Jazz Pharmaceuticals

Jazz Pharmaceuticals Announces Third Quarter 2023 Financial Results and Updates Financial Guidance

November 08, 2023

- 3Q23 total revenues of \$972 million -

- Combined revenues from key growth drivers, Xywav[®], Epidiolex[®] and Rylaze[®], increased 24% year-over-year -

- Raising total and Oncology revenue guidance at the mid-points -

- Plan to initiate zanidatamab rolling biologics license application (BLA) submission this year for accelerated approval in second-line (2L) biliary tract cancers (BTC) -

DUBLIN, Nov. 8, 2023 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced financial results for the third quarter of 2023 and provided business updates.

"We have once again delivered strong financial results from increasingly diversified revenue streams and remain well-positioned for long-term growth. Low-sodium *Xywav* grew 30% year-over-year despite additional competition, with continued compelling adoption across both narcolepsy and idiopathic hypersomnia (IH). *Epidiolex* is well-positioned to deliver on its blockbuster potential as a differentiated treatment option with multiple ex-U.S. launches expected through 2024. Oncology net product sales grew 17% year-over-year and our Oncology therapeutic area remains on course to reach approximately \$1 billion in annual revenue this year," said Bruce Cozadd, chairman and chief executive officer of Jazz Pharmaceuticals. "We have raised our 2023 total revenue guidance yet again, as well as our Oncology revenue guidance, at the mid-points. We are increasing our investment in R&D based on our confidence in zanidatamab to raise the standard of care for patients and create long-term value for Jazz. Our disciplined capital deployment and strong execution has also enabled us to increase investment in our key commercial franchises, while delivering on our full year GAAP net income and non-GAAP adjusted net income guidance. We remain well-positioned to achieve Vision 2025."

"We now expect as many as five late-stage readouts from our robust R&D pipeline by the end of 2024 and continue to progress multiple early-stage programs in both neuroscience and oncology. We plan to initiate the zanidatamab rolling BLA submission this year for accelerated approval in 2L BTC and expect to complete it in the first half of 2024. Our pivotal, Phase 3 trial of Epidyolex[®] in Japan is progressing well and we now anticipate top-line data in the second half of 2024. Nearer term catalysts include the anticipated readout of JZP150 Phase 2 top-line data in PTSD and initial proof-of-concept from JZP441 in healthy volunteers. The breadth and depth of our expanded R&D pipeline continues to add to the diversification and transformation of our company together with the ability to improve patients' lives," said Rob lannone, M.D., M.S.C.E., executive vice president, global head of research and development of Jazz Pharmaceuticals.

Key Highlights

- Xywav net product sales grew 30% year-over-year; annualizing at \$1.3 billion.
- Total oxybate revenue, including royalties from authorized generics (AGs), is annualizing at \$1.9 billion; 68% of 3Q23 total oxybate revenues were driven by *Xywav*.
- Epidiolex/Epidyolex net product sales grew 9% year-over-year with continued global launch momentum; top-line data from pivotal, Phase 3 trial in Japan expected in 2H24.
- Rylaze net product sales grew 43% year-over-year supported by multiple demand drivers.
- Plan to initiate zanidatamab rolling BLA submission this year for accelerated approval in 2L BTC; expect to complete BLA in 1H24.
- Robust pipeline with as many as five late-stage data readouts expected by the end of 2024.
- Increased R&D investment driven by confidence in robust pipeline; reaffirmed full year GAAP net income and non-GAAP adjusted net income (ANI) guidance.

Business Updates

Key Commercial Products

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

- Xywav net product sales increased 30% to \$331.6 million in 3Q23 compared to the same period in 2022; expect Xywav to remain the oxybate of choice.
- There were approximately 12,050 active Xywav patients exiting 3Q23.
- The Company continued to present data supporting its scientific leadership in sleep disorders and highlighting the impact of low-sodium *Xywav* for patients with narcolepsy and IH.
 - At <u>Psych Congress 2023</u>, a review of multiple clinical trials demonstrated oxybate improves sleep quality, sleep architecture and measures of disrupted nighttime sleep in narcolepsy, independent of once- or twice-nightly dosing.
 - At <u>World Sleep 2023</u>, results from the TENOR study of adults with narcolepsy showed the most common patient-reported reasons for utilizing *Xywav* individualized dosing regimens were to avoid morning grogginess, help fall asleep and improve sleep quality. Results from another study, CV-RHYTHM, found patients with IH experienced a greater burden of cardiovascular comorbidities, including stroke, heart attacks and heart failure than those without IH, emphasizing the importance of holistic management to treat underrecognized sleep disorders.

