Agios Pharmaceuticals (AGIO)

$50.81 (As of 07/14/20)

Price Target (6-12 Months): **$54.00**

Long Term: 6-12 Months	**Zacks Recommendation:** (Since: 06/15/20) Prior Recommendation: Outperform	**Neutral**
Short Term: 1-3 Months	**Zacks Rank:** (1-5)	**3-Hold**
	Zacks Style Scores:	VGM:D
	Value: F | Growth: C | Momentum: A	

Summary

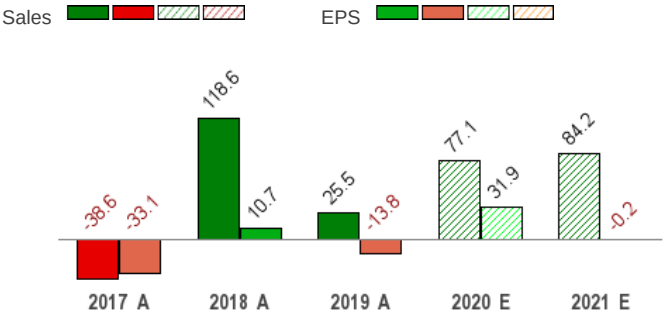
Agios' leukemia drug Tibsovo has been performing steadily since its launch and driving growth. The drug's label expansion studies are also advancing well with the FDA granting a nod in the first-line setting in 2019. Moreover, Tibsovo is under review in the EU wherein a tentative approval will further boost growth. Agios' progress with its pipeline looks impressive too. Agios' collaboration agreements look lucrative as it gets regular funds and royalties from sales. However, Agios' heavy dependence on Celgene for royalties remains a constant worry. It is also facing adversities from the COVID-19 pandemic with several data readouts now being delayed. Stiff competition is another matter of concern. Shares of the company have outperformed the industry in the year so far.

Price, Consensus & Surprise

Data Overview

52 Week High-Low	**$56.75 - $27.77**
20 Day Average Volume (sh)	**643,977**
Market Cap	**$3.5 B**
YTD Price Change	**6.4%**
Beta	**2.14**
Dividend / Div Yld	**$0.00 / 0.0%**
Industry	**Medical - Products**
Zacks Industry Rank	**Bottom 43% (144 out of 251)**
Last EPS Surprise	**65.3%**
Last Sales Surprise	**182.2%**
EPS F1 Est- 4 week change	**-1.2%**
Expected Report Date	**08/06/2020**
Earnings ESP	**1.4%**
P/E TTM	**NA**
P/E F1	**NA**
PEG F1	**NA**
P/S TTM	**20.0**

Sales and EPS Growth Rates (Y/Y %)



Sales Estimates (millions of $)

	Q1	Q2	Q3	Q4	Annual*
2021	35 E	38 E	41 E	41 E	385 E
2020	87 A	35 E	42 E	45 E	209 E
2019	30 A	26 A	26 A	35 A	118 A

EPS Estimates

	Q1	Q2	Q3	Q4	Annual*
2021	-$1.22 E	-$1.27 E	-$1.24 E	-$1.25 E	-$4.68 E
2020	-$0.59 A	-$1.42 E	-$1.32 E	-$1.42 E	-$4.67 E
2019	-$1.59 A	-$1.87 A	-$1.81 A	-$1.60 A	-$6.86 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 07/14/2020. The reports text is as of 07/15/2020.

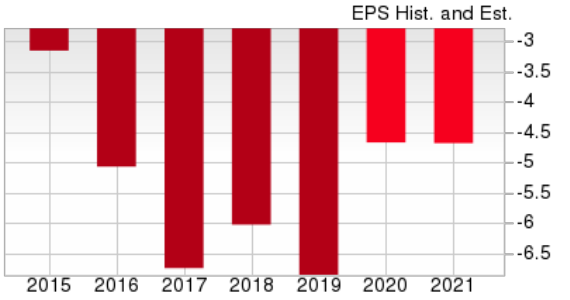
Overview

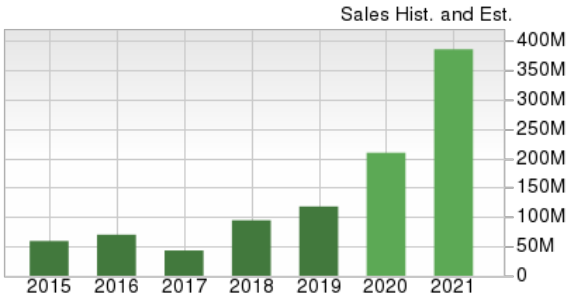
Cambridge, MA-based Agios Pharmaceuticals, Inc. is a development-stage biopharmaceutical company focused on development of treatments for cancer and rare genetic metabolic disorders, a subset of orphan genetic metabolic diseases.

