

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934**

**August 6, 2019  
Date of Report (Date of earliest event reported)**

**JAZZ PHARMACEUTICALS PUBLIC LIMITED COMPANY**  
(Exact name of registrant as specified in its charter)

**Ireland  
(State or Other Jurisdiction  
of Incorporation)**

**001-33500  
(Commission  
File No.)**

**98-1032470  
(IRS Employer  
Identification No.)**

**Fifth Floor, Waterloo Exchange, Waterloo Road, Dublin 4, Ireland D04 E5W7  
(Address of principal executive offices, including zip code)**

**011-353-1-634-7800  
(Registrant's telephone number, including area code)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary shares, nominal value \$0.0001 per share	JAZZ	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 2.02. Results of Operations and Financial Condition.**

On August 6, 2019, Jazz Pharmaceuticals plc (the “Company”) issued a press release (the “Press Release”) announcing financial results for the Company for the quarter ended June 30, 2019. A copy of the Press Release is furnished as Exhibit 99.1 to this current report.

The information in this Item 2.02 and in the Press Release furnished as Exhibit 99.1 to this current report shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 2.02 and in the Press Release furnished as Exhibit 99.1 to this current report shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#"><u>Press Release dated August 6, 2019.</u></a>





**JAZZ PHARMACEUTICALS ANNOUNCES SECOND QUARTER 2019  
FINANCIAL RESULTS**

**Total Revenues Increased 7% to \$534 Million**

**GAAP Diluted EPS of \$4.56; Adjusted Diluted EPS of \$4.05**

**Launched Sunosi in Early July in the U.S.**

**Expansion of Defitelio into Japan Following Nippon Shinyaku Co., Ltd. Receipt of Marketing Authorization**

**Children's Oncology Group Presented Positive Vyxeos Data in Children and Young Adults with Relapsed/Refractory AML at ASCO 2019**

**Purchased Redx's Pan-RAF Inhibitor Program for the Potential Treatment of RAF and RAS Mutant Tumors**

DUBLIN, August 6, 2019 -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced financial results for the second quarter of 2019 and updated 2019 financial guidance.

"2019 has been notable for significant execution and accomplishments across all aspects of our business, including strong financial results, the U.S. launch of Sunosi and further expansion and diversification of our development pipeline through internal and acquired R&D programs," said Bruce Cozadd, chairman and chief executive officer of Jazz Pharmaceuticals. "In the second half of the year, we are focused on continuing to deliver innovative therapies to patients and value to shareholders by preparing to file an NDA for JZP-258, our novel oxybate product candidate, advancing our R&D programs and planning for the potential approval of solriamfetol in the EU."

"We look forward to initiating multiple Vyxeos studies and to working with the Children's Oncology Group to initiate a pivotal Phase 2/3 study this year for JZP-458, our recombinant crisantaspase product candidate for the treatment of acute lymphoblastic leukemia," said Robert Iannone, M.D., M.S.C.E., executive vice president, research and development, of Jazz Pharmaceuticals. "With the addition of the pan-RAF inhibitor program and our exosome therapeutics collaboration, we continue to grow and diversify our R&D pipeline."

## Financial Highlights

(In thousands, except per share amounts and percentages)	Three Months Ended June 30,			Six Months Ended June 30,		
	2019	2018	Change	2019	2018	Change
Total revenues	\$ 534,133	\$ 500,479	7%	\$ 1,042,319	\$ 945,092	10%
GAAP net income	\$ 261,898	\$ 92,321	184%	\$ 347,099	\$ 138,312	151%
Adjusted net income	\$ 232,537	\$ 214,636	8%	\$ 445,710	\$ 397,007	12%
GAAP EPS	\$ 4.56	\$ 1.50	204%	\$ 6.01	\$ 2.26	166%
Adjusted EPS	\$ 4.05	\$ 3.49	16%	\$ 7.72	\$ 6.48	19%

GAAP net income for the second quarter of 2019 was \$261.9 million, or \$4.56 per diluted share, compared to \$92.3 million, or \$1.50 per diluted share, for the second quarter of 2018.

Non-GAAP adjusted net income for the second quarter of 2019 was \$232.5 million, or \$4.05 per diluted share, compared to \$214.6 million, or \$3.49 per diluted share, for the second quarter of 2018. Reconciliations of applicable GAAP reported to non-GAAP adjusted information are included at the end of this press release.

