

Ironwood Pharma (IRWD)

\$9.85 (As of 04/23/20)

Price Target (6-12 Months): **\$11.00**

Long Term: 6-12 Months

Zacks Recommendation:

Neutral

(Since: 01/03/20)

Prior Recommendation: Outperform

Short Term: 1-3 Months

Zacks Rank: (1-5)

3-Hold

Zacks Style Scores:

VGM:B

Value: D

Growth: A

Momentum: C

Summary

Ironwood's Linzess has been performing encouragingly on the back of strong demand and expansion in new patient population and geographic regions. Ironwood is focused on further label expansions of the drug. Meanwhile, Ironwood's separation into two companies is increasing operational performance and strategic flexibility. The amendment of agreements related to Linzess rights in China and Japan with its partners is likely to boost margins. Shares have outperformed the industry in the past year. However, competition in Linzess' target markets is intensifying. Any Linzess-related pipeline/regulatory setbacks will weigh heavily on the stock as the rest of its pipeline is mostly mid-stage in nature. Earnings estimates have moved down ahead of Q1 earnings. The company has a mixed record of earnings surprises in the recent quarters.

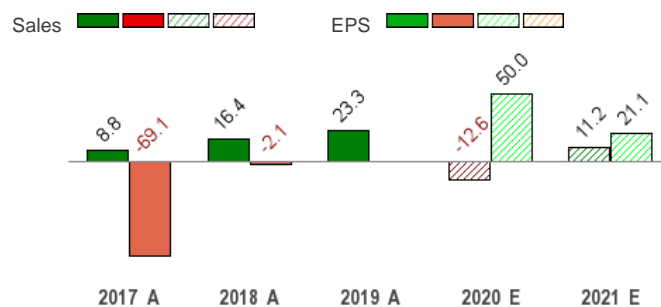
Price, Consensus & Surprise



Data Overview

52 Week High-Low	\$14.10 - \$7.91
20 Day Average Volume (sh)	1,574,907
Market Cap	\$1.6 B
YTD Price Change	-26.0%
Beta	1.75
Dividend / Div Yld	\$0.00 / 0.0%
Industry	Medical - Drugs
Zacks Industry Rank	Top 4% (11 out of 253)

Sales and EPS Growth Rates (Y/Y %)



Last EPS Surprise	36.4%
Last Sales Surprise	15.1%
EPS F1 Est- 4 week change	-3.4%
Expected Report Date	05/06/2020
Earnings ESP	9.1%

Sales Estimates (millions of \$)

	Q1	Q2	Q3	Q4	Annual*
2021	109 E	119 E	122 E	125 E	416 E
2020	87 E	95 E	102 E	107 E	374 E
2019	69 A	102 A	131 A	126 A	428 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2021	\$0.25 E	\$0.32 E	\$0.36 E	\$0.40 E	\$0.69 E
2020	\$0.11 E	\$0.13 E	\$0.16 E	\$0.20 E	\$0.57 E
2019	-\$0.26 A	\$0.08 A	\$0.40 A	\$0.30 A	\$0.38 A

*Quarterly figures may not add up to annual.

P/E TTM	18.9
P/E F1	17.3
PEG F1	NA
P/S TTM	3.6

The data in the charts and tables, including the Zacks Consensus EPS and Sales estimates, is as of 04/23/2020. The reports text is as of 04/24/2020.

Overview

Cambridge, MA-based Ironwood Pharmaceuticals, Inc. is focused on the development and commercialization of treatments primarily addressing gastrointestinal (GI) diseases. Linzess (linaclotide) was launched in December 2012 in collaboration with Allergan for patients suffering from irritable bowel syndrome with constipation (IBS-C; 290 mcg) or chronic idiopathic constipation (CIC; 145 mcg & 72 mcg). Ironwood and Allergan co-develop and co-commercialize Linzess and equally share Linzess' U.S. collaboration profits or losses as well as all development costs. Linzess is marketed by Allergan for IBS-C in Europe and Canada under the brand name Constella. Ironwood receives royalties on sales of Constella in Europe and Canada from Allergan.

