Jazz Pharmaceuticals Announces Second Quarter 2021 Financial Results

August 3, 2021

Closed GW Pharmaceuticals plc Acquisition, Creating an Innovative, High-Growth, Global Biopharma Leader
41% of Net Product Sales from Recently Launched or Acquired Products
Strong Xywav™ Adoption with 5,100 Active Patients Exiting the Second Quarter
FDA Approval and Launch of Rylaze™ in the U.S.
Expect to Initiate Pivotal Phase 3 Trial of Epidiolex® for Epilepsy with Myoclonic-Atonic Seizures in First Half 2022
Total Revenues Increased 34% to $751.8 Million Compared to Second Quarter 2020
2021 Total Revenue Guidance Affirmed at $3.02 Billion to $3.18 Billion

DUBLIN, Aug. 3, 2021 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced financial results for the second quarter of 2021 and affirmed non-GAAP adjusted financial guidance for 2021.

"As we enter what we expect to be a period of sustained growth, I have never been more excited about the future for Jazz. The recent approval and launches of Xywav and Rylaze exemplify Jazz today. We are rapidly establishing ourselves as an innovative biopharmaceutical company with expanding R&D capabilities and substantial commercial prowess, underscored by our consistent execution across the business. The addition of the GW cannabinoid platform and related pipeline complement and enhance our own growing R&D capabilities, accelerating our ability to improve the lives of patients," said Bruce Cozadd, chairman and chief executive officer of Jazz Pharmaceuticals. "We have now executed four of five planned product launches since the beginning of 2020 and look forward to our anticipated launch of Xywav in idiopathic hypersomnia later this year, a critical step forward for these underserved patients. With 41% of our second quarter net product sales from recently launched or acquired products, we are well on track to meet our revenue diversification targets while driving significant shareholder value."

Robert Iannone, M.D., M.S.C.E., executive vice president, research and development and chief medical officer, added, "We are excited that Rylaze was recently approved in the United States and is now broadly available to acute lymphoblastic leukemia and lymphoblastic lymphoma patients in critical need. We aim to further leverage our proven R&D capabilities to deliver on the significant value of our pipeline and the GW cannabinoid platform. The shared values and patient-centricity among the Jazz and GW teams, coupled with the successful ongoing integration, will further enhance our ability to innovate and execute, including the planned initiations of a Phase 3 pivotal trial for Epidiolex in epilepsy with myoclonic-atonic seizures and the third Phase 3 nabiximols clinical trial in multiple sclerosis-related spasticity."

Business Updates

Corporate Development

On May 5, 2021, the Company completed the acquisition of GW Pharmaceuticals plc (GW) for a total value of approximately $7.2 billion, or $6.8 billion net of GW cash. The Company secured $5.35 billion of financing to fund the GW transaction. The financing structure supports the Company's plans for rapid deleveraging to its stated targets while also continuing to make investments to grow the business. The combined company is a leader in neuroscience with a global commercial and operational footprint, well positioned to maximize the value of its diversified portfolio.

Neuroscience

Oxybate (Xyrem® and Xywav):

- Net product sales for the combined oxybate business increased 3% to $458.3 million in the second quarter of 2021 compared to the same period in 2020.
- Average active oxybate patients on therapy were approximately 15,900 in the second quarter of 2021, an increase of approximately 5% compared to the same period in 2020.

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

- *Xywav* net product sales were $124.2 million in the second quarter of 2021.
- There were approximately 5,100 active patients on *Xywav* exiting the second quarter of 2021.
- In June 2021, FDA recognized seven years of Orphan Drug Exclusivity for Xywav.
- FDA published its summary of clinical superiority findings for Xywav 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, and 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.
- The Company has achieved its goal of obtaining broad payer coverage, having entered into agreements with all three of the largest pharmacy benefit managers.

Xyrem (sodium oxybate) oral solution**:**

- *Xyrem* net product sales decreased 25% to $334.2 million in the second quarter of 2021 compared to the same period in 2020.

Xywav in Idiopathic Hypersomnia

- FDA has granted Priority Review Designation and accepted the supplemental New Drug Application (sNDA) for *Xywav* in adult patients with idiopathic hypersomnia (IH). The Prescription Drug Fee User Act (PDUFA) target date for an FDA decision has been set for August 12, 2021, which is in line with the Company's objective of launching in the fourth quarter of 2021 following risk evaluation and mitigation strategy (REMS) implementation.

