

Jazz Pharmaceuticals (JAZZ)

\$99.60 (As of 03/30/20)

Price Target (6-12 Months): **\$110.00**

Long Term: 6-12 Months

Zacks Recommendation:

Neutral

(Since: 03/29/20)

Prior Recommendation: Underperform

Short Term: 1-3 Months

Zacks Rank: (1-5)

3-Hold

Zacks Style Scores:

VGM:B

Value: B

Growth: C

Momentum: C

Summary

Jazz reported impressive fourth-quarter results with earnings and revenues beating estimates. The company's Xyrem generates the majority of the company's sales, and consequently any setback is likely to hamper Jazz's top line. Xyrem is set to face generic competition from 2023 along with other branded drugs under development. Moreover, Jazz has been facing supply crunch for its leukemia drug, Erwinaze, owing to constrained manufacturing capacity. These supply challenges are expected to continue in 2020. Meanwhile, its newest drug Vyxeos faces strong competition in the acute myeloid leukemia market. However, management seems confident that Xyrem will continue to generate volume growth in future quarters. The company's new drug Sunosi complements its existing sleep disorder portfolio.

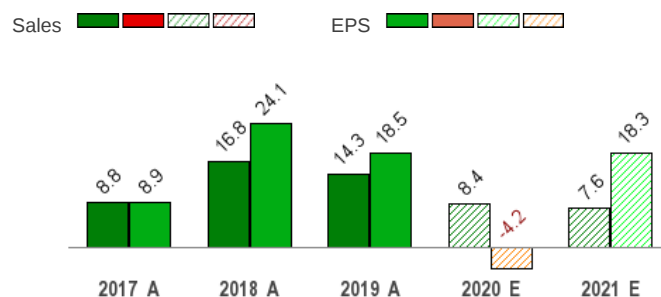
Price, Consensus & Surprise



Data Overview

52 Week High-Low	\$154.24 - \$86.88
20 Day Average Volume (sh)	919,819
Market Cap	\$5.6 B
YTD Price Change	-33.3%
Beta	1.32
Dividend / Div Yld	\$0.00 / 0.0%
Industry	Medical - Drugs
Zacks Industry Rank	Top 10% (26 out of 254)

Sales and EPS Growth Rates (Y/Y %)



Last EPS Surprise	6.3%
Last Sales Surprise	3.2%
EPS F1 Est- 4 week change	0.0%
Expected Report Date	05/05/2020
Earnings ESP	0.0%
P/E TTM	6.1
P/E F1	6.4
PEG F1	0.7
P/S TTM	2.6

Sales Estimates (millions of \$)

	Q1	Q2	Q3	Q4	Annual*
2021	593 E	597 E	633 E	650 E	2,522 E
2020	541 E	585 E	597 E	628 E	2,343 E
2019	508 A	534 A	538 A	582 A	2,162 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2021	\$4.60 E	\$4.24 E	\$4.22 E	\$4.57 E	\$18.40 E
2020	\$4.16 E	\$2.45 E	\$4.23 E	\$4.34 E	\$15.55 E
2019	\$3.67 A	\$4.05 A	\$4.10 A	\$4.42 A	\$16.23 A

*Quarterly figures may not add up to annual.

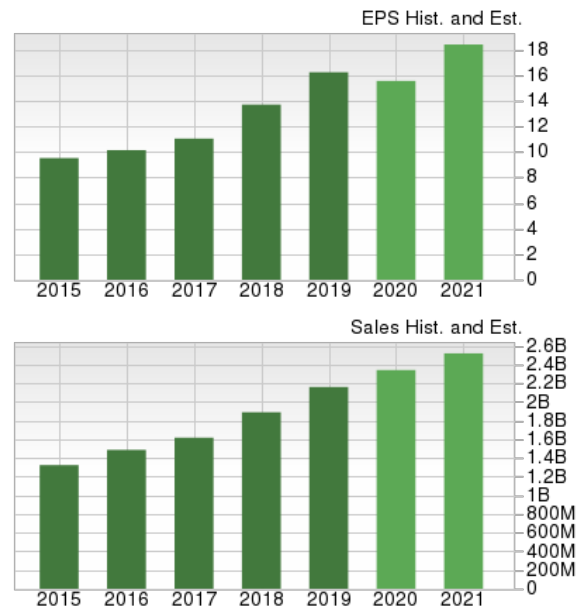
The data in the charts and tables, including the Zacks Consensus EPS and Sales estimates, is as of 03/30/2020. The reports text is as of 03/31/2020.

