

Acceleron Pharma Inc. (XLRN)

Acceleron Reports 4Q13 Results; We Are Buyers into NKF

MARKET DATA

Price	\$49.01
52-Week Range:	\$16.78 - \$57.89
Shares Out. (M):	26.5
Market Cap (\$M):	\$1,298.8
Average Daily Vol. (000):	314.0
Cash (M):	\$116
Cash/Share:	\$3.74
Enterprise Value (M):	\$1,360
Float (M):	27.0
LT Debt (M):	\$11

Source: Thomson Reuters and JMP Securities LLC

MARKET OUTPERFORM | Price: \$49.01 | Target Price: \$53.00

INVESTMENT HIGHLIGHTS

Near-term focus on preliminary sotatercept ESRD data at NKF meeting; reiterate our Market Outperform rating on Acceleron Pharma and \$53 price target based on DCF and SOTP valuation methodologies. As a development-stage biotech company, Acceleron continues to be a story of successful advancement of hematology assets, ACE-536 and sotatercept, as well as dalantercept against development milestones rather than earnings results. On the conference call, management reiterated recent updates with ACE-536 and sotatercept in beta-thalassemia and ESRD, respectively. Reported net loss of \$18.1MM was greater than our estimate of \$1.97MM and \$0.05MM consensus, primarily due to non-cash expense related to mark-market recognition of outstanding warrants to purchase common stock post-IPO. Collaboration revenue of \$11.5MM in 4Q13 was in line with our estimate, and slightly below consensus of \$13.7MM, while operating expense of \$15.0MM was slightly greater than our estimate of \$13.2MM, and below consensus of \$15.9MM. The company finished the quarter with \$113MM in cash and cash equivalents, which, together with proceeds from a recent follow-on offering, contribute to a pro-forma cash balance of \$242MM.

Phase IIa data presentation with sotatercept at NKF presents the next opportunity for upside. Consistent with its updated S-1 filing in January, the company noted dose-dependent hemoglobin (Hgb) increases following sotatercept treatment in the first of two Phase II studies in patients with ESRD. Data from the Phase IIa trial are being presented at the National Kidney Foundation Meeting (April 22 to 26, Las Vegas). Data from this study could inform the selection of approvable endpoints in any potential registration directed study. As a reminder, a second, two-part Phase IIb study in ESRD was initiated in December, first establishing an appropriate dosing regimen through a 60-patient, dose-escalation portion, before proceeding with a randomized ~230 patient trial comparing sotatercept versus ESA, monitoring for primary endpoints of change in Hgb and bone turnover.

ACE-536 update at EHA to give further clarity on the path forward in transfusion dependent beta-thal. Recall, ACE-536 is being evaluated for its ability to stimulate erythrocyte production and alleviate anemia for patients with non-transfusion dependent (NTD) and transfusion dependent (TD) beta-thalassemia in a Phase II dose-escalation study. Data to date indicate dose-dependent stimulation of Hgb levels (>1.5g/dL at 0.6mg/kg) in NTD patients. Comments made during the conference call now indicate that ACE-536 is capable of reducing transfusion frequency in TD patients. Our checks suggest that transfusion frequency reductions of $\geq 30\%$ could be a clinically meaningful endpoint with TD disease. ACE-536 data in both TD and NTD patients, together with sotatercept updates in MDS and beta-thal, will be presented in full at the upcoming EHA meeting, June 12-15 in Milan.

FY DEC	2012A	2013A	2014E
Revenue (\$M) 1Q	--	\$15.0	\$4.9
2Q	--	\$26.4	\$5.2
3Q	--	\$4.3	\$5.4
4Q	--	\$11.5	\$20.9
FY	\$15.3	\$57.2	\$36.4
EPS 1Q	--	\$0.12	(\$0.38)
2Q	--	\$0.44	(\$0.38)
3Q	--	(\$5.62)	(\$0.42)
4Q	--	(\$0.64)	\$0.04
FY	(\$1.43)	(\$4.15)	(\$1.13)
P/E	NM	NM	NM
Previous FY	NC	(\$0.55)	(\$0.81)

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE



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Development timelines for dalantercept in RCC remain unchanged, with forays in HCC and GBM expected near term. The company reiterated its expectation of initiating the randomized expansion portion of the ongoing Phase II, second-line RCC trial in combination with axitinib (Inlyta) during 1Q14 (112 patients). Results from the dose-escalation portion of the study will be presented at ASCO in June. In addition, a Phase IIa combination study with sorafenib (Nexavar) in HCC is expected to begin in 2Q14, meanwhile the Phase II GBM study in combination with bevacizumab (Avastin) is expected to be initiated during 2H14.

