Agios Pharmaceuticals (AGIO)

$52.69 (As of 01/27/20)

Price Target (6-12 Months): **$56.00**

Long Term: 6-12 Months	**Zacks Recommendation:** (Since: 02/18/19) Prior Recommendation: Underperform	**Neutral**
Short Term: 1-3 Months	**Zacks Rank:** (1-5)	**3-Hold**
	Zacks Style Scores:	VGM:F
	Value: F | Growth: F | Momentum: A	

Summary

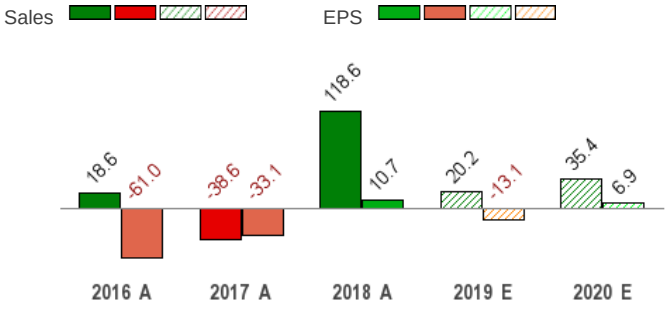
Agios's first wholly owned precision medicine Tibsovo has been performing steadily since its launch. The drug's label expansion studies are also advancing well with the FDA granting approval for the first-line setting in May. Tibsovo is also under review in the EU with a decision expected in the second half of 2020. Agios' progress with its pipeline candidates has been impressive too. Though the company's collaboration with partner Celgene (now part of Bristol-Myers) looks lucrative as the latter provides the company with regular funds and royalties from Idhifa sales. However, Agios' heavy dependence on Celgene for royalties remains a constant worry. Stiff competition from big pharma companies is another matter of concern for the company. Shares have underperformed the industry in the past year.

Price, Consensus & Surprise

Data Overview

52 Week High-Low	**$68.94 - $28.36**
20 Day Average Volume (sh)	**752,212**
Market Cap	**$3.1 B**
YTD Price Change	**10.4%**
Beta	**2.35**
Dividend / Div Yld	**$0.00 / 0.0%**
Industry	**Medical - Products**
Zacks Industry Rank	**Top 42% (107 out of 255)**
Last EPS Surprise	**2.2%**
Last Sales Surprise	**-10.2%**
EPS F1 Est- 4 week change	**0.0%**
Expected Report Date	**02/13/2020**
Earnings ESP	**8.5%**
P/E TTM	**NA**
P/E F1	**NA**
PEG F1	**NA**
P/S TTM	**27.6**

Sales and EPS Growth Rates (Y/Y %)



Sales Estimates (millions of $)

	Q1	Q2	Q3	Q4	Annual*
2020	29 E	32 E	36 E	40 E	153 E
2019	30 A	26 A	26 A	31 E	113 E
2018	9 A	40 A	15 A	30 A	94 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2020	-$1.69 E	-$1.75 E	-$1.73 E	-$1.78 E	-$6.35 E
2019	-$1.59 A	-$1.87 A	-$1.81 A	-$1.78 E	-$6.82 E
2018	-$1.63 A	-$1.19 A	-$1.63 A	-$1.58 A	-$6.03 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 01/27/2020. The reports text is as of 01/28/2020.

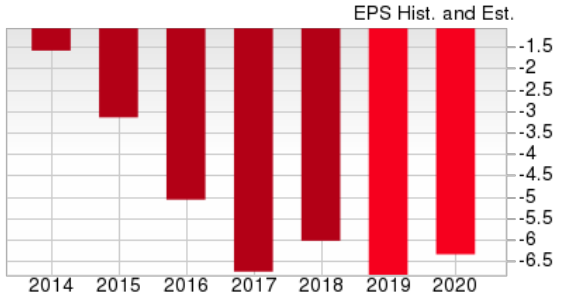
Overview

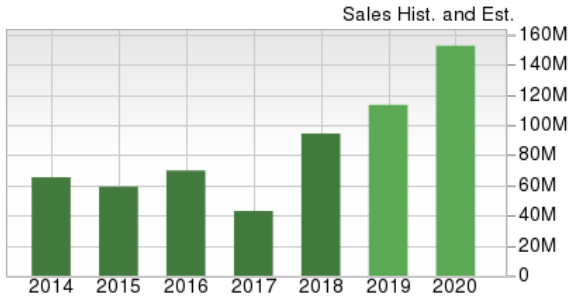
Cambridge, MA-based Agios Pharmaceuticals, Inc. is a development-stage biopharmaceutical company focused on development of treatments for cancer and rare genetic metabolic disorders, a subset of orphan genetic metabolic diseases.

