# Jazz Pharmaceuticals Announces Third Quarter 2019 Financial Results

November 05, 2019

**Total Revenues Increased 15% to $538 Million**
**GAAP Diluted EPS of $1.78; Adjusted Diluted EPS of $4.10**
**2019 Total Revenues Guidance Increased to $2.10-$2.18 Billion, an Increase of 11-15% Over 2018**
**2019 EPS Guidance Updated to $8.00-$9.00 on a GAAP Basis, an Increase of 10-23% Over 2018**
**2019 EPS Guidance Increased to $15.50-$16.15 on an Adjusted Basis, an Increase of 13-18% Over 2018**
**Positive JZP-258 Phase 3 Data Presented at the World Sleep Congress in September; Plan to Submit NDA in January 2020 and Redeem Priority Review Voucher**
**FDA Granted Fast Track Designation to JZP-458 for the Treatment of ALL/LBL**
**Acquired Cavion, Inc. and its Lead Product Candidate, a Potential Treatment for Essential Tremor, Broadening Company's Neuroscience Therapeutic Focus into Movement Disorders**

DUBLIN, Nov. 5, 2019 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced financial results for the third quarter of 2019 and updated 2019 financial guidance.

"In the third quarter, we delivered strong revenue and adjusted EPS growth ahead of our expectations. As a result, we are raising our revenue and adjusted EPS guidance for 2019," said Bruce Cozadd, chairman and chief executive officer of Jazz Pharmaceuticals. "Following the recent presentation of the positive JZP-258 Phase 3 data at the World Sleep Congress, we are looking forward to submitting the NDA in January 2020 and plan to redeem our priority review voucher for this submission. The quarter included our U.S. new product launch of Sunosi and execution on other key commercial, R&D and corporate development goals, further positioning us for long-term sustainable growth."

"We made significant progress during the quarter, advancing multiple development programs and expanding our pipeline with the acquisition of Cavion, including JZP-385, a Phase 2 investigational candidate for the treatment of essential tremor," said Robert Iannone, M.D., M.S.C.E., executive vice president, research and development, of Jazz Pharmaceuticals. "Importantly, given the urgent patient need, we finalized the protocol for the Phase 2/3 study of JZP-458, our recombinant Erwinia asparaginase, for acute lymphoblastic leukemia and one year after submitting our IND, we are working toward recruiting the first patient in this pivotal study."

**Financial Highlights**

| (In thousands, except per share amounts and percentages) | Three Months Ended September 30, | | | Nine Months Ended September 30, | | |
|---|---|---|---|---|---|---|
| | 2019 | 2018 | Change | 2019 | 2018 | Change |
| Total revenues | $ 537,702 | $ 469,373 | 15% | $ 1,580,021 | $ 1,414,465 | 12% |
| GAAP net income | $ 102,276 | $ 149,316 | (32)% | $ 449,375 | $ 287,628 | 56% |
| Adjusted net income | $ 235,278 | $ 221,655 | 6% | $ 680,988 | $ 618,662 | 10% |
| GAAP EPS | $ 1.78 | $ 2.41 | (26)% | $ 7.80 | $ 4.68 | 67% |
| Adjusted EPS | $ 4.10 | $ 3.58 | 15% | $ 11.81 | $ 10.06 | 17% |

GAAP net income for the third quarter of 2019 was $102.3 million, or $1.78 per diluted share, compared to $149.3 million, or $2.41 per diluted share, for the third quarter of 2018. GAAP net income and EPS for the third quarter of 2019 included the impact of acquired in-process research and development expense primarily related to the company's acquisition of Cavion, Inc. (Cavion).

Non-GAAP adjusted net income for the third quarter of 2019 was $235.3 million, or $4.10 per diluted share, compared to $221.7 million, or $3.58 per diluted share, for the third quarter of 2018. Reconciliations of applicable GAAP reported to non-GAAP adjusted information are included at the end of this press release.