Epidiolex/Epidyolex® (cannabidiol)**:**

- *Epidiolex/Epidyolex* net product sales were $109.5 million in the second quarter of 2021. This includes sales from May 5, 2021, the closing date of the GW Acquisition.
- On an unaudited pro forma basis, net product sales in the second quarter of 2021 increased by 32% to $155.9 million compared to the same period in 2020.
- The Company expects to initiate a Phase 3 pivotal trial of Epidiolex for Epilepsy with Myoclonic-Atonic Seizures (EMAS), also known as Doose syndrome, in the first half of 2022. EMAS represents the fourth target indication for *Epidiolex.*

Sunosi® (solriamfetol)**:**

- *Sunosi* net product sales increased by 41% to $12.1 million in the second quarter of 2021 compared to the same period of 2020.
- In the second quarter of 2021, U.S. prescriptions increased by 25% compared to the first quarter of 2021.

Nabiximols:

- The Company expects to initiate the third Phase 3 nabiximols clinical trial in multiple sclerosis (MS)-related spasticity this year.
- The two ongoing Phase 3 clinical trials in MS-related spasticity continue to progress.

JZP385:

- JZP385, a highly selective modulator of T-type calcium channels, is in clinical development for the potential treatment of essential tremor.
- The Company expects to initiate a Phase 2b trial in late 2021.

JZP150:

- JZP150, a fatty acid amide hydrolase (FAAH) inhibitor, is in clinical development for the potential treatment of post-traumatic stress disorder.
- The Company expects to initiate a Phase 2 trial in late 2021.

Oncology

Zepzelca ™ (lurbinectedin)

- *Zepzelca* net product sales were $55.9 million in the second quarter of 2021.
- Sequential demand growth over the first two quarters of 2021 was 8% and 9% respectively, offset mainly by reduced inventory holding by distributors.
- Robust *Zepzelca* development program planned:

- The Company's partner, PharmaMar, plans to initiate a confirmatory trial in second-line small cell lung cancer (SCLC) later this year. If positive, this trial would confirm the benefit of *Zepzelca* in the treatment of SCLC when patients progress following first-line treatment with a platinum-based regimen.
- The Company is collaborating with Roche to initiate a Phase 3 pivotal clinical trial in first-line extensive stage SCLC in combination with immunotherapy this year.
- The Company expects to initiate a Phase 2 basket trial in early 2022 to explore lurbinectedin monotherapy in patients with select advanced or metastatic solid tumors. Cohorts will include advanced urothelial cancer, large cell neuroendocrine tumor of the lung, and homologous recombinant deficient positive (HRD+) cancers.
- The Company has initiated a Phase 4 observational study to collect real world safety and outcome data in adult *Zepzelca* monotherapy patients with extensive stage small cell lung cancer who progress on or after prior platinum-containing chemotherapy.

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

- On June 30, 2021, FDA approved *Rylaze* under the Real-Time Oncology Review program for use as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma (LBL) in pediatric patients one month and older and adult patients who have developed hypersensitivity to *E. coli*-derived asparaginase.
- *Rylaze* was launched and commercially available in the U.S. on July 15, 2021.
- *Rylaze* is the only recombinant *Erwinia* asparaginase manufactured product that maintains a clinically meaningful level of asparaginase activity throughout the entire duration of treatment. It was developed by Jazz to address the needs of patients and healthcare providers for an innovative, high-quality *Erwinia* asparaginase with reliable supply.
- *Rylaze* was granted orphan drug designation for the treatment of ALL/LBL by FDA in June 2021.
- The Company will continue to work with FDA and plans to submit additional data in support of a Monday/Wednesday/Friday dosing schedule. Part B of the study is evaluating intravenous administration and is ongoing. The company also plans to submit this data for presentation at a future medical meeting.
- The Company anticipates that data from the current development program will support regulatory filings in Europe in 2022 and is currently working with an in-country partner to advance the program for filing, approval and launch in Japan.

Vyxeos® (daunorubicin and cytarabine) liposome for injection**:**

- *Vyxeos* net product sales increased 18% to $31.5 million in the second quarter of 2021 compared to the same period in 2020.

Defitelio® (defibrotide sodium) / defibrotide**:**

- *Defitelio*/defibrotide net product sales increased 13% to $48.1 million in the second quarter of 2021 compared to the same period in 2020.

Erwinaze® / Erwinase® (asparaginase *Erwinia chrysanthemi*)**:**

- *Erwinaze/Erwinase* net product sales decreased 13% to $28.3 million in the second quarter of 2021 compared to the same period in 2020.
- The Company's agreement with Porton Biopharma Limited terminated on December 31, 2020. The Company had the right to sell certain *Erwinaze* inventory post-termination. Sale of this inventory was completed in June 2021.