In the second quarter of 2019, the company recorded a one-time tax benefit of \$112.3 million, or \$1.96 per diluted share, on a GAAP basis, resulting from an intra-entity intellectual property asset transfer. This tax benefit has been excluded from adjusted net income and the related per share measures for the three and six months ended June 30, 2019. In the second quarter of 2018, GAAP net income included an impairment charge of \$42.9 million resulting from the company's sale of its rights related to Prialt® (ziconotide) intrathecal infusion.

## Corporate Updates

In July 2019, the company launched Sunosi™ (solriamfetol) in the U.S. after receiving a schedule IV designation from the U.S. Drug Enforcement Agency (DEA). Sunosi is the first and only dual-acting dopamine and norepinephrine reuptake inhibitor approved to improve wakefulness in adult patients with excessive daytime sleepiness (EDS) associated with narcolepsy or obstructive sleep apnea (OSA).

The company today announced the appointment of Neena M. Patil as General Counsel. Ms. Patil will oversee all legal matters for the company. Ms. Patil has been practicing law for nearly 20 years and was most recently Senior Vice President, General Counsel and Corporate Secretary for Abeona Therapeutics Inc. Prior to Abeona, Ms. Patil was Vice President for Legal Affairs, Associate General Counsel and Assistant Corporate Secretary at Novo Nordisk and held various positions at other global pharmaceutical companies. Ms. Patil received a JD from the University of Michigan Law School, a Masters in Health Services Administration from the University of Michigan School of Public Health and an undergraduate Bachelor of Arts degree from Georgetown University.

## Key Regulatory/R&D Updates

In June 2019, the Children's Oncology Group (COG) presented positive Phase 1/2 Vyxeos data at the American Society of Clinical Oncology (ASCO) annual meeting in children and young adults with relapsed/refractory acute myeloid leukemia (AML). Overall response rate<sup>1</sup> was 81.1%, with 70% of patients achieving best response after cycle 1 with Vyxeos and the percent of patients who achieved minimal residual disease (MRD) negative status was 75% post-cycle 1 and 84% overall. Given the robust overall response rate, the company intends to discuss the data and its plans for regulatory submissions with health authorities.

In June 2019, Nippon Shinyaku Co., Ltd. announced that Japan's Ministry of Health, Labour and Welfare approved the marketing authorization of Defitelio® injection 200mg (defibrotide sodium) for the treatment of sinusoidal obstruction syndrome/hepatic veno-occlusive disease.

In July 2019, the company acquired Redx Pharma plc's (Redx) pan-RAF inhibitor program for the potential treatment of RAF and RAS mutant tumors. Under the terms of the agreement, the company made an upfront payment of \$3.5 million. Redx is eligible to receive up to \$203 million in development, regulatory and commercial milestone payments from the company, and incremental tiered mid-single digit royalties, based on any future net sales.

In August 2019, the company announced positive results of a Phase 1 study for JZP-458, its recombinant crisantaspase product candidate, and plans to initiate a single-arm, pivotal Phase 2/3 study. JZP-458 is being evaluated as a potential treatment option for patients with acute lymphoblastic leukemia (ALL)/lymphoblastic lymphoma (LBL) who have had hypersensitivity to *E. coli*-based asparaginase products.

<sup>1</sup> Comprised of complete remission + complete remission with incomplete platelet recovery + complete remission with incomplete hematologic recovery (CR+CRp+CRi).

