



## Jazz Pharmaceuticals Announces First Quarter 2016 Financial Results

May 10, 2016

### Strong Top- and Bottom-line Growth Total Revenues of \$336 Million Driven by Strong Sales of Xyrem

DUBLIN, May 10, 2016 /PRNewswire/ -- Jazz Pharmaceuticals plc (Nasdaq: JAZZ) today announced financial results for the first quarter of 2016 and updated financial guidance for 2016.

"During the first quarter of 2016, we executed on our business model by delivering strong top- and bottom-line growth and commenced promotion of Defitelio in the U.S. immediately following FDA approval. Defitelio is the first and only approved treatment in the U.S. for patients who develop hepatic VOD with renal or pulmonary dysfunction following hematopoietic stem-cell transplantation," said Bruce C. Cozadd, chairman and chief executive officer of Jazz Pharmaceuticals plc. "For 2016, we will continue to invest in the organic growth of our key products, including new indications, and the advancement of our development pipeline. Diversification of our product portfolio through internal and corporate development efforts remains a high priority as we seek to identify and acquire differentiated and long-lived therapeutic options for patients."

Adjusted net income for the first quarter of 2016 was \$141.0 million, or \$2.26 per diluted share, compared to \$125.1 million, or \$1.99 per diluted share, for the first quarter of 2015.

GAAP net income for the first quarter of 2016 was \$74.1 million, or \$1.19 per diluted share, compared to \$70.7 million, or \$1.12 per diluted share, for the first quarter of 2015. Reconciliations of applicable GAAP reported to non-GAAP adjusted information are included in this press release.

#### Financial Highlights

(In thousands, except per share amounts and percentages)	Three Months Ended March 31,		
	2016	2015	Change
Total revenues	\$ 336,010	\$ 309,303	8.6 %
Adjusted net income	\$ 140,995	\$ 125,068	12.7 %
GAAP net income	\$ 74,121	\$ 70,700	4.8 %
Adjusted EPS	\$ 2.26	\$ 1.99	13.6 %
GAAP EPS	\$ 1.19	\$ 1.12	6.3 %

#### Total Revenues

Total revenues were as follows:

(In thousands)	Three Months Ended March 31,	
	2016	2015
Xyrem® (sodium oxybate) oral solution	\$ 249,537	\$ 212,690
Erwinaze® / Erwinase® (asparaginase <i>Erwinia chrysanthemi</i> )	51,173	50,353
Defitelio® (defibrotide sodium) / defibrotide	17,897	17,363
Prialt® (ziconotide) intrathecal infusion	6,209	6,764
Psychiatry	7,002	9,093
Other	2,098	10,772
Product sales, net	333,916	307,035
Royalties and contract revenues	2,094	2,268
Total revenues	\$ 336,010	\$ 309,303

Net product sales increased by 9% in the first quarter of 2016 compared to the same period in 2015 primarily due to higher net product sales of Xyrem.

Erwinaze/Erwinase net product sales increased by 2% in the first quarter of 2016 compared to the same period in 2015. Although Erwinaze net product sales increased, as a consequence of constrained manufacturing capacity, the company has had a limited ability to build sufficient inventory levels that can be used to absorb supply disruptions. In the first quarter of 2016, the company experienced supply challenges that temporarily disrupted its ability to supply certain markets.

Defitelio/defibrotide product sales increased by 3% in the first quarter of 2016 compared to the same period in 2015. The increase in net product sales was partially offset by the impact of foreign exchange on sales made in euro.