In July 2018, Agios' wholly owned product Tibsovo, an IDHm inhibitor, received FDA approval for relapsed/refractory acute myeloid leukemia (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 with a decision expected by 2020 end. Last June, Agios out-licensed rights to market Tibsovo in China to CStone Pharmaceuticals for the given indication. Tibsovo recorded sales of 59.9 million in 2019.

Agios developed another product, Idhifa, in collaboration with partner Celgene Corporation, a wholly owned subsidiary of Bristol-Myers Squibb Company. 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.

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' rare genetic diseases candidate, mitapivat, is being developed for treating patients with (PK) deficiency. The company's other pipeline candidates are vorasidenib and AG-270, which are being developed for various cancer indications.

In 2019, the company generated $117.9 million in total revenues, reflecting a rise of 24.9% year over year.

Reasons To Buy:

> FDA approval of leukemia drug Tibsovo was a huge boost for Agios. The drug's label expansion studies are also advancing well.

- **Shares Outperforming Industry:** Shares of Agios have outperformed its industry year to date.

- **Tibsovo Approval, a Huge Boost:** The FDA approval of Tibsovo in July 2018 offered a huge boost to 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, which generates substantial product sales. Tibsovo contributed to around 50% of Agios' total revenues in 2019.

  The drug is also under review in the EU for the same indication with a decision expected by the end of 2020 wherein a tentative approval will further boost growth.

- **Tibsovo Label Expansion Studies Promising:** 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.

  Meanwhile, Tibsovo is 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 2021. 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 the above indication by the end of 2020 and mid-2021.

  Meanwhile, last December, the FDA granted Breakthrough Therapy designation to Tibsovo for treating relapsed/refractory myelodysplastic syndrome (MDS) in adult patients with a susceptible IDH1 mutation. Enrollment completion in this study is expected in 2021.

- **Strong Pipeline:** Agios' rare genetic diseases candidate, mitapivat, is being developed for treating patients with (PK) deficiency. It is conducting the single-arm ACTIVATE-T study for addressing PK in patients who are on regular blood transfusions, and also the ACTIVATE study for treating PK deficiency in patients with no regular blood transfusions. Top-line data from both studies is awaited between 2020 end and mid-2021. Agios also completed enrollment in the phase II DRIVE PK study on mitapivat for transfusion-independent adult patients with PK deficiency.

  Agios' other product candidates are vorasidenib and AG-270. The company is currently enrolling patients in the registration-enabling phase III INDIGO study on vorasidenib for treating Grade 2 non-enhancing glioma with an IDH1or IDH 2 mutation.

  AG-270 is being developed in a phase I study for addressing multiple tumor types carrying methylthioadenosine phosphorylase (MTAP)-deleted tumors. Moreover, in March 2020, the FDA cleared an investigational new drug (IND) application for AG-946, a next-generation pyruvate kinase-R (PKR) activator. A phase I study on the same is expected to start in mid-2020.

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

- **Solid Royalties from Celgene:** 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 2019, Agios earned $39.3 million from Celgene as collaboration revenues and $10.5 million as royalties on Idhifa sales.

- **Favorable Debt Profile:** Agios has a favorable debt profile. As of Mar 31, 2020, the company's total debt (current and long-term debt) was approximately $111 million. The company's cash, cash equivalents, and marketable securities were approximately $529 million, as of the end of March 2020. Hence the company has enough resources to pay off its total debt. Agios is less likely to file for bankruptcy in case of insolvency. The company's debt to capital ratio of 15.1 at the end of March 31, 2020 has increased only slightly from 15.0 at the end of December 31, 2019.

Reasons To Sell:

- **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.

  In the first quarter of 2020, Agios discontinued the in-house development of AG-636, which was in phase I developmentfor treating advanced lymphoma due to limited enrollment. Similar setbacks in the future will hurt the stock significantly.

> 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 April 2016 hence Agios no longer receives payments from Celgene with respect to extensions of the discovery phase under the agreement. Meanwhile, in December 2019, Celgene withdrew the marketing application for Idhifa in Europe.

  In March 2020, Celgene declined to extend the metabolic immuno-oncology research collaboration with Agios. Further, it decided not to exercise its option to gain the rights to AG-270, which is currently being evaluated in a phase I study as a combo regime with taxane-based therapy to potentially treat methylthioadenosine phosphorylase (MTAP)-deleted non-small cell lung cancer and pancreatic cancer.

