



Jazz Pharmaceuticals Announces First Quarter 2018 Financial Results

May 08, 2018

Total Revenues Increased 18% to \$445 Million

Supplemental New Drug Application Submitted to FDA for Xyrem in the Treatment of Pediatric Narcolepsy Patients with Cataplexy and Excessive Daytime Sleepiness

DUBLIN, May 8, 2018 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced financial results for the first quarter of 2018 and updated financial guidance for 2018.

"The first quarter was highlighted by strong revenue growth, cash flow generation and execution across the organization that led to significant progress toward our 2018 goals," said Bruce Cozadd, chairman and chief executive officer of Jazz Pharmaceuticals. "The recent submission of our supplemental NDA for Xyrem for pediatric narcolepsy patients and FDA acceptance of our NDA for solriamfetol for excessive sleepiness in patients with narcolepsy or OSA result from our focused investment in advancing our promising R&D pipeline. Over the next 18 months, we look forward to fueling our portfolio with innovative product candidates and delivering on multiple regulatory milestones and product launches."

GAAP net income for the first quarter of 2018 was \$46.0 million, or \$0.75 per diluted share, compared to \$86.5 million, or \$1.41 per diluted share, for the first quarter of 2017.

Adjusted net income for the first quarter of 2018 was \$182.4 million, or \$2.98 per diluted share, compared to \$141.2 million, or \$2.31 per diluted share, for the first quarter of 2017. Reconciliations of applicable GAAP reported to non-GAAP adjusted information are included at the end of this press release.

Financial Highlights

(In thousands, except per share amounts and percentages)	Three Months Ended		Change
	March 31,		
	2018	2017	
Total revenues	\$ 444,613	\$ 376,053	18 %
GAAP net income	\$ 45,991	\$ 86,511	(47) %
Adjusted net income	\$ 182,371	\$ 141,222	29 %
GAAP EPS	\$ 0.75	\$ 1.41	(47) %
Adjusted EPS	\$ 2.98	\$ 2.31	29 %

Total Revenues

(In thousands)	Three Months Ended	
	March 31,	
	2018	2017
Xyrem® (sodium oxybate) oral solution	\$ 316,777	\$ 272,326
Erwinaze® / Erwinase® (asparaginase <i>Erwinia chrysanthemi</i>)	50,627	51,388
Defitelio® (defibrotide sodium) / defibrotide	35,061	35,900
Vyxeos® (daunorubicin and cytarabine) liposome for injection	26,228	—
Prialt® (ziconotide) intrathecal infusion	6,126	7,717
Other	6,028	6,347
Product sales, net	440,847	373,678
Royalties and contract revenues	3,766	2,375
Total revenues	\$ 444,613	\$ 376,053

Total revenues increased 18% in the first quarter of 2018 compared to the same period in 2017 due to an increase in net product sales of Xyrem and the launch of Vyxeos.

Xyrem net product sales increased 16% in the first quarter of 2018 compared to the same period in 2017.

Erwinaze/Erwinase net product sales in the first quarter were consistent with the same period in 2017. The company is currently experiencing supply disruptions and expects that there may be further supply challenges during 2018.

Defitelio/defibrotide net product sales in the first quarter of 2018 were consistent with the same period in 2017. The company continues to expect inter-quarter variability in Defitelio net sales given that veno-occlusive disease is an ultra-rare disease.

Vyxeos net product sales were \$26.2 million in the first quarter of 2018. Vyxeos launched in the U.S. in August 2017.

Operating Expenses

(In thousands, except percentages)	Three Months Ended	
	March 31,	
	2018	2017
GAAP:		

Cost of product sales	\$ 33,919	\$ 25,065
<i>Gross margin</i>	92.3 %	93.3 %
Selling, general and administrative	\$ 207,213	\$ 144,255
<i>% of total revenues</i>	46.6 %	38.4 %
Research and development	\$ 62,667	\$ 44,928
<i>% of total revenues</i>	14.1 %	11.9 %

**Three Months Ended
March 31,**

(In thousands, except percentages)	<u>2018</u>	<u>2017</u>
Non-GAAP adjusted:		
Cost of product sales	\$ 32,225	\$ 23,819
<i>Gross margin</i>	92.7 %	93.6 %
Selling, general and administrative	\$ 131,979	\$ 118,450
<i>% of total revenues</i>	29.7 %	31.5 %
Research and development	\$ 47,292	\$ 40,786
<i>% of total revenues</i>	10.6 %	10.8 %