Financial Highlights

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands, except per share amounts)	2021	2020	2021	2020
Total revenues	$ 751,811	$ 562,436	$ 1,359,392	$ 1,097,162
GAAP net income (loss)	$ (363,316)	$ 114,801	$ (241,484)	$ (43,032)
Adjusted net income[1]	$ 240,575	$ 207,316	$ 469,394	$ 233,149
GAAP EPS	$ (6.11)	$ 2.06	$ (4.17)	$ (0.77)
Adjusted EPS[1]	$ 3.90	$ 3.71	$ 7.82	$ 4.14

1. Commencing in 2020, following consultation with the staff of the Division of Corporation Finance of the U.S. Securities and Exchange Commission, the Company no longer excludes upfront and milestone payments from the Company's non-GAAP adjusted net income, its line item components and non-GAAP adjusted EPS. See "Non-GAAP Financial Measures" below.

GAAP net income (loss) for the second quarter of 2021 was ($363.3 million), or ($6.11) per diluted share, compared to $114.8 million, or $2.06 per diluted share, for the second quarter of 2020.

Non-GAAP adjusted net income for the second quarter of 2021 was $240.6 million, or $3.90 per diluted share, compared to $207.3 million, or $3.71 per diluted share, for the second quarter of 2020.

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

Total Revenues

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands)	2021	2020	2021	2020
Xyrem	$ 334,182	$ 446,808	$ 669,732	$ 854,683
Xywav	124,164	—	199,580	—
Total Oxybate	458,346	446,808	869,312	854,683
Epidiolex/Epidyolex[1]	109,481	—	109,481	—
Sunosi	12,124	8,578	23,730	10,502
Sativex® (delta-9-tetrahydrocannabiol and cannabidiol)[1]	1,961	—	1,961	—
Total Neuroscience	581,912	455,386	1,004,484	865,185
Zepzelca	55,924	—	110,258	—
Vyxeos	31,453	26,568	64,608	59,288
Defitelio/defibrotide	48,096	42,714	97,715	90,146
Erwinaze/Erwinase	28,314	32,683	69,382	70,415
Total Oncology	163,787	101,965	341,963	219,849
Other	2,641	852	5,424	3,374
Product sales, net	748,340	558,203	1,351,871	1,088,408
Royalties and contract revenues	3,471	4,233	7,521	8,754
Total revenues	$ 751,811	$ 562,436	$ 1,359,392	$ 1,097,162

1. Net product sales for Epidiolex and Sativex are included from the closing of the GW Acquisition on May 5, 2021.

Total revenues increased 34% in the second quarter of 2021 compared to the same period in 2020.

- Products launched or acquired since 2019 accounted for 41% of total net product sales in the second quarter of 2021.
- Neuroscience net product sales in the second quarter of 2021 increased 28% to $581.9 million compared to the same period in 2020. Oxybate net product sales increased to $458.3 million led by strong *Xywav* net product sales of $124.2 million partially offset by a decrease in *Xyrem* net product sales as a result of the strong adoption of *Xywav* by existing *Xyrem* patients. *Epidiolex/Epidyolex* net product sales from the date of acquisition were $109.5 million.
- Oncology net product sales in the second quarter of 2021 increased 61% to $163.8 million compared to the same period in 2020 primarily driven by robust *Zepzelca* net product sales of $55.9 million. *Zepzelca* launched in the U.S. in July 2020.

Operating Expenses and Effective Tax Rate

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands, except percentages)	2021	2020	2021	2020
GAAP:				
Cost of product sales	$ 119,194	$ 28,008	$ 159,383	$ 56,665

Gross margin	*84.1%*	*95.0%*	*88.2%*	*94.8%*
Selling, general and administrative	$ 429,031	$ 191,406	$ 689,539	$ 399,806
% of total revenues	*57.1%*	*34.0%*	*50.7%*	*36.4%*
Research and development	$ 132,696	$ 78,922	$ 209,269	$ 165,029
% of total revenues	*17.7%*	*14.0%*	*15.4%*	*15.0%*
Acquired in-process research and development	$ —	$ 3,000	$ —	$ 205,250
Impairment charge	$ —	$ —	$ —	$ 136,139
Income tax provision	$ 228,621	$ 54,754	$ 246,640	$ 3,467
Effective tax rate	*N/A(1)*	*31.9%*	*N/A(1)*	*(9.2)%*

(1) Our effective tax rates for the three and six months ended June 30, 2021 on a GAAP basis are not meaningful metrics.

