Jazz Pharmaceuticals Announces First Quarter 2023 Financial Results and Affirms 2023 Financial Guidance

May 10, 2023

Focus on commercial execution drove 1Q23 total revenues of $892.8 million
Continued adoption of Xywav®; net product sales increased 49% 1Q23 compared to 1Q22
Confident in blockbuster potential of Epidiolex®; net product sales increased 20% 1Q23 compared to 1Q22
Strong Rylaze® demand drove 58% increase in net product sales 1Q23 compared to 1Q22
Enhanced pipeline positioned to deliver at least three late-stage data readouts by the end of 2024

DUBLIN, May 10, 2023 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced financial results for the first quarter of 2023, affirmed 2023 financial guidance and provided business updates.

"This quarter, we once again delivered strong commercial results, advanced our efforts to unlock the tremendous potential of our pipeline and built on our record of driving operational excellence. On the commercial front, key products launched over the past several years are demonstrating impressive and durable performance with *Xywav* annualizing at more than $1 billion and our oncology therapeutic area approaching $1 billion in annual revenue, driven by *Rylaze* and Zepzelca®. Adoption of low-sodium *Xywav* continues to grow across both narcolepsy and idiopathic hypersomnia (IH), and we expect *Xywav* to remain the oxybate of choice in 2023. We remain confident in the blockbuster potential of *Epidiolex*/Epidyolex® and its significant additional growth opportunities, and we look forward to continued strong in-person engagement with customers globally," said Bruce Cozadd, chairman and chief executive officer of Jazz Pharmaceuticals. "Our strong execution and robust pipeline position us well to achieve Vision 2025 and create meaningful value for our shareholders."

"Our enhanced pipeline is positioned to deliver at least three late-stage data readouts by the end of 2024, including JZP150 in post-traumatic stress disorder (PTSD), suvecaltamide in essential tremor (ET) and zanidatamab in first-line gastroesophageal adenocarcinoma (1L GEA)," said Rob Iannone, M.D., M.S.C.E., executive vice president, global head of research and development of Jazz Pharmaceuticals. "These late-stage trials are exploring new therapies with the potential to transform the lives of patients affected by diseases where substantial unmet medical need remains."

Key Highlights

- Continued confidence that low-sodium *Xywav* will remain the oxybate of choice in 2023; already annualizing at more than $1 billion.
- *Epidiolex/Epidyolex* continues to grow year-over-year with an expanding global prescriber base.
- Strong *Rylaze* demand drove net product sales of $85.9 million in 1Q23.
- Pipeline positioned to deliver at least three late-stage data readouts by the end of 2024, including JZP150 in PTSD, suvecaltamide in ET and zanidatamab in 1L GEA.
- The Company will host a KOL investor webcast to review the HERIZON-BTC-01 trial data, which will be presented at the 2023 ASCO Annual Meeting.
- 1Q23 total revenues increased 10% to $892.8 million compared to 1Q22.
- On track to achieve full year revenue expectations; full year financial guidance affirmed.

Business Updates

Key Commercial Products

Oxybate (Xywav and Xyrem®):

- Total revenues for the combined oxybate business, including royalties from a high-sodium oxybate authorized generic (AG) in 1Q23, increased 6% to $458.0 million in 1Q23 compared to the same period in 2022.
- Average active Jazz oxybate patients on therapy was approximately 17,400 in 1Q23, an increase of 5% compared to the same period in 2022.

Xywav (calcium, magnesium, potassium, and sodium oxybates) oral solution:

- *Xywav* net product sales increased 49% to $277.8 million in 1Q23 compared to the same period in 2022.
- *Xywav* is the Company's largest product by net product sales, annualizing at more than $1 billion, as a result of continued adoption in both narcolepsy and IH.
- There were approximately 11,050 active *Xywav* patients exiting 1Q23.

Xywav for Narcolepsy:

- There were approximately 9,050 narcolepsy patients taking *Xywav* exiting 1Q23.
- The benefits of reducing sodium intake resonate with patients and prescribers as the large majority of new-to-oxybate narcolepsy patients continue to be prescribed *Xywav*.
- FDA continues to recognize seven years of Orphan Drug Exclusivity (ODE), through July 2027, for *Xywav* in narcolepsy. FDA published its summary of clinical superiority findings stating that "*Xywav* is clinically superior to *Xyrem* by means of greater safety because *Xywav* provides a greatly reduced chronic sodium burden compared to *Xyrem*." Further, FDA 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." For clarity, the authorized generics of *Xyrem* contain the exact same drug product as branded *Xyrem*.
- 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 is a branded, fixed-dose, high-sodium oxybate that 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.

