September 2, 2014

WELLS FARGO SECURITIES

# *Equity Research*

## Alder Biopharmaceuticals, Inc.

**ALDR: Claza Return A Setback;**
**Significant Opportunity Remains For '403**

**Outperform / V**

Sector: Biotechnology
Market Weight

- **Summary:** Today (9/2), ALDR announced BMS is returning worldwide rights to Clazakizumab after deciding to end further development of the drug, a monoclonal antibody to the inflammatory cytokine IL-6. While this is a both a developmental and financial setback as it reduces the likelihood of Claza getting over the line, would push out potential timelines, and will eliminate sizable potential near and medium term milestones, the asset return does not appear related to the drug's efficacy/safety profile – meaning it could still potentially be developed in other, likely smaller indications, and importantly, migraine drug ALD403 will remain a key value driver for the company, in our view. We are reducing our valuation range to $19-21 from $22-24, but continue to believe the '403 migraine program is undervalued, and the stock could rebound as data in the anti-CGRP space generates interest in the long-term opportunity for drugs like '403. As such, we still see a buying opportunity. We are lowering our 2015E loss per share to -$1.20 from -$0.30.
- **BMS returning rights to Clazakizumab after a portfolio review.** BMS' stated decision to discontinue was driven by a review of its portfolio of drug candidates in its pipeline, and we had the opportunity to confirm this with BMS; we believe the high costs of a potential RA pivotal program, coupled with some of the other advancements in BMS's pipeline particularly in immuno-oncology, rather than any new or concerning efficacy/safety data, are likely what led to BMS's decision to prioritize resources away from the drug. As part of the discontinuation, the Clazakizumab drug supply for clinical development and complete data from phase II will be returned to ALDR, and ALDR also stands to benefit from BMS' heavy investment in the scale-up of manufacturing for the antibody. Recall Clazakizumab had been through several phase II RA studies, showing comparable efficacy to TNF-alpha inhibitors with potentially better remission rates, and a safety profile in-line with other anti-IL-6 therapeutics, with favorable once-monthly SC dosing.
- *Continued on the following page*

***Earnings Estimate Revised Down***

| EPS | 2013A | 2014E Curr. | 2014E Prior | 2015E Curr. | 2015E Prior |
|---|---|---|---|---|---|
| **Q1** (Mar.) | NE | ($5.38) A | NC | NE | |
| **Q2** (June) | (5.27) | (0.40) A | NC | NE | |
| **Q3** (Sep.) | NE | (0.28) | NC | NE | |
| **Q4** (Dec.) | NE | (0.31) | NC | NE | |
| **FY** | ($20.57) | ($1.53) | NC | **($1.20)** | **(0.30)** |
| **CY** | ($20.57) | ($1.53) | | ($1.20) | |
| **FY P/EPS** | NM | NM | | NM | |
| **Rev.(MM)** | $19 | $19 | | $20 | |

*Source: Company Data, Wells Fargo Securities, LLC estimates, and Reuters*
*NA = Not Available, NC = No Change, NE = No Estimate, NM = Not Meaningful*
*V = Volatile, = Company is on the Priority Stock List*

*The sum of the quarterly earnings per share amounts may not equal the total for the year due to the effects of rounding and dilution as a result of issuing common shares during the year*

| | |
|---|---|
| Ticker | ALDR |
| Price (09/02/2014) | $14.25 |
| 52-Week Range: | $9-23 |
| Shares Outstanding: (MM) | 29.9 |
| Market Cap.: (MM) | $426.1 |
| S&P 500: | 1,998.84 |
| Avg. Daily Vol.: | 95,352 |
| Dividend/Yield: | $0.00/0.0% |
| LT Debt: (MM) | $0.0 |
| LT Debt/Total Cap.: | 0.0% |
| ROE: | NM |
| 3-5 Yr. Est. Growth Rate: | NM |
| CY 2014 Est. P/EPS-to-Growth: | NM |
| Last Reporting Date: | 08/05/2014 After Close |

*Source: Company Data, Wells Fargo Securities, LLC estimates, and Reuters*

**Valuation Range: $19.00 to $21.00** from $22.00 to $24.00
Our valuation range is based on applying a 25x multiple to our 2022 estimated EPS and discounting at 15%, blended with 7x sales multiple of 2022 estimated sales, and discounting at 12%. Risks include emergence of a safety signal, and competition in the migraine/RA spaces.

