

Jazz Pharmaceuticals Announces First Quarter 2021 Financial Results

May 04, 2021

Strong Xywav™ Adoption With 3,900 Active Xywav Patients Exiting The First Quarter
Continued Zepzelca™ Growth Across Second-Line SCLC Setting
Xywav in Idiopathic Hypersomnia Granted FDA Priority Review and an August 12, 2021, PDUFA Target Action Date
On Track to Close Acquisition of GW Pharmaceuticals plc in Early May, Creating an Innovative, High-Growth, Global Biopharma Leader
Secured \$5.35 Billion Financing Including \$1.5 Billion Senior Secured Notes in Connection with GW Acquisition
23% of Revenue from Recently Launched Products; Total Revenues Increased 14% to \$607.6 Million Compared to First Quarter 2020
2021 Total Revenue Guidance Affirmed at \$2.55 Billion to \$2.70 Billion

DUBLIN, May 4, 2021 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced financial results for the first quarter of 2021 and affirmed financial guidance for 2021.

"Demand for Xywav is strong, as both patients and physicians embrace the health benefits associated with reducing daily sodium intake. We also continue to see robust uptake of Zepzelca among both platinum-resistant and platinum-sensitive small cell lung cancer patients, consistent with the positive feedback we've received on its profile," said Bruce Cozadd, chairman and chief executive officer of Jazz Pharmaceuticals. "We are on track to deliver significant revenue growth and diversification in 2022, are poised for two additional product launches this year and look forward to completing the acquisition of GW Pharmaceuticals this month, all key milestones in our transformation to an innovative biopharmaceutical company and neuroscience leader."

Robert Iannone, M.D., M.S.C.E., executive vice president, research and development and chief medical officer, added, "Across our R&D organization, we've continued our track record of strong execution. We presented positive Xywav data in idiopathic hypersomnia (IH) at the American Academy of Neurology Annual Meeting. We are also pleased to have announced that FDA granted priority review of Xywav in IH with a PDUFA goal date set for August 12, 2021, bringing us another step closer to delivering this important treatment to patients with IH, for whom there is currently no FDA-approved therapy. Further, our JZP458 program remains on track with a potential approval in mid-2021. I'm proud that our continued execution enables us to bring life-changing medicines to often overlooked patient groups with significant unmet need."

Business Updates**Corporate Development**

On February 3, 2021, the Company announced that it had entered into a definitive agreement to acquire GW Pharmaceuticals plc (GW) for \$220.00 per American Depositary Share, in the form of \$200 in cash and \$20 in Jazz ordinary shares, based on the volume weighted average price of Jazz ordinary shares on Nasdaq for the 15 consecutive trading day period beginning on the 18th trading day immediately preceding the closing date of the transaction, for a total value of approximately \$7.2 billion, or \$6.7 billion net of GW cash. The Company has secured \$5.35 billion of financing to support the GW transaction; \$1.5 billion as senior secured notes and a \$3.85 billion term loan. This financing structure supports the Company's rapid deleveraging to its stated targets.

All shareholder and regulatory approvals required for the acquisition have now been obtained. Completion of the acquisition remains subject to the sanction by the High Court of Justice of England and Wales (Court) and other customary closing conditions. The Court hearing to sanction the acquisition is currently scheduled for May 5, 2021, and the completion of the acquisition is expected to occur shortly thereafter. Upon close of the transaction, the combined company will be 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 1% to \$411.0 million in the first quarter of 2021 compared to the same period in 2020.
- Average active oxybate patients on therapy were approximately 15,700 in the first quarter of 2021, an increase of approximately 4% compared to the same period in 2020.
- Strong Xywav uptake, coupled with utilization of our patient access programs, resulted in a 3% decrease in revenue bottle volume in the first quarter of 2021 compared to the same period in 2020.

