Jazz Pharmaceuticals Announces Second Quarter 2020 Financial Results

August 4, 2020

Strong Financial and Operational Performance in the Second Quarter

Total Revenues Increased 5% Compared to Second Quarter 2019

2020 Total Revenue Guidance Increased to a Range of $2.225 Billion to $2.325 Billion

2020 GAAP EPS Guidance Increased to $3.40 - $4.85

2020 Adjusted EPS Guidance Increased to $11.90 - $13.00

On Track to Deliver Diversified Top-line Growth with up to Five Product Launches Through 2021

DUBLIN, Aug. 4, 2020 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced financial results for the second quarter of 2020 and updated its 2020 financial guidance.

"I am proud that we delivered strong financial and operational results above our expectations despite challenges arising from the COVID-19 pandemic," said Bruce Cozadd, chairman and chief executive officer of Jazz Pharmaceuticals. "With the strong performance of Xyrem and the recent FDA approval of Xywav, we are well-positioned to ensure the durability and growth of our oxybate business with differentiated products."

"The second quarter was highlighted by the approval of Zepzelca, and our subsequent strong launch, which was accomplished within six months of closing the licensing agreement with PharmaMar," continued Mr. Cozadd. "We also innovated around the challenges of the pandemic, pivoting to a timely virtual launch of Sunosi in Germany and implementing robust measures to facilitate continued progress of our clinical development programs and regulatory filings."

"Through the issuance of $1 billion of senior notes in the second quarter, we strengthened our financial position and increased our capacity for a broader set of corporate development opportunities," concluded Mr. Cozadd. "With multiple commercial launches, the expansion of our innovative pipeline, strategic capital allocation, and projected durable revenue growth and diversification, this is a transformative year for us, and we are excited about the opportunities ahead for patients and shareholders."

The company is on track to execute up to five key launches through 2020 and 2021:

- European rolling launch of Sunosi (initiated May 2020);
- U.S. launch of Zepzelca (initiated July 2020);
- U.S. launch of Xywav in the fourth quarter of 2020 following the implementation of the risk evaluation and mitigation strategy (REMS);
- U.S. launch of JZP-458 (recombinant *Erwinia* asparaginase) targeted for mid-2021, following a Biologics License Application (BLA) submission and approval; and
- U.S. launch of a new indication for Xywav in idiopathic hypersomnia (IH) targeted for late 2021 following a supplemental New Drug Application (sNDA) submission and approval.

The company expects these launches to enhance the durability and long-term growth of its neuroscience business and the significant near-term and long-term value of its oncology business.

Business Updates

COVID-19

- In the second quarter of 2020, the company experienced an impact to its business due to reduced patient and healthcare provider interactions, declines in sales representative access to healthcare providers, global government imposed stay-at-home orders, closure of sleep laboratories and treatment centers and the shift to caring for COVID-19 patients.
- Throughout the pandemic, the company has leveraged technology and innovation to continue to engage healthcare professionals. The company's field forces have resumed face-to-face engagement with healthcare providers where possible.
- The company's mid- and late-stage clinical trial activity has seen limited impact. The company has taken measures to implement remote and virtual approaches to its clinical trial activities, including remote data monitoring where possible, to maintain patient safety and trial continuity and preserve study integrity.
- The company currently expects to have adequate global supply of Xyrem, Sunosi, Defitelio, Vyxeos and Zepzelca for the remainder of 2020, as well as adequate commercial product availability for Xywav to support the planned U.S. launch later this year.
- Throughout the pandemic, the company has supported local communities and patient-focused organizations in COVID-19 relief efforts and remains focused on the safety and well-being of its employees.

Neuroscience

Xyrem:

- Xyrem net product sales increased 8% to $446.8 million in the second quarter of 2020 and 9% to $854.7 million in the first half of 2020, compared to the same periods in 2019.
- During the quarter, revenue bottle volume growth was 5% and average active patients on therapy grew 3% compared to the second quarter of 2019.
- New patient enrollment trended upwards beginning in the latter half of the second quarter following the COVID-19 related decline late in the first quarter of 2020.