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands, except percentages)	2021	2020	2021	2020
Non-GAAP adjusted:				
Cost of product sales	$ 50,226	$ 26,087	$ 88,419	$ 53,071
Gross margin	*93.3%*	*95.3%*	*93.5%*	*95.1%*
Selling, general and administrative	$ 269,440	$ 170,386	$ 497,840	$ 358,190
% of total revenues	*35.8%*	*30.3%*	*36.6%*	*32.6%*
Research and development	$ 118,525	$ 71,259	$ 186,455	$ 150,981
% of total revenues	*15.8%*	*12.7%*	*13.7%*	*13.8%*
Acquired in-process research and development	$ —	$ 3,000	$ —	$ 205,250
Income tax provision	$ 30,262	$ 73,085	$ 67,921	$ 77,772
Effective tax rate	*11.2%*	*25.9%*	*12.8%*	*24.9%*

Operating expenses changed over the prior year periods primarily due to the following:

- Cost of product sales increased in the second quarter of 2021 compared to the same period in 2020, on a GAAP and non-GAAP adjusted basis, primarily due to increased net product sales as a result of the GW Acquisition. In addition, an acquisition accounting inventory fair value step-up expense of $66.0 million impacted GAAP cost of product sales.
- Selling, general and administrative (SG&A) expenses increased in the second quarter of 2021 compared to the same period in 2020, on a GAAP and on a non-GAAP adjusted basis, primarily due to an increase in compensation-related expenses driven by higher headcount as a result of the GW Acquisition, increased investment in sales, marketing and launch activities primarily related to *Sunosi, Xywav* and *Zepzelca* in the U.S. and the addition of costs related to *Epidiolex*. SG&A expenses in the second quarter of 2021 on a GAAP basis also included transaction and integration related expenses of $129.5 million related to the GW Acquisition.
- Research and development expenses increased in the second quarter of 2021 compared to the same period in 2020, on a GAAP and on a non-GAAP adjusted basis, primarily due to the addition of costs related to clinical programs for *Epidiolex*, nabiximols and cannabinoids, an increase in costs for JZP385 and an increase in compensation-related expenses due to higher headcount primarily driven by the GW Acquisition.
- On a GAAP basis, our income tax provision for the three months ended June 30, 2021, included an expense of $251.4 million arising on the remeasurement of our U.K. net deferred tax liability, which arose primarily in relation to the GW Acquisition, due to a change in the statutory tax rate in the U.K. following enactment of the UK Finance Act 2021. Due to the impact of this expense, our effective tax rate for the three months ended June 30, 2021, on a GAAP basis is not a meaningful metric.
- On a non-GAAP basis, the decrease in the effective tax rate in the second quarter of 2021 compared to the same period in 2020 was primarily due to the impact in 2020 of the disallowance of certain interest deductions, provision for the settlement reached with the French tax authorities, and the impact of the change in income mix.

Cash Flow and Balance Sheet

As of June 30, 2021, cash and cash equivalents were $891.4 million, and the outstanding principal balance of the Company's long-term debt was $7.1 billion. In addition, the Company had undrawn borrowing capacity under a revolving credit facility of $500.0 million.

For the six months ended June 30, 2021, the Company generated $326.7 million of cash from operations.

2021 Financial Guidance[1]

Jazz Pharmaceuticals is reaffirming its previously communicated full year 2021 non-GAAP financial guidance and updating its 2021 GAAP guidance. This guidance reflects the Company's current and future expected operational performance, including COVID-19 related impacts, the strength of its underlying operations and the prioritization of new and ongoing value creating development projects.

	Guidance provided as of	
(In millions)	June 17, 2021	August 3, 2021
Revenues	$3,020 - $3,180	$3,020 - $3,180
Total net product sales	$3,010 - $3,165	$3,010 - $3,165
-Neuroscience	$2,260 - $2,360	$2,260 - $2,360
-Oncology	$715 - $835	$715 - $835

GAAP:

	Guidance provided as of	
(In millions, except per share amounts and percentages)	June 17, 2021	August 3, 2021
Gross margin %	86%	85%
SG&A expenses	$1,468 - $1,560	$1,468 - $1,560
SG&A expenses as % of total revenues	*46% - 52%*	*46% - 52%*
R&D Expenses	$542 - $596	$542 - $596
R&D expenses as % of total revenues	*17% - 20%*	*17% - 20%*
Effective tax rate	18% - 21%	(58%) - (102%)
Net loss per diluted share	($4.70) – ($2.00)	($9.40) – ($6.70)[2]
Weighted-average ordinary shares used in per share calculations	62	60

Non-GAAP:

	Guidance provided as of	
(In millions, except per share amounts and percentages)	June 17, 2021	August 3, 2021
Gross margin %	93%	93%[3,7]
SG&A expenses	$1,120 - $1,180	$1,120 - $1,180[4,7]
SG&A expenses as % of total revenues	*35% - 39%*	*35% - 39%*
R&D Expenses	$500 - $540	$500 - $540[5,7]
R&D expenses as % of total revenues	*16% - 18%*	*16% - 18%*
Effective tax rate	13% - 15%	13% - 15%[6,7]
Net income per diluted share	$13.40 - $14.70	$13.40 - $14.70[2,7]
Weighted-average ordinary shares used in per share calculations	62	62

1. The Company's 2021 financial guidance includes the anticipated results of the acquired GW business from the date of acquisition (May 5, 2021) and related acquisition accounting adjustments, which are subject to change if the company obtains additional information during the measurement period (up to one year from the acquisition date); any such change could be material.