**Key Corporate and R&D Updates**

In August 2019, the company acquired Cavion in a merger transaction. Under the terms of the agreement, the former Cavion shareholders received an upfront payment of $52.5 million and have the potential to receive additional payments of up to $260.0 million upon the achievement of certain clinical, regulatory and commercial milestones, for a total potential consideration of $312.5 million. Cavion's lead molecule, CX-8998, now JZP-385, has been evaluated in a Phase 2 randomized, placebo-controlled clinical study and demonstrated proof-of-concept as a potential treatment for essential tremor.

In September 2019, the company presented positive results from the Phase 3 study of JZP-258, which demonstrate the efficacy of JZP-258 for the treatment of cataplexy and excessive daytime sleepiness (EDS) in adults with narcolepsy. The JZP-258 study met its primary and key secondary endpoints demonstrating highly statistically significant differences in weekly number of cataplexy attacks and Epworth Sleepiness Scale scores compared to placebo. JZP-258 is a novel oxybate formulation with a unique composition of cations resulting in 92% less sodium, or approximately 1 to 1.5 grams less sodium per night, than Xyrem® (sodium oxybate) oral solution.

In October 2019, the company announced that the first patient was enrolled in an exploratory Phase 2 clinical trial evaluating the ability of defibrotide to prevent neurotoxicity in patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) receiving chimeric antigen receptor t-cell (CAR T-cell) therapy.

In October 2019, U.S. Food and Drug Administration (FDA) granted Fast Track designation to JZP-458 for the treatment of acute lymphoblastic leukemia (ALL)/lymphoblastic lymphoma (LBL).

Today, the company announced that it expects to submit the JZP-258 New Drug Application (NDA) in January 2020 and plans to redeem its priority review voucher for this submission.

Today, the company announced that Mike Miller will retire from his role as Executive Vice President, U.S. Commercial effective March 31, 2020. Mr. Miller will continue as an employee of the company through June 30, 2020, to ensure a smooth transition to new leadership. The company plans to begin a search for Mr. Miller's successor soon.

**Select 2019 Milestones***

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

✓ Launched for the treatment of cataplexy or EDS in pediatric narcolepsy in March

**JZP-258**

✓ Announced positive top-line results from Phase 3 narcolepsy study in March

✓ Received Orphan Drug Designation from FDA for idiopathic hypersomnia indication

✓ Presented positive results from Phase 3 narcolepsy study at World Sleep Congress meeting in September

• NDA submission as early as year-end (now intend to submit January 2020)

**Sunosi® (solriamfetol)**

✓ Received FDA approval for EDS in narcolepsy or obstructive sleep apnea (OSA) in March

✓ Received U.S. Drug Enforcement Agency scheduling decision in June

✓ Launched in the U.S. in July

✓ Identified EDS associated with Major Depressive Disorder as a new area of interest

• Obtain EU approval for EDS in narcolepsy or OSA as early as year-end (now anticipate Committee for Medicinal Products for Human Use (CHMP) opinion November 2019; expect European Medicines Agency (EMA) decision early 2020)

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

✓ Positive data presented by Children's Oncology Group (COG) in children and young adults with relapsed/refractory acute myeloid leukemia (AML) at American Society of Clinical Oncology (ASCO) in June

✓ Activated sites for Phase 1 attenuated dose finding study of Vyxeos in higher risk myelodysplastic syndrome (MDS) through MD Anderson collaboration (FPI 2Q19)

✓ Activated sites for Phase 1b study of low intensity therapy of Vyxeos in combination with venetoclax in first-line, unfit AML (FPI 4Q19)

✓ 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 (FPI 3Q19)

✓ Activated sites for Phase 2 study in patients with high-risk MDS through the European Myelodysplastic Syndromes Cooperative Group (FPI 3Q19)

• Activate sites for Phase 1b master trial of Vyxeos in combination with various targeted agents in first-line, fit AML

• Potential interim combination data results from studies conducted through MD Anderson collaboration

• Activate sites in the COG Phase 3 study in newly diagnosed pediatric patients with AML

• Activate sites for Phase 2 study in newly diagnosed, fit, older adults with high-risk AML

