Agios Pharmaceuticals

AACR Preview: Expect Proof-of-Concept for AG-221 and Broader Technology Platform to Be Established

Neutral

AGIO, AGIO US
Price: $36.56

▲ **Price Target: $40.00**
Previous: $35.00

Upcoming AG-221 (IDH2) phase 1 data at AACR (4/5-4/9; San Diego) will be a key catalyst for AGIO shares. We continue to receive a number of questions on expectations for the phase 1 data set heading into AACR. Indeed, the phase 1 data are not just key for the AG-221 program as there will be read-through to the overall Agios technology platform. We had the opportunity to catch up with Agios recently. We continue to believe rapid reduction of the key biomarker of 2-hydroxyglutarate (2-HG) will be sufficient to establish proof-of-concept (POC). That said, we would view early responses as significantly de-risking and a near-term value driver for AGIO shares; however, this is not our baseline assumption heading into AACR. As we expect POC to be established in the AACR data set, we are increasing our December 2014 to $40 from $35. However, the 2013 IPO class/early clinical stage companies continue to come under pressure and Agios' key programs are still very early stage. Our Neutral rating and price target increase balance strong science and expectations for AACR with the early stage of the company.

- **Phase 1 design overview.** Recall, that the phase 1 trial assesses AG-221 2x/daily with the primary endpoint of safety/tolerability and establishment of a maximum tolerated dose (MTD) in patients with advanced hematologic malignancies (R/R AML, advanced myelodyspasia and myeloproliferative disease). We expect the majority of patients in the trial will have AML, given the prevalence of IDH2 mutations within that disease. Key secondary endpoints include PK/PD, response/clinical activity, and assessment of 2-HG levels. Recall, it is thought 2-HG levels contribute to malignant transformation.

- **What do we know about the phase 1 trial?** On the 4Q13 call, it was announced that initial clinical data from the phase 1 trial would be presented at AACR, well ahead of initial expectations of YE14 for a first look at data. We note the trial is still in the dose escalation phase and an MTD has not been reached. The extent of data that will be presented at AACR is unclear (i.e., # of patients, duration of exposure, etc) but the longest patients have likely been dosed for only ~5 cycles, assuming no discontinuations. Of note, expansion cohorts are expected to start in 2014 (no change in timelines).

Biotechnology

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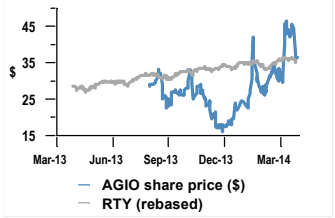

Agios Pharmaceuticals (AGIO;AGIO US)

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 ($)	36.56
Date Of Price	27 Mar 14
52-week Range ($)	49.79-15.77
Market Cap ($ mn)	548.10
Fiscal Year End	Dec
Shares O/S (mn)	15
Price Target ($)	40.00
Price Target End Date	30-Dec-14

See page 5 for analyst certification and important disclosures.

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- **What do we need to see for POC to be established?** In our view, rapid declines of 2-HG would be sufficient to establish proof-of-concept. Indeed, we are expecting to see this with AG-221 at AACR, as the pre-clinical data would support this result. For reference, at ASH 2014, pre-clinical data not only showed a rapid decline in 2-HG, but also dose dependent decrease in blasts in bone marrow and increase in CD15+.

- **What other data points will we be looking for/reference comparator?** Clearly, the focus will be on potential evidence of responses and the overall response rate, as this would indicate clinical activity. Indeed, our expectations for response rates are among the most frequent questions we have received since the 4Q earnings call. Our baseline assumption is responses are NOT likely to be observed, given limited duration of trial, and that CRs/PRs should be viewed as upside. While there is no direct comparator, for reference, in a phase 1 study of Celgene's oral CC-486, 2/13 R/R AML patients had responses (median treatment duration 4 cycles, range 1-14 cycles; Gore et al. 2011).

- **AACR presentation information:** Presentation of the phase 1 data will occur Sunday, April 6th between 3:45-4:05pm PST at a session called "Novel Immune and Targeted Therapies for Hematologic Malignancies and Solid Tumors" (abstract # CT103; Ballroom 20A-C). Of note, Agios will also host an analyst day at the conference post presentation of the phase 1 data. Importantly, our understanding is that late-breaker abstracts for the conference will be available Friday, 4/4. While there could be some qualitative commentary in the AG-221 abstract, our sense is that the majority of key data is likely to be saved for the formal presentation.

- **Reiterate Neutral rating.** Increasing December 2014 PT to $40 from $35.

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Investment Thesis, Valuation and Risks

Agios Pharmaceuticals *(Neutral; Price Target: $40.00)*

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. 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. The scientific rationale appears very robust to us, but key programs are only now entering the clinic. Our Neutral rating balances strong science and potential of differentiated therapeutics with the company's early development stage.

Valuation

We are increasing our December 2014 price target to $40 from $35. Our December 2014 price target of $40 for AGIO is based on a comparable company analysis. For comparables we use select biotech companies with a focus on oncology and orphan diseases. Our comparable group has a mean market cap of ~$1.4B and a firm value of ~$1.3B. Since Agios is currently only entering the clinic with key programs relative to our comparable companies, which are deep in clinical development, we apply what we consider an appropriate ~10% discount.

Risks to Rating and Price Target

Upside risks include 1) faster-than-anticipated development of lead assets and 2) quicker path to market. Downside risks include 1) failure to show differentiated therapeutic benefit of lead assets or trial failure, 2) FDA requires long development pathway, and 3) out-year financing risk.