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

- Selling, general and administrative (SG&A) expenses increased in the first quarter of 2018 compared to the same period in 2017 on a GAAP and on a non-GAAP adjusted basis due to higher expenses resulting from expansion of the company's business, including expenses supporting the potential EU launch of Vyxeos and U.S. launch of solriamfetol. SG&A expenses in the first quarter of 2018 on a GAAP basis also included an estimated loss contingency of \$57.0 million related to an ongoing U.S. Department of Justice (DOJ) investigation of our support of 501(c)(3) organizations that provide financial assistance to Medicare patients. In April 2018, the company reached an agreement in principle with the DOJ on a proposal for a civil settlement of potential claims relating to the investigation, subject to negotiation of a definitive settlement agreement and other contingencies.
- Research and development (R&D) expenses increased in the first quarter of 2018 compared to the same period in 2017 on a GAAP and on a non-GAAP adjusted basis due to an increase in expenses related to the company's ongoing pre-clinical and clinical development programs and regulatory activities. R&D expenses in the first quarter of 2018 on a GAAP basis also included milestone payments of \$11.0 million related to the U.S. Food and Drug Administration's (FDA) acceptance for filing of the company's New Drug Application (NDA) for solriamfetol.

Cash Flow and Balance Sheet

As of March 31, 2018, cash, cash equivalents and investments were \$708.2 million, and the outstanding principal balance of the company's long-term debt was \$1.8 billion. During the first quarter of 2018, we generated \$162.4 million of cash from operations, used \$34.5 million to repurchase approximately 238,000 ordinary shares under the company's share repurchase program at an average cost of \$145.34 per ordinary share and made milestone payments totaling \$11.0 million.

Recent Developments

In March 2018, the FDA accepted for filing with standard review the company's NDA seeking marketing approval for solriamfetol, an investigational medicine for the treatment of excessive sleepiness in adult patients with narcolepsy or obstructive sleep apnea (OSA). The Prescription Drug User Fee Act (PDUFA) date for an FDA decision is December 20, 2018.

In April 2018, the company entered into an agreement with Spark Therapeutics, Inc. to purchase a rare pediatric disease priority review voucher (PRV) for \$110 million that will allow the company to accelerate the review process by the FDA for one of its future regulatory submissions.

In April 2018, the company submitted a supplemental NDA to the FDA seeking marketing approval for Xyrem in the treatment of pediatric narcolepsy patients with cataplexy and excessive daytime sleepiness.

2018 Financial Guidance

Jazz Pharmaceuticals is updating its full year 2018 financial guidance as follows (in millions, except per share amounts and percentages):

Revenues*	\$1,880-\$1,930
Total net product sales*	\$1,865-\$1,910
-Xyrem net sales*	\$1,320-\$1,350
-Erwinaze/Erwinase net sales	\$190-\$220
-Defitelio/defibrotide net sales	\$145-\$165
-Vyxeos net sales	\$130-\$155
GAAP gross margin %	93%
Non-GAAP adjusted gross margin % ^{1,5}	93%
GAAP SG&A expenses*	\$660-\$699
Non-GAAP adjusted SG&A expenses ^{2,5}	\$525-\$555
GAAP R&D expenses*	\$232-\$255
Non-GAAP adjusted R&D expenses ^{3,5}	\$205-\$225
GAAP effective tax rate	18%-21%
Non-GAAP adjusted effective tax rate ^{4,5}	17%-19%

GAAP net income per diluted share*	\$6.60-\$7.70
Non-GAAP adjusted net income per diluted share* ⁵	\$12.75-\$13.25

* Updated May 8, 2018

1. Excludes \$6-\$9 million of share-based compensation expense from estimated GAAP gross margin.
2. Excludes \$78-\$87 million of share-based compensation expense and \$57 million of estimated loss contingency from estimated GAAP SG&A expenses.
3. Excludes \$16-\$19 million of share-based compensation expense and \$11 million of milestone payments from estimated GAAP R&D expenses.
4. Excludes the income tax effect of adjustments between GAAP reported and non-GAAP adjusted net income.
5. 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 2018 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 2018 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 9868758.

A replay of the conference call will be available through May 15, 2018 by dialing +1 855 859 2056 in the U.S., or +1 404 537 3406 outside the U.S., and entering passcode 9868758. 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) is an international biopharmaceutical company focused on improving patients' lives by identifying, developing and commercializing meaningful products that address unmet medical needs. The company has a diverse portfolio of products and product candidates with a focus in the areas of sleep and hematology/oncology. In these areas, Jazz Pharmaceuticals markets Xyrem® (sodium oxybate) oral solution, Erwinaze® (asparaginase *Erwinia chrysanthemi*), Defitelio® (defibrotide sodium) and Vyxeos® (daunorubicin and cytarabine) liposome for injection in the U.S. and markets Erwinase® and Defitelio® (defibrotide) in countries outside the U.S. For country-specific product information, please visit www.jazzpharmaceuticals.com/products. 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. In this regard, the components of non-GAAP adjusted net income, including non-GAAP cost of product sales, non-GAAP selling, general and administrative expenses and non-GAAP research and development 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 condensed 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 2018 financial guidance, the company's expectations for advancing its promising R&D pipeline, fueling its portfolio with innovative product candidates and delivering on multiple regulatory milestones and product launches, the company's expectations for future Erwinaze supply challenges and inter-quarter variability in Defitelio net sales, the company's potential use of the PRV to accelerate the review process by the