**Investment Thesis:**
We believe Alder is undervalued based on the long-term promise of ALD403 and Clazakizumab.

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**Please see page 5 for rating definitions, important disclosures and required analyst certifications**
**All estimates/forecasts are as of 09/02/14 unless otherwise stated.**





## Company Description:

Alder Biopharmaceuticals, based in Bothell, Washington, is a clinical stage biopharmaceutical company with differentiated antibody discovery and manufacturing platform to design and select antibodies that have the potential to maximize efficacy in various therapeutic indications including inflammatory and neurological conditions. Additionally, the company's proprietary manufacturing platform, MabXpress, has potential to streamline the manufacturing process compared with the more traditional biologics manufacturing systems, potentially resulting in faster, more scalable, and more cost effective. The company's lead and wholly-owned program, ALD403, is in ph.II and the clinical data thus far supports strong treatment effect in treating migraine. Clazakizumab (anti-IL-6 antibody) is partnered with BMY and it is currently undergoing studies in ph.II for RA and psoriatic arthritis. The company has 4 additional programs in preclinical stage expected to enter the clinic in the future.

## Continued from Front Page Bullets

- **While this does not necessarily suggest anything newly negative on the drug's efficacy or safety profile, some creative efforts would likely be required to efficiently move Claza forward.** Given the potential costs to conduct a phase III RA study (+$500MM), we believe it is impractical for ALDR to bring the asset forward in a broad RA program on its own next year. We believe ALDR may explore other smaller autoimmune indications or perhaps even other areas (cachexia, GVHD, solid tumors) where Clazakizumab's method of action could provide benefit, and could potentially enable less onerous development paths. The company could also potentially out-license Clazakizumab to capture the value that has been created thus far in the asset without the need for significant spend. We have adjusted our model to reflect a 1-year to 2-year launch delay for Clazakizumab, and now model substantially lower sales assuming a niche indication like psoriatic arthritis or a smaller autoimmune/inflammatory market (to $281MM from $1.2B in 2022), a potential smaller-scale partnership to offset development costs, and a lower probability (20%, from 70%) of ultimate success. The loss of the potential near-$400MM in pre-commercial milestones possible from BMS in the current Claza indications is a negative, given Claza's potential to fund '403 and other programs, and we have adjusted our model accordingly. We have also adjusted our valuation to use probability-adjusted 2022, rather than 2020, EPS and sales estimates to better capture the long-term revenue potential of the migraine program with the Clazakizumab change.

- **We see no change to '403, which we have long viewed as ALDR's more differentiated asset.** Development timelines for '403 remain intact, and ALDR plans to move the drug into a phase IIb IV dose-ranging IV formulation study in chronic migraine later this year, and into a phase IIb subcutaneous formulation study in the first half of 2015. Recall that '403 inhibits CGRP, a well-validated target implicated in the trigger of migraine headaches, and initial ph.II data demonstrated clear, sustained reductions in migraine frequency, including elimination of migraine in some patients, with a single dose and no side effects. Several other biopharma competitors with drug candidates targeting CGRP are due to see data in the next few months, including AMGN, which anticipates seeing data from its phase IIb dose-ranging study of AMG 334 in episodic migraine patients by the end of 2014, and TEVA, for which phase II data of its externally acquired LBR-101 compound is due to read-out around Q1 2015. We believe data readouts over the next six months will increase investor (as well as KOL and industry) attention to the migraine space, and will ultimately benefit ALDR. We see $1.45B in '403 sales by 2023, with what we believe are reasonably conservative penetration estimates.

**Upcoming Milestones**

| Product | Event | Timeline |
|---|---|---|
| ALD403 | Initiate ph.IIb IV dose-ranging study in chronic migraine | 2H14 |
| | Initiate ph.IIb SC dose-ranging study in high-frequency migraine | 1Q15 |
| | Data from ph.IIb studies | 2015 |
| | Potentially initiate ph.III program | 2016 |
| | Potential ph.III data | 2017/2018 |
| Clazakizumab | Publication of ph.II psoriatic arthritis study by BMY | 4Q14 (ACR) |
| | Potential publication of previously-presented ph.II RA study | 4Q14 |
| | Completion of dose-ranging ph.IIb RA follow-on study | 1H15 |
| | Presentation of ph.IIb dose-ranging RA data | Mid-2015 (EULAR) |
| | Initiation of ph.III program | 2015 |

