Jazz Pharmaceuticals Announces Third Quarter 2024 Financial Results

November 06, 2024

– 14% year-over-year revenue increase from combined key growth drivers:
Xywav®, Epidiolex® and Rylaze® –
– 2024 total revenue guidance affirmed at $4.0 to $4.1 billion –
– Zanidatamab 2L BTC PDUFA date of November 29, 2024 –
– Plan to submit sNDA for Zepzelca® in 1L ES-SCLC in 1H25 –

DUBLIN, Nov. 6, 2024 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced financial results for the third quarter of 2024 and updated guidance for 2024.

"Jazz once again delivered record revenues of more than $1.05 billion and a 14% year-over-year increase in revenue from our key growth drivers combined. We continue to see robust patient demand for *Xywav* with approximately 400 net patient additions in the third quarter, supported by physician and patient appreciation of a low-sodium treatment option. Strong sleep[1] performance coupled with continued *Epidiolex* performance gives us confidence in maintaining our total revenue guidance of $4.0 to $4.1 billion for 2024," said Bruce Cozadd, chairman and chief executive officer, Jazz Pharmaceuticals. "We're preparing for the anticipated launch of zanidatamab in the fourth quarter in 2L BTC, where there remains a high unmet medical need. We expect to provide the first chemotherapy-free dual HER2-targeted bispecific antibody indicated for BTC as well as an opportunity for HCPs to gain important experience ahead of future indications. In addition, results from the Phase 3 IMforte trial were highly encouraging, and we plan to submit an sNDA for *Zepzelca* in the first half of 2025 to support expansion into the 1L maintenance setting in ES-SCLC."

Key Highlights

- Key growth drivers grew 14% combined year-over-year.
- Combination of *Zepzelca* and atezolizumab demonstrated statistically significant and clinically meaningful improvement in OS and PFS primary endpoints, demonstrating the potential of the regimen to delay disease progression in ES-SCLC and extend survival for patients.
- Zanidatamab:
  - PDUFA date of November 29; expect 2L BTC commercial launch in 4Q24, following approval.
  - Top-line PFS data from zanidatamab in Phase 3 1L GEA estimated to be 2Q25.
  - Initiated a Phase 2 pan-tumor trial to evaluate HER2-positive solid tumors.
- 2024 Financial Guidance:
  - Affirming 2024 total revenue guidance of $4.0 to $4.1 billion.
  - Affirming neuroscience revenue guidance of $2.825 to $2.925 billion.
  - Lowering oncology revenue guidance to $1.08 to $1.13 billion.
  - Lowering GAAP R&D expense guidance to $862 to $908 million and non-GAAP R&D expense guidance to $790 to $830 million,[2] primarily driven by strategic pipeline prioritization.
  - Raising GAAP EPS guidance range to $6.70 to $8.50 and non-GAAP EPS guidance range to $19.50 to $20.60.[2]

1 Total Sleep revenue includes: Xywav, branded Xyrem and high-sodium oxybate authorized generic royalty revenues.
2 See "Non-GAAP Financial Measures."

Business Updates

Commercial Updates

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

- *Xywav* net product sales were $388.5 million in 3Q24, an increase of 17% compared to the same period in 2023.
- There were approximately 400 net patient adds for a total of approximately 13,625 active *Xywav* patients exiting 3Q24 comprised of:
  - Approximately 10,075 **narcolepsy** patients.
  - Approximately 3,550 **idiopathic hypersomnia (IH)** patients, with 250 net patient adds.
- As the only low-sodium oxybate and the only therapy approved to treat IH, expect *Xywav* to remain the oxybate of choice.
- Presented top-line results from the Phase 4 DUET (Develop hypersomnia Understanding by Evaluating low-sodium oxybate Treatment) trial at the Psych Congress 2024, which demonstrated efficacy and safety consistent with narcolepsy and IH Phase 3 data. The prospective trial assesses the effect of *Xywav* treatment on excessive daytime sleepiness, polysomnography parameters and functional outcomes in adults with narcolepsy or IH.

Xyrem® (sodium oxybate) oral solution and high-sodium oxybate authorized generic (AG) royalties:

- *Xyrem* net product sales were $58.1 million in 3Q24, a decrease of 54% compared to the same period in 2023.
- Royalties from high-sodium oxybate AGs were $58.2 million in 3Q24, an increase of $29.2 million compared to the same period in 2023.