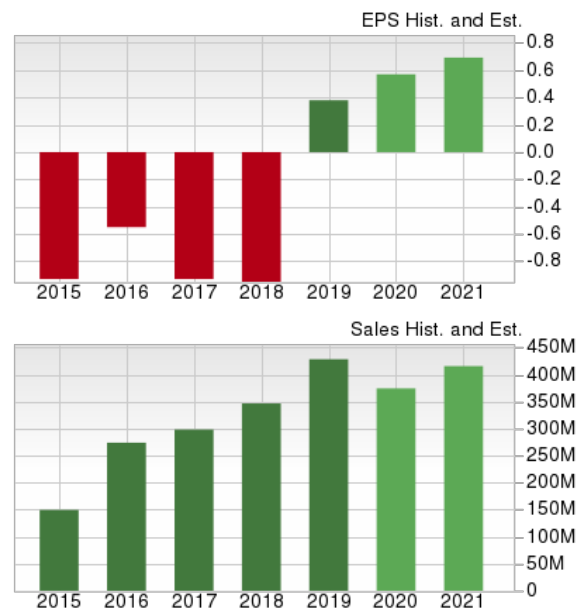
In Japan, Ironwood has partnered with Astellas Pharma for the development and commercialization of Linzess and with AstraZeneca in China, Hong Kong and Macau. Linzess received approval for IBS-C indication in Japan in December 2016 and for chronic constipation (CC) in August 2018. Meanwhile in January 2019, the drug was approved in China for IBS-C.

Ironwood has also partnered with Allergan for the development and commercialization of Linzess in all other territories worldwide.

Meanwhile, in a bid to expand its reach among primary care physicians and gastroenterologists and earn additional funds, Ironwood has signed co-promotion deals with Alnylam for Givlaari [acute hepatic porphyria (AHP)] in the United States.

In April 2019, the company completed the spin-off of its soluble guanylate cyclase (sGC) segment into a separate, publicly traded company, Cyclacel Therapeutics.

Ironwood's revenues in 2019 were up 23.6% to \$428.4 million.



Reasons To Buy:

- ▲ **Linzess Performance Encouraging:** Following the approval of Linzess in 2012, the sales of the drug has grown significantly on back of strong demand.

Ironwood is working on expanding managed care access to Linzess and lowering out-of-pocket costs. Moreover, since 2016 CVS/Caremark has granted Linzess an exclusive preferred position on its formulary. The company will commence a new direct-to-consumer (DTC) campaign in the first half of 2020. Previous DTC campaigns have supported the drug's growth. Moreover, withdrawal of prescription MiraLAX is also favorably impacting sales.

Linzess has blockbuster potential, if approved for additional indications. We are also encouraged by Ironwood's partnership deals with companies like Allergan.

Linzess has the potential to be a blockbuster product. By the end of 2020, Ironwood expects annual sales of Linzess to cross \$1 billion. The company is also progressing well with development of the drug in Japan and China. Per IQVIA data, Linzess is the leading prescribed drug for adult patients in the United States with IBS-C or CIC. Ironwood estimates that its IBS-C/CIC franchise, including Linzess and the delayed release formulation (upon approval), may represent a peak U.S. sales opportunity of over \$2 billion, with additional global potential. Moreover, Linzess is well protected by patents and is unlikely to face generic competition before March 2029. Ironwood and Allergan are working to strengthen the patent further.

- ▲ **Pipeline Progress Encouraging:** Ironwood and Allergan are looking to broaden Linzess' label to include new indications, populations and formulations.

In November 2019, the companies submitted a supplemental new drug application seeking label expansion of Linzess in additional abdominal symptoms associated with IBS-C, including bloating and discomfort. Linzess is also being evaluated as a potential treatment for pediatric patients with IBS-C and functional constipation. Efforts are on to expand in ex-U.S. territories as well. Ironwood and Allergan are also developing a delayed release formulation of Linzess - delayed release-2 (MD-7246) to address patient populations suffering from all forms of IBS. In May 2019, the company initiated a phase IIb study to evaluate MD-7246 for treating IBS-D. The companies have completed enrollment and expect to report top-line data by mid-2020.

Meanwhile, to capture the lucrative GI market, Ironwood is developing several candidates. Its most advanced pipeline candidate is IW-3718, which is being evaluated in two identical phase III studies for treating persistent refractory gastroesophageal reflux disease (GERD). Results from both studies are expected in the second half of 2020.

- ▲ **Strong Partnerships:** We are positive on Ironwood's agreement with Allergan for the development and commercialization of Linzess both in the United States and Europe. Given Allergan's expertise and strong presence both in the United States and EU markets, we believe it is a suitable partner for Ironwood. The company is co-promoting Givlaari as a treatment for AHP with Alnylam in the United States.

The company also has a deal with Astellas for the development of Linzess in Japan. Ironwood has an agreement with AstraZeneca for Linzess in China, Hong Kong and Macau. The collaborations have not only reduced the cost of developing the drug, these also act as a source of revenues for Ironwood. Additional partnerships in other territories will be a positive for the company.