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

- Xywav net product sales were \$75.4 million in the first quarter of 2021.
- There were approximately 3,900 active patients on Xywav exiting the first quarter of 2021, following the U.S. launch in November 2020.
- The Company has achieved its goal of obtaining broad payer coverage, having entered into agreements with all three of the largest pharmacy benefit managers and coverage now at 80% of commercial lives. The Company continues to work with other payers to further expand coverage.

Xyrem (sodium oxybate) oral solution:

- Xyrem net product sales decreased 18% to \$335.6 million in the first quarter of 2021 compared to the same period in 2020.

Xywav in Idiopathic Hypersomnia

- The U.S. Food and Drug Administration (FDA) has granted Priority Review Designation and confirmed the supplemental New Drug Application (sNDA) seeking approval for Xywav in adult patients with idiopathic hypersomnia (IH). The Prescription Drug Fee User Act (PDUFA) target action date for an FDA decision has been set for August 12, 2021, which is in line with the objective of launching in the fourth quarter of 2021.
- Positive Phase 3 trial results were presented at the American Academy of Neurology annual meeting in April 2021. The efficacy and safety results demonstrate the potential Xywav has for helping people living with IH, an often debilitating neurologic sleep disorder for which there are currently no approved treatments in the U.S.

Sunos® (solriamfetol):

- Sunosi net product sales were \$11.6 million in the first quarter of 2021, compared to \$1.9 million in the same period of 2020 following the U.S. launch in July 2019.
- In the first quarter of 2021, U.S. prescriptions increased 10% compared to the fourth quarter of 2020.

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 mid-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 \$54.3 million in the first quarter of 2021, with continued growth across both platinum-resistant and platinum-sensitive patients in second-line small cell lung cancer (SCLC). Zepzelca was launched in the U.S. in July 2020.
- The Company anticipates initiating a Phase 3 trial evaluating immunotherapy plus lurbinectedin maintenance therapy, compared to immunotherapy alone, in patients with extensive-stage SCLC after induction chemotherapy in 2021.
- The Company and Pharma Mar, S.A. (PharmaMar) continue to engage with FDA regarding the confirmatory data package.

JZP458 (recombinant *Erwinia* asparaginase):

- In December 2020, the Company initiated the submission of a Biologics License Application (BLA) to FDA for JZP458 for intramuscular use as a component of a multi-agent chemotherapeutic regimen for the treatment of Acute Lymphoblastic Leukemia (ALL) or Lymphoblastic Lymphoma (LBL) in adult and pediatric patients who have developed hypersensitivity or silent inactivation to *E. coli*-derived asparaginase.
- The BLA will be reviewed under the Real Time Oncology Review program (RTOR) an initiative of FDA's Oncology Center of Excellence designed to expedite the delivery of safe and effective cancer treatments to patients.
- The Company is targeting a mid-2021 launch in the U.S., subject to FDA approval.
- The Company continues to prioritize global development of JZP458 with the objective of ensuring that ALL/LBL patients have access to a reliably-produced, high-quality recombinant asparaginase.
- Enrollment in the pivotal Phase 2/3 trial continues beyond the current RTOR submission, with the recent initiation of the intravenous cohort.

Vyxeos® (daunorubicin and cytarabine) liposome for injection:

- Vyxeos net product sales increased 1% to \$33.2 million in the first quarter of 2021 compared to the same period in 2020.
- FDA approved a revised label for Vyxeos to include a new indication for newly-diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) in pediatric patients aged one year and older.

Defitelio® (defibrotide sodium) / defibrotide:

- Defitelio/defibrotide net product sales increased 5% to \$49.6 million in the first quarter of 2021 compared to the same period in 2020.

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

- Erwinaze/Erwinase net product sales increased 9% to \$41.1 million in the first quarter of 2021 compared to \$37.7 million for the same period in 2020.
- The Company's agreement with Porton Biopharma Limited terminated on December 31, 2020. The Company has the right to sell certain Erwinaze inventory post-termination and expects to distribute this Erwinaze inventory during the first half of 2021. Once sales of available inventory are complete, the Company will cease recording net sales of Erwinaze.

