ 496,716

**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, 2024, December 31, 2025 and December 31, 2026, respectively. The number of shares that vest is determined based on the Company's achievement with respect to the performance criteria. For PRSUs granted prior to 2024, the amount of shares that vest will be subject to adjustment based on the application of a relative TSR modifier. For PRSUs granted in 2024, the relative TSR represents one of the performance metrics. In both cases, the number of shares that may be earned ranges between 0% and 200% of the target number of PRSUs granted.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

The following table summarizes information as of December 31, 2024 and activity during 2024 related to our PRSUs:

	Number of PRSUs (In thousands)	Weighted-Average Grant-Date Fair Value	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (In thousands)
Outstanding at January 1, 2024	664	\$ 173.30		
PRSUs granted	377	131.04		
PRSUs released	(124)	190.81		
PRSUs forfeited	(136)	169.40		
Outstanding at December 31, 2024	<u>781</u>	<u>\$ 150.82</u>	1.1	<u>\$ 96,218</u>

As of December 31, 2024, total compensation cost not yet recognized related to unvested PRSUs was \$37.3 million, which is expected to be recognized over a weighted-average period of 1.1 years.

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. In 2024, 2023 and 2022, we granted PRSUs to employees with a weighted-average grant date fair value of \$131.04, \$156.91 and \$178.78, respectively. The Company evaluated the performance targets in the context of its current long-range financial plan and its product candidate development pipeline and recognized compensation expense based on the probable number of awards that will ultimately vest. In 2024, 124,000 PRSUs were released, with 80,000 ordinary shares issued and 44,000 ordinary shares withheld for tax purposes. The total fair value of shares vested was \$14.8 million during 2024.

**Share Options**

There were no share options granted in 2024, 2023 and 2022.

The following table summarizes information as of December 31, 2024 and activity during 2024 related to our share option plans:

	Shares Subject to Outstanding Options (In thousands)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (In thousands)
Outstanding at January 1, 2024	2,716	\$ 141.55		
Options exercised	(14)	115.81		
Options forfeited	(8)	163.35		
Options expired	(536)	148.99		
Outstanding at December 31, 2024	<u>2,158</u>	<u>\$ 139.79</u>	3.2	<u>\$ 3,562</u>
Vested and expected to vest at December 31, 2024	2,158	\$ 139.79	3.2	\$ 3,562
Exercisable at December 31, 2024	2,158	\$ 139.79	3.2	\$ 3,562

Aggregate intrinsic value shown in the table above is equal to the difference between the exercise price of the underlying share options and the fair value of our ordinary shares for share options that were in the money. The aggregate intrinsic value changes based on the fair market value of our ordinary shares. The aggregate intrinsic value of share options exercised was \$0.2 million, \$6.3 million and \$34.8 million during 2024, 2023 and 2022, respectively. We issued new ordinary shares upon exercise of share options.

As of December 31, 2024, total compensation cost not yet recognized related to unvested share options was \$0.1 million, which is expected to be recognized over a weighted-average period of 0.1 years.

As of December 31, 2024, total compensation cost not yet recognized related to grants under the ESPP was \$7.6 million, which is expected to be recognized over a weighted-average period of 1.1 years.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**
**Nominal Strike Price Options**

During the second quarter of 2021, we issued nominal strike price options to replace certain unvested GW awards, in connection with the GW Acquisition, with a weighted-average grant date fair value of \$170.82. The fair value of nominal strike price options was determined on the date of the grant based on the market price of our ordinary shares as of that date.

The following table summarizes information as of December 31, 2024 and activity during 2024 related to our nominal strike price options:

	Shares Subject to Outstanding Options (In thousands)	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (In thousands)
Outstanding at January 1, 2024	27	\$ 0.02		
Options exercised	(8)	0.02		
Outstanding at December 31, 2024	<u>19</u>	<u>\$ 0.02</u>	6.0	\$ 2,374
Vested and expected to vest at December 31, 2024	19	\$ 0.02	6.0	\$ 2,374
Exercisable at December 31, 2024	19	\$ 0.02	6.0	\$ 2,374

The aggregate intrinsic value of nominal strike price options exercised was \$0.9 million, \$3.9 million and \$8.4 million during 2024, 2023 and 2022, respectively. We issued new ordinary shares upon exercise of nominal strike price options.

**20. Employee Benefit Plans**

We maintain a qualified 401(k) savings plan, in which all U.S. based employees are eligible to participate, provided they meet the requirements of the plan. We match certain employee contributions under the 401(k) savings plan and for the years ended December 31, 2024, 2023 and 2022 we recorded expense of \$16.4 million, \$13.4 million and \$10.6 million, respectively, related to this plan.

We also operate a number of defined contribution retirement plans for certain non-U.S. based employees. Expenses related to contributions to such plans for the years ended December 31, 2024, 2023 and 2022 were \$15.2 million, \$14.0 million and \$14.6 million, respectively.

**21. Income Taxes**

The components of income (loss) before income tax benefit and equity in loss of investees were as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Ireland	\$ 497,860	\$ 449,214	\$ (50,311)
United Kingdom	(411,356)	(643,096)	(963,598)
United States	29,594	(6,056)	224,453
Other	354,253	497,867	416,672
Total	<u>\$ 470,351</u>	<u>\$ 297,929</u>	<u>\$ (372,784)</u>

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The following table sets forth the details of income tax benefit (in thousands):

	Year Ended December 31,		
	2024	2023	2022
<b>Current</b>			
Ireland	\$ 97,680	\$ 77,343	\$ 61,550
United Kingdom	207	7,726	1,454
United States	22,065	20,803	37,823
Other	(3,054)	34,433	32,779
Total current tax expense	116,898	140,305	133,606
<b>Deferred, exclusive of other components below</b>			
Ireland	(20,022)	(10,919)	(62,011)
United Kingdom	(114,600)	(150,506)	(193,219)
United States	(63,162)	(89,246)	(9,086)
Other	(11,481)	(8,990)	(11,144)
Total deferred, exclusive of other components	(209,265)	(259,661)	(275,460)
<b>Deferred, change in tax rates</b>			
United Kingdom	—	268	(16,990)
United States	955	(824)	201
Other	(17)	—	(2)
Total deferred, change in tax rates	938	(556)	(16,791)
Total deferred tax benefit	(208,327)	(260,217)	(292,251)
<b>Total income tax benefit</b>	<b>\$ (91,429)</b>	<b>\$ (119,912)</b>	<b>\$ (158,645)</b>

Our income tax benefit was \$91.4 million, \$119.9 million and \$158.6 million in 2024, 2023 and 2022, respectively, 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, patent box benefits, foreign derived intangible income benefits and originating tax credits. Our income tax benefit in 2024 decreased compared to 2023 primarily due to the change in income mix across jurisdictions, partially offset by patent box benefits. Our income tax benefit in 2023 decreased compared to 2022 primarily due to pretax losses from payments for acquired IPR&D made in 2022 and the 2022 impairment of our acquired IPR&D asset as a result of the decision to discontinue our nabiximols program, partially offset by the change in income mix across jurisdictions.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

The reconciliation between income tax expense (benefit) at the Irish statutory trading income tax rate of 12.5 percent, the jurisdiction of tax domicile of Jazz Pharmaceuticals, applied to income before the income tax expense (benefit) and equity in loss of investees and our reported income tax benefit was as follows (in thousands):

	Year Ended December 31,		
	2024	2023	2022
Income tax expense (benefit) at the statutory income tax rate	\$ 58,794	\$ 37,241	\$ (46,598)
Change in valuation allowance	201,996	75,081	95,051
Deduction on subsidiary equity	(180,460)	(153,655)	(158,488)
Change in estimates	(106,007)	(5,472)	(14,065)
Patent box incentive benefit	(65,413)	(13,862)	(6,203)
Research and other tax credits	(65,255)	(49,900)	(27,976)
Foreign derived intangible income benefit	(39,470)	(42,400)	(29,541)
Foreign income tax rate differential	38,346	(7,763)	5,863
Non-deductible financing costs	22,437	15,705	4,504
Tax deficiencies/(excess tax benefits) from share-based compensation	18,074	3,959	(1,690)
Non-deductible compensation	10,889	14,092	13,505
Change in unrecognized tax benefits	9,767	(12,612)	5,029
Change in tax rate	938	(605)	(16,790)
Non-deductible facility expense	22	16,618	8,093
Non-deductible royalty expense	—	—	6,274
Other	3,913	3,661	4,387
Reported income tax benefit	<u>\$ (91,429)</u>	<u>\$ (119,912)</u>	<u>\$ (158,645)</u>

The 2024 patent box incentive benefit above includes a non-recurring benefit of \$40.9 million related to a claim for benefits in Italy in respect of tax years 2020 to 2023. The 2024 change in estimates above includes a benefit of \$103.3 million that is fully offset by a related change in valuation allowance, resulting in a net nil impact to our income tax benefit.

Significant components of our net deferred tax assets (liabilities) were as follows (in thousands):

	December 31,	
	2024	2023
Deferred tax assets:		
Deduction on subsidiary equity carryforwards	\$ 393,960	\$ 212,015
Operating loss carryforwards	307,413	296,490
Capitalized research and development	295,779	201,186
Intangible assets	243,391	238,062
Tax credit carryforwards	127,483	142,854
Accrued liabilities	115,290	128,948
Share-based compensation	47,486	48,403
Indirect effects of unrecognized tax benefits	35,000	40,811
Other	15,714	19,340
Total deferred tax assets	<u>1,581,516</u>	<u>1,328,109</u>
Valuation allowance	(509,190)	(312,340)
Deferred tax assets, net of valuation allowance	<u>1,072,326</u>	<u>1,015,769</u>
Deferred tax liabilities:		
Intangible assets	(1,130,485)	(1,290,425)
Inventories	(47,802)	(81,995)
Other	(10,530)	(13,221)
Total deferred tax liabilities	<u>(1,188,817)</u>	<u>(1,385,641)</u>
Net deferred tax liabilities	<u>\$ (116,491)</u>	<u>\$ (369,872)</u>

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

The net change in valuation allowance was an increase of \$196.9 million, \$77.6 million, and \$80.5 million in 2024, 2023 and 2022, respectively.