Overview

Dublin, Ireland-based Jazz Pharmaceuticals is a specialty biopharmaceutical company with a focus in the areas of sleep and hematology/oncology. Key drugs include Xyrem for cataplexy and excessive daytime sleepiness (EDS) in narcolepsy patients, Erwinaze for acute lymphoblastic leukemia (ALL) patients who have developed hypersensitivity to E.coli-derived asparaginase, Defitelio for the treatment of patients with hepatic veno-occlusive disease (VOD) with renal or pulmonary dysfunction following hematopoietic stem cell transplantation (HSCT) and Vyxeos for the treatment of adults with two types of acute myeloid leukemia (AML). Sunosi (solriamfetol) was approved for excessive sleepiness in narcolepsy & obstructive sleep apnea (OSA) in March 2019.

Jazz has bolstered its commercial portfolio and pipeline through acquisitions. These include addition of marketed drugs – Defitelio, Vyxeos, Erwinaze and Sunosi. Jazz also added Sunosi, through one of these acquisitions. Jazz is targeting launch of four products in the 2020-2021 period including lurbinectedin, JZP-258 and JZP-458 following approval.

The company generates the majority of its revenues from Xyrem sales. The drug registered sales of \$1.64 billion in 2019, up 16.9% from 2018 and generated almost 76% of total revenues, in 2019. Full-year sales for the company rose 14% year over year to \$2.16 billion in 2019.



Reasons To Buy:

▲ **Xyrem has Strong Commercial Potential:** Xyrem has immense commercial potential considering that it is the only FDA approved product for both cataplexy and EDS. Sales reps continue to educate healthcare providers on narcolepsy and the use of Xyrem with a focus on physicians with high narcolepsy potential and low Xyrem utilization. Volume trends for Xyrem improved in the last two years supported by the company's disease awareness education efforts, which led to increased diagnosis rate of new narcolepsy patients. Management seems confident of generating volume growth in the rest of 2020.

Jazz's sleep franchise should continue to perform well. The company is looking to broaden Xyrem's label by expanding the targeted patient population.

The company is also striving to expand Xyrem's label. In 2018, the FDA granted approval for Xyrem's label expansion to include the pediatric patients with cataplexy or EDS. Jazz launched the drug for pediatric patients in March 2019, which is bringing in additional sales. Moreover, settlement of all patent litigation related to generic version removes an overhang. There is no generic competition expected till 2022 as of now.

▲ **Strong Sleep Disorder Portfolio:** Jazz's sleep disorder portfolio looks strong with the launch of Sunosi and several ongoing and planned development activities in the sleep therapeutic area.

In March 2019, Sunosi (solriamfetol), received approval in the United States for excessive sleepiness in narcolepsy & OSA and was launched in the United States in July 2019. The drug is showing encouraging initial uptake trend along with improved coverage. The drug was approved in Europe for a similar indication in January 2020 with rolling launch expected to start from mid-2020. According to Jazz, there is significant unmet need in narcolepsy and OSA in both the United States and Europe. The company plans to develop Sunosi as a potential treatment for EDS in other sleep or central nervous system disorders, including major depressive disorder (MDD). A phase III study is planned to start in mid-2020 to evaluate Sunosi in MDD patients.

Other than Sunosi, Jazz has also developed JZP-258 (a low sodium formulation of Xyrem) in phase III studies for EDS and cataplexy in narcolepsy patients. The drug is under review in the United States. A decision is expected by Jul 21, 2020. JZP-258 is also being studied for Idiopathic hypersomnia, or IH in a phase III study.

▲ **Oncology Drugs Add Strong Growth and Diversification:** Apart from a strong sleep disorder, Jazz also has three marketed oncology drugs in its portfolio, which were internally developed or added through acquisitions. The company is also developing a few new oncology candidates and is also focused on expanding the labels of marketed drugs — Defitelio, Vyxeos and Erwinaze. These products bring additional revenues as well as diversify Jazz's marketed portfolio. The marketed oncology drugs generated more than 20% of the product revenues in 2019. Successful label expansion and new drug development will further boost revenues.