Financial Highlights

(In thousands, except per share amounts)	Three Months Ended March 31,	
	2021	2020
Total revenues	\$ 607,581	\$ 534,726
GAAP net income (loss)	\$ 121,832	\$ (157,833)
Adjusted net income ¹	\$ 228,819	\$ 25,833
GAAP EPS	\$ 2.09	\$ (2.82)
Adjusted EPS ¹	\$ 3.92	\$ 0.45

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 for the first quarter of 2021 was \$121.8 million, or \$2.09 per diluted share, compared to a GAAP net loss of \$157.8 million, or \$2.82 per diluted share, for the first quarter of 2020. Non-GAAP adjusted net income for the first quarter of 2021 was \$228.8 million, or \$3.92 per diluted share, compared to \$25.8 million, or \$0.45 per diluted share, for the first quarter of 2020.

The GAAP net loss and non-GAAP adjusted net income for the first quarter of 2020 included the post-tax impact of a \$200.0 million upfront payment made to PharmaMar for the exclusive U.S. commercialization and development rights to Zepzelca. The GAAP net loss for the first quarter of 2020 also included the post-tax impact of an impairment charge of \$136.1 million following the Company's decision to stop enrollment in its Phase 3 clinical trial of defibrotide for the prevention of veno-occlusive disease (VOD).

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

Total Revenues

(In thousands)	Three Months Ended March 31,	
	2021	2020
Xyrem® (sodium oxybate) oral solution	\$ 335,550	\$ 407,875
Xywav™ (calcium, magnesium, potassium, and sodium oxybates) oral solution	75,416	—
Total Oxybate	410,966	407,875
Sunosi® (solriamfetol)	11,606	1,924
Total Neuroscience	422,572	409,799
Zepzelca™ (lurbicetidin)	54,334	—
Vyxeos® (daunorubicin and cytarabine) liposome for injection	33,155	32,720
Defitelio® (defibrotide sodium) / defibrotide	49,619	47,432
Erwinaze® / Erwinase® (asparaginase <i>Erwinia chrysanthemi</i>)	41,068	37,732
Total Oncology	178,176	117,884
Other	2,783	2,522
Product sales, net	603,531	530,205
Royalties and contract revenues	4,050	4,521
Total revenues	\$ 607,581	\$ 534,726

Total revenues increased 14% in the first quarter of 2021 compared to the same period in 2020.

- Products launched since 2019 accounted for 23% of total net product sales in the first quarter of 2021.
- Neuroscience net product sales in the first quarter of 2021 increased 3% to \$422.6 million compared to the same period in 2020 and oxybate net product sales increased to \$411.0 million led by strong Xywav net product sales of \$75.4 million partially offset by a decrease in Xyrem net product sales driven by the strong adoption of Xywav by existing Xyrem patients. Oxybate revenue bottle volumes were impacted by our patient access programs. Sunosi net product sales increased by \$9.7 million compared to the first quarter of 2020.
- Oncology net product sales in the first quarter of 2021 increased 51% to \$178.2 million compared to the same period in 2020 driven primarily by robust Zepzelca net product sales of \$54.3 million. Zepzelca launched in the U.S. in July 2020.