- ▲ **Spin-off of Cyclerion Encouraging:** Separation of Ironwood's sGC pipeline into another entity, Cyclerion, should be a positive. The transaction improved operating margin in the past couple of quarters, following the separation, by bringing down research and development costs. The company will also be able to put more efforts in building its GI products, especially Linzess. Moreover, the spin-off along with some restructuring initiatives is also reducing the workforce, leading to further decrease in operating expenses. The company's operating cash flow turned positive in the third quarter of 2019.
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Reasons To Sell:

▼ **Over-Dependence on Linzess:** While we are pleased with the performance of Linzess, we are concerned about the company's dependence on the product for growth. Any negative news related to Linzess would adversely impact the company and its growth prospects. Although the performance of Linzess improved in 2019, customer buying patterns can have unfavorable impact in future years as seen earlier.

Competition in CIC and IBS-C, Linzess' target markets, is intensifying.

Meanwhile in August 2018, Ironwood terminated its licensing agreement with AstraZeneca related to Zurampic and all products containing lesinurad, including Duzallo (fixed-dose combination of lesinurad and allopurinol). The termination was based on unfavorable data from a study exploring a path for value creation of lesinurad-based products. This has impacted the top line unfavorably as expected. Moreover, upon completion of the termination of lesinurad franchise, the company solely depends on Linzess for the majority of its revenues.

▼ **Pipeline Candidates Still a Few Years from Commercialization:** Ironwood's mid/late-stage nature of the pipeline runs its own risk. Although the company has a couple of mid/late-stage candidates in its pipeline, it will be several years before any of these candidates are close to commercialization. Moreover, we note that clinical development involves a high degree of risk. Gaining approval for pipeline candidates has become more difficult given the tough regulatory environment. Development and regulatory setbacks for pipeline candidates would be a major disappointment for the company and have an adverse impact on the shares.

In April 2016, Ironwood announced disappointing top-line data from an exploratory phase IIa study on IW-9179 in patients with diabetic gastroparesis and decided to discontinue the development of the candidate for gastroparesis.

▼ **Competitive and Pricing Pressure:** Currently approved products for IBS-C and CIC include Takeda's Amitiza and Motegrity as well as laxatives and over-the-counter fiber supplements. Additional competition has entered the market in the form of Synergy's Trulance (plecanatide), which is marketed for treating CIC as well as IBS-C. In September 2019, Ardelyx received approval for Isbrela from the FDA for the treatment of IBS-C. Moreover, several other GI candidates are in late-stage development for Linzess' targeted indications. We are concerned about stiff competition limiting the sales potential of Linzess. Linzess is also facing pricing pressure in the United States, which is impacting sales.

Last Earnings Report

Ironwood Q4 Earnings and Revenues Beat Estimates

Ironwood reported fourth-quarter 2019 adjusted earnings of 30 cents per share, surpassing the Zacks Consensus Estimate of 22 cents. Earnings also came in higher than 4 cents recorded in the year-ago quarter.

Total revenues of \$126.3 million comprehensively beat the Zacks Consensus Estimate of \$109.7 million. However, revenues were down 3.4% year over year, primarily due to lower linacotide API sales.

Quarter Ending **12/2019**

Report Date	Feb 13, 2020
Sales Surprise	15.14%
EPS Surprise	36.36%
Quarterly EPS	0.30
Annual EPS (TTM)	0.52

Quarter in Detail

As reported by partner Allergan, Linzess net sales totaled \$231.2 million in the United States, up 12.6% year over year.

Ironwood's share of net profits from sales of Linzess in the United States (included in collaborative revenues) was \$101.6 million in the fourth quarter, up approximately 24.5% year over year.

Per data provided by IQVIA, volume of prescribed Linzess capsules in the fourth quarter increased about 13% year over year.

Sales of linacotide API to Ironwood's Japanese partner, Astellas Pharma, were \$20.6 million compared with \$45.9 million in the year-ago period. Ironwood recorded \$4.1 million in linacotide royalties, co-promotion and other revenues, compared with \$3.2 million in the year-ago period.

We note that Ironwood amended its agreements with two partners — Astellas Pharma and AstraZeneca — related to development and commercialization of Linzess in Japan and China, respectively, in 2019. Per the amended terms of the agreements, Ironwood will stop supply of linacotide API and will receive royalties on sales of Linzess in Japan and China, beginning 2020.

2019 Results

Ironwood posted full-year revenues of \$428.4 million, representing year-over-year growth of 23.6%. Adjusted earnings per share were 55 cents against loss per share of 69 cents in the year-ago period.

