Jazz Pharmaceuticals Announces Third Quarter 2020 Financial Results

November 2, 2020

Strong Financial and Operational Performance in Third Quarter 2020

Total Revenues Increased 12% Compared to Third Quarter 2019

Strong Demand for Zepzelca Following July Launch

Launched Xywav for Narcolepsy in the U.S.

Announced Clinically Meaningful Phase 3 Top-Line Results for JZP-258 in Idiopathic Hypersomnia

2020 Total Revenue Guidance Increased to a Range of $2.32 Billion to $2.38 Billion

DUBLIN, Nov. 2, 2020 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced financial results for the third quarter of 2020 and updated its 2020 financial guidance.

"We delivered strong financial results this quarter, with increasingly diversified revenues fueled by the recent launch of Zepzelca, an innovative new treatment for relapsed small cell lung cancer, which we expect to be a catalyst for significant growth in our oncology portfolio. During 2020, we are demonstrating our operational agility as we navigate through the COVID-19 pandemic and deliver on a set of critically important objectives," said Bruce Cozadd, chairman and chief executive officer of Jazz Pharmaceuticals. "This is a transformative year for Jazz and today marks our third product launch in 2020, keeping us on track to execute up to five key launches through 2020 and 2021. We continue to build upon our strong foundation by investing in assets to further diversify and expand our innovative neuroscience and oncology pipelines. We are excited about the opportunities ahead to deliver life-changing therapies for patients and drive enhanced shareholder value."

Robert Iannone, M.D., M.S.C.E., executive vice president, research and development, of Jazz Pharmaceuticals added, "We achieved multiple key R&D objectives in the third quarter, highlighted by FDA approval of Xywav in narcolepsy. We are encouraged by compelling top-line data for JZP-258 in idiopathic hypersomnia and are preparing to submit our supplemental NDA in the first quarter of 2021. With the significant progress and successes in our regulatory and R&D operations this year, we are poised to bring multiple new and highly differentiated treatment options to patients in areas of high unmet medical need."

The company successfully executed on multiple prioritized objectives for 2020 across its business, including commercial, regulatory and R&D operations, despite the COVID-19 pandemic. Highlights of these achievements year-to-date include:

- Launched Xywav in early November 2020 for the treatment of cataplexy or excessive daytime sleepiness (EDS) in narcolepsy;
- Announced positive top-line results in the JZP-258 Phase 3 study in idiopathic hypersomnia (IH); received U.S. Fast Track designation;
- Launched Zepzelca in the U.S. in early July 2020, six months after acquiring the U.S. licensing rights;
- Rapidly added clinical sites and enrolled patients into the Phase 2/3 pivotal study of JZP-458 in acute lymphoblastic leukemia (ALL) or lymphoblastic lymphoma with a potential launch in mid-2021 following Biologics License Application (BLA) submission and approval; and
- Initiated the European rolling launch for Sunosi in May 2020.

Business Updates

Neuroscience

Xyrem:

- Xyrem net product sales increased 5% to $447.8 million in the third quarter of 2020 compared to the same period in 2019.
- For the quarter, revenue bottle volume growth was 4% and average active patients on therapy grew 2% compared to the third quarter of 2019.

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

- On November 2, 2020, the company commenced its U.S. launch of Xywav, the first and only lower sodium oxybate therapy for the treatment of cataplexy or EDS in narcolepsy patients 7 years of age and older.
- The company has robust patient access programs in place and is focused on obtaining broad commercial payer coverage for Xywav, which has been priced at parity to Xyrem.
- In October 2020, the company announced positive top-line results from its Phase 3 pivotal study of JZP-258 for the treatment of IH. The company expects to submit a supplemental New Drug Application (sNDA) in the first quarter of 2021, with an objective of launching in the fourth quarter of 2021. The U.S. Food and Drug Administration (FDA) granted Fast Track designation for JZP-258 in IH in September 2020.