Epidiolex/Epidyolex (cannabidiol):

- *Epidiolex/Epidyolex* net product sales were $251.6 million in 3Q24, an increase of 18% compared to the same period in 2023.
- Outside of the U.S., *Epidyolex* is approved in more than 35 countries.

- Presented data at the European Epilepsy Congress 2024 demonstrating clinically meaningful reductions in drop seizures in patients with Lennox-Gastaut syndrome and subgroup analyses from the BECOME Caregiver Survey showing most caregivers reported patient improvements in seizure and non-seizure outcomes.
- Ongoing data generation of the seizure and non-seizure benefits of *Epidiolex*, including from the EpiCom study in tuberous sclerosis complex, to be presented at American Epilepsy Society 2024.

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

- *Rylaze/Enrylaze* net product sales were $98.8 million in 3Q24, a decrease of 6% compared to the same period in 2023.
- There is a temporary impact to *Rylaze* revenue due to a recent update to pediatric acute lymphoblastic leukemia (ALL) protocols regarding timing of asparaginase administration. The Company does not expect this impact will affect ongoing demand and expects revenue will normalize by early 2025.

Zepzelca (lurbinectedin):

- *Zepzelca* net product sales were $85.8 million in 3Q24, an increase of 10% compared to the same period in 2023.
- The Company announced statistically significant and clinically meaningful overall survival (OS) and progression-free survival (PFS) results from the Phase 3 clinical trial, conducted in partnership with Roche, evaluating *Zepzelca* in combination with Tecentriq® (atezolizumab) in first-line (1L) extensive-stage (ES) small cell lung cancer (SCLC). Based on positive results from the trial, the Company plans to submit a supplemental New Drug Application (sNDA) for *Zepzelca* in 1L ES-SCLC in the first half of 2025.

Key Pipeline Highlights

Zanidatamab:

- In 2Q24, the U.S. FDA accepted and granted Priority Review of the Biologics License Application for zanidatamab with a target action date of November 29, 2024. If approved, zanidatamab would be the first HER2-targeted treatment specifically approved for biliary tract cancer (BTC) in the U.S. A confirmatory trial in 1L metastatic BTC is ongoing.
- The pivotal HERIZON-GEA-01 trial, evaluating zanidatamab in 1L gastroesophageal adenocarcinoma (GEA), is expected to read out in 2Q25.
- Data presented at ESMO 2024 demonstrated sustained clinical antitumor activity in HER2-positive metastatic GEA. Updated results from the Phase 2 trial included a confirmed objective response rate of 84%, duration of response of 18.7 months, median PFS of 15.2 months and a Kaplan-Meier–estimated OS of 59% at 30 months.
- The Phase 3 EmpowHER-BC-303 trial to evaluate zanidatamab plus chemotherapy or trastuzumab plus chemotherapy in patients with HER2-positive breast cancer whose disease has progressed on previous trastuzumab deruxtecan (T-DXd) treatment is enrolling patients.
- The Company initiated a Phase 2 DiscovHER-Pan-206 pan-tumor trial in HER2-positive solid tumors.

Senior Notes Offering and Concurrent Share Repurchases

In the third quarter of 2024, the Company completed a private placement of $1.0 billion aggregate principal amount of 3.125% exchangeable senior notes due 2030, or 2030 Notes. The Company intends to use a portion of the proceeds from the private placement to make a payment on the Term Loan B following the mid-January 2025 expiration of the 1% prepayment premium period in place after the recent repricing. Concurrently with this transaction, the Company repurchased approximately $150.0 million of its ordinary shares. The Company paid for such repurchases with existing cash on hand, and such share repurchases were effected as part of the Company's share repurchase program announced in July 2024.

Financial Highlights

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands, except per share amounts)	2024	2023	2024	2023
Total revenues	$ 1,054,969	$ 972,140	$ 2,980,777	$ 2,822,269
GAAP net income	$ 215,055	$ 146,820	$ 369,005	$ 320,678
Non-GAAP adjusted net income	$ 416,924	$ 340,148	$ 963,866	$ 950,538
GAAP earnings per share	$ 3.42	$ 2.14	$ 5.63	$ 4.67
Non-GAAP adjusted EPS	$ 6.61	$ 4.84	$ 14.42	$ 13.29

GAAP net income for 3Q24 was $215.1 million, or $3.42 per diluted share, compared to $146.8 million, or $2.14 per diluted share, for 3Q23.

