

Equity Research

Alder Biopharmaceuticals, Inc.

ALDR: We Are Initiating Coverage With An Outperform Rating

Outperform / V

Sector: Biotechnology

Market Weight

Initiation of Coverage

• **Summary:** We are initiating coverage of ALDR shares with an Outperform rating and a \$22-24 valuation range. We believe the company's two lead assets, ALD403 for migraine and Clazakizumab for autoimmune diseases, both have strong efficacy/safety profiles, clear paths to approval, and blockbuster potential. We believe ALDR shares considerably undervalue the future milestone, royalty, and sales revenue the two agents could generate and expect appreciation for the stock as the programs progress. Our valuation is based on a blend of probability-adjusted, discounted out-year EPS and revenue multiples.

• **We believe ALD403 puts ALDR on the leading edge of a potential significant shift in migraine treatment, providing a future blockbuster opportunity.** ALD403 is part of an emerging class, anti-CGRP antibodies, being developed specifically for the reduction in migraines attacks for frequent headache sufferers. In a recently reported proof-of-concept study, a single IV dose of '403 significantly reduced headache frequency for months, with some patients becoming headache-free, with no safety signals. Though additional studies will need to be done to optimize dose and delivery and confirm long-term benefits, barring emergence of any toxicity we believe the agent has a good probability of ultimately gaining approval--particularly given that it already demonstrated benefits on a registration-enabling endpoint. Our physician feedback suggests a drug of this profile would be embraced by clinicians and patients, alike, and even allowing for other competing anti-CGRP entrants, we believe the market is large enough such a \$1.5B+ market opportunity could be readily achievable.

• **We believe Clazakizumab could be a competitive entrant in the large RA/PsA space that generates meaningful milestone and royalty revenue for ALDR.** Clazakizumab, an anti-IL-6 antibody completing phase II for RA, has demonstrated efficacy and safety comparable to other biologics for the disease in several studies and has a validated mechanism, making it highly likely to ultimately reach the market, in our view. Though the autoimmune development and commercial space is highly crowded, we believe Clazakizumab has several features that could provide it with an advantageous overall profile among non-TNF therapies, and we believe even a relatively small slice of the large RA/PsA market and use primarily after anti-TNFs would still generate \$1.5B+ in sales and \$250MM+ in royalties to ALDR--helped by the commercial experience of its partner, BMY. Additionally, the pre-commercial milestones receivable from partner BMY in RA, which we believe are low risk, should generate nearly \$400MM for ALDR in the coming years--themselves even more than the company's current market cap.

Valuation Range: \$22.00 to \$24.00 from NE to NE

Our valuation range is based on applying a 30x multiple to our 2020 estimated EPS and discounting at 15%, blended with 3x sales multiple of 2020 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.

Please see page 7 for rating definitions, important disclosures and required analyst certifications

All estimates/forecasts are as of 06/02/14 unless otherwise stated.

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	2013A	2014E	2015E	
EPS		Curr.	Prior	Curr.
Q1 (Mar.)	NE	(\$0.25)	NE	NE
Q2 (June)	NE	(0.26)	NE	NE
Q3 (Sep.)	NE	(0.24)	NE	NE
Q4 (Dec.)	NE	(0.25)	NE	NE
FY	(\$0.94)	(\$1.00)	NE	(\$0.15)
CY	(\$0.94)	(\$1.00)		(\$0.15)
FY P/E	NM	NM		NM
Rev.(MM)	\$19	\$17		\$51

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

Ticker	ALDR
Price (05/30/2014)	\$10.74
52-Week Range:	\$9-11
Shares Outstanding: (MM)	29.9
Market Cap.: (MM)	\$321.1
S&P 500:	1,923.57
Avg. Daily Vol.:	0
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/E-to-Growth:	NM
Last Reporting Date:	01/01/2014

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

Brian Abrahams, M.D., Senior Analyst

(212) 214-8060 /

brian.abrahams@wellsfargo.com

Matthew J. Andrews, Associate Analyst

(617) 603-4218 /

matthew.j.andrews@wellsfargo.com

Shin Kang, Ph.D., Associate Analyst

(212) 214-5036 /

shin.kang@wellsfargo.com

Together we'll go far



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.