• Activate sites for Phase 2 study in a broader age range of adults with high-risk AML

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

✓ Positive results from DEFIFrance study presented at European Society for Blood and Marrow Transplant meeting in March

✓ Nippon Shinyaku Co., Ltd. received marketing authorization for Defitelio in Japan in June and launched in September

✓ Activated sites for exploratory Phase 2 study in CAR T-cell therapy associated neurotoxicity (FPI 4Q19)

✓ Completed enrollment in prevention of acute graft-vs-host disease Phase 2 study

• Conduct interim analysis (IA) in the prevention of hepatic veno-occlusive disease (VOD) study (now expect to conduct 1H20)

**x** Activate sites for Phase 2 study in transplant-associated thrombotic microangiopathy (activities discontinued)

**JZP-458**

✓ FDA granted Fast Track designation to JZP-458 for the treatment of ALL/LBL

• Activate sites for single-arm, pivotal Phase 2/3 clinical study in ALL/LBL

**CombiPlex®**

• Continue Investigational New Drug enabling activities for a solid tumor combination; progress exploratory activities for other hematology/oncology candidates

* Milestones denoted as ✓=completed, x=not completed, •=milestones planned for 2019. FPI = First Patient In

**Total Revenues**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| (In thousands) | 2019 | 2018 | 2019 | 2018 |
| Xyrem® (sodium oxybate) oral solution | $ 425,644 | $ 357,251 | $ 1,207,173 | $ 1,030,036 |
| Erwinaze® / Erwinase® (asparaginase Erwinia chrysanthemi) | 34,024 | 41,134 | 122,545 | 150,474 |
| Defitelio® (defibrotide sodium) / defibrotide | 37,604 | 36,177 | 125,159 | 111,736 |
| Vyxeos® (daunorubicin and cytarabine) liposome for injection | 29,581 | 21,038 | 89,886 | 75,217 |
| Sunosi® (solriamfetol) | 987 | — | 987 | — |
| Other | 4,481 | 9,597 | 13,325 | 34,676 |
| Product sales, net | 532,321 | 465,197 | 1,559,075 | 1,402,139 |
| Royalties and contract revenues | 5,381 | 4,176 | 20,946 | 12,326 |
| Total revenues | $ 537,702 | $ 469,373 | $ 1,580,021 | $ 1,414,465 |

Total revenues increased 15% in the third quarter of 2019 compared to the same period in 2018.

Xyrem net product sales increased 19% in the third quarter of 2019 compared to the same period in 2018.

Erwinaze/Erwinase net product sales decreased 17% in the third quarter of 2019 compared to the same period in 2018 due to ongoing supply and manufacturing issues at the sole manufacturer, resulting in limited product availability during the quarter. The company anticipates ongoing manufacturing issues and supply disruptions for the fourth quarter of 2019 and in 2020.

Defitelio/defibrotide net product sales increased 4% in the third quarter of 2019 compared to the same period in 2018. The company continues to expect inter-quarter variability in Defitelio net sales.

Vyxeos net product sales increased 41% in the third quarter of 2019 compared to the same period in 2018 primarily due to the ongoing EU launch. The company continues to implement its education and outreach initiatives while advancing a development program to support potential expanded uses of Vyxeos.

Sunosi net product sales were $1.0 million in the third quarter of 2019, following the U.S. launch in July 2019.

**Operating Expenses**

| (In thousands, except percentages) | Three Months Ended September 30, 2019 | Three Months Ended September 30, 2018 | Nine Months Ended September 30, 2019 | Nine Months Ended September 30, 2018 |
|---|---|---|---|---|
| GAAP: | | | | |
| Cost of product sales | $ 31,400 | $ 26,574 | $ 92,582 | $ 95,207 |
| Gross margin | 94.1% | 94.3% | 94.1% | 93.2% |
| Selling, general and administrative | $ 178,706 | $ 155,873 | $ 522,667 | $ 521,665 |
| % of total revenues | 33.2% | 33.2% | 33.1% | 36.9% |
| Research and development | $ 79,855 | $ 51,160 | $ 202,344 | $ 169,959 |
| % of total revenues | 14.9% | 10.9% | 12.8% | 12.0% |
| Impairment charges | $ — | $ — | $ — | $ 42,896 |
| Acquired in-process research and development | $ 51,775 | $ — | $ 109,975 | $ — |
| Income tax provision (benefit) | $ 10,903 | $ 19,348 | $ (38,631) | $ 75,018 |
| Effective tax rate | 9.5% | 11.4% | (9.3)% | 20.6% |