  Notably, 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' Q1 Loss Narrower Than Expected, Revenues Beat

Quarter Ending	03/2020
Report Date	**Apr 30, 2020**
Sales Surprise	**182.24%**
EPS Surprise	**65.29%**
Quarterly EPS	**-0.59**
Annual EPS (TTM)	**-5.87**

Agios reportedfirst-quarter 2020 loss of 59 cents per share, much narrower than the Zacks Consensus Estimate of a loss of $1.70 as well as the year-ago loss of $1.59.

Total revenues of $87.1 million were above the Zacks Consensus Estimate of $31 million. The top line also grew significantly year over year, mainly owing to increased collaboration revenues and product sales.

Tibsovo generated sales of $22.7 million in the first quarter, reflecting a sequential increase of 15.8%. The growth in Tibsovo sales was on a strong uptake of the drug in both the newly-diagnosed and relapsed and refractory AML setting.

Royalty revenues earned from Celgene, now part of Bristol-Myers, were $3.3 million on Idhifa net sales in the reported quarter.

Collaboration revenues were $61.1 million in the quarter compared with $18.9 million in the year-ago quarter. This huge surge in collaboration revenues was attributable to Agios' recognition of the majority of deferred revenues under its collaboration with Celgene during the first quarter of 2020.

Research & development expenses declined 4.5% year over year to $91.3 million due to ramped-down activity of clinical studies for pipeline development.

General and administrative expenses increased 21.1% year over year to $38.5 million on account of higher personnel costs.

Agios ended the first quarter with cash, cash equivalents and marketable securities of $613.1 million, lower than the sequential quarter's $717.8 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 June 2022.

Meanwhile, due to the coronavirus (COVID-19) pandemic, Agios expects some delays in its clinical programs and patient enrollment in studies. Several important data readouts and enrollment completion in studies are now expected by the end of 2020 and mid-2021, which was earlier planned by the end of 2020.

Recent News

Proof-of-Concept Established in Sickle Cell Disease Study on Mitapivat – Jun 12

Agios announced that based on a preliminary analysis, clinical proof-of-concept has been established in the phase I study on mitapivat for patients with sickle cell disease.

Divests Idhifa Royalty Rights to Royalty Pharma – Jun 12

Agios announced that it has sold tiered, sales-based royalty rights on worldwide net sales of Bristol Myers' Idhifa along with rights to receive up to $55 million in outstanding regulatory milestone payments from the latter, to Royalty Pharma for $255 million.

Orphan Drug Tag for Mitapivat to Treat Thalassemia – Jun 8

Agios announced that the FDA has granted an orphan drug designation to its first-in-class pyruvate kinase-R (PKR) activator mitapivat for the treatment of patients with thalassemia. The candidate is an investigational, oral, small molecule allosteric activator of wild-type and a variety of mutated PKR enzymes.

Gets Positive Opinion on Orphan Drug Tag for Mitapivat - Mar 30

Agios announced that the European Medicines Agency's (EMA) Committee for orphan medicinal products rendered a positive opinion on the application for orphan drug designation for Agios' investigational medicine mitapivat as a potential treatment for pyruvate kinase (PK) deficiency.

Update on Agreement with Celgene (now part of Bristol Myers) - Mar 25

Agios announced that it has updated its collaboration agreement with Celgene, a wholly owned subsidiary of Bristol Myers, who has now declined to exercise its option to gain right for AG-270, currently in a phase I study in combination with taxane-based therapy as a potential treatment for methylthioadenosine phosphorylase (MTAP)-deleted non-small cell lung cancer and pancreatic cancer.

Gets FDA Clearence for AG-946 - Mar 23

Agios announced that the FDA has cleared the investigational new drug (IND) application for AG-946, a next-generation pyruvate kinase-R (PKR) activator. The company plans to begin a phase I study on AG-946 in mid-2020.

Valuation

Agios' shares are up 6.4% in the year-to-date period and 8% over the trailing 12-month period. Stocks in the Zacks sub-industry and the Zacks Medical sector are down 9.1% and 2.6% in the year-to-date period, respectively. Over the past year, the Zacks sub-industry is down 6.9% while the sector is up 3%.

The S&P 500 index is down 1.8% in the year-to-date period but up 5.7% in the past year.

The stock is currently trading at 5.60X trailing 12-month book value, which compares to 2.84X for the Zacks sub-industry, 4.25X for the Zacks sector and 4.32X for the S&P 500 index.