Source: Company reports and Wells Fargo Securities, LLC estimates

**Product Pipeline**

| Product (partner) | Indication/mechanism | Status |
|---|---|---|
| ALD403 | Migraine (anti-CGRP antibody) | Phase IIb |
| Clazakizumab (BMY) | RA, psoriatic arthritis (anti-IL-6 antibody) | Phase IIb |

Source: Company reports and Wells Fargo Securities, LLC

**Alder Biopharmaceuticals (ALDR)**
Statement of Operations

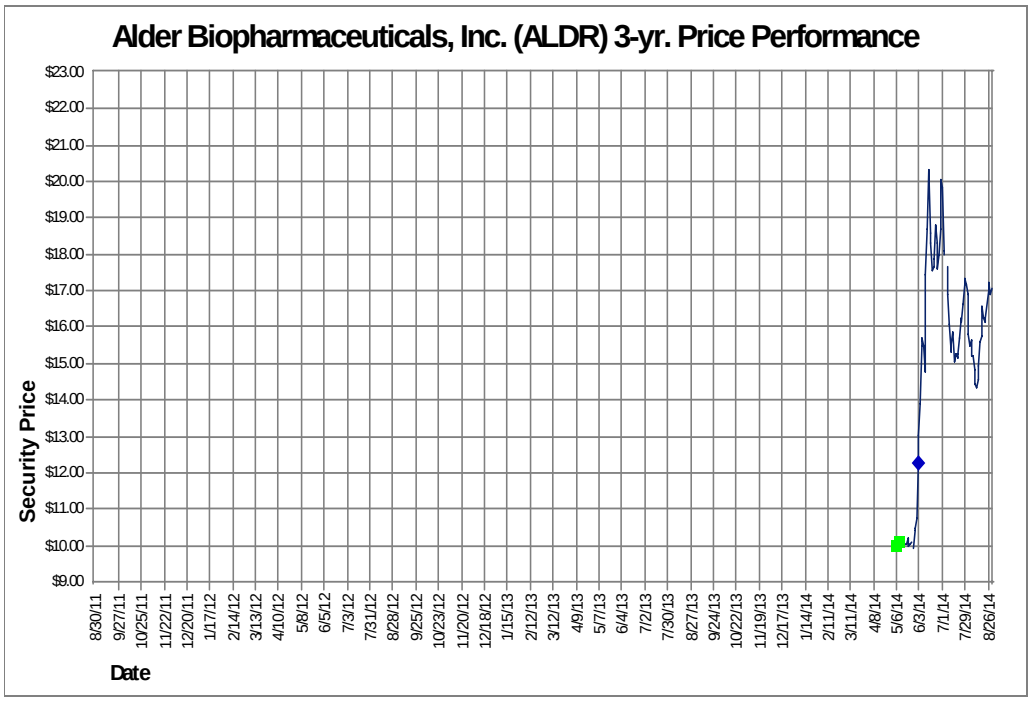
| | 2012A | 2013A | 2014E | 2015E | 2016E | 2017E | 2018E | 2019E | 2020E | 2021E | 2022E | 2023E |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Revenues | | | | | | | | | | | | |
| *Clazakizumab sales (PsA or smaller autoimmune/inflamm market)* | | | | | | | | | *$101,666* | *$200,189* | *$280,890* | *$370,732* |
| *ALD403 sales* | | | | | | | | *91,549* | *311,435* | *641,157* | *1,027,741* | *1,448,953* |
| Clazakizumab royalties | - | - | - | - | - | - | - | - | 16,267 | 33,031 | 47,751 | 64,878 |
| ALD403 U.S. sales | - | - | - | - | - | - | - | 91,549 | 264,479 | 505,197 | 767,467 | 1,052,724 |
| ALD403 Ex-U.S. royalties | - | - | - | - | - | - | - | - | 7,982 | 23,113 | 44,247 | 67,359 |
| Collaborative and license agreements/revenue (1) | 20,067 | 18,796 | 18,574 | 20,143 | 43,714 | 38,714 | 73,714 | 31,571 | 84,071 | 34,071 | 26,571 | 8,000 |
| **Total revenues, net** | **$20,067** | **$18,796** | **$18,574** | **$20,143** | **$43,714** | **$38,714** | **$73,714** | **$123,120** | **$372,799** | **$595,413** | **$886,036** | **$1,192,961** |
| Expenses | | | | | | | | | | | | |
| Cost of goods sold | | | | | | | | $6,408 | $18,514 | $35,364 | $53,723 | $73,691 |
| Research and development | $30,669 | $31,883 | $36,877 | $47,940 | $66,157 | $82,697 | $99,236 | $103,205 | $98,045 | $93,143 | $96,869 | $100,743 |
| Selling, general and administrative | $7,217 | $7,674 | $12,236 | $13,460 | $14,806 | $20,728 | $62,183 | $93,275 | $121,258 | $145,509 | $151,329 | $157,383 |
| **Total operating expenses** | **$37,886** | **$39,557** | **$49,113** | **$61,400** | **$80,963** | **$103,424** | **$161,419** | **$202,889** | **$237,816** | **$274,016** | **$301,921** | **$331,817** |
| **Operating Income** | **($17,819)** | **($20,761)** | **($30,539)** | **($41,257)** | **($37,249)** | **($64,710)** | **($87,705)** | **($79,768)** | **$134,983** | **$321,397** | **$584,115** | **$861,144** |
| Interest income | $101 | $54 | $38 | $166 | $277 | $336 | $215 | $90 | $201 | $613 | $1,475 | $2,898 |
| Other income | - | 158 | - | - | - | - | - | - | - | - | - | - |
| Interest expense | (88) | - | - | - | - | - | - | - | - | - | - | - |
| Other expense | - | (64) | - | - | - | - | - | - | - | - | - | - |
| **Total other income** | **$13** | **$148** | **$38** | **$166** | **$277** | **$336** | **$215** | **$90** | **$201** | **$613** | **$1,475** | **$2,898** |
| **Income before taxes** | **($17,806)** | **($20,613)** | **($30,501)** | **($41,091)** | **($36,972)** | **($64,374)** | **($87,490)** | **($79,678)** | **$135,184** | **$322,010** | **$585,590** | **$864,042** |
| Income tax (expenses) | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | ($2,704) | ($25,761) | ($87,839) | ($190,089) |
| **Net income** | ($17,806) | ($20,613) | ($30,501) | ($41,091) | ($36,972) | ($64,374) | ($87,490) | ($79,678) | $132,480 | $296,249 | $497,752 | $673,953 |
| **Earnings Per Share** | **($19.54)** | **($20.57)** | **($1.53)** | **($1.20)** | **($1.06)** | **($1.64)** | **($2.19)** | **($1.79)** | **$2.56** | **$5.65** | **$9.38** | **$12.56** |
| Shares Outstanding (Basic) | 911 | 1,002 | 19,877 | 34,150 | 34,750 | 39,350 | 39,950 | 44,550 | 45,150 | 45,750 | 46,350 | 46,950 |
| Shares Outstanding (Diluted) | | | 26,566 | 40,839 | 41,439 | 46,039 | 46,639 | 51,239 | 51,839 | 52,439 | 53,039 | 53,639 |