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

- In July 2020, the U.S. Food and Drug Administration (FDA) approved the NDA for Xywav, a new differentiated standard of oxybate therapy for the treatment of cataplexy or excessive daytime sleepiness (EDS) in narcolepsy patients 7 years of age and older.
- The approval of Xywav is the culmination of nearly a decade of research and development reflecting the company's ongoing efforts to address the needs of narcolepsy patients.
- The company believes Xywav will become the oxybate treatment of choice for patients.
- Xywav has 92 percent less sodium than Xyrem, which translates into a reduction of approximately 1,000 to 1,500 milligrams per day for a patient prescribed an oxybate product.
    - The label for Xywav, unlike Xyrem, does not include a warning to prescribers to monitor patients sensitive to sodium intake, including patients with heart failure, hypertension or renal impairment.
    - There is a well-accepted relationship between dietary sodium and blood pressure as well as published hypertension guidelines which underscore the independent association between excessive consumption of sodium and increased risk of stroke, cardiovascular disease and other adverse outcomes.
- Multiple and flexible Xywav dosing options are available for adult and pediatric patients and existing Xyrem patients can readily cross over to Xywav at the same dose level.
- The joint Xywav and Xyrem REMS implementation is on schedule to support the launch of Xywav in the fourth quarter of 2020.
- To ensure timely and broad patient access, Xywav will be priced at parity to Xyrem.
- The company expects top-line data in the Xywav Phase 3 pivotal study for the treatment of IH in the fourth quarter of 2020 and submission of a sNDA to FDA as early as the first quarter of 2021. The company is targeting a late 2021 launch.

Sunosi:

- Sunosi net product sales were $8.6 million in the second quarter of 2020, compared to $1.9 million in the first quarter of 2020. The company launched Sunosi in the U.S. in July 2019.
- Net sales in the second quarter of 2020 benefited from lower gross-to-net deductions, and a 12% increase in U.S. prescriptions compared to the first quarter of 2020. Sunosi was approved by the European Medicines Agency (EMA) in January 2020 and launched in Germany in May 2020.
- At the end of the second quarter, approximately 85% of commercially insured U.S. patients had access to coverage for Sunosi.

JZP-385

- JZP-385, a highly selective modulator of T-type calcium channels, is in clinical development for the potential treatment of essential tremor.
- The company is initiating a new healthy volunteer study in August 2020 to evaluate a modified release formulation.
- Study start-up activities will begin later this year to enable initiation of a Phase 2b study in early 2021.

Oncology

Zepzelca™ (lurbinectedin):

- In June 2020, Zepzelca received accelerated approval by FDA for the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy.
- In July 2020, the company launched Zepzelca in the U.S. and the National Comprehensive Cancer Network (NCCN) added Zepzelca to the Clinical Practice Guidelines in Oncology for SCLC as a preferred treatment in patients who relapse in six months or less after prior systemic therapy and as a recommended regimen in patients who relapse more than six months after prior systemic therapy.
- All contracts with distributors and GPOs were in place at launch.
- The company is experiencing strong initial physician reception and uptake of Zepzelca across academic and community accounts and the sales force is actively engaging with target prescribers through live and virtual interactions.

Erwinaze:

- Erwinaze/Erwinase net product sales increased by $5.1 million to $32.7 million in the second quarter of 2020 compared to the same period in 2019.
- Erwinaze availability continues to be impacted by ongoing supply and manufacturing issues at the owner and sole manufacturer of the product, Porton Biopharma Limited (PBL), and the company continues to expect inter-quarter variability in Erwinaze net product sales due to timing and availability of supply.
- The company's current agreement with PBL will terminate on December 31, 2020. The company has the right to sell certain Erwinaze inventory post-termination and expects to distribute available Erwinaze supply through the first half of 2021.

JZP-458 (recombinant *Erwinia* asparaginase):

- The company continues to progress development of JZP-458 to ensure that acute lymphoblastic leukemia patients have access to a reliable, high-quality recombinant product.
- The pivotal Phase 2/3 study is continuing, with nearly all planned clinical sites activated and patient enrollment progressing well.
- The company expects to submit a BLA as early as year-end, with an objective of launching in the U.S. in mid-2021.