Over the past five years, the stock has traded as high as 11.25X and as low as 2.90X, with a 5-year median of 5.51X. Our Neutral recommendation indicates that the stock will perform in-line with the market. Our $54.00 price target reflects, 5.95X 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	5.6	2.84	4.25	4.32
	5-Year High	11.25	3.48	5.07	4.56
	5-Year Low	2.9	2.2	2.94	2.83
	5-Year Median	5.51	2.8	4.29	3.7
P/S TTM	Current	19.95	3.66	2.99	3.38
	5-Year High	134.36	4.41	4.08	3.68
	5-Year Low	13.52	2.7	2.29	2.42
	5-Year Median	34.83	3.71	3.19	3.21

As of 07/14/2020

Industry Analysis **Zacks Industry Rank:** Bottom 43% (144 out of 251)

Top Peers

Company (Ticker)	Rec	Rank
Bayer Aktiengesellschaft **(BAYRY)**	Outperform	1
Eli Lilly and Company **(LLY)**	Outperform	1
AbbVie Inc. **(ABBV)**	Neutral	3
ASLAN Pharmaceuticals Ltd. **(ASLN)**	Neutral	3
AstraZeneca PLC **(AZN)**	Neutral	2
Jazz Pharmaceuticals PLC **(JAZZ)**	Neutral	3
Novartis AG **(NVS)**	Neutral	3
Pfizer Inc. **(PFE)**	Neutral	3

Industry Comparison Industry: Medical - Products

Industry Peers

	AGIO	X Industry	S&P 500	ABBV	ASLN	AZN
Zacks Recommendation (Long Term)	Neutral	-	-	Neutral	Neutral	Neutral
Zacks Rank (Short Term)	3	-	-	3	3	2
VGM Score	D	-	-	B	B	B
Market Cap	3.50 B	323.79 M	21.89 B	146.01 B	57.37 M	141.66 B
# of Analysts	6	3	14	4	2	5
Dividend Yield	0.00%	0.00%	1.86%	4.77%	0.00%	3.45%
Value Score	F	-	-	A	F	B
Cash/Price	0.15	0.11	0.07	0.29	0.28	0.03
EV/EBITDA	-7.57	0.10	12.84	14.07	-1.28	22.77
PEG Ratio	NA	5.33	2.92	2.13	NA	1.60
Price/Book (P/B)	5.60	3.30	3.06	NA	NA	11.60
Price/Cash Flow (P/CF)	NA	16.94	11.89	9.57	NA	17.04
P/E (F1)	NA	36.95	21.54	9.41	NA	26.57
Price/Sales (P/S)	20.03	5.15	2.27	4.29	NA	5.61
Earnings Yield	-9.19%	-0.53%	4.38%	10.62%	-21.79%	3.76%
Debt/Equity	0.17	0.10	0.76	-8.53	-4.58	1.32
Cash Flow ($/share)	-6.90	-0.01	6.94	10.33	-0.73	3.17
Growth Score	C	-	-	B	A	C
Hist. EPS Growth (3-5 yrs)	NA%	13.05%	10.85%	21.62%	NA	-2.89%
Proj. EPS Growth (F1/F0)	31.92%	5.88%	-9.64%	17.47%	47.30%	16.11%
Curr. Cash Flow Growth	18.64%	4.54%	5.51%	8.78%	-43.94%	2.12%
Hist. Cash Flow Growth (3-5 yrs)	NA%	7.87%	8.55%	19.92%	NA	-0.86%
Current Ratio	8.41	2.73	1.30	3.14	4.47	0.75
Debt/Capital	14.33%	14.48%	44.46%	NA	NA	56.87%
Net Margin	-205.20%	-25.53%	10.54%	24.77%	NA	5.94%
Return on Equity	-63.85%	-7.96%	15.75%	-169.80%	-643.33%	33.97%
Sales/Assets	0.22	0.54	0.54	0.46	NA	0.42
Proj. Sales Growth (F1/F0)	77.60%	0.00%	-2.52%	36.54%	0.00%	9.64%
Momentum Score	A	-	-	D	A	B
Daily Price Chg	0.81%	0.70%	1.60%	1.03%	0.56%	1.39%
1 Week Price Chg	-5.01%	-0.25%	-0.41%	-2.07%	-5.56%	-0.07%
4 Week Price Chg	4.81%	0.00%	-0.71%	2.93%	-6.28%	0.75%
12 Week Price Chg	11.92%	13.05%	15.18%	23.03%	0.00%	7.81%
52 Week Price Chg	8.01%	-3.33%	-6.45%	42.96%	-44.58%	34.28%
20 Day Average Volume	643,977	286,358	2,246,780	6,851,025	110,301	5,205,179
(F1) EPS Est 1 week change	0.00%	0.00%	0.00%	-0.32%	1.27%	0.20%
(F1) EPS Est 4 week change	-1.23%	0.00%	0.00%	-0.32%	1.27%	0.20%
(F1) EPS Est 12 week change	30.69%	-9.76%	-6.22%	3.37%	27.33%	1.09%
(Q1) EPS Est Mthly Chg	-1.15%	0.00%	0.00%	0.00%	4.76%	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	F
Growth Score	C
Momentum Score	A
VGM Score	D

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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