Acceleron Pharma Inc. (XLRN)

2Q14 Results; Bull Thesis Intact Heading into 4Q Updates

MARKET OUTPERFORM | Price: $28.43 | Target Price: $53.00

MARKET DATA

Price	$28.43
52-Week Range:	$16.78 - $57.89
Shares Out. (M):	26.5
Market Cap ($M):	$753.4
Average Daily Vol. (000):	121.0
Cash (M):	$204
Cash/Share:	$6.49
Enterprise Value (M):	$933
Float (M):	27.0
LT Debt (M):	$0

Source: Thomson Reuters and JMP Securities LLC

FY DEC		2013A	2014E	2015E
Revenue ($M)	1Q	$15.0	$3.3A	$5.2
	2Q	$26.4	$4.1A	$5.4
	3Q	$4.3	$5.4	$20.9
	4Q	$11.5	$5.9	$34.8
	FY	**$57.2**	**$18.7**	**$57.9**
EPS	1Q	$0.12	($0.30)A	--
	2Q	$0.44	($0.52)A	--
	3Q	($5.62)	($0.42)	--
	4Q	($0.64)	($0.42)	--
	FY	**($4.15)**	**($1.68)**	**($0.77)**
	Previous FY	NC	($1.01)	($1.12)

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE

INVESTMENT HIGHLIGHTS

Next meaningful data updates expected toward YE at ASN and ASH; reiterate Market Outperform rating and $53 price target, based on DCF and SOTP valuation methodologies on Acceleron Pharma. As a development stage biotechnology company, Acceleron continues to be a story of successful advancement of hematology assets, ACE-536 and sotatercept, as well as dalantercept, against development milestones. Reported net loss for the quarter was $16.6 million, or EPS of ($0.52), greater than both JMP and consensus estimates of ($0.37) and ($0.46), respectively, due to a one-time litigation settlement charge of $5 million. Collaboration revenue of $4.1 million was below our estimated $5.2 million, and in line with consensus, while operating expenses (outside of the litigation charge) of $16.4 million were in line with consensus. Acceleron finished the quarter with $204 million in cash and cash equivalents, guiding to a cash runway into 2H17. As noted on the call, upcoming potential catalysts from the sotatercept/ACE-536 franchise are weighted toward YE14E, including updated Phase II CKD data at ASN, and Phase II beta-thalassemia and MDS data at ASH. We expect both sets of presentations to provide meaningful read-throughs to later stage development.

Additional cohort and bone biomarker data to be the focus of updated sotatercept Phase II CKD data at ASN in November. Recall, Phase II CKD data presented at the European Renal Association meeting in June included hemoglobin responses from 0.3 and 0.5mg/kg treatment cohorts. Updated data to be presented at ASN will contain hemoglobin responses from a third cohort of 0.7mg/kg, as well as bone biomarker and bone density data across all dosing cohorts, with ameliorating bone effects being a primary driver behind the value proposition of sotatercept in CKD in the view of both Acceleron and its partner Celgene (CELG, MO, $102).

Phase III beta-thalassemia candidate selection anticipated by YE14, followed by two separate trials in NTD and TD patients in mid-2015. We expect Phase II beta-thalassemia updates at ASH, including potentially two additional cohorts in the ACE-536 study (1.0 and 1.25mg/kg), as well as with sotatercept (1.0 and 1.5 mg/kg), to provide a clearer picture on the clinical prospects for the candidates being advanced to Phase III trials. We view the incremental delay to the initiation of Phase III, from YE14/1Q15 previously to mid-2015, as a non-significant event over the longer-term valuation of the stock. Additionally, we view the move to conduct separate studies in non-transfusion dependent versus transfusion dependent patients as prudent, given likely differences in approval end-points, and potential recruitment rates between the patient sub-populations.

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The path forward in MDS, while under evaluation in collaboration with CELG, is more a matter of where, not if. Recall that at EHA, XLRN presented compelling data with ACE-536 in non-del5q low/intermediate risk MDS patients exposed to various prior therapy, including ESAs and/or Revlimid. While recently announced positive top-line Phase III data with Revlimid in the non-del5q setting challenges the true unmet need and market opportunity to be addressed by sotatercept/ACE-536, we anticipate that meaningful opportunity remains either among non-Revlimid responders, or as combination therapy.

