Acceleron Pharma Inc. (XLRN)

Acceleron Reports 3Q13; Data Stream About to Kick Off

MARKET DATA

Price	$19.53
52-Week Range:	$18.50 - $26.73
Shares Out. (M):	26.5
Market Cap ($M):	$517.5
Average Daily Vol. (000):	80.0
Cash (M):	$116
Cash/Share:	$4.13
Enterprise Value (M):	$842
Float (M):	24.3
LT Debt (M):	$14

Source: Thomson Reuters and JMP Securities LLC

FY DEC		2012A	2013E	2014E
Revenue ($M)	1Q	--	$15.0A	$4.9
	2Q	--	$26.4A	$12.2
	3Q	--	$4.3A	$5.4
	4Q	--	$4.7	$20.9
	FY	**$15.3**	**$50.4**	**$43.4**
EPS	1Q	--	$0.12A	($0.33)
	2Q	--	$0.44A	($0.09)
	3Q	--	($5.62)A	($0.34)
	4Q	--	($0.32)	$0.13
	FY	**($1.43)**	**($0.82)**	**($0.57)**
	P/E	NM	NM	NM
	Previous FY	NC	($0.17)	($0.53)

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE

MARKET OUTPERFORM | Price: $19.53 | Target Price: $32.00

INVESTMENT HIGHLIGHTS

Acceleron Pharma's near-term focus is on Sotatercept β-thalessemia update at ASH in December; reiterate our Market Outperform rating and $32 price target, based on our DCF, CAGR, and comparable company valuation methodologies. We remind investors that as a development-stage biotechnology company, the focus for Acceleron is on the successful advancement of its hematology assets, sotatercept and ACE-536 for β-thalassemia and MDS, as well as dalantercept for RCC, rather than earnings results. Management reiterated development timelines for each of these programs today, with a particular emphasis on updates from the dose escalation portion of the sotatercept Phase II trial in β-thalassemia patients to be presented by its partner Celgene at ASH on December 9. Reported net loss of $18.5MM was greater than our $8.5MM estimate and $10.2MM consensus, primarily due to non-cash expense related to the mark-to-market requirement for outstanding warrants to purchase common stock post-IPO. Collaboration revenue of $4.3MM was in line with our estimate, while operating expense of $11.2MM was moderately lower than our $12.9MM estimate. Specifically, the company reported R&D expense of $8.1MM and G&A expense of $3.1MM that were moderately lower than our estimates of $9.1MM and $3.8MM respectively. Acceleron finished the quarter with $116MM in cash and cash equivalents. A comparison of 3Q13 results versus JMP and consensus estimates is provided in Figure 2.

Interim sotatercept β-thalassemia data from the 0.5mg/kg cohort to be presented at ASH. Recall that Acceleron, through its strategic partner Celgene (CELG, MO, $175 PT), is conducting a two-stage Phase II trial of sotatercept in patients with β-thalessemia, first to establish an effective dose in the dose escalation portion and, once established, to assess broader clinical efficacy in an expansion phase. At ASH, investors can expect to see data from the third dosing cohort of 0.5mg/kg, in addition to longer follow-up from patients multiply-dosed at 0.1 and 0.3mg/kg. It is worth noting, however, that these updates will not be a part of the ASH abstract release tomorrow. Enrollment of a fourth cohort at 0.75mg/kg is currently ongoing. As noted on the conference call, Acceleron views durable hemoglobin increases of ≥1.5g/dL as a marker of meaningful clinical benefit in the indication.

Development timelines for sotatercept, ACE-536, and dalantercept remain largely unchanged. During the conference call, management reiterated guidance of updated results from Phase II trials of sotatercept and ACE-536 in MDS and β-thalassemia in 2Q14 (likely at EHA) and again in 4Q14. The company also reaffirmed Celgene's plans to initiate a Phase IIb study of sotatercept in patients with end-stage renal disease (ESRD) with osteopenia during 4Q13/1Q14 - an indication which, if meaningfully successful, offers appreciable upside to our current valuation.