Xywav for Narcolepsy:

- Continued growth of *Xywav* in narcolepsy, despite additional competition, with approximately 9,500 narcolepsy patients taking *Xywav* exiting 3Q23.
- The benefits of reducing sodium intake continue to resonate with patients and prescribers.

Xywav for Idiopathic Hypersomnia (IH):

- There were approximately 2,550 IH patients taking Xywav exiting 3Q23.
- Jazz survey of sleep specialists indicates 70% anticipate increasing their prescribing of *Xywav* for IH over the next six months, and new prescribers continued to grow in 3Q23.
- Xywav remains the first and only FDA-approved treatment demonstrating improvement across multiple symptoms, including sleep inertia,

which has a significant impact on patients' quality of life and daily function.

Xyrem[®] (sodium oxybate) oral solution:

• Xyrem net product sales decreased 51% to \$125.1 million in 3Q23 compared to the same period in 2022, reflecting the continued adoption of Xywav by patients with narcolepsy and the launch of high-sodium oxybate AGs in 2023.

Oxybate (Xywav, Xyrem and AG Royalties):

- Total oxybate revenue, including royalties from AGs, is annualizing at \$1.9 billion.
- Royalties from high-sodium oxybate AGs were \$28.9 million in 3Q23, which reflect a significant increase over 1H23 and the fixed-rate royalty structures of the AG agreements in 2H23.

Epidiolex/Epidyolex (cannabidiol):

- Epidiolex/Epidyolex net product sales increased 9% to \$213.7 million in 3Q23 compared to the same period in 2022.
- Epidiolex/Epidyolex global prescriber base increasing with multiple launches ongoing and anticipated outside of the U.S. through 2024, further positioning Epidiolex/Epidyolex to achieve blockbuster status.
- Demand driven by compelling efficacy data from *Epidiolex* in combination with clobazam, increased penetration in adults and long-term care settings, and beyond seizure benefits from the BECOME caregiver survey in in Dravet syndrome (DS) and Lennox-Gastaut syndrome (LGS).
- Additional opportunity for growth coming from continued data generation, including potential beyond seizure benefits from the EpiCom study in tuberous sclerosis complex (TSC) and multiple publications at AES 2023.
- A pivotal, Phase 3 trial of Epidyolex in DS, LGS and TSC in Japan is enrolling patients and top-line data from the trial are expected in 2H24.

Rylaze/Enrylaze (asparaginase erwinia chrysanthemi (recombinant)-rywn):

- Rylaze net product sales increased 43% to \$104.9 million compared to the same period in 2022.
- Continued strong *Rylaze* demand driven by multiple factors, including increased use in adolescents and young adults with acute lymphoblastic leukemia (ALL) and additional switching of patients from *E. coli*-based asparaginase to *Rylaze* due to non-hypersensitivity treatment-related issues.
- The European Commission <u>granted</u> marketing authorization for Enrylaze[®] (JZP458; a recombinant *Erwinia* asparaginase or crisantaspase), marketed as *Rylaze* in the U.S. and Canada, for use as a component of a multi-agent chemotherapeutic regimen for the treatment of ALL and lymphoblastic lymphoma in adult and pediatric patients (1 month and older) who developed hypersensitivity or silent inactivation to *E. coli*-derived asparaginase. The Company is planning to begin a rolling launch later this year.

Zepzelca[®] (lurbinectedin):

- Zepzelca net product sales increased 11% to \$78.0 million in 3Q23 compared to the same period in 2022.
- The Company expects top-line data from the Phase 3 trial evaluating first-line (1L) use of Zepzelca to readout at the end of 2024 or early 2025. The trial is assessing the combination with Tecentriq® (atezolizumab), compared to Tecentriq alone, as maintenance therapy in patients with extensive-stage small cell lung cancer after induction chemotherapy, in partnership with F. Hoffmann-La Roche Ltd (Roche).

Key Pipeline Highlights

Zanidatamab:

- Zanidatamab is a novel bispecific antibody that simultaneously binds two non-overlapping epitopes of HER2, resulting in multiple mechanisms of action, potent immune activation and encouraging antitumor activity in patients.
- The Company plans to initiate the zanidatamab rolling BLA submission this year for accelerated approval in 2L BTC and expects to complete the rolling submission 1H24.
- The Company has alignment with FDA on a confirmatory trial in 1L metastatic BTC, where there remains unmet patient need.
- The pivotal HERIZON-GEA-01 trial, evaluating zanidatamab in 1L gastroesophageal adenocarcinoma, is ongoing and top-line data are expected in 2024.
- The Company, along with partners, <u>presented</u> zanidatamab data at ESMO Congress 2023. Results from a Phase 1b/2 study of zanidatamab plus chemotherapy in combination with tislelizumab for the 1L treatment of HER2-positive gastric/gastroesophageal junction adenocarcinoma demonstrated antitumor activity with a confirmed ORR of 75.8%, median duration of response of 22.8 months and median PFS of 16.7 months and safety was consistent with previous findings.