Please note that the company's operating cash flow turned positive in the third quarter of 2019, following the separation of its soluble guanylate cyclase (sGC) pipeline into another entity, Cyclerion Therapeutics, in April 2019.

Guidance

Ironwood provided its guidance for total revenues in 2020. The company expects full-year revenues in 2020 to be in the range of \$360-\$380 million. The company expects adjusted EBITDA to be more than \$105 million in 2020. It also expects net sales of Linzess to grow by mid-single digit percentage point.

Recent News

Provides Update on Impact of COVID-19 – Mar 26

Ironwood announced that it is continuing development of its pipeline candidates amid the coronavirus pandemic. The company has completed enrolment in the phase II study evaluating MD-7246 for the treatment of abdominal pain associated with IBS with diarrhea and continues to expect to report top-line data in mid-2020.

However, the company stated that the pandemic is impacting enrolment in the phase III study evaluating Linzess for treating GERD. The study has reached 70% of its enrolment target but the company is currently assessing the situation and plans to provide an update on timing for top-line data after having some clarity. Top-line data was previously expected in the second half of 2020.

Settles Linzess Patent Litigation With Sandoz – Jan 6

Ironwood and partner Allergan announced that they have settled a patent litigation related to Linzess with Sandoz, the generic division of Novartis. Sandoz had filed an abbreviated new drug application, seeking approval for a generic version of Linzess in the United States. Per the settlement terms, Sandoz will be able to market generic version of Linzess, beginning Feb 5, 2030, subject to FDA approval.

Amends Collaboration Agreement with AstraZeneca – Sep 18

Ironwood announced that it has amended the collaboration agreement with AstraZeneca related to development and commercialization of Linzess in China, including Hong Kong and Macau. Per the amended terms, Ironwood has granted AstraZeneca exclusive rights to develop, manufacture, and commercialize Linzess in these territories. AstraZeneca will be responsible for all expenses associated with Linzess and Ironwood will no longer be jointly funding the development and commercialization of Linzess neither will it share profits on the drug's sales in China. The company will receive royalties on net sales of Linzess in China and included territories.

Per the terms of the amended agreement, Ironwood is eligible to receive payments up to a total of \$125 million, which includes \$35 million in non-contingent payments and \$90 million payment contingent to achieving certain annual net sales targets. It received \$32.4 million of the non-contingent payments and recorded the same as revenues in the third quarter.

Valuation

Ironwood's shares are down 26% in the year-to-date period and 18.6% over the trailing 12-month period. Stocks in the Zacks sub-industry and sector are down 14.1% and 4.8% in the year-to-date period. Over the past year, stocks in the sub-industry are down 14.7% while stocks in the sector are up 0.7%.

The S&P 500 Index is down 13.2% in the year-to-date period and 4.8% in the past year.

The stock is currently trading at 3.55X trailing 12-month sales per share which compares to 2.35X for the Zacks sub-industry, 2.98X for the Zacks sector and 3.02X for the S&P 500 Index.

Over the past five years, the stock has traded as high as 22.73X and as low as 2.97X, with a 5-year median of 8.41X. Our Neutral recommendation indicates that the stock will perform in line with the market. Our \$11.00 price target reflects 3.96X trailing 12-month sales per share.

Industry Analysis Zacks Industry Rank: Top 4% (11 out of 253)



Top Peers

Company (Ticker)	Rec	Rank
Tetraphase Pharmaceuticals, Inc. (TTPH)	Outperform	1
Allergan plc (AGN)	Neutral	3
Ardelyx, Inc. (ARDX)	Neutral	2
Bausch Health Cos Inc. (BHC)	Neutral	3
Evoke Pharma, Inc. (EVOK)	Neutral	3
Horizon Therapeutics Public Limited Company (HZNP)	Neutral	3
Mallinckrodt public limited company (MNK)	Neutral	3
Teva Pharmaceutical Industries Ltd. (TEVA)	Neutral	3