For more details, please see our full-length report, to be published shortly.

Investment Thesis

We are initiating coverage of Alder Biopharmaceuticals with an Outperform rating and a \$22-24 valuation range. We believe the company's two lead assets, ALD403 for migraine and Clazakizumab for autoimmune diseases, both have strong efficacy/safety profiles, clear paths to approval, and blockbuster potential. We believe ALDR shares considerably undervalue the future milestone, royalty, and sales revenue the two agents could generate, and expect appreciation for the stock as the programs progress.

With ALD403, we believe Alder has the opportunity to be on the leading edge of a significant shift in the treatment of migraine, which could drive considerable long-term value. There are believed to be 36 million people in the United States who suffer from migraine headaches, and while the triptan class of drugs effectively helps shorten and ameliorate episodes, prevention of migraines from occurring would be a significant step forward for many who suffer from frequent attacks. Prophylactic options have been limited to Botox, relegated to the more severe cases and cumbersome to administer, and older, repurposed oral drugs with non-optimal efficacy and safety. Alder's ALD403 is part of an emerging class of prophylactic therapies, antibodies against CGRP, a vasoactive protein also believed to modulate the sensation of pain in migraines. In a recently reported pilot study, ALD403 led to significant reductions in headache frequency compared to placebo, with a group of patients becoming completely headache-free; data from a competing antibody from Lilly at a similar stage of development appeared comparable, corroborating the treatment effects with such a mechanistic approach are likely real. Safety of Alder's antibody (as well as Lilly's) has appeared clean, suggesting that antibodies to CGRP will not share the same liver toxicity problem that led to the discontinuation of small molecule CGRP antagonists that had been explored in the past. Though additional studies will be needed to optimize dose and delivery, including determining the right administration frequency if the antibody were given subcutaneously (SC), we believe the data to date suggest a good probability that ALD403 will ultimately reach the market, assuming safety remains clean, particularly given that headache frequency—where the drug already showed clear benefits—is a registrational endpoint in migraine prevention.

We see blockbuster potential for ALD403 despite the presence of competitors, with potential for meaningful operating leverage. The development space among anti-CGRP antibodies is becoming crowded, with three other antibodies at similar stages; Alder's is among the furthest along to have demonstrated positive proof of concept, though several of the other companies have greater developmental and commercial resources than Alder, which will likely make it a competitive race. Still, in the end, based on our physician feedback, we believe antibodies designed specifically for migraine prevention, with efficacy and safety properties ALD403 has demonstrated, would get significant adoption into a large market we see as capable of supporting multiple potential entrants. Even with what we believe are very achievable 4-5% penetration rates among high-frequency and chronic migraineurs treated with prophylaxis, we believe the market opportunity could exceed \$1.4 billion in just the fourth year of launch (2023E). Alder would also likely be able to sell the drug itself in the United States and would likely incur very low cost of goods given its high-efficiency antibody production platform, enabling the company to extract significant value from the agent.

We believe Clazakizumab could be a competitive entrant in the very large rheumatoid arthritis (RA)/psoriatic arthritis (PsA) space, helping generate meaningful milestone and royalty revenue for Alder. Clazakizumab is an anti-IL-6 antibody completing phase II development in RA and also being explored in PsA. Targeting the IL-6 pathway in autoimmune diseases has been well validated by the success of Roche's Actemra, which sells more than \$1 billion annually. And in nine clinical studies, including a recently reported head-to-head study versus leading biologic Humira, Clazakizumab has demonstrated response rates competitive with other biologics in RA patients with safety comparable to Actemra. The commercial and development space for RA biologics is very crowded (and as such, the regulatory bar high),