JZP150:

- JZP150, a selective fatty acid amide hydrolase, or FAAH, inhibitor, is in clinical development for the potential treatment of post-traumatic stress disorder (PTSD).
- Patient enrollment is now complete in the Phase 2 PTSD trial and top-line data are expected in January 2024.
- 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 essential tremor (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 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:

- JZP815 potently inhibits both monomer- and dimer-driven RAF signaling and prevents paradoxical pathway activation induced by BRAF selective inhibition.
- A Phase 1 trial evaluating JZP815 in patients with advanced or metastatic solid tumors with MAPK pathway alterations is ongoing and a trial in progress poster of the Phase 1 study was presented at ESMO Congress 2023.

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.
- JZP898 received Investigational New Drug application clearance and the Company expects to initiate a Phase 1 clinical trial by the end of the year.

Continued Repurchases under Previously Announced \$1.5 Billion Share Repurchase Program

The Company continued repurchases of its ordinary shares on the open market in the third quarter of 2023 as part of its previously authorized and announced share repurchase program. As of September 30, 2023, approximately \$261 million remained available and authorized for share repurchases, after the purchase of approximately \$75 million shares during the third quarter of 2023. The timing and amount of repurchases under the program will depend on a variety of factors, including the price of the Company's ordinary shares, alternative investment opportunities, restrictions under the Company's credit agreement, corporate and regulatory requirements and market conditions.

Financial Highlights

	Three Months Ended September 30,					ths Ended nber 30,	
(In thousands, except per share amounts)		2023		2022	 2023		2022
Total revenues	\$	972,140	\$	940,652	\$ 2,822,269	\$	2,687,251
GAAP net income (loss)	\$	146,820	\$	(19,648)	\$ 320,678	\$	16,664
Non-GAAP adjusted net income	\$	340,148	\$	370,438	\$ 950,538	\$	937,837
GAAP earnings (loss) per share	\$	2.14	\$	(0.31)	\$ 4.67	\$	0.26
Non-GAAP adjusted EPS	\$	4.84	\$	5.17	\$ 13.29	\$	13.21

GAAP net income (loss) for 3Q23 was \$146.8 million, or \$2.14 per diluted share, compared to \$(19.6) million, or \$(0.31) per diluted share, for 3Q22.

Non-GAAP adjusted net income for 3Q23 was \$340.1 million, or \$4.84 per diluted share, compared to \$370.4 million, or \$5.17 per diluted share, for 3Q22.

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

Total Revenues

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

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

Total revenues increased 3% in 3Q23 compared to the same period in 2022.

• Total neuroscience revenue, including high-sodium oxybate AG royalty revenue, was \$704.0 million in 3Q23 compared to \$711.4 million in 3Q22. Neuroscience net product sales in 3Q23 decreased 5% to \$675.1 million compared to the same period in 2022 driven by decreased *Xyrem* revenues, reflecting the continued strong adoption of *Xywav* by patients with narcolepsy and availability of high-sodium oxybate AGs, offset by increased *Xywav* and *Epidiolex/Epidyolex* net product sales. High-sodium oxybate AG royalty revenue relates primarily to royalty revenue received from Hikma Pharmaceuticals plc on net sales of a high-sodium oxybate AG product.

• Oncology net product sales in 3Q23 increased 17% to \$260.4 million compared to the same period in 2022 primarily driven by the continued growth in *Rylaze* product sales, which increased 43% to \$104.9 million.

Operating Expenses and Effective Tax Rate

	Three Months Ended September 30,				 Nine Mon Septen	ths Ended ber 30,	
(In thousands, except percentages)		2023		2022	 2023		2022
GAAP:							
Cost of product sales	\$	102,153	\$	133,661	\$ 328,334	\$	373,153
Gross margin		89.1 %		85.7 %	88.1 %		86.0 %
Selling, general and administrative	\$	308,310	\$	358,478	\$ 947,071	\$	1,033,764
% of total revenues		31.7 %		38.1 %	33.6 %		38.5 %
Research and development	\$	234,402	\$	148,870	\$ 633,050	\$	417,898
% of total revenues		24.1 %		15.8 %	22.4 %		15.6 %
Acquired in-process research and development	\$	_	\$	_	\$ 1,000	\$	69,148
Impairment charge	\$	_	\$	133,648	\$ _	\$	133,648
Income tax benefit	\$	(47,176)	\$	(43,027)	\$ (86,823)	\$	(58,603)
Effective tax rate ¹		(47.4) %		71.6 %	(36.7) %		178.7 %

(1) The GAAP effective tax rate decreased for the three and nine months ended September 30, 2023 compared to the same periods in 2022, primarily due to the mix of pre-tax income and losses across tax jurisdictions and the impact of the nabiximols impairment, which was recognized in 3Q22. The nine months ended September 30, 2022 was also impacted by the Sunosi divestment.