Source: Company reports and Wells Fargo Securities, LLC estimates

Note: In 000's $, except per share amounts; Fiscal year ends December 31

(1) includes milestone payments and amortization of upfront payments

# Required Disclosures




| | Date | Publication Price ($) | Rating Code | Val. Rng. Low | Val. Rng. High | Close Price ($) |
|---|---|---|---|---|---|---|
| ❐ | 5/8/2014 | | IPO at $10.00 | | | |
| | 6/2/2014 | | Abrahams, M.D. | | | |
| ◆ | 6/2/2014 | 10.74 | 1 | 22.00 | 24.00 | 12.26 |

Source: Wells Fargo Securities, LLC estimates and Reuters data

Symbol Key

| | | | |
|---|---|---|---|
| ▼ | Rating Downgrade | ◆ | Initiation, Resumption, Drop or Suspend |
| ▲ | Rating Upgrade | ■ | Analyst Change |
| ● | Valuation Range Change | ❐ | Split Adjustment |

Rating Code Key

| | | | |
|---|---|---|---|
| 1 | Outperform/Buy | SR | Suspended |
| 2 | Market Perform/Hold | NR | Not Rated |
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**ALDR:** Risks include emergence of a safety signal, and competition in the migraine/RA spaces.

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As of: September 2, 2014

| | |
|---|---|
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