Acceleron Pharma Inc. (XLRN)

Acceleron Reports 1Q14 Results; We Remain buyers into ASCO and EHA

MARKET DATA

Price	$31.75
52-Week Range:	$16.78 - $57.89
Shares Out. (M):	26.5
Market Cap ($M):	$841.4
Average Daily Vol. (000):	209.0
Cash (M):	$214
Cash/Share:	$6.81
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	$5.2	$5.4
	3Q	$4.3	$5.4	$20.9
	4Q	$11.5	$20.9	$34.8
	FY	**$57.2**	**$34.8**	**$42.9**
EPS	1Q	$0.12	($0.30)A	($0.37)
	2Q	$0.44	($0.37)	($0.41)
	3Q	($5.62)	($0.41)	$0.05
	4Q	($0.64)	$0.05	($1.01)
	FY	**($4.15)**	**($1.01)**	**($1.12)**
Previous FY		NC	($1.13)	($1.24)

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE

MARKET OUTPERFORM | Price: $31.75 | Target Price: $53.00

INVESTMENT HIGHLIGHTS

Productive Q1 carrying forward to strong showings at ASCO and EHA; reiterate our Market Outperform rating 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/oncology assets - ACE-536, sotatercept, and dalantercept - against development milestones. Reported net loss for the quarter was $9.1MM or ($0.30) EPS, better than JMP and consensus estimates of ($0.38) and ($0.44), respectively. Collaboration revenue of $3.3MM was below our estimated $4.9MM and above consensus of $2.8MM, while operating expense of $15.5MM was in line with consensus. Acceleron finished the quarter with $214MM in cash and cash equivalents, guiding to a cash runway into 2H17. In addition to reviewing year-to-date progress with ACE-536 for B-thalassemia, sotatercept in ESRD, and recent dalantercept activity in RCC, management briefly outlined upcoming presentations at EHA as well as plans to explore sickle cell anemia as a target indication within the ACE-536 hematology franchise.

Dalantercept RCC responses are all the more encouraging given the heavy prior treatment background for many patients. As noted in the ASCO abstract release yesterday evening, the combination of dalantercept plus Inlyta (axitinib) achieved 25% PR and 50% SD, comparing favorably to single-agent Inlyta in second-line RCC. As noted on the call, several patients achieving PR were exposed to at least three prior lines of therapy, including sequences of TKI and mTOR or immune checkpoint inhibitors, yet managed to mount partial remissions lasting six to 10 months upon treatment with the dalantercept combination. These data bode well for the forthcoming randomized Phase II study comparing dalantercept (0.9mg/kg) plus Inlyta versus Inlyta alone in 130 patients with TKI-refractory RCC.

Three oral abstracts for ACE-536 and sotatercept make for a strong anticipated showing at EHA. These presentations will include separate Phase II B-thalassemia data with ACE-536 and sotatercept (dose-escalation and longer-term, follow-up updates from data disclosed in January and at ASH, respectively), as well as first initial data from ACE-536 in MDS. We remind investors that EHA abstracts will become available online on May 21.

Sickle cell disease seen as natural fit to the ACE-536 development pipeline. Among planned presentations at EHA, Acceleron will present initial pre-clinical data of ACE-536 in a humanized mouse model of sickle cell disease (SCD). By way of background, SCD is a hereditary blood disorder caused by the misfolding of hemoglobin protein downstream of an autosomal recessive point mutation. The aberrant hemoglobin causes cell sickling (deformations to red blood cell shape and elasticity), causing SCD patients to suffer frequently from ischemia, painful vaso-occlusive crises, organ

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damage and hemolysis-induced anemia, similar to that of B-thalassemia (see below for further background information). Forthcoming pre-clinical data suggest that treatment with ACE-536 may alleviate these symptoms by reversing the degree of cell sickling. Given pathophysiogical and epidemiological similarities to B-thal, the unmet need and dearth of new therapy development in the indication, SCD appears well suited, in our view, to ACE-536 and the broader hematology franchise.

Acceleron represents a compelling opportunity in the biotech 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 (CELG, MO, $205 PT).