2. The Company expects the transaction to be dilutive to both GAAP and non-GAAP adjusted net income per diluted share in 2021. On a GAAP basis, this is expected to be primarily due to an increase in the amortization of acquisition-related intangible assets and transaction and integration related expenses, the amortization of inventory fair value step-up, increased interest expense and an increase in number of outstanding shares relating to the GW Acquisition. On a non-GAAP adjusted basis, this is expected to be due to increased cash interest expense and an increase in the number of outstanding shares.

3. Excludes $220-$260 million of amortization of acquisition-related inventory fair value step-up, $8-$10 million of share-based compensation expense and $2-$4 million of transaction and integration related expenses relating to the GW Acquisition from estimated GAAP gross margin.

4. Excludes $221-$245 million of transaction and integration related expenses relating to the GW Acquisition and $127-$135 million of share-based compensation expense from estimated GAAP SG&A expenses.

5. Excludes $35-$45 million of share-based compensation expense and $7-$11 million of transaction and integration related expenses relating to the GW Acquisition from estimated GAAP R&D expenses.

6. Excludes the income tax effect of adjustments between GAAP net income and non-GAAP adjusted net income and an expense of $251 million arising on the remeasurement of our U.K. net deferred tax liability, which arose primarily in relation to the GW Acquisition, due to a change in the statutory tax rate in the U.K. following enactment of the UK Finance Act 2021.

7. 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 2021 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 2021 second quarter results. The live webcast may be accessed from the Investors section of the Company's website at www.jazzpharmaceuticals.com. Please connect to the website prior to the start of the conference call to ensure adequate time for any software downloads that may be necessary. Investors may participate in the conference call by dialing +1 855 353 7924 in the U.S., or +1 503 343 6056 outside the U.S., and entering passcode 7187077.

A replay of the conference call will be available through August 10, 2021 by dialing +1 855 859 2056 in the U.S., or +1 404 537 3406 outside the U.S., and entering passcode 7187077. An archived version of the webcast will be available for at least one week in the Investors section of the Company's 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. For more information, please visit www.jazzpharmaceuticals.com and follow @JazzPharma on Twitter.

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 (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 non-GAAP adjustments and impact of the change in the statutory tax rate in the U.K. In this regard, the components of non-GAAP adjusted net income, including non-GAAP cost of product sales, non-GAAP SG&A expenses and non-GAAP 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. In particular, the Company believes 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 and 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 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. For example, commencing in 2020, the Company no longer excludes upfront and milestone payments from the Company's non-GAAP adjusted net income, its line item components and non-GAAP adjusted net income per diluted share. 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 2021 financial guidance and the Company's expectations related thereto; the potential launch of Xywav in IH and the timing thereof; the completion of integration in connection with the acquisition of GW Pharmaceuticals and the anticipated benefits of the addition of the GW Pharmaceuticals pipeline and cannabinoid platform to the Company's own pipeline; the anticipated supply and other benefits of Rylaze to patients and healthcare providers; the value of the Company's development platform; expected initiations of Epidiolex, nabiximols, JZP385, JZP150 and Zepzelca clinical trials and the timing thereof; the potential approval of nabiximols in MS Spasticity; the Company's plans to submit additional data for Rylaze; the therapeutic potential of the Company's product candidates; the value of the Company's diversified product portfolio; the Company's financing structure supporting its plans for rapid deleveraging to its stated targets; 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 and other key marketed products; effectively launching and commercializing the Company's other products and 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, including the risk that the Company's supplemental new drug application seeking approval for Xywav in IH may not be approved by FDA 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 such as those being experienced, and expected to continue to be experienced, by the Company as a result of the effects of the COVID-19 pandemic; the Company's failure to realize the expected benefits of its acquisition of GW Pharmaceuticals, including the risk that the legacy GW Pharmaceuticals business will not be integrated successfully or that such integration may be more difficult, time-consuming or costly than expected; the ultimate duration and severity of the COVID-19 pandemic and resulting global economic, financial, and healthcare system disruptions and the current and potential future negative impacts to the Company's business operations and financial results; regulatory initiatives and changes in tax laws; market volatility; protecting and enhancing the Company's intellectual property rights; 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; government investigations, legal proceedings and other actions; identifying and acquiring, in-licensing or developing additional products or product candidates, 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 to fund its debt service obligations, de-lever and meet its stated leverage targets; the Company's ability to achieve expected future financial performance and results and the uncertainty of future tax, accounting and other provisions and estimates; the possibility that, if the Company does not achieve the perceived benefits of the acquisition of GW Pharmaceuticals as rapidly or to the extent anticipated by financial analysts or investors, the market price of the Company's ordinary shares could decline; 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' and GW Pharmaceuticals' Securities and Exchange Commission filings and reports, including the Company's Annual Report on Form 10-K for the year ended December 31, 2020, GW Pharmaceuticals' Annual Report on Form 10-K for the year ended December 31, 2020, and future filings and reports by the Company, including the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2021. 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 (LOSS)
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenues:				
Product sales, net	$ 748,340	$ 558,203	$ 1,351,871	$ 1,088,408
Royalties and contract revenues	3,471	4,233	7,521	8,754
Total revenues	751,811	562,436	1,359,392	1,097,162
Operating expenses:				
Cost of product sales (excluding amortization of acquired developed technologies)	119,194	28,008	159,383	56,665
Selling, general and administrative	429,031	191,406	689,539	399,806
Research and development	132,696	78,922	209,269	165,029
Intangible asset amortization	140,480	62,974	208,672	125,821
Acquired in-process research and development	—	3,000	—	205,250