Sunosi:

- Sunosi net product sales were $9.1 million in the third quarter of 2020, compared to $1.0 million in the same period of 2019. The company launched Sunosi in the U.S. in July 2019.
- In the third quarter of 2020, U.S. prescriptions increased 7% compared to the second quarter of 2020.
- At the end of the third quarter of 2020, more than 90% 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 completed its healthy volunteer study in September 2020 to evaluate a modified release formulation.
- Study start-up activities will begin in the fourth quarter of 2020 to enable initiation of a Phase 2b study in the first half of 2021.

Oncology

Zepzelca:

- In July 2020, the company launched Zepzelca in the U.S. for the treatment of adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy.
- Zepzelca net product sales were $36.9 million in the third quarter of 2020, reflecting the significant unmet need in metastatic SCLC and Zepzelca's product profile. There was strong physician interest and uptake of Zepzelca across academic and community settings.

Erwinaze:

- Erwinaze/Erwinase net product sales decreased to $20.1 million in the third quarter of 2020 compared to $34.0 million for the same period in 2019 due to ongoing supply and manufacturing issues at the owner and sole manufacturer of the product, Porton Biopharma Limited (PBL). 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 during the first half of 2021.

JZP-458 (recombinant *Erwinia* asparaginase):

- The company continues to prioritize development of JZP-458 to ensure that ALL patients have access to a reliable, high-quality recombinant product, given the ongoing supply issues with Erwinaze.

- The pivotal Phase 2/3 study is continuing, and patient enrollment is progressing well.
- In September 2020, FDA granted Rare Pediatric Disease designation for JZP-458 for the treatment of pediatric ALL.
- The company continues to target a mid-2021 launch in the U.S. and expects to submit a BLA as early as year-end 2020.

Defitelio:

- Defitelio/defibrotide net product sales increased 34% to $50.2 million in the third quarter of 2020 compared to the same period in 2019. Late in the second quarter of 2020, the company observed an increase in hematopoietic stem cell transplants that had previously been postponed due to the COVID-19 pandemic, and this trend continued through the third quarter.
- The top-line results from the Phase 2 proof-of-concept study for prevention of acute graft-versus-host disease demonstrated a modest trend toward a benefit with Defitelio. The safety profile was consistent with previously reported clinical studies. Following an evaluation of the full data, a decision will be made about any further research for the prevention of acute graft-versus-host disease.

Vyxeos:

- Vyxeos net product sales increased 4% to $30.8 million in the third quarter of 2020 compared to the same period in 2019.
- Vyxeos clinical data has been submitted for presentation at the upcoming American Society of Hematology virtual meeting in December 2020, including preliminary data from a Phase 2 clinical study being conducted by the University of Texas MD Anderson Cancer Center evaluating Vyxeos in combination with venetoclax in relapsed/refractory or *de novo* acute myeloid leukemia.

Corporate

- In September 2020, the company entered into a new research collaboration agreement with Redx Pharma plc (Redx) to discover and develop drug candidates for two cancer targets in the Ras/Raf/MAP kinase pathway.
- In October 2020, the company entered into an asset purchase and exclusive license agreement with SpringWorks Therapeutics, Inc. (SpringWorks) for a fatty acid amide hydrolase inhibitor (FAAH) program. The company will initially focus on developing the FAAH inhibitor, PF-04457845 (PF-'845), for the potential treatment of post-traumatic stress disorder and associated symptoms.

Financial Highlights

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands, except per share amounts)	2020	2019	2020	2019
Total revenues	$ 600,888	$ 537,702	$ 1,698,050	$ 1,580,021
GAAP net income	$ 148,234	$ 102,276	$ 105,202	$ 449,375
Adjusted net income[1]	$ 242,109	$ 235,278	$ 475,258	$ 631,988
GAAP EPS	$ 2.64	$ 1.78	$ 1.87	$ 7.80
Adjusted EPS[1]	$ 4.31	$ 4.10	$ 8.44	$ 10.96

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 three and nine months ended September 30, 2019 have been updated to reflect this change. See "Non-GAAP Financial Measures" below.

GAAP net income for the third quarter of 2020 was $148.2 million, or $2.64 per diluted share, compared to $102.3 million, or $1.78 per diluted share, for the third quarter of 2019.

