

## Agios Pharmaceuticals

### Updated AG-221 Data Continues To Support Compelling Profile; Increasing PT \$60 From \$55

Over the weekend, updated phase 1 data for AG-221 (IDH2) in hematological malignancies were presented at the European Hematology Association (EHA) meeting. We had the opportunity to speak to Agios shortly after the data were presented and wanted to pass on few thoughts. We continue to view the updated phase 1 data as compelling, with 14/25 evaluable patients achieving a response and no majority safety concerns / discontinuations related to therapy. Importantly, multiple expansion cohorts are on track to start in 2H14 (we estimate 4Qe). Agios continues to make very solid progress across key programs (AG-221, AG-120, and AG-348). We are reiterating our Overweight rating on AGIO shares and increasing our December 2014 PT to \$60 from \$55 on increased probability of success and slightly increased technology value.

- **Efficacy; data continue to be compelling:** We believe the EHA update continues to support the emerging / compelling clinical profile of AG-221. Indeed, there were 14 of 25 evaluable patients that had a response, with 6 complete responses (CRs), 2 CRs with incomplete platelet recovery (CRp), and 1 CR with incomplete hematologic recovery (CRi). Of note, there were 5 partial responses (PRs) and 5 patients with stable disease (SD). Based on our conversation with Agios, our sense is that SD patients are early in course of treatment and that 1 patient from AACR that had a CRp transitioned to a CR. Of note, 4/4 MDS patients had a response, with 1 CR and 1 CRp. Importantly, there have been no relapses to date in patients that observed a response. Additionally, we note, in line with AACR, rapid 2HG declines were observed.
- **Safety; no major surprises:** There were no major safety concerns in the updated data, in our view. Importantly, there are no discontinuations due to AG-221 and the 7 deaths observed to date were not attributed to study drug. Grade 3 AEs as of 5/23/14, which occurred in 4 patients, include: confusion, respiratory failure, leukocytosis, anorexia, nausea and diarrhea. We note that the Grade 3 AEs of confusion and respiratory failure were known from the April AACR data.

## Overweight

**AGIO, AGIO US**

Price: \$47.50

▲ **Price Target: \$60.00**  
Previous: \$55.00

### Biotechnology

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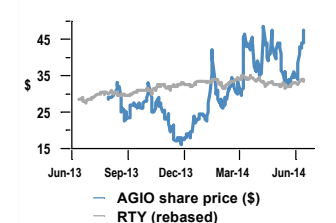
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### Price Performance



### Agios Pharmaceuticals (AGIO;AGIO US)

| FYE Dec                           | 2013A  | 2014E   | 2015E  |
|-----------------------------------|--------|---------|--------|
| Analyst Adjusted Diluted EPS (\$) |        |         |        |
| Q1 (Mar)                          | (0.39) | (0.39)A | -      |
| Q2 (Jun)                          | (2.74) | (0.39)  | -      |
| Q3 (Sep)                          | (0.48) | (0.45)  | -      |
| Q4 (Dec)                          | (0.40) | (0.49)  | -      |
| FY                                | (2.83) | (1.71)  | (0.84) |

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

### Company Data

|                       |             |
|-----------------------|-------------|
| Price (\$)            | 47.50       |
| Date Of Price         | 13 Jun 14   |
| 52-week Range (\$)    | 49.79-15.77 |
| Market Cap (\$ mn)    | 712.11      |
| Fiscal Year End       | Dec         |
| Shares O/S (mn)       | 15          |
| Price Target (\$)     | 60.00       |
| Price Target End Date | 30-Dec-14   |

### See page 5 for analyst certification and important disclosures.

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- **Next steps / expansion cohorts:** The next update for AG-221 will likely be at ASH 2014 (Dec 6-9; San Francisco); however, we note, based on the company's prior commentary, it is possible that Agios moves to expansion cohorts before an MTD is established. Expansion cohorts with AG-221 are expected to start in 2H14. We suspect Agios is likely to move to expansion cohorts in 4Q. Indeed, based on our conversation with the company, there are ongoing analyses related to go forward dosing regimen. That said, in conjunction with the updated AG-221 data at EHA, the company did announce the 4 expansions which will be studied (n=~25 in each cohort): R/R AML 60+ years, R/R AML less than 60 years, treatment naïve AML patients, and an other hematologic malignancy cohort.
- **Conference call TODAY @ 8:30am EST:** 1-877-377-7098 (US); 1-631-291-4547 (OUS); passcode: 49387254
- **Reiterate Overweight rating.** We are increasing our December 2014 PT to \$60 from \$55 on increased probability of success for AG-221 and slightly increased technology value.