Non-GAAP adjusted net income for 3Q24 was $416.9 million, or $6.61 per diluted share, compared to $340.1 million, or $4.84 per diluted share, for 3Q23.

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

Total Revenues

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2024	2023	2024	2023
Xywav	$ 388,466	$ 331,633	$ 1,072,238	$ 935,958
Xyrem	58,114	125,110	184,526	463,009
Epidiolex/Epidyolex	251,558	213,711	697,376	604,846
Sativex	4,586	4,627	13,704	14,531
Total Neuroscience	702,724	675,081	1,967,844	2,018,344
Rylaze/Enrylaze	98,780	104,859	309,359	292,479

Zepzelca	85,843	77,994	241,990	215,523
Defitelio/defibrotide	65,818	47,730	158,915	132,917
Vyxeos	34,313	29,827	109,348	100,583
Total Oncology	284,754	260,410	819,612	741,502
Other	2,229	2,907	8,497	9,758
Product sales, net	989,707	938,398	2,795,953	2,769,604
High-sodium oxybate AG royalty revenue	58,157	28,921	162,268	36,531
Other royalty and contract revenues	7,105	4,821	22,556	16,134
Total revenues	$ 1,054,969	$ 972,140	$ 2,980,777	$ 2,822,269

Total revenues increased 9% in 3Q24 compared to the same period in 2023.

Total neuroscience revenue, including high-sodium oxybate AG royalty revenue, was $760.9 million in 3Q24, an increase of 8% compared to $704.0 million in 3Q23, primarily due to increased *Xywav* and *Epidiolex/Epidyolex* net product sales and increased high-sodium oxybate AG royalty revenue partially offset by decreased *Xyrem* revenues.

Oncology net product sales were $284.8 million in 3Q24, an increase of 9% compared to the same period in 2023, and included higher net product sales from *Defitelio/defibrotide* which increased 38% to $65.8 million primarily due to timing of orders and *Zepzelca* which increased 10% to $85.8 million. In 3Q24, *Rylaze* net product sales were negatively affected by a recent update to pediatric ALL protocols regarding timing of asparaginase administration.

Operating Expenses and Effective Tax Rate

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands, except percentages)	2024	2023	2024	2023
GAAP:				
Cost of product sales	$ 111,611	$ 102,153	$ 317,000	$ 328,334
Gross margin	*88.7 %*	*89.1 %*	*88.7 %*	*88.1 %*
Selling, general and administrative	$ 325,772	$ 308,310	$ 1,016,007	$ 947,071
% of total revenues	*30.9 %*	*31.7 %*	*34.1 %*	*33.6 %*
Research and development	$ 199,919	$ 234,402	$ 643,500	$ 633,050
% of total revenues	*19.0 %*	*24.1 %*	*21.6 %*	*22.4 %*
Acquired in-process research and development	$ —	$ —	$ 10,000	$ 1,000
Income tax benefit[1]	$ (14,533)	$ (47,176)	$ (33,517)	$ (86,823)
Effective tax rate [1]	*(7.2) %*	*(47.4) %*	*(9.9) %*	*(36.7) %*

1. The GAAP income tax benefit decreased in the three and nine months ended September 30, 2024, compared to the same periods in 2023, due to the change in income mix across our jurisdictions. The nine months ended September 30, 2024 were also impacted by tax shortfalls from share-based compensation.

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands, except percentages)	2024	2023	2024	2023
Non-GAAP adjusted:				
Cost of product sales	$ 72,844	$ 67,119	$ 209,405	$ 197,841
Gross margin	*92.6 %*	*92.8 %*	*92.5 %*	*92.9 %*
Selling, general and administrative	$ 288,672	$ 273,042	$ 903,557	$ 810,428
% of total revenues	*27.4 %*	*28.1 %*	*30.3 %*	*28.7 %*
Research and development	$ 180,992	$ 217,767	$ 588,470	$ 583,704
% of total revenues	*17.2 %*	*22.4 %*	*19.7 %*	*20.7 %*
Acquired in-process research and development	$ —	$ —	$ 10,000	$ 1,000
Income tax expense[1]	$ 41,683	$ 7,378	$ 130,999	$ 72,785
Effective tax rate[1]	*9.1 %*	*2.1 %*	*11.9 %*	*7.1 %*

1. The non-GAAP income tax expense increased in the three and nine months ended September 30, 2024, compared to the same periods in 2023, due to the change in income mix across our jurisdictions. The nine months ended September 30, 2024 were also impacted by tax shortfalls from share-based compensation.

