# Agios Pharmaceuticals (AGIO)

**$37.36** (As of 03/25/20)

Price Target (6-12 Months): **$39.00**

| | | |
|---|---|---|
| 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: D | |

## Summary

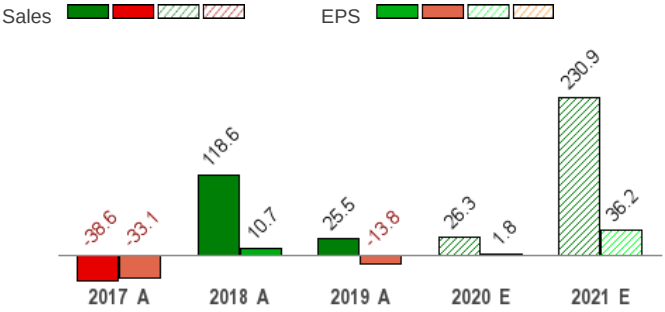
Agios's first wholly owned precision medicine Tibsovo has been performing steadily since its launch and driving growth. The drug's label expansion studies are also advancing well with the FDA granting a nod in the first-line setting in May 2019. Moreover, Tibsovo is under review in the EU wherein a tentative approval will further boost growth. Agios' progress with its pipeline candidates has been impressive too. Its collaboration with Celgene looks lucrative as the latter provides 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 | **$68.89 - $27.77** |
| 20 Day Average Volume (sh) | **767,921** |
| Market Cap | **$2.5 B** |
| YTD Price Change | **-24.4%** |
| Beta | **2.30** |
| Dividend / Div Yld | **$0.00 / 0.0%** |
| Industry | **Medical - Products** |
| Zacks Industry Rank | **Top 19% (49 out of 254)** |
| Last EPS Surprise | **10.1%** |
| Last Sales Surprise | **14.0%** |
| EPS F1 Est- 4 week change | **-0.2%** |
| Expected Report Date | **05/07/2020** |
| Earnings ESP | **1.8%** |
| P/E TTM | **NA** |
| P/E F1 | **NA** |
| PEG F1 | **NA** |
| P/S TTM | **21.0** |

## Sales and EPS Growth Rates (Y/Y %)




## Sales Estimates (millions of $)

| | Q1 | Q2 | Q3 | Q4 | Annual* |
|---|---|---|---|---|---|
| 2021 | 38 E | 41 E | 74 E | 99 E | 493 E |
| 2020 | 31 E | 36 E | 39 E | 43 E | 149 E |
| 2019 | 30 A | 26 A | 26 A | 35 A | 118 A |

## EPS Estimates

| | Q1 | Q2 | Q3 | Q4 | Annual* |
|---|---|---|---|---|---|
| 2021 | -$1.60 E | -$1.70 E | -$1.25 E | -$1.05 E | -$4.30 E |
| 2020 | -$1.70 E | -$1.73 E | -$1.70 E | -$1.80 E | -$6.74 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 03/25/2020. The reports text is as of 03/26/2020.

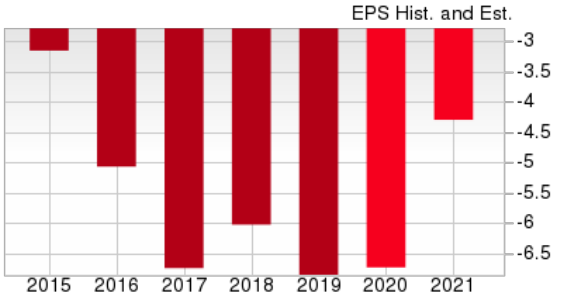
## Overview

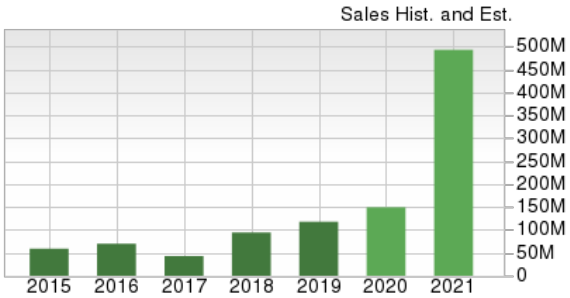
Cambridge, MA-based Agios Pharmaceuticals, Inc. is a development-stage biopharmaceutical company focused on development of treatments for cancer and rare genetic metabolic disorders, a subset of orphan genetic metabolic diseases.