The following table summarizes the presentation of deferred tax assets and liabilities (in thousands):

	December 31,	
	2024	2023
Deferred tax assets	\$ 560,245	\$ 477,834
Deferred tax liabilities	(676,736)	(847,706)
Net deferred tax liabilities	\$ (116,491)	\$ (369,872)

As of December 31, 2024, we had NOL and tax credit carryforwards for U.S. federal income tax purposes of \$11.0 million and \$20.5 million, respectively, available to reduce future income subject to income taxes. The U.S. federal NOL carryforwards will expire, if not utilized, in the tax years 2025 to 2033 and the U.S. federal tax credits will expire, if not utilized, in the tax years 2027 to 2044. In addition, we had \$4.9 million of NOL carryforwards and \$5.8 million of tax credit carryforwards as of December 31, 2024 available to reduce future taxable income for U.S. state income tax purposes. The U.S. state NOL carryforwards will expire, if not utilized, in the tax years 2025 to 2034. As of December 31, 2024, there were NOL and other carryforwards for income tax purposes of \$1,125.6 million, \$790.3 million and \$374.8 million available to reduce future income subject to income taxes in Malta, the United Kingdom and Ireland respectively. The NOLs and other carryforwards generated in Malta, the United Kingdom and Ireland have no expiration date. We also had foreign tax credit carryforwards in Ireland, as of December 31, 2024, of \$100.9 million, which may only be utilized against certain sources of income. The foreign tax credit carryforwards have no expiration date.

Utilization of certain of our NOL and tax credit carryforwards in the U.S. is subject to an annual limitation due to the ownership change limitations provided by Sections 382 and 383 of the Internal Revenue Code and similar state provisions. Such an annual limitation may result in the expiration of certain NOLs and tax credits before future utilization. In addition, as a result of the Azur Merger, until 2022 we were subject to certain limitations under the Internal Revenue Code in relation to the utilization of U.S. NOLs to offset U.S. taxable income resulting from certain transactions.

Valuation allowances require an assessment of both positive and negative evidence when determining whether it is more likely than not that deferred tax assets are recoverable. Such assessment is required by tax-paying component. Our valuation allowance was \$509.2 million and \$312.3 million as of December 31, 2024 and 2023, respectively, for certain Irish, U.S. (federal and state) and foreign deferred tax assets which we maintain until sufficient positive evidence exists to support reversal. As part of the overall change in valuation allowance, we recognized a net income tax expense of \$202.0 million, \$76.2 million and \$95.1 million in 2024, 2023 and 2022, respectively, relating primarily to the creation of a valuation allowance against certain deferred tax assets primarily associated with carryforwards in foreign subsidiaries and foreign tax credit carryforwards in Ireland. We periodically evaluate the likelihood of the realization of deferred tax assets and will adjust such amounts in light of changing facts and circumstances including, but not limited to, future projections of taxable income, tax legislation, rulings by relevant taxing authorities, the progress of tax examinations and the regulatory approval of products currently under development. Realization of the deferred tax assets is dependent on future taxable income. The Company believes that it is more likely than not to generate sufficient taxable income to realize the deferred tax assets carried as of December 31, 2024 for which no valuation allowance has been recognized.

No provision has been made for income tax on undistributed earnings of the Company's foreign subsidiaries where such earnings are considered indefinitely reinvested in the foreign operations. Temporary differences related to such earnings totaled \$1.6 billion as of December 31, 2024. In the event of the distribution of those earnings in the form of dividends, a sale of the subsidiaries, or certain other transactions, we may be liable for income taxes, subject to an adjustment, if any, for foreign tax credits. The Company estimates that it would incur additional income taxes of up to \$81.0 million on repatriation of these unremitted earnings to Ireland.

We only 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 positions which we judge may not be sustained upon examination.

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

A reconciliation of our unrecognized tax benefits follows (in thousands):

	December 31,		
	2024	2023	2022
Balance at the beginning of the year	\$ 122,694	\$ 143,976	\$ 137,867
Increases related to current year tax positions	32,559	15,004	25,128
Increases related to prior year tax positions	—	224	2,794
Decreases related to prior year tax positions	(150)	(12,702)	(164)
Decreases related to settlements with taxing authorities	(2,605)	—	(223)
Lapse of the applicable statute of limitations	(26,520)	(23,808)	(21,426)
Balance at the end of the year	<u>\$ 125,978</u>	<u>\$ 122,694</u>	<u>\$ 143,976</u>

The unrecognized tax benefits were included in income taxes payable, other non-current liabilities and deferred tax assets, net, in our consolidated balance sheets. Interest related to income taxes is recorded in income tax benefit in our consolidated statements of income (loss). As of December 31, 2024 and 2023, our accrued interest related to income taxes was \$8.6 million and \$8.4 million, respectively. Interest related to income taxes recognized in the consolidated statements of income (loss) were not significant. Included in the balance of unrecognized tax benefits were potential benefits of \$86.8 million and \$77.1 million at December 31, 2024 and 2023, respectively, that, if recognized, would affect the effective tax rate on income. The Company believes that it is reasonably possible that \$26.7 million of its currently remaining unrecognized tax benefits may be recognized by the end of 2025 as a result of a lapse of the statute of limitations.

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 2020. 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 2020 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 January 2023, we received tax assessment notices from the Luxembourg taxing authorities for all open tax years relating to certain transfer pricing and other adjustments. The notices propose additional Luxembourg income tax of approximately \$23.3 million, translated at the foreign exchange rate as at December 31, 2024. We disagree with the proposed assessments and are contesting them vigorously.

The Government of Ireland, the jurisdiction in which Jazz Pharmaceuticals Plc is incorporated, transposed the Global Minimum Tax Pillar Two rules into domestic legislation as part of the Finance (No. 2) Act 2023 (the "Finance Act"). The Finance Act closely follows the EU Minimum Tax Directive and certain OECD Guidance released to date. The Company is within the scope of these rules, which took effect from January 1, 2024. Under the new legislation, we are liable to pay a top-up tax for the difference between the Pillar Two effective tax rate per jurisdiction and the 15% minimum rate. The rules on how to calculate the Pillar Two effective tax rate are detailed and highly complex and specific adjustments envisaged in the Pillar Two legislation can give rise to different effective tax rates compared to those calculated for accounting purposes. We account for Pillar Two top-up taxes as a current tax when they are incurred. We do not believe we were subject to the top-up tax in 2024. The proportion of our profit before tax which is subject to the top-up tax and our exposure to Pillar Two top-up taxes in future years will depend on factors such as future revenues, costs and foreign currency exchange rates. We will continue to monitor changes in law and guidance in relation to Pillar Two.

**Schedule II**  
**Valuation and Qualifying Accounts**  
**(In thousands)**

		Balance at beginning of period	Additions charged to costs and expenses	Other Additions	Deductions	Balance at end of period
<b>For the year ended December 31, 2024</b>						
Allowance for doubtful accounts	(1)	\$ 242	\$ 5,981	\$ —	\$ —	\$ 6,223
Allowance for sales discounts	(1)	5,962	24,334	—	(16,253)	14,043
Allowance for chargebacks	(1)	14,932	212,389	—	(214,896)	12,425
Deferred tax asset valuation allowance	(2)(3)	312,340	205,894	—	(9,044)	509,190
<b>For the year ended December 31, 2023</b>						
Allowance for doubtful accounts	(1)	\$ 242	\$ —	\$ —	\$ —	\$ 242
Allowance for sales discounts	(1)	2,980	22,334	—	(19,352)	5,962
Allowance for chargebacks	(1)	14,621	185,886	—	(185,575)	14,932
Deferred tax asset valuation allowance	(2)(3)	234,732	76,670	1,368	(430)	312,340
<b>For the year ended December 31, 2022</b>						
Allowance for doubtful accounts	(1)	\$ 298	\$ —	\$ —	\$ (56)	\$ 242
Allowance for sales discounts	(1)	2,126	20,133	—	(19,279)	2,980
Allowance for chargebacks	(1)	11,389	135,854	—	(132,622)	14,621
Deferred tax asset valuation allowance	(2)(3)	154,255	95,947	—	(15,470)	234,732

- (1) Shown as a reduction of accounts receivable. Charges related to sales discounts and chargebacks are reflected as a reduction of revenue.
- (2) Additions to the deferred tax asset valuation allowance charged to costs and expenses relate to movements on certain Irish, U.S. (federal and state) and other foreign deferred tax assets where we continue to maintain a valuation allowance until sufficient positive evidence exists to support reversal.
- (3) Deductions from the deferred tax asset valuation allowance include movements relating to utilization of NOLs and tax credit carryforwards, release in valuation allowance and other movements including adjustments following finalization of tax returns and currency translation adjustments.

## DESCRIPTION OF SHARE CAPITAL

The following description of the share capital of Jazz Pharmaceuticals plc, or the Company, is a summary. This summary does not purport to be complete and is qualified in its entirety by reference to the Irish Companies Act 2014 (as amended), or the Companies Act, and the complete text of the Company's amended and restated memorandum and articles of association, which amended and restated memorandum and articles of association, or the Company's Constitution, are filed as Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission, or SEC, on August 9, 2016. You should read those laws and documents carefully.

### Capital Structure

#### *Authorized Share Capital*

The authorized share capital of the Company is €40,000 and \$30,000, divided into 4,000,000 non-voting euro deferred shares with nominal value of €0.01 per share and 300,000,000 ordinary shares with nominal value of \$0.0001 per share.

The Company may issue shares subject to the maximum authorized share capital contained in the Company's Constitution. The authorized share capital may be increased or reduced (but not below the number of shares then issued and outstanding) by a resolution approved by a simple majority of the votes cast at a general meeting, in person or by proxy, of the Company's shareholders (referred to under Irish law as an "ordinary resolution"). The shares comprising the Company's authorized share capital may be divided into shares of such nominal value as the resolution shall prescribe. As a matter of Irish law, the directors of a company may issue new ordinary or preferred shares for cash without shareholder approval once authorized to do so by the memorandum and articles of association or by an ordinary resolution adopted by the shareholders at a general meeting. The authorization may be granted for a maximum period of five years, at which point it must be renewed by the shareholders by an ordinary resolution.

The Company's board of directors is authorized pursuant to shareholder resolutions passed on July 29, 2021 to issue new ordinary or preferred shares for cash without shareholder approval for a period of five years from the date of the passing of the resolutions.

The rights and restrictions to which ordinary shares are subject are prescribed in the Company's Constitution. The Company's Constitution permits it to issue preferred shares once authorized to do so by ordinary resolution. The Company may, by ordinary resolution and without obtaining any vote or consent of the holders of any class or series of shares, unless expressly provided by the terms of that class or series of shares, provide from time to time for the issuance of other classes or series of shares and to establish the characteristics of each class or series,

including the number of shares, designations, relative voting rights, dividend rights, liquidation and other rights, redemption, repurchase or exchange rights and any other preferences and relative, participating, optional or other rights and limitations not inconsistent with applicable law.

Irish law does not recognize fractional shares held of record. Accordingly, the Company's Constitution does not provide for the issuance of fractional shares, and the official Irish register of the Company will not reflect any fractional shares. Whenever an alteration or reorganization of the Company's share capital would result in any shareholder becoming entitled to fractions of a share, the Company's board of directors may, on behalf of those shareholders that would become entitled to fractions of a share, sell the shares representing the fractions for the best price reasonably obtainable, to any person and distribute the proceeds of the sale in due proportion among those members.