Jazz is evaluating Defitelio in a phase III study for the prevention of VOD in high-risk patients. Two mid-stage studies are evaluating the drug for prevention of acute graft versus host disease (aGVHD) and prevention of CAR T-cell associated neurotoxicity in patients with relapsed or refractory DLBCL. Top-line data from aGVHD study is expected in the second half of 2020. Meanwhile, Jazz is also evaluating Vyxeos in other AML patient populations, such as pediatric patients and adults with standard or intermediate risk AML, in combination with targeted AML treatments and in new populations (myelodysplastic syndromes, or MDS).

The company has two late-stage oncology candidates in its pipeline – JZP-458 and lurbinectedin. A pivotal phase II/III study initiated in December 2019 is evaluating JZP-458 as a treatment for patients with acute lymphoblastic leukemia (ALL)/lymphoblastic lymphoma (LBL), who are hypersensitive to E. coli-derived asparaginase products. Lurbinectedin's NDA seeking approval in relapsed small cell lung cancer (SCLC) is under review in the United States. A decision is expected on Aug 16, 2020.

▲ **Regular Acquisitions/Collaborations to Boost Portfolio:** Jazz has added several drugs to its marketed portfolio and clinical-stage candidates to its pipeline through acquisitions or collaborations. The company continues to look for portfolio expansion through acquisitions or partnerships. In December 2019, the company acquired U.S. rights to a late-stage small cell lung cancer candidate, lurbinectedin, from Ireland-based PharmaMar. In August 2019, the company acquired private biotech Cavion adding a mid-stage movement disorder candidate (JZP-358). In July 2019, the company acquired Redx Pharma's pan-RAF inhibitor program for developing treatment for RAF and RAS mutant tumors. In January 2019, Jazz collaborated with Codiak BioSciences, to develop and commercialize exosome therapeutics to treat cancer. It also includes an exclusive license for five targets to be developed using Codiak's exosome platform. Other deals include the acquisition of biopharma company Gentium in December 2013, which added Defitelio to its portfolio. The company also acquired worldwide development, manufacturing and commercial rights to Sunosi (solriamfetol) from Aerial BioPharma in January 2014. In July 2016, Jazz acquired Celator, which added Vyxeos to its pipeline.

Reasons To Sell:

▼ **Regulation on Xyrem and Competition:** Xyrem is a controlled substance with a highly restricted distribution channel subject to a risk evaluation and mitigation strategy (REMS). In February 2015, the FDA approved Jazz's Xyrem REMS requiring distribution through a single pharmacy. Single pharmacy can put pressure on patient access as well as the overall healthcare delivery system. Moreover, the FDA plans to evaluate the Xyrem REMS on an ongoing basis and reserves the rights to make modifications if required, which can either lower entry barriers for companies looking to market generic versions of Xyrem or make it more expensive or difficult to market the drug.

The earlier-than-expected entry of Xyrem generics and any pipeline setback would weigh heavily on the stock.

Jazz had been involved in patent infringement lawsuits with generic drug makers for Xyrem. Several generic versions of Xyrem may hit the market in 2023. Launch of Xyrem's generic will unfavorably impact sales of the company's major drug. With nearly three-fourth of sales coming from Xyrem this will severely impact the company's top-line and weigh on share price. Moreover, the market for EDS in patients with narcolepsy is highly competitive, given the presence of Teva's Nuvigil and generic versions of Provigil, among others. Moreover, other companies are also developing treatments for similar indication including Avadel Pharmaceuticals' sodium oxybate formulation, FT-218, and Axsome Therapeutics' reboxetine.

▼ **Erwinaze Supply Constraints:** In 2019 and 2018, Jazz faced supply constraints for Erwinaze due to supply and manufacturing issues at the sole manufacturer, PDL. The company expects the supply disruptions to continue in 2020. Moreover, in February 2019, Jazz received termination notice from Porton Biopharma related to license and supply of Erwinaze which is set to expire by 2020 end. Without renewing the agreement, Jazz will not be able to sell Erwinaze beginning 2021, except for certain Erwinaze inventory for 12 months post termination of the agreement.