Impairment charge	—	—	—	136,139
Total operating expenses	821,401	364,310	1,266,863	1,088,710
Income (loss) from operations	(69,590)	198,126	92,529	8,452
Interest expense, net	(69,420)	(26,210)	(96,796)	(44,706)
Foreign exchange gain (loss)	2,950	(464)	3,893	(1,596)
Income (loss) before income tax provision and equity in (gain) loss of investees	(136,060)	171,452	(374)	(37,850)
Income tax provision	228,621	54,754	246,640	3,467
Equity in (gain) loss of investees	(1,365)	1,897	(5,530)	1,715
Net income (loss)	$ (363,316)	$ 114,801	$ (241,484)	$ (43,032)
Net income (loss) per ordinary share:				
Basic	$ (6.11)	$ 2.07	$ (4.17)	$ (0.77)
Diluted	$ (6.11)	$ 2.06	$ (4.17)	$ (0.77)
Weighted-average ordinary shares used in per share calculations - basic	59,448	55,413	57,966	55,684
Weighted-average ordinary shares used in per share calculations - diluted	59,448	55,864	57,966	55,684

JAZZ PHARMACEUTICALS PLC
PRO FORMA NET PRODUCT SALES
(In thousands)
(Unaudited)

The following unaudited pro forma information represents the net product sales for the three and six months ended June 30, 2021, compared to the same periods in 2020, as if the GW Acquisition had been completed on January 1, 2020:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Xyrem	$ 334,182	$ 446,808	$ 669,732	$ 854,683
Xywav	124,164	—	199,580	—
Total Oxybate	458,346	446,808	869,312	854,683
Epidiolex/Epidyolex	155,868	117,741	304,130	233,883
Sunosi	12,124	8,578	23,730	10,502
Sativex® (delta-9-tetrahydrocannabiol and cannabidiol)	3,548	3,488	7,728	7,873
Total Neuroscience	629,886	576,615	1,204,900	1,106,941
Zepzelca	55,924	—	110,258	—
Defitelio	48,096	42,714	97,715	90,146
Vyxeos	31,453	26,568	64,608	59,288
Erwinaze/Erwinase	28,314	32,683	69,382	70,415
Total Oncology	163,787	101,965	341,963	219,849
Other	2,641	852	5,424	3,374
Product sales, net	$ 796,314	$ 679,432	$ 1,552,287	$ 1,330,164

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

	June 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 891,400	$ 1,057,769
Investments	—	1,075,000
Accounts receivable, net of allowances	506,660	396,490
Inventories	1,251,259	95,396
Prepaid expenses	104,455	62,422
Other current assets	200,190	152,491
Total current assets	2,953,964	2,839,568
Property, plant and equipment, net	277,066	127,935
Operating lease assets	149,254	129,169
Intangible assets, net	7,588,029	2,195,051
Goodwill	1,887,699	958,303
Deferred tax assets, net	296,493	254,916
Deferred financing costs	13,406	5,238
Other non-current assets	47,082	25,721
Total assets	$ 13,212,993	$ 6,535,901
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 64,826	$ 26,945
Accrued liabilities	561,091	352,732
Current portion of long-term debt	248,585	246,322
Income taxes payable	3,645	25,200
Deferred revenue	2,441	2,546
Total current liabilities	880,588	653,745
Deferred revenue, non-current	1,510	2,315
Long-term debt, less current portion	6,489,315	1,848,516
Operating lease liabilities, less current portion	156,556	140,035
Deferred tax liabilities, net	1,421,027	130,397
Other non-current liabilities	132,507	101,148
Total shareholders' equity	4,131,490	3,659,745
Total liabilities and shareholders' equity	$ 13,212,993	$ 6,535,901