Non-GAAP adjusted net income for the third quarter of 2020 was $242.1 million, or $4.31 per diluted share, compared to $235.3 million, or $4.10 per diluted share, in the third 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 September 30,		Nine Months Ended September 30,	
(In thousands)	2020	2019	2020	2019
Xyrem® (sodium oxybate) oral solution	$ 447,809	$ 425,644	$ 1,302,492	$ 1,207,173
Defitelio® (defibrotide sodium) / defibrotide	50,241	37,604	140,387	125,159
Erwinaze® / Erwinase® (asparaginase *Erwinia chrysanthemi*)	20,145	34,024	90,560	122,545
Vyxeos® (daunorubicin and cytarabine) liposome for injection	30,825	29,581	90,113	89,886
Zepzelca™ (lurbinectedin)	36,941	—	36,941	—
Sunosi® (solriamfetol)	9,116	987	19,618	987
Other	1,872	4,481	5,246	13,325
Product sales, net	596,949	532,321	1,685,357	1,559,075
Royalties and contract revenues	3,939	5,381	12,693	20,946
Total revenues	$ 600,888	$ 537,702	$ 1,698,050	$ 1,580,021

Total revenues increased 12% in the third quarter of 2020 compared to the same period in 2019.

- Oncology net product sales in the third quarter of 2020 increased 37% to $138.2 million compared to the same period in 2019 led by strong initial Zepzelca net sales of $36.9 million and a $12.6 million increase in Defitelio net product sales, partially offset by a decrease in Erwinaze net product sales of $13.9 million.
- Neuroscience net product sales in the third quarter of 2020 increased 7% to $456.9 million compared to the same period in 2019 led by continued strong growth in Xyrem net product sales.

Operating Expenses and Effective Tax Rate

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands, except percentages)	2020	2019	2020	2019
GAAP:				
Cost of product sales	$ 42,095	$ 31,400	$ 98,760	$ 92,582
Gross margin	*92.9 %*	*94.1 %*	*94.1 %*	*94.1 %*
Selling, general and administrative	$ 207,255	$ 178,706	$ 607,061	$ 522,667
% of total revenues	*34.5 %*	*33.2 %*	*35.8 %*	*33.1 %*
Research and development	$ 78,647	$ 79,855	$ 243,676	$ 202,344
% of total revenues	*13.1 %*	*14.9 %*	*14.4 %*	*12.8 %*
Acquired in-process research and development	$ 10,000	$ 51,775	$ 215,250	$ 109,975
Impairment charge	$ —	$ —	$ 136,139	$ —
Income tax provision (benefit)	$ 19,283	$ 10,903	$ 22,750	$ (38,631)
Effective tax rate	*11.5 %*	*9.5 %*	*17.5 %*	*(9.3) %*

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands, except percentages)	2020	2019	2020	2019
Non-GAAP adjusted:				
Cost of product sales	$ 40,176	$ 29,415	$ 93,247	$ 87,230
Gross margin	*93.3 %*	*94.5 %*	*94.5 %*	*94.4 %*
Selling, general and administrative	$ 186,281	$ 158,404	$ 544,471	$ 461,310

% of total revenues	*31.0 %*	*29.5 %*	*32.1 %*	*29.2 %*
Research and development	$ 71,184	$ 73,357	$ 222,165	$ 184,427
% of total revenues	*11.8 %*	*13.6 %*	*13.1 %*	*11.7 %*
Acquired in-process research and development	$ 10,000	$ 3,500	$ 215,250	$ 61,700
Income tax provision	$ 38,268	$ 29,655	$ 116,040	$ 127,396
Effective tax rate	*13.6 %*	*11.2 %*	*19.5 %*	*16.7 %*

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

- Selling, general and administrative (SG&A) expenses increased in the third quarter of 2020 compared to the same period in 2019 on a GAAP and on a non-GAAP adjusted basis primarily due to increased investment in sales, marketing and launch activities related to certain of the company's products.
- Research and development (R&D) expenses decreased in the third quarter of 2020 compared to the same period in 2019, on a GAAP and on a non-GAAP adjusted basis, primarily due to an $11.0 million milestone payable to Pfenex, Inc. in the third quarter of 2019, partially offset by an increase in expenses in the third quarter of 2020 related to the progress made on the company's clinical and pre–clinical development programs, including JZP-458 and JZP-385.