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With dalantercept, the company expects to initiate the randomized expansion portion of the ongoing Phase II, second-line RCC trial in combination with axitinib (Inlyta) by 1Q14 (112 patients) and present top-line results from the dose escalation phase of the study in 1Q14. The company recently confirmed 1.2mg/kg as the recommended Phase II dose, in combination with full-dose axitinib, reporting minimal overlapping or additive toxicity. Finally, the company anticipates clinical updates from two ongoing, single-agent Phase II trials of dalantercept in endometrial cancer and ovarian cancer, sponsored by the Gynecologic Oncology Group (GOG), in 4Q13 or 1Q14, which should inform the potential for further development in either indication and similarly offer potential upside to our valuation.

Impact of 3Q13 results to our model. We have made changes to our model (Figure 3) to reflect the 3Q13 earnings update. FY13 operating expense has been moderately reduced, while other expense has increased to reflect 3Q13 actual results. Outstanding share count estimates have been moderately increased to reflect the reported outstanding share count as of Sept 30. The net effect of these changes has been a lowering of our EPS estimates for FY13 and subsequent years, with negligible impact to our price target valuation.

FIGURE 1. Upcoming Milestones

Timing	Drug	Milestones
4Q13	Sotatercept	Update from Sotatercept Phase II trial in β-thalassemia at ASH (Dec 9)
4Q13/1Q14	Sotatercept	Initiation of Phase II trial in patients with end-stage renal disease (ESRD)
4Q13/1Q14	Dalantercept	Preliminary data from Phase II, GOG-sponsored trials in endometrial and ovarian cancer
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 & ACE-536	Presentation of dose escalation Phase II results in β-thalassemia and MDS
3Q14	Dalantercept	Initiation of Phase II trial(s) in additional indication(s)
4Q14	Sotatercept & ACE-536	Final results from Phase II trials in β-thalassemia and MDS
4Q14	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: Company presentations and JMP Securities LLC

FIGURE 2. 3Q13 Results versus JMP and Consensus Estimates

Acceleron Pharma (XLRN) Abridged Income Statement ($ MM)	3Q13 Results			
	JMP Estimate	Street Consensus	Actual	Variance (JMP vs. Actual)
Total Revenues	**4.33**	**5.48**	**4.27**	**0.06**
Operating Expenses	**12.90**	**14.22**	**11.15**	**1.75**
Research and development	9.10		8.14	0.96
General and administrative	3.80		3.01	0.79
Operating income (loss)	**(8.57)**	**(8.74)**	**(6.88)**	**(1.69)**
Other income (expense)	**0.04**		**(11.63)**	**11.67**
Pretax Income (loss)	**(8.53)**	**(10.20)**	(18.51)	9.98
Net Income (loss)	**(8.53)**	**(10.20)**	(18.51)	9.98
EPS Calculations				
Basic EPS	**$ (0.36)**	**$ (0.46)**	**$ (5.62)**	**$ (5.26)**
Diluted EPS	**$ (0.36)**	**$ (0.46)**	**$ (5.62)**	**$ (5.26)**
Basic shares outstanding	23.630		4.406	19.223
Diluted shares outstanding	23.630		4.406	19.223