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

	Six Months Ended June 30,	
	2021	2020
Net cash provided by operating activities	$ 326,692	$ 455,488
Net cash used in investing activities	(5,175,238)	(801,245)
Net cash provided by financing activities	4,682,312	494,851
Effect of exchange rates on cash and cash equivalents	(135)	(356)

Net increase (decrease) in cash and cash equivalents	$ (166,369)	$ 148,738

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
GAAP reported net income (loss)	**$ (363,316)**	**$ 114,801**	**$ (241,484)**	**$ (43,032)**
Intangible asset amortization	140,480	62,974	208,672	125,821
Share-based compensation expense	43,411	30,604	77,896	59,258
Transaction and integration related expenses[1]	133,328	—	141,590	—
Non-cash interest expense[2]	22,322	17,268	38,010	29,268
Acquisition accounting inventory fair value step-up	65,991	—	65,991	—
Impairment charge[3]	—	—	—	136,139
Income tax effect of above adjustments	(53,021)	(18,331)	(72,661)	(74,305)
Impact of U.K. tax rate change[4]	251,380	—	251,380	—
Non-GAAP adjusted net income	$ 240,575	$ 207,316	$ 469,394	$ 233,149
GAAP reported net income (loss) per diluted share	**$ (6.11)**	**$ 2.06**	**$ (4.17)**	**$ (0.77)**
Non-GAAP adjusted net income per diluted share	$ 3.90	$ 3.71	$ 7.82	$ 4.14
Weighted-average ordinary shares used in diluted per share calculations - GAAP	59,448	55,864	57,966	55,684
Weighted-average ordinary shares used in diluted per share calculations - non-GAAP	61,686	55,864	60,047	56,328

Explanation of Adjustments and Certain Line Items:

1. Transaction and integration related expenses related to the GW Acquisition.

2. Non-cash interest expense associated with debt discount and debt issuance costs.

3. Impairment charge related to the Company's decision to stop enrollment in its Phase 3 clinical trial of defibrotide for the prevention of veno-occlusive disease.

4. Expense arising on the remeasurement of our U.K. net deferred tax liability, which arose primarily in relation to the GW Acquisition, due to a change in the statutory tax rate in the U.K. following enactment of the UK Finance Act 2021.

JAZZ PHARMACEUTICALS PLC
RECONCILIATIONS OF GAAP REPORTED TO NON-GAAP ADJUSTED INFORMATION
CERTAIN LINE ITEMS - FOR THE THREE MONTHS ENDED JUNE 30, 2021 and 2020
(In thousands, except percentages)
(Unaudited)

	Three months ended June 30, 2021							
	Cost of product sales	Gross margin	Selling, general and administrative	Research and development	Intangible asset amortization	Interest expense, net	Income tax provision	Effective tax rate
GAAP Reported	**$ 119,194**	***84.1%***	**$ 429,031**	**$ 132,696**	**$ 140,480**	**$ 69,420**	**$ 228,621**	***N/A(1)***
Non-GAAP Adjustments:								
Intangible asset amortization	—	—	—	—	(140,480)	—	—	—
Share-based compensation expense	(2,572)	*0.4*	(30,046)	(10,793)	—	—	—	—
Transaction and integration related expenses	(405)	—	(129,545)	(3,378)	—	—	—	—
Non-cash interest expense	—	—	—	—	—	(22,322)	—	—
Acquisition accounting inventory fair value step-up	(65,991)	*8.8*	—	—	—	—	—	—
Income tax effect of above adjustments	—	—	—	—	—	—	53,021	*N/A(1)*
Impact of U.K. tax rate change	—	—	—	—	—	—	(251,380)	*N/A(1)*
Total of Non-GAAP adjustments	(68,968)	*9.2*	(159,591)	(14,171)	(140,480)	(22,322)	(198,359)	*N/A(1)*
Non-GAAP Adjusted	$ 50,226	*93.3%*	$ 269,440	$ 118,525	$ —	$ 47,098	$ 30,262	*11.2%*

(1) Due to the impact of the U.K tax change, the GAAP effective tax rate is not a meaningful metric.