Cash Flow and Balance Sheet

As of September 30, 2020, cash, cash equivalents and investments were $1.9 billion, and the outstanding principal balance of the company's long-term debt was $2.4 billion.

During the nine months ended September 30, 2020, the company generated $713.4 million of cash from operations, made upfront and milestone payments totaling $300.0 million to Pharma Mar, S.A. (PharmaMar) under a license agreement and used $146.5 million to repurchase shares under the company's share repurchase program.

In the nine months ended September 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 September 30, 2020, the remaining amount authorized for share repurchases under the company's share repurchase program was $431.2 million.

2020 Financial Guidance

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

As a result of the company's strong commercial performance and successful adaptation to the COVID-19 environment, the company is increasing its total 2020 revenue guidance. The company is increasing its oncology net product sales guidance driven by the significant momentum of Zepzelca, and is raising the lower end of its neuroscience net sales guidance.

The company is raising the lower end of its guidance for GAAP and non-GAAP adjusted net income and EPS while continuing to invest significantly in the diversification of its pipeline and increasing investment in the company's most important products and product launches, as reflected in the increased acquired IPR&D expense and GAAP and non-GAAP adjusted SG&A guidance.

	Guidance provided as of	
(In millions)	**August 4, 2020**	**November 2, 2020**
Revenues	$2,225 - $2,325	$2,320 - $2,380
Total net product sales	$2,210 - $2,310	$2,300 - $2,360
-Neuroscience	$1,725 - $1,800	$1,760 - $1,800
-Oncology	$445 - $525	$525 - $565

GAAP:

	Guidance provided as of	
(In millions, except per share amounts and percentages)	**August 4, 2020**	**November 2, 2020**
Gross margin %	94%	94%
SG&A expenses	$785 - $843	$820 - $858
SG&A expenses as % of total revenues	*34% - 38%*	*34% - 37%*
R&D Expenses	$302 - $338	$302 - $338
R&D expenses as % of total revenues	*13% - 15%*	*13% - 15%*
Acquired in-process research and development expenses	$205	$251
Impairment charge	$136	$136
Effective tax rate	19% - 26%	10% - 17%[1]
Net income per diluted share	$3.40 - $4.85	$3.70 - $4.85

Non-GAAP:

	Guidance provided as of	
(In millions, except per share amounts and percentages)	**August 4, 2020**	**November 2, 2020**
Gross margin %	94%	94%[2,7]
SG&A expenses	$700 - $750	$735 - $765[3,7]
SG&A expenses as % of total revenues	*30% - 34%*	*31% - 33%*
R&D Expenses	$275 - $305	$275 - $305[4,7]
R&D expenses as % of total revenues	*12% - 14%*	*12% - 13%*
Acquired in-process research and development expenses	$205	$251[5]
Effective tax rate	19% - 22%	16% - 18%[1,6,7]
Net income per diluted share	$11.90 - $13.00	$12.20 - $13.00[5,7]

1. Decrease primarily reflects a benefit that the company will recognize in the fourth quarter of 2020 following the release of reserves related to unrecognized tax benefits upon expiration of a statute of limitations.
2. Excludes $8-$9 million of share-based compensation expense from estimated GAAP gross margin.
3. Excludes $85-$93 million of share-based compensation expense from estimated GAAP SG&A expenses.
4. Excludes $27-$33 million of share-based compensation expense from estimated GAAP R&D expenses.
5. 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 $205 million or $3.67 per diluted share, respectively, primarily related to the post-tax impact of the upfront payments made to PharmaMar and SpringWorks in 2020.
6. Excludes the income tax effect of adjustments between GAAP reported and non-GAAP adjusted net income.
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 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. EST (9:30 p.m. GMT) to provide a business and financial update and discuss its 2020 third 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 2756835.

