

Agios Pharmaceuticals

AG-221 Interim Phase 1 Data Robust and De-risking; Upgrading to Overweight

We are upgrading AGIO shares to Overweight from Neutral and increasing our Dec 2014 price target to \$55 from \$40. In our view, the interim phase 1 data presented at the AACR meeting yesterday were substantially de-risking for AG-221 (IDH2 program) and the broader technology platform, particularly for AG-120 (IDH1 program). Our prior Neutral rating on AGIO shares reflected a hesitation to ascribe a clinical stage valuation based on strong pre-clinical data. With robust interim phase 1 data on AG-221, however, the risk profile declines rather dramatically and the addressable markets are much more evaluable, which merits an Overweight rating, in our view. These AG-221 data are now the first clinical data to support what we had already considered to be very strong science at Agios; the fact that 6/7 evaluable patients achieved a clinical response, with the majority being complete responses, was well ahead of expectations. Indeed, physician commentary at AACR has been very encouraging. With no dose limiting toxicities (DLTs) reached yet, key questions will shift to duration of therapy, dosing regimen, next steps for the programs, and away from clinical proof-of-concept. In this note, we are introducing our AG-221 revenue models; we estimate that the agent could peak at \$1B globally, which increases to \$3B+ for the company's total oncology program (i.e., inclusion of AG-120).

- **Key takeaways from Agios analyst event:** Additional points on responses - The responses in the study were evaluated by investigators only, given in phase 1 trials robust responses are not expected. That said, it is likely that a centralized review will be part of the protocol in later assessments. It was also noted that in the 6 patients with responses, neutrophils normalized in all patients. Duration of therapy - Our sense is that in future cohorts the company will try to maximize duration of response, by enrolling patients that are not eligible for transplant or had received a prior transplant. Sepsis related death - We spoke to an investigator in the study who noted that sepsis / infection is a very common manifestation of acute leukemias. The investigator was not concerned about this AE in the study. IDH2 mutation prevalence - Lead investigator Dr. Eytan Stein (MSKCC) noted that with increased testing of IDH2 mutation, he expects the prevalence of the mutation to increase.

▲ Overweight

Previous: Neutral

AGIO, AGIO US

Price: \$35.48

▲ Price Target: \$55.00

Previous: \$40.00

Biotechnology

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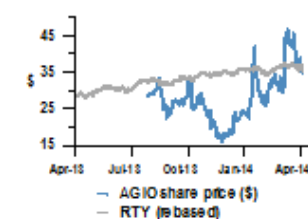
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Price Performance



Agios Pharmaceuticals (AGIO;AGIO US)

FYE Dec	2013A	2014E	2015E
Analyst Adjusted Diluted EPS (\$)			
Q1 (Mar)	(0.39)	(0.28)	-
Q2 (Jun)	(2.74)	(0.32)	-
Q3 (Sep)	(0.48)	(0.36)	-
Q4 (Dec)	(0.40)	(0.37)	-
FY	(2.83)	(1.33)	(0.51)

Source: Company data, Bloomberg, J.P. Morgan estimates.

Company Data

Price (\$)	35.48
Date Of Price	04 Apr 14
52-week Range (\$)	49.79-15.77
Market Cap (\$ mn)	1,105.31
Fiscal Year End	Dec
Shares O/S (mn)	31
Price Target (\$)	55.00
Price Target End Date	31-Dec-14

See page 7 for analyst certification and important disclosures.