▼ **Pipeline Setbacks:** Jazz has had its share of pipeline setbacks. Although solriamfetol achieved improvement in patients in a phase II study evaluating it in EDS and Parkinson's disease, the company discontinued further development in May 2019. In June 2019, Jazz's partner, ImmunoGen, discontinued development of its anti-body drug conjugate candidate, IMG779, for which Jazz possessed opt-in rights. In January 2016, the company terminated a phase II pivotal study on JZP-416 due to the occurrence of hypersensitivity-like reactions in patients suffering from ALL who are hypersensitive to pegylated E. coli-derived asparaginase. In addition to this, the company terminated a study evaluating Erwinaze in patients (18 to 39 years) suffering from ALL who are hypersensitive to E. coli-derived asparaginase due to its inability to enroll patients. Moreover, the company along with its partner Concert Pharmaceuticals decided not to move sleep disorder candidate, JZP-386, into the next stage of development following phase I study results.

Jazz decided to discontinue the late-stage development of Leukotac after the candidate failed in a clinical study as a treatment for patients who developed steroid-refractory acute graft-versus-host disease post allogeneic hematopoietic stem cell transplant. Discontinuation of development of important candidates could affect the company's growth prospects significantly.

Last Earnings Report

Jazz Pharmaceuticals Q4 Earnings and Sales Beat Estimates

Jazz Pharmaceuticals delivered adjusted earnings of \$4.42 per share for the fourth quarter of 2019, which surpassed the Zacks Consensus Estimate of \$4.16. Earnings rose 21% from the year-ago figure driven by higher sales, which made up for higher operating expense.

Total revenues in the reported quarter rose 22% year over year to \$581.7 million and also beat the Zacks Consensus Estimate of \$564.0 million. This can be attributed to higher product sales.

Quarter Ending **12/2019**

Report Date	Feb 25, 2020
Sales Surprise	3.23%
EPS Surprise	6.25%
Quarterly EPS	4.42
Annual EPS (TTM)	16.24

Quarter in Detail

Net product sales increased 23.4% from the year-ago quarter to \$576.5 million. Royalties and contract revenues declined 42.8% to \$5.21 million in the quarter.

Sales of Xyrem rose 16% year over year to \$435.4 million. Sales were driven by 5% rise in bottle volume growth. The average number of active Xyrem patients increased 4.5%.

Erwinaze/Erwinase revenues were \$54.9 million, up 126.3% year over year due to favorable timing of supply availability.

Defitelio sales rose 27% year over year to \$47.8 million in the quarter. Vyxeos generated sales of \$31.5 million, up 23% from the year-ago period, primarily due to the ongoing launch in EU.

Sunosi recorded sales of \$2.7 million in the quarter compared with \$1 million in the third quarter.

Other product sales declined 14% to \$4.2 million.

Adjusted selling, general and administrative (SG&A) expenses rose 38.5% to \$196.9 million driven by higher expenses for business expansion and costs to support the launch of Sunosi in the United States.

Adjusted research and development (R&D) expenses increased 75.6% to \$90.0 million, primarily due to higher expenses related to development of the company's pipeline and partnered programs.

2019 Results

Full-year 2019 sales rose 14% to \$2.16 billion, slightly beating the Zacks Consensus Estimate of \$2.15 billion. However, sales were within the guided range of \$2.10-\$2.18 billion.

Adjusted earnings of \$16.23 per share beat Zacks Consensus Estimate of \$15.95 and came ahead of the guided range of \$15.50 - \$16.15. Earnings rose 18% year over year.

2020 Guidance

The company issued its financial guidance for 2020.

It expects earnings in the range of \$12.50 - \$13.40 in 2020. Total revenues are expected to be in the range of \$2.32-\$2.40 billion.

The 2020 sales range indicates growth of 7-11% over 2019 levels. However, the earnings range indicates a significant decline from 2019 levels due to changes in Jazz's reporting method for upfront and milestone payments. The company said that from 2020, it will not adjust upfront and milestone payments for the calculation of adjusted/non-GAAP earnings per share. It made an upfront payment of \$200 million in January to PharmaMar, which hurt its after-tax 2020 adjusted EPS guidance by around \$3.13 per share.