A replay of the conference call will be available through November 9, 2020 by dialing +1 855 859 2056 in the U.S., or +1 404 537 3406 outside the U.S., and entering passcode 2756835. 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 life-changing medicines for people 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 medicine and movement disorders, and in oncology, including hematologic malignancies 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 (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 three and nine months ended September 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 nine months ended September 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 and the company's expectations related thereto; the company's expectation that Zepzelca will be a catalyst for significant growth in its oncology portfolio; statements about the company's investment in assets to further diversify and expand its innovative neuroscience and oncology pipelines and the company's opportunities to deliver life-changing therapies for patients and drive enhanced shareholder value; the company's belief that it is poised to bring multiple new and highly differentiated treatment options to patients in areas of high unmet medical need; the company's focus on obtaining broad commercial payer coverage for Xywav; the company's goal of ensuring that ALL patients have access to a reliable, high-quality recombinant product; the company's expected clinical development, regulatory submissions and product launches, and the timing thereof, including with respect to JZP-458 and JZP-258 in idiopathic hypersomnia; expected JZP-385 study start-up activities and the initiation of a Phase 2b study and the timing thereof; the company's initial focus on PF-'845 for the potential treatment of post-traumatic stress disorder and associated symptoms; a potential future decision on further research for the prevention of acute graft-versus-host-disease; the company's expectation of inter-quarter variability in Erwinaze net product sales due to timing and availability of; 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 the company's oxybate products 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 and license agreements with third parties; 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 June 30, 2020 and future filings and reports by the company, including the company's Quarterly Report on Form 10-Q for the quarter ended September 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.

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,	
	2020	2019	2020	2019
Revenues:				
Product sales, net	$ 596,949	$ 532,321	$ 1,685,357	$ 1,559,075
Royalties and contract revenues	3,939	5,381	12,693	20,946
Total revenues	600,888	537,702	1,698,050	1,580,021
Operating expenses:				
Cost of product sales (excluding amortization of acquired developed technologies)	42,095	31,400	98,760	92,582
Selling, general and administrative	207,255	178,706	607,061	522,667
Research and development	78,647	79,855	243,676	202,344
Intangible asset amortization	66,684	62,863	192,505	181,324
Acquired in-process research and development	10,000	51,775	215,250	109,975
Impairment charge	—	—	136,139	—
Total operating expenses	404,681	404,599	1,493,391	1,108,892
Income from operations	196,207	133,103	204,659	471,129
Interest expense, net	(27,428)	(17,861)	(72,134)	(54,017)
Foreign exchange loss	(639)	(1,033)	(2,235)	(3,577)
Income before income tax provision (benefit) and equity in loss of investees	168,140	114,209	130,290	413,535
Income tax provision (benefit)	19,283	10,903	22,750	(38,631)
Equity in loss of investees	623	1,030	2,338	2,791
Net income	$ 148,234	$ 102,276	$ 105,202	$ 449,375
Net income per ordinary share:				
Basic	$ 2.67	$ 1.80	$ 1.89	$ 7.90
Diluted	$ 2.64	$ 1.78	$ 1.87	$ 7.80
Weighted-average ordinary shares used in per share calculations - basic	55,545	56,674	55,637	56,860
Weighted-average ordinary shares used in per share calculations - diluted	56,236	57,438	56,297	57,647

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

	September 30, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 741,942	$ 637,344
Investments	1,175,000	440,000
Accounts receivable, net of allowances	361,664	355,987
Inventories	91,404	78,608
Prepaid expenses	58,305	39,434
Other current assets	127,258	78,895
Total current assets	2,555,573	1,630,268
Property, plant and equipment, net	128,204	131,506
Operating lease assets	130,717	139,385
Intangible assets, net	2,241,107	2,440,977
Goodwill	937,099	920,018
Deferred tax assets, net	254,810	221,403
Deferred financing costs	5,802	7,426
Other non-current assets	38,646	47,914
Total assets	$ 6,291,958	$ 5,538,897
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 67,063	$ 45,732
Accrued liabilities	302,071	269,686
Current portion of long-term debt	243,999	33,387
Income taxes payable	25,910	10,965
Deferred revenue	3,090	4,720
Total current liabilities	642,133	364,490
Deferred revenue, non-current	2,951	4,861
Long-term debt, less current portion	1,843,685	1,573,870
Operating lease liabilities, less current portion	141,925	151,226
Deferred tax liabilities, net	141,588	224,095
Other non-current liabilities	142,475	109,374
Total shareholders' equity	3,377,201	3,110,981
Total liabilities and shareholders' equity	$ 6,291,958	$ 5,538,897