| (In thousands, except percentages) | Three Months Ended September 30, 2019 | Three Months Ended September 30, 2018 | Nine Months Ended September 30, 2019 | Nine Months Ended September 30, 2018 |
|---|---|---|---|---|
| Non-GAAP adjusted: | | | | |
| Cost of product sales | $ 29,415 | $ 25,049 | $ 87,230 | $ 90,185 |
| Gross margin | 94.5% | 94.6% | 94.4% | 93.6% |
| Selling, general and administrative | $ 158,404 | $ 136,895 | $ 461,310 | $ 406,580 |
| % of total revenues | 29.5% | 29.2% | 29.2% | 28.7% |
| Research and development | $ 73,357 | $ 46,560 | $ 184,427 | $ 145,275 |
| % of total revenues | *13.6%* | *9.9%* | *11.7%* | *10.3%* |
| Acquired in-process research and development | $ 3,500 | $ — | $ 5,700 | $ — |
| Income tax provision | $ 29,655 | $ 30,266 | $ 134,396 | $ 119,295 |
| Effective tax rate | *11.2%* | *12.0%* | *16.4%* | *16.1%* |

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

- Selling, general and administrative (SG&A) expenses increased in the third quarter of 2019 compared to the same period in 2018 on a GAAP and on a non-GAAP adjusted basis primarily due to expenses related to the expansion of the company's business, including the U.S. launch of Sunosi.
- Research and development (R&D) expenses increased in the third quarter of 2019 on a GAAP and on a non-GAAP adjusted basis primarily due to expenses related to the company's expanding pre-clinical and clinical development programs and support of its partner programs, including a milestone of $11.0 million payable to Pfenex, Inc. under a license and option agreement to develop and commercialize multiple early stage hematology product candidates.

**Cash Flow and Balance Sheet**

As of September 30, 2019, cash, cash equivalents and investments were $1.1 billion, and the outstanding principal balance of the company's long-term debt was $1.8 billion. During the nine months ended September 30, 2019, the company generated $688.6 million of cash from operations, used $191.1 million to repurchase shares under the company's share repurchase program, made milestone payments totaling $80.5 million related to Sunosi, and made upfront payments of $52.5 million to acquire Cavion, Inc. and $56.0 million to Codiak BioSciences, Inc. (Codiak) under a collaboration agreement.

In the nine months ended September 30, 2019, the company repurchased approximately 1.5 million ordinary shares under the company's share repurchase program at an average cost of $131.48 per ordinary share. As of September 30, 2019, the remaining amount authorized for share repurchases was $188.1 million. In October 2019, the company's board of directors increased the share repurchase program by $500 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[1] | $2,100 - $2,180 |
| Total net product sales[1] | $2,080 - $2,155 |
| -Xyrem net sales | $1,600 - $1,640 |
| -Erwinaze/Erwinase net sales | $160 - $195 |
| -Defitelio/defibrotide net sales | $160 - $180 |
| -Vyxeos net sales | $120 - $135 |
| GAAP gross margin % | 94% |
| Non-GAAP adjusted gross margin %[2,8] | 94% |
| GAAP SG&A expenses | $712 - $740 |
| Non-GAAP adjusted SG&A expenses[3,8] | $630 - $650 |
| GAAP R&D expenses | $267 - $292 |
| GAAP Acquired in-process research and development expenses | $110 |
| Non-GAAP adjusted R&D expenses[4,8] | $245 - $265 |
| GAAP effective tax rate[5] | (9%) - (6%) |
| Non-GAAP adjusted effective tax rate[6,8] | 14% - 16% |
| GAAP net income per diluted share[7] | $8.00 - $9.00 |
| Non-GAAP adjusted net income per diluted share[8] | $15.50 - $16.15 |