Source: JMP Securities LLC and Bloomberg

FIGURE 3. Changes to Our Model

Acceleron Pharma (XLRN)	4Q13E		FY 2013E		FY 2014E		FY 2015E		FY 2016E	
($ MM)	Old	New	Old	New	Old	New	Old	New	Old	New
Collaboration Revenue	**4.7**	**4.7**	**50.5**	**50.4**	**43.4**	**43.4**	**42.9**	**42.9**	**91.2**	**91.2**
COGS	**-**	-	**-**	-	**-**	-	**-**	-	**-**	-
Gross Profit	**4.7**	4.7	**50.5**	50.4	**43.4**	43.4	**42.9**	42.9	**91.2**	91.2
Operating Expenses	**13.2**	**13.2**	**50.3**	**48.5**	**57.6**	**57.6**	**77.2**	**77.2**	**90.7**	**90.7**
Research and development	9.3	9.3	36.1	35.1	39.7	39.7	57.5	57.5	69.0	69.0
General and administrative	3.9	3.9	14.2	13.4	17.9	17.9	19.7	19.7	21.7	21.7
Operating income (loss)	**(8.5)**	(8.5)	**0.2**	1.9	**(14.2)**	(14.2)	**(34.3)**	(34.3)	**0.5**	0.5
Other income (expense)	**0.0**	(0.5)	**(2.5)**	(14.7)	**0.2**	(1.8)	**0.2**	(1.8)	**0.2**	(1.8)
Pretax Income	**(8.5)**	(9.0)	**(2.3)**	(12.8)	**(14.0)**	(16.0)	**(34.1)**	(36.1)	**0.7**	(1.3)
Provision for Income Tax	-	-	-	-	2.1	2.4	8.5	9.0	(0.2)	0.4
Net Income	**(8.5)**	(9.0)	**(4.2)**	(21.0)	**(14.0)**	(16.0)	**(25.6)**	(27.1)	**0.5**	(0.9)
Basic EPS	**($0.32)**	**$ (0.32)**	**($0.17)**	**$ (0.82)**	**($0.53)**	**$ (0.57)**	**($0.95)**	**$ (0.95)**	**$0.02**	**$ (0.03)**
Diluted EPS	**($0.32)**	**$ (0.32)**	**($0.17)**	**$ (0.82)**	**($0.53)**	**$ (0.57)**	**($0.95)**	**$ (0.95)**	**$0.01**	**$ (0.03)**
Basic shares outstanding	26.4	28.1	24.3	25.6	26.58	28.3	26.91	28.6	27.47	29.1
Diluted shares outstanding	26.4	28.1	24.3	25.6	26.58	28.3	26.91	28.6	38.76	29.1

Source: JMP Securities LLC, Company filings

FIGURE 4. Updated Income Statement

Income Statement ($MM)	1Q13A	2Q13A	3Q13A	4Q13E	2013E	1Q14E	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E
Product Sales and Royalties:														
Sotatercept / ACE-536 Royalty Revenue											-	3.3	34.7	123.9
Dalantercept											-	-	-	41.9
Total Product Sales and Royalties	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	3.3	34.7	165.8
Collaboration Revenue:														
Licensing and milestones	12.5	22.9	0.0	0.0	35.4	0.0	7.0	0.0	15.0	22.0	17.5	60.0	50.0	100.0
Cost-sharing, net	2.5	3.5	4.3	4.7	15.0	4.9	5.2	5.4	5.9	21.4	25.4	28.0	30.8	33.8
Contract Manufacturing														
Total Revenue	15.0	26.4	4.3	4.7	50.4	4.9	12.2	5.4	20.9	43.4	42.9	91.2	115.4	299.6
Cost of Goods Sold														4.2
Gross Profit	15.0	26.4	4.3	4.7	50.4	4.9	12.2	5.4	20.9	43.4	42.9	91.2	115.4	295.4
Operating Expenses:														
Research and Development	8.8	8.9	8.1	9.3	35.1	9.6	9.8	10.0	10.3	39.7	57.5	69.0	79.3	87.3
General and administrative	3.1	3.4	3.0	3.9	13.4	4.1	4.3	4.6	4.9	17.9	19.7	21.7	30.4	34.9
Cost of contract manufacturing revenue														
Total operating expenses	11.9	12.3	11.2	13.2	48.5	13.7	14.1	14.6	15.2	57.6	77.2	90.7	109.7	122.2
Operating income (loss)	3.1	14.2	(6.9)	(8.5)	1.9	(8.8)	(2.0)	(9.2)	5.8	(14.2)	(34.3)	0.5	5.7	173.2
Other income (expense):														
Other expense, net	(1.1)	(0.4)		0.0	(1.4)	0.0	0.0	0.0	0.0	0.2	0.2	0.2	0.2	0.2
Interest income	0.0	0.0			0.0									
Interest expense	(0.4)	(0.7)	(0.5)	(0.5)	(2.2)	(0.5)	(0.5)	(0.5)	(0.5)	(2.0)	(2.0)	(2.0)	(2.0)	(2.0)
Total other income, net	(1.5)	(1.1)	(11.6)	(0.5)	(14.7)	(0.5)	(0.5)	(0.5)	(0.5)	(1.8)	(1.8)	(1.8)	(1.8)	(1.8)
Pretax income (loss)	1.6	13.1	(18.5)	(9.0)	(12.8)	(9.2)	(2.4)	(9.6)	5.3	(16.0)	(36.1)	(1.3)	3.8	171.3
Income tax benefit (provision)										2.4	9.0	0.4	(1.3)	(60.0)
Tax Rate										*15%*	*25%*	*30%*	*35%*	*35%*
Comprehensive income (loss)	1.647	13.1	(18.5)	(9.0)	(12.8)	(9.2)	(2.4)	(9.6)	5.3	(16.0)	(27.1)	(0.9)	2.5	111.4
Pro forma net income (loss) applicable to common	2.7	10.1	(24.8)	(9.0)	(21.0)	(9.2)	(2.4)	(9.6)	5.3	(16.0)	(27.1)	(0.9)	2.5	111.4
Pro forma Basic EPS to common shareholders	$ 0.13	$ 0.48	$ (5.62)	$ (0.32)	$ (0.82)	$ (0.33)	$ (0.09)	$ (0.34)	$ 0.19	$ (0.57)	$ (0.95)	$ (0.03)	$ 0.08	$ 3.64
Pro forma Diluted EPS to common shareholders	$ 0.12	$ 0.44	$ (5.62)	$ (0.32)	$ (0.82)	$ (0.33)	$ (0.09)	$ (0.34)	$ 0.13	$ (0.57)	$ (0.95)	$ (0.03)	$ 0.06	$ 2.70
Basic shares outstanding	20.5	21.0	4.4	28.1	25.6	28.1	28.2	28.2	28.3	28.3	28.6	29.1	29.8	30.6
Diluted shares outstanding	22.2	23.1	4.4	28.1	25.6	28.1	28.2	28.2	42.3	28.3	28.6	29.1	40.4	41.2

