Ironwood Pharma (IRWD)

$9.98 (As of 06/18/20)

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

Long Term: 6-12 Months	**Zacks Recommendation:** (Since: 01/05/20) Prior Recommendation: Outperform	**Neutral**
Short Term: 1-3 Months	**Zacks Rank:** (1-5)	**4-Sell**
	Zacks Style Scores:	VGM:A
	Value: C | Growth: A | Momentum: A	

Summary

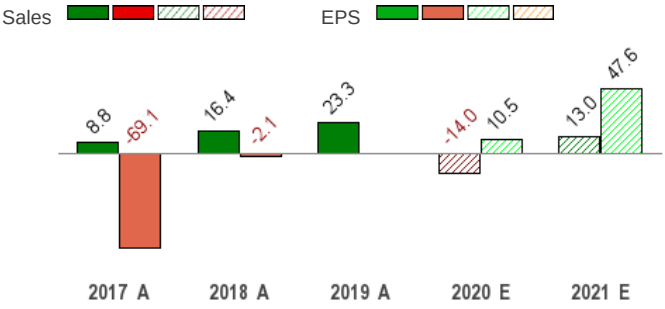
Ironwood's Linzess has been performing encouragingly on the back of strong demand and expansion in new patient population and geographic regions. Ironwood is focused on further label expansions of the drug. Meanwhile, Ironwood's separation into two companies is increasing operational performance and 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.

Price, Consensus & Surprise

Data Overview

52 Week High-Low	**$14.10 - $7.91**
20 Day Average Volume (sh)	**2,734,418**
Market Cap	**$1.6 B**
YTD Price Change	**-25.0%**
Beta	**1.46**
Dividend / Div Yld	**$0.00 / 0.0%**
Industry	**Medical - Drugs**
Zacks Industry Rank	**Top 24% (61 out of 253)**
Last EPS Surprise	**-63.6%**
Last Sales Surprise	**-7.9%**
EPS F1 Est- 4 week change	**4.5%**
Expected Report Date	**08/04/2020**
Earnings ESP	**32.4%**
P/E TTM	**12.2**
P/E F1	**23.8**
PEG F1	**NA**
P/S TTM	**3.6**

Sales and EPS Growth Rates (Y/Y %)



Sales Estimates (millions of $)

	Q1	Q2	Q3	Q4	Annual*
2021	96 E	106 E	115 E	124 E	416 E
2020	80 A	82 E	100 E	108 E	368 E
2019	69 A	102 A	131 A	126 A	428 A

EPS Estimates

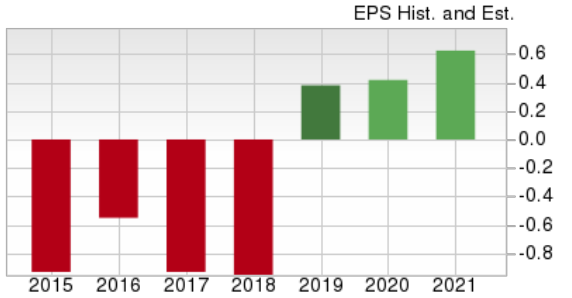
	Q1	Q2	Q3	Q4	Annual*
2021	$0.14 E	$0.21 E	$0.27 E	$0.33 E	$0.62 E
2020	$0.04 A	$0.07 E	$0.16 E	$0.19 E	$0.42 E
2019	-$0.26 A	$0.08 A	$0.40 A	$0.30 A	$0.38 A

*Quarterly figures may not add up to annual.

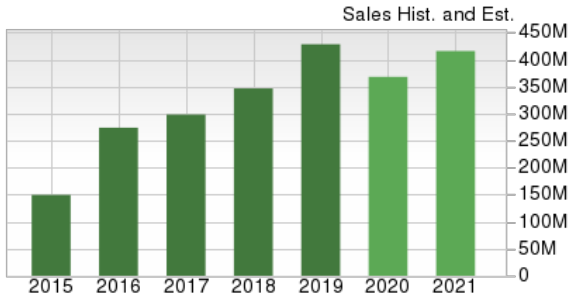
The data in the charts and tables, including the Zacks Consensus EPS and Sales estimates, is as of 06/18/2020. The reports text is as of 06/19/2020.

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, Cyclerion Therapeutics.

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

Reasons To Buy:

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

- **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 commenced a new direct-to-consumer (DTC) campaign in April 2020. Previous DTC campaigns have supported the drug's growth. Moreover, withdrawal of prescription MiraLAX is also favorably impacting sales.