Defitelio:

- Defitelio/defibrotide net product sales decreased 7% to $42.7 million in the second quarter of 2020 compared to the same period in 2019. During the second quarter of 2020, demand was impacted by a reduction in the number of hematopoietic stem cell transplants performed due to COVID-19. The company observed a recovery in demand towards the end of the second quarter.
- The company expects top-line results from the Phase 2 proof-of-concept study for prevention of acute graft-versus-host disease in late 2020.

Vyxeos:

- Vyxeos net product sales decreased 15% to $26.6 million in the second quarter of 2020 compared to the same period in 2019. During the second quarter of 2020, Vyxeos sales were impacted by COVID-19 treatment recommendations to opt for oral or less intensive outpatient therapies for cancer patients. The company observed a recovery in demand late in the second quarter, particularly as hospitals adopted procedures to accommodate the care of non-COVID-19 patients.
- At the American Society of Clinical Oncology Annual Meeting in May, the 5-year overall survival data from the Phase 3 pivotal study demonstrated that improved survival with Vyxeos was maintained in the overall study population. These data support prior evidence that Vyxeos has the ability to contribute to durable remissions in older patients with newly diagnosed high-risk/secondary acute myeloid leukemia.

Corporate

- In June 2020, following FDA approval of Zepzelca, the company made a milestone payment of $100.0 million to Pharma Mar, S.A. (PharmaMar) in accordance with its exclusive U.S. license agreement. The company capitalized the payment, resulting in an increase in intangible assets.

Financial Highlights

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands, except per share amounts)	2020	2019	2020	2019
Total revenues	$ 562,436	$ 534,133	$ 1,097,162	$ 1,042,319
GAAP net income (loss)	$ 114,801	$ 261,898	$ (43,032)	$ 347,099
Adjusted net income[1]	$ 207,316	$ 232,537	$ 233,149	$ 396,710
GAAP EPS	$ 2.06	$ 4.56	$ (0.77)	$ 6.01
Adjusted EPS[1]	$ 3.71	$ 4.05	$ 4.14	$ 6.87

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. For purposes of comparability, non-GAAP adjusted financial measures for the six months ended June 30, 2019 have been updated to reflect this change. See "Non-GAAP Financial Measures" below.

GAAP net income for the second quarter of 2020 was $114.8 million, or $2.06 per diluted share, compared to $261.9 million, or $4.56 per diluted share, for the second quarter of 2019. On a GAAP basis, in the second quarter of 2019, the company recorded a one-time tax benefit of $112.3 million, or $1.96 per diluted share, resulting from an intra-entity intellectual property asset transfer.

Non-GAAP adjusted net income for the second quarter of 2020 was $207.3 million, or $3.71 per diluted share, compared to $232.5 million, or $4.05 per diluted share, in the second quarter of 2019. 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)	2020	2019	2020	2019
Xyrem® (sodium oxybate) oral solution	$ 446,808	$ 413,212	$ 854,683	$ 781,529
Defitelio® (defibrotide sodium) / defibrotide	42,714	46,055	90,146	87,555
Erwinaze® / Erwinase® (asparaginase *Erwinia chrysanthemi*)	32,683	27,622	70,415	88,521
Vyxeos® (daunorubicin and cytarabine) liposome for injection	26,568	31,362	59,288	60,305
Sunosi® (solriamfetol)	8,578	—	10,502	—
Other	852	5,172	3,374	8,844
Product sales, net	558,203	523,423	1,088,408	1,026,754
Royalties and contract revenues	4,233	10,710	8,754	15,565
Total revenues	$ 562,436	$ 534,133	$ 1,097,162	$ 1,042,319

Total revenues increased 5% in the second quarter of 2020 compared to the same period in 2019. Total net product sales increased 7% in the second quarter of 2020 compared to the same period in 2019 primarily due to an increase in Xyrem, Sunosi and Erwinaze net product sales, partially offset by a decrease in Vyxeos and Defitelio net product sales.