Changes in operating expenses in 3Q24 over the prior year period are primarily due to the following:

- Cost of product sales, on a GAAP basis, increased in 3Q24 compared to the same period in 2023, primarily due to higher product sales, net and higher acquisition accounting inventory fair value step-up expense. Cost of product sales, on a non-GAAP adjusted basis, increased in 3Q24 compared to the same period in 2023, primarily due to higher product sales, net.
- Selling, general and administrative (SG&A) expenses, on a GAAP and on a non-GAAP adjusted basis, increased in 3Q24 compared to the same period in 2023, primarily due to increased compensation-related expenses driven by higher headcount in support of our key growth drivers.
- Research and development (R&D) expenses, on a GAAP and on a non-GAAP adjusted basis, decreased in 3Q24 compared to the

same period in 2023, primarily due to lower clinical program costs as a result of JZP150 costs incurred in 3Q23 and lower zanidatamab costs.

Cash Flow and Balance Sheet

As of September 30, 2024, cash, cash equivalents and investments were $2.6 billion, and the outstanding principal balance of the Company's long-term debt was $6.2 billion. In addition, the Company had undrawn borrowing capacity under a revolving credit facility of $500.0 million. In 3Q24, we repaid the $575.0 million aggregate principal amount of the 1.50% exchangeable senior notes due 2024, or 2024 Notes, and completed the private placement of the 2030 Notes. For the nine months ended September 30, 2024, the Company generated $997.3 million of cash from operations reflecting strong business performance and continued financial discipline.

2024 Financial Guidance

The Company is updating its full year 2024 financial guidance as follows:

(In millions)	November 6, 2024	July 31, 2024
Revenues	$4,000 - $4,100	$4,000 - $4,100
–Neuroscience (includes royalties from high-sodium oxybate AG)	$2,825 - $2,925	$2,825 - $2,925
–Oncology	$1,080 - $1,130	$1,100 - $1,150

GAAP:

(In millions, except per share amounts and percentages)	November 6, 2024	July 31, 2024
Gross margin %	89 %	89 %
SG&A expenses	$1,339 - $1,392	$1,366 - $1,426
SG&A expenses as % of total revenues	*33% - 35%*	*33% - 36%*
R&D expenses	$862 - $908	$887 - $935
R&D expenses as % of total revenues	*21% - 23%*	*22% - 23%*
Effective tax rate	(17)% - (2)%	(22)% - (3)%
Net income	$430 - $550	$385 - $530
Net income per diluted share[5]	$6.70 - $8.50	$6.00 - $8.00
Weighted-average ordinary shares used in per share calculations	66	67

Non-GAAP:

(In millions, except per share amounts and percentages)	November 6, 2024	July 31, 2024
Gross margin %	93%[1,6]	93 %
SG&A expenses	$1,190 - $1,230[2,6]	$1,190 - $1,230
SG&A expenses as % of total revenues	*29% - 31%*	*29% - 31%*
R&D expenses	$790 - $830[3,6]	$810 - $850
R&D expenses as % of total revenues	*19% - 21%*	*20% - 21%*
Effective tax rate	10% - 12%[4,6]	10% - 12%
Net income	$1,275 - $1,350[6]	$1,275 - $1,350
Net income per diluted share[5]	$19.50 - $20.60[6]	$19.20 - $20.30
Weighted-average ordinary shares used in per share calculations	66	67

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1. Excludes $125-$145 million of amortization of acquisition-related inventory fair value step-up and $14-$15 million of share-based compensation expense.
2. Excludes $149-$162 million of share-based compensation expense.
3. Excludes $72-$78 million of share-based compensation expense.
4. Excludes 27%-14% from the GAAP effective tax rate of (17)%-(2)% 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 10%-12%.
5. Diluted EPS calculations for 2024 include an estimated 3.5 million shares related to the assumed conversion of the 2.000% exchangeable senior notes due 2026, or the 2026 Notes, and the associated interest expense, net of tax, add-back to net income of $11 million and $10 million, on a GAAP and on a non-GAAP adjusted basis, respectively, under the "if converted" method. In July 2024, we made the irrevocable election to net share settle the 2026 Notes. This election is expected to increase our full-year net income per diluted share guidance by $0.15 to $0.25 per share, on a GAAP basis, and $0.70 to $0.75 per share, on a non-GAAP adjusted basis, as a result of an estimated decrease in the weighted-average outstanding shares of 2.9 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 2024 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 2024 third quarter results.

