Jazz Pharmaceuticals Announces First Quarter 2017 Financial Results

May 9, 2017

DUBLIN, May 9, 2017 /PRNewswire/ --

Total Revenues Increased 12% to \$376 Million

Settled Xyrem Patent Litigation with First ANDA Filer

Completed Rolling NDA Submission for Vyxeos (CPX-351)

Announced Positive Top-Line Data for JZP-110 in Obstructive Sleep Apnea and Narcolepsy and for Xyrem in Pediatric Narcolepsy

Jazz Pharmaceuticals plc (Nasdag: JAZZ) today announced financial results for the first quarter of 2017 and updated financial guidance for 2017.

"The first part of 2017 has been an exceptionally productive period for us in R&D as we announced top-line data for our three JZP-110 Phase 3 studies and our Xyrem Phase 2/3 pediatric study, completed the Vyxeos NDA submission while preparing for potential FDA approval and launch, started additional clinical programs and advanced other key development projects," said Bruce Cozadd, chairman and chief executive officer of Jazz Pharmaceuticals. "With increased clarity around Xyrem longevity, we remain focused on delivering on our growth strategy, including preparing for the launch of additional products, such as Vyxeos, and investing in corporate development activities with the goal of further diversifying and expanding our product portfolio and offering important new therapeutic options to patients while increasing shareholder value."

GAAP net income for the first quarter of 2017 was \$86.5 million, or \$1.41 per diluted share, compared to \$75.8 million, or \$1.21 per diluted share, for the first quarter of 2016.

Adjusted net income for the first quarter of 2017 was \$141.2 million, or \$2.31 per diluted share, compared to \$134.6 million, or \$2.15 per diluted share, for the first quarter of 2016. Reconciliations of applicable GAAP reported to non-GAAP adjusted information are included at the end of this press release.

Financial Highlights

	<u>Th</u>	ree Months	Ende	d March 31,		
(In thousands, except per share amounts and percentages)		2017		2016	Chan	nge
Total revenues	\$	376,053	\$	336,010	11.9	%
GAAP net income	\$	86,511	\$	75,812	14.1	%
Adjusted net income	\$	141,222	\$	134,568	4.9	%
GAAP EPS	\$	1.41	\$	1.21	16.5	%
Adjusted EPS	\$	2.31	\$	2.15	7.4	%

Total Revenues

		ch 31,
(In thousands)	2017	2016
Xyrem® (sodium oxybate) oral solution	\$ 272,326	\$ 249,537
Erwinaze® / Erwinase® (asparaginase Erwinia chrysanthemi)	51,388	51,173
Defitelio® (defibrotide sodium) / defibrotide	35,900	17,897
Prialt® (ziconotide) intrathecal infusion	7,717	6,209
Other	6,347	9,100
Product sales, net	373,678	333,916
Royalties and contract revenues	2,375	2,094
Total revenues	\$ 376,053	\$ 336,010

Net product sales increased 12% in the first quarter of 2017 compared to the same period in 2016 primarily due to higher net product sales of Xyrem and Defitelio.

Three Months Ended

Xyrem net product sales increased 9% in the first quarter of 2017 compared to the same period in 2016.

Erwinaze/Erwinase net product sales in the first quarter of 2017 were consistent with net product sales in the same period in 2016. During the quarter, the company continued to experience supply challenges, which resulted in fluctuations in inventory levels and temporary disruptions to the company's ability to supply certain markets. The company expects that temporary supply disruptions will continue in 2017, including in the U.S.

Defitelio/defibrotide net product sales increased 101% in the first quarter of 2017 compared to the same period in 2016 primarily due to the launch of Defitelio in the U.S. in April 2016 and strong growth in sales in other markets. Net product sales in the U.S. were \$11.6 million in the first quarter of 2017.