Impact of 4Q13 results to our model. We have made few changes to our model (Figure 3), with negligible impact to our price target valuation. Quarterly FY14 R&D and G&A expense have been moderately increased to reflect the new run rate set by 4Q13 actual results. The effect of these changes has been a lowering of our quarterly and FY EPS estimates for 2014 and subsequent years.

FIGURE 1. Upcoming Milestones

Timing	Drug	Milestones
1Q14	Sotatercept & ACE-536	Initiation of RP2D expansion cohorts in ongoing β -thalassemia Phase II trials
1Q14	Dalantercept	Preliminary data from dose-escalation stage of Phase II RCC trial in combination with axitinib; start of randomized stage versus axitinib alone
2Q14	Sotatercept	Presentation of data in ESRD at National Kidney Foundation meeting (April 22 nd – 26 th , 2014 - Las Vegas, NV)
2Q14	Dalantercept	Initiation of Phase IIa study in HCC in combination with Nexavar
2Q14	Sotatercept & ACE-536	Presentation of dose escalation Phase II results in β -thalassemia and MDS at ASCO (May 30 th – June 3 rd) and EHA (June 12 th -15 th)
3Q14	Dalantercept	Initiation of Phase II trial plus Avastin in GBM
4Q14	Sotatercept & ACE-536	Final results from Phase II trials in β -thalassemia and MDS
4Q14/1Q15	Sotatercept & ACE-536	Initiation of Phase III trial in β -thalassemia and/or MDS
4Q14	ACE-083	Initiation of Phase I trial in muscular dystrophy

Source: JMP Securities LLC and Company Reports

FIGURE 2. 4Q13 Results versus JMP and Consensus Estimates

Accelaron Pharma (XLRN) Abridged Income Statement (\$ MM)	4Q13 Results			
	JMP Estimate	Street Consensus	Actual	Variance (JMP vs. Actual)
Total Revenues	11.69	13.67	11.52	(0.16)
Operating Expenses	13.20	15.89	14.97	(1.77)
Research and development	9.30		10.22	(0.92)
General and administrative	3.90		4.76	(0.86)
Operating income (loss)	(1.52)	(2.23)	(3.45)	(1.94)
Other income (expense)	(0.46)		(14.66)	(14.20)
Pretax Income (loss)	(1.97)	(2.97)	(18.11)	(16.14)
Net Income (loss)	(1.97)	(0.05)	(18.11)	(16.14)
EPS Calculations				
Basic EPS	\$ (0.07)	\$ (0.08)	\$ (0.64)	\$ (0.57)
Diluted EPS	\$ (0.07)	\$ (0.08)	\$ (0.64)	\$ (0.57)
Basic shares outstanding	28.22		28.12	(0.10)
Diluted shares outstanding	28.22		28.12	(0.10)

Source: JMP Securities LLC and Company Reports

FIGURE 3. Changes to Our Model

Accelaron Pharma (XLRN) (\$ MM)	1Q14E		2Q14E		3Q14E		4Q14E		FY 2014E		FY 2015E	
	Old	New	Old	New	Old	New	Old	New	Old	New	Old	New
Collaboration Revenue	4.9	4.9	5.2	5.2	5.4	5.4	20.9	20.9	36.4	36.4	42.9	42.9
COGS	-	-	-	-	-	-	-	-	-	-	-	-
Gross Profit	4.9	4.9	5.2	5.2	5.4	5.4	20.9	20.9	36.4	36.4	42.9	42.9
Operating Expenses	13.7	15.8	14.1	16.5	14.6	18.0	15.2	18.8	57.6	69.1	77.2	92.6
Research and development	9.6	10.8	9.8	11.3	10.0	12.5	10.3	12.9	39.7	47.5	57.5	68.9
General and administrative	4.1	5.0	4.3	5.2	4.6	5.5	4.9	5.9	17.9	21.6	19.7	23.8
Operating income (loss)	(8.8)	(10.9)	(9.0)	(11.3)	(9.2)	(12.6)	5.8	2.1	(21.2)	(32.7)	(34.3)	(49.7)
Other income (expense)	(0.5)	(0.5)	(0.5)	(0.5)	(0.5)	(0.5)	(0.5)	(0.5)	(1.8)	(1.8)	(1.8)	(1.8)
Pretax Income	(9.2)	(11.3)	(9.4)	(11.8)	(9.6)	(13.0)	5.3	1.6	(23.0)	(34.5)	(36.1)	(51.6)
Provision for Income Tax	-	-	-	-	-	-	-	-	3.5	5.2	9.0	12.9
Net Income	(9.2)	(11.3)	(9.4)	(11.8)	(9.6)	(13.0)	5.3	1.6	(23.0)	(34.5)	(27.1)	(38.7)
Basic EPS	(\$0.31)	\$ (0.38)	(\$0.31)	\$ (0.38)	(\$0.31)	\$ (0.42)	\$0.17	\$ 0.05	(\$0.75)	\$ (1.13)	(\$0.87)	\$ (1.24)
Diluted EPS	(\$0.31)	\$ (0.38)	(\$0.31)	\$ (0.38)	(\$0.31)	\$ (0.42)	\$0.12	\$ 0.04	(\$0.75)	\$ (1.13)	(\$0.87)	\$ (1.24)
Basic shares outstanding	29.6	29.6	30.8	30.8	30.9	30.9	31.0	31.0	30.61	30.6	31.24	31.2
Diluted shares outstanding	29.6	29.6	30.8	30.8	30.9	30.9	44.9	44.9	30.61	30.6	31.24	31.2