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- **Efficacy:** As we had expected, there was rapid and robust inhibition of 2-HG in the phase 1 trials, which we believe would have established proof-of-concept alone. Indeed, there was pre-clinical data to support this. The major surprise in the study was the early clinical response rate, which beat expectations (6/7 patients with a clinical response). Indeed, responses occurred early in many patients (30mg BID dose: 1 CR and 1 CRp; 50mg BID: 2 CRs, 1 CPr, and 1 PR). Importantly, we note, both the lead investigator and the discussant of the study highlighted the R/R AML patients enrolled in the study would have had very poor outcomes with current standard of care.
- **Safety:** Overall, we do not have any major safety concerns. On the safety side, there has been no dose limited toxicities to date and AG-221 has been well-tolerated. As of March 20th, 22 patients have enrolled the study with 16 patients still on study. There were 4 deaths in the study and all were related to disease related sepsis and occurred in cycle 1 (3 in cohort 1 and 1 in cohort 4). Of note, Grade 2 AEs included hyperleukocytosis / differentiation syndrome, while Grade 3 AEs included confusion / respiratory failure due to sepsis.
- **Market estimates:** We are introducing our revenue builds for AG-221 and AG-120. We assume a price of \$15k/cycle, which is slightly ahead of Pomalyst, and very conservatively assume duration of therapy between 8-10 cycles. Of note, we do not include AG-348 in PK Deficiency in our model. AG-221 – We assume a global launch in the 2017/2018 timeframe and that Celgene opts in upon MTD being established. We estimate peak AG-221 sales of \$990M, with Agios receiving ~\$150M in peak royalties (assume 15% royalty rate; see Table 1). AG-120 – Recall, Agios has already opted into US rights for AG-120 and we assume Celgene will opt into OUS rights. We assume a global launch in the 2018/2019 timeframe. We estimate peak AG-120 sales of \$2.1B, with Agios retaining \$950M at peak in the US, plus an additional ~\$135M in royalties on OUS sales (assumes a 12.5% OUS royalty rate; see Table 2).
- **Valuation:** We are changing our valuation methodology for Agios from a comparable companies analysis to NPV / SOTP. We project sales for AG-221 and AG-120 through to 2027, assume no terminal value, and an 8% discount rate. We further assume a 70% probability of success for AG-221 and 50% for AG-120. We believe these estimates accurately reflect the data reported at AACR, the company's innovative science, with the relatively early stage of the company's pipeline. We derive a value of \$7/sh for AG-221, \$15/sh for the US rights to AG-120, and \$3/sh for the OUS rights (assuming Celgene exercises its opt-in). These valuations, taken in combination with \$26/sh for the technology platform and net cash of \$4/sh, support our December 2014 PT of \$55.
- **Upgrading to Overweight from Neutral.** Increasing December 2014 PT to \$55 from \$40.

Table 1: AG-221 Revenue Build

	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
AML and MPD population w/IDH2	9200	9292	9385	9479	9574	9669	9766	9864	9962	10062	10163
AG-221 penetration	5%	10%	20%	30%	35%	40%	45%	50%	55%	60%	65%
Total # of patients on therapy	460	929	1877	2844	3351	3868	4395	4932	5479	6037	6606
Price	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000
Cycles	10	10	10	10	10	10	10	10	10	10	10
Total cost	\$150,000	\$150,000	\$150,000	\$150,000	\$150,000	\$150,000	\$150,000	\$150,000	\$150,000	\$150,000	\$150,000
AG-221 Sales (in millions)	\$69	\$139	\$282	\$427	\$503	\$580	\$659	\$740	\$822	\$906	\$991
Royalty to Agios	\$10	\$21	\$42	\$64	\$75	\$87	\$99	\$111	\$123	\$136	\$149

Source: J.P. Morgan estimates.