		Months Ended Ni ptember 30,				Months Ended ptember 30,		
(In thousands, except percentages)	2023		2022		2023		2022	
Non-GAAP adjusted:								
Cost of product sales	\$ 67,119	\$	57,103	\$	197,841	\$	158,554	
Gross margin	92.8 %		93.9 %		92.9 %		94.1 %	
Selling, general and administrative	\$ 273,042	\$	274,747	\$	810,428	\$	814,941	
% of total revenues	28.1 %		29.2 %		28.7 %		30.3 %	
Research and development	\$ 217,767	\$	120,802	\$	583,704	\$	360,980	
% of total revenues	22.4 %		12.8 %		20.7 %		13.4 %	
Acquired in-process research and development	\$ _	\$	_	\$	1,000	\$	69,148	
Income tax expense	\$ 7,378	\$	44,386	\$	72,785	\$	137,996	
Effective tax rate	2.1 %		10.6 %		7.1 %		12.7 %	

Changes in operating expenses in 3Q23 over the prior year period are primarily due to the following:

- Cost of product sales decreased in 3Q23 compared to the same period in 2022, on a GAAP basis, primarily due to lower acquisition accounting inventory fair value step-up expense, partially offset by changes in product mix. Cost of product sales increased in 3Q23 compared to the same period in 2022, on a non-GAAP adjusted basis, primarily due to changes in product mix.
- Selling, general and administrative (SG&A) expenses decreased in 3Q23 compared to the same period in 2022, on a GAAP basis, primarily
 due to restructuring and program termination costs incurred in 3Q22. SG&A expenses, on a GAAP and on a non-GAAP adjusted basis,
 included decreased compensation-related expenses and increased investment in our priority programs.
- Research and development (R&D) expenses increased in 3Q23 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 zanidatamab, as well as our other key pipeline programs.
- The impairment charge in 3Q22, on a GAAP basis, related to an acquired IPR&D asset impairment relating to the discontinuation of our nabiximols program.

Cash Flow and Balance Sheet

As of September 30, 2023, cash, cash equivalents and investments were \$1.6 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 nine months ended September 30, 2023, the Company generated \$924.7 million of cash from operations reflecting strong business performance and continued financial discipline.

2023 Financial Guidance

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

(In millions)	November 8, 2023	August 9, 2023
Revenues	\$3,750 - \$3,875	\$3,725 - \$3,875
-Neuroscience (includes royalties from high-sodium oxybate AG)	\$2,715 - \$2,825	\$2,715 - \$2,825
-Oncology	\$975 - \$1,050	\$950 - \$1,050

GAAP:

(In millions, except per share amounts and percentages)	November 8, 2023	August 9, 2023
Gross margin %	89 %	89 %
SG&A expenses	\$1,240 - \$1,295	\$1,220 - \$1,295
SG&A expenses as % of total revenues	32% - 35%	31% - 35%
R&D expenses	\$844 - \$888	\$739 - \$793
R&D expenses as % of total revenues	22% - 24%	19% - 21%
Effective tax rate	(59)% - (33)%	(35)% - (15)%

Net income	\$450 - \$565	\$450 - \$565
Net income per diluted share ⁵	\$6.60 - \$8.15	\$6.60 - \$8.15
Weighted-average ordinary shares used in per share calculations ⁵	72	72

Non-GAAP:

(In millions, except per share amounts and percentages)	November 8, 2023	August 9, 2023
Gross margin %	93% ^{1,6}	93 %
SG&A expenses	\$1,065 - \$1,105 ^{2,6}	\$1,045 - \$1,105
SG&A expenses as % of total revenues	27% - 29%	27% - 30%
R&D expenses	\$780 - \$820 ^{3,6}	\$675 - \$725
R&D expenses as % of total revenues	20% - 22%	17% - 19%
Effective tax rate	4% - 6% ^{4,6}	8% - 10%
Net income	\$1,290 - \$1,340 ⁶	\$1,290 - \$1,340
Net income per diluted share ⁵	\$18.15 - \$19.00 ⁶	\$18.15 - \$19.00
Weighted-average ordinary shares used in per share calculations ⁵	72	72

1. Excludes \$135-\$155 million of amortization of acquisition-related inventory fair value step-up and \$14-\$15 million of share-based compensation expense.

