Acceleron Pharma Inc. (XLRN)

β-Thalassemia ASH Data Impress as Sotatercept Goes Up in Dose

MARKET DATA

Price	$27.24
52-Week Range:	$16.78 - $26.73
Shares Out. (M):	26.5
Market Cap ($M):	$721.9
Average Daily Vol. (000):	87.0
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

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE

MARKET OUTPERFORM | Price: $27.24 | Target Price: $32.00

INVESTMENT HIGHLIGHTS

Updated Phase IIa sotatercept data in β-thalassemia show increasing hemoglobin response with dose escalation, with minimal impact on safety; reiterate Market Outperform and $32 price target on Acceleron Pharma based on our DCF, CAGR, and comparable company valuation methodologies. The clinical update was shared as a poster presentation this morning (Abstract #3448). Patients treated in the newest cohort with available data of 0.5mg/kg yielded a clear increase in mean hemoglobin counts with increasing duration versus 0.1 and 0.3 mg/kg. Among non-transfusion dependent (NTD) patients, one-third (2/6) achieved Hb increases greater than 2g/dL compared to 0% and 16% among patients treated at 0.1 and 0.3mg/kg, respectively. These data exceeded our expectations for a 1.5g/dL Hb increase. The data also indicate a linear relationship between Hb response and exposure to drug, suggesting the potential for improvement in the rate of ≥2g/dL Hb responses as exposure levels normalize with greater duration. Overall, the data, in our view, are very encouraging. We suspect further gains in treatment effect can be had with continued dose escalation. A 0.75mg/kg cohort is currently enrolling.

Additional thoughts on efficacy. In addition to appreciable hemoglobin induction in patients treated at 0.5mg/kg, we were impressed by the duration and high proportion of patients that continue to derive benefit at 0.3mg/kg (7/8 patients on therapy for ≥52 weeks). Two patients treated in the 0.5mg/kg cohort saw Hb increases high enough to (>11g/dL) to enable a dose delay before resuming therapy – a testament to the drug's robust activity, in our view.

Increasing dose shows minimal impact to safety profile. One treatment related adverse event of Grade 3 ventricular extra systoles (premature ventricular contraction) was observed in the 0.5mg/kg cohort; however, this patient had presented with ventricular extra systoles at baseline. Similar for adverse events observed at the lowest dose of 0.1mg/kg, Grade 3 bone pain was observed in patients with baseline osteoporosis, while grade 2 phlebitis was observed in patients with related baseline comorbidity. In our opinion, Sotatercept's safety profile is more impressive when placed in context, suggesting appreciable headroom at higher dosing cohorts.

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, $175 PT). In our opinion, the company's first wave of product candidates, validated by Celgene's significant investment, is but the tip of the iceberg that, over time, should create significant value for shareholders.

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FIGURE 1. Upcoming Milestones

Timing	Drug	Milestones
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 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, JMP Securities LLC

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

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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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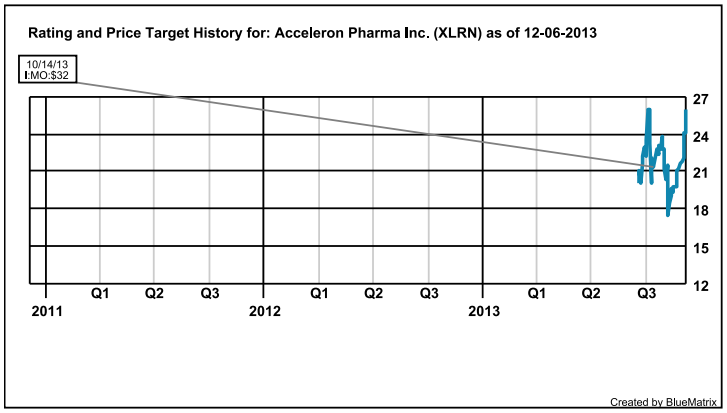
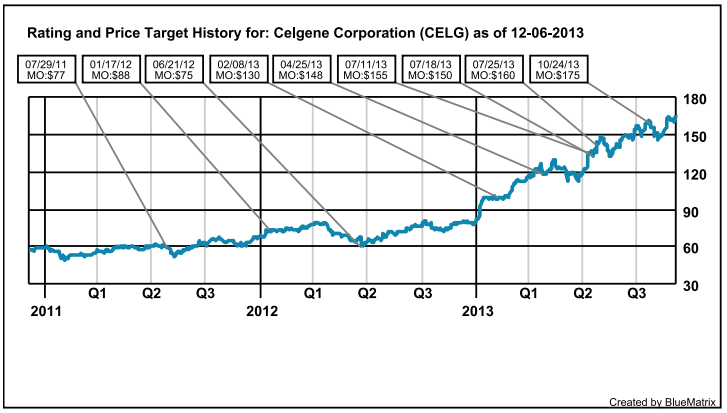
MARKET OUTPERFORM	Buy	228	*54.68%*	Buy	228	*54.68%*	89	*39.04%*
MARKET PERFORM	Hold	139	*33.33%*	Hold	139	*33.33%*	25	*17.99%*
MARKET UNDERPERFORM	Sell	5	*1.20%*	Sell	5	*1.20%*	0	*0%*
COVERAGE IN TRANSITION		45	*10.79%*		45	*10.79%*	0	*0%*
TOTAL:		417	*100%*		417	*100%*	114	*27.34%*

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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