Audio webcast/conference call:
U.S. Dial-In Number: +1 800 715 9871
Ireland Dial-In Number: +353 1800 943 926
Additional global dial-in numbers are available here.
Passcode: 5080203

Interested parties may access the live audio webcast 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, 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. Jazz is headquartered in Dublin, Ireland with research and development laboratories, manufacturing facilities and employees in multiple countries committed to serving patients worldwide. 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 2024 financial guidance and the Company's expectations related thereto and anticipated catalysts; expectations that Xywav will remain the oxybate of choice; expectations of high-sodium oxybate AG royalty revenue in 2024; the ability to generate long-term sustainable growth and value; the Company's advancement of pipeline programs and the timing of development activities, regulatory activities and submissions related thereto, including plans to submit a sNDA for Zepzelca in 1L ES-SCLC in the first half of 2025 and the anticipated launch of zanidatamab in 2L BTC; planned or anticipated clinical trial events, including with respect to initiations, enrollment and data read-outs, and the anticipated timing thereof, including: top-line PFS data from a Phase 3 trial of zanidatamab in 1L GEA, plans to initiate a Phase 1b trial of JZP441 in type 1 narcolepsy patients; and the Company's development, regulatory and commercialization strategy, including the Company's expectations to executing multiple Epidyolex launches through 2024; the Company's expectations with respect to its products and product candidates and the potential of the Company's products and product candidates and the potential regulatory path related thereto; the Company's capital allocation and corporate development strategy; the potential successful future development, manufacturing, regulatory and commercialization activities; 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; 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; 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, Xywav, Rylaze and Epidiolex/Epidyolex and other marketed products; the introduction of new products into the U.S. market that compete with, or otherwise disrupt the market for the Company's 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; 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 and exclusivity 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, 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; the timing and availability of alternative investment opportunities; 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, 2023, as supplemented by our Quarterly Report on Form 10-Q for the quarter ended March 31, 2024, 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 September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Revenues:				
Product sales, net	$ 989,707	$ 938,398	$ 2,795,953	$ 2,769,604
Royalties and contract revenues	65,262	33,742	184,824	52,665
Total revenues	1,054,969	972,140	2,980,777	2,822,269
Operating expenses:				
Cost of product sales (excluding amortization of acquired developed technologies)	111,611	102,153	317,000	328,334
Selling, general and administrative	325,772	308,310	1,016,007	947,071
Research and development	199,919	234,402	643,500	633,050
Intangible asset amortization	157,457	154,883	468,410	456,731
Acquired in-process research and development	—	—	10,000	1,000
Total operating expenses	794,759	799,748	2,454,917	2,366,186
Income from operations	260,210	172,392	525,860	456,083
Interest expense, net	(58,702)	(71,497)	(186,841)	(219,114)
Foreign exchange loss	(701)	(1,377)	(1,887)	(566)
Income before income tax benefit and equity in loss (gain) of investees	200,807	99,518	337,132	236,403
Income tax benefit	(14,533)	(47,176)	(33,517)	(86,823)
Equity in loss (gain) of investees	285	(126)	1,644	2,548
Net income	$ 215,055	$ 146,820	$ 369,005	$ 320,678
Net income per ordinary share:				
Basic	$ 3.50	$ 2.33	$ 5.93	$ 5.05
Diluted	$ 3.42	$ 2.14	$ 5.63	$ 4.67
Weighted-average ordinary shares used in per share calculations - basic	61,414	63,114	62,275	63,532
Weighted-average ordinary shares used in per share calculations - diluted	63,174	71,293	67,511	72,866

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

	September 30, 2024	**December 31, 2023**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,218,135	$ 1,506,310
Investments	400,000	120,000
Accounts receivable, net of allowances	723,639	705,794
Inventories	539,302	597,039
Prepaid expenses	155,132	185,476
Other current assets	354,215	320,809
Total current assets	4,390,423	3,435,428
Property, plant and equipment, net	176,422	169,646
Operating lease assets	77,164	65,340
Intangible assets, net	5,144,217	5,418,039
Goodwill	1,804,646	1,753,130
Deferred tax assets, net	583,218	477,834
Deferred financing costs	4,395	6,478
Other non-current assets	75,231	67,464
Total assets	$ 12,255,716	$ 11,393,359
LIABILITIES AND SHAREHOLDERS' EQUITY		