Source: JMP Securities LLC, Company filings

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 to the company's share price.

Financial. Following its IPO, we estimate that Acceleron will end 4Q13 with approximately $87MM in cash and cash equivalents - adequate resources to fund operations into 2015, according to Acceleron 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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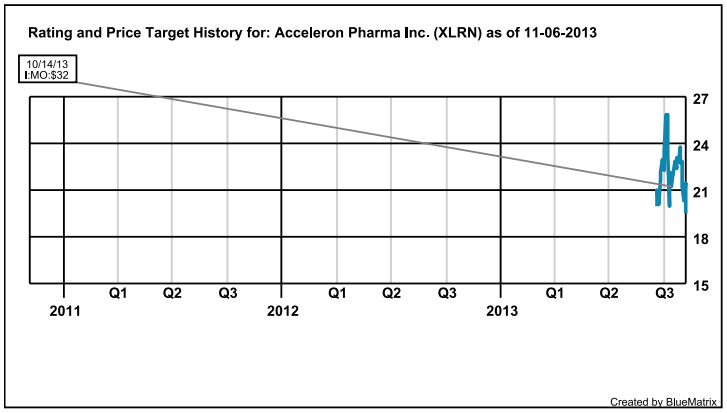
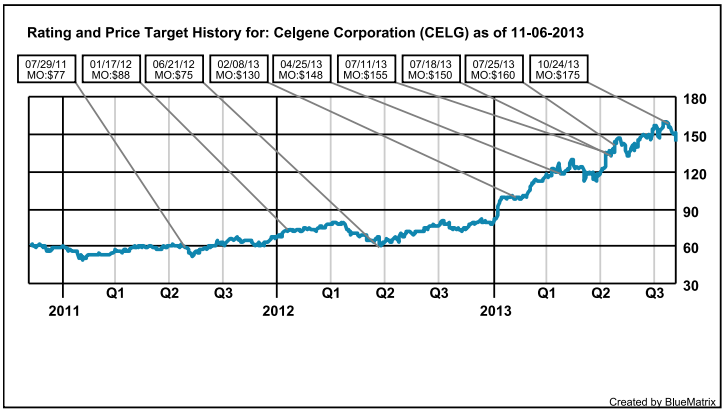
MARKET OUTPERFORM	Buy	251	*61.67%*	Buy	251	*61.67%*	81	*32.27%*
MARKET PERFORM	Hold	150	*36.86%*	Hold	150	*36.86%*	23	*15.33%*
MARKET UNDERPERFORM	Sell	6	*1.47%*	Sell	6	*1.47%*	0	*0%*
TOTAL:		407	*100%*		407	*100%*	104	*25.55%*

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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