#### Operating Expenses

Operating expenses were as follows:

(In thousands, except percentages)	Three Months Ended March 31,	
	2016	2015

GAAP:		
Cost of product sales	\$ 23,439	\$ 28,298
<i>Gross margin</i>	93.0 %	90.8 %
Selling, general and administrative	\$ 128,765	\$ 112,388
<i>% of total revenues</i>	38.3 %	36.3 %
Research and development	\$ 31,252	\$ 27,181
<i>% of total revenues</i>	9.3 %	8.8 %
Acquired in-process research and development	\$ 8,750	\$ —

Non-GAAP adjusted:		
Cost of product sales	\$ 22,640	\$ 27,603
<i>Gross margin</i>	93.2 %	91.0 %
Selling, general and administrative	\$ 102,611	\$ 95,041
<i>% of total revenues</i>	30.5 %	30.7 %
Research and development	\$ 27,962	\$ 23,696
<i>% of total revenues</i>	8.3 %	7.7 %

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 2016 compared to the same period in 2015, on a GAAP and non-GAAP adjusted basis, primarily due to higher headcount and other expenses resulting from the expansion of the company's business.
- Research and development (R&D) expenses increased in the first quarter of 2016 compared to the same period in 2015, on a GAAP and non-GAAP adjusted basis, primarily due to higher costs for clinical studies and outside services for the development of JZP-110 and line extensions for the company's existing products.
- Acquired in-process research and development (IPR&D) expense in the first quarter of 2016 related to an upfront payment of \$8.8 million the company made in connection with its acquisition of intellectual property and know-how related to recombinant crisantaspase.

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

As of March 31, 2016, cash, cash equivalents and investments were \$980.5 million, and the outstanding principal balance of the company's long-term debt was \$1.3 billion. Cash, cash equivalents and investments decreased during the quarter primarily due to repurchases under the company's share repurchase program, partially offset by cash generated by the business. During the first quarter of 2016, the company repurchased 1.1 million ordinary shares for \$134.4 million, at an average cost of \$123.77 per ordinary share.

In March 2016, the company recorded a \$150.0 million milestone owed to Sigma-Tau Pharmaceuticals, Inc., which was triggered by the U.S. Food and Drug Administration approval of Defitelio on March 30, 2016. The milestone was capitalized as an intangible asset and was paid by the company in April 2016.

#### **2016 Financial Guidance**

Jazz Pharmaceuticals is updating its full year 2016 financial guidance, which is as follows (in millions, except per share amounts and percentage):

Revenues	\$1,490-\$1,550
Total net product sales	\$1,482-\$1,542
-Xyrem net sales	\$1,095-\$1,130
-Erwinaze/Erwinase net sales	\$200-\$225
-Defitelio/defibrotide net sales	\$100-\$125
Adjusted gross margin % <sup>1,4</sup>	93%
Adjusted SG&A expenses <sup>2,4</sup>	\$390-\$410
Adjusted R&D expenses <sup>3,4</sup>	\$115-\$130
GAAP net income per diluted share	\$6.76-\$7.41
Non-GAAP adjusted net income per diluted share <sup>*4</sup>	\$11.10-\$11.50

\* Updated May 10, 2016 to reflect a decrease in weighted-average shares to 62 million.

1. Excludes \$6 million of share-based compensation expense from estimated GAAP gross margin of 93%.
2. Excludes \$87-\$95 million of share-based compensation expense and \$6 million of expenses related to certain legal proceedings and restructuring from estimated GAAP SG&A expenses of \$483-\$511 million.
3. Excludes \$17-\$19 million of share-based compensation expense from estimated GAAP R&D expenses of \$132-\$149 million.
4. See "Non-GAAP Financial Measures" below. Reconciliations of non-GAAP adjusted guidance measures are included above and in the tables accompanying 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 2016 first quarter results. The live webcast may be accessed from the Investors & Media 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 90587993.

A replay of the conference call will be available through May 17, 2016 by dialing +1 855 859 2056 in the U.S., or +1 404 537 3406 outside the U.S., and entering passcode 90587993. An archived version of the webcast will be available for at least one week in the Investors & Media section of the Jazz Pharmaceuticals website at [www.jazzpharmaceuticals.com](http://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*) and Defitelio® (defibrotide sodium) in the U.S. and markets Erwinase® and Defitelio® (defibrotide) in countries outside the U.S. For more information, please visit [www.jazzpharmaceuticals.com](http://www.jazzpharmaceuticals.com).