and several other IL-6 targeted agents are in late-stage development. Still, Clazakizumab appears to have several features we believe could resonate well in the market, including some evidence it produces higher remission rates than other drugs, which should be appreciated by clinicians as they set higher goals for patient outcomes, with a long half-life enabling monthly delivery. Our physician suggests that a new agent like Clazakizumab is unlikely to replace the entrenched anti-TNF agents used extensively in RA patients failing DMARDs; however, with RA patients often cycling through multiple therapies, growing rheumatologist experience with IL-6 targeted agents, Clazakizumab's differentiating features potentially adding up to a best-in-class non-TNF biologic, and partner Bristol-Myers Squibb's considerable development and commercial experience in the space, we believe Clazakizumab is likely to be approved and adopted. Even with use primarily in TNF failures and uptake a fraction of that of the market leader, we believe Clazakizumab could still generate worldwide sales of \$1.5 billion by 2023, potentially providing royalties to Alder of more than \$250 million. In addition to sales royalties, Alder also stands to gain nearly \$400 million in development and regulatory milestones in RA alone, which, given our view that Clazakizumab is highly likely to succeed in phase III, we believe will provide a key source of non-dilutive funding over the next several years--and themselves even exceed the company's current market cap.

Valuation

We have established a \$22-24 valuation range for Alder shares. We base our valuation analysis on our probability-adjusted revenue projections for ALD403 in migraine and Clazakizumab in RA and PsA. We assume a 25% probability of success for ALD403, given that the drug is early stage and the class is new, balancing that with the very promising initial signals of activity. We assume a 70% probability of success for Clazakizumab in autoimmune indications, which we believe is appropriate given the extensive efficacy and safety data, clear path to approval in these indications, and generally validated mechanism of action. Assuming approximately 45 million diluted shares outstanding, which accounts for a potentially dilutive capital raise between now and the launch of these drugs, but also assumes some receipt of milestones and a potential up-front payment for ALD403, we arrive at a probability-adjusted 2020 EPS estimate of \$2.11. Applying a 30x multiple, which we believe is appropriate for a company of Alder's size and potential, and discounting back 15% for approximately five and a half years, yields a per share valuation of \$29. Using a valuation analysis based on sales multiples, using a 3x multiple (which accounts for the sales blend between ALD403, which the company will likely sell itself in the United States, and Clazakizumab, on which the company receives royalties, as well as accounting for the fact that this year would likely substantially precede ALD403's peak sales period), and discounting back at 12% would yield a potential valuation of \$18. Combining these two methodologies, we believe our valuation range of \$22-24 is appropriate.

Exhibit 1. Valuation Analysis

Year:	2020E	Discount (yrs)	5.6	EPS:	\$4.84	Shares out:	45,339
Product:	Indication:	Region	Probability of success:	Sales (MM)	Net to company:	EPS contribution:	Probability-weighted EPS contribution:
ALD403	Migraine	WW	25%	\$311	41%	\$2.82	\$0.70
Clazakizumab	RA, PsA	WW	70%	\$605	15%	\$2.00	\$1.40
Total			Prob-weighted sales	\$501		\$4.82	\$2.11
Discount Rate:							
EPS Multiple:	5%	10%	15%	20%	25%		
15	\$24	\$19	\$14	\$11	\$9		
20	\$32	\$25	\$19	\$15	\$12		
25	\$40	\$31	\$24	\$19	\$15		
30	\$48	\$37	\$29	\$23	\$18		
35	\$56	\$43	\$34	\$27	\$21		
40	\$64	\$49	\$39	\$30	\$24		
Discount Rate:							
Sales Multiple:	10%	11%	12%	13%	14%		
2	\$13	\$12	\$12	\$11	\$11		
3	\$19	\$19	\$18	\$17	\$16		
4	\$26	\$25	\$23	\$22	\$21		

Source: Wells Fargo Securities, LLC estimates

Upcoming Milestones and Product Pipeline

Exhibit 2. Upcoming milestones

Product	Event	Timeline
ALD403	Finalize ph.IIb plan in dialogue with FDA	2H14
	Initiate ph.IIb dose-ranging study in high-frequency migraine	4Q14
	Complete enrollment in ph.IIb	mid-2015
	Data from ph.IIb study	end-2015
	Potentially initiate ph.III program	mid-2016
	Potentially initiate ph.IIb SC study	2H15
	Initiate ph.III program for IV	2H16
	Initiate ph.III program for SC	2017
	Potential ph.III data	2017/2018
Clazakizumab	Completed dose-ranging ph.IIb RA study	4Q14
	Potential publication of previously-presented ph.II RA study	4Q14
	Presentation of ph.IIb dose-ranging RA data	Mid-2015 (EULAR)
	Initiation of ph.III program	2015
	Potential presentation of ph.II psoriatic arthritis data	4Q14 (ACR)