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 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' other pipeline candidates are vorasidenib, AG-270 and AG-636 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 company's collaboration with Celgene is also encouraging.

- **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 in the second half of 2020.

- **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 2020. 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. 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.

- **Strong Pipeline:** Agios' rare genetic diseases candidate, mitapivat, is being developed for treating patients with (PK) deficiency. The company completed enrollment in two pivotal studies on mitapivat. 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 closed enrollment in the phase II DRIVE PK study on mitapivat in transfusion-independent adult patients with PK deficiency.

  Agios' other product candidates are vorasidenib, AG-270 and AG-636. 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 IDH1 mutation. Meanwhile, AG-636 is being evaluated in a phase I dose escalation study for treating advanced lymphoma.

  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 is expected to start in mid-2020.

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

- **Strong Partner in 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

## Reasons To Sell:

- **Shares Underperforming Industry:** Shares of Agios have lagged its industry in the past year. The stock has lost 45.3% versus the industry's decline of 23.3%.

- **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. 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 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' Q4 Loss Narrower Than Expected, Revenues Beat**

| Quarter Ending | 12/2019 |
|---|---|
| Report Date | **Feb 13, 2020** |
| Sales Surprise | **13.97%** |
| EPS Surprise | **10.11%** |
| Quarterly EPS | **-1.60** |
| Annual EPS (TTM) | **-6.87** |

Agios reported fourth-quarter 2019 loss of $1.60 per share, narrower than the Zacks Consensus Estimate of a loss of $1.78 but slightly wider than the year-ago loss of $1.58.

Total revenues in the reported quarter were $35.4 million, higher than the Zacks Consensus Estimate of $31 million. Moreover, revenues grew 18% on a year-over-year basis. The year-over-year top-line growth is driven by a strong uptake of Tibsovo in the frontline and relapsed/refractory acute myeloid leukemia (AML) settings. The drug generated sales worth $19.6 million in the fourth quarter, reflecting a sequential rise of 12.6%.

Royalty revenues earned from Celgene were $3 million on Idhifa net sales in the reported quarter while collaboration revenues were $12.9 million.

Research & development expenses rose 13.2% year over year to $106.2 million, largely due to higher cost of late-stage clinical studies for pipeline development.

General and administrative expenses increased 9.1% year over year to $34.8 million in the quarter on account of higher investments and personnel costs.

Agios ended the fourth quarter with cash, cash equivalents and marketable securities of $717.8 million, lower than the sequential quarter's level of $540.5 million. The company expects this cash balance and revenues recognized from Tibsovo as well as royalties to effectively fund its current operational plans for at least through the end of 2021.

## Recent News

**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.

**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 down 24.4% in the year-to-date period and 45.3% over the trailing 12-month period. Stocks in the Zacks sub-industry and the Zacks Medical sector are down 25.8% and 21% in the year-to-date period, respectively. Over the past year, the Zacks sub-industry is down 23.3% and the sector is down 21.4%.

The S&P 500 index is down 30.2% in the year-to-date period and down 21.1% in the past year.

The stock is currently trading at 3.32X trailing 12-month book value, which compares to 2.40X for the Zacks sub-industry, 2.99X for the Zacks sector and 3.30X 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 5.61X. Our Neutral recommendation indicates that the stock will perform in-line with the market. Our $39.00 price target reflects, 3.58X 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 | 3.32 | 2.4 | 2.99 | 3.3 |
| | 5-Year High | 11.25 | 4.3 | 5.05 | 4.56 |
| | 5-Year Low | 2.9 | 2.18 | 2.8 | 2.85 |
| | 5-Year Median | 5.61 | 2.77 | 4.3 | 3.63 |
| P/S TTM | Current | 19.57 | 3.07 | 2.55 | 2.65 |
| | 5-Year High | 134.36 | 4.34 | 4.17 | 3.69 |
| | 5-Year Low | 15.73 | 2.79 | 2.38 | 2.43 |
| | 5-Year Median | 37.49 | 3.66 | 3.28 | 3.19 |

