Acceleron Pharma Inc. (XLRN)

Raising Price Target to $53 on Inclusion of ESRD Market for Sotatercept

MARKET DATA

Price	$45.83
52-Week Range:	$16.78 - $43.70
Shares Out. (M):	26.5
Market Cap ($M):	$1,214.5
Average Daily Vol. (000):	332.0
Cash (M):	$116
Cash/Share:	$4.13
Enterprise Value (M):	$678
Float (M):	24.2
LT Debt (M):	$11

Source: Thomson Reuters and JMP Securities LLC

FY DEC		2012A	2013E	2014E
Revenue ($M)	1Q	--	$15.0A	$4.9
	2Q	--	$26.4A	$5.2
	3Q	--	$4.3A	$5.4
	4Q	--	$11.7	$20.9
	FY	**$15.3**	**$57.4**	**$36.4**
EPS	1Q	--	$0.12A	($0.33)
	2Q	--	$0.44A	($0.33)
	3Q	--	($5.62)A	($0.34)
	4Q	--	($0.07)	$0.13
	FY	**($1.43)**	**($0.55)**	**($0.81)**
	P/E	NM	NM	NM

Source: Company reports and JMP Securities LLC

STOCK PRICE PERFORMANCE

MARKET OUTPERFORM | Price: $45.83 | Target Price: $53.00

INVESTMENT HIGHLIGHTS

We reiterate our Market Outperform rating on Acceleron Pharma and increase our price target from $36 to $53, based on market potential of sotatercept for use in ESRD patients with anemia. The market for anemia in end stage renal disease (ESRD) has been dominated in the past two decades by Amgen's (AMGN, Not Covered) erythropoiesis stimulating agent (ESA) Epogen. While annual U.S. sales of Epogen are ~$2 billion, heavy ESA use in ESRD patients on hemodialysis (HD) is a known risk factor for cardiovascular complications, hypertension, and death. In a study of 94,569 ESRD patients sponsored by the National Kidney Foundation (NKF), patient cohorts that were administered the highest doses of Epogen had both greater mortality rates and lower hematocrit levels indicating a reduced responsiveness to the drug (Zhang Y, et al. Am J Kidney Disease, 2004). The authors also found a significant non-linear relationship between increased Epogen dose and mortality ($p<0.0001$), with the steepest increase in relative risk for death found after the 72.5th dose percentile (>20,000 U/wk). Clinicians could, therefore, reduce the relative risk of death in over a quarter of ESRD patients being dosed with Epogen above these levels by switching to an anemia drug with a mechanism of action that does not target the EPO-receptor. Sotatercept is well positioned for this role as it functions by blocking negative regulators of red blood cell (RBC) differentiation in the TGF-beta superfamily. In addition, sotatercept inhibits activin A, a TGF-beta ligand whose inhibition has been shown to reduce bone loss and vascular calcification associated with renal osteodystrophy.

Positive data from current sotatercept Phase II trials in ESRD critical for success. Currently, XLRN is partnered with Celgene (CELG, MO, $175 PT) in two Phase II trials in ESRD. The first is a Phase IIa dose escalation trial (NCT01146574) seeking to evaluate pharmacodynamics as primary outcomes, and safety, efficacy, and tolerability as secondary outcomes. The second Phase II trial (NCT01999582) is a randomized, open-label study of intravenous and subcutaneous administration of sotatercept in subjects with ESRD on hemodialysis switched from ESAs. Primary outcomes focus on pharmacodynamics and adverse events, but secondary outcomes will measure both efficacy and bone turnover. Both trials are critical for sotatercept's success, as demonstrating safety with similar or better efficacy in treating anemia compared to ESAs will allow sotatercept to gain market share from Epogen. In addition, an ability to demonstrate reduction in bone loss could enable sotatercept to become the new gold standard for anemic ESRD patients suffering from renal osteodystrophy. We expect XLRN to present data for sotatercept in ESRD at the spring NKF meeting taking place April 22-26 in Las Vegas, NV. The company will also be presenting data on the use of sotatercept and ACE-536 at ASCO (May 30th – June 3) and EHA (June 12-15) in the MDS and beta-thalassemia patient setting.

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Addition of ESRD patient population for sotatercept drives $53 price target in our XLRN model. The ESRD population currently taking ESAs for anemia is over 300,000 in the U.S. and close to one million WW. Based on the increased risk of death associated with high-dose Epogen discussed above, we believe 27.5% of this patient population would be eligible for switching to an anemia drug without an EPO-receptor dependent mechanism of action. A conservative market penetration of 15-18% in these high-dose EPO patients is sufficient to increase our price target from $36 to $53, based on our SOTP ($50) and DCF ($56) valuation methodologies.