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 from estimated GAAP R&D expenses.
5. Includes an income tax benefit of $112.3 million related to an intra-entity intellectual property asset transfer.
6. 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.
7. Includes expected intangible asset amortization of $111 million in the fourth quarter of 2019 as a result of the Company's notification to the FDA of its intention to redeem its priority review voucher for the planned NDA submission for JZP-258.
8. 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. EST (9:30 p.m. GMT) to provide a business and financial update and discuss its 2019 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 9398898.

A replay of the conference call will be available through November 12, 2019 by dialing +1 855 859 2056 in the U.S., or +1 404 537 3406 outside the U.S., and entering passcode 9398898. 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 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), Erwinase® and Vyxeos® liposomal 44 mg/100 mg powder for concentrate for solution for infusion in countries outside the U.S. For country-specific product information, please visit www.jazzpharma.com/medicines. For more information, please visit www.jazzpharmaceuticals.com and follow us on Twitter at @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, as applicable, the income tax benefit related to an intra-entity intellectual property asset transfer and the impact of the U.S. Tax Cuts and Job Act (U.S. Tax Act). 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 planned submission of an NDA for JZP-258 (with the redemption of a priority review voucher in connection with the submission) and the timing thereof, the company's potential for long-term sustainable growth, the company's plans to advance its Vyxeos clinical development program and to initiate a pivotal Phase 2/3 study of JZP-458 for the treatment of ALL, the therapeutic potential of the company's product candidates, including JZP-258, JZP-458, JZP-385, as well as defibrotide in the prevention of CAR T-cell therapy associated neurotoxicity in patients with relapsed or refractory DLBCL receiving axicabtagene ciloleucel, the company's expectations of Erwinaze supply disruptions in 2019 and 2020, 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 Sunosi 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 June 30, 2019 and future filings and reports by the company, including the company's Quarterly Report on Form 10-Q for the quarter ended September 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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| Revenues: | | | | |
| Product sales, net | $ 532,321 | $ 465,197 | $ 1,559,075 | $ 1,402,139 |
| Royalties and contract revenues | 5,381 | 4,176 | 20,946 | 12,326 |
| Total revenues | 537,702 | 469,373 | 1,580,021 | 1,414,465 |
| Operating expenses: | | | | |
| Cost of product sales (excluding amortization of intangible assets) | 31,400 | 26,574 | 92,582 | 95,207 |
| Selling, general and administrative | 178,706 | 155,873 | 522,667 | 521,665 |
| Research and development | 79,855 | 51,160 | 202,344 | 169,959 |
| Intangible asset amortization | 62,863 | 46,989 | 181,324 | 154,955 |
| Impairment charges | — | — | — | 42,896 |
| Acquired in-process research and development | 51,775 | — | 109,975 | — |
| Total operating expenses | 404,599 | 280,596 | 1,108,892 | 984,682 |
| Income from operations | 133,103 | 188,777 | 471,129 | 429,783 |
| Interest expense, net | (17,861) | (18,920) | (54,017) | (59,171) |
| Foreign exchange loss | (1,033) | (756) | (3,577) | (5,181) |
| Loss on extinguishment and modification of debt | — | — | — | (1,425) |
| Income before income tax provision (benefit) and equity in loss of investees | 114,209 | 169,101 | 413,535 | 364,006 |
| Income tax provision (benefit) | 10,903 | 19,348 | (38,631) | 75,018 |
| Equity in loss of investees | 1,030 | 437 | 2,791 | 1,360 |
| Net income | $ 102,276 | $ 149,316 | $ 449,375 | $ 287,628 |
| Net income per ordinary share: | | | | |
| Basic | $ 1.80 | $ 2.47 | $ 7.90 | $ 4.78 |
| Diluted | $ 1.78 | $ 2.41 | $ 7.80 | $ 4.68 |
| Weighted-average ordinary shares used in per share calculations - basic | 56,674 | 60,476 | 56,860 | 60,196 |
| Weighted-average ordinary shares used in per share calculations - diluted | 57,438 | 61,857 | 57,647 | 61,493 |