Xywav for Idiopathic Hypersomnia (IH):

- There were approximately 2,000 IH patients taking *Xywav* exiting 1Q23.
- Recent Jazz survey of sleep specialists indicates 70% anticipate increasing their prescribing of *Xywav* for IH over the next six months.
- *Xywav* is the first and only treatment approved by FDA to treat the full condition of IH.
- FDA recognized ODE for IH extending regulatory exclusivity to August 2028.

Xyrem (sodium oxybate) oral solution:

- *Xyrem* net product sales decreased 28% to $178.1 million in 1Q23 compared to the same period in 2022, reflecting the continued adoption of *Xywav* by patients with narcolepsy and the launch of a high-sodium oxybate AG in January 2023.
- Royalties from high-sodium oxybate AG were $2.1 million in 1Q23. Due to the royalty structures within the AG agreements, we expect the royalties from AG to be significantly higher in the second half of 2023 relative to the first half.

Epidiolex/Epidyolex (cannabidiol):

- *Epidiolex/Epidyolex* net product sales increased 20% to $188.9 million in 1Q23 compared to the same period in 2022.
- A pivotal Phase 3 trial of *Epidyolex* for Dravet syndrome, Lennox-Gastaut syndrome and tuberous sclerosis complex in Japan is enrolling patients.
- *Epidiolex/Epidyolex* global prescriber base is increasing with multiple launches expected outside of the U.S. this year.
- Additional *Epidiolex* growth opportunities underscored by BECOME survey's caregiver reported outcomes beyond seizure control, and compelling data for use of *Epidiolex* in combination with clobazam.
- *Epidyolex* is launched and reimbursed in all five key European markets: United Kingdom, Germany, Italy, Spain and France.

Rylaze (asparaginase *erwinia chrysanthemi* (recombinant)-rywn):

- *Rylaze* net product sales increased 58% to $85.9 million in 1Q23 compared to the same period in 2022.
- Continued strong demand for *Rylaze* reflects the significant unmet patient need for a high-quality, reliable supply of *Erwinia* asparaginase for patients with acute lymphoblastic leukemia.
- In May 2022, the Company completed the Marketing Authorization Application submission to European Medicines Agency for a Monday/Wednesday/Friday dosing schedule and intramuscular and intravenous administration for JZP458 (approved as *Rylaze* in the U.S.) with potential for approval in 2023.
- The Company is also continuing to evaluate patient need in other geographies.

Zepzelca (lurbinectedin):

- *Zepzelca* net product sales increased 13% to $67.2 million in 1Q23 compared to the same period in 2022.
- *Zepzelca* is the treatment of choice in second-line (2L) small cell lung cancer (SCLC) setting.
- *Zepzelca* development program highlights:
    - The EMERGE-201 Phase 2 basket trial evaluating *Zepzelca* as monotherapy in select relapsed/refractory solid tumors is ongoing.
    - Phase 3 trial in partnership with F. Hoffmann-La Roche Ltd (Roche) to evaluate 1L use of *Zepzelca* in combination with Tecentriq® (atezolizumab), compared to Tecentriq alone, as maintenance therapy in patients with extensive-stage SCLC after induction chemotherapy is ongoing. The Company expects complete enrollment in the trial by the end of 2023.
    - The Company's partner, PharmaMar, is conducting the Phase 3 confirmatory trial, LAGOON, in 2L SCLC. If positive, this trial could confirm the benefit of *Zepzelca* in the treatment of SCLC when patients progress following 1L treatment with a platinum-based regimen.