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

	Nine Months Ended September 30,	
	2020	2019
Net cash provided by operating activities	$ 713,377	$ 688,603
Net cash provided by (used in) investing activities	(1,080,889)	3,753
Net cash provided by (used in) financing activities	472,195	(205,965)
Effect of exchange rates on cash and cash equivalents	(85)	(838)
Net increase in cash and cash equivalents	$ 104,598	$ 485,553

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,	
	2020	2019	2020	2019
GAAP reported net income	**$ 148,234**	**$ 102,276**	**$ 105,202**	**$ 449,375**
Intangible asset amortization	66,684	62,863	192,505	181,324
Share-based compensation expense	30,356	28,785	89,614	84,626
Impairment charge[1]	—	—	136,139	—
Acquired IPR&D asset acquisition[2]	—	48,275	—	48,275
Non-cash interest expense[3]	15,820	11,831	40,613	34,415
Loss on extinguishment of debt	—	—	4,475	—
Income tax effect of above adjustments	(18,985)	(18,752)	(93,290)	(53,753)
Income tax benefit related to intra-entity intellectual property asset transfer	—	—	—	(112,274)
Non-GAAP adjusted net income	$ 242,109	$ 235,278	$ 475,258	$ 631,988
GAAP reported net income per diluted share	**$ 2.64**	**$ 1.78**	**$ 1.87**	**$ 7.80**
Non-GAAP adjusted net income per diluted share	$ 4.31	$ 4.10	$ 8.44	$ 10.96
Weighted-average ordinary shares used in diluted per share calculations	56,236	57,438	56,297	57,647

Explanation of Adjustments and Certain Line Items:
1. 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.
2. Relates to the acquisition of Cavion, Inc. in the three months ended September 30, 2019.
3. 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 SEPTEMBER 30, 2020 and 2019
(In thousands, except percentages)
(Unaudited)

	Three months ended September 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	**$ 42,095**	***92.9%***	**$ 207,255**	**$ 78,647**	**$ 66,684**	**$ 27,428**	**$ 19,283**	***11.5%***
Non-GAAP Adjustments:								
Intangible asset amortization	—	—	—	—	(66,684)	—	—	—

Share-based compensation expense	(1,919)	*0.4*	(20,974)	(7,463)	—	—	—	—
Non-cash interest expense	—	—	—	—	—	(15,820)	—	—
Income tax effect of above adjustments	—	—	—	—	—	—	18,985	*2.1*
Total of Non-GAAP adjustments	(1,919)	*0.4*	(20,974)	(7,463)	(66,684)	(15,820)	18,985	*2.1*
Non-GAAP Adjusted	$ 40,176	*93.3%*	$ 186,281	$ 71,184	$ —	$ 11,608	$ 38,268	*13.6%*

	Three months ended September 30, 2019								
	Cost of product sales	**Gross margin**	**Selling, general and administrative**	**Research and development**	**Intangible asset amortization**	**Acquired IPR&D**	**Interest expense, net**	**Income tax provision (benefit)**	**Effective tax rate**
GAAP Reported	**$ 31,400**	***94.1%***	**$ 178,706**	**$ 79,855**	**$ 62,863**	**$ 51,775**	**$ 17,861**	**$ 10,903**	***9.5%***
Non-GAAP Adjustments:									
Intangible asset amortization	—	—	—	—	(62,863)	—	—	—	—
Share-based compensation expense	(1,985)	*0.4*	(20,302)	(6,498)	—	—	—	—	—
Acquired IPR&D asset acquisition	—	—	—	—	—	(48,275)	—	—	—
Non-cash interest expense	—	—	—	—	—	—	(11,831)	—	—
Income tax effect of above adjustments	—	—	—	—	—	—	—	18,752	*1.7*
Total of Non-GAAP adjustments	(1,985)	*0.4*	(20,302)	(6,498)	(62,863)	(48,275)	(11,831)	18,752	*1.7*
Non-GAAP Adjusted	$ 29,415	*94.5%*	$ 158,404	$ 73,357	$ —	$ 3,500	$ 6,030	$ 29,655	*11.2%*