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

| | September 30, 2019 | December 31, 2018 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 795,175 | $ 309,622 |
| Investments | 275,000 | 515,000 |
| Accounts receivable, net of allowances | 267,031 | 263,838 |
| Inventories | 71,108 | 52,956 |
| Prepaid expenses | 30,841 | 25,017 |
| Other current assets | 81,401 | 67,572 |
| Total current assets | 1,520,556 | 1,234,005 |
| Property, plant and equipment, net | 129,472 | 200,358 |
| Operating lease assets | 141,878 | — |
| Intangible assets, net | 2,593,030 | 2,731,334 |
| Goodwill | 906,725 | 927,630 |
| Deferred tax assets, net | 183,944 | 57,879 |
| Deferred financing costs | 7,971 | 9,589 |
| Other non-current assets | 44,274 | 42,696 |
| Total assets | $ 5,527,850 | $ 5,203,491 |
| **LIABILITIES AND SHAREHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 70,104 | $ 40,602 |
| Accrued liabilities | 238,740 | 264,887 |
| Current portion of long-term debt | 33,387 | 33,387 |
| Income taxes payable | 43,488 | 1,197 |

| | | |
|---|---|---|
| Deferred revenue | 4,720 | 5,414 |
| Total current liabilities | 390,439 | 345,487 |
| Deferred revenue, non-current | 6,041 | 9,581 |
| Long-term debt, less current portion | 1,570,781 | 1,563,025 |
| Operating lease liabilities, less current portion | 153,434 | — |
| Deferred tax liabilities, net | 250,167 | 309,097 |
| Other non-current liabilities | 102,583 | 218,879 |
| Total shareholders' equity | 3,054,405 | 2,757,422 |
| Total liabilities and shareholders' equity | $ 5,527,850 | $ 5,203,491 |

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

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2019** | **2018** |
| Net cash provided by operating activities | $ 688,603 | $ 580,808 |
| Net cash provided by (used in) investing activities | 3,753 | (434,479) |
| Net cash used in financing activities | (205,965) | (32,674) |
| Effect of exchange rates on cash and cash equivalents | (838) | (672) |
| Net increase in cash and cash equivalents | $ 485,553 | $ 112,983 |

**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, | |
|---|---|---|---|---|
| | **2019** | **2018** | **2019** | **2018** |
| GAAP reported net income | $ 102,276 | $ 149,316 | $ 449,375 | $ 287,628 |
| Intangible asset amortization | 62,863 | 46,989 | 181,324 | 154,955 |
| Share-based compensation expense | 28,785 | 25,103 | 84,626 | 75,718 |
| Loss contingency | — | — | — | 57,000 |
| Impairment charges and disposal costs | — | — | — | 43,969 |
| Upfront and milestone payments [(a)] | 48,275 | — | 104,275 | 11,000 |
| Non-cash interest expense | 11,831 | 11,165 | 34,415 | 32,669 |
| Income tax effect of above adjustments | (18,752) | (13,786) | (60,753) | (47,145) |
| Income tax benefit related to intra-entity intellectual property asset transfer | — | — | (112,274) | — |
| U.S. Tax Act impact | — | 2,868 | — | 2,868 |
| Non-GAAP adjusted net income | $ 235,278 | $ 221,655 | $ 680,988 | $ 618,662 |
| GAAP reported net income per diluted share | $ 1.78 | $ 2.41 | $ 7.80 | $ 4.68 |
| Non-GAAP adjusted net income per diluted share | $ 4.10 | $ 3.58 | $ 11.81 | $ 10.06 |
| Weighted-average ordinary shares used in diluted per share calculations | 57,438 | 61,857 | 57,647 | 61,493 |

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

(a) Amount includes $48,275 attributed to acquired in-process research and development expense related to the acquisition of Cavion in the three and nine months ended September 30, 2019. The nine month period ended September 30, 2019 also includes a $56,000 upfront payment to Codiak under a collaboration agreement.