Progress is on track with dalantercept and ACE-083. In addition to initiating the randomized expansion cohort portion of the Phase II trial of dalantercept, plus axitinib in TKI-refractory RCC, XLRN announced the initiation of a front-line HCC trial in combination with standard of care sorafenib. The initiation Phase I testing with ACE-083 for the treatment of muscle wasting is slated to begin by YE14.

Acceleron represents a compelling opportunity in the biotechnology space over the course of the next several years. Our view is drawn from the company's focus and understanding of TGF beta biology, as well as developmental and commercialization advantages offered through its strategic partnership with Celgene.

FIGURE 1. Upcoming Potential Milestones

Timing	Drug	Milestones
4Q14E	Sotatercept	Phase IIa CKD update at ASN Meeting
4Q14E	Sotatercept & ACE-536	Interim update from Phase II trials in β-thalassemia and MDS at ASH
4Q14E	ACE-083	Initiation of Phase I trial in muscular dystrophy
Mid-2015E	Sotatercept & ACE-536	Initiation of Phase III trial in β-thalassemia and/or MDS

Source: JMP Securities LLC and Company Reports

REVIEW OF 2Q14 RESULTS AND CHANGES TO OUR MODEL

Reported net loss for the quarter of $16.6 million was greater than both JMP and consensus estimates of $11.3 million and $13 million, respectively. Collaboration revenue of $4.1 million was below our estimated $5.2 million, and in line with consensus. R&D expense of $12.7 million was moderately higher than our estimated $11.9 million, while SG&A expense of $3.7 million was slightly lower than our expected $4.6 million. Acceleron finished the quarter with $204 million in cash and cash equivalents, guiding to a cash runway that extends into 2H17.

We have made few changes to our model (Figure 3), with a negligible impact to our price target valuation. Anticipated milestone revenue of $15 million in 4Q14 has been delayed to 2015. Quarterly 3Q14 and 4Q14 R&D expense have been moderately increased, to reflect with the new run-rate set by 2Q14 actual results. As result of these changes, we now forecast 2014 EPS of ($1.68) compared to ($1.01) previously.

FIGURE 2. 2Q14 Results vs. JMP and Consensus Estimates

Acceleron Pharma (XLRN) Abridged Income Statement ($ MM)	2Q14 Results			
	JMP Estimate	Street Consensus	Actual	Variance (JMP vs. Actual)
Total Revenues	**5.19**	**4.10**	**4.08**	**(1.11)**
Operating Expenses	**16.50**	**16.50**	**16.39**	**0.11**
Research and development	11.90		12.68	(0.78)
General and administrative	4.60		3.71	0.89
One-time litigation charge			**5.00**	
Operating income (loss)	**(11.32)**	**(12.40)**	**(17.31)**	**6.00**
Other income (expense)	**0.04**		**0.76**	**(0.72)**
Pretax Income (loss)	**(11.28)**	**(12.95)**	(16.55)	5.28
Net Income (loss)	**(11.28)**	**(12.95)**	(16.55)	5.28
EPS Calculations				
Basic EPS	**$ (0.37)**	**$ (0.46)**	**$ (0.52)**	**$ (0.16)**
Diluted EPS	**$ (0.37)**	**$ (0.46)**	**$ (0.52)**	**$ (0.16)**
Basic shares outstanding	30.81		31.55	(0.74)
Diluted shares outstanding	30.81		31.55	(0.74)