Table 2: AG-120 Revenue Build

AG-120 (IDH1): Hematology

US / Eu / Japan IDH1 Populaton

	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
WW AML and MPD populaton w/IDH1	5600	5656	5713	5770	5827	5886	5945	6004	6064	6125	6186
WW% refractory	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%
WW Addressable patient population	3360	3394	3428	3462	3496	3531	3567	3602	3638	3675	3712
US		1357	1371	1385	1399	1413	1427	1441	1455	1470	1485
AG-120 penetration		5%	10%	20%	30%	35%	40%	45%	50%	55%	60%
Total # of patients on therapy		68	343	692	1049	1236	1427	1621	1819	2021	2227
Price		\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000
Cycles		8	8	8	8	8	8	8	8	8	8
Total cost		\$120,000	\$120,000	\$120,000	\$120,000	\$120,000	\$120,000	\$120,000	\$120,000	\$120,000	\$120,000
US AG-120 Sales (in millions)		\$8	\$41	\$83	\$126	\$148	\$171	\$195	\$218	\$243	\$267
EU / Japan		2036	2057	2077	2098	2119	2140	2161	2183	2205	2227
AG-120 penetration			5%	10%	20%	30%	35%	40%	45%	50%	55%
Total # of patients on therapy			103	208	420	636	749	865	982	1102	1225
Price			\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000
Cycles			8	8	8	8	8	8	8	8	8
Total cost			\$120,000	\$120,000	\$120,000	\$120,000	\$120,000	\$120,000	\$120,000	\$120,000	\$120,000
ROW AG-120 Sales (in millions)			\$12	\$25	\$50	\$76	\$90	\$104	\$118	\$132	\$147
Royalty to Agios			\$2	\$3	\$6	\$10	\$11	\$13	\$15	\$17	\$18
WW AG-120 Hematology Sales (in millions)		\$8	\$53	\$108	\$176	\$225	\$261	\$298	\$336	\$375	\$414
AG-120 Hematology Sales to Agios		\$8	\$43	\$86	\$132	\$158	\$182	\$207	\$233	\$259	\$286

AG-120 (IDH1): Solid Tumor

US / Eu / Japan IDH1 Populaton

	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027
WW Glioma w/IDH1	11000	11110	11221	11333	11447	11561	11677	11793	11911	12031	12151
WW Cholangiocarcinoma w/IDH1	1600	1616	1632	1648	1665	1682	1698	1715	1733	1750	1767
WW Chondrosarcoma w/IDH1	4600	4646	4692	4739	4787	4835	4883	4932	4981	5031	5081
WW Addressable populaton	17200	17372	17546	17721	17898	18077	18258	18441	18625	18811	19000
US		6949	7018	7088	7159	7231	7303	7376	7450	7525	7600
AG-120 penetration		5%	10%	20%	30%	35%	40%	45%	50%	55%	60%
Total # of patients on therapy		347	702	1418	2148	2531	2921	3319	3725	4139	4560
Price		\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000
Cycles		10	10	10	10	10	10	10	10	10	10
Total cost		\$150,000	\$150,000	\$150,000	\$150,000	\$150,000	\$150,000	\$150,000	\$150,000	\$150,000	\$150,000
US AG-120 Sales (in millions)		\$52	\$105	\$213	\$322	\$380	\$438	\$498	\$559	\$621	\$684
EU / Japan			10527	10633	10739	10846	10955	11064	11175	11287	11400
AG-120 penetration			5%	10%	20%	30%	35%	40%	45%	50%	55%
Total # of patients on therapy			526	1063	2148	3254	3834	4426	5029	5643	6270
Price			\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000	\$15,000
Cycles			10	10	10	10	10	10	10	10	10
Total cost			\$150,000	\$150,000	\$150,000	\$150,000	\$150,000	\$150,000	\$150,000	\$150,000	\$150,000
ROW AG-120 Sales (in millions)			\$79	\$159	\$322	\$488	\$575	\$664	\$754	\$847	\$940
Royalty to Agios			\$10	\$20	\$40	\$61	\$72	\$83	\$94	\$106	\$118
WW AG-120 Solid Tumor Sales (in millions)		\$52	\$184	\$372	\$644	\$868	\$1,013	\$1,162	\$1,313	\$1,467	\$1,624
Total AG-120 Solid Tumor Sales to Agios		\$52	\$115	\$233	\$362	\$441	\$510	\$581	\$653	\$727	\$802
Total AG-120 Sales (in millions)		\$60	\$238	\$480	\$821	\$1,092	\$1,274	\$1,460	\$1,649	\$1,842	\$2,039
Total AG-120 Cashflows to Agios (in millions)		\$60	\$158	\$319	\$495	\$598	\$693	\$788	\$886	\$986	\$1,087

Source: J.P. Morgan estimates.