**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 | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | September 30, 2019 | | | | September 30, 2018 | | | |
| | **GAAP Reported** | **Adjustments** | | **Non-GAAP Adjusted** | **GAAP Reported** | **Adjustments** | | **Non-GAAP Adjusted** |
| Total revenues | **$ 537,702** | $ — | | $ 537,702 | **$ 469,373** | $ — | | $ 469,373 |
| Cost of product sales (excluding amortization of intangible assets) | **31,400** | (1,985) | (a) | 29,415 | **26,574** | (1,525) | (a) | 25,049 |
| Selling, general and administrative | **178,706** | (20,302) | (b) | 158,404 | **155,873** | (18,978) | (b) | 136,895 |
| Research and development | **79,855** | (6,498) | (c) | 73,357 | **51,160** | (4,600) | (c) | 46,560 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Intangible asset amortization | **62,863** | (62,863) | | — | **46,989** | (46,989) | | — |
| Acquired in-process research and development | **51,775** | (48,275) | (d) | 3,500 | **—** | — | | — |
| Interest expense, net | **17,861** | (11,831) | (e) | 6,030 | **18,920** | (11,165) | (e) | 7,755 |
| Foreign exchange loss | **1,033** | — | | 1,033 | **756** | — | | 756 |
| Income before income tax provision and equity in loss of investees | **114,209** | 151,754 | (f) | 265,963 | **169,101** | 83,257 | (f) | 252,358 |
| Income tax provision | **10,903** | 18,752 | (g) | 29,655 | **19,348** | 10,918 | (g) | 30,266 |
| Effective tax rate (h) | ***9.5%*** | | | *11.2%* | ***11.4%*** | | | *12.0%* |
| Equity in loss of investees | **1,030** | — | | 1,030 | **437** | — | | 437 |
| Net income | **$ 102,276** | $ 133,002 | (i) | $ 235,278 | **$ 149,316** | $ 72,339 | (i) | $ 221,655 |
| Net income per diluted share | **$ 1.78** | | | $ 4.10 | **$ 2.41** | | | $ 3.58 |

**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)**

| | **Nine Months Ended** | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | **September 30, 2019** | | | | **September 30, 2018** | | | |
| | **GAAP Reported** | **Adjustments** | | **Non-GAAP Adjusted** | **GAAP Reported** | **Adjustments** | | **Non-GAAP Adjusted** |
| Total revenues | **$ 1,580,021** | $ — | | $ 1,580,021 | **$ 1,414,465** | $ — | | $ 1,414,465 |
| Cost of product sales (excluding amortization of intangible assets) | **92,582** | (5,352) | (j) | 87,230 | **95,207** | (5,022) | (j) | 90,185 |
| Selling, general and administrative | **522,667** | (61,357) | (k) | 461,310 | **521,665** | (115,085) | (k) | 406,580 |
| Research and development | **202,344** | (17,917) | (l) | 184,427 | **169,959** | (24,684) | (l) | 145,275 |
| Intangible asset amortization | **181,324** | (181,324) | | — | **154,955** | (154,955) | | — |
| Acquired in-process research and development | **109,975** | (104,275) | (m) | 5,700 | **—** | — | | — |
| Impairment charges | **—** | — | | — | **42,896** | (42,896) | | — |
| Interest expense, net | **54,017** | (34,415) | (e) | 19,602 | **59,171** | (32,669) | (e) | 26,502 |
| Foreign exchange loss | **3,577** | — | | 3,577 | **5,181** | — | | 5,181 |
| Loss on extinguishment and modification of debt | **—** | — | | — | **1,425** | — | | 1,425 |
| Income before income tax provision (benefit) and equity in loss of investees | 413,535 | **404,640** | **(n)** | **818,175** | **364,006** | **375,311** | **(n)** | **739,317** |
| **Income tax provision (benefit)** | **(38,631)** | 173,027 | (o) | 134,396 | **75,018** | 44,277 | (o) | 119,295 |
| Effective tax rate (h) | ***(9.3)%*** | | | *16.4%* | ***20.6%*** | | | *16.1%* |
| Equity in loss of investees | **2,791** | — | | 2,791 | **1,360** | — | | 1,360 |
| Net income | **$ 449,375** | $ 231,613 | (p) | $ 680,988 | **$ 287,628** | $ 331,034 | (p) | $ 618,662 |
| Net income per diluted share | **$ 7.80** | | | $ 11.81 | **$ 4.68** | | | $ 10.06 |