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 22nd – 26th, 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 30th – June 3rd) and EHA (June 12th-15th)
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

BRIEF BACKGROUND ON SICKLE CELL DISEASE (SCD)

Sickle cell disease (SCD) is an autosomal recessive disorder caused by a single missense mutation (A-to-T) in the sixth codon of the beta chain coding region for hemoglobin, resulting in a mutant form of the protein, referred to as hemoglobin S (HbS). HbS contains a non-polar valine instead of glutamate at the sixth position of the beta subchain, leading to a hydrophobic pocket around that residue and an increased propensity for intracellular polymerization of HbS under deoxygenated conditions, and ultimately the characteristic sickling of red blood cells (RBC). These changes in the physiology of affected red blood cells leading to increased adhesion, forming of aggregates, occlusion of the capillaries, and inhibition of the delivery of oxygen to the tissues. This ultimately leads to necrosis of the affected tissues and severe pain resulting from chronic inflammation of bone, joints or visceral organics that are persistently affected. These acute crises are the most frequent reason for emergency department visits and hospitalization for SCD patients. Patients with chronic SCD also typically develop vasculopathy, which can restrict blood circulation further. The chronic blockage of blood vessels contributes to the development of anemia (low blood count).

Today, therapeutic approaches have commonly relied on symptomatic treatment of the pain, typically managed with a combination of hydration and opioids. Other approaches have tried to reduce polymerization of hemoglobin molecules by upregulating hemoglobin F. To this end, hydroxyurea was found to be effective in reducing some of the associated symptomology including vaso-occlusive crisis (VOC). A number of other drugs have been evaluated as potential interventional strategies, however, all have demonstrated marginal efficacy or been associated with severe toxicities.

REVIEW 1Q14 RESULTS AND CHANGES OUR MODEL.

Reported net loss for the quarter was $9.1MM or ($0.30) EPS, better than JMP and consensus estimates of ($0.38) and ($0.44), respectively. Collaboration revenue of $3.3MM was below our estimated $4.9MM and above consensus of $2.8MM, while operating expense of $15.5MM was in line with consensus. Acceleron finished the quarter with $214MM 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 negligible impact to our price target valuation. Quarterly 2Q14 R&D and G&A expense have been moderately increased and decreased, respectively, to reflect with the new run rate set by 1Q14 actual results. Projected interest expense has been reduced to reflect the retirement of venture debt. As a result of these changes, we now forecast FY14 EPS of ($1.01), compared to ($1.13) previously.

FIGURE 2. 1Q14 Results vs. JMP and Consensus Estimates

Acceleron Pharma (XLRN) Abridged Income Statement ($ MM)	1Q14 Results JMP Estimate	Street Consensus	Actual	Variance (JMP vs. Actual)
Total Revenues	**4.92**	**2.85**	**3.31**	**(1.61)**
Operating Expenses	**15.80**	**15.35**	**15.52**	**0.29**
Research and development	10.80		11.77	(0.97)
General and administrative	5.00		3.75	1.25
Operating income (loss)	**(10.89)**	**(12.50)**	**(12.21)**	**1.32**
Other income (expense)	**(0.46)**		**3.09**	**(3.55)**
Pretax Income (loss)	**(11.35)**	**(13.10)**	(9.12)	(2.23)
Net Income (loss)	**(11.35)**	**(13.10)**	(9.12)	(2.23)
EPS Calculations				
Basic EPS	**$ (0.38)**	**$ (0.44)**	**$ (0.30)**	**$ 0.08**
Diluted EPS	**$ (0.38)**	**$ (0.44)**	**$ (0.30)**	**$ 0.08**
Basic shares outstanding	29.56		30.32	(0.76)
Diluted shares outstanding	29.56		30.32	(0.76)