Key Pipeline Highlights

Zanidatamab:

- Zanidatamab is a bispecific antibody that can simultaneously bind two non-overlapping epitopes of HER2, known as biparatopic binding. This unique design results in multiple mechanisms of action including dual HER2 signal blockade, increased binding and removal of HER2 protein from the cell surface, and potent effector function leading to encouraging antitumor activity in patients.
- Initial focus is in biliary tract cancers (BTC) and GEA with potential to transform the current standard of care in multiple HER2-expressing cancers.
- Positive top-line data from the pivotal HERIZON-BTC-01 clinical trial has the potential to support regulatory submissions for zanidatamab as a monotherapy in patients with previously treated HER2-amplifed and expressing BTC.
- Data from the HERIZON-BTC-01 clinical trial will be presented at the 2023 ASCO Annual Meeting on Friday, June 2, 2023; the Company will host an investor webcast with Dr. Shubham Pant, M.D., MBBS, Professor in the Department of Gastrointestinal Medical Oncology with a joint appointment in the Department of the Investigational Cancer Therapeutics at The University of Texas MD Anderson Cancer Center, to review the BTC data.
- In January 2023, the Company and Zymeworks announced the first overall survival data of 84% at 18 months from a Phase 2 trial of zanidatamab in combination with chemotherapy in 1L patients with HER2-expressing metastatic GEA.
- The pivotal trial, HERIZON-GEA-01, evaluating zanidatamab in 1L GEA is ongoing and top-line data are expected in 2024.

JZP150:

- JZP150, a selective fatty acid amide hydrolase, or FAAH, inhibitor, is in clinical development for the potential treatment of PTSD.
- Patient enrollment is ongoing in a Phase 2 trial and top-line data readout is anticipated in late 2023.
- The Company received Fast Track Designation for JZP150 development in PTSD from FDA, underscoring the significant unmet medical needs of patients.

Suvecaltamide (JZP385):

- Suvecaltamide, a highly selective and state dependent modulator of T-type calcium channels, is in clinical development for the treatment of ET and Parkinson's disease tremor.
- Patient enrollment is ongoing in the Phase 2b ET trial and top-line data readout is anticipated in 1H24.
- A Phase 2 trial in patients with Parkinson's disease tremor is ongoing.

JZP441:

- JZP441, is a potent, highly selective oral orexin-2 receptor agonist designed to activate orexin signaling with the potential to be applicable in the treatment of narcolepsy, IH and other sleep disorders.
- A Phase 1 development program to evaluate safety, tolerability, pharmacokinetics and pharmacodynamics of JZP441 in sleep-deprived healthy volunteers is ongoing.
- The Company expects initial proof of concept in healthy volunteers in 2023.

JZP815:

- A Phase 1 trial evaluating JZP815 in patients with advanced or metastatic solid tumors with MAPK pathway alterations is ongoing.
- The pan-RAF inhibitor program is part of a novel class of next-generation precision oncology therapies that has the potential to benefit cancer patients with high unmet needs in multiple different solid tumors.

JZP898:

- JZP898 is an engineered IFNα cytokine pro-drug that is activated specifically within the tumor microenvironment where it can stimulate IFNα receptors on cancer-fighting immune effector cells.
- The Company expects to file an Investigational New Drug (IND) application for JZP898 in the U.S. this year.

Financial Highlights

	Three Months Ended March 31,	
(In thousands, except per share amounts)	2023	2022
Total revenues	$ 892,812	$ 813,721
GAAP net income	$ 69,420	$ 1,647
Non-GAAP adjusted net income	$ 285,261	$ 261,934
GAAP earnings per share	$ 1.04	$ 0.03
Non-GAAP adjusted EPS	$ 3.95	$ 3.73

GAAP net income for 1Q23 was $69.4 million, or $1.04 per diluted share, compared to $1.6 million, or $0.03 per diluted share, for 1Q22.

Non-GAAP adjusted net income for 1Q23 was $285.3 million, or $3.95 per diluted share, compared to $261.9 million, or $3.73 per diluted share, for 1Q22.

Reconciliations of applicable GAAP reported to non-GAAP adjusted information are included at the end of this press release.

Total Revenues

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

Total revenues	$ 892,812	$ 813,721

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

Total revenues increased 10% in 1Q23 compared to the same period in 2022.

- Total neuroscience revenue, including high-sodium oxybate AG royalty revenue, was $654.0 million in 1Q23 compared to $612.1 million in 1Q22. Neuroscience net product sales in 1Q23 increased 7% to $651.9 million compared to the same period in 2022 primarily driven by increased *Xywav* and *Epidiolex/Epidyolex* net product sales, partially offset by the decline in *Xyrem* revenues, reflecting the continued strong adoption of *Xywav* by patients with narcolepsy and the launch of a high-sodium oxybate AG in January 2023. High-sodium oxybate AG royalty revenue relates to royalty revenue received from Hikma Pharmaceuticals plc on net sales of a high-sodium oxybate AG product.
- Oncology net product sales in 1Q23 increased 16% to $228.9 million compared to the same period in 2022 primarily driven by the continued growth in *Rylaze* product sales, which increased 58% to $86.0 million.