Source: JMP Securities LLC and Company Reports

FIGURE 4. Updated Income Statement

Acceleron Pharma (XLRN)	4Q13E	2013E	1Q14E	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Income Statement (\$MM)	4Q13E	2013E	1Q14E	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Product Sales and Royalties:													
Sotatercept / ACE-536 Royalty Revenue								-	3.3	65.3	201.9	452.3	819.6
Dalantercept								-	-	-	41.9	90.1	213.8
Total Product Sales and Royalties	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.3	65.3	243.8	542.3	1,033.3
Collaboration Revenue:													
Licensing and milestones	7.0	42.4	0.0	0.0	0.0	15.0	15.0	17.5	60.0	50.0	100.0	50.0	0.0
Cost-sharing, net	4.7	15.0	4.9	5.2	5.4	5.9	21.4	25.4	28.0	30.8	33.8	37.2	40.9
Contract Manufacturing													
Total Revenue	11.5	57.2	4.9	5.2	5.4	20.9	36.4	42.9	91.2	146.1	377.6	629.5	1,074.3
Cost of Goods Sold											4.2	8.1	19.2
Gross Profit	11.5	57.2	4.9	5.2	5.4	20.9	36.4	42.9	91.2	146.1	373.4	621.4	1,055.0
Operating Expenses:													
Research and Development	10.2	36.1	10.8	11.3	12.5	12.9	47.5	68.9	82.7	95.0	104.6	114.0	124.2
General and administrative	4.8	14.2	5.0	5.2	5.5	5.9	21.6	23.8	26.1	36.6	42.1	46.7	50.4
Cost of contract manufacturing revenue													
Total operating expenses	15.0	50.3	15.8	16.5	18.0	18.8	69.1	92.6	108.8	131.6	146.6	160.7	174.7
Operating income (loss)	(3.5)	7.0	(10.9)	(11.3)	(12.6)	2.1	(32.7)	(49.7)	(17.6)	14.4	226.8	460.8	880.4
Total other income, net	(14.7)	(28.9)	(0.5)	(0.5)	(0.5)	(0.5)	(1.8)	(1.8)	(1.8)	(1.8)	(1.8)	(1.8)	(1.8)
Pretax income (loss)	(18.1)	(21.9)	(11.3)	(11.8)	(13.0)	1.6	(34.5)	(51.6)	(19.4)	12.6	224.9	458.9	878.5
Income tax benefit (provision)							5.2	12.9	5.8	(4.4)	(78.7)	(160.6)	(307.5)
Tax Rate							15%	25%	30%	35%	35%	35%	35%
Comprehensive income (loss)	(18.1)	(21.9)	(11.3)	(11.8)	(13.0)	1.6	(34.5)	(38.7)	(13.6)	8.2	146.2	298.3	571.0
Pro forma net income (loss) applicable to common	(18.1)	(39.0)	(11.3)	(11.8)	(13.0)	1.6	(34.5)	(38.7)	(13.6)	8.2	146.2	298.3	571.0
Pro forma Basic EPS to common shareholders	\$ (0.64)	\$ (4.15)	\$ (0.38)	\$ (0.38)	\$ (0.42)	\$ 0.05	\$ (1.13)	\$ (1.24)	\$ (0.43)	\$ 0.25	\$ 4.40	\$ 8.78	\$ 16.46
Pro forma Diluted EPS to common shareholders	\$ (0.64)	\$ (4.15)	\$ (0.38)	\$ (0.38)	\$ (0.42)	\$ 0.04	\$ (1.13)	\$ (1.24)	\$ (0.43)	\$ 0.19	\$ 3.33	\$ 6.68	\$ 12.56
Basic shares outstanding	28.1	9.4	29.6	30.8	30.9	31.0	30.6	31.2	31.8	32.5	33.2	34.0	34.7
Diluted shares outstanding	28.1	9.4	29.6	30.8	30.9	44.9	30.6	31.2	31.8	43.1	43.9	44.7	45.5

Source: JMP Securities LLC and Company Reports

Company Description

Acceleron Pharma (XLRN) is a Cambridge, MA biotechnology company focused on the discovery, development, and commercialization of its ligand trap fusion proteins directed against components of TGF β signaling pathway. These fusion proteins have shown clinical potential in the treatment of anemia disorders related to β -thalassemia and myelodysplastic syndromes, as well as in the treatment of solid cancers, muscle wasting disorders, and other indications impacted by dysregulated TGF β .