Source: JMP Securities LLC and Company Reports

FIGURE 3. Changes to Our Model

Acceleron Pharma (XLRN) ($ MM)	2Q14E		3Q14E		4Q14E		FY 2014E		FY 2015E		FY 2016E	
	Old	New	Old	New	Old	New	Old	New	Old	New	Old	New
Collaboration Revenue	**5.2**	**5.2**	**5.4**	**5.4**	**20.9**	**20.9**	**36.4**	**34.8**	**42.9**	**42.9**	**91.2**	**91.2**
COGS	**-**	-	**-**	-	**-**	-	**-**	-	**-**	-	**-**	-
Gross Profit	**5.2**	5.2	**5.4**	5.4	**20.9**	20.9	**36.4**	34.8	**42.9**	42.9	**91.2**	91.2
Operating Expenses	**16.5**	**16.5**	**18.0**	**18.0**	**18.8**	**18.8**	**69.1**	**68.8**	**92.6**	**92.9**	**108.8**	**109.3**
Research and development	11.3	11.9	12.5	12.5	12.9	12.9	47.5	49.1	68.9	71.1	82.7	85.4
General and administrative	5.2	4.6	5.5	5.5	5.9	5.9	21.6	19.8	23.8	21.7	26.1	23.9
Operating income (loss)	**(11.3)**	(11.3)	**(12.6)**	(12.6)	**2.1**	2.1	**(32.7)**	(34.0)	**(49.7)**	(49.9)	**(17.6)**	(18.1)
Other income (expense)	**(0.5)**	0.0	**(0.5)**	0.0	**(0.5)**	0.0	**(1.8)**	3.2	**(1.8)**	3.2	**(1.8)**	3.2
Pretax Income	**(11.8)**	(11.3)	**(13.0)**	(12.5)	**1.6**	2.1	**(34.5)**	(30.8)	**(51.6)**	(46.7)	**(19.4)**	(14.8)
Provision for Income Tax	-	-	-	-	-	-	5.2	4.6	12.9	11.7	5.8	4.5
Net Income	**(11.8)**	(11.3)	**(13.0)**	(12.5)	**1.6**	2.1	**(34.5)**	(30.8)	**(38.7)**	(35.1)	**(13.6)**	(10.4)
Basic EPS	**($0.38)**	**$ (0.37)**	**($0.42)**	**$ (0.41)**	**$0.05**	**$ 0.07**	**($1.13)**	**$ (1.01)**	**($1.24)**	**$ (1.12)**	**($0.43)**	**$ (0.33)**
Diluted EPS	**($0.38)**	**$ (0.37)**	**($0.42)**	**$ (0.41)**	**$0.04**	**$ 0.05**	**($1.13)**	**$ (1.01)**	**($1.24)**	**$ (1.12)**	**($0.43)**	**$ (0.33)**
Basic shares outstanding	30.8	30.8	30.9	30.9	31.0	31.0	30.61	30.6	31.2	31.2	31.8	31.8
Diluted shares outstanding	30.8	30.8	30.9	30.9	44.9	44.9	30.61	30.6	31.2	31.2	31.8	31.8

Source: JMP Securities LLC and Company Reports

FIGURE 4. Updated Income Statement

Income Statement ($MM)	1Q14A	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	3.3	65.3	243.8	542.3	1,033.3
Collaboration Revenue:											
Licensing and milestones	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	3.3	5.2	5.4	5.9	19.8	25.4	28.0	30.8	33.8	37.2	40.9
Contract Manufacturing											
Total Revenue	3.3	5.2	5.4	20.9	34.8	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	3.3	5.2	5.4	20.9	34.8	42.9	91.2	146.1	373.4	621.4	1,055.0
Operating Expenses:											
Research and Development	11.8	11.9	12.5	12.9	49.1	71.1	85.4	98.2	108.0	117.7	128.3
General and administrative	3.8	4.6	5.5	5.9	19.8	21.7	23.9	33.5	38.5	42.7	46.1
Cost of contract manufacturing revenue											
Total operating expenses	15.5	16.5	18.0	18.8	68.8	92.9	109.3	131.6	146.5	160.4	174.4
Operating income (loss)	(12.2)	(11.3)	(12.6)	2.1	(34.0)	(49.9)	(18.1)	14.4	226.9	461.0	880.6
Total other income, net	3.1	0.0	0.0	0.0	3.2	3.2	3.2	3.2	3.2	3.2	3.2
Pretax income (loss)	(9.1)	(11.3)	(12.5)	2.1	(30.8)	(46.7)	(14.8)	17.6	230.1	464.2	883.8
Income tax benefit (provision)					4.6	11.7	4.5	(6.2)	(80.6)	(162.5)	(309.3)
Tax Rate					*15%*	*25%*	*30%*	*35%*	*35%*	*35%*	*35%*
Comprehensive income (loss)	(9.1)	(11.3)	(12.5)	2.1	(30.8)	(35.1)	(10.4)	11.5	149.6	301.7	574.5
Pro forma net income (loss) applicable to common	(9.1)	(11.3)	(12.5)	2.1	(30.8)	(35.1)	(10.4)	11.5	149.6	301.7	574.5
Pro forma Basic EPS to common shareholders	$ (0.30)	$ (0.37)	$ (0.41)	$ 0.07	$ (1.01)	$ (1.12)	$ (0.33)	$ 0.35	$ 4.50	$ 8.89	$ 16.56
Pro forma Diluted EPS to common shareholders	$ (0.30)	$ (0.37)	$ (0.41)	$ 0.05	$ (1.01)	$ (1.12)	$ (0.33)	$ 0.27	$ 3.41	$ 6.76	$ 12.64
Basic shares outstanding	30.3	30.8	30.9	31.0	30.6	31.2	31.8	32.5	33.2	34.0	34.7
Diluted shares outstanding	30.3	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 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 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 ≥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.