### ***Issued Share Capital***

As of December 31, 2024, 60,631,659 ordinary shares were issued and outstanding. In addition, as of December 31, 2024, 4,000,000 non-voting euro deferred shares were issued and outstanding at that time, which shares are held by nominees in order to satisfy an Irish legislative requirement to maintain a minimum level of issued share capital denominated in euro. The euro deferred shares, which are not listed on any stock exchange and are not the subject of any registration, carry no voting rights and are not entitled to receive any dividend or distribution. On a return of assets, whether on liquidation or otherwise, the euro deferred shares will entitle the holder thereof only to the repayment of the amounts paid up on such shares after repayment of the capital paid up on ordinary shares plus the payment of \$5,000,000 on each of the ordinary shares and the holders of the euro deferred shares (as such) will not be entitled to any further participation in the assets or profits of the Company.

### **Preemption Rights, Share Warrants and Share Options**

Under Irish law, certain statutory preemption rights apply automatically in favor of shareholders where shares are to be issued for cash. However, the Company has opted out of these preemption rights by way of shareholder resolution as permitted under Irish law. Irish law provides that this opt-out expires every five years unless renewed by a resolution approved by not less than 75% of the votes cast at a general meeting, in person or by proxy, of the Company's shareholders (referred to under Irish law as a "special resolution"). The Company's current opt-out was approved by shareholder resolutions passed at the Company's 2024 annual general meeting on July 25, 2024 (the "AGM") and is limited to the allotment of equity securities up to an aggregate nominal value of US\$1,263.68 (12,636,816 shares) (being equivalent to approximately 20% of the aggregate nominal value of the Company's issued ordinary share capital as at the last practicable date prior to the issue of the notice of the AGM). This opt-out will expire 18 months from July 25, 2024 and if it is not renewed before that date, shares issued for cash will need to be offered to existing shareholders on a pro rata basis to their existing shareholding before the shares may be issued to any new shareholders. The statutory preemption rights do not apply (i) where shares are issued for non-cash consideration (such as in a stock-for-stock acquisition), (ii) to the issue of non-equity shares (that is, shares that

have the right to participate only up to a specified amount in any income or capital distribution) or (iii) where shares are issued pursuant to an employee stock option or similar equity plan.

The Company's Constitution provides that, subject to any shareholder approval requirement under any laws, regulations or the rules of any stock exchange to which it is subject, the Company's board of directors is authorized, from time to time, in its discretion, to grant such persons, for such periods and upon such terms as it deems advisable, options to purchase such number of shares of any class or classes or of any series of any class as the Company's board of directors may deem advisable, and to cause warrants or other appropriate instruments evidencing such options to be issued. The Companies Act provides that, save to the extent the constitution of a company provides otherwise, the directors of a company may issue options. The Company is subject to the rules of The NASDAQ Stock Market LLC and the U.S. Internal Revenue Code of 1986, or the Code, which require shareholder approval of certain equity plan and share issuances. The Company's board of directors may issue shares upon exercise of validly issued warrants or options without shareholder approval or authorization, except as described above (up to the relevant authorized share capital limit).

## **Dividends**

Under Irish law, dividends and distributions may only be made from distributable reserves. Distributable reserves generally means accumulated realized profits less accumulated realized losses and includes reserves created by way of capital reduction. In addition, no distribution or dividend may be made unless the Company's net assets are equal to, or in excess of, the aggregate of its called up share capital plus undistributable reserves and the distribution does not reduce its net assets below such aggregate. Undistributable reserves include the share premium account, the par value of shares acquired by the Company and the amount by which the Company's accumulated unrealized profits, so far as not previously utilized by any capitalization, exceed the Company's accumulated unrealized losses, so far as not previously written off in a reduction or reorganization of capital.

The determination as to whether or not the Company has sufficient distributable reserves to fund a dividend must be made by reference to its "relevant financial statements." The "relevant financial statements" are either the last set of unconsolidated annual audited financial statements or other financial statements properly prepared in accordance with the Companies Act, which give a "true and fair view" of the Company's unconsolidated financial position and accord with accepted accounting practice. The relevant financial statements must be filed in the Companies Registration Office (the official public registry for companies in Ireland).

The Company's Constitution authorizes the directors to declare dividends without shareholder approval to the extent they appear justified by profits lawfully available for distribution. The Company's board of directors may also recommend a dividend to be approved and declared by the shareholders at a general meeting. The Company's board of directors may direct that the payment be made by distribution of assets, shares or cash, and no dividend issued may exceed the amount recommended by the directors. The dividends declared by the directors or shareholders may be paid in the form of cash or non-cash assets and may be paid in dollars or any other currency.

The Company's board of directors may deduct from any dividend payable to any shareholder any amounts payable by such shareholder to the Company in relation to its shares.

The Company may issue shares with preferred rights to participate in dividends declared by the Company from time to time, as determined by ordinary resolution. The holders of preferred shares may, depending on their terms, rank senior to ordinary shares in terms of dividend rights and/or be entitled to claim arrears of a declared dividend out of subsequently declared dividends in priority to ordinary shareholders.

## **Share Repurchases, Redemptions and Conversions**

### ***Overview***

The Company's Constitution provides that, unless the board specifically determines otherwise, any ordinary share that it has agreed to acquire shall be deemed to be a redeemable share. Accordingly, for Irish law purposes, the repurchase of ordinary shares by the Company may technically be effected as a redemption of those shares as described below under "*—Repurchases and Redemptions.*" If the Company's Constitution did not contain such provision, repurchases by the Company would be subject to many of the same rules that apply to purchases of its ordinary shares by subsidiaries described below under "*—Purchases by the Company's Subsidiaries,*" including the shareholder approval requirements described below, and the requirement that any purchases on market be effected on a "recognized stock exchange," which, for purposes of the Companies Act, includes The NASDAQ Global Select Market. Neither Irish law nor any of the Company's constituent documents places limitations on the right of nonresident or foreign owners to vote or hold its ordinary shares. Except where otherwise noted, references herein to repurchasing or buying back ordinary shares refer to the redemption of ordinary shares by the Company or the purchase of ordinary shares by one of its subsidiaries, in each case in accordance with the Company's Constitution and Irish law as described below.

### ***Repurchases and Redemptions***

Under Irish law, a company may issue redeemable shares and redeem them out of distributable reserves or the proceeds of a new issue of shares for that purpose. Please see also "*—Dividends.*" The Company may not purchase any of its shares if, as a result of such purchase, the nominal value of its issued share capital which is not redeemable would be less than 10% of the nominal value of its total issued share capital. All redeemable shares must also be fully-paid. Redeemable shares may, upon redemption, be cancelled or held in treasury. Based on the provisions of the Company's Constitution, shareholder approval will not be required to redeem its shares.

The Company may also be given an additional general authority to purchase its ordinary shares on market by way of ordinary resolution, which would take effect on the same terms and be subject to the same conditions as applicable to purchases by the Company's subsidiaries as described below.

Repurchased and redeemed shares may be cancelled or held as treasury shares. The nominal value of treasury shares held by the Company at any time must not exceed 10% of the aggregate of the par value and share premium received in respect of the allotment of the Company shares together with the par value of any shares acquired by the Company. The Company may not exercise any voting rights in respect of any shares held as treasury shares.

Treasury shares may be cancelled by the Company or re-issued subject to certain conditions.

#### ***Purchases by the Company's Subsidiaries***

Under Irish law, an Irish or non-Irish subsidiary of the Company may purchase the Company's shares either on market or off market. For a subsidiary of the Company to make purchases on market of ordinary shares, the Company's shareholders must provide general authorization for such purchase by way of ordinary resolution. However, as long as this general authority has been granted, no specific shareholder authority for a particular on market purchase by a subsidiary of ordinary shares is required. For a purchase of ordinary shares by a subsidiary of the Company off market, the proposed purchase contract must be authorized by special resolution of the Company's shareholders before the contract is entered into. The person whose ordinary shares are to be bought back cannot vote in favor of the special resolution and, from the date of the notice of the meeting at which the resolution approving the contract is proposed, the purchase contract must be on display or must be available for inspection by the Company's shareholders at the registered office of the Company.

In order for one of the Company's subsidiaries to make an on market purchase of its shares, such shares must be purchased on a "recognized stock exchange." The NASDAQ Global Select Market, on which ordinary shares are currently listed, is specified as a recognized stock exchange for this purpose by Irish law.

The number of shares held by the Company's subsidiaries at any time will count as treasury shares and will be included in any calculation of the permitted treasury share threshold of 10% of the aggregate of the par value and share premium received in respect of the allotment of the Company shares together with the par value of any shares acquired by the Company. While a subsidiary holds the Company's shares, it cannot exercise any voting rights in respect of those shares and no dividend or other payment (including any payment in a winding up of the Company) shall be payable in respect of those shares. The acquisition of ordinary shares by a subsidiary must be funded out of distributable reserves of the subsidiary.

#### **Lien on Shares, Calls on Shares and Forfeiture of Shares**

The Company's Constitution provides that it has a first and paramount lien on every share that is not a fully paid up share for all amounts payable at a fixed time or called in respect of that share. Subject to the terms of their allotment, directors may call for any unpaid amounts in respect of any shares to be paid, and if payment is not made, the shares may be forfeited. These provisions are standard inclusions in the memorandum and articles of association of an Irish public company limited by shares such as the Company's and are only applicable to ordinary shares that have not been fully paid up.

## **Bonus Shares**

Under the Company's Constitution, the Company's board of directors may resolve to capitalize any amount for the time being standing to the credit of any of the Company's reserve accounts or to the credit of the profit and loss account which is not available for distribution through the issuance of fully paid up bonus shares on the same basis of entitlement as would apply in respect of a dividend distribution.

## **Consolidation and Division; Subdivision**

Under the Company's Constitution, the Company may, by ordinary resolution, consolidate and divide all or any of its share capital into shares of larger nominal value than its existing shares or subdivide its shares into smaller amounts than are fixed by the Company's Constitution.

## **Reduction of Share Capital**

The Company may, by ordinary resolution, reduce its authorized share capital in any way. The Company also may, by special resolution and subject to confirmation by the Irish High Court, reduce or cancel its issued share capital (which includes share premium) in any manner permitted by the Companies Act.

## **Annual Meetings of Shareholders**

The Company is required to hold an annual general meeting at intervals of no more than 15 months from the previous annual general meeting, provided that an annual general meeting is held in each calendar year following the first annual general meeting and no more than nine months after the Company's fiscal year-end. The Company's articles of association provide that shareholder meetings may be held outside of Ireland (subject to compliance with the Companies Act). Where a company holds its annual general meeting or extraordinary general meeting outside of Ireland, the Companies Act requires that the company, at its own expense, make all necessary arrangements to ensure that members can by technological means participate in the meeting without leaving Ireland (unless all of the members entitled to attend and vote at the meeting consent in writing to the meeting being held outside of Ireland).

Notice of an annual general meeting must be given to all of the Company's shareholders and to its auditors. The Company's Constitution provides for a minimum notice period of 21 clear days, which is the minimum permitted under Irish law.