Investment Thesis, Valuation and Risks

Agios Pharmaceuticals (*Overweight; Price Target: \$55.00*)

Investment Thesis

Agios's core science focuses on identifying drug targets in dysregulated metabolic pathways. In particular, with the use of high-throughput mass spectrometry and the "flux biochemistry" approach, many drug targets have been identified that modulate critical biological pathways. Indeed, the science appears very strong to us. The company's three lead assets are early stage: AG-221 (IDH2m inhibitor) and AG-120 (IDH1m inhibitor), both for oncology indications, and AG-348 (PKR activator), for an orphan disease known as pyruvate kinase deficiency. Importantly, positive early data at AACR 2014 for AG-221 de-risk not only this asset but also AG-120, as well as the broader technology platform, in our view. Our Overweight rating is based on strong science that has now been translated to the clinic.

Valuation

We are increasing our December 2014 price target to \$55 from \$40. Our \$55 December 2014 price target for AGIO is based on our sum-of-the-parts analysis of AG-221, AG-120, the platform technology/IP and cash. We project sales for AG-221 and AG-120 through to 2027, assume no terminal value, and an 8% discount rate. We further assume a 70% probability of success for AG-221 and 50% for AG-120. We believe these estimates accurately reflect the data reported at AACR, the company's innovative science, with the relatively early stage of the company's pipeline. We derive a value of \$7/sh for AG-221, \$15/sh for the US rights to AG-120, and \$3/sh for the OUS rights (assuming Celgene exercises its opt-in). These valuations, taken in combination with \$26/sh for the technology platform and net cash of \$4/sh, support our December 2014 PT of \$55.

Risks to Rating and Price Target

Downside risks include 1) failure to show differentiated therapeutic benefit of lead assets or trial failure in later-stage trials (AG-221, AG-120, and AG-348), 2) FDA requires long development pathway, 3) while in the out-years, limited market uptake, and 4) out-year financing risk.