2. Excludes \$152-\$167 million of share-based compensation expense and \$23 million of restructuring costs.

3. Excludes \$64-\$68 million of share-based compensation expense.

4. Excludes 63%-39% from the GAAP effective tax rate of (59)%-(33)% 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 4%-6%.

5. Diluted EPS calculations for 2023 include an estimated 8 million shares related to the assumed conversion of the Exchangeable Senior Notes and the associated interest expense add-back to net income of \$25 million and \$22 million, on a GAAP and on a non-GAAP adjusted basis, respectively, under the "if converted" method. In August 2023, we made the irrevocable election to net share settle our 2024 Notes. This election is expected to impact our full-year net income per diluted share guidance by \$0.05 to \$0.10 per share, on a GAAP basis, and \$0.25 to \$0.40 per share, on a Non-GAAP adjusted basis, as a result of an estimated decrease in the weighted-average shares outstanding of 1 million shares.

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. GMT) to provide a business and financial update and discuss its 2023 third quarter results.

Audio webcast/conference call:

U.S. Dial-In Number: +1 888 350 4423 Ireland Dial-In Number: +353 1800 943 926 Additional global dial-in numbers are available <u>here</u>. Passcode: 6907242

Interested parties may access the live audio webcast via the Investors section of the Jazz Pharmaceuticals website at <u>www.jazzpharmaceuticals.com</u>. 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, as well as certain non-GAAP adjusted net income (and the related per share measure) and its line item components exclude from GAAP reported net income (loss) (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 and Oncology 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 through 2024; expectations with respect to AGs; 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 up to five late-stage data readouts by the end of 2024, expectations to initiate a Phase 1 clinical trial of JZP898 by the end of this year and proof of concept of JZP441 in 2023, expectations of top-line data from a Phase 2 trial of JZP150 for PTSD in the near term, a Phase 3 trial of zanidatamab for GEA in 2024 and a Phase 3 trial of Epidyolex for DS, LGS and TSC in Japan in the first half of 2024; 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 and the potential regulatory path related thereto; expectations that Xywav will remain the oxybate of choice; 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; the timing and amount of repurchases of the Company's ordinary shares; settlements of the Notes; 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, Rylaze and Epidiolex/Epidyolex and other key marketed products; the introduction of new products into the U.S. market that compete with, or otherwise disrupt the market for the Company's oxybate products and product candidates; 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 Pharmaceuticals, 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 and recent and potential banking disruptions; 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 corporate development transactions and 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; fluctuations in the market price and trading volume of the Company's ordinary shares; restrictions on repurchases of capital stock; the timing and availability of alternative investment opportunities; the Company's ability to pay cash amounts and issue ordinary shares due upon exchange of the Notes; 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 June 30, 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 forwardlooking 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 (LOSS) (In thousands, except per share amounts) (Unaudited)

_	Three Months Ended September 30,			 	ths Ended nber 30,	
	2023		2022	 2023		2022
Revenues:						
Product sales, net	\$ 938,39	98 \$	935,766	\$ 2,769,604	\$	2,673,903
Royalties and contract revenues	33,74	12	4,886	 52,665		13,348
Total revenues	972,14	40	940,652	2,822,269		2,687,251
Operating expenses:						
Cost of product sales (excluding amortization of						
acquired developed technologies)	102,15	53	133,661	328,334		373,153
Selling, general and administrative	308,37	10	358,478	947,071		1,033,764
Research and development	234,40)2	148,870	633,050		417,898
Intangible asset amortization	154,88	33	141,232	456,731		461,782
Acquired in-process research and development		_	—	1,000		69,148
Impairment charge			133,648	 _		133,648
Total operating expenses	799,74	48	915,889	2,366,186		2,489,393
Income from operations	172,39	92	24,763	 456,083		197,858
Interest expense, net	(71,49	7)	(80,244)	(219,114)		(214,117)
Foreign exchange loss	(1,37	7)	(4,649)	(566)		(16,532)
Income (loss) before income tax benefit and equity in loss						
(gain) of investees	99,5 <i>°</i>	18	(60,130)	236,403		(32,791)
Income tax benefit	(47,17	6)	(43,027)	(86,823)		(58,603)

Equity in loss (gain) of investees	(126)	2,545	2,548	9,148
Net income (loss)	\$ 146,820	\$ (19,648)	\$ 320,678	\$ 16,664
Net income (loss) per ordinary share:				
Basic	\$ 2.33	\$ (0.31)	\$ 5.05	\$ 0.27
Diluted	\$ 2.14	\$ (0.31)	\$ 4.67	\$ 0.26
Weighted-average ordinary shares used in per share calculations - basic	 63,114	 62,785	 63,532	 62,365
Weighted-average ordinary shares used in per share calculations - diluted	 71,293	 62,785	 72,866	 63,388