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

	Nine months ended September 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	**$ 98,760**	***94.1%***	**$ 607,061**	**$ 243,676**	**$ 192,505**	**$ 136,139**	**$ 72,134**	**$ 22,750**	***17.5%***
Non-GAAP Adjustments:									
Intangible asset amortization	—	—	—	—	(192,505)	—	—	—	—
Share-based compensation expense	(5,513)	*0.4*	(62,590)	(21,511)	—	—	—	—	—
Impairment charges	—	—	—	—	—	(136,139)	—	—	—
Non-cash interest expense	—	—	—	—	—	—	(40,613)	—	—
Loss on extinguishment of debt	—	—	—	—	—	—	(4,475)	—	—
Income tax effect of above adjustments	—	—	—	—	—	—	—	93,290	*2.0*
Total of Non-GAAP adjustments	(5,513)	*0.4*	(62,590)	(21,511)	(192,505)	(136,139)	(45,088)	93,290	*2.0*
Non-GAAP Adjusted	$ 93,247	*94.5%*	$ 544,471	$ 222,165	$ —	$ —	$ 27,046	$ 116,040	*19.5%*

	Nine months ended September 30, 2019								
	Cost of product sales	**Gross margin**	**Selling, general and administrative**	**Research and development**	**Intangible asset amortization**	**Acquired IPR&D**	**Interest expense, net**	**Income tax provision (benefit)**	**Effective tax rate**
GAAP Reported	**$ 92,582**	***94.1%***	**$ 522,667**	**$ 202,344**	**$ 181,324**	**$ 109,975**	**$ 54,017**	**$ (38,631)**	***(9.3)%***
Non-GAAP Adjustments:									
Intangible asset amortization	—	—	—	—	(181,324)	—	—	—	—
Share-based compensation expense	(5,352)	*0.3*	(61,357)	(17,917)	—	—	—	—	—
Acquired IPR&D asset acquisition	—	—	—	—	—	(48,275)	—	—	—

Non-cash interest expense	—	—	—	—	—	—	(34,415)	—	—
Income tax effect of above adjustments	—	—	—	—	—	—	—	53,753	*(1.2)*
Income tax benefit related to intra-entity intellectual property asset transfer	—	—	—	—	—	—	—	112,274	*27.2*
Total of Non-GAAP adjustments	(5,352)	*0.3*	(61,357)	(17,917)	(181,324)	(48,275)	(34,415)	166,027	*26.0*
Non-GAAP Adjusted	$ 87,230	*94.4%*	$ 461,310	$ 184,427	$ —	$ 61,700	$ 19,602	$ 127,396	*16.7%*

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

GAAP net income	**$205 - $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	$685 - $730
GAAP net income per diluted share	**$3.70 - $4.85**
Non-GAAP adjusted net income per diluted share	$12.20 - $13.00
Weighted-average ordinary shares used in per share calculations	56

Contacts:

Investors:
Kathee Littrell
Vice President, Investor Relations
Jazz Pharmaceuticals plc
Ireland, +353 1 634 7887
U.S., +1 650 496 2717

Media:
Jacqueline Kirby
Vice President, Corporate Affairs & Government Relations
Jazz Pharmaceuticals plc
Ireland, +353 1 697 2141
U.S., +1 215 867 4910

View original content to download multimedia:http://www.prnewswire.com/news-releases/jazz-pharmaceuticals-announces-third-quarter-2020-financial-results-301165088.html

SOURCE Jazz Pharmaceuticals plc