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, which is sponsoring clinical trials for sotatercept in MDS, multiple myeloma, Diamond-Blackfan anemia and myelofibrosis. In addition, a second TGF-beta candidate, ACE-536, is currently under study in beta-thalassemia and may be the first of Acceleron's products to make it to market. 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.

FIGURE 1. XLRN - Some-of-the-Parts (SOTP) Model Summary

Sum of Parts Acceleron NPV	WW	US	Ex-US
Sotatercept/ACE-536 B-Thalassemia	**$ 20.57**	$ 2.63	$ 17.93
Sotatercept/ACE-536 MDS	**$ 4.06**	$ 2.23	$ 1.83
Sotatercept ESRD	**$ 16.70**	$ 11.39	$ 5.31
Dalantercept	**$ 4.99**	$ 4.03	$ 0.96
Cash and Equivs on Hand	**$ 3.24**		
Total NPV	**$ 49.56**	**$ 20.28**	**$ 26.04**

Source: JMP Securities LLC and Company Reports

FIGURE 2. Sotatercept in ESRD - NPV Model

Sotatercept ESRD	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
US Sales ($MM)				$ -	$ 146	$ 313	$ 671	$ 1,078	$ 1,443	$ 1,752	$ 1,986	$ 2,127	$ 2,278
US Royalty %				*20%*	*20%*	*20%*	*22%*	*22%*	*22%*	*24%*	*24%*	*24%*	*24%*
US Royalty ($MM)				$ -	$ 29	$ 63	$ 148	$ 237	$ 317	$ 420	$ 477	$ 511	$ 547
Contribution Margin				*100%*	*95%*	*90%*	*85%*	*75%*	*65%*	*65%*	*65%*	*65%*	*65%*
Operating Margin				**0.0**	**27.8**	**56.4**	**125.5**	**177.9**	**206.4**	**273.3**	**309.9**	**331.9**	**355.4**
Terminal Value													**1,545.4**
Discount Period				2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0
PV of CF to XLRN				**0.0**	**14.2**	**23.1**	**41.1**	**46.6**	**43.3**	**45.8**	**41.6**	**35.6**	**30.5**
Discount Rate	25%												
Terminal Growth	2%												
NPV	**$ 321.94**												
# Shares outstanding (mm)	28.3												
Incremental price per share	**$ 11.39**												
Ex-US Sales ($MM)				$ -	$ -	$ -	$ 97	$ 421	$ 858	$ 1,210	$ 1,576	$ 1,833	$ 1,920
US Royalty %				*20%*	*20%*	*20%*	*20%*	*20%*	*20%*	*20%*	*21%*	*21%*	*21%*
Ex-US Royalty ($MM)				$ -	0	$ -	$ 19	$ 84	$ 172	$ 242	$ 331	$ 385	$ 403
Contribution Margin						*90%*	*85%*	*75%*	*65%*	*65%*	*65%*	*65%*	*65%*
Royalty to Acceleron					**0.0**	**0.0**	**16.6**	**63.2**	**111.5**	**157.3**	**215.1**	**250.2**	**262.1**
Terminal Value													**1,048.2**
Discount Period				2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0	11.0
PV of CF to XLRN				**0.0**	**0.0**	**0.0**	**5.4**	**16.6**	**23.4**	**26.4**	**28.9**	**26.9**	**22.5**
Discount Rate	25%												
Terminal Growth	0%												
NPV	**$ 150.00**												
# Shares outstanding (mm)	28.3												
Incremental price per share	**$ 5.31**												