Operating Expenses and Effective Tax Rate

	Three Months Ended March 31,	
(In thousands, except percentages)	**2023**	**2022**
GAAP:		
Cost of product sales	$ 128,644	$ 115,284
Gross margin	*85.5 %*	*85.8 %*
Selling, general and administrative	$ 297,917	$ 308,813
% of total revenues	*33.4 %*	*38.0 %*
Research and development	$ 189,410	$ 129,981
% of total revenues	*21.2 %*	*16.0 %*
Income tax expense (benefit)[1]	$ (15,324)	$ 536
Effective tax rate [1]	*(27.8) %*	*8.5 %*

1. The GAAP income tax benefit for 1Q23 increased as a result of the mix of pre-tax income and losses across tax jurisdictions, and increases in our patent box and foreign derived intangible income benefits.

	Three Months Ended March 31,	
(In thousands, except percentages)	**2023**	**2022**
Non-GAAP adjusted:		
Cost of product sales	$ 64,728	$ 48,206
Gross margin	*92.7 %*	*94.0 %*
Selling, general and administrative	$ 260,515	$ 258,701
% of total revenues	*29.2 %*	*31.8 %*
Research and development	$ 173,918	$ 116,459
% of total revenues	*19.5 %*	*14.3 %*
Income tax expense	$ 40,197	$ 55,223
Effective tax rate	*12.3 %*	*17.2 %*

Changes in operating expenses in 1Q23 over the prior year period are primarily due to the following:

- Cost of product sales increased in 1Q23 compared to the same period in 2022, on a GAAP and on a non-GAAP adjusted basis, primarily due to changes in product mix.
- Selling, general and administrative (SG&A) expenses, on a GAAP basis, decreased in 1Q23 compared to the same period in 2022 primarily due to transaction and integration expenses related to the acquisition of GW Pharmaceuticals plc (GW) and Sunosi® (solriamfetol) related spend incurred in 1Q22, partially offset by increased investment in our priority programs. SG&A expenses, on a non-GAAP adjusted basis, were in line with the same period in 2022.
- Research and development (R&D) expenses increased in 1Q23 compared to the same period in 2022, on a GAAP and on a non-GAAP adjusted basis, primarily due to the inclusion of costs related to clinical programs for zanidatamab, as well as JZP815, JZP898 and JZP441, offset by a decrease in costs related to JZP458.

Cash Flow and Balance Sheet

As of March 31, 2023, cash and cash equivalents were $1.2 billion, and the outstanding principal balance of the Company's long-term debt was $5.8 billion. In addition, the Company had undrawn borrowing capacity under a revolving credit facility of $500 million. For the three months ended March 31, 2023, the Company generated $320.7 million of cash from operations which is an increase of $111.7 million as compared to the same period in 2022, reflecting strong business performance and continued financial discipline.

2023 Financial Guidance

The Company is affirming its full year 2023 financial guidance as follows:

(In millions)	**Guidance**
Revenues	$3,675 - $3,875

–Neuroscience (includes royalties from high-sodium oxybate AG)	$2,675 - $2,825
–Oncology	$950 - $1,050

(In millions, except per share amounts and percentages)	GAAP	Non-GAAP
Gross margin %	89 %	93%[1,6]
SG&A expenses	$1,197 - $1,277	$1,045 - $1,105[2,6]
SG&A expenses as % of total revenues	*31% - 35%*	*27% - 30%*
R&D expenses	$739 - $797	$675 - $725[3,6]
R&D expenses as % of total revenues	*19% - 22%*	*17% - 20%*
Effective tax rate	(32)% - (8)%	9% - 11%[4,6]
Net income	$410 - $560	$1,240 - $1,310[6]
Net income per diluted share[5]	$5.90 - $7.90	$16.90 - $17.85[6]
Weighted-average ordinary shares used in per share calculations[5]	75	75