## Select 2019 Milestones

Programs	2019 Milestones*
Xyrem® (sodium oxybate) oral solution	<ul style="list-style-type: none"> <li>✓ Launched for the treatment of cataplexy or EDS in pediatric narcolepsy in March</li> </ul>
JZP-258	<ul style="list-style-type: none"> <li>✓ Announced positive top-line results from the Phase 3 narcolepsy study in March</li> <li>✓ Received Orphan Drug Designation from FDA for the idiopathic hypersomnia indication</li> <li>• Top-line results from the Phase 3 narcolepsy study to be presented at the World Sleep Congress meeting in September</li> <li>• NDA submission as early as year-end</li> </ul>
Sunosi™ (solriamfetol)	<ul style="list-style-type: none"> <li>✓ Received FDA approval for EDS in narcolepsy or OSA in March</li> <li>✓ Received DEA scheduling decision in June</li> <li>✓ Launched in the U.S. in July</li> <li>✓ Identified EDS associated with Major Depressive Disorder as a new area of interest</li> <li>• Obtain EU approval for EDS in narcolepsy or OSA as early as year-end</li> </ul>
Vyxeos® (daunorubicin and cytarabine) liposome for injection	<ul style="list-style-type: none"> <li>✓ Positive data presented by COG in children and young adults with relapsed/refractory AML at ASCO in June</li> <li>✓ Activated sites for Phase 1 attenuated dose finding study of Vyxeos in higher risk myelodysplastic syndrome (MDS) through MD Anderson collaboration</li> <li>✓ Activated sites for Phase 1b study of low intensity therapy of Vyxeos in combination with venetoclax in first-line, unfit AML</li> <li>✓ Activated sites for Phase 3 study in adult patients with newly diagnosed standard- and high-risk AML through the AML Study Group, a cooperative group</li> <li>✓ Activated sites for Phase 2 study in patients with high-risk MDS through the European Myelodysplastic Syndromes Cooperative Group</li> <li>• Potential interim combination data results from studies conducted through MD Anderson collaboration</li> <li>• Activate sites for Phase 3 study in newly diagnosed pediatric patients with AML (COG)</li> <li>• Activate sites for Phase 2 study in newly diagnosed, fit, older adults with high-risk AML</li> <li>• Activate sites for Phase 2 study in a broader age range of adults with high-risk AML</li> </ul>
Defitelio® (defibrotide sodium) / defibrotide	<ul style="list-style-type: none"> <li>✓ Positive results from DEFIFrance study presented at European Society for Blood and Marrow Transplant meeting in March</li> <li>✓ Nippon Shinyaku Co., Ltd. received marketing authorization for Defitelio in Japan in June</li> <li>• Provide an update regarding the timing of the interim analysis in the prevention of hepatic veno-occlusive disease (VOD) study</li> <li>• Complete enrollment in prevention of acute graft-vs-host disease Phase 2 study</li> <li>• Activate sites for exploratory Phase 2 study in chimeric antigen receptor t-cell therapy associated neurotoxicity</li> <li>• Activate sites for Phase 2 study in transplant-associated thrombotic microangiopathy</li> </ul>
JZP-458	<ul style="list-style-type: none"> <li>• Activate sites for single-arm, pivotal Phase 2/3 clinical study later this year in ALL/LBL</li> </ul>
CombiPlex®	<ul style="list-style-type: none"> <li>• Continue Investigational New Drug enabling activities for one solid tumor combination and progress exploratory activities for other hematology/oncology candidates</li> </ul>

\* Milestones denoted as ✓ have been completed; all other milestones are planned or expected in 2019 unless otherwise noted.

## Total Revenues

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
(In thousands)				
Xyrem® (sodium oxybate) oral solution	\$ 413,212	\$ 356,008	\$ 781,529	\$ 672,785
Erwinaze® / Erwinase® (asparaginase <i>Erwinia chrysanthemi</i> )	27,622	58,713	88,521	109,340
Defitelio® (defibrotide sodium) / defibrotide	46,055	40,498	87,555	75,559
Vyxeos® (daunorubicin and cytarabine) liposome for injection	31,362	27,951	60,305	54,179
Other	5,172	12,925	8,844	25,079
Product sales, net	523,423	496,095	1,026,754	936,942
Royalties and contract revenues	10,710	4,384	15,565	8,150
Total revenues	\$ 534,133	\$ 500,479	\$ 1,042,319	\$ 945,092

Total revenues increased 7% in the second quarter of 2019 compared to the same period in 2018.

Xyrem net product sales increased 16% in the second quarter of 2019 compared to the same period in 2018.

Erwinaze/Erwinase net product sales decreased 53% in the second quarter of 2019 compared to the same period in 2018 due to ongoing quality and supply issues at the sole manufacturer resulting in minimal supply during the quarter. The company anticipates inter-quarter variability in Erwinaze net sales due to expected supply disruptions during the second half of 2019.

Defitelio/defibrotide net product sales increased 14% in the second quarter of 2019 compared to the same period in 2018 primarily due to an increase in volumes. The second quarter included a shipment to Nippon Shinyaku following the recent approval of Defitelio in Japan. The company continues to expect inter-quarter variability in Defitelio net sales.