Agios Pharmaceuticals: Summary of Financials

Income Statement - Annual	FY13A	FY14E	FY15E	FY16E	Income Statement - Quarterly	1Q14E	2Q14E	3Q14E	4Q14E
Revenues	26	36	66	31	Revenues	9	9	9	9
Cost of products sold	0	0	0	0	Cost of products sold	0	0	0	0
Gross profit	-	-	-	-	Gross profit	-	-	-	-
SG&A	(10)	(13)	(13)	(14)	SG&A	(3)	(3)	(3)	(3)
R&D	(55)	(67)	(71)	(74)	R&D	(15)	(16)	(18)	(18)
Operating income	(39)	(44)	(18)	(57)	Operating income	(9)	(11)	(12)	(13)
EBITDA	(39)	(44)	(18)	(57)	EBITDA	(9)	(11)	(12)	(13)
Net interest (income) / expense	(4)	(0)	1	1	Net interest (income) / expense	0	0	(0)	(0)
Other income / (expense)	-	-	-	-	Other income / (expense)	-	-	-	-
Income taxes	0	0	0	0	Income taxes	0	0	0	0
Net income - GAAP	(42)	(45)	(18)	(56)	Net income - GAAP	(9)	(10)	(12)	(13)
Net income - recurring	(42)	(45)	(18)	(56)	Net income - recurring	(9)	(10)	(12)	(13)
Diluted shares outstanding	15	34	35	36	Diluted shares outstanding	32	33	34	35
EPS - excluding non-recurring	(2.83)	(1.33)	(0.51)	(1.57)	EPS - excluding non-recurring	(0.28)	(0.32)	(0.36)	(0.37)
EPS - recurring	(2.83)	(1.33)	(0.51)	(1.57)	EPS - recurring	(0.28)	(0.32)	(0.36)	(0.37)
Balance Sheet and Cash Flow Data	FY13A	FY14E	FY15E	FY16E	Ratio Analysis	FY13A	FY14E	FY15E	FY16E
Cash and cash equivalents	180	132	115	-	Sales growth	1.8%	39.1%	84.4%	(52.2%)
Accounts receivable	-	-	-	-	EBIT growth	69.1%	14.0%	(58.7%)	210.0%
Inventories	-	-	-	-	EPS growth - recurring	139.9%	(53.1%)	(61.6%)	208.7%
Other current assets	2	1	2	-	Gross margin	-	-	-	-
Current assets	219	170	153	-	EBIT margin	(152.2%)	(124.7%)	(27.9%)	(181.3%)
PP&E	4	4	5	-	EBITDA margin	(152.2%)	(124.7%)	(27.9%)	(181.3%)
Total assets	226	174	158	-	Tax rate	(0.9%)	0.0%	0.0%	0.0%
Total debt	-	-	-	-	Net margin	(166.1%)	(125.7%)	(27.0%)	(179.3%)
Total liabilities	93	88	88	-	Net Debt / EBITDA	-	-	-	-
Shareholders' equity	133	86	70	-	Net Debt / Capital (book)	-	-	-	-
Net income (including charges)	(42)	(45)	(18)	-	Return on assets (ROA)	(23.3%)	(22.3%)	(10.6%)	(70.9%)
D&A	1	1	2	-	Return on equity (ROE)	(47.9%)	(40.7%)	(22.6%)	(160.2%)
Change in working capital	0	(5)	0	-	Enterprise value / sales	-	-	-	-
Other	8	1	1	-	Enterprise value / EBITDA	-	-	-	-
Cash flow from operations	(33)	(47)	(15)	-	Free cash flow yield	(5.8%)	(4.0%)	(1.4%)	(0.1%)
Capex	(2)	(2)	(2)	-					
Free cash flow	(31)	(48)	(17)	(1)					
Cash flow from investing activities	122	(2)	(2)	-					
Cash flow from financing activities	0	0	0	-					
Dividends	-	-	-	-					
Dividend yield	-	-	-	-					

Source: Company reports and J.P. Morgan estimates.

Note: \$ in millions (except per-share data). Fiscal year ends Dec

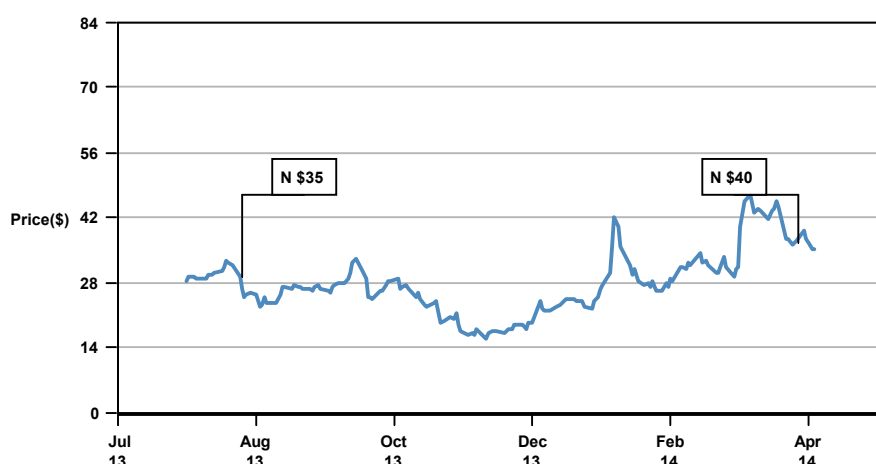
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Agios Pharmaceuticals (AGIO, AGIO US) Price Chart



Date	Rating	Share Price (\$)	Price Target (\$)
19-Aug-13	N	29.11	35.00
28-Mar-14	N	36.56	40.00

Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends.
Initiated coverage Aug 19, 2013.

The chart(s) show J.P. Morgan's continuing coverage of the stocks; the current analysts may or may not have covered it over the entire period.

J.P. Morgan ratings or designations: OW = Overweight, N= Neutral, UW = Underweight, NR = Not Rated

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