The only matters which must, as a matter of Irish law, be transacted at an annual general meeting are the presentation of the annual financial statements and reports of the directors and auditors, a review by the shareholders of the company's affairs, the appointment of new auditors and the fixing of the auditor's remuneration (or delegation of same). If no resolution is made in respect of the reappointment of an existing auditor at an annual general meeting, the existing auditor will be deemed to have continued in office.

## **Extraordinary General Meetings of Shareholders**

Extraordinary general meetings may be convened by (i) the Company's board of directors, (ii) on requisition of the Company's shareholders holding not less than 10% of its paid up share capital carrying voting rights, (iii) on requisition of the Company's auditors or (iv) in exceptional cases, by order of the court. Extraordinary general meetings are generally held for the purpose of approving shareholder resolutions as may be required from time to time. At any extraordinary general meeting only such business shall be conducted as is set forth in the notice thereof.

Notice of an extraordinary general meeting must be given to all of the Company's shareholders and to its auditors. Under Irish law and the Company's Constitution, the minimum notice periods are 21 clear days' notice in writing for an extraordinary general meeting to approve a special resolution and 14 clear days' notice in writing for any other extraordinary general meeting.

In the case of an extraordinary general meeting convened by the Company's shareholders, the proposed purpose of the meeting must be set out in the requisition notice. Upon receipt of any such valid requisition notice, the Company's board of directors has 21 days to convene a meeting of its shareholders to vote on the matters set out in the requisition notice. This meeting must be held within two months of the receipt of the requisition notice. If the Company's board of directors does not convene the meeting within such 21-day period, the requisitioning shareholders, or any of them representing more than one half of the total voting rights of all of them, may themselves convene a meeting, which meeting must be held within three months of the Company's receipt of the requisition notice.

If the Company's board of directors becomes aware that its net assets are not greater than half of the amount of the Company's called-up share capital, it must convene an extraordinary general meeting of its shareholders not later than 28 days from the date that they learn of this fact to consider how to address the situation.

## **Quorum for General Meetings**

The Company's Constitution provides that no business shall be transacted at any general meeting unless a quorum is present. One or more of the Company's shareholders present in person or by proxy holding not less than a majority of the Company's issued and outstanding shares entitled to vote at the meeting in question constitute a quorum.

## **Voting**

At general meetings of the Company, a resolution put to the vote of the meeting is decided on a poll. The Company's Constitution provides that its board of directors or its chairman may determine the manner in which the poll is to be taken and the manner in which the votes are to be counted.

Each shareholder is entitled to one vote for each ordinary share that he or she holds as of the record date for the meeting. Voting rights may be exercised by shareholders registered in the Company's share register as of the record date for the meeting or by a duly appointed proxy, which proxy need not be a shareholder. Where interests in shares are held by a nominee trust company, such company may exercise the rights of the beneficial holders on their behalf as their proxy. All proxies must be appointed in the manner prescribed by the Company's Constitution, which permits shareholders to notify the Company of their proxy appointments electronically in such manner as may be approved by the Company's board of directors.

In accordance with the Company's Constitution, it may from time to time be authorized by ordinary resolution to issue preferred shares. These preferred shares may have such voting rights as may be specified in the terms of such preferred shares (e.g., they may carry more votes per share than ordinary shares or may entitle their holders to a class vote on such matters as may be specified in the terms of the preferred shares). Treasury shares or the Company's shares that are held by its subsidiaries are not entitled to be voted at general meetings of shareholders.

Irish law requires special resolutions of the Company's shareholders at a general meeting to approve certain matters. Examples of matters requiring special resolutions include:

- amending the objects or memorandum of association of the Company;
- amending the articles of association of the Company;
- approving a change of name of the Company;
- authorizing the entering into of a guarantee or provision of security in connection with a loan, quasi-loan or credit transaction to a director or a person who is deemed to be "connected" to a director for the purposes of the Companies Act;
- opting out of preemption rights on the issuance of new shares;
- re-registration of the Company from a public limited company to a private company;
- variation of class rights attaching to classes of shares (where the articles of association do not provide otherwise);
- purchase of the Company's shares off market;
- reduction of issued share capital;
- sanctioning a compromise/scheme of arrangement with creditors or shareholders;
- resolving that the Company be wound up by the Irish courts;
- resolving in favor of a shareholders' voluntary winding-up; and
- setting the re-issue price of treasury shares.

### **Unanimous Shareholder Consent to Action Without Meeting**

The Companies Act provides that shareholders may approve an ordinary or special resolution of shareholders without a meeting only if (i) all shareholders sign the written resolution and (ii) the company's articles of association permit written resolutions of shareholders (the Company's articles of association contain the appropriate authorizations for this purpose).

### **Variation of Rights Attaching to a Class or Series of Shares**

Under the Company's Constitution and the Companies Act, any variation of class rights attaching to its issued shares must be approved by a special resolution of the Company's shareholders of the affected class or with the consent in writing of the holders of three-quarters of all the votes of that class of shares.

The provisions of the Company's Constitution relating to general meetings apply to general meetings of the holders of any class of the Company's shares except that the necessary quorum is determined in reference to the shares of the holders of the class. Accordingly, for general meetings of holders of a particular class of the Company's shares, a quorum consists of the holders present in person or by proxy representing at least one half of the issued shares of the class.

### **Inspection of Books and Records**

Under Irish law, shareholders have the right to: (i) receive a copy of the Company's Constitution and any act of the Irish Government which alters its memorandum; (ii) inspect and obtain copies of the minutes of general meetings and the Company's resolutions; (iii) inspect and receive a copy of the register of shareholders, register of directors and secretaries, register of directors' interests and other statutory registers maintained in respect of the ordinary shares; (iv) receive copies of financial statements and directors' and auditors' reports which have previously been sent to shareholders prior to an annual general meeting; and (v) receive financial statements of any of the Company's subsidiaries that have previously been sent to shareholders prior to an annual general meeting for the preceding ten years. The Company's auditors also have the right to inspect all of the Company's books, records and vouchers. The auditors' report must be circulated to the shareholders with the Company's financial statements prepared in accordance with Irish law 21 clear days before the annual general meeting and must be read to the shareholders at the Company's annual general meeting.

### **Acquisitions**

An Irish public limited company may be acquired in a number of ways, including:

- a court-approved scheme of arrangement under the Companies Act. A scheme of arrangement with shareholders requires a court order from the Irish High Court and the approval of a majority in number representing 75% in value of the shareholders present and voting in person or by proxy at a meeting called to approve the scheme;

- through a tender or takeover offer by a third party for all of the Company's shares. Where the holders of 80% or more of the Company's shares have accepted an offer for their shares, the remaining shareholders may also be statutorily required to transfer their shares, and if the bidder does not exercise its "squeeze out" right, then the non-accepting shareholders also have a statutory right to require the bidder to acquire their shares on the same terms. If the Company's shares were to be listed on the main securities market of Euronext Dublin or another main securities market or regulated stock exchange in the European Union, this threshold would be increased to 90%; and
- by way of a merger with an EU-incorporated company under the EU Directive 2017/1132 relating to certain aspects of Company Law (as amended) and the European Communities (Cross-Border Conversions, Mergers and Divisions) Regulations 2023 (as amended). Such a merger must be approved by a special resolution.

Irish law does not generally require shareholder approval for a sale, lease or exchange of all or substantially all of a company's property and assets, unless the company is listed on a regulated stock exchange in the European Union.

### **Appraisal Rights**

Generally, under Irish law, shareholders of an Irish company do not have dissenters' or appraisal rights. Under the European Communities (Cross-Border Conversions, Mergers and Divisions) Regulations 2023 (as amended) governing the merger of an Irish company limited by shares such as the Company and a company incorporated in the European Economic Area (the European Economic Area includes all member states of the European Union and Norway, Iceland and Liechtenstein), or if we are being merged with another Irish company, under the Companies Act, a shareholder (i) who voted against the special resolution approving the merger or (ii) of a company in which 90% of the shares are held by the other party to the merger, has the right to request that the company acquire its shares for cash at a price determined in accordance with the share exchange ratio set out in the merger agreement.

### **Disclosure of Interests in Shares**

Under the Companies Act, subject to certain limited exceptions, a person must notify the Company (but not the public) if, as a result of a transaction, such person will become interested in three percent or more of the Company's voting shares, or if as a result of a transaction a shareholder who was interested in more than three percent of its voting shares ceases to be so interested. Where any person is interested in more than three percent of the Company's voting shares, such person must notify the Company of any alteration of his or her interest that brings his or her total holding through the nearest whole percentage number, whether an increase or a reduction. The relevant percentage figure is calculated by reference to the aggregate nominal value of the voting shares in which the person is interested as a proportion of the entire nominal value of the Company's issued share capital (or any such class of share capital in issue). Where the percentage level of the person's interest does not amount to a whole percentage,

this figure may be rounded down to the next whole number. The Company must be notified within five business days of the transaction or alteration of the person's interests that gave rise to the notification requirement. If a person fails to comply with these notification requirements, such person's rights in respect of any of the Company's shares he or she holds will not be enforceable, either directly or indirectly. However, such person may apply to the court to have the rights attaching to such shares reinstated.

In addition to these disclosure requirements, the Company, under the Companies Act, may, by notice in writing, require a person whom the Company knows or has reasonable cause to believe to be, or at any time during the three years immediately preceding the date on which such notice is issued to have been, interested in shares comprised in the Company's relevant share capital to: (i) indicate whether or not it is the case; and (ii) where such person holds or has during that time held an interest in the Company's shares, to provide additional information, including the person's own past or present interests in the Company's shares. If the recipient of the notice fails to respond within the reasonable time period specified in the notice, the Company may apply to a court for an order directing that the affected shares be subject to certain restrictions, as prescribed by the Companies Act, as follows:

- any transfer of those shares or, in the case of unissued shares, any transfer of the right to be issued with shares and any issue of shares, shall be void;
- no voting rights shall be exercisable in respect of those shares;
- no further shares shall be issued in right of those shares or in pursuance of any offer made to the holder of those shares; and
- no payment shall be made of any sums due from the Company on those shares, whether in respect of capital or otherwise.

The court may also order that shares subject to any of these restrictions be sold with the restrictions terminating upon the completion of the sale.

In the event the Company is in an offer period pursuant to the Irish takeover rules, as defined below, accelerated disclosure provisions apply for persons holding an interest in the Company's securities of one percent or more.

#### **Anti-Takeover Provisions**

##### ***Irish Takeover Rules and Substantial Acquisition Rules***

A transaction in which a third party seeks to acquire 30% or more of the voting rights of the Company and certain other acquisitions of the Company's securities are governed by the Irish Takeover Panel Act 1997 and the Irish Takeover Rules 2022 made thereunder, which are referred to herein as the "Irish takeover rules," and are regulated by the Irish Takeover Panel. The "General Principles" of the Irish takeover rules and certain important aspects of the Irish takeover rules are described below.