Current liabilities:		
Accounts payable	$ 85,425	$ 102,750
Accrued liabilities	858,578	793,914
Current portion of long-term debt	31,000	604,954
Income taxes payable	54,974	35,074
Total current liabilities	1,029,977	1,536,692
Long-term debt, less current portion	6,080,802	5,107,988
Operating lease liabilities, less current portion	71,115	59,225
Deferred tax liabilities, net	791,784	847,706
Other non-current liabilities	110,971	104,751
Total shareholders' equity	4,171,067	3,736,997
Total liabilities and shareholders' equity	$ 12,255,716	$ 11,393,359

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

	Nine Months Ended September 30,	
	2024	**2023**
Net cash provided by operating activities	$ 997,328	$ 924,668
Net cash used in investing activities	(314,908)	(264,860)
Net cash provided by (used in) financing activities	28,791	(204,948)
Effect of exchange rates on cash and cash equivalents	614	(652)
Net increase in cash and cash equivalents	$ 711,825	$ 454,208

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

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2024		**2023**		**2024**		**2023**	
	Net Income	**Diluted EPS[1]**	**Net Income**	**Diluted EPS[1]**	**Net Income**	**Diluted EPS[1]**	**Net Income**	**Diluted EPS[1]**
GAAP reported	**$ 215,055**	**$ 3.42**	**$ 146,820**	**$ 2.14**	**$ 369,005**	**$ 5.63**	**$ 320,678**	**$ 4.67**
Intangible asset amortization	157,457	2.49	154,883	2.17	468,410	6.94	456,731	6.27
Share-based compensation expense	59,760	0.95	56,115	0.79	177,855	2.63	173,900	2.39
Acquisition accounting inventory fair value step-up	35,034	0.55	30,822	0.43	97,220	1.44	119,094	1.63
Other costs[2]	—	—	—	—	—	—	23,488	0.32
Non-cash interest expense[3]	5,834	0.09	6,062	0.09	15,892	0.24	16,255	0.23
Income tax effect of above adjustments	(56,216)	(0.89)	(54,554)	(0.77)	(164,516)	(2.44)	(159,608)	(2.19)
Effect of assumed conversion of Exchangeable Senior Notes[1]	—	—	—	(0.01)	—	(0.02)	—	(0.03)
Non-GAAP adjusted	$ 416,924	$ 6.61	$ 340,148	$ 4.84	$ 963,866	$ 14.42	$ 950,538	$ 13.29
Weighted-average ordinary shares used in diluted per share calculations - GAAP and non-GAAP[1]	**63,174**		**71,293**		**67,511**		**72,866**	

Explanation of Adjustments and Certain Line Items:

1. Diluted EPS was calculated using the "if-converted" method in relation to the 2024 Notes and the 2026 Notes, which we refer to collectively as the Exchangeable Senior Notes. In August 2023 and July 2024, we made irrevocable elections to net share settle the 2024 Notes and the 2026 Notes, respectively. As a result, the assumed issuance of ordinary shares upon exchange of the Exchangeable Senior 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 each period up to the date each irrevocable election was made. Net income per diluted share, on a GAAP and a non-GAAP adjusted basis, for the three and nine months ended September 30, 2024 included 1.3 million shares and 4.7 million shares, respectively, related to the assumed conversion of the 2026 Notes and the associated interest expense, net of tax, add-back to GAAP reported net income of $1.0 million and $10.8 million, respectively, and the associated interest expense, net of tax, add-back to non-GAAP adjusted net income of $0.9 million and $9.7 million, respectively. Net income per diluted share, on a GAAP and on a non-GAAP adjusted basis, 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 the Exchangeable Senior Notes and the associated interest expense, net of tax, add-back to GAAP reported net income of $5.9 million and $20.0 million, respectively, and the associated interest expense, net of tax, add-back to non-GAAP adjusted net income of $5.2 million and $17.8 million, respectively.