Total product sales are predicted in the range of \$2.31-\$2.38 billion. The oxybate franchise (Xyrem and JZP-258) sales are expected in the range of \$1.71-\$1.76 billion. Erwinaze/Erwinase sales are forecast in the band of \$185-\$215 million. Defitelio sales are expected in the range of \$180-\$200 million. Vyxeos sales guidance is in the range of \$135-\$165 million. Jazz's guidance for Sunosi net sales is \$30 million - \$50 million.

While adjusted SG&A expenses are anticipated in the range of \$770 million to \$810 million, adjusted R&D expenses are expected to be in the band of \$285 million to \$315 million.

Recent News

FDA Accepts JZP-258 NDA – Mar 25

Jazz announced that the FDA has accepted its NDA seeking approval for JZP-258 as a treatment for cataplexy and EDS associated with narcolepsy in patients seven years or older. The FDA has also granted priority review to the NDA and a decision is expected by Jul 21, 2020.

FDA Accepts Lurbinectedin NDA – Feb 17

Jazz announced that the FDA has accepted an NDA seeking accelerated approval of lurbinectedin as a treatment for patients with SCLC, whose disease have progressed after treatment with platinum-containing therapy. The NDA was granted priority review and a decision from the FDA is expected by Aug 16, 2020. The NDA was submitted by PharmaMar in December 2019 based on data from a phase II monotherapy basket study.

Files NDA for JZP-258 – Jan 22

Jazz announced that it has submitted a NDA seeking approval for JZP-258 as a treatment for cataplexy and EDS associated with narcolepsy in patients seven years or younger. The company has redeemed a priority review voucher for the NDA submission.

Sunosi Gets Approval in Europe – Jan 20

Jazz announced that the European Commission approved Sunosi. The drug will be available in Europe as a treatment to improve wakefulness and reduce EDS in adults with narcolepsy (with or without cataplexy) or OSA, whose EDS has not been satisfactorily treated by primary OSA therapy.

Valuation

Jazz's shares are down 31.5% in the year-to-date period and 28.5% over the trailing 12-month period. Stocks in the Zacks sub-industry and sector are down 19.4% and 12.9% in the year-to-date period. Over the past year, stocks in the sub-industry and the sector are down 24.8% and 12.3%, respectively.

The S&P 500 Index is down 18.5% in the year-to-date period and 8.9% in the past year.

The stock is currently trading at 2.64X trailing 12-month sales per share which compares to 2.25X for the Zacks sub-industry, 2.76X for the Zacks sector and 2.84X for the S&P 500 Index.

Over the past five years, the stock has traded as high as 9.68X and as low as 2.32X, with a 5-year median of 5.61X. Our Neutral recommendation indicates that the stock will perform in line with the market. Our \$110.00 price target reflects 2.92X trailing 12-month sales per share.

The table below shows summary valuation data for JAZZ

Valuation Multiples - JAZZ					
		Stock	Sub-Industry	Sector	S&P 500
P/S TTM	Current	2.64	2.25	2.76	2.84
	5-Year High	9.68	4.25	4.17	3.69
	5-Year Low	2.32	1.91	2.34	2.43
	5-Year Median	5.61	2.65	3.26	3.19
P/B TTM	Current	1.81	1.29	3.36	3.53
	5-Year High	8.83	13.2	5.05	4.55
	5-Year Low	1.6	0.98	2.84	2.85
	5-Year Median	3.73	2.53	4.3	3.63

As of 03/30/2020

Industry Analysis Zacks Industry Rank: Top 10% (26 out of 254)



Top Peers

Avadel Pharmaceuticals PLC. (AVDL)	Outperform
Alkermes plc (ALKS)	Neutral
Alexion Pharmaceuticals, Inc. (ALXN)	Neutral
BioMarin Pharmaceutical Inc. (BMRN)	Neutral
Endo International plc (ENDP)	Neutral
Horizon Therapeutics Public Limited Company (HZNP)	Neutral
Ionis Pharmaceuticals, Inc. (IONS)	Neutral
Incyte Corporation (INCY)	Underperform