## ***General Principles***

The Irish takeover rules are built on the following General Principles which will apply to any transaction regulated by the Irish Takeover Panel:

- in the event of an offer, all holders of securities of the target company must be afforded equivalent treatment and, if a person acquires control of a company, the other holders of securities must be protected;
- the holders of securities in the target company must have sufficient time and information to enable them to reach a properly informed decision on the offer; where it advises the holders of securities, the board of directors of the target company must give its views on the effects of the implementation of the offer on employment, employment conditions and the locations of the target company's place of business;
- a target company's board of directors must act in the interests of the company as a whole and must not deny the holders of securities the opportunity to decide on the merits of the offer;
- false markets must not be created in the securities of the target company, the bidder or any other company concerned by the offer in such a way that the rise or fall of the prices of the securities becomes artificial and the normal functioning of the markets is distorted;
- a bidder can only announce an offer after ensuring that he or she can pay in full the consideration offered, if such is offered, and after taking all reasonable measures to secure the implementation of any other type of consideration;
- a target company may not be hindered in the conduct of its affairs longer than is reasonable by an offer for its securities (this is a recognition that an offer will disrupt the day-to-day running of a target company, particularly if the offer is hostile and the board of directors of the target company must direct its attention to resisting the offer); and
- an acquisition of securities (whether such acquisition is to be effected by one transaction or a series of transactions) shall take place only at an acceptable speed and shall be subject to adequate and timely disclosure. Specifically, the acquisition of 10% or more of the issued voting shares within a seven day period that would take a shareholder's holding to or above 15% of the issued voting shares (but less than 30%) is prohibited, subject to certain exemptions.

## ***Mandatory Bid***

Under certain circumstances, a person who acquires ordinary shares, or other of the Company's voting securities, may be required under the Irish takeover rules to make a mandatory cash offer for the remaining issued and outstanding voting securities at a price not less than the highest price paid for the securities by the acquiror, or any parties acting in concert with the acquiror, during the previous 12 months. This mandatory bid requirement is triggered if an acquisition of securities would increase the aggregate holding of an acquiror, including the holdings

of any parties acting in concert with the acquiror, to securities representing 30% or more of the voting rights in the Company, unless the Irish Takeover Panel otherwise consents. An acquisition of securities by a person holding, together with its concert parties, securities representing between 30% and 50% of the voting rights in the Company would also trigger the mandatory bid requirement if, after giving effect to the acquisition, the percentage of the voting rights held by that person (together with its concert parties) would increase by 0.05% within a 12-month period. Any person (excluding any parties acting in concert with the holder) holding securities representing more than 50% of the voting rights of a company is not subject to these mandatory offer requirements in purchasing additional securities.

#### ***Voluntary bid; Requirements to Make a Cash Offer and Minimum Price Requirements***

If a person makes a voluntary offer to acquire the issued and outstanding ordinary shares of the Company and the bidder acquired ordinary shares in the three-month period prior to the commencement of the offer period, the offer price must not be less than the highest price paid for ordinary shares by the bidder or its concert parties during that period. The Irish Takeover Panel has the power to extend the “look back” period to 12 months if the Irish Takeover Panel, taking into account the General Principles, believes it is appropriate to do so.

If the bidder or any of its concert parties has acquired more than 10% of the issued and outstanding ordinary shares (i) during the period of 12 months prior to the commencement of the offer period or (ii) at any time after the commencement of the offer period, the offer must be in cash (or accompanied by a full cash alternative) and the price per ordinary share must not be less than the highest price paid by the bidder or its concert parties during, in the case of (i), the 12-month period prior to the commencement of the offer period or, in the case of (ii), the offer period. The Irish Takeover Panel may apply this rule to a bidder who, together with its concert parties, has acquired less than 10% of the total ordinary shares in the 12-month period prior to the commencement of the offer period if the Irish Takeover Panel, taking into account the General Principles, considers it just and proper to do so.

An offer period will generally commence on the date of the first announcement of the offer or proposed offer. Where an offer period is commenced by the announcement of a possible offer, the potential offeror must, by no later than 42 days following the date of the possible offer announcement, either (i) announce a firm intention to make an offer for us in accordance with Rule 2.7 of the Irish takeover rules or (ii) announce that it does not intend to make such an offer, in which case the announcement will be treated as a statement to which Rule 2.8 of the Irish Takeover Rule applies. This deadline can be extended at our request with the consent of the Irish Takeover Panel in accordance with Rule 2.6(c) of the Irish takeover rules.

#### ***Substantial Acquisition Rules***

The Irish takeover rules also contain rules governing substantial acquisitions of shares and other voting securities which restrict the speed at which a person may increase his or her holding of shares and rights over shares to an aggregate of between 15% and 30% of the voting rights of the Company. Except in certain circumstances, an

acquisition or series of acquisitions of shares or rights over shares representing 10% or more of the voting rights of the Company is prohibited, if such acquisition(s), when aggregated with shares or rights already held, would result in the acquirer holding 15% or more but less than 30% of the voting rights of the Company and such acquisitions are made within a period of seven days. These rules also require accelerated disclosure of acquisitions of shares or rights over shares relating to such holdings.

### ***Frustrating Action***

Under the Irish takeover rules, the Company's board of directors is not permitted to take any action that might frustrate an offer for its shares once the Company's board of directors has received an approach that may lead to an offer or has reason to believe that such an offer is or may be imminent, subject to certain exceptions. Potentially frustrating actions such as (i) the issue of shares, options or convertible securities, (ii) material acquisitions or disposals, (iii) entering into contracts other than in the ordinary course of business or (iv) any action, other than seeking alternative offers, which may result in frustration of an offer, are prohibited during the course of an offer or at any earlier time during which the Company's board of directors has reason to believe an offer is or may be imminent. Exceptions to this prohibition are available where:

- the action is approved by the Company's shareholders at a general meeting; or
- the Irish Takeover Panel has given its consent, where:
- it is satisfied the action would not constitute frustrating action;
- the Company's shareholders holding more than 50% of the voting rights state in writing that they approve the proposed action and would vote in favor of it at a general meeting;
- the action is taken in accordance with a contract entered into prior to the announcement of the offer (or any earlier time at which the Company's board of directors considered the offer to be imminent); or
- the decision to take such action was made before the announcement of the offer and either has been at least partially implemented or is in the ordinary course of business.

### ***Other Provisions***

Certain other provisions of Irish law or the Company's Constitution may be considered to have anti-takeover effects, including advance notice requirements for director nominations and other shareholder proposals, as well those described under the following captions: "*—Capital Structure—Authorized Share Capital*" (regarding issuance of preferred shares), "*—Preemption Rights, Share Warrants and Share Options*," "*—Disclosure of Interests in Shares*" and "*—Corporate Governance*."

## Corporate Governance

The Company's Constitution delegates the day-to-day management of the Company to the board of directors. The Company's board of directors may then delegate the management of the Company to committees of the board of directors (consisting of one or more members of the board of directors) or executives; regardless, the Company's board of directors remains responsible, as a matter of Irish law, for the proper management of the affairs of the company. Committees may meet and adjourn as they determine proper. A vote at any committee meeting will be determined by a majority of votes of the members present.

The Company's board of directors has a standing audit committee, a compensation committee and a nominating and corporate governance committee, with each committee comprised solely of independent directors, as prescribed by The NASDAQ Global Select Market listing standards and SEC rules and regulations. The Company has adopted corporate governance policies, including a code of conduct and an insider trading policy, as well as an open door reporting policy and a comprehensive compliance program.

The Companies Act require a minimum of two directors. The Company's Constitution provides that the board may determine the size of the board from time to time.

The Company's board of directors is divided into three classes, designated Class I, Class II and Class III. The term of the Class I directors will expire on the date of the 2027 annual general meeting; the term of the Class II directors will expire on the date of the 2025 annual general meeting; and the term of the Class III directors will expire on the date of the 2026 annual general meeting. At each annual general meeting of shareholders, successors to the class of directors whose term expires at that annual general meeting are elected for a three-year term. In no case will any decrease in the number of directors shorten the term of any incumbent director. A director may hold office until the annual general meeting of the year in which his or her term expires and until his or her successor is elected and duly qualified, subject to his or her prior death, resignation, retirement, disqualification or removal from office.

Directors are elected by ordinary resolution at a general meeting. Irish law requires majority voting for the election of directors, which could result in the number of directors falling below the prescribed minimum number of directors due to the failure of nominees to be elected. Accordingly, the Company's Constitution provides that if, at any general meeting of shareholders, the number of directors is reduced below the minimum prescribed by the Constitution due to the failure of any person nominated to be a director to be elected, then, in such circumstances, the nominee or nominees who receive the highest number of votes in favor of election will be elected in order to maintain such prescribed minimum number of directors. Each director elected in this manner will remain a director (subject to the provisions of the Companies Act and the articles of association) only until the conclusion of the next annual general meeting unless he or she is reelected.

Under the Companies Act and notwithstanding anything contained in the Constitution or in any agreement between the Company and a director, the Company's shareholders may, by an ordinary resolution, remove a director from office before the expiration of his or her term at a meeting held on no less than 28 days' notice and at which the director is entitled to be heard. The power of removal is without prejudice to any claim for damages for breach of contract (e.g. employment contract) that the director may have against the Company in respect of his removal.

The Company's Constitution provides that the board of directors may fill any vacancy occurring on the board of directors. If the Company's board of directors fills a vacancy, the director's term expires at the next annual general meeting. A vacancy on the board of directors created by the removal of a director may be filled by the shareholders at the meeting at which such director is removed and, in the absence of such election or appointment, the remaining directors may fill the vacancy.

#### **Legal Name; Formation; Fiscal Year; Registered Office**

Jazz Pharmaceuticals Public Limited Company is the Company's current legal and commercial name. The Company was incorporated in Ireland on March 15, 2005 as a private limited company (registration number 399192) under the name Azur Pharma Limited. Azur Pharma Limited was re-registered as a public limited company named Azur Pharma Public Limited Company effective October 20, 2011, and was subsequently renamed Jazz Pharmaceuticals Public Limited Company on January 16, 2012. The Company's fiscal year ends on December 31st and its registered address is Fifth Floor, Waterloo Exchange, Waterloo Road, Dublin 4, Ireland D04 E5W7.

#### **Duration; Dissolution; Rights Upon Liquidation**

The Company's duration is unlimited. The Company may be dissolved and wound up at any time by way of a shareholders' voluntary winding up or a creditors' winding up. In the case of a shareholders' voluntary winding up, a special resolution of shareholders is required. The Company may also be dissolved by way of court order on the application of a creditor, or by the Companies Registration Office as an enforcement measure where it has failed to file certain returns.