Operating Expenses

Three Months Ended March 31

			11 51,						
(In thousands, except percentages)	2017				2016				
GAAP:									
Cost of product sales	\$	25,065		\$	23,439				
Gross margin		93.3	%		93.0	%			
Selling, general and administrative	\$	144,255		\$	128,765				
% of total revenues		38.4	%		38.3	%			
Research and development	\$	44,928		\$	31,252				
% of total revenues		11.9	%		9.3	%			
Acquired in-process research and development	\$	_		\$	8,750				

Three Months Ended

	h 31,					
(In thousands, except percentages)	2017				2016	
Non-GAAP adjusted:						
Cost of product sales	\$	23,819		\$	22,640	
Gross margin		93.6	%		93.2	%
Selling, general and administrative	\$	118,450		\$	102,611	
% of total revenues		31.5	%		30.5	%
Research and development	\$	40,786		\$	27,962	
% of total revenues		10.8	%		8.3	%

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 2017 compared to the same period in 2016 on a GAAP and on a non-GAAP adjusted basis primarily due to higher headcount and other expenses resulting from the expansion of the company's business, including expenses related to the potential U.S. launch of Vyxeos ™(cytarabine and daunorubicin liposome injection).
- Research and development (R&D) expenses increased in the first quarter of 2017 compared to the same period in 2016
 on a GAAP and on a non-GAAP adjusted basis and included costs related to the completion of the rolling new drug
 application (NDA) submission for Vyxeos; increased expenses for continued investments in oxybate-related R&D programs,
 including the initiation of a clinical study of JZP-258; and an increase in headcount required to support these activities.

Cash Flow and Balance Sheet

As of March 31, 2017, cash, cash equivalents and investments were \$407.0 million, and the outstanding principal balance of the company's long-term debt was \$2.0 billion. During the first quarter of 2017, the company made a \$150.0 million repayment of borrowings under the company's revolving credit facility and used \$13.9 million to repurchase approximately 118,000 ordinary shares under the company's share repurchase program at an average cost of \$117.65 per ordinary share. Cash flows from operations were \$164.5 million in the first quarter of 2017.

Recent Developments

In March 2017, the company enrolled the first patient in a Phase 3 clinical study evaluating JZP-258, an investigational oxybate product candidate with 90 percent less sodium content than Xyrem, for the treatment of cataplexy and excessive daytime sleepiness in adult narcolepsy patients with cataplexy.

In March and April 2017, the company announced positive efficacy and top-line safety results from the global Phase 3 studies evaluating JZP-110 for the treatment of excessive sleepiness in adult patients with obstructive sleep apnea (TONES 3 and TONES 4) and for the treatment of excessive sleepiness in adult patients with narcolepsy (TONES 2).

In March 2017, the company entered into license agreements with Nippon Shinyaku Co., Ltd. for the development and commercialization of Defitelio and Vyxeos in Japan.

On March 31, 2017, the company completed the rolling submission of an NDA to the U.S. Food and Drug Administration (FDA) for Vyxeos, an investigational treatment for acute myeloid leukemia.

In April 2017, the company entered into agreements with Hikma Pharmaceuticals PLC (Hikma) resolving the company's patent litigation with Hikma related to Xyrem.

In April 2017, the company announced positive efficacy and top-line safety results from the global Phase 2/3 study evaluating Xyrem for the treatment of cataplexy in pediatric patients with narcolepsy.

2017 Financial Guidance

Jazz Pharmaceuticals is updating its full year 2017 financial guidance as follows (in millions, except per share amounts and percentages):

Revenues	\$1,625-\$1,700
Total net product sales	\$1,617-\$1,692
-Xyrem net sales*	\$1,200-\$1,230
-Erwinaze/Erwinase net sales	\$205-\$225
-Defitelio/defibrotide net sales	\$130-\$150

-Vyxeos (CPX-351) net sales ¹	\$10-\$20
GAAP gross margin %	93%
Non-GAAP adjusted gross margin % ^{2,5}	93%
GAAP SG&A expenses*	\$521-\$556
Non-GAAP adjusted SG&A expenses ^{3,5}	\$440-\$460
GAAP R&D expenses*	\$185-\$216
Non-GAAP adjusted R&D expenses ^{4,5}	\$165-\$180
GAAP net income per diluted share	\$6.55-\$7.55
Non-GAAP adjusted net income per diluted share ⁵	\$10.70-\$11.30

^{*} Updated May 9, 2017.

- 1. Guidance assumes FDA approval and launch of Vyxeos (CPX-351) in the U.S. in 2017.
- 2. Excludes \$5 million of share-based compensation expense from estimated GAAP gross margin.
- 3. Excludes \$75-\$90 million of share-based compensation expense and \$6 million of expenses related to certain legal proceedings and restructuring from estimated GAAP SG&A expenses.
- 4. Excludes \$20-\$25 million of share-based compensation expense and \$0-\$11 million of milestone payments from estimated GAAP R&D expenses.
- 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 2017 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 2017 first quarter results. The live webcast may be accessed from the Investors & Media 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 6947297.