	Three months ended June 30, 2020							
	Cost of product sales	Gross margin	Selling, general and administrative	Research and development	Intangible asset amortization	Interest expense, net	Income tax provision	Effective tax rate
GAAP Reported	**$ 28,008**	***95.0%***	**$ 191,406**	**$ 78,922**	**$ 62,974**	**$ 26,210**	**$ 54,754**	***31.9%***
Non-GAAP Adjustments:								
Intangible asset amortization	—	—	—	—	(62,974)	—	—	—
Share-based compensation expense	(1,921)	*0.3*	(21,020)	(7,663)	—	—	—	—
Non-cash interest expense	—	—	—	—	—	(17,268)	—	—
Income tax effect of above adjustments	—	—	—	—	—	—	18,331	*(6.0)*
Total of Non-GAAP adjustments	(1,921)	*0.3*	(21,020)	(7,663)	(62,974)	(17,268)	18,331	*(6.0)*
Non-GAAP Adjusted	$ 26,087	*95.3%*	$ 170,386	$ 71,259	$ —	$ 8,942	$ 73,085	*25.9%*

JAZZ PHARMACEUTICALS PLC
RECONCILIATIONS OF GAAP REPORTED TO NON-GAAP ADJUSTED INFORMATION
CERTAIN LINE ITEMS - FOR THE SIX MONTHS ENDED JUNE 30, 2021 and 2020
(In thousands, except percentages)
(Unaudited)

	Six months ended June 30, 2021							
	Cost of product sales	Gross margin	Selling, general and administrative	Research and development	Intangible asset amortization	Interest expense, net	Income tax provision	Effective tax rate
GAAP Reported	**$ 159,383**	***88.2%***	**$ 689,539**	**$ 209,269**	**$ 208,672**	**$ 96,796**	**$ 246,640**	***N/A(1)***
Non-GAAP Adjustments:								
Intangible asset amortization	—	—	—	—	(208,672)	—	—	—
Share-based compensation expense	(4,568)	*0.4*	(53,892)	(19,436)	—	—	—	—
Transaction and integration related expenses	(405)	—	(137,807)	(3,378)	—	—	—	—

Non-cash interest expense	—	—	—	—	—	(38,010)	—	—
Acquisition accounting inventory fair value step-up	(65,991)	*4.9*	—	—	—	—	—	—
Income tax effect of above adjustments	—	—	—	—	—	—	72,661	*N/A(1)*
Impact of U.K. tax rate change	—	—	—	—	—	—	(251,380)	*N/A(1)*
Total of Non-GAAP adjustments	(70,964)	*5.3*	(191,699)	(22,814)	(208,672)	(38,010)	(178,719)	*N/A(1)*
Non-GAAP Adjusted	$ 88,419	*93.5%*	$ 497,840	$ 186,455	$ —	$ 58,786	$ 67,921	*12.8%*

(1) Due to the impact of the U.K tax change, the GAAP effective tax rate is not a meaningful metric.

	Six months ended June 30, 2020								
	Cost of product sales	**Gross margin**	**Selling, general and administrative**	**Research and development**	**Intangible asset amortization**	**Impairment charge**	**Interest expense, net**	**Income tax provision**	**Effective tax rate**
GAAP Reported	**$ 56,665**	***94.8%***	**$ 399,806**	**$ 165,029**	**$ 125,821**	**$ 136,139**	**$ 44,706**	**$ 3,467**	***(9.2)%***
Non-GAAP Adjustments:									
Intangible asset amortization	—	—	—	—	(125,821)	—	—	—	—
Share-based compensation expense	(3,594)	*0.3*	(41,616)	(14,048)	—	—	—	—	—
Impairment charge	—	—	—	—	—	(136,139)	—	—	—
Non-cash interest expense	—	—	—	—	—	—	(29,268)	—	—
Income tax effect of above adjustments	—	—	—	—	—	—	—	74,305	*34.1*
Total of Non-GAAP adjustments	(3,594)	*0.3*	(41,616)	(14,048)	(125,821)	(136,139)	(29,268)	74,305	*34.1*
Non-GAAP Adjusted	$ 53,071	*95.1%*	$ 358,190	$ 150,981	$ —	$ —	$ 15,438	$ 77,772	*24.9%*

JAZZ PHARMACEUTICALS PLC
RECONCILIATION OF GAAP TO NON-GAAP ADJUSTED 2021 NET INCOME GUIDANCE
(In millions, except per share amounts)
(Unaudited)

GAAP net loss	**($560) – ($400)**
Intangible asset amortization	525 – 545
Acquisition accounting inventory fair value step-up	220 – 260
Share-based compensation expense	170 – 190
Transaction and integration related expenses	230 – 260
Non-cash interest expense	90 – 110
Income tax effect of above adjustments	(195) - (205)
Impact of UK tax rate change	251
Non-GAAP adjusted net income	$830 – $910
GAAP net loss per diluted share	**($9.40) – ($6.70)**
Non-GAAP adjusted net income per diluted share	$13.40 – $14.70
Weighted-average ordinary shares used in per share calculations - GAAP	60
Weighted-average ordinary shares used in per share calculations - Non-GAAP	62

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