The Company's Constitution provides that the ordinary shareholders are entitled to participate pro rata in a winding up, but their right to do so may be subject to the rights of any preferred shareholders to participate under the terms of any series or class of preferred shares.

#### **Certificated Shares**

Pursuant to the Companies Act, a shareholder is entitled to be issued a share certificate on request and subject to payment of a nominal fee.

## **No Sinking Fund**

Ordinary shares have no sinking fund provisions.

## **Stock Exchange Listing**

Ordinary shares are listed on The NASDAQ Global Select Market under the trading symbol "JAZZ." Ordinary shares are not currently intended to be listed on the Irish Stock Exchange.

## **Transfer and Registration of Shares**

The transfer agent and registrar for ordinary shares is Computershare Trust Company, N.A. Its address is 250 Royall Street, Canton, MA 02021. An affiliate of the transfer agent maintains the share register, registration in which is determinative of ownership of ordinary shares. A shareholder who holds shares beneficially is not the holder of record of such shares. Instead, the depository (for example, Cede & Co., as nominee for DTC) or other nominee is the holder of record of those shares. Accordingly, a transfer of shares from a person who holds such shares beneficially to a person who also holds such shares beneficially through a depository or other nominee will not be registered in the Company's official share register, as the depository or other nominee will remain the record holder of any such shares.

A written instrument of transfer is required under Irish law in order to register on the Company's official share register any transfer of shares (i) from a person who holds such shares directly to any other person, (ii) from a person who holds such shares beneficially but not directly to a person who holds such shares directly, or (iii) from a person who holds such shares beneficially to another person who holds such shares beneficially where the transfer involves a change in the depository or other nominee that is the record owner of the transferred shares. An instrument of transfer is also required for a shareholder who directly holds shares to transfer those shares into his or her own broker account (or vice versa). Such instruments of transfer may give rise to Irish stamp duty, which must be paid prior to registration of the transfer on the Company's official Irish share register. However, a shareholder who directly holds shares may transfer those shares into his or her own broker account (or vice versa) without giving rise to Irish stamp duty provided there is no change in the ultimate beneficial ownership of the shares as a result of the transfer and the transfer is not made in contemplation of a sale of the shares.

Any transfer of ordinary shares that is subject to Irish stamp duty will not be registered in the name of the buyer unless an instrument of transfer is duly stamped and provided to the transfer agent. The Company, in its absolute discretion and insofar as the Companies Act or any other applicable law permit, may, or may provide that any of its subsidiaries will, pay Irish stamp duty arising on a transfer of ordinary shares on behalf of the transferee of such ordinary shares. If stamp duty resulting from the transfer of ordinary shares which would otherwise be payable by the transferee is paid by the Company or any of its subsidiaries on behalf of the transferee, then in those circumstances, the Company will, on its behalf or on behalf of its subsidiary (as the case may be), be entitled to (i) seek reimbursement of the stamp duty from the transferee, (ii) set-off the stamp duty against any dividends payable

to the transferee of those ordinary shares and (iii) to claim a first and permanent lien on ordinary shares on which stamp duty has been paid by the Company or its subsidiary for the amount of stamp duty paid. The Company's lien shall extend to all dividends paid on those ordinary shares. Parties to a share transfer may assume that any stamp duty arising in respect of a transaction in ordinary shares has been paid unless one or both of such parties is otherwise notified.

The Company's Constitution delegates to the secretary or assistant secretary of the Company the authority, on behalf of the Company, to execute an instrument of transfer on behalf of a transferring party. Under the Company's Constitution, the directors can also authorize any person to execute an instrument of transfer on behalf of a transferring party in certain circumstances.

In order to help ensure that the official share register is regularly updated to reflect trading of ordinary shares occurring through normal electronic systems, the Company intends to regularly produce any required instruments of transfer in connection with any transactions for which stamp duty is paid (subject to the reimbursement and set-off rights described above). In the event that the Company notifies one or both of the parties to a share transfer that it believes stamp duty is required to be paid in connection with the transfer and that the Company will not pay the stamp duty, the parties may either themselves arrange for the execution of the required instrument of transfer (and may request a form of instrument of transfer from the Company for this purpose) or request that the Company execute an instrument of transfer on behalf of the transferring party. In either event, if the parties to the share transfer have the instrument of transfer duly stamped (to the extent required) and then provide it to the Company's transfer agent, the buyer will be registered as the legal owner of the relevant shares on the Company's official Irish share register (subject to the suspension right described below).

The directors may suspend registration of transfers from time to time, not exceeding 30 days in aggregate each year.

### **Irish Restrictions on Import and Export of Capital**

Except as indicated below, there are no restrictions on non-residents of Ireland dealing in Irish domestic securities, which includes ordinary shares of Irish companies. Except as indicated below, dividends and redemption proceeds also continue to be freely transferable to non-resident holders of such securities.

It is an offence under Irish law (pursuant to various statutory instruments) to transfer funds or make funds or economic resources available, directly or indirectly to any person or entity in contravention of Irish, EU or United Nations sanctions or to otherwise contravene Irish, EU or United Nations sanctions. Any transfer of, or payment in respect of, securities involving a person or entity that is currently the subject of Irish, EU or United Nations sanctions or any person or entity controlled by any of the foregoing, or any person acting on behalf of the foregoing, may be subject to restrictions pursuant to such sanctions as implemented into Irish law. The Financial Transfers Act, 1992, provides that the Irish Minister for Finance can make provision for the restriction of financial transfers

between Ireland and other countries and persons. Financial transfers are broadly defined and include all transfers that would be movements of capital or payments within the meaning of the treaties governing the member states of the European Union. The acquisition or disposal of interests in shares issued by an Irish incorporated company and associated payments falls within this definition. In addition, dividends or payments on redemption or purchase of shares and payments on a liquidation of an Irish incorporated company would fall within this definition. The Financial Transfers Act, 1992 and underlying EU regulations prohibit financial transfers with certain persons and entities listed in the EU Consolidated Financial Sanctions List and United Nations Security Council Consolidated List, without the prior permission of the Central Bank of Ireland.

Any transfer of, or payment in respect of, a share or interest in a share involving the government of any country that is currently the subject of United Nations sanctions, any person or body controlled by any of the foregoing, or by any person acting on behalf of the foregoing, may be subject to restrictions pursuant to such sanctions as implemented into Irish law.

# Sign-On Bonus Repayment Agreement

Name: Philip Johnson

In exchange for receiving a sign-on bonus offered to me by Jazz Pharmaceuticals, Inc. ("Jazz Pharmaceuticals") which is outlined in my Offer Package, I acknowledge and agree to the following Sign-On Bonus Repayment Agreement (the "Agreement"):

1) I understand and agree that the sign-on bonus to be provided to me by Jazz Pharmaceuticals is conditional upon my continued employment with Jazz Pharmaceuticals (or an affiliated entity) for a minimum of twenty-four (24) months from my start date. Because this bonus is being provided in consideration for my employment for twenty-four (24) months from my start date, all amounts expended by Jazz Pharmaceuticals pursuant to this Agreement, including but not limited to tax withholdings, constitute an advance to me. Half of the bonus amount will become earned and no longer subject to repayment only upon my completion of twelve (12) months of employment, and the second half of the bonus amount will become earned and no longer subject to repayment only upon my completion of twenty-four (24) months of employment.

2) I understand and agree that, if within twenty-four (24) months after my start date, either I resign my employment for any reason or I am terminated by Jazz Pharmaceuticals for Cause (as defined below), I am obligated to repay to Jazz Pharmaceuticals, no later than 30 days after my last day of employment (unless Jazz Pharmaceuticals agrees, in writing, to a different payment schedule), the amount of the bonus paid to me which has not been earned as of the employment termination date. If the resignation or termination occurs within twelve (12) months after my start date, I agree to repay the entire amount of the bonus. If the resignation or termination occurs more than twelve (12) months and less than twenty-four (24) months after my start date, I agree to repay one-half of the bonus amount. For purposes of this Agreement, Cause shall mean any of the following: (i) unsatisfactory job performance; (ii) violation of Jazz Pharmaceuticals policy or of any global policy applicable to me (including but not limited to the Jazz Global Code of Conduct); (iii) serious misconduct; (iv) breach of any of my contractual obligations; and (v) any other action or omission that is considered cause for termination of employment under applicable law.

3) I hereby authorize Jazz Pharmaceuticals to deduct from any salary or other amounts due me, the amount of all or any part of the sign-on bonus that I am obligated to repay to Jazz Pharmaceuticals, to the greatest extent permitted by applicable law.

4) I understand and agree to reimburse Jazz Pharmaceuticals for any and all reasonable costs incurred in enforcing this Agreement, including but not limited to attorneys' fees and court costs.

5) I understand and agree that this Agreement does not constitute a contract of employment or a guarantee of employment for any period of time. My employment is at-will at all times, which means that either I or Jazz Pharmaceuticals may terminate the employment relationship at any time, with or without cause, and with or without advance notice.

6) I understand that this Agreement represents the entire agreement between me and Jazz Pharmaceuticals with respect to my sign-on bonus and supersedes any other promises, representations or agreements concerning my sign-on bonus, whether written or oral. The terms of this Agreement may not be modified or waived unless such modification or waiver is agreed to in writing signed by me and an authorized representative of Jazz Pharmaceuticals. Nothing contained herein shall be held to alter, vary, or affect any of the terms or conditions of my employment with Jazz Pharmaceuticals. The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of any other provision of this Agreement, which shall remain in full force and effect.

**Signature** : X /s/ Philip Johnson

**Date:**

25 February 2024

**JAZZ PHARMACEUTICALS PLC**  
**INSIDER TRADING POLICY**

During the course of your service with **Jazz Pharmaceuticals plc**, a company formed under the laws of Ireland (together with its subsidiaries, the “**Company**”), you may receive important information that is not yet publicly available, *i.e.*, not disclosed to the public in a press release or filing with the Securities and Exchange Commission (the “**SEC**”), about the Company or about other companies with which the Company conducts business, as applicable (“**material non-public information**”). Because of your access to this information, you may be in a position to profit financially by buying or selling or in some other way dealing in the Company’s securities or securities of another publicly-traded company, or to disclose such information to a third party who profits from such a transaction (a “**tippee**”).

The Board of Directors of Jazz Pharmaceuticals plc has adopted this Insider Trading Policy (the “**Policy**”) to promote compliance with federal, state and foreign securities laws that prohibit certain persons who are aware of material non-public information about a company from: (i) trading in securities of that company; or (ii) providing material non-public information to other persons who may trade on the basis of that information. This Policy applies to all members of the Board of Directors of Jazz Pharmaceuticals plc and employees of the Company, as well as certain consultants designated by the Company (collectively, “**Covered Persons**”), and the other persons subject to this Policy as described below under “Additional Persons Subject to this Policy.”