In July 2018, Agios' wholly owned product Tibsovo, an IDHm inhibitor, received FDA approval for R/R AML with a susceptible IDH1 mutation as detected by an FDA-approved test. The candidate is also under review in the EU for the same indication. Last June, Agios out-licensed rights to market Tibsovo in China to CStone Pharmaceuticals for the given indication. Tibsovo recorded sales of $13.8 million in 2018.

Agios developed another product Idhifa in collaboration with partner Celgene Corporation (now part of Bristol-Myers). In August 2017, the FDA granted Celgene an approval for Idhifa to treat adult patients with relapsed or refractory acute myeloid leukemia (R/R AML) and an isocitrate dehydrogenase 2 or IDH2, mutation. Idhifa is owned by Celgene while Agios is entitled to receive royalties on the drug's net sales. Idhifa is under review in the EU.

IDH1 and IDH2 mutations are found in a wide range of hematological malignancies and solid tumors including AML, chondrosarcoma and cholangiocarcinoma where both the treatment options and prognosis for patients are poor.





Agios' other pipeline candidates are vorasidenib, AG-270 and AG-636, which are being developed for various cancer indications.

In 2018, the company generated $94.3 million in total revenues, reflecting a surge of 119.3% year over year.

Reasons To Buy:

> FDA approval of leukemia drug Tibsovo was a huge boost for Agios. The company's collaboration with Celgene is also encouraging.

- **Tibsovo Approval, a Huge Boost; Label Expansion Studies Ongoing:** The FDA approval of Tibsovo in July 2018 offered a huge boost for the company given the immense commercial potential in the target market - AML patients with IDH-1 mutation. The FDA approval also lowered the company's heavy dependence solely on Celgene for revenues as Tibsovo is Agios' wholly owned product and it records product sales from the drug. The drug is also under review in the EU for the same indication with a decision expected in the second half of 2020.

  In May 2019, Tibsovo was approved by the FDA in the first-line setting. This nod was crucial as it expands the drug's eligible patient population and should drive sales higher in the future quarters.

  Tibsovo is also being evaluated in combination with Celgene's Vidaza for treating newly diagnosed AML patients, who are ineligible for intensive chemotherapy. Agios plans to conclude enrollment in the study by 2020. In February 2019, Agios presented updated data from the study, which showed that the safety profile of the combo regime is consistent with the safety profile observed for Tibsovo and Vidaza alone. The FDA has granted a Breakthrough Therapy designation to this combo for the given indication.

  Tibsovo is also being evaluated in the phase III ClarIDHy study in previously treated patients with IDH1 mutant cholangiocarcinoma also called bile-duct cancer. In May 2019, Tibsovo met the primary endpoint of this study. The company expects to file an sNDA for including the above indication in Tibsovo's label by the end of 2019. Currently, there are no treatment options available to treat this cancer. Meanwhile, in December 2019, the FDA granted Breakthrough Therapy designation to Tibsovo for treating relapsed/refractory myelodysplastic syndrome (MDS) in adult patients with a susceptible IDH1 mutation.

- **Strong Pipeline:** Agios' rare genetic diseases candidate, mitapivat, is being developed for treating patients with (PK) deficiency. The company is also looking to close enrollment in two pivotal studies on mitapivat by the end of 2019. The studies are single-arm ACTIVATE-T analyses for addressing PK deficiency in up to 40 patients, who are on regular blood transfusions, and the ACTIVATE study for treating PK deficiency in up to 80 patients with no regular blood transfusions. Agios also plans to initiate a phase II proof of concept analysis on mitapivat for thalassemia in the second half of 2019.

  Agios' other product candidates are vorasidenib, AG-270 and AG-636. The company plans to begin a registration-enabling phase III study on vorasidenib for treating Grade 2 non-enhancing glioma with an IDH1 mutation by this year-end. Meanwhile, AG-636 is in phase I development for treating advanced lymphoma.