Operating Expenses and Effective Tax Rate

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands, except percentages)	2020	2019	2020	2019
GAAP:				
Cost of product sales	$ 28,008	$ 27,676	$ 56,665	$ 61,182
Gross margin	*95.0 %*	*94.7 %*	*94.8 %*	*94.0 %*
Selling, general and administrative	$ 191,406	$ 176,014	$ 399,806	$ 343,961
% of total revenues	*34.0 %*	*33.0 %*	*36.4 %*	*33.0 %*
Research and development	$ 78,922	$ 62,384	$ 165,029	$ 122,489
% of total revenues	*14.0 %*	*11.7 %*	*15.0 %*	*11.8 %*
Acquired in-process research and development	$ 3,000	$ 2,200	$ 205,250	$ 58,200
Impairment charge	$ —	$ —	$ 136,139	$ —
Income tax provision (benefit)	$ 54,754	$ (78,650)	$ 3,467	$ (49,534)
Effective tax rate	*31.9 %*	*(42.7) %*	*(9.2) %*	*(16.5) %*

	Three Months Ended June 30,		Six Months Ended June 30,	
(In thousands, except percentages)	2020	2019	2020	2019
Non-GAAP adjusted:				
Cost of product sales	$ 26,087	$ 25,968	$ 53,071	$ 57,815
Gross margin	*95.3 %*	*95.0 %*	*95.1 %*	*94.4 %*
Selling, general and administrative	$ 170,386	$ 155,329	$ 358,190	$ 302,906
% of total revenues	*30.3 %*	*29.1 %*	*32.6 %*	*29.1 %*
Research and development	$ 71,259	$ 56,488	$ 150,981	$ 111,070
% of total revenues	*12.7 %*	*10.6 %*	*13.8 %*	*10.7 %*
Acquired in-process research and development	$ 3,000	$ 2,200	$ 205,250	$ 58,200
Income tax provision	$ 73,085	$ 52,027	$ 77,772	$ 97,741
Effective tax rate	*25.9 %*	*18.2 %*	*24.9 %*	*19.7 %*

Operating expenses increased over the prior year period primarily due to the following:

- Selling, general and administrative (SG&A) expenses increased in the second quarter of 2020 compared to the same period in 2019 on a GAAP and on a non-GAAP adjusted basis due to increased investment in sales, marketing and launch activities related to the company's priority products and product candidates, as well as an increase in other expenses related to the expansion of the company's business.
- Research and development (R&D) expenses increased in the second quarter of 2020 compared to the same period in 2019 on a GAAP and on a non-GAAP adjusted basis primarily due to the pivotal JZP-458 study, as well as expenses related to progress made on the company's other clinical and pre-clinical development programs.

The effective tax rate increased over the prior year period primarily due to the following:

- On a GAAP basis, in the second quarter of 2019, the company recorded a one-time tax benefit of $112.3 million, or $1.96 per diluted share, resulting from an intra-entity intellectual property asset transfer. The increase in the effective tax rate in the second quarter of 2020 compared to the same period in 2019 was primarily due to the impact of the intra-entity intellectual property asset transfer. Excluding this effect, the increase in the effective tax rate for the second quarter of 2020 compared to the same period in 2019 was primarily due to the impact of the disallowance of certain interest deductions, and provision for a proposed settlement reached with the French tax authorities in respect of an ongoing tax audit.
- On a non-GAAP basis, the increase in the effective tax rate in the second quarter of 2020 compared to the same period in 2019 was primarily due to the impact of the disallowance of certain interest deductions, and provision for a proposed settlement reached with the French tax authorities in respect of an ongoing tax audit.

Cash Flow and Balance Sheet

As of June 30, 2020, cash, cash equivalents and investments were $1.7 billion, and the outstanding principal balance of the company's long-term debt was $2.4 billion. In the second quarter of 2020, the company issued $1.0 billion aggregate principal amount of 2.00% exchangeable senior notes due 2026 (2026 Notes) and used $332.9 million of the $981.4 million in net proceeds from the offering to repurchase $332.9 million aggregate principal amount of the company's 1.875% exchangeable senior notes due 2021 (2021 Notes). The remaining principal balance of the 2021 Notes was $242.1 million as of June 30, 2020. The remaining net proceeds from the issuance of the 2026 Notes will be used for general corporate purposes, including additional repurchases of the 2021 Notes. In June 2020, the company repaid a total of $500.0 million of borrowings under the company's revolving credit facility, which the company had drawn down in April 2020.