## Investment Thesis, Valuation and Risks

### **Agios Pharmaceuticals** (*Overweight; Price Target: \$60.00*)

#### **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 and EHA 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 \$60 from \$55. Our \$60 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 75% probability of success for AG-221 (from 70% previously) and 50% for AG-120. We believe these estimates accurately reflect the data reported at AACR / EHA, the company's innovative science, with the relatively early stage of the company's pipeline. We derive a value of \$7/share for AG-221, \$15/share for the US rights to AG-120, and \$3/share for the OUS rights (assuming Celgene exercises its opt-in). These valuations, taken in combination with \$29/share for the technology platform (was \$26/share previously) and net cash of \$4/share, support our December 2014 PT of \$60.

#### **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    | 1Q14A    | 2Q14E    | 3Q14E   | 4Q14E    |
|-------------------------------------|--------|--------|--------|--------|---------------------------------|----------|----------|---------|----------|
| Revenues                            | 26     | 36     | 66     | 31     | Revenues                        | 8A       | 9        | 9       | 9        |
| Cost of products sold               | 0      | 0      | 0      | 0      | Cost of products sold           | 0A       | 0        | 0       | 0        |
| Gross profit                        | -      | -      | -      | -      | Gross profit                    | -        | -        | -       | -        |
| SG&A                                | (10)   | (13)   | (14)   | (14)   | SG&A                            | (3)A     | (3)      | (3)     | (4)      |
| R&D                                 | (55)   | (79)   | (81)   | (84)   | R&D                             | (17)A    | (19)     | (21)    | (22)     |
| Operating income                    | (39)   | (57)   | (30)   | (67)   | Operating income                | (12)A    | (13)     | (15)    | (17)     |
| EBITDA                              | (39)   | (57)   | (30)   | (67)   | EBITDA                          | (12)A    | (13)     | (15)    | (17)     |
| Net interest (income) / expense     | (4)    | (0)    | 1      | 1      | Net interest (income) / expense | 0A       | 0        | (0)     | (0)      |
| Other income / (expense)            | -      | -      | -      | -      | Other income / (expense)        | -        | -        | -       | -        |
| Income taxes                        | 0      | 0      | 0      | 0      | Income taxes                    | 0A       | 0        | 0       | 0        |
| Net income - GAAP                   | (42)   | (57)   | (29)   | (66)   | Net income - GAAP               | (12)A    | (13)     | (15)    | (17)     |
| Net income - recurring              | (42)   | (57)   | (29)   | (66)   | Net income - recurring          | (12)A    | (13)     | (15)    | (17)     |
| Diluted shares outstanding          | 15     | 33     | 35     | 36     | Diluted shares outstanding      | 31A      | 34       | 34      | 35       |
| EPS - excluding non-recurring       | (2.83) | (1.71) | (0.84) | (1.85) | EPS - excluding non-recurring   | (0.39)A  | (0.39)   | (0.45)  | (0.49)   |
| EPS - recurring                     | (2.83) | (1.71) | (0.84) | (1.85) | EPS - recurring                 | (0.39)A  | (0.39)   | (0.45)  | (0.49)   |
| Balance Sheet and Cash Flow Data    | FY13A  | FY14E  | FY15E  | FY16E  | Ratio Analysis                  | FY13A    | FY14E    | FY15E   | FY16E    |
| Cash and cash equivalents           | 180    | 213    | 185    | 0      | Sales growth                    | 1.8%     | 39.1%    | 84.4%   | (52.2%)  |
| Accounts receivable                 | -      | -      | -      | -      | EBIT growth                     | 69.1%    | 46.4%    | (47.8%) | 124.9%   |
| Inventories                         | -      | -      | -      | -      | EPS growth - recurring          | 139.9%   | (39.6%)  | (51.0%) | 121.3%   |
| Other current assets                | 2      | 1      | 2      | -      | Gross margin                    | -        | -        | -       | -        |
| Current assets                      | 219    | 251    | 223    | 0      | EBIT margin                     | (152.2%) | (160.2%) | (45.3%) | (213.5%) |
| PP&E                                | 4      | 4      | 5      | -      | EBITDA margin                   | (152.2%) | (160.2%) | (45.3%) | (213.5%) |
| Total assets                        | 226    | 256    | 229    | 0      | Tax rate                        | (0.9%)   | 0.0%     | 0.0%    | 0.0%     |
| Total debt                          | -      | -      | -      | -      | Net margin                      | (166.1%) | (161.2%) | (44.3%) | (211.4%) |
| Total liabilities                   | 93     | 88     | 88     | -      | Net Debt / EBITDA               | -        | -        | -       | -        |
| Shareholders' equity                | 133    | 168    | 140    | -      | Net Debt / Capital (book)       | -        | -        | -       | -        |
| Net income (including charges)      | (42)   | (57)   | (29)   | -      | Return on assets (ROA)          | (23.3%)  | (23.7%)  | (12.0%) | (57.9%)  |
| D&A                                 | 1      | 1      | 2      | -      | Return on equity (ROE)          | (47.9%)  | (38.0%)  | (18.9%) | (94.3%)  |
| Change in working capital           | 0      | (5)    | 0      | -      | Enterprise value / sales        | 20.0     | 15.3     | 7.9     | -        |
| Other                               | 8      | 1      | 1      | -      | Enterprise value / EBITDA       | NM       | NM       | NM      | -        |
| Cash flow from operations           | (33)   | (59)   | (26)   | -      | Free cash flow yield            | (4.3%)   | (3.8%)   | (1.8%)  | (0.0%)   |
| Capex                               | (2)    | (2)    | (2)    | -      |                                 |          |          |         |          |
| Free cash flow                      | (31)   | (61)   | (29)   | (1)    |                                 |          |          |         |          |
| Cash flow from investing activities | 122    | 92     | (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