1. Excludes $135-$155 million of amortization of acquisition-related inventory fair value step-up and $14-$16 million of share-based compensation expense.
2. Excludes $152-$172 million of share-based compensation expense.
3. Excludes $64-$72 million of share-based compensation expense.
4. Excludes 41%-19% from the GAAP effective tax rate of (32%)-(8%) relating to the income tax effect of adjustments between GAAP net income and non-GAAP adjusted net income, resulting in a non-GAAP adjusted effective tax rate of 9%-11%.
5. Diluted EPS calculations for 2023 include 9 million shares related to the assumed conversion of the Exchangeable Senior Notes and the associated interest expense add-back to net income of $28 million and $25 million, on a GAAP and on a non-GAAP adjusted basis, respectively, under the "if converted" method.
6. See "Non-GAAP Financial Measures" below. Reconciliations of non-GAAP adjusted guidance measures are included above and, in the table titled "Reconciliation of GAAP to non-GAAP Adjusted 2023 Net Income Guidance" at the end of this press release.

Conference Call Details

Jazz Pharmaceuticals will host an investor conference call and live audio webcast today at 4:30 p.m. ET (9:30 p.m. IST) to provide a business and financial update and discuss its 2023 first quarter results.

Interested parties may register for the call in advance here or via the Investors section of the Jazz Pharmaceuticals website at www.jazzpharmaceuticals.com. To ensure a timely connection, it is recommended that participants register at least 15 minutes prior to the scheduled webcast.

A replay of the webcast will be available via the Investors section of the Jazz Pharmaceuticals website at www.jazzpharmaceuticals.com.

About Jazz Pharmaceuticals

Jazz Pharmaceuticals plc (NASDAQ: JAZZ) is a global biopharmaceutical company whose purpose is to innovate to transform the lives of patients and their families. We are dedicated to developing life-changing medicines for people with serious diseases - often with limited or no therapeutic options. We have a diverse portfolio of marketed medicines and novel product candidates, from early- to late-stage development, in neuroscience and oncology. Within these therapeutic areas, we are identifying new options for patients by actively exploring small molecules and biologics, and through innovative delivery technologies and cannabinoid science. Jazz is headquartered in Dublin, Ireland and has employees around the globe, serving patients in nearly 75 countries. Please visit www.jazzpharmaceuticals.com for more information.

Non-GAAP Financial Measures

To supplement Jazz Pharmaceuticals' financial results and guidance presented in accordance with U.S. generally accepted accounting principles (GAAP), the Company uses certain non-GAAP (also referred to as adjusted or non-GAAP adjusted) financial measures in this press release and the accompanying tables. In particular, the Company presents non-GAAP adjusted net income (and the related per share measure) and its line item components, as well as certain non-GAAP adjusted financial measures derived therefrom, including non-GAAP adjusted gross margin percentage and non-GAAP adjusted effective tax rate. Non-GAAP adjusted net income (and the related per share measure) and its line item components exclude from GAAP reported net income (and the related per share measure) and its line item components certain items, as detailed in the reconciliation tables that follow, and in the case of non-GAAP adjusted net income (and the related per share measure), adjust for the income tax effect of the non-GAAP adjustments. In this regard, the components of non-GAAP adjusted net income, including non-GAAP adjusted cost of product sales, SG&A expenses and R&D expenses, are income statement line items prepared on the same basis as, and therefore components of, the overall non-GAAP adjusted net income measure.

The Company believes that each of these non-GAAP financial measures provides useful supplementary information to, and facilitates additional analysis by, investors and analysts and that each of these non-GAAP financial measures, when considered together with the Company's financial information prepared in accordance with GAAP, can enhance investors' and analysts' ability to meaningfully compare the Company's results from period to period, to its forward-looking guidance, and to identify operating trends in the Company's business. In addition, these non-GAAP financial measures are regularly used by investors and analysts to model and track the Company's financial performance. Jazz Pharmaceuticals' management also regularly uses these non-GAAP financial measures internally to understand, manage and evaluate the Company's business and to make operating decisions, and compensation of executives is based in part on certain of these non-GAAP financial measures. Because these non-GAAP financial measures are important internal measurements for Jazz Pharmaceuticals' management, the Company also believes that these non-GAAP financial measures are useful to investors and analysts since these measures allow for greater transparency with respect to key financial metrics the Company uses in assessing its own operating performance and making operating decisions. These non-GAAP financial measures are not meant to be considered in isolation or as a substitute for comparable GAAP measures; should be read in conjunction with the Company's consolidated financial statements prepared in accordance with GAAP; have no standardized meaning prescribed by GAAP; and are not prepared under any comprehensive set of accounting rules or principles in the reconciliation tables that follow. In addition, from time to time in the future there may be other items that the Company may exclude for purposes of its non-GAAP financial measures; and the Company has ceased, and may in the future cease, to exclude items that it has historically excluded for purposes of its non-GAAP financial measures. Likewise, the Company may determine to modify the nature of its adjustments to arrive at its non-GAAP financial measures. Because of the non-standardized definitions of non-GAAP financial measures, the non-GAAP financial measures as used by Jazz Pharmaceuticals in this press release and the accompanying tables have limits in their usefulness to investors and may be calculated differently from, and therefore may not be directly comparable to, similarly titled measures used by other companies.