Source: JMP Securities LLC and Company Reports

FIGURE 3. Changes to Our Model

Acceleron Pharma (XLRN)	3Q14E		4Q14E		FY 2014E		FY 2015E		FY 2016E	
($ MM)	Old	New	Old	New	Old	New	Old	New	Old	New
Collaboration Revenue	**5.4**	**5.4**	**20.9**	**5.9**	**34.8**	**18.7**	**42.9**	**57.9**	**91.2**	**91.2**
COGS	**-**	-	**-**	-	**-**	-	**-**	-	**-**	-
Gross Profit	**5.4**	5.4	**20.9**	5.9	**34.8**	18.7	**42.9**	57.9	**91.2**	91.2
Operating Expenses	**18.0**	**18.6**	**18.8**	**19.4**	**68.8**	**69.9**	**92.9**	**94.8**	**109.3**	**111.6**
Research and development	12.5	13.1	12.9	13.5	49.1	51.0	71.1	74.0	85.4	88.8
General and administrative	5.5	5.5	5.9	5.9	19.8	18.9	21.7	20.7	23.9	22.8
Operating income (loss)	**(12.6)**	(13.2)	**2.1**	(13.5)	**(34.0)**	(51.2)	**(49.9)**	(36.8)	**(18.1)**	(20.4)
Other income (expense)	**0.0**	0.0	**0.0**	0.0	**3.2**	3.9	**3.2**	3.9	**3.2**	3.9
Pretax Income	**(12.5)**	(13.1)	**2.1**	(13.5)	**(30.8)**	(47.3)	**(46.7)**	(32.9)	**(14.8)**	(16.5)
Provision for Income Tax	-	-	-	-	4.6	7.8	11.7	8.2	4.5	4.9
Net Income	**(12.5)**	(13.1)	**2.1**	(13.5)	**(30.8)**	(52.3)	**(35.1)**	(24.7)	**(10.4)**	(11.5)
Basic EPS	**($0.41)**	**$ (0.42)**	**$0.07**	**$ (0.42)**	**($1.01)**	**$ (1.68)**	**($1.12)**	**$ (0.77)**	**($0.33)**	**$ (0.36)**
Diluted EPS	**($0.41)**	**$ (0.42)**	**$0.05**	**$ (0.42)**	**($1.01)**	**$ (1.68)**	**($1.12)**	**$ (0.77)**	**($0.33)**	**$ (0.36)**
Basic shares outstanding	30.9	31.6	31.0	31.7	30.61	31.1	31.2	31.9	31.8	32.5
Diluted shares outstanding	30.9	31.6	44.9	31.7	30.61	31.1	31.2	31.9	31.8	32.5

Source: JMP Securities LLC and Company Reports

FIGURE 4. Updated Income Statement

Income Statement ($MM)	1Q14A	2Q14A	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	3.3	65.3	243.8	542.3	1,033.3
Collaboration Revenue:											
Licensing and milestones	0.7	0.0	0.0	0.0	0.7	32.5	60.0	50.0	100.0	50.0	0.0
Cost-sharing, net	2.6	4.1	5.4	5.9	18.0	25.4	28.0	30.8	33.8	37.2	40.9
Contract Manufacturing											
Total Revenue	3.3	4.1	5.4	5.9	18.7	57.9	91.2	146.1	377.6	629.5	1,074.3
Cost of Goods Sold									4.2	8.1	19.2
Gross Profit	3.3	4.1	5.4	5.9	18.7	57.9	91.2	146.1	373.4	621.4	1,055.0
Operating Expenses:											
Research and Development	11.8	12.7	13.1	13.5	51.0	74.0	88.8	102.1	112.3	122.5	133.5
General and administrative	3.8	3.7	5.5	5.9	18.9	20.7	22.8	32.0	36.7	40.8	44.0
Litigation settlement		5.0									
Cost of contract manufacturing revenue											
Total operating expenses	15.5	21.4	18.6	19.4	74.9	94.8	111.6	134.1	149.1	163.2	177.5
Operating income (loss)	(12.2)	(17.3)	(13.2)	(13.5)	(56.2)	(36.8)	(20.4)	12.0	224.3	458.2	877.5
Total other income, net	3.1	0.8	0.0	0.0	3.9	3.9	3.9	3.9	3.9	3.9	3.9
Pretax income (loss)	(9.1)	(16.6)	(13.1)	(13.5)	(52.3)	(32.9)	(16.5)	15.9	228.2	462.1	881.4
Income tax benefit (provision)					7.8	8.2	4.9	(5.6)	(79.9)	(161.7)	(308.5)
Tax Rate					*15%*	*25%*	*30%*	*35%*	*35%*	*35%*	*35%*
Comprehensive income (loss)	(9.1)	(16.6)	(13.1)	(13.5)	(52.3)	(24.7)	(11.5)	10.3	148.4	300.4	572.9
Pro forma net income (loss) applicable to common	(9.1)	(16.6)	(13.1)	(13.5)	(52.3)	(24.7)	(11.5)	10.3	148.4	300.4	572.9
Pro forma Basic EPS to common shareholders	$ (0.30)	$ (0.52)	$ (0.42)	$ (0.42)	$ (1.68)	$ (0.77)	$ (0.36)	$ 0.31	$ 4.37	$ 8.67	$ 16.18
Pro forma Diluted EPS to common shareholders	$ (0.30)	$ (0.52)	$ (0.42)	$ (0.42)	$ (1.68)	$ (0.77)	$ (0.36)	$ 0.24	$ 3.33	$ 6.62	$ 12.41
Basic shares outstanding	30.3	31.6	31.6	31.7	31.1	31.9	32.5	33.2	33.9	34.7	35.4
Diluted shares outstanding	30.3	31.6	31.6	31.7	31.1	31.9	32.5	43.8	44.6	45.4	46.2