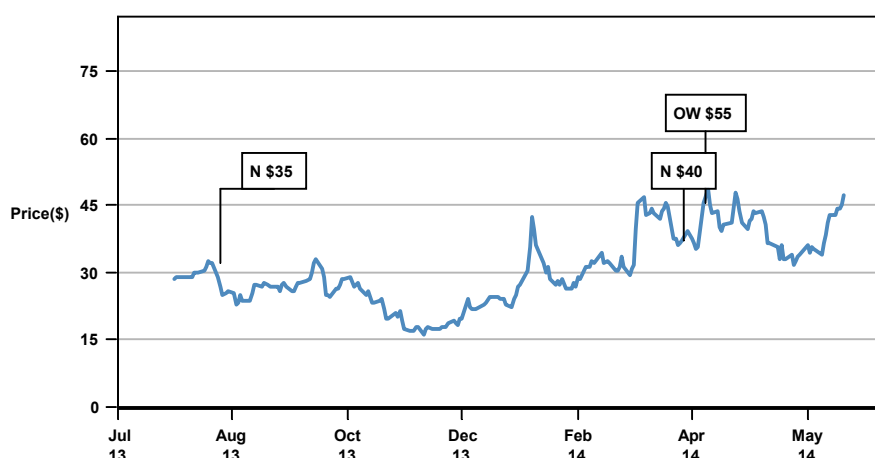
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Agios Pharmaceuticals (AGIO, AGIO US) Price Chart



| Date      | Rating | Share Price (\$) | Price Target (\$) |
|-----------|--------|------------------|-------------------|
| 19-Aug-13 | N      | 31.91            | 35.00             |
| 28-Mar-14 | N      | 37.02            | 40.00             |
| 07-Apr-14 | OW     | 45.35            | 55.00             |

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

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