  AG-270 is being developed in a phase I study for the treatment of cancers carrying methylthioadenosine phosphorylase (MTAP)-deleted tumors. During third-quarter 2019, Agios initiated two combination arms to conduct the phase I study of AG-270 in MTAP-deleted tumors.

  Successful development and potential commercialization of these candidates will drive the company's growth in the future.

- **Strong Partner in Celgene (now part of Bristol-Myers):** In May 2016, Agios and Celgene announced a new global strategic collaboration for the discovery, development and commercialization of novel therapies utilizing Agios' innovative cellular metabolism research platform. Agios is eligible to receive notable milestone payment upon achievement of certain criteria. Terms of the Celgene deal are lucrative as Agios is eligible to receive clinical, regulatory and commercial milestone payments plus royalties on net sales of products resulting under the collaboration. For 2018, Agios earned $60.6 million from Celgene as collaboration revenues and $7.2 million as royalty revenues on Idhifa sales.

Reasons To Sell:

- **Shares Underperforming Industry:** Shares of Agios have lagged its industry in the past year. The stock has increased 4.8% compared to the industry's rally of 19.1%.

- **Pipeline Setback:** In December 2016, company announced its decision to discontinue the development of AG-519. The decision was taken after the verbal notification of a clinical hold by the FDA, which led the company to withdraw its investigational new drug application for the candidate. The decision to discontinue the development of AG-519 was disappointing.

Agios is highly dependent on Celgene for royalties and regular funds. Pipeline setbacks too remain a threat as well.

- **High Dependence on Celgene for Pipeline Progress:** The company depends heavily on Celgene for revenues, which it earns in the form of collaboration revenues and royalty revenues on Idhifa sales. The discovery phase under the 2010 agreement concluded in Apr 2016 and Agios no longer receives payments from Celgene with respect to extensions of the discovery phase under the agreement. Also, the execution of the new global strategic metabolic immuno-oncology collaboration with Celgene as planned is important for Agios as it stands to receive funds from the deal.

  In September 2018, following the termination of the vorasidenib (formerly AG-881) agreement, Agios acquired the worldwide rights to vorasidenib from partner Celgene. The candidate was earlier jointly developed by the companies. Agios now needs funds to develop this candidate further.

Last Earnings Report

Agios' Q3 Loss Narrower Than Expected, Revenues Miss

Quarter Ending	09/2019
Report Date	Oct 31, 2019
Sales Surprise	-10.15%
EPS Surprise	2.16%
Quarterly EPS	-1.81
Annual EPS (TTM)	-6.85

Agios reported third-quarter 2019 loss of $1.81 per share, narrower than the Zacks Consensus Estimate of a loss of $1.85 but wider than the year-ago loss of $1.63.

Total revenues in the reported quarter were $26 million, lower than the Zacks Consensus Estimate of $29 million but higher than the year-ago revenue figure of $15 million. Revenues increased year-over-year, driven by a strong uptake of Tibsovo in the frontline and relapsed/refractory acute myeloid leukemia (AML) settings. The drug generated sales of $17.4 million in the third quarter of 2019, reflecting a sequential surge of 27%.

Meanwhile, royalty revenues earned from Celgene were $2.7 million on Idhifa net sales in the reported quarter while collaboration revenues were $5.5 million.

Research & development expenses rose 23.1% year over year to $101.7 million, largely due to higher cost of late-stage clinical studies for pipeline development.

General and administrative expenses increased 6.1% year over year to $33 million in the quarter.

Agios ended the third quarter with cash, cash equivalents and marketable securities of $540.5 million, lower than the sequential quarter's tally of $624 million. The company expects this cash balance and revenues recognized from Tibsovo and royalties to effectively fund its current operational plans for at least through 2020.

Recent News

Provides Strategic Vision for 2025 - Jan 12

Agios announced "Agios 2025" a six-year strategic vision. As part of this, the company expects to have four marketed medicines in its portfolio along with achieving several other milestones by the end of 2025.

Tibsovo Gets FDA's Breakthrough Therapy Tag for MDS — Dec 16

Agios announced that the FDA has granted Breakthrough Therapy designation to Tibsovo for the treatment of relapsed/refractory myelodysplastic syndrome (MDS) in adult patients with a susceptible IDH1 mutation.