Caution Concerning Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to: the Company's growth prospects and future financial and operating results, including the Company's 2023 financial guidance and the Company's expectations related thereto and anticipated catalysts; the Company's

expectations for total revenue growth in 2023 and anticipated product sales; expectations of continued growth in net sales of Xywav, Epidiolex/Epidyolex and the oncology portfolio; the blockbuster potential of Epidiolex/Epidyolex and its significant additional growth opportunities; the Company's expectations to executing multiple Epidyolex ex-U.S. launches this year; expectations that the royalties from AG will be higher in the second half of 2023 relative to the first half; the Company's ability to achieve Vision 2025 and the Company's progress related thereto; the Company's development, regulatory and commercialization strategy; the Company's advancement of pipeline programs and the timing of development activities, regulatory activities and submissions related thereto, including the ability to deliver at least three late-stage data readouts by the end of 2024, expectations to file an IND application for JZP898 in the U.S. this year and proof of concept of JZP441 in 2023; the Company's expectations with respect to its products and product candidates and the potential of the Company's products and product candidates, including the potential of zanidatamab to transform the current standard of care in multiple HER2-expressing cancers; expectations that Xywav will remain the oxybate of choice in 2023; the Company's capital allocation and corporate development strategy; the potential successful future development, manufacturing, regulatory and commercialization activities; the Company's expectation of meaningful growth as part of its Vision 2025; growing and diversifying the Company's revenue, investing in its pipeline of novel therapies, and delivering innovative therapies for patients and the potential benefits of such therapies; the Company's ability to realize the commercial potential of its products; the Company's net product sales and goals for net product sales from new and acquired products; the Company's views and expectations relating to its patent portfolio, including with respect to expected patent protection, as well as expectations with respect to exclusivity; planned or anticipated clinical trial events, including with respect to initiations, enrollment and data read-outs, and the anticipated timing thereof; the Company's clinical trials confirming clinical benefit or enabling regulatory submissions; planned or anticipated regulatory submissions and filings, and the anticipated timing thereof; potential regulatory approvals, including for Rylaze; and other statements that are not historical facts. These forward-looking statements are based on the Company's current plans, objectives, estimates, expectations and intentions and inherently involve significant risks and uncertainties.

Actual results and the timing of events could differ materially from those anticipated in such forward- looking statements as a result of these risks and uncertainties, which include, without limitation, risks and uncertainties associated with: maintaining or increasing sales of and revenue from the Company's oxybate products, Zepzelca and other key marketed products; effectively launching and commercializing the Company's other products and product candidates; the successful completion of development and regulatory activities with respect to the Company's product candidates, obtaining and maintaining adequate coverage and reimbursement for the Company's products; the time-consuming and uncertain regulatory approval process, including the risk that the Company's current and/or planned regulatory submissions may not be submitted, accepted or approved by applicable regulatory authorities in a timely manner or at all; the costly and time-consuming pharmaceutical product development and the uncertainty of clinical success, including risks related to failure or delays in successfully initiating or completing clinical trials and assessing patients; the Company's failure to realize the expected benefits of its acquisition of GW, including the failure to realize the blockbuster potential of Epidiolex; global economic, financial, and healthcare system disruptions and the current and potential future negative impacts to the Company's business operations and financial results; geopolitical events, including the conflict between Russia and Ukraine and related sanctions; macroeconomic conditions, including global financial markets, rising interest rates and inflation; regulatory initiatives and changes in tax laws; market volatility; protecting and enhancing the Company's intellectual property rights and the Company's commercial success being dependent upon the Company obtaining, maintaining and defending intellectual property protection for its products and product candidates; delays or problems in the supply or manufacture of the Company's products and product candidates; complying with applicable U.S. and non-U.S. regulatory requirements, including those governing the research, development, manufacturing and distribution of controlled substances; government investigations, legal proceedings and other actions; identifying and consummating corporate development transactions, financing these transactions and successfully integrating acquired product candidates, products and businesses; the Company's ability to realize the anticipated benefits of its collaborations and license agreements with third parties; the sufficiency of the Company's cash flows and capital resources; the Company's ability to achieve targeted or expected future financial performance and results and the uncertainty of future tax, accounting and other provisions and estimates; the Company's ability to meet its projected long-term goals and objectives, including as part of Vision 2025, in the time periods that the Company anticipates, or at all, and the inherent uncertainty and significant judgments and assumptions underlying the Company's long-term goals and objectives; and other risks and uncertainties affecting the Company, including those described from time to time under the caption "Risk Factors" and elsewhere in Jazz Pharmaceuticals' Securities and Exchange Commission filings and reports, including the Company's Annual Report on Form 10-K for the year ended December 31, 2022, as supplemented by our Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, and future filings and reports by the Company. Other risks and uncertainties of which the Company is not currently aware may also affect the Company's forward-looking statements and may cause actual results and the timing of events to differ materially from those anticipated.