FDA for one of its future regulatory submissions 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, such as the potential U.S. introduction of a generic version of Xyrem before the entry dates specified in the company's settlements with certain companies that have filed abbreviated new drug applications with the FDA seeking approval to market a generic version of Xyrem or on terms that are different from those contemplated by the settlements; ongoing patent litigation and related proceedings; effectively commercializing the company's other products and product candidates; the time-consuming and uncertain regulatory approval process, including the risk that the company's regulatory submissions, including the solriamfetol NDA, the Xyrem supplemental NDA and the marketing authorization application for Vyxeos in the European Union, may not be approved by applicable regulatory authorities in a timely manner or at all; 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 and other actions, including the risk that the company may not ultimately reach a final settlement with the DOJ to resolve an investigation relating to the company's support of 501(c)(3) organizations that provide financial assistance to Medicare patients; obtaining and maintaining appropriate pricing and reimbursement for the company's products; pharmaceutical product development and the uncertainty of clinical success, including risks related to failure or delays in initiating or completing clinical trials; identifying and acquiring, in-licensing or developing additional products or product candidates, financing these transactions and successfully integrating acquired businesses; potential restrictions on the company's ability and flexibility to pursue share repurchases and future strategic opportunities as a result of its substantial outstanding debt obligations; the 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 Annual Report on Form 10-K for the year ended December 31, 2017 and future filings and reports by the company, including the company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018. 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. The forward-looking statements herein are made only as of the date hereof or as of the dates indicated in the forward-looking statements, even if they are subsequently made available by the company on its website or otherwise. The company undertakes no obligation to update or supplement any forward-looking statements to reflect actual results, new information, future events, changes in its expectations or other circumstances that exist after the date as of which the forward-looking statements were made.

JAZZ PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF INCOME
(In thousands, except per share amounts)
(Unaudited)

	Three Months Ended	
	March 31,	
	2018	2017
Revenues:		
Product sales, net	\$ 440,847	\$ 373,678
Royalties and contract revenues	3,766	2,375
Total revenues	<u>444,613</u>	<u>376,053</u>
Operating expenses:		
Cost of product sales (excluding amortization of intangible assets)	33,919	25,065
Selling, general and administrative	207,213	144,255
Research and development	62,667	44,928
Intangible asset amortization	53,007	25,665
Total operating expenses	<u>356,806</u>	<u>239,913</u>
Income from operations	87,807	136,140
Interest expense, net	(20,605)	(18,844)
Foreign exchange loss	(1,728)	(1,464)
Income before income tax provision and equity in loss of investees	65,474	115,832
Income tax provision	19,146	29,160
Equity in loss of investees	337	161
Net income	<u>\$ 45,991</u>	<u>\$ 86,511</u>
Net income per ordinary share:		
Basic	<u>\$ 0.77</u>	<u>\$ 1.44</u>
Diluted	<u>\$ 0.75</u>	<u>\$ 1.41</u>
Weighted-average ordinary shares used in per share calculations - basic	<u>59,928</u>	<u>59,880</u>
Weighted-average ordinary shares used in per share calculations - diluted	<u>61,178</u>	<u>61,178</u>

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

	March 31,	December 31,
	2018	2017
ASSETS		

Current assets:		
Cash and cash equivalents	\$ 453,169	\$ 386,035
Investments	255,000	215,000
Accounts receivable, net of allowances	281,424	224,129
Inventories	46,384	43,245
Prepaid expenses	27,476	23,182
Other current assets	62,868	76,686
Total current assets	1,126,321	968,277
Property, plant and equipment, net	178,920	170,080
Intangible assets, net	2,953,146	2,979,127
Goodwill	960,509	947,537
Deferred tax assets, net	38,103	34,559
Deferred financing costs	7,144	7,673
Other non-current assets	22,985	16,419
Total assets	<u>\$ 5,287,128</u>	<u>\$ 5,123,672</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 46,933	\$ 24,368
Accrued liabilities	240,544	198,779
Current portion of long-term debt	45,117	40,605
Income taxes payable	36,048	21,577
Deferred revenue	6,977	8,618
Total current liabilities	375,619	293,947
Deferred revenue, non-current	13,641	16,115
Long-term debt, less current portion	1,537,044	1,540,433
Deferred tax liabilities, net	382,072	383,472
Other non-current liabilities	192,181	176,608
Total shareholders' equity	2,786,571	2,713,097
Total liabilities and shareholders' equity	<u>\$ 5,287,128</u>	<u>\$ 5,123,672</u>