Source: Company reports and Wells Fargo Securities, LLC estimates

Exhibit 3. Product pipeline

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

Source: Company reports and Wells Fargo Securities, LLC

Investment Risks

Clinical Development Risk. ALD403 is relatively early stage, having been in phase I development and one proof-of-concept phase II study. On the efficacy side, it is possible that the promising migraine prevention results observed in phase II will not be replicated in larger studies, especially given the tendency of these studies to show a high placebo effect and the more modest benefits when results are looked at in terms of mean reductions in headache days. Although LFT elevations observed with small molecule approaches to CGRP inhibition do not appear to be an issue with anti-CGRP antibodies, there is still a risk that this or other side effects could emerge over multiple doses in larger studies, which could preclude future regulatory approval or commercial viability. It could be important for Alder to succeed in developing a subcutaneous form of ALD403 in order to maximize its competitive positioning, and though a SC was tested in phase I, the company has not yet demonstrated proof of concept yet with an SC-administered ALD403. The drug has also not yet been tested in chronic migraine; failure to replicate the promising efficacy in chronic migraine patients could result in a less favorable label and reduce the market opportunity. Regarding Clazakizumab, partner BMY and Alder still need to conduct an additional study in order to optimize the dose, given that there was no clear dose dependence; and if activity at the overlapping doses does not replicate prior data, it could call into question the validity of the promising phase IIb data previously reported. It may be important for future clinical studies of Clazakizumab to confirm the potential remission advantages over other therapies in order to optimize its competitive positioning.

Commercial Risk. Both of Alder's products would potentially enter crowded competitive markets, presenting commercial risk. There are several other companies developing anti-CGRP antibodies for migraine, with differences between the programs not entirely elicited at this point. Subtle nuances like dosing and administration differences could ultimately result in significant differences in adoption between anti-CGRP antibodies for migraine, and these likely will not become apparent until programs from Alder and competitors move forward further in clinical development. Alder intends to market '403 on its own in the United States, which, while potentially maximizing profit, would require considerable investment; additionally, the company does not have any commercial experience, and would potentially be competing with others, like Amgen and Lilly, with considerable experience and large infrastructures. Generic agents are currently used in migraine prophylaxis, and though these have efficacy and safety limitations, it is not unreasonable to expect insurers to require patients try such therapies first before moving on to more expensive therapies like '403, which could reduce '403's ultimate market opportunity. Given that the anti-CGRP antibodies could be the first class of drugs specifically designed for migraine prophylaxis, the ultimate market has not yet been established and there is a risk that such drugs will not be embraced as broadly as expected, which would reduce '403's revenue potential. Regarding Clazakizumab, there are numerous biologics for RA and similar autoimmune diseases well entrenched in the market, and multiple other therapies, including those targeting IL-6, in late-stage clinical development. Although the market size is large, as multiple additional therapies potentially reach the market, the ultimate opportunity for Clazakizumab could become smaller, making it even more important for Clazakizumab to continue to demonstrate properties that incrementally differentiate it from other therapies.

Regulatory Risk. Given the large number of migraine and RA/PsA patients potentially served by ALD403 and Clazakizumab, respectively, the FDA and EMA would likely require large phase III programs for both agents. Competition in both spaces could potentially slow pivotal study enrollment, which would delay potential approvability and revenue to Alder. The bar for safety for both drugs would likely be very high, and any unforeseen toxicity issue emerging with either agent could meaningfully reduce the likelihood of approval.

Financing Risk. We would not expect Clazakizumab and ALD403 to reach the market until the 2018-19 time frame, potentially leading to sustainable profitability for Alder by 2020. We believe milestones from the BMY collaboration on Clazakizumab should help Alder cover future development costs, as could a potential up-front payment for ex-U.S. rights to ALD403. However, until such milestones/payments are received, and in the case that they are not received, Alder will likely need to raise additional capital through secondary stock and/or convertible debt offerings to support the additional development of their candidates, which could lead to dilution of existing shareholders.