### **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. The company believes that each of these non-GAAP financial measures provides useful information to management, investors and analysts by excluding items that may not be indicative of the company's core operating results and business outlook, such as intangible asset amortization and share-based compensation expense, among other items, and by including, in the case of non-GAAP adjusted net income and the related per share measures, adjustments to convert the income tax provision to the estimated amount of taxes that are payable in cash. Jazz Pharmaceuticals' management 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. In addition, Jazz Pharmaceuticals believes that these non-GAAP financial measures are useful to investors because they enhance investors' ability to compare the company's results from period to period; allow for greater transparency with respect to key financial metrics the company uses in making operating decisions; and are regularly used by investors and analysts to model and track the company's financial performance.

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. 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, investment in the growth of the company's key products and advancement of the company's development pipeline, diversification of the company's product portfolio, 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 introduction of generic competition or other competitive sodium oxybate products; regulatory restrictions and requirements applicable to Xyrem and ongoing patent litigation and related proceedings; effectively commercializing the company's other products and product candidates; 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; the difficulty and uncertainty of pharmaceutical product development and the uncertainty of clinical success; identifying and acquiring, in-licensing or developing additional products or product candidates and financing and integrating these transactions; 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, 2015 and future filings and reports by the company, including the company's Form 10-Q for the quarter ended March 31, 2016. 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 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)**

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2016</b>	<b>2015</b>
Revenues:		
Product sales, net	\$ 333,916	\$ 307,035

Royalties and contract revenues	2,094	2,268
Total revenues	<u>336,010</u>	<u>309,303</u>
Operating expenses:		
Cost of product sales (excluding amortization of intangible assets)	23,439	28,298
Selling, general and administrative	128,765	112,388
Research and development	31,252	27,181
Acquired in-process research and development	8,750	—
Intangible asset amortization	<u>22,642</u>	<u>24,677</u>
Total operating expenses	<u>214,848</u>	<u>192,544</u>
Income from operations	121,162	116,759
Interest expense, net	(12,192)	(16,245)
Foreign currency gain (loss)	<u>(819)</u>	<u>2,245</u>
Income before income tax provision	108,151	102,759
Income tax provision	<u>34,030</u>	<u>32,059</u>
Net income	<u>\$ 74,121</u>	<u>\$ 70,700</u>
Net income per ordinary share:		
Basic	<u>\$ 1.21</u>	<u>\$ 1.16</u>
Diluted	<u>\$ 1.19</u>	<u>\$ 1.12</u>
Weighted-average ordinary shares used in per share calculations - basic	<u>61,142</u>	<u>60,803</u>
Weighted-average ordinary shares used in per share calculations - diluted	<u>62,474</u>	<u>62,964</u>