Operating Expenses and Effective Tax Rate

(In thousands, except percentages)	Three Months Ended March 31,	
	2021	2020
GAAP:		
Cost of product sales	\$ 40,189	\$ 28,657
Gross margin	93.3 %	94.6 %
Selling, general and administrative	\$ 260,508	\$ 208,400
% of total revenues	42.9 %	39.0 %
Research and development	\$ 76,573	\$ 86,107
% of total revenues	12.6 %	16.1 %
Acquired in-process research and development	\$ —	\$ 202,250
Impairment charge	\$ —	\$ 136,139
Income tax provision (benefit)	\$ 18,019	\$ (51,287)
Effective tax rate	13.3 %	24.5 %

(In thousands, except percentages)	Three Months Ended March 31,	
	2021	2020
Non-GAAP adjusted:		
Cost of product sales	\$ 38,193	\$ 26,984
Gross margin	93.7 %	94.9 %
Selling, general and administrative	\$ 228,400	\$ 187,804
% of total revenues	37.6 %	35.1 %
Research and development	\$ 67,930	\$ 79,722
% of total revenues	11.2 %	14.9 %
Acquired in-process research and development	\$ —	\$ 202,250
Income tax provision	\$ 37,659	\$ 4,687
Effective tax rate	14.4 %	15.4 %

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

- Selling, general and administrative (SG&A) expenses increased in the first quarter of 2021 compared to the same period in 2020 on a GAAP and on a non-GAAP adjusted basis primarily due to increased investment in sales, marketing and launch activities with the commencement of the Sunosi direct-to-consumer television marketing campaign and the continuation of the launches of Xywav and Zepzelca in the U.S., as well as an increase in other expenses primarily related to the expansion of the commercial operations. SG&A expenses in the first quarter of 2021 on a GAAP basis also included transaction expenses related to the proposed GW acquisition.

- Research and development expenses decreased in the first quarter of 2021 compared to the same period in 2020, on a GAAP and on a non-GAAP adjusted basis, primarily due to a decrease in expenses related to the Company's clinical programs.
- Acquired in-process research and development (IPR&D) expense in the first quarter of 2020 on a GAAP and on a non-GAAP adjusted basis primarily related to a \$200.0 million upfront payment to PharmaMar for the exclusive U.S. commercialization and development rights to Zepzelca.
- In the first quarter of 2020, the Company recorded an impairment charge of \$136.1 million on a GAAP basis following the Company's decision to stop enrollment in its Phase 3 clinical trial of defibrotide for the prevention of VOD.
- The effective tax rate for the first quarter of 2021 compared to the same period in 2020 decreased on a GAAP basis primarily due to the impact of the defibrotide IPR&D asset impairment charge, the acquired IPR&D expense primarily relating to the \$200.0 million upfront payment to PharmaMar, and changes in income mix among the various jurisdictions in which we operate.

Cash Flow and Balance Sheet

As of March 31, 2021, cash, cash equivalents and investments were \$2.4 billion, and the outstanding principal balance of the Company's long-term debt was \$2.4 billion. In the first quarter of 2021, the Company generated \$285.0 million of cash from operations.

2021 Financial Guidance¹

The Company is affirming its full year 2021 financial guidance as follows:

(In millions)	Guidance
Revenues	\$2,550 - \$2,700
Total net product sales	\$2,540 - \$2,685
-Neuroscience	\$1,785 - \$1,885
-Oncology	\$715 - \$835

(In millions, except per share amounts and percentages)	GAAP	Non-GAAP
Gross margin %	93%	93% ^{2,6}
SG&A expenses	\$1,032 - \$1,100	\$905 - \$945 ^{3,6}
SG&A expenses as % of total revenues	38% - 43%	34% - 37%
R&D Expenses	\$365 - \$410	\$330 - \$370 ^{4,6}
R&D expenses as % of total revenues	14% - 16%	12% - 15%
Effective tax rate	18% - 20%	16% - 18% ^{5,6}
Net income per diluted share	\$8.30 - \$10.45	\$15.65 - \$16.85 ⁶

1. Jazz Pharmaceuticals' full year 2021 guidance is provided on a standalone basis and does not reflect the impact of the proposed acquisition of GW Pharmaceuticals. Jazz Pharmaceuticals plans to provide updated guidance following the close of the planned transaction.
2. Excludes \$8-\$10 million of share-based compensation expense from estimated GAAP gross margin.
3. Excludes \$102-\$115 million of share-based compensation expense and \$25-\$40 million of expenses relating to the proposed acquisition, which are expected to be incurred prior to the transaction close, from estimated GAAP SG&A expenses.
4. Excludes \$35-\$40 million of share-based compensation expense from estimated GAAP R&D expenses.
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 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 first 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 8765706.