During the six months ended June 30, 2020, the company generated $455.5 million of cash from operations, made upfront and milestone payments totaling $300.0 million to PharmaMar under a license agreement and used $146.5 million to repurchase shares under the company's share repurchase program.

In the six months ended June 30, 2020, the company repurchased approximately 1.2 million ordinary shares under the company's share repurchase program at an average cost of $121.98 per ordinary share. As of June 30, 2020, the remaining amount authorized for share repurchases under the company's share repurchase program was $431.2 million.

2020 Financial Guidance

As noted above, Jazz Pharmaceuticals is updating its full year 2020 financial guidance. This guidance reflects the company's current and future expected operational performance, including the impact of COVID-19, and reflects the durability of its products, the strength of its underlying operations and the prioritization of new and ongoing value creating development projects.

(in millions)	**Guidance provided as of**	
	May 5, 2020	**August 4, 2020**
Revenues	$2,120 - $2,260	$2,225 - $2,325
Total net product sales	$2,105 - $2,240	$2,210 - $2,310
-Neuroscience	$1,650 - $1,740	$1,725 - $1,800
-Oncology	$420 - $510	$445 - $525

GAAP:

(in millions, except per share amounts and percentages)	**Guidance provided as of**	
	May 5, 2020	**August 4, 2020**
Gross margin %	94%	94%
SG&A expenses	$785 - $843	$785 - $843
SG&A expenses as % of total revenues	*35% - 40%*	*34% - 38%*
R&D Expenses	$277 - $313	$302 - $338
R&D expenses as % of total revenues	*12% - 15%*	*13% - 15%*
Acquired in-process research and development expenses	$202	$205
Impairment charge	$136	$136
Effective tax rate	22% - 29%	19% - 26%
Net income per diluted share	$2.70 - $4.30	$3.40 - $4.85

Non-GAAP:

(in millions, except per share amounts and percentages)	**Guidance provided as of**	
	May 5, 2020	**August 4, 2020**
Gross margin %	94%[1,6]	94%[1,6]
SG&A expenses	$700 - $750[2,6]	$700 - $750[2,6]
SG&A expenses as % of total revenues	*31% - 35%*	*30% - 34%*
R&D Expenses	$250 - $280[3,6]	$275 - $305[3,6]
R&D expenses as % of total revenues	*11% - 13%*	*12% - 14%*
Acquired in-process research and development expenses	$202[4]	$205[4]
Effective tax rate	20% - 23%[5,6]	19% - 22%[5,6]
Net income per diluted share	$11.25 - $12.50[4,6]	$11.90 - $13.00[4,6]

1. Excludes $8-$9 million of share-based compensation expense from estimated GAAP gross margin.
2. Excludes $85-$93 million of share-based compensation expense from estimated GAAP SG&A expenses.
3. Excludes $27-$33 million of share-based compensation expense from estimated GAAP R&D expenses.
4. 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 EPS. The impact of this change to the company's 2020 non-GAAP adjusted net income and non-GAAP adjusted EPS guidance is approximately $175 million or $3.13 per diluted share, respectively, primarily related to the post-tax impact of the $200 million upfront payment made to PharmaMar in January 2020.
5. Excludes the income tax effect of adjustments between GAAP reported and non-GAAP adjusted net income.
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 2020 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. EDT (9:30 p.m. IST) to provide a business and financial update and discuss its 2020 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 2644219.