Vyxeos net product sales increased 12% in the second quarter of 2019 compared to the same period in 2018 primarily due to the ongoing EU launch. The company continues to implement its intensive education and outreach initiatives while advancing a broad development program to support potential expanded uses of Vyxeos.

## Operating Expenses

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
(In thousands, except percentages)				
GAAP:				
Cost of product sales	\$ 27,676	\$ 34,714	\$ 61,182	\$ 68,633
<i>Gross margin</i>	94.7 %	93.0%	94.0 %	92.7%
Selling, general and administrative	\$ 176,014	\$ 158,579	\$ 343,961	\$ 365,792
<i>% of total revenues</i>	33.0 %	31.7%	33.0 %	38.7%
Research and development	\$ 62,384	\$ 56,132	\$ 122,489	\$ 118,799
<i>% of total revenues</i>	11.7 %	11.2%	11.8 %	12.6%
Impairment charges	\$ —	\$ 42,896	\$ —	\$ 42,896
Acquired in-process research and development	\$ 2,200	\$ —	\$ 58,200	\$ —
Income tax provision (benefit)	\$ (78,650)	\$ 36,524	\$ (49,534)	\$ 55,670
<i>Effective tax rate</i>	(42.7)%	28.2%	(16.5)%	28.6%

(In thousands, except percentages)	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Non-GAAP adjusted:				
Cost of product sales	\$ 25,968	\$ 32,911	\$ 57,815	\$ 65,136
<i>Gross margin</i>	95.0%	93.4%	94.4%	93.0%
Selling, general and administrative	\$ 155,329	\$ 137,706	\$ 302,906	\$ 269,685
<i>% of total revenues</i>	29.1%	27.5%	29.1%	28.5%
Research and development	\$ 56,488	\$ 51,423	\$ 111,070	\$ 98,715
<i>% of total revenues</i>	10.6%	10.3%	10.7%	10.4%
Acquired in-process research and development	\$ 2,200	\$ —	\$ 2,200	\$ —
Income tax provision	\$ 52,027	\$ 50,336	\$ 104,741	\$ 89,029
<i>Effective tax rate</i>	18.2%	19.0%	19.0%	18.3%

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

- Selling, general and administrative (SG&A) expenses increased in the second quarter of 2019 compared to the same period in 2018 on a GAAP and on a non-GAAP adjusted basis primarily due to higher expenses related to the U.S. launch of Sunosi and an increase in headcount and other expenses to support expansion of the business.
- Research and development (R&D) expenses increased in the second quarter of 2019 on a GAAP and on a non-GAAP adjusted basis primarily due to expenses related to the company's pre-clinical and clinical development programs and its partner programs.

### **Cash Flow and Balance Sheet**

As of June 30, 2019, cash, cash equivalents and investments were \$882.7 million and the outstanding principal balance of the company's long-term debt was \$1.8 billion. During the six months ended June 30, 2019, the company generated \$351.1 million of cash from operations, used \$171.1 million to repurchase shares, made an upfront payment of \$56.0 million to Codiak BioSciences, Inc. under a collaboration agreement and made milestone payments totaling \$25.5 million related to Sunosi.

In the six months ended June 30, 2019, the company repurchased approximately 1.3 million ordinary shares under the company's share repurchase program at an average cost of \$131.17 per ordinary share. As of June 30, 2019, the remaining amount authorized for share repurchases was \$208.0 million.

## 2019 Financial Guidance

Jazz Pharmaceuticals is updating its full year 2019 financial guidance as follows (in millions, except per share amounts and percentages):

Revenues <sup>*1</sup>	\$2,070 - \$2,150
Total net product sales <sup>*1</sup>	\$2,055 - \$2,125
-Xyrem net sales*	\$1,550 - \$1,590
-Erwinaze/Erwinase net sales	\$160 - \$195
-Defitelio/defibrotide net sales	\$155 - \$180
-Vyxeos net sales	\$120 - \$150
GAAP gross margin %	94%
Non-GAAP adjusted gross margin % <sup>2,6</sup>	94%
GAAP SG&A expenses	\$702 - \$740
Non-GAAP adjusted SG&A expenses <sup>3,6</sup>	\$620 - \$650
GAAP R&D expenses*	\$257 - \$303
GAAP Acquired in-process research and development expenses*	\$62
Non-GAAP adjusted R&D expenses <sup>4,6</sup>	\$235 - \$265
GAAP effective tax rate*	0% - 3%
Non-GAAP adjusted effective tax rate <sup>5,6</sup>	17% - 19%
GAAP net income per diluted share*	\$9.40 - \$10.75
Non-GAAP adjusted net income per diluted share <sup>6</sup>	\$14.30 - \$15.00

\* Updated August 6, 2019.