2. Costs related to program terminations.
3. Non-cash interest expense associated with debt issuance costs.

JAZZ PHARMACEUTICALS PLC
RECONCILIATIONS OF GAAP REPORTED TO NON-GAAP ADJUSTED INFORMATION
CERTAIN LINE ITEMS - FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2024 AND 2023
(In thousands, except percentages)
(Unaudited)

	Three months ended September 30, 2024						
	Cost of product sales	**Gross margin**	**Selling, general and administrative**	**Research and development**	**Intangible asset amortization**	**Interest expense, net**	**Income tax expense (benefit)**
GAAP Reported	**$ 111,611**	***88.7 %***	**$ 325,772**	**$ 199,919**	**$ 157,457**	**$ 58,702**	**$ (14,533)**
Non-GAAP Adjustments:							
Intangible asset amortization	—	—	—	—	(157,457)	—	—
Share-based compensation expense	(3,733)	*0.4*	(37,100)	(18,927)	—	—	—
Acquisition accounting inventory fair value step-up	(35,034)	*3.5*	—	—	—	—	—
Non-cash interest expense	—	—	—	—	—	(5,834)	—
Income tax effect of above adjustments	—	—	—	—	—	—	56,216
Total of non-GAAP adjustments	(38,767)	*3.9*	(37,100)	(18,927)	(157,457)	(5,834)	56,216
Non-GAAP Adjusted	$ 72,844	*92.6 %*	$ 288,672	$ 180,992	$ —	$ 52,868	$ 41,683

	Three months ended September 30, 2023						
	Cost of product sales	**Gross margin**	**Selling, general and administrative**	**Research and development**	**Intangible asset amortization**	**Interest expense, net**	**Income tax expense (benefit)**
GAAP Reported	**$ 102,153**	***89.1 %***	**$ 308,310**	**$ 234,402**	**$ 154,883**	**$ 71,497**	**$ (47,176)**
Non-GAAP Adjustments:							
Intangible asset amortization	—	—	—	—	(154,883)	—	—
Share-based compensation expense	(4,212)	*0.5*	(35,268)	(16,635)	—	—	—
Non-cash interest expense	—	—	—	—	—	(6,062)	—
Acquisition accounting inventory fair value step-up	(30,822)	*3.2*	—	—	—	—	—
Income tax effect of above adjustments	—	—	—	—	—	—	54,554
Total of non-GAAP adjustments	(35,034)	*3.7*	(35,268)	(16,635)	(154,883)	(6,062)	54,554
Non-GAAP Adjusted	$ 67,119	*92.8 %*	$ 273,042	$ 217,767	$ —	$ 65,435	$ 7,378

JAZZ PHARMACEUTICALS PLC
RECONCILIATIONS OF GAAP REPORTED TO NON-GAAP ADJUSTED INFORMATION
CERTAIN LINE ITEMS - FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2024 AND 2023
(In thousands, except percentages)
(Unaudited)

	Nine months ended September 30, 2024							
	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)**
GAAP Reported	**$ 317,000**	***88.7 %***	**$ 1,016,007**	**$ 643,500**	**$ 468,410**	**$ 10,000**	**$ 186,841**	**$ (33,517)**
Non-GAAP Adjustments:								
Intangible asset amortization	—	—	—	—	(468,410)	—	—	—
Share-based compensation expense	(10,375)	*0.4*	(112,450)	(55,030)	—	—	—	—
Non-cash interest expense	—	—	—	—	—	—	(15,892)	—
Acquisition accounting inventory fair value step-up	(97,220)	*3.4*	—	—	—	—	—	—
Income tax effect of above adjustments	—	—	—	—	—	—	—	164,516
Total of non-GAAP adjustments	(107,595)	*3.8*	(112,450)	(55,030)	(468,410)	—	(15,892)	164,516
Non-GAAP Adjusted	$ 209,405	*92.5 %*	$ 903,557	$ 588,470	$ —	$ 10,000	$ 170,949	$ 130,999

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

JAZZ PHARMACEUTICALS PLC
RECONCILIATION OF GAAP TO NON-GAAP ADJUSTED 2024 NET INCOME AND DILUTED EPS GUIDANCE
(In millions, except per share amounts)
(Unaudited)

	Net Income	Diluted EPS
GAAP guidance	**$430 - $550**	**$6.70 - $8.50**
Intangible asset amortization	605 - 645	9.10 - 9.85
Acquisition accounting inventory fair value step-up	125 - 145	1.90 - 2.20
Share-based compensation expense	235 - 255	3.55 - 3.90
Non-cash interest expense	20 - 30	0.30 - 0.45
Income tax effect of above adjustments	(210) - (220)	(3.15) - (3.35)
Non-GAAP guidance	$1,275 - $1,350	$19.50 - $20.60
Weighted-average ordinary shares used in per share calculations - GAAP and non-GAAP	66	

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