A replay of the conference call will be available through August 11, 2020 by dialing +1 855 859 2056 in the U.S., or +1 404 537 3406 outside the U.S., and entering passcode 2644219. 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 dedicated to developing and commercializing life-changing medicines that transform the lives of patients with serious diseases - often with limited or no options. We have a diverse portfolio of marketed medicines and novel product candidates, from early- to late-stage development, in key therapeutic areas. Our focus is in neuroscience, including sleep and movement disorders, and in oncology, including hematologic and solid tumors. We actively explore new options for patients including novel compounds, small molecule advancements, biologics and innovative delivery technologies. Jazz is headquartered in Dublin, Ireland and has employees around the globe, serving patients in more than 90 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 the income tax benefit related to an intra-entity intellectual property asset transfer. 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 EPS. For purposes of comparability, non-GAAP adjusted financial measures for the six months ended June 30, 2019 have been updated to reflect this change. Accordingly, such payments are not excluded from its non-GAAP financial measures for the three and six months ended June 30, 2020 and 2019, or from 2020 non-GAAP adjusted net income guidance and non-GAAP adjusted net income per diluted share guidance as detailed in the reconciliation tables that follow. 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.

"Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995

This press release contains forward-looking statements, including, but not limited to, statements related to Jazz Pharmaceuticals' future financial and operating results, including the company's updated 2020 financial guidance; the company's belief that it is well-positioned to ensure the durability and growth of its oxybate business with differentiated products and that 2020 is a transformative year for the company with multiple commercial launches, the expansion of its innovative pipeline, strategic capital allocation and projected revenue growth and diversification; the company's expectation that its 2020 and 2021 product launches will enhance the durability and long-term growth of its neuroscience business and the significant near- and long-term value of its oncology business; the company's expected clinical development and regulatory milestones and the timing thereof, including with respect to JZP-458, Xywav in idiopathic hypersomnia and defibrotide for the prevention of acute graft-versus-host disease; the company's expectation of interquarter variability in Erwinaze net product sales due to timing and availability of supply and its expectation of distributing Erwinaze supply through the first half of 2021; 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: 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; maintaining or increasing sales of and revenue from Xyrem and other key marketed products; effectively launching and commercializing the company's other products and product candidates; the time-consuming and uncertain regulatory approval process, including the risk that the company's 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 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; 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; obtaining and maintaining adequate coverage and reimbursement for the company's products; 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 with third parties for the development of product candidates; the company's ability to achieve expected future financial performance and results and the uncertainty of future tax and other provisions and estimates; 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 plc's Securities and Exchange Commission filings and reports (Commission File No. 001-33500), including the company's Quarterly Report on Form 10-Q for the quarter ended March 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, 2020. In addition, while the company expects the COVID-19 pandemic to continue to adversely affect its business operations and financial results, the extent of the impact on the company's ability to generate sales of and revenues from its approved products, execute on new product launches, its clinical development and regulatory efforts, its corporate development objectives and the value of and market for its ordinary shares, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration and severity of the pandemic, governmental "stay-at-home" orders and travel restrictions, quarantines, social distancing and business closure requirements in the U.S., Ireland and other countries, and the effectiveness of actions taken globally to contain and treat the disease. Moreover, 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.

CONDENSED CONSOLIDATED STATEMENTS OF INCOME (LOSS)
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenues:				
Product sales, net	$ 558,203	$ 523,423	$ 1,088,408	$ 1,026,754
Royalties and contract revenues	4,233	10,710	8,754	15,565
Total revenues	562,436	534,133	1,097,162	1,042,319
Operating expenses:				
Cost of product sales (excluding amortization of acquired developed technologies)	28,008	27,676	56,665	61,182
Selling, general and administrative	191,406	176,014	399,806	343,961
Research and development	78,922	62,384	165,029	122,489
Intangible asset amortization	62,974	61,576	125,821	118,461
Acquired in-process research and development	3,000	2,200	205,250	58,200
Impairment charge	—	—	136,139	—
Total operating expenses	364,310	329,850	1,088,710	704,293
Income from operations	198,126	204,283	8,452	338,026
Interest expense, net	(26,210)	(18,234)	(44,706)	(36,156)
Foreign exchange loss	(464)	(1,933)	(1,596)	(2,544)
Income (loss) before income tax provision (benefit) and equity in loss of investees	171,452	184,116	(37,850)	299,326
Income tax provision (benefit)	54,754	(78,650)	3,467	(49,534)
Equity in loss of investees	1,897	868	1,715	1,761
Net income (loss)	$ 114,801	$ 261,898	$ (43,032)	$ 347,099
Net income (loss) per ordinary share:				
Basic	$ 2.07	$ 4.62	$ (0.77)	$ 6.09
Diluted	$ 2.06	$ 4.56	$ (0.77)	$ 6.01
Weighted-average ordinary shares used in per share calculations - basic	55,413	56,707	55,684	56,955
Weighted-average ordinary shares used in per share calculations - diluted	55,864	57,427	55,684	57,753