Since 2008, the company has benefited by robust strategic collaboration with Celgene related to its development lead programs, sotatercept and ACE-536, entitling the company to full reimbursement on both programs and eligibility for up to \$567MM in development, regulatory, and commercial milestones, and a $\geq 20\%$ royalty on worldwide sales, by our estimates. Sotatercept and ACE-536 are currently in Phase II trials for the treatment of β -thalassemia and low/intermediate-1 MDS with pivotal Phase III trials expected to initiate in the first half of 2014.

Dalantercept, the company's wholly owned, clinical-stage fusion protein, is directed against ALK1, a key mediator of tumor angiogenesis that functions independently from the VEGF axis. Dalantercept is currently in Phase II evaluation for the treatment of second-line RCC in combination with TKI therapy.

Investment Risks

Clinical. Drug development is an inherently risky business. Clinical trials always carry a risk of failure and Acceleron's assets (sotatercept, ACE-536, Dalantercept, or future drug candidates) may fail to demonstrate meaningful enough levels of efficacy in current or future clinical trials.

Regulatory and commercial. The ability of Acceleron or its partners to market its drugs depends on those drugs obtaining approval from the FDA and foreign regulatory agencies. Failure to achieve approval or delays in the timelines to approval could negatively impact the company's share price.

Competitive. Hereditary anemic disorders represent an increasingly competitive field and Acceleron faces competition from companies with development-stage drug candidates addressing similar biologic mechanisms, and from companies attempting to broaden the applicable indications for products already approved for use. Some of these companies may possess substantially greater R&D and commercial resources than Acceleron or its partners. As such, there is no assurance Acceleron will be competitive or differentiated from other drug products.

Partners. Acceleron has formed development and commercial partnerships with Celgene and is highly dependent on these partnerships for non-dilutive sources of capital, and for the potential commercialization of sotatercept and/or ACE-536. Changes to these partnership arrangements could have a substantially negative impact on the company's share price.

Financial. Following its IPO we estimated that Acceleron would end 4Q13 with approximately \$87MM in cash and cash equivalents - adequate resources to fund operations into 2015, according to Acceleron's financial guidance. We anticipate that Acceleron is likely to seek additional equity financing in the form of a secondary offering in order to complete the development of its drug candidates, creating dilution risk for existing shareholders.

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Market Outperform (MO): JMP Securities expects the stock price to outperform relevant market indices over the next 12 months.

Market Perform (MP): JMP Securities expects the stock price to perform in line with relevant market indices over the next 12 months.

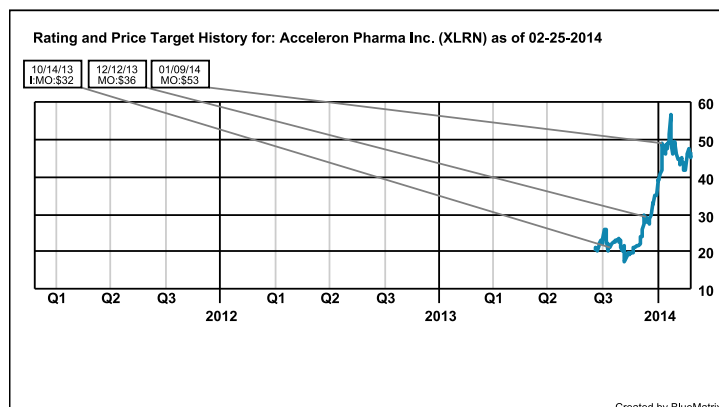
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MARKET OUTPERFORM	Buy	241	56.05%	Buy	241	56.05%	90	37.34%
MARKET PERFORM	Hold	138	32.09%	Hold	138	32.09%	21	15.22%
MARKET UNDERPERFORM	Sell	8	1.86%	Sell	8	1.86%	0	0%
COVERAGE IN TRANSITION		43	10.00%		43	10.00%	0	0%
TOTAL:		430	100%		430	100%	111	25.81%

Stock Price Chart of Rating and Target Price Changes:

Note: First annotation denotes initiation of coverage or 3 years, whichever is shorter. If no target price is listed, then the target price is N/A. In accordance with NASD Rule 2711, the chart(s) below reflect(s) price range and any changes to the rating or price target as of the end of the most recent calendar quarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.



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