Income Statement

Alder Biopharmaceuticals (ALDR)
Statement of Operations

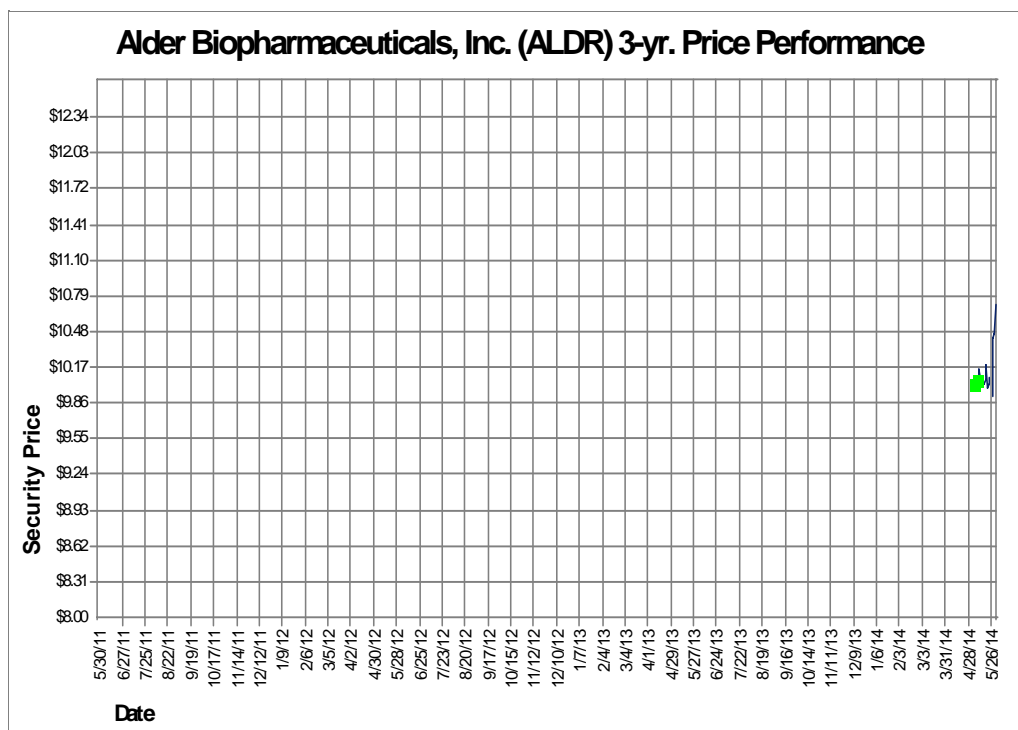
	2012A	2013A	10E	20E	30E	40E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
Revenues																
Ciazakizumab sales																
ALD403 sales																
Ciazakizumab royalties																
ALD403 U.S. sales	-	-	-	-	-	-	-	-	-	-	10,242	48,163	96,797	146,321	203,156	266,976
ALD403 Ex-U.S. royalties	-	-	-	-	-	-	-	-	-	-	-	91,549	264,479	505,197	767,467	1,052,724
Collaborative and license agreements/revenue (1)	-	-	-	-	-	-	-	-	-	-	-	-	7,982	23,113	44,247	67,359
	20,067	18,796	4,800	4,036	4,036	4,036	16,907	51,143	34,714	84,714	184,714	92,571	87,571	37,571	72,571	79,000
Total revenues, net	\$20,067	\$18,796	\$4,800	\$4,036	\$4,036	\$4,036	\$16,907	\$51,143	\$34,714	\$84,714	\$184,714	\$232,284	\$456,830	\$712,202	\$1,087,441	\$1,466,059
Expenses																
Cost of goods sold																
Research and development	\$30,669	\$31,883	\$7,800	\$8,200	\$8,500	\$9,000	\$33,500	\$45,225	\$62,411	\$76,013	\$93,616	\$5,408	\$18,514	\$35,364	\$53,723	\$73,691
Selling, general and administrative	\$7,217	\$7,674	\$2,400	\$2,600	\$2,650	\$2,700	\$10,350	\$11,385	\$12,524	\$17,533	\$22,599	\$97,360	\$92,492	\$87,868	\$91,382	\$95,038
	\$37,886	\$39,557	\$10,200	\$10,800	\$11,150	\$11,700	\$43,850	\$56,610	\$74,934	\$95,546	\$116,214	\$182,667	\$213,573	\$246,312	\$273,109	\$301,853
Total operating expenses	\$37,886	\$39,557	\$10,200	\$10,800	\$11,150	\$11,700	\$43,850	\$56,610	\$74,934	\$95,546	\$116,214	\$182,667	\$213,573	\$246,312	\$273,109	\$301,853
Operating income	\$17,819	\$18,761	\$5,400	\$6,764	\$7,114	\$7,664	\$26,943	\$5,467	\$40,220	\$10,832	\$48,742	\$49,617	\$243,256	\$465,890	\$814,332	\$1,164,206
Interest income	\$101	\$54	\$9	\$23	\$36	\$31	\$99	\$166	\$278	\$296	\$273	\$323	\$579	\$1,253	\$2,500	\$4,467
Other income	-	158	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Interest expense	(88)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other expense	-	(64)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total other income	\$13	\$148	\$9	\$23	\$36	\$31	\$99	\$166	\$278	\$296	\$273	\$323	\$579	\$1,253	\$2,500	\$4,467
Income before taxes	\$17,806	\$20,613	\$5,391	\$6,742	\$7,078	\$7,633	\$26,844	\$5,301	\$39,942	\$10,536	\$49,015	\$49,939	\$243,836	\$467,143	\$816,832	\$1,168,673
Income tax (expenses)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	(\$980)	(\$1,998)	(\$24,384)	(\$79,414)	(\$179,703)	(\$303,865)
Net income	\$17,806	\$20,613	\$5,391	\$6,742	\$7,078	\$7,633	\$26,844	\$5,301	\$39,942	\$10,536	\$48,035	\$47,942	\$219,452	\$387,729	\$637,129	\$864,818
Earnings Per Share	(\$19.54)	(\$0.34)	(\$0.25)	(\$0.26)	(\$0.24)	(\$0.25)	(\$1.00)	(\$0.15)	(\$1.10)	(\$0.29)	\$1.09	\$1.07	\$4.84	\$6.44	\$13.69	\$18.35
Shares Outstanding (Basic)	911	21,889	21,889	26,900	29,900	30,050	26,935	35,650	36,250	36,850	37,450	38,050	38,650	39,250	39,850	40,450
Shares Outstanding (Diluted)			28,578	32,589	36,589	36,739	33,623	42,339	42,939	43,539	44,139	44,739	45,339	45,939	46,539	47,139