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

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

Net income per ordinary share:

Basic	$ 1.09	$ 0.03
Diluted	$ 1.04	$ 0.03
Weighted-average ordinary shares used in per share calculations - basic	63,494	61,865
Weighted-average ordinary shares used in per share calculations - diluted	73,771	62,907

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

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

JAZZ PHARMACEUTICALS PLC
SUMMARY OF CASH FLOWS
(In thousands)
(Unaudited)

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

JAZZ PHARMACEUTICALS PLC
RECONCILIATIONS OF GAAP REPORTED TO NON-GAAP ADJUSTED INFORMATION
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended March 31,

	2023	2022
GAAP reported net income	**$ 69,420**	**$ 1,647**
Intangible asset amortization	149,786	172,094
Acquisition accounting inventory fair value step-up	60,458	63,943
Share-based compensation expense	56,352	47,629
Non-cash interest expense[1]	4,766	12,168
Transaction and integration related expenses[2]	—	11,130
Costs related to disposal of a business[3]	—	8,010
Income tax effect of above adjustments	(55,521)	(54,687)
Non-GAAP adjusted net income	$ 285,261	$ 261,934
GAAP reported net income per diluted share[4]	**$ 1.04**	**$ 0.03**
Non-GAAP adjusted net income per diluted share[4]	$ 3.95	$ 3.73
Weighted-average ordinary shares used in diluted per share calculations - GAAP	**73,771**	**62,907**
Weighted-average ordinary shares used in diluted per share calculations - non-GAAP	73,771	71,950

Explanation of Adjustments and Certain Line Items:

1. Non-cash interest expense associated with debt issuance costs.
2. Transaction and integration expenses related to the acquisition of GW.
3. Costs related to disposal of Sunosi to Axsome and associated restructuring.
4. Diluted EPS was calculated using the "if-converted" method in relation to the Exchangeable Senior Notes. GAAP reported net income per diluted share for the three months ended March 31, 2023 includes 9.0 million shares related to the assumed conversion of the Exchangeable Senior Notes and the associated interest expense add-back to GAAP net income of $7.0 million. There was no impact on GAAP reported net income per diluted share for the three months ended March 31, 2022, as the Exchangeable Senior Notes were anti-dilutive. Non-GAAP adjusted net income per diluted share for the three months ended March 31, 2023 and the three months ended March 31, 2022 include 9.0 million shares related to the assumed conversion of the Exchangeable Senior Notes and the associated interest expense add-back to adjusted net income of $6.3 million.