1. Includes minimal net sales contribution from Sunosi in the U.S.
2. Excludes \$6-\$8 million of share-based compensation expense from estimated GAAP gross margin.
3. Excludes \$82-\$90 million of share-based compensation expense from estimated GAAP SG&A expenses.
4. Excludes \$22-\$27 million of share-based compensation expense and \$0-\$11 million of milestone payments from estimated GAAP R&D expenses.
5. Excludes the income tax effect of adjustments between GAAP reported and non-GAAP adjusted net income and the income tax benefit related to an intra-entity intellectual property asset transfer.
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 2019 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 2019 second quarter results. The live webcast may be accessed from the Investors section of the company's website at [www.jazzpharmaceuticals.com](http://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 5590569.

A replay of the conference call will be available through August 13, 2019 by dialing +1 855 859 2056 in the U.S., or +1 404 537 3406 outside the U.S., and entering passcode 5590569. 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](http://www.jazzpharmaceuticals.com).

## **About Jazz Pharmaceuticals plc**

Jazz Pharmaceuticals plc (Nasdaq: JAZZ), a global biopharmaceutical company, is dedicated to developing life-changing medicines for people with limited or no options. As a leader in sleep medicine and with a growing hematology/oncology portfolio, Jazz has a diverse portfolio of products and product candidates in development, and is focused on transforming biopharmaceutical discoveries into novel medicines. Jazz Pharmaceuticals markets Sunosi™ (solriamfetol), Xyrem® (sodium oxybate) oral solution, Defitelio® (defibrotide sodium), Erwinaze® (asparaginase *Erwinia chrysanthemi*) and Vyxeos® (daunorubicin and cytarabine) liposome for injection in the U.S. and markets Defitelio® (defibrotide), Erwinaze® and Vyxeos® 44 mg/100 mg powder for concentrate for solution for infusion in countries outside the U.S. For country-specific product information, please visit <https://www.jazzpharma.com/medicines>. For more information, please visit [www.jazzpharmaceuticals.com](http://www.jazzpharmaceuticals.com) and follow us on Twitter at [@JazzPharma](https://twitter.com/JazzPharma).

## **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 reported GAAP 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. 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 its 2019 financial guidance, the company's planned or expected 2019 milestones and the timing thereof, the company's continuing activities to deliver innovative therapies to patients and value to shareholders, including its planned NDA for JZP-258, advancement of its R&D programs and potential approval of solriamfetol in the EU, the planned initiation of multiple Vyxeos studies, the planned initiation of a Phase 2/3 study for JZP-458, the company's recombinant crisantaspase product candidate, the company's intention to discuss data and plans for regulatory submissions with health authorities with respect to Vyxeos, planned activities under the company's collaboration agreement with Redx, potential future payments to Redx, anticipated inter-quarter variability in Erwinaze net sales due to expected supply disruptions during the second half of 2019, the company's expectations of inter-quarter variability in Defitelio net sales, potential expanded uses of Vyxeos, and other statements that are not historical facts. These forward-looking statements are based on the company's current plans, objectives, estimates, expectations and intentions and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks and uncertainties associated with: maintaining or increasing sales of and revenue from Xyrem; effectively commercializing the company's other products and product candidates, including with respect to the recent commercial launch of Sunosi in the U.S. and potential launch in the EU; the time-consuming and uncertain regulatory approval process, including the risk that the company's current and planned regulatory submissions, including the solriamfetol marketing authorization application in the EU and the planned JZP-258 NDA, may not be submitted, accepted or approved by applicable regulatory authorities in a timely manner or at all; 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; 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; the company's ability to maintain rights to its products and product candidates, including Erwinaze; complying with applicable U.S. and non-U.S. regulatory requirements; government investigations 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 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, 2019 and future filings and reports by the company, including the company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2019. 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 June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
<b>Revenues:</b>				
Product sales, net	\$ 523,423	\$ 496,095	\$ 1,026,754	\$ 936,942
Royalties and contract revenues	10,710	4,384	15,565	8,150
Total revenues	534,133	500,479	1,042,319	945,092
<b>Operating expenses:</b>				
Cost of product sales (excluding amortization of intangible assets)	27,676	34,714	61,182	68,633
Selling, general and administrative	176,014	158,579	343,961	365,792
Research and development	62,384	56,132	122,489	118,799
Intangible asset amortization	61,576	54,959	118,461	107,966
Impairment charges	—	42,896	—	42,896
Acquired in-process research and development	2,200	—	58,200	—
Total operating expenses	329,850	347,280	704,293	704,086
Income from operations	204,283	153,199	338,026	241,006
Interest expense, net	(18,234)	(19,646)	(36,156)	(40,251)
Foreign exchange loss	(1,933)	(2,697)	(2,544)	(4,425)
Loss on extinguishment and modification of debt	—	(1,425)	—	(1,425)
Income before income tax provision (benefit) and equity in loss of investees	184,116	129,431	299,326	194,905
Income tax provision (benefit)	(78,650)	36,524	(49,534)	55,670
Equity in loss of investees	868	586	1,761	923
Net income	\$ 261,898	\$ 92,321	\$ 347,099	\$ 138,312
<b>Net income per ordinary share:</b>				
Basic	\$ 4.62	\$ 1.53	\$ 6.09	\$ 2.30
Diluted	\$ 4.56	\$ 1.50	\$ 6.01	\$ 2.26
Weighted-average ordinary shares used in per share calculations - basic	56,707	60,177	56,955	60,053
Weighted-average ordinary shares used in per share calculations - diluted	57,427	61,438	57,753	61,309