Establishes Proof-of-Concept for Mitapivat — Dec 8

Agios announced that based on preliminary analysis of the phase II study on mitapivat for treating patients with non-transfusion-dependent thalassemia, clinical proof-of-concept has been established. The study is evaluating the efficacy, safety, pharmacokinetics and pharmacodynamics of treatment with mitapivat in patients with non-transfusion-dependent thalassemia (NTDT). The primary endpoint of the study is hemoglobin response.

Valuation

Agios' shares are up 4.8% over the trailing 12-month period. Over the past year, the Zacks sub-industry is up 19.1% and the sector is up 4.1%.

The S&P 500 index is up 22.1% in the past year.

The stock is currently trading at 6.92X trailing 12-month book value, which compares to 3.22X for the Zacks sub-industry, 4.49X for the Zacks sector and 4.43X for the S&P 500 index.

Over the past five years, the stock has traded as high as 11.25X and as low as 3.27X, with a 5-year median of 5.74X. Our Neutral recommendation indicates that the stock will perform in-line with the market. Our $56.00 price target reflects, 7.35X trailing 12-month book value.

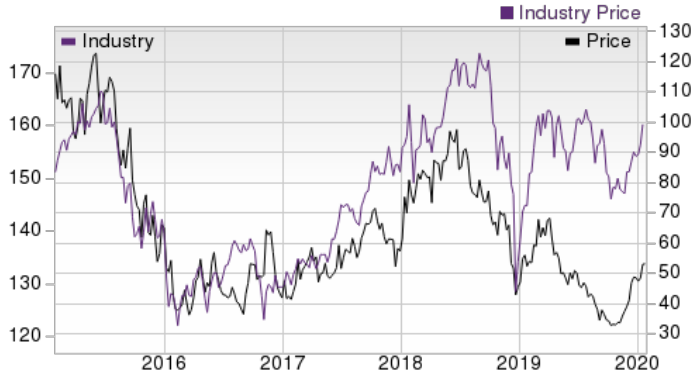
The table below shows summary valuation data for AGIO

Valuation Multiples - AGIO

		Stock	Sub-Industry	Sector	S&P 500
P/B TTM	Current	6.92	3.22	4.49	4.43
	5-Year High	11.25	4.3	5.02	4.55
	5-Year Low	3.27	2.21	3.43	2.85
	5-Year Median	5.74	2.77	4.29	3.62
P/S TTM	Current	27.55	4.33	3.1	3.51
	5-Year High	134.36	4.42	4.15	3.65
	5-Year Low	15.73	3.14	2.69	2.51
	5-Year Median	38.95	3.67	3.26	3.16

As of 01/27/2020

Industry Analysis **Zacks Industry Rank:** Top 42% (107 out of 255)



Top Peers

ASLAN Pharmaceuticals Ltd. **(ASLN)**	Outperform
Eli Lilly and Company **(LLY)**	Outperform
Pfizer Inc. **(PFE)**	Outperform
AbbVie Inc. **(ABBV)**	Neutral
AstraZeneca PLC **(AZN)**	Neutral
Bayer Aktiengesellschaft **(BAYRY)**	Neutral
Jazz Pharmaceuticals PLC **(JAZZ)**	Neutral
Novartis AG **(NVS)**	Neutral