A replay of the conference call will be available through May 11, 2021 by dialing +1 855 859 2056 in the U.S., or +1 404 537 3406 outside the U.S., and entering passcode 8765706. 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 malignancies and solid tumors. We actively explore new options for patients including novel compounds, small molecules, 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. 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. 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' growth prospects and future financial and operating results, including the company's 2021 financial guidance and the company's expectations related thereto; the company delivering significant revenue diversification in 2022; statements about the company's 2021 commercial and R&D objectives, including statements regarding potential regulatory approvals, initiation of clinical development trials, and expansion and diversification of the company's pipeline and business; the potential of Xywav in IH; statements related to the proposed acquisition of GW Pharmaceuticals and the anticipated timing, results and benefits thereof; the company working to further expand commercial payer coverage for Xywav; the company's objective of ensuring that ALL/LBL patients have access to a reliably produced, high-quality recombinant asparaginase; the company's expected clinical development, regulatory submissions and product launches, and the timing thereof; expected initiations of JZP385, JZP150 and Zepzelca trials and the timing thereof; the company's expectations regarding the distribution of Erwinaze; the company's financing structure supporting the company's rapid deleveraging and positioning the company to meet its stated leverage 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: Jazz Pharmaceuticals' and GW Pharmaceuticals' ability to complete the acquisition on the proposed terms or on the anticipated timeline, or at all, including risks and uncertainties related to securing the sanction of the High Court of Justice of England and Wales and satisfaction of other closing conditions to consummate the acquisition; the occurrence of any event, change or other circumstance that could give rise to the termination of the definitive transaction agreement relating to the proposed transaction; risks related to diverting the attention of GW Pharmaceuticals and Jazz Pharmaceuticals management from ongoing business operations; failure to realize the expected benefits of the acquisition; significant transaction costs and/or unknown or inestimable liabilities; the risk that GW Pharmaceuticals' business will not be integrated successfully or that such integration may be more difficult, time-consuming or costly than expected; Jazz Pharmaceuticals' ability to obtain the expected financing to consummate the acquisition; risks related to future opportunities and plans for the combined company, including the uncertainty of expected future regulatory filings, financial performance and results of the combined company following completion of the acquisition; GW Pharmaceuticals' dependence on the successful commercialization of Epidiolex/Epidyolex and the uncertain market potential of Epidiolex; pharmaceutical product development and the uncertainty of clinical success; the regulatory approval process, including the risks that GW Pharmaceuticals may be unable to submit anticipated regulatory filings on the timeframe anticipated, or at all, or that GW Pharmaceuticals may be unable to obtain regulatory approvals of any of its product candidates, including nabiximols and Epidiolex for additional indications, in a timely manner or at all; disruption from the proposed acquisition of GW Pharmaceuticals, making it more difficult to conduct business as usual or maintain relationships with customers, employees or suppliers; the possibility that, if Jazz Pharmaceuticals does not achieve the perceived benefits of the acquisition as rapidly or to the extent anticipated by financial analysts or investors, the market price of Jazz Pharmaceuticals' ordinary shares could decline; regulatory initiatives and changes in tax laws; market volatility; 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 process 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 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 and other provisions and estimates; and other risks and uncertainties affecting the company and GW Pharmaceuticals, 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, GW Pharmaceuticals' definitive proxy statement filed with the SEC on March 15, 2021, GW Pharmaceuticals' Form 10-Q for the quarter ended March 31, 2021, and future filings and reports by either company. 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 (LOSS)
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended	
	March 31,	
	2021	2020
Revenues:		
Product sales, net	\$ 603,531	\$ 530,205
Royalties and contract revenues	4,050	4,521
Total revenues	607,581	534,726
Operating expenses:		
Cost of product sales (excluding amortization of acquired developed technologies)	40,189	28,657
Selling, general and administrative	260,508	208,400
Research and development	76,573	86,107
Intangible asset amortization	68,192	62,847
Acquired in-process research and development	—	202,250
Impairment charge	—	136,139
Total operating expenses	445,462	724,400
Income (loss) from operations	162,119	(189,674)
Interest expense, net	(27,376)	(18,496)
Foreign exchange gain (loss)	943	(1,132)
Income (loss) before income tax provision (benefit) and equity in gain of investees	135,686	(209,302)
Income tax provision (benefit)	18,019	(51,287)
Equity in gain of investees	(4,165)	(182)
Net income (loss)	<u>\$ 121,832</u>	<u>\$ (157,833)</u>
Net income (loss) per ordinary share:		
Basic	<u>\$ 2.16</u>	<u>\$ (2.82)</u>
Diluted	<u>\$ 2.09</u>	<u>\$ (2.82)</u>
Weighted-average ordinary shares used in per share calculations - basic	<u>56,468</u>	<u>55,956</u>
Weighted-average ordinary shares used in per share calculations - diluted	<u>58,393</u>	<u>55,956</u>