As of 03/24/2020

## Industry Analysis **Zacks Industry Rank:** Top 19% (49 out of 254)


## Top Peers

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

## Industry Comparison Industry: Medical - Products

Industry Peers

| | AGIO Neutral | X Industry | S&P 500 | ABBV Neutral | ASLN Neutral | AZN Neutral |
|---|---|---|---|---|---|---|
| **VGM Score** | F | - | - | A | F | C |
| Market Cap | 2.47 B | 264.04 M | 17.21 B | 99.66 B | 31.40 M | 107.31 B |
| # of Analysts | 6 | 2 | 13 | 2 | 1 | 5 |
| Dividend Yield | 0.00% | 0.00% | 2.52% | 6.99% | 0.00% | 4.55% |
| **Value Score** | F | - | - | B | F | C |
| Cash/Price | 0.25 | 0.11 | 0.07 | 0.39 | 0.69 | 0.06 |
| EV/EBITDA | -4.95 | 0.53 | 10.28 | 10.27 | NA | 17.39 |
| PEG Ratio | NA | 2.22 | 1.56 | 1.42 | NA | 1.25 |
| Price/Book (P/B) | 3.32 | 2.71 | 2.27 | NA | NA | 7.35 |
| Price/Cash Flow (P/CF) | NA | 13.97 | 9.16 | 6.53 | NA | 12.91 |
| P/E (F1) | NA | 22.49 | 13.51 | 6.41 | NA | 20.26 |
| Price/Sales (P/S) | 20.97 | 3.96 | 1.74 | 3.00 | NA | 4.40 |
| Earnings Yield | -18.68% | 0.00% | 7.33% | 15.59% | -51.02% | 4.94% |
| Debt/Equity | 0.17 | 0.12 | 0.70 | -7.71 | -30.05 | 1.11 |
| Cash Flow ($/share) | -6.90 | -0.00 | 7.01 | 10.33 | -1.31 | 3.17 |
| **Growth Score** | F | - | - | B | F | D |
| Hist. EPS Growth (3-5 yrs) | NA% | 11.68% | 10.85% | 21.82% | NA | -2.79% |
| Proj. EPS Growth (F1/F0) | 1.77% | 9.51% | 3.92% | 17.73% | 25.74% | 15.31% |
| Curr. Cash Flow Growth | 18.64% | 3.94% | 5.93% | 8.78% | 5.70% | 2.12% |
| Hist. Cash Flow Growth (3-5 yrs) | NA% | 7.71% | 8.55% | 19.92% | NA | -0.86% |
| Current Ratio | 6.59 | 2.59 | 1.23 | 3.18 | 4.14 | 0.86 |
| Debt/Capital | 14.28% | 15.15% | 42.57% | NA | 52.85% | 52.63% |
| Net Margin | -348.97% | -15.25% | 11.64% | 23.69% | NA | 5.38% |
| Return on Equity | -73.42% | -10.96% | 16.74% | -162.54% | -129.37% | 32.24% |
| Sales/Assets | 0.15 | 0.61 | 0.54 | 0.51 | NA | 0.40 |
| Proj. Sales Growth (F1/F0) | 26.63% | 5.32% | 2.57% | 43.93% | 290.00% | 9.61% |
| **Momentum Score** | D | - | - | B | A | A |
| Daily Price Chg | 6.02% | 4.67% | 11.24% | 4.64% | -0.02% | 5.44% |
| 1 Week Price Chg | -10.17% | -6.21% | -16.96% | -19.39% | -17.36% | -6.76% |
| 4 Week Price Chg | -22.74% | -22.22% | -26.70% | -24.32% | -51.50% | -13.15% |
| 12 Week Price Chg | -24.42% | -22.29% | -30.27% | -23.78% | -51.73% | -17.99% |
| 52 Week Price Chg | -45.26% | -30.53% | -21.88% | -16.43% | -76.51% | -4.77% |
| 20 Day Average Volume | 767,921 | 276,042 | 4,249,353 | 16,558,661 | 171,363 | 6,130,093 |
| (F1) EPS Est 1 week change | 0.00% | 0.00% | -0.11% | 0.00% | 0.00% | 0.00% |
| (F1) EPS Est 4 week change | -0.17% | -0.02% | -1.58% | 0.00% | 17.58% | 0.00% |
| (F1) EPS Est 12 week change | -6.14% | -2.06% | -2.61% | 11.91% | 17.58% | -3.07% |
| (Q1) EPS Est Mthly Chg | 0.44% | 0.00% | -1.24% | 0.00% | 25.93% | 0.00% |

## 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 | D |
| 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

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