  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 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 and patient populations.

  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.

  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 2021.

- **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, is 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.

- **Favorable Debt Profile:** Ironwood has a favorable debt profile. As of Mar 31, 2020, the company's debt to total capital ratio was 1.19, which compared unfavorably with the industry's 0.52. However, the company's ratio has declined over the past few quarters. The company had debt to total capital ratio of 1.9 at 2018-end. A lower ratio indicates lower financial risk. Moreover, the company's cash and equivalent of $232 million is sufficient to pay its short-term debt of $2 million in case of insolvency. The company's Times Interest Earned improved to 3.5X in first-quarter 2020, compared with 2.6X in the previous quarter. This suggest that the company is capable of meeting its interest obligations from operating earnings.

Reasons To Sell:

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

- **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.

  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 lenisurad 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 a few 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. Meanwhile, the company discontinued development of a delayed-release formulation of Linzess, MD-7246, following failure in phase II study in May 2020. Any further development and any regulatory setbacks for pipeline candidates would be a major disappointment for the company and have an adverse impact on shares.

- **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 Q1 Earnings and Revenues Miss Estimates

Quarter Ending	03/2020
Report Date	**May 06, 2020**
Sales Surprise	**-7.90%**
EPS Surprise	**-63.64%**
Quarterly EPS	**0.04**
Annual EPS (TTM)	**0.82**

Ironwood reported first-quarter 2020 adjusted earnings of 4 cents per share, which missed the Zacks Consensus Estimate of 11 cents. The company had incurred an adjusted loss of 26 cents in the year-ago quarter.

Total revenues of $79.9 million also missed the Zacks Consensus Estimate of $86.8 million. However, revenues were up 16.3% year over year due to higher sales of Linzess as well as linaclotide API.

Quarter in Detail

As reported by partner Allergan, Linzess net sales totaled 172.2 million in the United States, up 6.7% year over year.

Ironwood's share of net profits from sales of Linzess in the United States (included in collaborative revenues) was $71.4 million in the first quarter, up approximately 11% year over year.

Per data provided by IQVIA, volume of prescribed Linzess capsules in the first quarter increased about 11% year over year.

On its first-quarter earnings call, Ironwood stated that it observed a higher rate of growth in Linzess sales during the last two weeks of the first quarter of 2020, which the company believes was due to stockpiling by patients amid the COVID-19 pandemic.

Sales of linaclotide API were $5.5 million compared with $2.6 million in the year-ago period. Ironwood recorded $3.3 million in linaclotide royalties, co-promotion and other revenues, compared with $1.8 million in the year-ago period.

2020 Guidance

Ironwood stated that the COVID-19 pandemic has not caused significant disruptions in manufacturing operations and supply of Linzess in the United States. However, the extent of future impact is uncertain. Hence, the company withdrew its previous guidance for 2020 except that for adjusted EBITDA.

The company continues to expect adjusted EBITDA to be more than $105 million in 2020.

Recent News

Discontinues MD-7246 Development – May 27

Ironwood announced that the delayed-release formulation of Linzess — MD-7246 — has failed to meet primary as well secondary endpoints in a phase II study. The study was evaluating MD-7246 in patients with abdominal pain associated with IBS-D. Data showed that MD-7246 failed to achieve statistically significant improvements in abdominal pain compared to placebo

Based on the study data, Ironwood and its partner AbbVie are planning to discontinue the development of MD-7246.

Ironwood had previously reported data from another phase II study evaluating the candidate in patients with IBS-C in 2016. Data from the IBS-C study showed that MD-7246 numerically improved abdominal pain relative to placebo with no effect on bowel function.

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-lone 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

AmendsCollaboration 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 25% in the year-to-date period and 11.4% over the trailing 12-month period. Stocks in the Zacks sub-industry and sector are down 5.3% and 2.3%, respectively, in the year-to-date period. Over the past year, stocks in the sub-industry are down 7.1% while stocks in the sector are down 1.9%.

The S&P 500 Index is down 3.3% in the year-to-date period but up 5.5% in the past year.

The stock is currently trading at 3.63X trailing 12-month sales per share which compares to 2.19X for the Zacks sub-industry, 3.02X for the Zacks sector and 3.35X for the S&P 500 Index.

Over the past five years, the stock has traded as high as 19.19X and as low as 2.97X, with a 5-year median of 8.31X. Our Neutral recommendation indicates that the stock will perform in line with the market. Our $11.00 price target reflects 4X trailing 12-month sales per share.