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

	March 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 2,097,533	\$ 1,057,769
Investments	335,000	1,075,000
Accounts receivable, net of allowances	413,976	396,490
Inventories	115,475	95,396
Prepaid expenses	57,185	62,422
Other current assets	147,727	152,491
Total current assets	3,166,896	2,839,568
Property, plant and equipment, net	123,863	127,935
Operating lease assets	125,738	129,169
Intangible assets, net	2,108,046	2,195,051
Goodwill	938,398	958,303
Deferred tax assets, net	258,454	254,916
Deferred financing costs	4,724	5,238
Other non-current assets	30,351	25,721
Total assets	<u>\$ 6,756,470</u>	<u>\$ 6,535,901</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 77,738	\$ 26,945
Accrued liabilities	374,035	352,732
Current portion of long-term debt	248,613	246,322
Income taxes payable	49,334	25,200
Deferred revenue	2,373	2,546
Total current liabilities	752,093	653,745
Deferred revenue, non-current	1,852	2,315
Long-term debt, less current portion	1,853,033	1,848,516
Operating lease liabilities, less current portion	136,020	140,035
Deferred tax liabilities, net	109,915	130,397
Other non-current liabilities	105,868	101,148
Total shareholders' equity	3,797,689	3,659,745
Total liabilities and shareholders' equity	<u>\$ 6,756,470</u>	<u>\$ 6,535,901</u>

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

	Three Months Ended	
	March 31,	
	2021	2020
Net cash provided by operating activities	\$ 284,997	\$ 272,969
Net cash provided by (used in) investing activities	737,132	(60,080)
Net cash provided by (used in) financing activities	18,276	(147,683)
Effect of exchange rates on cash and cash equivalents	(641)	(948)
Net increase in cash and cash equivalents	<u>\$ 1,039,764</u>	<u>\$ 64,258</u>

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

	Three Months Ended March 31,	
	2021	2020
GAAP reported net income (loss)	\$ 121,832	\$ (157,833)
Intangible asset amortization	68,192	62,847
Share-based compensation expense	34,485	28,654
Transaction-related expenses ¹	8,262	—
Non-cash interest expense ²	15,688	12,000
Impairment charge ³	—	136,139
Income tax effect of above adjustments	(19,640)	(55,974)
Non-GAAP adjusted net income	<u>\$ 228,819</u>	<u>\$ 25,833</u>
GAAP reported net income (loss) per diluted share	\$ 2.09	\$ (2.82)
Non-GAAP adjusted net income per diluted share	<u>\$ 3.92</u>	<u>\$ 0.45</u>
Weighted-average ordinary shares used in diluted per share calculations - GAAP	<u>58,393</u>	<u>55,956</u>
Weighted-average ordinary shares used in diluted per share calculations - non-GAAP	<u>58,393</u>	<u>56,792</u>

Explanation of Adjustments and Certain Line Items:

- Transaction expenses related to the proposed GW acquisition.
- Non-cash interest expense associated with debt discount and debt issuance costs.
- 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.