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 TGFβ 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 TGFβ.

Since 2008, the company has benefited from 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 ≥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 upon 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 upon 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 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.
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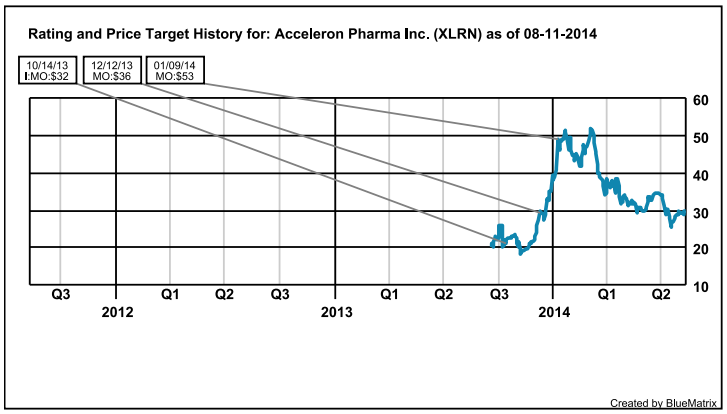
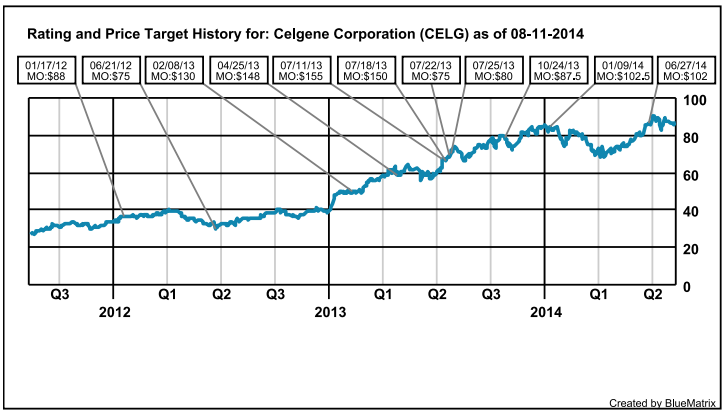
JMP Rating	Regulatory Equivalent	# Co's Under Coverage	*% of Total*	Regulatory Equivalent	# Co's Under Coverage	*% of Total*	# Co's Receiving IB Services in Past 12 Months	*% of Co's With This Rating*
MARKET OUTPERFORM	Buy	267	*60.14%*	Buy	267	*60.14%*	97	*36.33%*
MARKET PERFORM	Hold	137	*30.86%*	Hold	137	*30.86%*	18	*13.14%*
MARKET UNDERPERFORM	Sell	4	*0.90%*	Sell	4	*0.90%*	0	*0%*
COVERAGE IN TRANSITION		36	*8.11%*		36	*8.11%*	0	*0%*
TOTAL:		444	*100%*		444	*100%*	115	*25.90%*

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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