Industry Comparison Industry: Medical - Drugs				Industry Peers		
	IRWD	X Industry	S&P 500	HZNP	TEVA	TTPH
Zacks Recommendation (Long Term)	Neutral	-	-	Neutral	Neutral	Outperform
Zacks Rank (Short Term)	3	-	-	3	3	1
VGM Score	B	-	-	C	B	B
Market Cap	1.56 B	99.68 M	19.03 B	6.37 B	11.12 B	9.36 M
# of Analysts	3	3	14	5	13	2
Dividend Yield	0.00%	0.00%	2.23%	0.00%	0.00%	0.00%
Value Score	D	-	-	C	A	B
Cash/Price	0.11	0.28	0.05	0.17	0.18	2.30
EV/EBITDA	17.90	-1.40	11.66	20.35	73.75	0.13
PEG Ratio	NA	1.06	2.20	1.42	0.89	NA
Price/Book (P/B)	NA	2.71	2.56	2.87	0.74	0.19
Price/Cash Flow (P/CF)	17.04	11.02	10.31	9.66	2.62	NA
P/E (F1)	17.60	15.10	17.77	19.18	4.23	NA
Price/Sales (P/S)	3.64	5.03	1.97	4.90	0.64	1.27
Earnings Yield	5.79%	-18.76%	5.48%	5.22%	23.67%	-350.39%
Debt/Equity	-4.61	0.02	0.72	0.62	1.63	0.15
Cash Flow (\$/share)	0.58	-0.49	7.01	3.47	3.89	-20.04
Growth Score	A	-	-	C	D	B
Hist. EPS Growth (3-5 yrs)	NA%	3.80%	10.92%	10.63%	-18.67%	NA
Proj. EPS Growth (F1/F0)	50.00%	17.90%	-5.06%	-9.90%	0.38%	80.22%
Curr. Cash Flow Growth	-168.58%	4.73%	5.92%	10.70%	-9.67%	-2.98%
Hist. Cash Flow Growth (3-5 yrs)	20.48%	6.05%	8.55%	39.60%	-6.21%	-0.94%
Current Ratio	7.50	3.06	1.23	2.33	0.98	2.71
Debt/Capital	NA%	6.72%	43.90%	38.23%	61.99%	12.95%
Net Margin	5.02%	-115.64%	11.32%	44.08%	-5.75%	-950.18%
Return on Equity	-46.52%	-62.77%	16.60%	23.07%	16.57%	-181.52%
Sales/Assets	1.21	0.31	0.55	0.33	0.30	0.11
Proj. Sales Growth (F1/F0)	-12.60%	0.00%	-0.78%	1.55%	-4.93%	116.24%
Momentum Score	C	-	-	C	B	C
Daily Price Chg	-1.01%	0.00%	0.15%	-0.97%	3.46%	1.57%
1 Week Price Chg	5.85%	4.03%	0.42%	8.96%	1.08%	4.10%
4 Week Price Chg	-2.28%	7.21%	4.04%	18.03%	28.86%	26.47%
12 Week Price Chg	-19.06%	-16.80%	-21.19%	-4.23%	-0.88%	-45.11%
52 Week Price Chg	-18.60%	-32.89%	-15.14%	32.49%	-32.76%	-93.97%
20 Day Average Volume	1,574,907	160,422	2,802,273	2,036,681	17,013,940	209,803
(F1) EPS Est 1 week change	0.00%	0.00%	-0.10%	0.00%	0.00%	0.00%
(F1) EPS Est 4 week change	-3.39%	0.00%	-6.64%	-7.68%	-1.45%	0.00%
(F1) EPS Est 12 week change	-25.49%	0.00%	-11.78%	-11.12%	-4.34%	48.34%
(Q1) EPS Est Mthly Chg	-16.67%	0.00%	-10.38%	-22.13%	-4.95%	0.00%

Zacks Stock Rating System

We offer two rating systems that take into account investors' holding horizons: Zacks Rank and Zacks Recommendation. Each provides valuable insights into the future profitability of the stock and can be used separately or in combination with each other depending on your investment style.

Zacks Recommendation

The Zacks Recommendation aims to predict performance over the next 6 to 12 months. The foundation for the quantitatively determined Zacks Recommendation is trends in the company's estimate revisions and earnings outlook. The Zacks Recommendation is broken down into 3 Levels; Outperform, Neutral and Underperform. Unlike many Wall Street firms, we have an excellent balance between the number of Outperform and Neutral recommendations. Our team of 70 analysts are fully versed in the benefits of earnings estimate revisions and how that is harnessed through the Zacks quantitative rating system. But we have given our analysts the ability to override the Zacks Recommendation for the 1200 stocks that they follow. The reason for the analyst over-rides is that there are often factors such as valuation, industry conditions and management effectiveness that a trained investment professional can spot better than a quantitative model.

Zacks Rank

The Zacks Rank is our short-term rating system that is most effective over the one- to three-month holding horizon. The underlying driver for the quantitatively-determined Zacks Rank is the same as the Zacks Recommendation, and reflects trends in earnings estimate revisions.

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	D
Growth Score	A
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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