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Agios Pharmaceuticals: Summary of Financials

Income Statement - Annual	FY13A	FY14E	FY15E	FY16E
Revenues	26	36	66	31
Cost of products sold	0	0	0	0
Gross profit	-	-	-	-
SG&A	(10)	(13)	(13)	(14)
R&D	(55)	(67)	(71)	(74)
Operating income	(39)	(44)	(18)	(57)
EBITDA	(39)	(44)	(18)	(57)
Net interest (income) / expense	(4)	(0)	1	1
Other income / (expense)	-	-	-	-
Income taxes	0	0	0	0
Net income - GAAP	(42)	(45)	(18)	(56)
Net income - recurring	(42)	(45)	(18)	(56)
Diluted shares outstanding	15	34	35	36
EPS - excluding non-recurring	(2.83)	(1.33)	(0.51)	(1.57)
EPS - recurring	(2.83)	(1.33)	(0.51)	(1.57)

Balance Sheet and Cash Flow Data	FY13A	FY14E	FY15E	FY16E
Cash and cash equivalents	180	132	115	-
Accounts receivable	-	-	-	-
Inventories	-	-	-	-
Other current assets	2	1	2	-
Current assets	219	170	153	-
PP&E	4	4	5	-
Total assets	226	174	158	-
Total debt	-	-	-	-
Total liabilities	93	88	88	-
Shareholders' equity	133	86	70	-
Net income (including charges)	(42)	(45)	(18)	-
D&A	1	1	2	-
Change in working capital	0	(5)	0	-
Other	8	1	1	-
Cash flow from operations	(33)	(47)	(15)	-
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	-	-	-	-

Income Statement - Quarterly	1Q14E	2Q14E	3Q14E	4Q14E
Revenues	9	9	9	9
Cost of products sold	0	0	0	0
Gross profit	-	-	-	-
SG&A	(3)	(3)	(3)	(3)
R&D	(15)	(16)	(18)	(18)
Operating income	(9)	(11)	(12)	(13)
EBITDA	(9)	(11)	(12)	(13)
Net interest (income) / expense	0	0	(0)	(0)
Other income / (expense)	-	-	-	-
Income taxes	0	0	0	0
Net income - GAAP	(9)	(10)	(12)	(13)
Net income - recurring	(9)	(10)	(12)	(13)
Diluted shares outstanding	32	33	34	35
EPS - excluding non-recurring	(0.28)	(0.32)	(0.36)	(0.37)
EPS - recurring	(0.28)	(0.32)	(0.36)	(0.37)

Ratio Analysis	FY13A	FY14E	FY15E	FY16E
Sales growth	1.8%	39.1%	84.4%	(52.2%)
EBIT growth	69.1%	14.0%	(58.7%)	210.0%
EPS growth - recurring	139.9%	(53.1%)	(61.6%)	208.7%
Gross margin	-	-	-	-
EBIT margin	(152.2%)	(124.7%)	(27.9%)	(181.3%)
EBITDA margin	(152.2%)	(124.7%)	(27.9%)	(181.3%)
Tax rate	(0.9%)	0.0%	0.0%	0.0%
Net margin	(166.1%)	(125.7%)	(27.0%)	(179.3%)
Net Debt / EBITDA	-	-	-	-
Net Debt / Capital (book)	-	-	-	-
Return on assets (ROA)	(23.3%)	(22.3%)	(10.6%)	(70.9%)
Return on equity (ROE)	(47.9%)	(40.7%)	(22.6%)	(160.2%)
Enterprise value / sales	-	-	-	-
Enterprise value / EBITDA	-	-	-	-
Free cash flow yield	(5.6%)	(3.9%)	(1.4%)	(0.0%)

Source: Company reports and J.P. Morgan estimates.
Note: $ in millions (except per-share data).Fiscal year ends Dec

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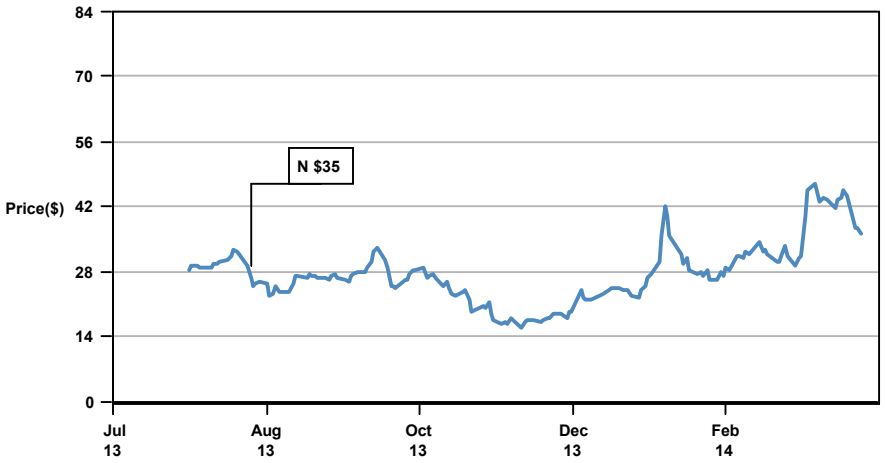
Agios Pharmaceuticals (AGIO, AGIO US) Price Chart



Date	Rating	Share Price ($)	Price Target ($)
19-Aug-13	N	29.11	35.00

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

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