**JAZZ PHARMACEUTICALS PLC**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**

(In thousands)

(Unaudited)

	June 30, 2019	December 31, 2018
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 637,739	\$ 309,622
Investments	245,000	515,000
Accounts receivable, net of allowances	311,249	263,838
Inventories	68,999	52,956
Prepaid expenses	31,712	25,017
Other current assets	75,367	67,572
Total current assets	1,370,066	1,234,005
Property, plant and equipment, net	127,183	200,358
Operating lease assets	144,746	—
Intangible assets, net	2,687,941	2,731,334
Goodwill	924,990	927,630
Deferred tax assets, net	184,383	57,879
Deferred financing costs	8,517	9,589
Other non-current assets	40,835	42,696
Total assets	\$ 5,488,661	\$ 5,203,491
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 82,222	\$ 40,602
Accrued liabilities	218,751	264,887
Current portion of long-term debt	33,387	33,387
Income taxes payable	30,413	1,197
Deferred revenue	4,720	5,414
Total current liabilities	369,493	345,487
Deferred revenue, non-current	7,221	9,581
Long-term debt, less current portion	1,567,842	1,563,025
Operating lease liabilities, less current portion	156,289	—
Deferred tax liabilities, net	283,669	309,097
Other non-current liabilities	120,713	218,879
Total shareholders' equity	2,983,434	2,757,422
Total liabilities and shareholders' equity	\$ 5,488,661	\$ 5,203,491

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

	Six Months Ended June 30,	
	2019	2018
Net cash provided by operating activities	\$ 351,100	\$ 359,333
Net cash provided by (used in) investing activities	163,414	(242,733)
Net cash used in financing activities	(186,502)	(18,702)
Effect of exchange rates on cash and cash equivalents	105	1,148
Net increase in cash and cash equivalents	<u>\$ 328,117</u>	<u>\$ 99,046</u>

**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,	
	2019	2018	2019	2018
GAAP reported net income	\$ 261,898	\$ 92,321	\$ 347,099	\$ 138,312
Intangible asset amortization	61,576	54,959	118,461	107,966
Share-based compensation expense	28,289	26,312	55,841	50,615
Loss contingency	—	—	—	57,000
Impairment charges and disposal costs	—	43,969	—	43,969
Upfront and milestone payments	—	—	56,000	11,000
Non-cash interest expense	11,451	10,887	22,584	21,504
Income tax effect of above adjustments	(18,403)	(13,812)	(42,001)	(33,359)
Income tax benefit related to intra-entity intellectual property asset transfer	(112,274)	—	(112,274)	—
Non-GAAP adjusted net income	<u>\$ 232,537</u>	<u>\$ 214,636</u>	<u>\$ 445,710</u>	<u>\$ 397,007</u>
GAAP reported net income per diluted share	<u>\$ 4.56</u>	<u>\$ 1.50</u>	<u>\$ 6.01</u>	<u>\$ 2.26</u>
Non-GAAP adjusted net income per diluted share	<u>\$ 4.05</u>	<u>\$ 3.49</u>	<u>\$ 7.72</u>	<u>\$ 6.48</u>
Weighted-average ordinary shares used in diluted per share calculations	<u>57,427</u>	<u>61,438</u>	<u>57,753</u>	<u>61,309</u>