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

	<u>March 31, 2016</u>	<u>December 31, 2015</u>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 979,780	\$ 988,785
Investments	764	—
Accounts receivable, net of allowances	223,802	209,685
Inventories	25,369	19,451
Prepaid expenses	18,472	20,699
Other current assets	<u>22,431</u>	<u>19,047</u>
Total current assets	1,270,618	1,257,667
Property and equipment, net	86,788	85,572
Intangible assets, net	1,348,160	1,185,606
Goodwill	670,991	657,139
Deferred tax assets, net, non-current	122,036	122,863
Deferred financing costs	6,843	7,209
Other non-current assets	<u>29,543</u>	<u>27,548</u>
Total assets	<u>\$ 3,534,979</u>	<u>\$ 3,343,604</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable	\$ 32,622	\$ 21,807
Accrued liabilities	307,504	164,070
Current portion of long-term debt	37,592	37,587
Income taxes payable	19,735	1,808
Deferred revenue	<u>1,378</u>	<u>1,370</u>
Total current liabilities	398,831	226,642
Deferred revenue, non-current	3,441	3,721
Long-term debt, less current portion	1,146,433	1,150,857
Deferred tax liability, net, non-current	299,627	294,485
Other non-current liabilities	79,207	69,253
Total shareholders' equity	<u>1,607,440</u>	<u>1,598,646</u>
Total liabilities and shareholders' equity	<u>\$ 3,534,979</u>	<u>\$ 3,343,604</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,	
	2016	2015
GAAP reported net income	\$ 74,121	\$ 70,700
Intangible asset amortization	22,642	24,677
Share-based compensation expense	24,183	20,819
Upfront and milestone payments	8,750	—
Expenses related to certain legal proceedings and restructuring	6,060	553
Transaction and integration related costs	—	155
Non-cash interest expense	5,362	6,016
Income tax adjustments	(123)	2,148
Non-GAAP adjusted net income	<u>\$ 140,995</u>	<u>\$ 125,068</u>
GAAP reported net income per diluted share	<u>\$ 1.19</u>	<u>\$ 1.12</u>
Non-GAAP adjusted net income per diluted share	<u>\$ 2.26</u>	<u>\$ 1.99</u>
Weighted-average ordinary shares used in diluted per share calculations	<u>62,474</u>	<u>62,964</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, 2016			March 31, 2015		
	GAAP Reported	Adjustments	Non-GAAP Adjusted	GAAP Reported	Adjustments	Non-GAAP Adjusted
Total revenues	\$ 336,010	\$ —	\$ 336,010	\$ 309,303	\$ —	\$ 309,303
Cost of product sales (excluding amortization of intangible assets)	23,439	(799) (a)	22,640	28,298	(695) (a)	27,603
Selling, general and administrative	128,765	(26,154) (b)	102,611	112,388	(17,347) (b)	95,041
Research and development	31,252	(3,290) (c)	27,962	27,181	(3,485) (c)	23,696
Acquired in-process research and development	8,750	(8,750)	—	—	—	—
Intangible asset amortization	22,642	(22,642)	—	24,677	(24,677)	—
Interest expense, net	12,192	(5,362) (d)	6,830	16,245	(6,016) (d)	10,229
Foreign currency (gain) loss	819	—	819	(2,245)	—	(2,245)
Income before income tax provision	108,151	66,997 (e)	175,148	102,759	52,220 (e)	154,979
Income tax provision	34,030	123 (f)	34,153	32,059	(2,148) (f)	29,911
Effective tax rate (g)	31.5 %		19.5 %	31.2 %		19.3 %
Net income	\$ 74,121	\$ 66,874 (h)	\$ 140,995	\$ 70,700	\$ 54,368 (h)	\$ 125,068
Net income per diluted share	\$ 1.19		\$ 2.26	\$ 1.12		\$ 1.99

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

- (a) Share-based compensation expense of \$689 and \$695 and expenses related to certain legal proceedings and restructuring of \$110 and \$0 for the three months ended March 31, 2016 and 2015, respectively.
- (b) Share-based compensation expense of \$20,204 and \$16,639, expenses related to certain legal proceedings and restructuring of \$5,950 and \$553 and transaction and integration costs of \$0 and \$155 for the three months ended March 31, 2016 and 2015, respectively.
- (c) Share-based compensation expense of \$3,290 and \$3,485 for the three months ended March 31, 2016 and 2015, 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 adjustments for acquired in-process research and development expense and intangible asset amortization, as applicable, for the respective three-month period.
- (f) Adjustments to convert the income tax provision to the estimated amount of taxes that are payable in cash for the respective three-month period.
- (g) Income tax provision divided by income before income tax provision 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 2016 NET INCOME GUIDANCE**  
(In millions, except per share amounts)  
(Unaudited)

GAAP net income *	\$418 - \$458
Intangible asset amortization	100 - 110
Share-based compensation expense	110 - 120
Upfront and milestone payments *	9
Expenses related to certain legal proceedings and restructuring *	6
Non-cash interest expense	20 - 24
Income tax adjustments	7 - 15
Non-GAAP adjusted net income	<u>\$688 - \$712</u>
GAAP net income per diluted share	<u>\$6.76 - \$7.41</u>
Non-GAAP adjusted net income per diluted share *	<u>\$11.10 - \$11.50</u>
Weighted-average ordinary shares used in per share calculations *	62

\* Updated May 10, 2016.



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SOURCE Jazz Pharmaceuticals plc

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