Industry Comparison Industry: Medical - Drugs				Industry Peers		
	JAZZ Neutral	X Industry	S&P 500	ALKS Neutral	ALXN Neutral	BMRN Neutral
VGM Score	B	-	-	B	B	B
Market Cap	5.59 B	82.74 M	18.21 B	2.27 B	19.38 B	14.84 B
# of Analysts	10	2	13	8	14	11
Dividend Yield	0.00%	0.00%	2.3%	0.00%	0.00%	0.00%
Value Score	B	-	-	C	B	D
Cash/Price	0.20	0.32	0.06	0.24	0.15	0.05
EV/EBITDA	6.61	-1.27	11.22	-19.52	7.28	456.18
PEG Ratio	0.72	1.05	1.74	27.55	0.62	NA
Price/Book (P/B)	1.81	2.40	2.41	2.09	1.71	4.75
Price/Cash Flow (P/CF)	4.48	9.33	9.70	24.76	7.47	129.46
P/E (F1)	6.54	14.32	15.12	45.18	7.89	51.59
Price/Sales (P/S)	2.59	4.55	1.96	1.94	3.88	8.71
Earnings Yield	15.61%	-18.87%	6.55%	2.22%	12.67%	1.94%
Debt/Equity	0.55	0.02	0.70	0.25	0.23	0.16
Cash Flow (\$/share)	22.22	-0.50	7.01	0.58	11.68	0.64
Growth Score	C	-	-	A	D	A
Hist. EPS Growth (3-5 yrs)	16.70%	3.96%	10.89%	NA	21.33%	NA
Proj. EPS Growth (F1/F0)	-4.18%	17.60%	1.80%	-55.11%	4.99%	71.95%
Curr. Cash Flow Growth	24.39%	6.68%	5.93%	-4.72%	28.27%	200.25%
Hist. Cash Flow Growth (3-5 yrs)	15.52%	6.21%	8.55%	-0.32%	20.68%	27.84%
Current Ratio	4.47	3.27	1.23	2.46	4.25	2.08
Debt/Capital	35.67%	6.75%	42.57%	20.17%	18.39%	13.47%
Net Margin	24.21%	-112.83%	11.64%	-16.79%	48.17%	-1.40%
Return on Equity	28.29%	-65.31%	16.74%	1.58%	21.29%	0.81%
Sales/Assets	0.40	0.32	0.54	0.66	0.33	0.38
Proj. Sales Growth (F1/F0)	9.56%	0.00%	2.08%	-10.54%	13.29%	16.33%
Momentum Score	C	-	-	D	A	C
Daily Price Chg	2.72%	0.00%	2.63%	0.00%	3.87%	3.75%
1 Week Price Chg	0.86%	7.11%	12.32%	7.62%	4.56%	8.84%
4 Week Price Chg	-20.39%	-19.61%	-18.22%	-32.20%	-9.26%	-12.62%
12 Week Price Chg	-31.71%	-26.11%	-23.36%	-25.96%	-18.13%	-2.48%
52 Week Price Chg	-30.32%	-42.61%	-17.22%	-59.94%	-35.52%	-7.76%
20 Day Average Volume	919,819	228,393	4,211,236	2,171,632	3,240,741	1,960,742
(F1) EPS Est 1 week change	0.00%	0.00%	-0.19%	0.00%	0.04%	0.00%
(F1) EPS Est 4 week change	0.00%	0.00%	-3.07%	0.00%	0.04%	-5.01%
(F1) EPS Est 12 week change	-9.54%	-0.59%	-4.15%	-257.14%	-9.66%	-29.85%
(Q1) EPS Est Mthly Chg	NA%	0.00%	-2.28%	0.00%	-0.07%	-5.38%

Zacks Style Scores

The Zacks Style Score is as a complementary indicator to the Zacks rating system, giving investors a way to focus on the highest rated stocks that best fit their own stock picking preferences.

Academic research has proven that stocks with the best Value, Growth and Momentum characteristics outperform the market. The Zacks Style Scores rate stocks on each of these individual styles and assigns a rating of A, B, C, D and F. We also produce the VGM Score (V for Value, G for Growth and M for Momentum), which combines the weighted average of the individual Style Scores into one score. This is perfectly suited for those who want their stocks to have the best scores across the board.

Value Score	B
Growth Score	C
Momentum Score	C
VGM Score	B

As an investor, you want to buy stocks with the highest probability of success. That means buying stocks with a Zacks Recommendation of Outperform, which also has a Style Score of an A or a B.

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