Industry Analysis **Zacks Industry Rank:** Top 24% (61 out of 253)

Top Peers

Company (Ticker)	Rec	Rank
AbbVie Inc. **(ABBV)**	Outperform	2
Ardelyx, Inc. **(ARDX)**	Neutral	3
Bausch Health Cos Inc. **(BHC)**	Neutral	3
Evoke Pharma, Inc. **(EVOK)**	Neutral	4
Horizon Therapeutics Public Limited Company **(HZNP)**	Neutral	2
Mallinckrodt public limited company **(MNK)**	Neutral	3
Teva Pharmaceutical Industries Ltd. **(TEVA)**	Neutral	3
Tetraphase Pharmaceuticals, Inc. **(TTPH)**	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	Neutral
Zacks Rank (Short Term)	4	-	-	2	3	3
VGM Score	A	-	-	D	A	C
Market Cap	1.59 B	113.35 M	21.93 B	9.24 B	13.43 B	18.16 M
# of Analysts	5	3	14	6	9	2
Dividend Yield	0.00%	0.00%	1.93%	0.00%	0.00%	0.00%
Value Score	C	-	-	C	A	F
Cash/Price	0.16	0.28	0.06	0.09	0.15	1.54
EV/EBITDA	17.85	-2.14	12.69	30.12	79.00	0.09
PEG Ratio	NA	1.04	2.97	1.49	0.84	NA
Price/Book (P/B)	NA	3.30	3.02	4.21	0.92	0.66
Price/Cash Flow (P/CF)	17.26	10.40	11.62	13.96	3.16	NA
P/E (F1)	23.95	15.86	21.45	26.88	4.97	NA
Price/Sales (P/S)	3.62	6.24	2.33	6.72	0.77	2.31
Earnings Yield	4.21%	-15.22%	4.37%	3.72%	20.16%	-158.00%
Debt/Equity	-6.25	0.01	0.77	0.62	1.68	0.06
Cash Flow ($/share)	0.58	-0.47	7.01	3.47	3.89	-20.04
Growth Score	A	-	-	F	B	A
Hist. EPS Growth (3-5 yrs)	NA%	4.67%	10.87%	8.06%	-19.38%	NA
Proj. EPS Growth (F1/F0)	10.00%	13.99%	-10.65%	-7.13%	3.15%	82.71%
Curr. Cash Flow Growth	-168.58%	2.52%	5.46%	10.70%	-9.67%	-2.98%
Hist. Cash Flow Growth (3-5 yrs)	20.48%	5.83%	8.55%	39.60%	-6.21%	-0.94%
Current Ratio	12.10	3.69	1.29	2.39	1.05	3.66
Debt/Capital	NA%	6.01%	45.14%	38.30%	62.65%	6.01%
Net Margin	19.14%	-132.39%	10.53%	43.06%	-4.73%	-798.18%
Return on Equity	-96.13%	-63.37%	16.06%	22.52%	18.10%	-210.86%
Sales/Assets	1.21	0.29	0.55	0.34	0.30	0.15
Proj. Sales Growth (F1/F0)	-14.07%	0.00%	-2.61%	11.90%	-3.90%	27.17%
Momentum Score	A	-	-	B	B	B
Daily Price Chg	-1.87%	0.00%	-0.07%	0.58%	2.16%	6.38%
1 Week Price Chg	-8.05%	-2.15%	-7.25%	-4.26%	-12.38%	-4.90%
4 Week Price Chg	-15.78%	0.92%	6.92%	1.04%	2.33%	8.70%
12 Week Price Chg	-0.99%	22.30%	16.91%	70.53%	55.70%	145.10%
52 Week Price Chg	-11.45%	-16.46%	-5.63%	96.55%	51.48%	-81.03%
20 Day Average Volume	2,734,418	334,130	2,574,456	2,110,903	9,962,502	1,804,025
(F1) EPS Est 1 week change	4.50%	0.00%	0.00%	0.00%	0.42%	0.00%
(F1) EPS Est 4 week change	4.50%	0.00%	0.00%	4.22%	1.02%	0.00%
(F1) EPS Est 12 week change	-29.15%	-1.01%	-14.21%	-16.44%	0.68%	12.61%
(Q1) EPS Est Mthly Chg	8.80%	0.00%	0.00%	5.37%	4.53%	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	C
Growth Score	A
Momentum Score	A
VGM Score	A

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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