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

	June 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 786,082	$ 637,344
Investments	910,000	440,000
Accounts receivable, net of allowances	351,920	355,987
Inventories	92,534	78,608
Prepaid expenses	49,109	39,434
Other current assets	112,701	78,895
Total current assets	2,302,346	1,630,268
Property, plant and equipment, net	128,259	131,506
Operating lease assets	133,179	139,385
Intangible assets, net	2,286,126	2,440,977
Goodwill	918,021	920,018
Deferred tax assets, net	243,395	221,403
Deferred financing costs	6,347	7,426
Other non-current assets	48,828	47,914
Total assets	$ 6,066,501	$ 5,538,897
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 50,043	$ 45,732
Accrued liabilities	266,918	269,686
Current portion of long-term debt	33,387	33,387
Income taxes payable	55,979	10,965
Deferred revenue	3,633	4,720
Total current liabilities	409,960	364,490
Deferred revenue, non-current	3,588	4,861
Long-term debt, less current portion	2,069,669	1,573,870
Operating lease liabilities, less current portion	144,264	151,226
Deferred tax liabilities, net	162,376	224,095
Other non-current liabilities	134,839	109,374
Total shareholders' equity	3,141,805	3,110,981
Total liabilities and shareholders' equity	$ 6,066,501	$ 5,538,897

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

	Six Months Ended June 30,	
	2020	2019
Net cash provided by operating activities	$ 455,488	$ 351,100
Net cash provided by (used in) investing activities	(801,245)	163,414
Net cash provided by (used in) financing activities	494,851	(186,502)
Effect of exchange rates on cash and cash equivalents	(356)	105
Net increase in cash and cash equivalents	$ 148,738	$ 328,117

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,	
	2020	2019	2020	2019
GAAP reported net income (loss)	**$ 114,801**	**$ 261,898**	**$ (43,032)**	**$ 347,099**
Intangible asset amortization	62,974	61,576	125,821	118,461
Share-based compensation expense	30,604	28,289	59,258	55,841
Impairment charge [(a)]	—	—	136,139	—
Non-cash interest expense [(b)]	12,793	11,451	24,793	22,584
Loss on extinguishment of debt	4,475	—	4,475	—
Income tax effect of above adjustments	(18,331)	(18,403)	(74,305)	(35,001)
Income tax benefit related to intra-entity intellectual property asset transfer	—	(112,274)	—	(112,274)
Non-GAAP adjusted net income	$ 207,316	$ 232,537	$ 233,149	$ 396,710
GAAP reported net income (loss) per diluted share	**$ 2.06**	**$ 4.56**	**$ (0.77)**	**$ 6.01**

Non-GAAP adjusted net income per diluted share	$ 3.71	$ 4.05	$ 4.14	$ 6.87
Weighted-average ordinary shares used in diluted per share calculations - GAAP	55,864	57,427	55,684	57,753
Weighted-average ordinary shares used in diluted per share calculations - non-GAAP	55,864	57,427	56,328	57,753

Explanation of Adjustments and Certain Line Items:

(a) Impairment charge related to the company's decision to stop enrollment in its Phase 3 clinical study of defibrotide for the prevention of veno-occlusive disease due to a determination by an Independent Data Monitoring Committee that it is highly unlikely that the study will reach its primary endpoint.

(b) Non-cash interest expense associated with debt discount and debt issuance costs.