**JAZZ PHARMACEUTICALS PLC**  
**RECONCILIATIONS OF GAAP REPORTED TO NON-GAAP ADJUSTED INFORMATION**  
**CERTAIN LINE ITEMS AND OTHER INFORMATION**  
(In thousands, except per share amounts and percentages)  
(Unaudited)

	Three Months Ended					
	June 30, 2019			June 30, 2018		
	GAAP Reported	Adjustments	Non-GAAP Adjusted	GAAP Reported	Adjustments	Non-GAAP Adjusted
Total revenues	\$ 534,133	\$ —	\$ 534,133	\$ 500,479	\$ —	\$ 500,479
Cost of product sales (excluding amortization of intangible assets)	27,676	(1,708) <sup>(a)</sup>	25,968	34,714	(1,803) <sup>(a)</sup>	32,911
Selling, general and administrative	176,014	(20,685) <sup>(b)</sup>	155,329	158,579	(20,873) <sup>(b)</sup>	137,706
Research and development	62,384	(5,896) <sup>(c)</sup>	56,488	56,132	(4,709) <sup>(c)</sup>	51,423
Intangible asset amortization	61,576	(61,576)	—	54,959	(54,959)	—
Acquired in-process research and development	2,200	—	2,200	—	—	—
Impairment charges	—	—	—	42,896	(42,896)	—
Interest expense, net	18,234	(11,451) <sup>(d)</sup>	6,783	19,646	(10,887) <sup>(d)</sup>	8,759
Foreign exchange loss	1,933	—	1,933	2,697	—	2,697
Loss on extinguishment and modification of debt	—	—	—	1,425	—	1,425
Income before income tax provision (benefit) and equity in loss of investees	184,116	101,316 <sup>(e)</sup>	285,432	129,431	136,127 <sup>(e)</sup>	265,558
Income tax provision (benefit)	(78,650)	130,677 <sup>(f)</sup>	52,027	36,524	13,812 <sup>(f)</sup>	50,336
Effective tax rate <sup>(g)</sup>	(42.7)%		18.2%	28.2%		19.0%
Equity in loss of investees	868	—	868	586	—	586
Net income	\$ 261,898	\$ (29,361) <sup>(h)</sup>	\$ 232,537	\$ 92,321	\$ 122,315 <sup>(h)</sup>	\$ 214,636
Net income per diluted share	\$ 4.56		\$ 4.05	\$ 1.50		\$ 3.49

**JAZZ PHARMACEUTICALS PLC**  
**RECONCILIATIONS OF GAAP REPORTED TO NON-GAAP ADJUSTED INFORMATION**  
**CERTAIN LINE ITEMS AND OTHER INFORMATION**  
(In thousands, except per share amounts and percentages)  
(Unaudited)