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

	Se	ptember 30, 2023	De	ecember 31, 2022
ASSETS				
Current assets:				
Cash and cash equivalents	\$	1,335,690	\$	881,482
Investments		250,000		_
Accounts receivable, net of allowances		627,841		651,493
Inventories		611,827		714,061
Prepaid expenses		109,990		91,912
Other current assets		310,404		267,192
Total current assets		3,245,752		2,606,140
Property, plant and equipment, net		222,476		228,050
Operating lease assets		65,038		73,326
Intangible assets, net		5,417,860		5,794,437
Goodwill		1,705,320		1,692,662
Deferred tax assets, net		464,367		376,247
Deferred financing costs		7,172		9,254
Other non-current assets		76,080		55,139
Total assets	\$	11,204,065	\$	10,835,255
LIABILITIES AND SHAREHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$	109,850	\$	90,758
Accrued liabilities		769,942		803,255
Current portion of long-term debt		604,507		31,000
Income taxes payable		89,026		7,717
Deferred revenue		4		463
Total current liabilities		1,573,329		933,193
Long-term debt, less current portion		5,110,757		5,693,341
Operating lease liabilities, less current portion		61,892		71,838
Deferred tax liabilities, net		841,234		944,337
Other non-current liabilities		127,480		106,812
Total shareholders' equity		3,489,373		3,085,734
Total liabilities and shareholders' equity	\$	11,204,065	\$	10,835,255

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

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

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

(Unaudited)

		Three Mon Septerr	nths Ended Aber 30,		Nine Months Ended September 30,				
	20	23	2022		2023		2022		
			Net Income						
	Net Income	Diluted EPS	(Loss)	Diluted EPS	Net Income	Diluted EPS	Net Income	Diluted EPS	
GAAP reported ¹	\$ 146,820	\$ 2.14	\$ (19,648)	\$ (0.31)	\$ 320,678	\$ 4.67	\$ 16,664	\$ 0.26	
Intangible asset amortization Share-based compensation	154,883	2.17	141,232	1.94	456,731	6.27	461,782	6.38	
expense	56,115	0.79	54,948	0.75	173,900	2.39	156,427	2.16	
Acquisition accounting inventory fair value step-up	30,822	0.43	70,964	0.97	119,094	1.63	203,189	2.81	
Restructuring and other	, -		-,		-,		,		
costs ²	_	_	57,625	0.79	23,488	0.32	57,625	0.80	
Non-cash interest expense ³	6,062	0.09	14,262	0.20	16,255	0.23	32,002	0.44	
Impairment charge ⁴ (Income) costs related to	_	_	133,648	1.83	_	_	133,648	1.85	
disposal of a business ⁵ Transaction and integration	_	_	(671)	(0.01)	_	_	49,539	0.68	
related expenses ⁶ Income tax effect of above	_	_	5,491	0.08	_	_	23,560	0.33	
adjustments Effect of assumed conversion	(54,554)	(0.77)	(87,413)	(1.20)	(159,608)	(2.19)	(196,599)	(2.71)	
of Exchangeable Senior Notes		(0.01)		0.13		(0.03)		0.21	
Non-GAAP adjusted ¹	\$ 340,148	\$ 4.84	\$ 370,438	\$ 5.17	\$ 950,538	\$ 13.29	\$ 937,837	\$ 13.21	
Weighted-average ordinary shares used in diluted per share calculations - GAAP	71,293		62,785		72,866		63,388		
Dilutive effect of	71,295		02,705		72,000		03,300		
Exchangeable Senior Notes ¹ Dilutive effect of employee equity incentive and purchase	_		9,044		_		9,044		
plans Weighted-average ordinary shares used in diluted per share			1,031						
calculations - non-GAAP	71,293		72,860		72,866		72,432		

Explanation of Adjustments and Certain Line Items:

- 1. Diluted EPS was calculated using the "if-converted" method in relation to the 1.50% exchangeable senior notes due 2024, or 2024 Notes and the 2.00% exchangeable senior notes due 2026, or 2026 Notes, which we refer to collectively as the Exchangeable Senior Notes. In August 2023, we made an irrevocable election to fix the settlement method for exchanges of the 2024 Notes to a combination of cash and ordinary shares of the Company with a specified cash amount per \$1,000 principal amount of the 2024 Notes of \$1,000. As a result, the assumed issuance of ordinary shares upon exchange of the 2024 Notes has only been included in the calculation of diluted net income per ordinary share, on a GAAP and on a non-GAAP adjusted basis, in the three and nine months ended September 30, 2023 up to the date the irrevocable election was made. GAAP reported net income per diluted share for the three and nine months ended September 30, 2023 included 7.6 million shares and 8.5 million shares, respectively, related to the assumed conversion of GAAP net income of \$5.9 million and \$20.0 million, respectively. There was no impact on GAAP reported net income per diluted share for the three and nine months ended share for the three and nine months ended September 30, 2022, as the Exchangeable Senior Notes were anti-dilutive. Non-GAAP adjusted net income per diluted share for the three and nine months ended September 30, 2023 included 7.6 million shares, respectively, related to the assumed conversion of the Exchangeable Senior Notes and the associated interest expense add-back to non-GAAP adjusted net income per diluted share for the three and nine months ended September 30, 2023 included 7.6 million shares, respectively, related to the assumed conversion of the Exchangeable Senior Notes and the associated interest expense add-back to non-GAAP adjusted net income of \$5.2 million and \$17.8 million, respectively. Non-GAAP adjusted net income per diluted share for the three and nine months ended September 30, 2022 included 9.0 million
- 2. Includes restructuring and costs related to program terminations.
- 3. Non-cash interest expense associated with debt issuance costs.
- 4. Impairment charge related to the IPR&D asset impairment following the discontinuation of our nabiximols program.
- 5. Loss on disposal of Sunosi to Axsome Therapeutics Inc. and associated costs.
- 6. Transaction and integration expenses related to the acquisition of GW Pharmaceuticals plc.

JAZZ PHARMACEUTICALS PLC RECONCILIATIONS OF GAAP REPORTED TO NON-GAAP ADJUSTED INFORMATION CERTAIN LINE ITEMS - FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2023 and 2022 (In thousands, except percentages) (Unaudited)

		Thr	ee months endeo	d September 30,	2023		
Cost of product sales \$ 102,153	Gross margin 89.1 %	Selling, general and administrative \$ 308,310	Research and development \$ 234,402	Intangible asset amortization \$ 154,883	Interest expense, net \$ 71,497	Income tax expense (benefit) \$ (47,176)	Effective <u>tax rate⁽¹⁾</u> (47.4) %

Non-GAAP Adjustments:								
Intangible asset amortization	—	_	—	—	(154,883)	_	—	—
Share-based compensation expense	(4,212)	0.5	(35,268)	(16,635)	_	_	_	_
Acquisition accounting inventory								
fair value step-up	(30,822)	3.2	_	_	_	_	_	_
Non-cash interest expense	_	_	_	—	—	(6,062)	—	_
Income tax effect of above								
adjustments							54,554	49.5
Total of non-GAAP adjustments	(35,034)	3.7	(35,268)	(16,635)	(154,883)	(6,062)	54,554	49.5
Non-GAAP Adjusted	\$ 67,119	92.8 %	\$ 273,042	\$ 217,767	\$ —	\$ 65,435	\$ 7,378	2.1 %

	Three months ended September 30, 2022								
	Cost of product sales	Gross margin	Selling, general and administrative	Research and development	Intangible asset amortization	Impairment charge	Interest expense, net	Income tax expense (benefit)	Effective tax rate ⁽¹⁾
GAAP Reported	\$ 133,661	85.7 %	\$ 358,478	\$ 148,870	\$ 141,232	\$ 133,648	\$ 80,244	\$ (43,027)	71.6 %
Non-GAAP Adjustments:									
Intangible asset									
amortization		_	—	—	(141,232)		—		—
Share-based									
compensation expense	(3,160)	0.3	(35,890)	(15,898)	_	—	—	—	—
Impairment charge	—	—	—	—	—	(133,648)	—	—	—
Income related to the									
disposal of a business	_	_	671	—	—	_	—	—	—
Restructuring and other	(0.050)		(40.075)	(11.001)					
costs	(2,359)	0.3	(43,375)	(11,891)	—	_	_		_
Transaction and	(75)		(5 407)	(270)					
integration related costs Non-cash interest	(75)	_	(5,137)	(279)					
expense							(14,262)		
Acquisition accounting	_	_	_	_	_	_	(14,202)	_	_
inventory fair value step-									
up	(70,964)	7.6	_	_	_		_		_
Income tax effect of	(-) /								
above adjustments	_	_	_	_	_	_	_	87,413	(61.0)
Total of non-GAAP									
adjustments	(76,558)	8.2	(83,731)	(28,068)	(141,232)	(133,648)	(14,262)	87,413	(61.0)
Non-GAAP Adjusted	\$ 57,103	93.9 %	\$ 274,747	\$ 120,802	\$ —	\$ —	\$ 65,982	\$ 44,386	10.6 %

(1) The GAAP effective tax rate decreased in the three months ended September 30, 2023 compared to the same period in 2022, primarily due to the mix of pre-tax income and losses across tax jurisdictions and the impact of the nabiximols impairment, which was recognized in 2022.