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

(a) Share-based compensation expense of $1,985 and $1,525 for the three months ended September 30, 2019 and 2018, respectively.
(b) Share-based compensation expense of $20,302 and $18,978 for the three months ended September 30, 2019 and 2018, respectively.
(c) Share-based compensation expense of $6,498 and $4,600 for the three months ended September 30, 2019 and 2018, respectively.
(d) Acquired in-process research and development expense of $48,275 arising from the acquisition of Cavion for the three months ended September 30, 2019.
(e) Non-cash interest expense associated with debt discount and debt issuance costs for the respective three-and nine-month periods.
(f) Sum of adjustments (a) through (e) plus the adjustment for intangible asset amortization, as applicable, for the respective three-month period.
(g) Income tax adjustments include the income tax effect of adjustments between GAAP reported and non-GAAP adjusted net income of $18,752 and $13,786 offset by the impact of the U.S. Tax Act of $0 and $2,868 for the three months ended September 30, 2019 and 2018, respectively.
(h) Income tax provision (benefit) divided by income before income tax provision (benefit) and equity in loss of investees for the respective three-and nine-month periods.
(i) Net of adjustments (f) and (g) for the respective three-month period.

(j) Share-based compensation expense of $5,352 and $5,022 for the nine months ended September 30, 2019 and 2018, respectively.
(k) Share-based compensation expense of $61,357 and $57,012, loss contingency of $0 and $57,000 and disposal costs of $0 and $1,073 for the nine months ended September 30, 2019 and 2018, respectively.
(l) Share-based compensation expense of $17,917 and $13,684 and upfront and milestone payments of $0 and $11,000 for the nine months ended September 30, 2019 and 2018, respectively.
(m) Acquired in-process research and development expense of $48,275 arising from the acquisition of Cavion and $56,000 upfront payment to Codiak under a collaboration agreement for the nine months ended September 30, 2019.
(n) Sum of adjustments (j), (k), (l), (m) and (e) plus the adjustments for intangible asset amortization and impairment charges, as applicable, for the respective nine-month period.

**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)**

(o) 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 $60,753 and $47,145, partially offset by the impact of the U.S. Tax Act of $0 and $2,868 for the nine months ended September 30, 2019 and 2018, respectively.
(p) Net of adjustments (n) and (o) for the respective nine-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[1,2] | $460 - $520 |
| Intangible asset amortization[1,2] | 350 - 370 |
| Share-based compensation expense | 110 - 125 |
| Upfront and milestone payments[1] | 104 |
| Non-cash interest expense | 40 - 50 |
| Income tax effect of adjustments[1] | (80) - (100) |
| Income tax benefit related to intra-entity intellectual property asset transfer | (112) |
| Non-GAAP adjusted net income[1] | $900 - $930 |
| GAAP net income per diluted share[1,2] | $8.00 - $9.00 |
| Non-GAAP adjusted net income per diluted share[1] | $15.50 - $16.15 |
| Weighted-average ordinary shares used in per share calculations | 58 |

1. Updated November 5, 2019.
2. Includes expected intangible asset amortization of $111 million in the fourth quarter of 2019 as a result of the Company's notification to the FDA of its intention to redeem its priority review voucher for the planned NDA submission for JZP-258.

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SOURCE Jazz Pharmaceuticals plc

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