Industry Comparison Industry: Medical - Products

Industry Peers

	AGIO Neutral	X Industry	S&P 500	ABBV Neutral	ASLN Outperform	AZN Neutral
VGM Score	F	-	-	A	F	B
Market Cap	3.10 B	299.20 M	23.86 B	124.25 B	67.95 M	128.30 B
# of Analysts	6	2	13	3	3	5
Dividend Yield	0.00%	0.00%	1.81%	5.62%	0.00%	1.80%
Value Score	F	-	-	B	F	C
Cash/Price	0.14	0.07	0.04	0.09	0.11	0.04
EV/EBITDA	-8.05	0.32	13.94	18.10	NA	19.69
PEG Ratio	NA	2.60	2.00	2.00	NA	1.45
Price/Book (P/B)	6.92	4.04	3.25	NA	5.15	9.39
Price/Cash Flow (P/CF)	NA	20.05	13.46	9.00	NA	15.22
P/E (F1)	NA	27.06	18.67	9.00	NA	23.40
Price/Sales (P/S)	27.58	5.25	2.62	3.78	NA	5.32
Earnings Yield	-12.05%	0.37%	5.35%	11.12%	-28.77%	4.27%
Debt/Equity	0.24	0.11	0.72	-4.03	1.12	1.29
Cash Flow ($/share)	-5.89	-0.00	6.92	9.34	-1.31	3.21
Growth Score	F	-	-	A	F	C
Hist. EPS Growth (3-5 yrs)	NA%	10.04%	10.68%	21.99%	NA	-2.47%
Proj. EPS Growth (F1/F0)	6.98%	13.55%	7.51%	4.63%	9.90%	15.09%
Curr. Cash Flow Growth	11.18%	5.21%	13.40%	33.63%	5.70%	-3.77%
Hist. Cash Flow Growth (3-5 yrs)	NA%	9.81%	8.78%	18.69%	NA	-5.68%
Current Ratio	5.30	2.77	1.22	1.15	1.88	0.92
Debt/Capital	19.43%	15.02%	42.92%	NA	52.85%	56.26%
Net Margin	-356.42%	-15.64%	11.39%	9.90%	NA	8.42%
Return on Equity	-70.07%	-6.74%	17.19%	-155.96%	-129.37%	38.63%
Sales/Assets	0.14	0.63	0.54	0.56	NA	0.40
Proj. Sales Growth (F1/F0)	34.58%	12.35%	4.09%	7.17%	290.00%	9.84%
Momentum Score	A	-	-	B	C	A
Daily Price Chg	-0.64%	-1.08%	-1.40%	0.57%	-2.75%	-0.77%
1 Week Price Chg	0.32%	-1.06%	-1.09%	-5.07%	-17.11%	-3.99%
4 Week Price Chg	9.86%	1.66%	-0.25%	-5.08%	4.43%	-2.22%
12 Week Price Chg	54.97%	4.55%	3.64%	1.24%	25.44%	1.64%
52 Week Price Chg	4.34%	3.51%	18.08%	8.92%	-40.45%	37.78%
20 Day Average Volume	752,212	155,196	1,615,215	7,843,008	490,805	2,058,981
(F1) EPS Est 1 week change	0.03%	0.00%	0.00%	-0.69%	0.00%	0.67%
(F1) EPS Est 4 week change	0.03%	0.00%	0.00%	-0.69%	0.00%	0.38%
(F1) EPS Est 12 week change	9.64%	-1.76%	-0.17%	-0.21%	26.61%	1.95%
(Q1) EPS Est Mthly Chg	1.46%	0.00%	0.00%	NA	0.00%	NA

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	F
Growth Score	F
Momentum Score	A
VGM Score	F

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.

Disclosures

This report contains independent commentary to be used for informational purposes only. The analysts contributing to this report do not hold any shares of this stock. The analysts contributing to this report do not serve on the board of the company that issued this stock.The EPS and revenue forecasts are the Zacks Consensus estimates, unless indicated otherwise on the reports first page. Additionally, the analysts contributing to this report certify that the views expressed herein accurately reflect the analysts personal views as to the subject securities and issuers. ZIR certifies that no part of the analysts compensation was, is, or will be, directly or indirectly, related to the specific recommendation or views expressed by the analyst in the report.

Additional information on the securities mentioned in this report is available upon request. This report is based on data obtained from sources we believe to be reliable, but is not guaranteed as to accuracy and does not purport to be complete. Any opinions expressed herein are subject to change.

ZIR is not an investment advisor and the report should not be construed as advice designed to meet the particular investment needs of any investor. Prior to making any investment decision, you are advised to consult with your broker, investment advisor, or other appropriate tax or financial professional to determine the suitability of any investment.This report and others like it are published regularly and not in response to episodic market activity or events affecting the securities industry.

This report is not to be construed as an offer or the solicitation of an offer to buy or sell the securities herein mentioned. ZIR or its officers, employees or customers may have a position long or short in the securities mentioned and buy or sell the securities from time to time.ZIR is not a broker-dealer.ZIR may enter into arms-length agreements with broker-dealers to provide this research to their clients.Zacks and its staff are not involved in investment banking activities for the stock issuer covered in this report.

ZIR uses the following rating system for the securities it covers. **Outperform-** ZIR expects that the subject company will outperform the broader U.S. equities markets over the next six to twelve months. **Neutral-** ZIR expects that the company will perform in line with the broader U.S. equities markets over the next six to twelve months. **Underperform-** ZIR expects the company will underperform the broader U.S. equities markets over the next six to twelve months.