A replay of the conference call will be available through May 16, 2017 by dialing +1 855 859 2056 in the U.S., or +1 404 537 3406 outside the U.S., and entering passcode 6947297. An archived version of the webcast will be available for at least one week in the Investors & Media 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*) 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.iazzpharmaceuticals.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. 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 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 2017 financial guidance, potential FDA approval and launch of Vyxeos in the U.S. in 2017, the company's growth strategy, including preparing for the launch of additional products and investing in corporate development activities with the goal of further diversifying and expanding the company's product portfolio and offering important new therapeutic options to patients while increasing shareholder value, the company's expectation for continuing Erwinaze supply disruptions 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 settlements with certain companies 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 regulatory approval process, including the risk that the company may be unable to obtain FDA approval for Vyxeos in the U.S. in 2017 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; obtaining and maintaining appropriate pricing and reimbursement for the company's products; pharmaceutical product development and the uncertainty of clinical success; 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; and the ability to achieve expected future financial performance and results; 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, 2016 and future filings and reports by the company, including the company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2017. 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.

Three Months Ended

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

		nths Ended ch 31,
	2017	2016
Revenues:		
Product sales, net	\$ 373,678	\$ 333,916
Royalties and contract revenues	2,375	2,094
Total revenues	376,053	336,010
Operating expenses:		
Cost of product sales (excluding amortization of intangible assets)	25,065	23,439
Selling, general and administrative	144,255	128,765
Research and development	44,928	31,252
Acquired in-process research and development	_	8,750
Intangible asset amortization	25,665	22,642
Total operating expenses	239,913	214,848
Income from operations	136,140	121,162
Interest expense, net	(18,844)	(12,192)
Foreign exchange loss	(1,464)	(819)
Income before income tax provision and equity in loss of investee	115,832	108,151
Income tax provision	29,160	32,339
Equity in loss of investee	161	
Net income	\$ 86,511	\$ 75,812
Net income per ordinary share:		
Basic	\$ 1.44	\$ 1.24
Diluted	\$ 1.41	\$ 1.21
Weighted-average ordinary shares used in per share calculations - basic	59,880	61,142
Weighted-average ordinary shares used in per share calculations - diluted	61,178	62,616

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

	March 31, 2017	D	ecember 31, 2016
ASSETS			
Current assets:			
Cash and cash equivalents	\$ 346,995	\$	365,963
Investments	60,000		60,000
Accounts receivable, net of allowances	243,035		234,244
Inventories	37,653		34,051
Prepaid expenses	38,118		24,501
Other current assets	 27,052		29,310
Total current assets	752,853		748,069
Property and equipment, net	119,913		107,490
Intangible assets, net	2,998,780		3,012,001
Goodwill	899,290		893,810
Deferred tax assets, net, non-current	18,038		15,060
Deferred financing costs	9,325		9,737
Other non-current assets	 17,625		14,060
Total assets	\$ 4,815,824	\$	4,800,227
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities:			
Accounts payable	\$ 29,144	\$	22,415
Accrued liabilities	183,645		193,268
Current portion of long-term debt	136,094		36,094
Income taxes payable	35,300		4,506
Deferred revenue	8,590		1,123
Total current liabilities	392,773		257,406
Deferred revenue, non-current	22,624		2,601
Long-term debt, less current portion	1,739,594		1,993,531
Deferred tax liability, net, non-current	548,038		556,733
Other non-current liabilities	128,809		112,617
Total shareholders' equity	 1,983,986		1,877,339
Total liabilities and shareholders' equity	\$ 4,815,824	\$	4,800,227

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

Three Months Ended

	March 31,					
		2017			2016	
Net cash provided by operating activities	\$	164,540		\$	151,654	
Net cash used in investing activities		(3,574)			(11,995)	
Net cash used in financing activities		(181,674)			(152,458)	
Effect of exchange rates on cash and cash equivalents		1,740			3,794	
Net decrease in cash and cash equivalents	\$	(18,968)		\$	(9,005)	

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

Three Months Ended

March 31,						
2017	2016					
\$ 86,511	\$ 75,812					
25,665	22,642					
25,193	24,183					
_	8,750					
6,000	6,060					
5,615	5,362					
(7,762)	(8,241)					
\$ 141,222	\$ 134,568					
\$ 1.41	\$ 1.21					
\$ 2.31	\$ 2.15					
	2017 \$ 86,511 25,665 25,193 — 6,000 5,615 (7,762) \$ 141,222					

62,616

(1) The income tax effect of the adjustments between GAAP reported and non-GAAP adjusted net income takes into account the tax treatment and related tax rate(s) that apply to each adjustment in the applicable tax jurisdiction(s).