JMP FACTS AND DISCLOSURES

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JMP Securities was manager or co-manager of a public offering of securities for Acceleron Pharma Inc. (XLRN) in the past 12 months, and received compensation for doing so.

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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.

Market Underperform (MU): JMP Securities expects the stock price to underperform relevant market indices over the next 12 months.

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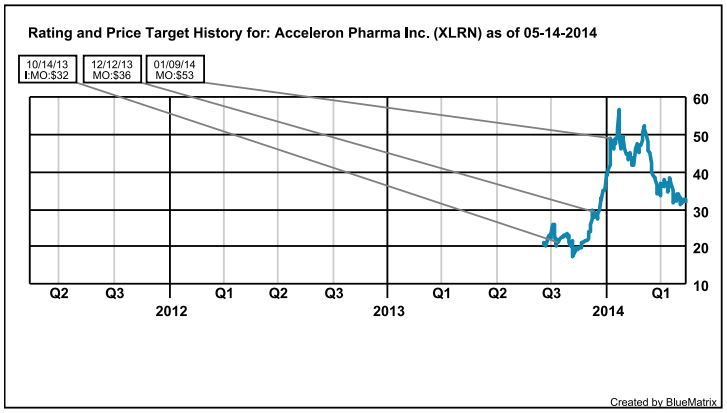
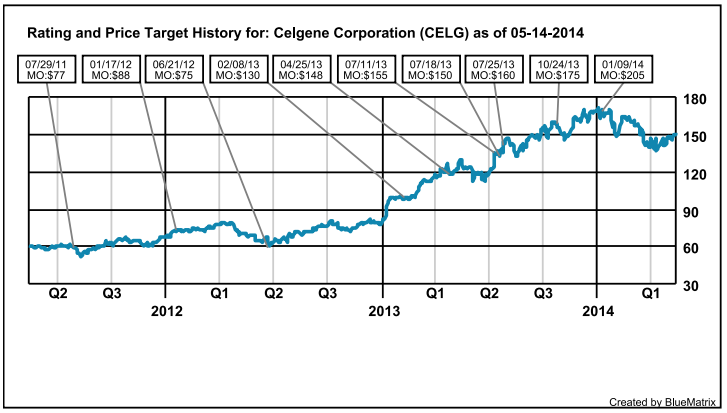
JMP Rating	Regulatory Equivalent	# Co's Under Coverage	*% of Total*	Regulatory Equivalent	# Co's Under Coverage	*% of Total*	# Co's Receiving IB Services in Past 12 Months	*% of Co's With This Rating*
MARKET OUTPERFORM	Buy	255	*58.09%*	Buy	255	*58.09%*	98	*38.43%*
MARKET PERFORM	Hold	136	*30.98%*	Hold	136	*30.98%*	17	*12.50%*
MARKET UNDERPERFORM	Sell	5	*1.14%*	Sell	5	*1.14%*	0	*0%*
COVERAGE IN TRANSITION		43	*9.79%*		43	*9.79%*	0	*0%*
TOTAL:		439	*100%*		439	*100%*	115	*26.20%*

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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