Acceleron Pharma Inc. (XLRN)

Interim Data Presented at NKF Indicate Growing Potential for Sotatercept in Treatment of Anemia in Hemodialysis Patients

MARKET OUTPERFORM | Price: $31.85 | Target Price: $53.00

MARKET DATA

Price	$31.85
52-Week Range:	$16.78 - $57.89
Shares Out. (M):	26.5
Market Cap ($M):	$844.0
Average Daily Vol. (000):	207.0
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

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)**

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE

INVESTMENT HIGHLIGHTS

Dose-dependent increase in hemoglobin and promising safety profile highlight budding success of sotatercept in ESRD; reiterate our Market Outperform rating on Acceleron Pharma and $53 price target based on our DCF and SOTP valuation methodologies. Recently, Acceleron Pharma and its collaboration partner Celgene (CELG, MO, $205 PT) presented interim data from a Phase IIa study of sotatercept in patients with end-stage renal disease (ESRD) at the National Kidney Foundation meeting (NKF) taking place April 23 - 26 in Las Vegas, NV. We are currently in attendance. Interim pharmacologic, hemoglobin (Hb), and safety data were presented by Dr. William Smith of Celgene Corporation from the first 28-day dose cycle for two dose groups of sotatercept (0.3 mg/kg and 0.5 mg/kg) versus placebo. In the interim data presented thus far, sotatercept exhibited linear PK characteristics and a half-life of 22 to 25 days. Baseline Hb in the three treatment groups was 9.7 g/dL in placebo, 9.3 g/dL in 0.3 mg/kg, and 8.8 g/dL in 0.5 mg/kg. After a single dose in the placebo, 0.3 mg/kg and 0.5 mg/kg sotatercept groups, mean peak hemoglobin in the first 28 days were increased by 0.1, 0.5, and 0.8 g/dL, respectively. In addition, while 40% of placebo-treated patients required rescue with erythropoietin-stimulating agents (ESAs), only 13% of the 0.3 mg/kg treated group and none of the 0.5 mg/kg treated patients did. An increase in hemoglobin of >1 g/dL was observed in 20% of placebo patients vs. 37% of 0.3 mg/kg and 40% in 0.5 mg/kg. There have been some questions as to why 20% of placebo patients would exhibit such a high response. However, consider that 20% represents only 1 of 5 placebo patients and that the increase may be related to administration of exogenous IV iron and folate as part of the stated study design to normalize serum TSAT and folate above minimum thresholds.

Safety profile for sotatercept has been strong to date, indicating an opportunity for significant improvement over ESAs. The sotatercept data presented at NKF suggest that adverse events (AEs) in the study were mostly mild, unrelated to study drug, and generally consistent with patients' medical histories. While there was one patient who had to discontinue participation in the study due to pre-existing hypertension, this patient should have been excluded as having violated the study protocol restrictions. Overall sotatercept was well tolerated, with AEs similar to those in the placebo group and no trend toward an increase in blood pressure. In addition, sotatercept was not associated with the development of anti-drug antibodies, injection site reactions, or hypersensitivity reactions. A summary of subject disposition for all study participants is detailed in Figure 1.

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Accrual of additional data points for Phase II studies key to unlocking value from successful anemia program. The Phase IIa interim results presented at NKF, while promising, should benefit from accrual of additional patients. Only two of the five patients treated with the 0.5 mg/kg dose have received the eight doses of sotatercept called for under the initial study design. The Phase IIa study also calls for both an additional fourth 0.7 mg/kg monthly treatment arm as well as a fifth 0.7 mg/kg loading dose followed by bi-weekly 0.4mg/kg treatment. Unfortunately, these data were not presented at NKF. Additional interim data from this Phase IIa study is expected to read-out at the European Renal Association meeting taking place in Amsterdam this May. Finally, Celgene plans to initiate an additional Phase IIb trial to begin enrollment in 2H2014.

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). In our opinion, the interim data presented at NKF is robust and shows potential for significant improvement in increasing hemoglobin and reducing adverse events in patients refractory to ESA use. Sotatercept is just part of the company's first wave of product candidates and is the tip of the iceberg that, in our opinion, should create significant value for shareholders over time.

FIGURE 1.Study Patient Disposition for All Subjects (n=20)

			Sotatercept	
		Placebo (n=5)	0.3 mg/kg (n=9)	0.5 mg/kg (n=6)
Still being followed (<200 days)	On Study Drug	0	0	3
	D/C study drug	2	0	2
Completed Study (>200 days)	Still on Study Drug	1	2	0
	D/C study drug	1	5	0
	Early Termination	1	2	1
	Total	5	9	6
	Protocol Violation	0	0	1
	Rescued By ESA	3	7	2

Source: Company reports

FIGURE 2. Upcoming Milestones

Timing	Drug	Milestones
2014 ASCO (May 30)	Sotatercept & ACE-536	Initiation of RP2D expansion cohorts in ongoing β-thalassemia Phase II trials
2014 ASCO (May 30)	Dalantercept	Preliminary data from dose-escalation stage of Phase II RCC trial in combination with axitinib; start of randomized stage versus axitinib alone
2014 EHA (Sept 12)	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 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.

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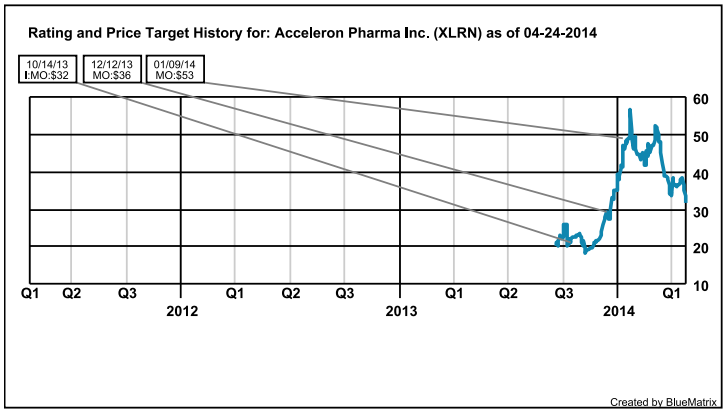
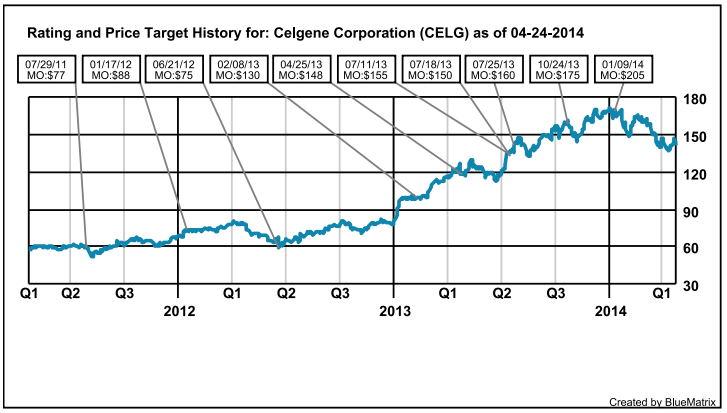
MARKET OUTPERFORM	Buy	254	*58.53%*	Buy	254	*58.53%*	98	*38.58%*
MARKET PERFORM	Hold	132	*30.41%*	Hold	132	*30.41%*	16	*12.12%*
MARKET UNDERPERFORM	Sell	6	*1.38%*	Sell	6	*1.38%*	0	*0%*
COVERAGE IN TRANSITION		42	*9.68%*		42	*9.68%*	0	*0%*
TOTAL:		434	*100%*		434	*100%*	114	*26.27%*

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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