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

								11116	FINIO	เนเจเ	LIIUCU						
	March 31, 2017 March 31, 2016																
		GAAP						Non-GAAI	P		GAAP					Non-GAA	Р
		Reported	<u> </u>	Ac	ljustments	<u>. </u>		Adjusted			Reported		Ad	ljustments	<u></u>	Adjusted	<u> </u>
Total revenues	\$	376,053		\$	_	_	\$	376,053		\$	336,010		\$	_	_	\$ 336,010	
Cost of product sales																	
(excluding amortization						(2)									(2)		
of intangible assets)		25,065			(1,246)	(a)		23,819			23,439			(799)	(a)	22,640	
Selling, general and administrative		144,255			(2E 90E)	(b)		118,450			128,765			(26.154)	(b)	102,611	
Research and		144,233			(25,805)	(-)		110,430			120,703			(26,154)	(-)	102,611	
development		44,928			(4,142)	(c)		40,786			31,252			(3,290)	(c)	27,962	
Acquired in-process		,			(-,)			,			,			(-,)		,	
research and																	
development		_			_			_			8,750			(8,750)		_	
Intangible asset																	
amortization		25,665			(25,665)	. D		_			22,642			(22,642)	<i>(</i> 1)	_	
Interest expense, net		18,844			(5,615)	(d)		13,229			12,192			(5,362)	(d)	6,830	
Foreign currency loss		1,464			_			1,464			819			_		819	
Income before income																	
tax provision and equity in loss of investee		115,832			62,473	(e)		178,305			108,151			66,997	(e)	175,148	
Income tax provision		29,160			7,762	(f)		36,922			32,339			8,241	(f)	40.580	
Effective tax rate (q)		25.2	%		1,102	()		20.7	%		29.9	%		0,241	()	23.2	%
Equity in loss of		20.2	70					20.7	70		23.3	70				20.2	70
investee		161			_			161			_			_		_	
Net income	\$	86,511		\$	54,711	(h)	\$	141,222		\$	75,812		\$	58,756	(h)	\$ 134,568	
Net income per diluted	•	•			,			,			•			•		,	
share	\$	1.41					\$	2.31		\$	1.21					\$ 2.15	

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

- (a) Share-based compensation expense of \$1,246 and \$689 and expenses related to certain legal proceedings and restructuring of \$0 and \$110 for the three months ended March 31, 2017 and 2016, respectively.
- (b) Share-based compensation expense of \$19,805 and \$20,204 and expenses related to certain legal proceedings and restructuring of \$6,000 and \$5,950 for the three months ended March 31, 2017 and 2016, respectively.
- (c) Share-based compensation expense of \$4,142 and \$3,290 for the three months ended March 31, 2017 and 2016, 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 and intangible asset amortization for the respective three-month period.
- (f) Income tax effect of the adjustments between GAAP reported and non-GAAP adjusted net income takes into account the tax treatment and related tax rate(s) that apply to each adjustment in the applicable tax jurisdiction(s) for the respective three-month period.
- (g) Income tax provision divided by income before income tax provision and equity in loss of investee 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 2017 NET INCOME GUIDANCE (In millions, except per share amounts) (Unaudited)

GAAP net income	\$400 - \$460
Intangible asset amortization	130 - 165
Share-based compensation expense	100 - 100
·	
Milestone payments*	0 - 11
Expenses related to certain legal proceedings and restructuring*	6
Non-cash interest expense	20 - 25

Income tax effect of adjustments	(40) - (60)
Non-GAAP adjusted net income	\$650 - \$690
·	
GAAP net income per diluted share	\$6.55-\$7.55
Non-GAAP adjusted net income per diluted share	\$10.70-\$11.30
·	
Weighted-average ordinary shares used in per share calculations	61

^{*} Updated May 9, 2017.



To view the original version on PR Newswire, visit: http://www.prnewswire.com/news-releases/jazz-pharmaceuticals-announces-first-quarter-2017-financial-results-300454503.html

SOURCE Jazz Pharmaceuticals plc

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