**Background**

For anyone to use inside information to gain personal benefit, or to pass on, or “tip,” inside information to someone who does so, is illegal. There is no “de minimis” test. Use of material non-public information to gain personal benefit and tipping are as illegal with respect to a few shares of stock as they are with respect to a large number of shares. You can be held liable both for your own transactions and for transactions effected by a tippee, or even a tippee of a tippee. Furthermore, it is important that the **appearance** as well as the fact of insider trading in securities be avoided. There are no exceptions to this Policy, except for certain transactions directly with the Company (as more fully described elsewhere in this Policy). However, the subsequent sale or other disposition of ordinary shares acquired in transactions with the Company **are** fully subject to these restrictions.

As a practical matter, it is sometimes difficult to determine whether you possess material non-public information. The key to determining whether non-public information you possess about a public company (which may be the Company or a company with which the Company does business) is “material non-public information” is whether dissemination of the information would be likely to affect the market price of the company’s stock or would be likely to be considered important, or “material,” by investors who are considering trading in that company’s securities. Certainly, if the information makes **you** want to trade, it would probably have the same effect on others. Both positive and negative information can be material. If you are aware of “material non-public information,” you may not trade in the applicable company’s securities, advise anyone else to do so or communicate the information to anyone else until you know that the information has

been disseminated to the public. This means that, in some circumstances, you may need to forego planned trading in a company's securities even though you planned to execute a transaction prior to learning of material non-public information and even though you believe that you may suffer an economic loss or sacrifice an anticipated profit by foregoing such transaction.

It is important to note that the prohibition against insider trading is absolute and applies even if the decision to trade is not "based" on any "material non-public information;" all that matters is whether you are *aware* of any "material non-public information" at the time of a transaction. It is also important to note that the U.S. federal securities laws do not recognize any mitigating circumstances to insider trading. **Accordingly, if you are aware of any "material non- public information" at the time of a planned transaction, you must wait until the information has been disseminated to the public in order to proceed with the transaction, subject only to the exceptions set forth in this Policy.**

There is no bright-line standard for assessing materiality; rather, materiality is based on an assessment of all of the facts and circumstances, and is often evaluated by relevant enforcement authorities with the benefit of hindsight. Although by no means an all-inclusive list, information about any of the following items may be considered to be "material non-public information" until it is publicly disseminated within the meaning of this Policy:

- financial results or forecasts;
- new products or product candidates;
- status of product or product candidate development or regulatory approvals;
- clinical data relating to products or product candidates;
- proposals, plans or agreements, even if preliminary in nature, involving mergers, acquisitions, divestitures, recapitalization, strategic alliances, licensing arrangements, or purchases or sales of substantial assets;
- public or private sales of debt or equity securities;
- events regarding the Company's securities (e.g., defaults on any senior securities, calls of securities for redemption, repurchase plans, declaration of stock splits or dividends, changes to the rights of security holders);
- significant scientific, clinical or regulatory developments or results;
- significant intellectual property developments;
- major contract awards or cancellations;
- achievement of development or commercialization milestones;
- changes in control, in senior management or in the board of directors;
- employee layoffs;
- a disruption in operations or breach or unauthorized access of property or assets, including facilities and information technology infrastructure;
- possible tender offers or proxy fights;
- accounting restatements;
- significant writeoffs;

- litigation, whether pending or threatened, resolution of such litigation and any positive or negative developments thereof, governmental investigations, criminal actions or indictments, civil actions and any collateral consequences;
- impending bankruptcy;
- licensees;
- timelines for pre-clinical studies or clinical trials;
- auditor notification that the Company may no longer rely on an auditor's audit report;
- levels of product sales and changes in price or discount policies;
- collaborations or corporate partnering relationships; and
- notice of issuance or denial of patents.

For information to be considered publicly disseminated, it must be widely disclosed through a press release, a properly noticed and publicly available webcast or conference call or a filing with the SEC, and a meaningful amount of time must have passed to allow the information to be fully disseminated. Information would not be considered publicly disseminated if it is available only to the Company's employees, or if it is only available to a select group of persons outside the Company. Generally, information about the Company will be considered publicly disseminated on the second trading day after the date on which the Company widely discloses the information through one of the means described above. For example, if the Company issues a press release on a Tuesday, then the information in the press release would be considered publicly disseminated as of the opening of trading on Thursday.

#### **Statement of Policy**

It is the policy of the Company that no Covered Person (or any other person subject to this Policy) who is aware of "material non-public information" about the Company may, directly, or indirectly through family members or other persons or entities:

1. Engage in transactions in Company securities, except as otherwise specified in this Policy;
2. Recommend to another person or entity the purchase or sale of any Company securities;
3. Disclose the "material non-public information" to persons within the Company whose jobs do not require them to have that information, or outside of the Company to other persons, unless any such disclosure is consistent with the Company's practices regarding the protection or authorized external disclosure of information regarding the Company; or
4. Assist anyone engaged in the above activities.

In addition, it is the policy of the Company that no Covered Person who, in the course of his or her relationship with the Company, learns of "material non-public information" about a company with which the Company does business may take any of the above actions with respect

to that company's securities until the information becomes public or is no longer material to the company.

#### **Transactions Subject to this Policy**

This Policy applies to all transactions in securities issued by the Company, as well as derivative securities that are not issued by the Company, such as exchange-traded put or call options or swaps relating to the Company's securities. Accordingly, for purposes of this Policy, the terms "*trade*," "*trading*" and "*transactions*" include not only purchases and sales of the Company's securities in the public market but also any other purchases, sales, transfers, gifts or other acquisitions and dispositions of ordinary or preference equity, options, warrants and other securities (including debt securities) and other arrangements or transactions that affect economic exposure to changes in the prices of these securities.

#### **Additional Persons Subject to this Policy**

This Policy applies to any family members who reside with you (including a spouse, a child, a child away at college, stepchildren, grandchildren, parents, stepparents, grandparents, siblings and in-laws), anyone else who lives in your household, and any family members who do not live in your household but whose transactions in the Company's securities are directed by a Covered Person or are subject to a Covered Person's influence or control, such as parents or children who consult with you before they trade in any Company securities (collectively referred to as "*Family Members*"). You are responsible for the transactions of these other persons and therefore should make them aware of the need to confer with you before they trade in Company securities, and you should treat all such transactions for the purposes of this Policy and applicable securities laws as if the transactions were for your own account. This Policy does not, however, apply to personal securities transactions of Family Members where the purchase or sale decision is made by a third party not controlled by, influenced by or related to you or your Family Members.

This Policy also applies to any entities that you influence or control, including any corporations, partnerships or trusts (collectively referred to as "*Controlled Entities*"), and transactions by these Controlled Entities should be treated for the purposes of this Policy and applicable securities laws as if they were for your own account. Family Members and Controlled Entities are sometimes referred to together in this Policy as "*Related Persons*".

#### **Quarterly Trading Windows**

Because "Restricted Insiders" (as defined below) are most likely to possess material non-public information about the Company, we ask them to do more than refrain from insider trading. In this regard, to minimize even the appearance of insider trading among our Restricted Insiders, the Company has established quarterly "trading windows" as being the *only* times that our Restricted Insiders and their Related Persons are permitted to trade in the Company's securities. This means that, except as described in this Policy, Restricted Insiders and their Related Persons may trade in the Company's securities *only* during an open "window period" commencing generally on the second trading day after the date on which the Company publicly releases its annual or quarterly financial results or any "material non-public information" and ending on the day that is three (3) weeks before the end of the next quarter. This "window" may be opened later,

be closed earlier or may not open if, in the judgment of the Company's Chief Legal Officer or his or her designee, there exists undisclosed information that would make trades in Company securities by Restricted Insiders inappropriate. Of course, even during an open window period, Restricted Insiders may not (unless an exception in this Policy applies) conduct any trades in the Company's securities while aware of material non-public information.

Any Restricted Insider who believes that special circumstances require him or her to trade outside of an open window period should consult with the Company's Chief Legal Officer or, in his or her absence, another member of the Company's legal department. Permission to trade outside of an open window period will be granted only where the circumstances are extenuating, the person requesting to trade is not in fact aware of any material non-public information, and there appears to be no significant risk that the trade may subsequently be questioned.

For purposes of this Policy, "**Restricted Insiders**" are (i) the executive officers of the Company (as defined under U.S. securities laws and identified as such for purposes of Section 16 of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), by the Company's Board of Directors), (ii) members of the Board of Directors of the Company and (iii) such other employees and designated consultants of the Company and its subsidiaries and other persons as the Company's Chief Legal Officer or his or her designee may designate from time to time because of such employee's access to sensitive Company information.

### **Event-Specific Trading Suspensions**

The Company may require the suspension of trading by any or all Covered Persons because of developments known to the Company and not yet disclosed to the public. Such decisions may be announced by the Company's Chief Legal Officer or his or her designee. In the event that you have been designated as a person who is subject to a trading suspension, you and your Related Persons are prohibited from engaging in **any** trading of the Company's securities during the period that the trading suspension remains in effect (and regardless of whether you are aware of material non-public information), and you must not disclose to others the fact of such trading suspension.

### **Special and Prohibited Transactions**

***Inherently Speculative Transactions.*** Under this Policy, Covered Persons are prohibited from engaging at any time in speculative trading activities with respect to the Company's securities, including engaging in any short sales, transactions in derivative securities such as put or call options, or other inherently speculative transactions with respect to the Company's securities. Stock options and other awards granted under the Company's equity incentive plans are not deemed to be derivative securities covered by this restriction.

***Hedging Transactions.*** Hedging or monetization transactions can be accomplished through a number of possible mechanisms, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds. Such hedging transactions may permit a Covered Person to continue to own the Company's securities, but without the full risks and rewards of ownership. When that occurs, such Covered Person may no longer have the same objectives as the Company's other shareholders. Therefore, Covered Persons are prohibited

from engaging in any such transactions. Notwithstanding the foregoing, Covered Persons may engage in general portfolio diversification transactions or investments in broad-based index funds.

***Margin Accounts and Pledged Securities.*** Securities held in a margin account as collateral for a margin loan may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a time when the pledgor is aware of material non-public information or otherwise is not permitted to trade in Company securities, Covered Persons are prohibited from holding Company securities in a margin account or otherwise pledging Company securities as collateral for a loan.

***Standing and Limit Orders.*** Standing and limit orders (except standing and limit orders under approved Rule 10b5-1 Plans, as discussed below) create heightened risks for insider trading violations similar to the use of margin accounts. There is no control over the timing of purchases or sales that result from standing instructions to a broker, and as a result the broker could execute a transaction when a Company employee, director or designated consultant is in possession of insider information. The Company therefore discourages placing standing or limit orders on the Company's securities. If a person subject to this policy determines that they must use a standing order or limit order (other than under an approved Rule 10b5-1 Plan as discussed below), the order should be limited to short duration and the person using such standing order or limit order is required to cancel such instructions immediately in the event restrictions are imposed on their ability to trade pursuant to the "Quarterly Trading Windows" and "Event-Specific Trading Suspensions" provisions above.