JAZZ PHARMACEUTICALS PLC
RECONCILIATIONS OF GAAP REPORTED TO NON-GAAP ADJUSTED INFORMATION
CERTAIN LINE ITEMS - FOR THE THREE MONTHS ENDED MARCH 31, 2021 and 2020
(In thousands, except percentages)
(Unaudited)

	Three months ended March 31, 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	\$ 40,189	93.3%	\$ 260,508	\$ 76,573	\$ 68,192	\$ 27,376	\$ 18,019	13.3%
Non-GAAP Adjustments:								
Intangible asset amortization	—	—	—	—	(68,192)	—	—	—
Share-based compensation expense	(1,996)	0.4	(23,846)	(8,643)	—	—	—	—
Transaction-related expenses	—	—	(8,262)	—	—	—	—	—
Non-cash interest expense	—	—	—	—	—	(15,688)	—	—
Income tax effect of above adjustments	—	—	—	—	—	—	19,640	1.1
Total of Non-GAAP adjustments	<u>(1,996)</u>	<u>0.4</u>	<u>(32,108)</u>	<u>(8,643)</u>	<u>(68,192)</u>	<u>(15,688)</u>	<u>19,640</u>	<u>1.1</u>
Non-GAAP Adjusted	<u>\$ 38,193</u>	<u>93.7%</u>	<u>\$ 228,400</u>	<u>\$ 67,930</u>	<u>\$ —</u>	<u>\$ 11,688</u>	<u>\$ 37,659</u>	<u>14.4%</u>

	Three months ended March 31, 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 (benefit)	Effective tax rate
GAAP Reported	\$ 28,657	94.6%	\$ 208,400	\$ 86,107	\$ 62,847	\$ 136,139	\$ 18,496	\$ (51,287)	24.5%
Non-GAAP Adjustments:									
Intangible asset amortization	—	—	—	—	(62,847)	—	—	—	—
Share-based compensation expense	(1,673)	0.3	(20,596)	(6,385)	—	—	—	—	—
Impairment charge	—	—	—	—	—	(136,139)	—	—	—
Non-cash interest expense	—	—	—	—	—	—	(12,000)	—	—
Income tax effect of above adjustments	—	—	—	—	—	—	—	55,974	(9.1)
Total of Non-GAAP adjustments	<u>(1,673)</u>	<u>0.3</u>	<u>(20,596)</u>	<u>(6,385)</u>	<u>(62,847)</u>	<u>(136,139)</u>	<u>(12,000)</u>	<u>55,974</u>	<u>(9.1)</u>
Non-GAAP Adjusted	<u>\$ 26,984</u>	<u>94.9%</u>	<u>\$ 187,804</u>	<u>\$ 79,722</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 6,496</u>	<u>\$ 4,687</u>	<u>15.4%</u>

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

GAAP net income	\$485 - \$610
Intangible asset amortization	210 - 230
Share-based compensation expense	145 - 165
Transaction-related expenses	25 - 40
Non-cash interest expense	55 - 65
Income tax effect of above adjustments	<u>(60) - (70)</u>
Non-GAAP adjusted net income	<u>\$915 - \$985</u>
GAAP net income per diluted share	\$8.30 - \$10.45
Non-GAAP adjusted net income per diluted share	<u>\$15.65 - \$16.85</u>

Weighted-average ordinary shares used in per share calculations 58 - 59

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