	Six Months Ended					
	June 30, 2019			June 30, 2018		
	GAAP Reported	Adjustments	Non-GAAP Adjusted	GAAP Reported	Adjustments	Non-GAAP Adjusted
Total revenues	\$ 1,042,319	\$ —	\$ 1,042,319	\$ 945,092	\$ —	\$ 945,092
Cost of product sales (excluding amortization of intangible assets)	61,182	(3,367) <sup>(i)</sup>	57,815	68,633	(3,497) <sup>(i)</sup>	65,136
Selling, general and administrative	343,961	(41,055) <sup>(i)</sup>	302,906	365,792	(96,107) <sup>(i)</sup>	269,685
Research and development	122,489	(11,419) <sup>(k)</sup>	111,070	118,799	(20,084) <sup>(k)</sup>	98,715
Intangible asset amortization	118,461	(118,461)	—	107,966	(107,966)	—
Acquired in-process research and development	58,200	(56,000)	2,200	—	—	—
Impairment charges	—	—	—	42,896	(42,896)	—
Interest expense, net	36,156	(22,584) <sup>(d)</sup>	13,572	40,251	(21,504) <sup>(d)</sup>	18,747
Foreign exchange loss	2,544	—	2,544	4,425	—	4,425
Loss on extinguishment and modification of debt	—	—	—	1,425	—	1,425
Income before income tax provision (benefit) and equity in loss of investees	299,326	252,886 <sup>(l)</sup>	552,212	194,905	292,054 <sup>(l)</sup>	486,959
Income tax provision (benefit)	(49,534)	154,275 <sup>(m)</sup>	104,741	55,670	33,359 <sup>(m)</sup>	89,029
Effective tax rate <sup>(g)</sup>	(16.5)%		19.0%	28.6%		18.3%
Equity in loss of investees	1,761	—	1,761	923	—	923
Net income	\$ 347,099	\$ 98,611 <sup>(n)</sup>	\$ 445,710	\$ 138,312	\$ 258,695 <sup>(n)</sup>	\$ 397,007
Net income per diluted share	\$ 6.01		\$ 7.72	\$ 2.26		\$ 6.48

Explanation of Adjustments and Certain Line Items (in thousands):

- (a) Share-based compensation expense of \$1,708 and \$1,803 for the three months ended June 30, 2019 and 2018, respectively.
- (b) Share-based compensation expense of \$20,685 and \$19,800 and disposal costs of \$0 and \$1,073 for the three months ended June 30, 2019 and 2018, respectively.
- (c) Share-based compensation expense of \$5,896 and \$4,709 for the three months ended June 30, 2019 and 2018, respectively.
- (d) Non-cash interest expense associated with debt discount and debt issuance costs for the respective three-and six-month periods.
- (e) Sum of adjustments (a) through (d) plus the adjustments for intangible asset amortization and impairment charges, as applicable, for the respective three-month period.
- (f) Income tax adjustments include the income tax benefit related to intra-entity intellectual property asset transfer of \$112,274 and \$0 and the income tax effect of adjustments between GAAP reported and non-GAAP adjusted net income of \$18,403 and \$13,812 for the three months ended June 30, 2019 and 2018, respectively.
- (g) Income tax provision (benefit) divided by income before income tax provision (benefit) and equity in loss of investees for the respective three-and six-month periods.
- (h) Net of adjustments (e) and (f) for the respective three-month period.
- (i) Share-based compensation expense of \$3,367 and \$3,497 for the six months ended June 30, 2019 and 2018, respectively.
- (j) Share-based compensation expense of \$41,055 and \$38,034, loss contingency of \$0 and \$57,000 and disposal costs of \$0 and \$1,073 for the six months ended June 30, 2019 and 2018, respectively.
- (k) Share-based compensation expense of \$11,419 and \$9,084 and upfront and milestone payments of \$0 and \$11,000 for the six months ended June 30, 2019 and 2018, respectively.
- (l) Sum of adjustments (i), (j), (k) and (d) plus the adjustment for intangible asset amortization, acquired in-process research and development and impairment charges, as applicable, for the respective six-month period.
- (m) Income tax adjustments include the income tax benefit related to an intra-entity intellectual property asset transfer of \$112,274 and \$0 and the income tax effect of adjustments between GAAP reported and non-GAAP adjusted net income of \$42,001 and \$33,359 for the six months ended June 30, 2019 and 2018, respectively.
- (n) Net of adjustments (l) and (f) for the respective six-month period.

**JAZZ PHARMACEUTICALS PLC**  
**RECONCILIATION OF GAAP TO NON-GAAP ADJUSTED 2019 NET INCOME GUIDANCE**  
(In millions, except per share amounts)  
(Unaudited)

GAAP net income*	\$540 - \$620
Intangible asset amortization	240 - 260
Share-based compensation expense	110 - 125
Upfront and milestone payments*	56 - 67
Non-cash interest expense	40 - 50
Income tax effect of adjustments	(75) - (95)
Income tax benefit related to intra-entity intellectual property asset transfer*	(112)
Non-GAAP adjusted net income	\$835 - \$875
GAAP net income per diluted share*	\$9.40 - \$10.75
Non-GAAP adjusted net income per diluted share	\$14.30 - \$15.00
Weighted-average ordinary shares used in per share calculations	58

\* Updated August 6, 2019.

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