#### **Exceptions to this Policy**

***Option Exercises; Tax Withholding.*** This Policy does not apply to the exercise of an employee stock option acquired pursuant to the Company's equity incentive plans for cash or, where permitted under the option, by a net exercise transaction with the Company. This Policy also does not apply to the exercise of a Company-permitted tax withholding right pursuant to which a person has elected to have the Company withhold ordinary shares subject to an option to satisfy tax withholding requirements. This Policy does apply, however, to any sale of ordinary shares as part of a broker-assisted cashless exercise of an option, or any other market sale for the purpose of generating the cash needed to pay the exercise price of an option or to pay taxes, or for any other purpose.

***Stock Vesting; Tax Withholding.*** This Policy does not apply to the vesting of restricted stock, restricted stock units or similar securities acquired pursuant to the Company's equity incentive plans, or the exercise of a Company-permitted tax withholding right pursuant to which you elect to have the Company withhold shares of stock to satisfy tax withholding requirements upon the vesting of any restricted stock, restricted stock unit or similar security. The Policy does apply, however, to any market sale of Company ordinary shares in connection with the vesting or exercise of such securities (or otherwise) whether or not for the purpose of generating the cash needed to pay the exercise price or pay taxes.

**ESPP.** This Policy does not apply to purchases of Company securities in the Company's employee stock purchase plan ("**ESPP**") resulting from your periodic contribution of money to the plan pursuant to the election you made at the time of your enrollment in the plan. This Policy also does not apply to purchases of Company securities resulting from lump sum contributions to the ESPP, provided that you elected to participate by lump sum payment at the beginning of the applicable enrollment period. This Policy does apply, however, to your sales of Company ordinary shares purchased pursuant to the ESPP.

**Rule 10b5-1 Trading Plans.** To the extent permissible under applicable laws, purchases or sales of the Company's securities made pursuant to, and in compliance with, a written plan (a "**Rule 10b5-1 Plan**") established by a Covered Person eligible to establish a Rule 10b5-1 Plan under Company policy and that meets the requirements of Rule 10b5-1 under the Exchange Act, may be made provided that (i) the Rule 10b5-1 Plan was established in good faith, in compliance with the requirements of Rule 10b5-1 and other applicable laws, at the time when such individual was not in possession of material non-public information about the Company and its subsidiaries and the Company had not imposed any trading suspension, (ii) the Rule 10b5-1 Plan was reviewed and approved in advance by the Company's Chief Legal Officer or his or her designee prior to establishment, solely to confirm compliance with this Policy, other applicable Company policies and applicable laws, and (iii) the Rule 10b5-1 Plan allows for the cancellation of a transaction and/or suspension of such Rule 10b5-1 Plan upon notice and request by the Company's Chief Legal Officer or his or her designee to the individual if any proposed trade (a) fails to comply with applicable laws (i.e., exceeding the number of shares that may be sold under Rule 144 of the Securities Act of 1933, as amended) or (b) would create material adverse consequences for the Company and its subsidiaries. The Company's Chief Legal Officer shall review and approve in advance any amendments to the Rule 10b5-1 Plan or the termination of the Rule 10b5-1 Plan, and any amendments or terminations of a Rule 10b5-1 Plan must be in accordance with the requirements of Rule 10b5-1 under the Exchange Act and applicable Company policies.

**Other Exceptions.** Any other purchase of Company securities from the Company or sales of Company securities to the Company are not subject to this Policy. Further, transactions in mutual funds that are invested in Company securities are not transactions subject to this Policy.

#### **Pre-Clearance and Advance Notice of Transactions**

In addition to the other requirements of this Policy, Restricted Insiders may not engage in any transaction in the Company's securities, including any purchase or sale in the open market, or other transfer of beneficial ownership (except stock option exercises and transactions effected pursuant to established Rule 10b5-1 Plans that require advance notice and review as described under "Exceptions to this Policy" above, and ESPP purchases) without first obtaining pre-clearance of the transaction from the Company's Chief Legal Officer or, in his or her absence, another member of the Company's legal department, at least one business day in advance of the proposed transaction. The Company's Chief Legal Officer or, in his or her absence, another member of the Company's legal department, will then determine whether the transaction may proceed and, if so, will assist in complying with any applicable reporting requirements under Section 16(a) of the Exchange Act. Pre-cleared transactions not completed within two trading days of clearance require new pre-clearance under the provisions of this paragraph. The Company may, at its discretion, shorten such period of time. Advance notice of an intent to exercise an

outstanding stock option shall be given to the Company's Chief Legal Officer or, in his or her absence, another member of the Company's legal department. To the extent possible, advance notice of upcoming transactions effected pursuant to established Rule 10b5-1 Plans shall be given to the Company's Chief Legal Officer or, in his or her absence, another member of the Company's legal department. Upon the completion of any transaction, the Restricted Insider must immediately (but in no event later than the same day) notify the Compliance Coordinator in accordance with the Company's Section 16 Compliance Program so that the Company may assist in any applicable Section 16 reporting obligations.

#### **Short-Swing Trading, Control Stock and Section 16 Reports**

Executive officers and directors subject to the reporting obligations under Section 16 of the Exchange Act should take care not to violate the prohibition on short-swing trading (within the meaning of Section 16(b) of the Exchange Act) and the restrictions on sales by control persons (under Rule 144), and should file all appropriate Section 16(a) reports (Forms 3, 4 and 5), all of which have been enumerated and described in a separate Section 16 Compliance Memorandum.

#### **Prohibition of Trading During Pension Fund Blackouts**

In accordance with Regulation BTR under the Exchange Act, no director or executive officer of the Company shall, directly or indirectly, purchase, sell or otherwise acquire or transfer any equity security of the Company (other than an exempt security) during any "blackout period" (as defined in Regulation BTR) with respect to such equity security, if such director or executive officer acquires or previously acquired such equity security in connection with his or her service or employment as a director or executive officer. This prohibition shall not apply to any transactions that are specifically exempted from Section 306(a)(1) of the Sarbanes-Oxley Act of 2002 (as set forth in Regulation BTR), including but not limited to, purchases or sales of the Company's securities made pursuant to, and in compliance with, a Rule 10b5-1 Plan; compensatory grants or awards of equity securities pursuant to a plan that, by its terms, permits executive officers and directors to receive automatic grants or awards and specifies the terms of the grants and awards; or by will or the laws of descent or pursuant to a domestic relations order. The Company shall timely notify each director and executive officer of any blackout periods in accordance with the provisions of Regulation BTR. Because Regulation BTR is very complex, no director or executive officer of the Company should engage in any transactions in its securities, even if believed to be exempt from Regulation BTR, without first consulting with the Chief Legal Officer.

#### **Policy Duration**

This Policy continues to apply to your transactions in the Company's securities even after your service with the Company has terminated. If you are in possession of material non-public information when your service terminates, you may not trade in the Company's securities until the information has become public or is no longer material. Further, if you leave the Company during a period in which you are suspended from trading under this Policy, then you may not trade the Company's securities or the securities of other applicable companies until the trading suspension period has ended.

### **Individual Responsibility**

Covered Persons subject to this Policy have ethical and legal obligations to maintain the confidentiality of information about the Company and to not engage in transactions in Company securities while aware of material non-public information. Each individual is responsible for making sure that he or she complies with this Policy, and for taking reasonable steps to ensure that any Family Member or Controlled Entity whose transactions are subject to this Policy also complies with this Policy. In all cases, the responsibility for determining whether an individual is aware of material non-public information rests with that individual, and any action on the part of the Company, or any officer or other employee or director of the Company, pursuant to this Policy (or otherwise), does not in any way constitute legal advice or insulate an individual from liability under applicable securities laws. You could be subject to severe legal penalties and disciplinary action by the Company for any conduct prohibited by this policy or applicable securities laws. See “Violations” below.

### **Violations**

Anyone who effects transactions in the Company’s securities or the securities of other public companies engaged in business transactions with the Company (or provides information to enable others to do so) on the basis of material non-public information is subject to both civil liability and criminal penalties, as well as disciplinary action by the Company. Please note that the Company intends to comply with all requests from the SEC, the NASDAQ Stock Market LLC, FINRA and other agencies with respect to information related to insider trading investigations. Any Covered Person who has questions about these matters should speak with his or her own attorney or with the Company’s Chief Legal Officer.

Any employee, officer or director who knows of or suspects a violation of this Policy is encouraged to report the violation immediately through the procedures set out in the Jazz Pharmaceuticals plc Code of Conduct and any related information regarding the compliance reporting system provided to employees.

### **Amendments**

The Company is committed to continuously reviewing and updating its policies and procedures. The Company therefore reserves the right to amend, alter or terminate this policy at any time and for any reason. A current copy of the Company’s policies regarding insider trading may be obtained on JazzNet.

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*Amended and restated by the Board of Directors of Jazz Pharmaceuticals plc on 4 May 2023.*

**Subsidiaries of the Registrant**

<b>Name</b>	<b>State/Jurisdiction of Incorporation</b>
Jazz Pharmaceuticals Ireland Limited	Ireland
Jazz Financing I DAC	Ireland
Jazz Pharmaceuticals Operations UK Limited	United Kingdom
Jazz Pharmaceuticals, Inc.	Delaware
Celator Pharmaceuticals Inc.	Delaware
Jazz Pharmaceuticals Research UK Limited	United Kingdom
Gentium S.r.l.	Italy
Jazz Pharmaceuticals UK Holdings Limited	United Kingdom
Jazz Securities DAC	Ireland
Jazz Financing Holdings Limited	Ireland
Jazz Financing Lux S.à.r.l	Luxembourg
Jazz Pharmaceuticals International Limited	Ireland
Jazz Investments Europe Limited	Malta
Jazz Capital Limited	Ireland
Jazz Pharmaceuticals UK Limited	United Kingdom
GW Pharmaceuticals Limited	United Kingdom

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the registration statements (No. 333-179075, No. 333-186886, No. 333-194131, No. 333-202269, No. 333-209767, No. 333-216338, No. 333-224757, No. 333-229889, No. 333-236636, No. 333-249807, No. 333-253417, No. 333-255895 and No. 333-263195) on Form S-8 of our reports dated February 26, 2025, with respect to the consolidated financial statements of Jazz Pharmaceuticals plc and financial statement schedule at Item 15(a)2 and the effectiveness of internal control over financial reporting.

/s/ KPMG

Dublin, Ireland  
February 26, 2025





**CERTIFICATION<sup>(1)</sup>**

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 Philip L. Johnson, Executive Vice President and Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company’s Annual Report on Form 10-K for the period ended December 31, 2024, 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: February 26, 2025

/s/ Bruce C. Cozadd

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**Bruce C. Cozadd**

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

/s/ Philip L. Johnson

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**Philip L. Johnson**

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

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(1) This certification accompanies the Annual Report on Form 10-K 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-K), 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.