JAZZ PHARMACEUTICALS PLC RECONCILIATIONS OF GAAP REPORTED TO NON-GAAP ADJUSTED INFORMATION CERTAIN LINE ITEMS - FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2023 and 2022 (In thousands, except percentages) (Unaudited)

	Nine months ended September 30, 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	\$ 328,334	88.1 %	\$ 947,071	\$ 633,050	\$ 456,731	\$ 1,000	\$ 219,114	\$ (86,823)	(36.7) %
Non-GAAP Adjustments: Intangible asset									
amortization	_	_	_	_	(456,731)	—	_	_	_
Share-based compensation expense	(11,399)	0.4	(113,155)	(49,346)	_	_	_	_	_
Restructuring and other costs	_	_	(23,488)	_	_	_	_	_	_
Non-cash interest			(,)				(40.055)		
expense Acquisition accounting	_	_	_	_	_	_	(16,255)	_	_
inventory fair value step-up Income tax effect of above	(119,094)	4.4	_	_	_	—	—	_	—
adjustments								159,608	43.8
Total of non-GAAP adjustments	(130,493)	4.8	(136,643)	(49,346)	(456,731)		(16,255)	159,608	43.8
Non-GAAP Adjusted	\$ 197,841	92.9 %	\$ 810,428	\$ 583,704	\$ —	\$ 1,000	\$ 202,859	\$ 72,785	7.1 %

	Nine months ended September 30, 2022									
	Cost of product sales	Gross margin	Selling, general and administrative	Research and development	Intangible asset amortization	Acquired IPR&D	Impairment charge	Interest expense, net	Income tax expense (benefit)	Effective tax rate (1)
GAAP Reported	\$ 373,153	86.0 %	\$ 1,033,764	\$ 417,898	\$ 461,782	\$ 69,148	\$ 133,648	\$ 214,117	\$ (58,603)	178.7 %
Non-GAAP Adjustments: Intangible asset					<i></i>					
amortization Share-based compensation	_	_	_	_	(461,782)	_	_	_	_	_
expense	(8,581)	0.3	(104,851)	(42,995)	—	_	_	_	_	—
Impairment charge	_	_	_	_	_	_	(133,648)	_	_	_
Costs related to the disposal of a business	_	_	(49,539)			_	_	_	_	_
Restructuring			(10,000)							
and other costs	(2,359)	0.1	(43,375)	(11,891)	_	—	_	_	_	_
Transaction and integration	(170)		(04.050)	(0.000)						
related costs	(470)	_	(21,058)	(2,032)	—	_	—	_	_	_
Non-cash interest expense	—	—	—	—	—	—	_	(32,002)	—	_
Acquisition accounting inventory fair value step-up	(203,189)	7.7						_		_
Income tax effect	,	7.7		_	_				_	_
adjustments Total of non-									196,599	(166.0)
GAAP adjustments	(214,599)	8.1	(218,823)	(56,918)	(461,782)		(133,648)	(32,002)	196,599	(166.0)
Non-GAAP Adjusted	\$ 158,554	94.1 %	\$ 814,941	\$ 360,980	\$ —	\$ 69,148	\$ —	\$ 182,115	\$ 137,996	12.7 %

(1) The GAAP effective tax rate decreased in the nine months ended September 30, 2023 compared to the same period in 2022, primarily due to the mix of pre-tax income and losses across tax jurisdictions and the impact of both the Sunosi divestment in 2022 and the nabiximols impairment, which was recognized in 2022.

JAZZ PHARMACEUTICALS PLC RECONCILIATION OF GAAP TO NON-GAAP ADJUSTED 2023 NET INCOME AND DILUTED EPS GUIDANCE

(In millions, except per share amounts)

(Unaudited)

	Net Income	Diluted EPS
GAAP guidance	\$450 - \$565	\$6.60 - \$8.15
Intangible asset amortization	580 - 615	8.00 - 8.50
Acquisition accounting inventory fair value step-up	135 - 155	1.85 - 2.15
Share-based compensation expense	230 - 250	3.20 - 3.45
Restructuring and other costs	23	0.30
Non-cash interest expense	20 - 30	0.30 - 0.40
Income tax effect of above adjustments	(215) - (230)	(2.95) - (3.20)
Effect of assumed conversion of Exchangeable Senior Notes		(0.05)
Non-GAAP guidance	\$1,290 - \$1,340	\$18.15 - \$19.00
Non-GAAP guidance	\$1,290 - \$1,340	\$18.15 - \$19.0

Weighted-average ordinary shares used in per share calculations - $\ensuremath{\mathsf{GAAP}}$ and non- $\ensuremath{\mathsf{GAAP}}$

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