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

	Three Months Ended	
	March 31,	
	2018	2017
Net cash provided by operating activities	\$ 162,359	\$ 164,540
Net cash used in investing activities	(47,149)	(3,574)
Net cash used in financing activities	(47,575)	(181,674)
Effect of exchange rates on cash and cash equivalents	(501)	1,740
Net increase (decrease) in cash and cash equivalents	<u>\$ 67,134</u>	<u>\$ (18,968)</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,	
	2018	2017
GAAP reported net income	\$ 45,991	\$ 86,511
Intangible asset amortization	53,007	25,665
Share-based compensation expense	24,303	25,193
Estimated loss contingency	57,000	—
Upfront and milestone payments	11,000	—
Expenses related to certain legal proceedings	—	6,000
Non-cash interest expense	10,617	5,615
Income tax effect	(19,547)	(7,762)
Non-GAAP adjusted net income	<u>\$ 182,371</u>	<u>\$ 141,222</u>
GAAP reported net income per diluted share	<u>\$ 0.75</u>	<u>\$ 1.41</u>
Non-GAAP adjusted net income per diluted share	<u>\$ 2.98</u>	<u>\$ 2.31</u>
Weighted-average ordinary shares used in diluted per share calculations	<u>61,178</u>	<u>61,178</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					
	March 31, 2018			March 31, 2017		
	GAAP Reported	Adjustments	Non-GAAP Adjusted	GAAP Reported	Adjustments	Non-GAAP Adjusted
Total revenues	\$ 444,613	\$ —	\$ 444,613	\$ 376,053	\$ —	\$ 376,053
Cost of product sales (excluding amortization of intangible assets)	33,919	(1,694) (a)	32,225	25,065	(1,246) (a)	23,819
Selling, general and administrative	207,213	(75,234) (b)	131,979	144,255	(25,805) (b)	118,450
Research and development	62,667	(15,375) (c)	47,292	44,928	(4,142) (c)	40,786
Intangible asset amortization	53,007	(53,007)	—	25,665	(25,665)	—
Interest expense, net	20,605	(10,617) (d)	9,988	18,844	(5,615) (d)	13,229
Foreign exchange loss	1,728	—	1,728	1,464	—	1,464
Income before income tax provision and equity in loss of investees	65,474	155,927 (e)	221,401	115,832	62,473 (e)	178,305
Income tax provision	19,146	19,547 (f)	38,693	29,160	7,762 (f)	36,922
Effective tax rate (g)	29.2 %		17.5 %	25.2 %		20.7 %
Equity in loss of investees	337	—	337	161	—	161
Net income	\$ 45,991	\$ 136,380 (h)	\$ 182,371	\$ 86,511	\$ 54,711 (h)	\$ 141,222
Net income per diluted share	\$ 0.75		\$ 2.98	\$ 1.41		\$ 2.31

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

- (a) Share-based compensation expense of \$1,694 and \$1,246 for the three months ended March 31, 2018 and 2017, respectively.
(b) Share-based compensation expense of \$18,234 and \$19,805, estimated loss contingency of \$57,000 and \$0 and expenses related to certain legal proceedings of \$0 and \$6,000 for the three months ended March 31, 2018 and 2017, respectively.
(c) Upfront and milestone payments of \$11,000 and \$0 and share-based compensation expense of \$4,375 and \$4,142 for the three months ended March 31, 2018 and 2017, respectively.
(d) Non-cash interest expense associated with debt discount and debt issuance costs for the respective three-month period.
(e) Sum of adjustments (a) through (d) plus the adjustment for intangible asset amortization for the respective three-month period.
(f) Income tax effect of adjustments between GAAP reported and non-GAAP adjusted net income for the respective three-month period.
(g) Income tax provision divided by income before income tax provision and equity in loss of investees for the respective three-month period.
(h) Net of adjustments (e) and (f) for the respective three-month period.

JAZZ PHARMACEUTICALS PLC
RECONCILIATION OF GAAP TO NON-GAAP ADJUSTED 2018 NET INCOME GUIDANCE
(In millions, except per share amounts)
(Unaudited)

GAAP net income	\$405 - \$470
Intangible asset amortization	200 - 220
Share-based compensation expense	100 - 115
Estimated loss contingency	57
Milestone payments	11
Non-cash interest expense	40 - 50
Income tax effect of adjustments	(60) - (75)
Non-GAAP adjusted net income	<u>\$780 - \$815</u>
GAAP net income per diluted share	<u>\$6.60-\$7.70</u>
Non-GAAP adjusted net income per diluted share	<u>\$12.75-\$13.25</u>

Weighted-average ordinary shares used in per share calculations

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SOURCE Jazz Pharmaceuticals plc

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