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			

Source: Wells Fargo Securities, LLC estimates and Reuters data

Symbol Key

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

Rating Code Key

- 1 Outperform/Buy
- 2 Market Perform/Hold
- 3 Underperform/Sell
- SR Suspended
- NR Not Rated
- NE No Estimate

Additional Information Available Upon Request

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ALDR: Risks include emergence of a safety signal, and competition in the migraine/RA spaces.

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1=Outperform: The stock appears attractively valued, and we believe the stock's total return will exceed that of the market over the next 12 months. BUY

2=Market Perform: The stock appears appropriately valued, and we believe the stock's total return will be in line with the market over the next 12 months. HOLD

3=Underperform: The stock appears overvalued, and we believe the stock's total return will be below the market over the next 12 months. SELL

SECTOR RATING

O=Overweight: Industry expected to outperform the relevant broad market benchmark over the next 12 months.

M=Market Weight: Industry expected to perform in-line with the relevant broad market benchmark over the next 12 months.

U=Underweight: Industry expected to underperform the relevant broad market benchmark over the next 12 months.

VOLATILITY RATING

V = A stock is defined as volatile if the stock price has fluctuated by +/-20% or greater in at least 8 of the past 24 months or if the analyst expects significant volatility. All IPO stocks are automatically rated volatile within the first 24 months of trading.

As of: June 1, 2014

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3% of companies covered by Wells Fargo Securities, LLC Equity Research are rated Underperform.

Wells Fargo Securities, LLC has provided investment banking services for 13% of its Equity Research Underperform-rated companies.

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