JAZZ PHARMACEUTICALS PLC
RECONCILIATIONS OF GAAP REPORTED TO NON-GAAP ADJUSTED INFORMATION
CERTAIN LINE ITEMS - FOR THE THREE MONTHS ENDED MARCH 31, 2023 and 2022
(In thousands, except percentages)
(Unaudited)

	Three months ended March 31, 2023								
	Cost of product sales	**Gross margin**	**Selling, general and administrative**	**Research and development**	**Intangible asset amortization**	**Acquired IPR&D**	**Interest expense, net**	**Income tax expense (benefit)**	**Effective tax rate[(1)]**
GAAP Reported	**$ 128,644**	***85.5 %***	**$ 297,917**	**$ 189,410**	**$ 149,786**	**$ 1,000**	**$ 74,147**	**$ (15,324)**	***(27.8) %***
Non-GAAP Adjustments:									
Intangible asset amortization	—	—	—	—	(149,786)	—	—	—	—
Share-based compensation expense	(3,458)	*0.4*	(37,402)	(15,492)	—	—	—	—	—
Acquisition accounting inventory fair value step-up	(60,458)	*6.8*	—	—	—	—	—	—	—
Non-cash interest expense	—	—	—	—	—	—	(4,766)	—	—
Income tax effect of above adjustments	—	—	—	—	—	—	—	55,521	*40.1*
Total of non-GAAP adjustments	(63,916)	*7.2*	(37,402)	(15,492)	(149,786)	—	(4,766)	55,521	*40.1*
Non-GAAP Adjusted	$ 64,728	*92.7 %*	$ 260,515	$ 173,918	$ —	$ 1,000	$ 69,381	$ 40,197	*12.3 %*

	Three months ended March 31, 2022							
	Cost of product sales	**Gross margin**	**Selling, general and administrative**	**Research and development**	**Intangible asset amortization**	**Interest expense, net**	**Income tax expense**	**Effective tax rate[(1)]**
GAAP Reported	**$ 115,284**	***85.8 %***	**$ 308,813**	**$ 129,981**	**$ 172,094**	**$ 70,684**	**$ 536**	***8.5 %***
Non-GAAP Adjustments:								
Intangible asset amortization	—	—	—	—	(172,094)	—	—	—
Share-based compensation expense	(2,816)	*0.3*	(32,514)	(12,299)	—	—	—	—
Costs related to the disposal of a business	—	—	(8,010)	—	—	—	—	—
Transaction and integration related costs	(319)	—	(9,588)	(1,223)	—	—	—	—

Non-cash interest expense	—	—	—	—	—	(12,168)	—	—
Acquisition accounting inventory fair value step-up	(63,943)	*7.9*	—	—	—	—	—	—
Income tax effect of above adjustments	—	—	—	—	—	—	54,687	*8.7*
Total of non-GAAP adjustments	(67,078)	*8.2*	(50,112)	(13,522)	(172,094)	(12,168)	54,687	*8.7*
Non-GAAP Adjusted	$ 48,206	*94.0 %*	$ 258,701	$ 116,459	$ —	$ 58,516	$ 55,223	*17.2 %*

(1) The GAAP effective tax rates were derived from the income tax benefit, which increased as a result of the mix of pre-tax income and losses across tax jurisdictions, and increases in our patent box and foreign derived intangible income benefits.

JAZZ PHARMACEUTICALS PLC
RECONCILIATION OF GAAP TO NON-GAAP ADJUSTED 2023 NET INCOME GUIDANCE
(In millions, except per share amounts)
(Unaudited)

GAAP net income	**$410 - $560**
Intangible asset amortization	555 - 595
Acquisition accounting inventory fair value step-up	135 - 155
Share-based compensation expense	230 - 260
Non-cash interest expense	20 - 30
Income tax effect of above adjustments	(190) - (210)
Non-GAAP adjusted net income	$1,240 - $1,310
GAAP net income per diluted share	**$5.90 - $7.90**
Non-GAAP adjusted net income per diluted share	$16.90 - $17.85
Weighted-average ordinary shares used in per share calculations - GAAP and non-GAAP	75

Contacts:

Investors:
Andrea N. Flynn, Ph.D.
Vice President, Head, Investor Relations
Jazz Pharmaceuticals plc
InvestorInfo@jazzpharma.com
Ireland +353 1 634 3211
U.S. +1 650 496 2717

Media:
Kristin Bhavnani
Head of Global Corporate Communications
Jazz Pharmaceuticals plc
CorporateAffairsMediaInfo@jazzpharma.com
Ireland +353 1 637 2141
U.S. +1 215 867 4948

View original content to download multimedia:https://www.prnewswire.com/news-releases/jazz-pharmaceuticals-announces-first-quarter-2023-financial-results-and-affirms-2023-financial-guidance-301821187.html

SOURCE Jazz Pharmaceuticals plc