JAZZ PHARMACEUTICALS PLC
RECONCILIATIONS OF GAAP REPORTED TO NON-GAAP ADJUSTED INFORMATION
CERTAIN LINE ITEMS - FOR THE THREE MONTHS ENDED JUNE 30, 2020 and 2019
(In thousands, except percentages)
(Unaudited)

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	—	—	—	—	—	(12,793)	—	—
Loss on extinguishment of debt	—	—	—	—	—	(4,475)	—	—
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 %*

Three months ended June 30, 2019

	Cost of product sales	Gross margin	Selling, general and administrative	Research and development	Intangible asset amortization	Interest expense, net	Income tax provision (benefit)	Effective tax rate
GAAP Reported	**$ 27,676**	***94.7 %***	**$ 176,014**	**$ 62,384**	**$ 61,576**	**$ 18,234**	**$ (78,650)**	***(42.7) %***
Non-GAAP Adjustments:								
Intangible asset amortization	—	—	—	—	(61,576)	—	—	—
Share-based compensation expense	(1,708)	*0.3*	(20,685)	(5,896)	—	—	—	—
Non-cash interest expense	—	—	—	—	—	(11,451)	—	—
Income tax effect of above adjustments	—	—	—	—	—	—	18,403	*(0.1)*
Income tax benefit related to intra-entity intellectual property asset transfer	—	—	—	—	—	—	112,274	*61.0*
Total of Non-GAAP adjustments	(1,708)	*0.3*	(20,685)	(5,896)	(61,576)	(11,451)	130,677	*60.9*
Non-GAAP Adjusted	$ 25,968	*95.0 %*	$ 155,329	$ 56,488	$ —	$ 6,783	$ 52,027	*18.2 %*

JAZZ PHARMACEUTICALS PLC
RECONCILIATIONS OF GAAP REPORTED TO NON-GAAP ADJUSTED INFORMATION
CERTAIN LINE ITEMS - FOR THE SIX MONTHS ENDED JUNE 30, 2020 and 2019
(In thousands)
(Unaudited)

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 charges	—	—	—	—	—	(136,139)	—	—	—
Non-cash interest expense	—	—	—	—	—	—	(24,793)	—	—
Loss on extinguishment of debt	—	—	—	—	—	—	(4,475)	—	—
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 %*

Six months ended June 30, 2019

	Cost of product sales	Gross margin	Selling, general and administrative	Research and development	Intangible asset amortization	Interest expense, net	Income tax provision (benefit)	Effective tax rate
GAAP Reported	**$ 61,182**	***94.0 %***	**$ 343,961**	**$ 122,489**	**$ 118,461**	**$ 36,156**	**$ (49,534)**	***(16.5) %***
Non-GAAP Adjustments:								
Intangible asset amortization	—	—	—	—	(118,461)	—	—	—
Share-based compensation expense	(3,367)	*0.4*	(41,055)	(11,419)	—	—	—	—
Non-cash interest expense	—	—	—	—	—	(22,584)	—	—
Income tax effect of above adjustments	—	—	—	—	—	—	35,001	*(1.3)*
Income tax benefit related to intra-entity intellectual property asset transfer	—	—	—	—	—	—	112,274	*37.5*
Total of Non-GAAP adjustments	(3,367)	*0.4*	(41,055)	(11,419)	(118,461)	(22,584)	147,275	*36.2*
Non-GAAP Adjusted	$ 57,815	*94.4 %*	$ 302,906	$ 111,070	$ —	$ 13,572	$ 97,741	*19.7 %*

JAZZ PHARMACEUTICALS PLC
RECONCILIATION OF GAAP TO NON-GAAP ADJUSTED 2020 NET INCOME GUIDANCE
(In millions, except per share amounts)
(Unaudited)

GAAP net income	**$190 - $270**
Intangible asset amortization	250 - 270
Share-based compensation expense	120 -135
Impairment charge	136
Loss on extinguishment of debt	4
Non-cash interest expense	50 - 60
Income tax effect of adjustments	(105) - (115)
Non-GAAP adjusted net income	$670 - $730
GAAP net income per diluted share	**$3.40 - $4.85**
Non-GAAP adjusted net income per diluted share	$11.90 - $13.00
Weighted-average ordinary shares used in per share calculations	56

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