Source: JMP Securities LLC and Company Reports

FIGURE 3. Sotatercept in ESRD - U.S. Market Potential

US										
Sotatercept in ESRD ($MM)	**2016E**	**2017E**	**2018E**	**2019E**	**2020E**	**2021E**	**2022E**	**2023E**	**2024E**	**2025E**
Epidemiology										
ESRD prevalence population	403,299	411,365	419,592	427,984	436,543	445,274	454,180	463,263	472,529	481,979
% growth	*2.0%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*	*2.0%*
% of Dialysis Population on ESA	*90%*	*90%*	*90%*	*90%*	*90%*	*90%*	*90%*	*90%*	*90%*	*90%*
# of ESRD Patients on ESAs	362,969	370,228	377,633	385,185	392,889	400,747	408,762	416,937	425,276	433,781
% high epo	*27.5%*	*27.5%*	*27.5%*	*27.5%*	*27.5%*	*27.5%*	*27.5%*	*27.5%*	*27.5%*	*27.5%*
Addresssable ESRD population	99,816	101,813	103,849	105,926	108,044	110,205	112,409	114,658	116,951	119,290
Sotatercept Penetration		***2%***	***4%***	***8%***	***12%***	***15%***	***17%***	***18%***	***18%***	***18%***
# of Patients on Sotatercept		2,036	4,154	8,474	12,965	16,531	19,110	20,638	21,051	21,472
Target cycles on therapy (4 week cycle)		12.0	12.0	12.0	12.0	12.0	12.0	12.0	12.0	12.0
% Less percent 1-year mortality		*20%*	*20%*	*20%*	*20%*	*20%*	*20%*	*20%*	*20%*	*20%*
Average cycles on therapy		9.6	9.6	9.6	9.6	9.6	9.6	9.6	9.6	9.6
Total Patient Cycles on Therapy		**19,548**	**39,878**	**81,351**	**124,467**	**158,696**	**183,452**	**198,128**	**202,091**	**206,133**
% growth			*104.0%*	*104.0%*	*53.0%*	*27.5%*	*15.6%*	*8.0%*	*2.0%*	*2.0%*
Cost per 3-week cycle of therapy in beta-thal	$ 9,500	$ 9,975	$ 10,474	$ 10,997	$ 11,547	$ 12,125	$ 12,731	$ 13,367	$ 14,036	$ 14,738
Implied cost per 4-week cycle in ESRD	$ 7,125	$ 7,481	$ 7,855	$ 8,248	$ 8,660	$ 9,094	$ 9,548	$ 10,026	$ 10,527	$ 11,053
% price increase		*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*	*5%*
US Sales of Sotatercept		**$146.2**	**$313.3**	**$671.0**	**$1,077.9**	**$1,443.1**	**$1,751.6**	**$1,986.4**	**$2,127.4**	**$2,278.4**

Source: JMP Securities LLC and Company Reports

FIGURE 4. Upcoming Milestones

Timing	Drug	Milestones
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	Presentation of data in ESRD at National Kidney Foundation meeting (April 22nd – 26th, 2014 - Las Vegas, NV)
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(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: 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 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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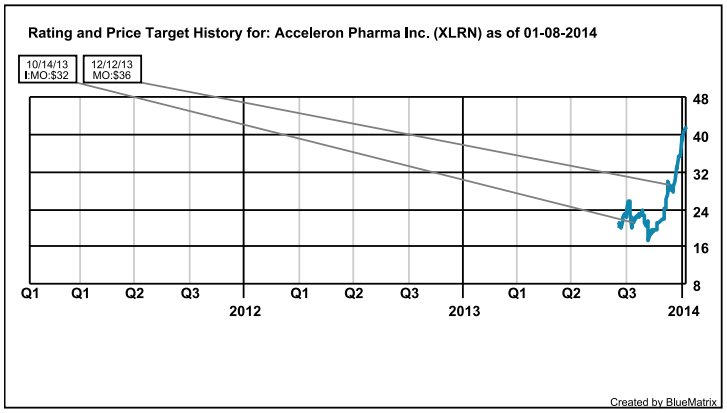
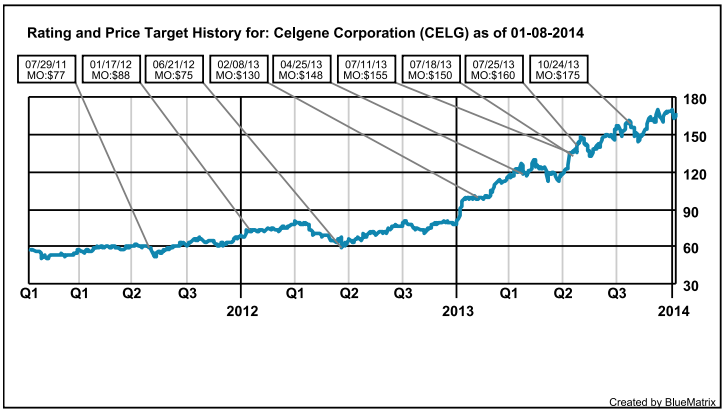
MARKET PERFORM	Hold	145	*33.33%*	Hold	145	*33.33%*	26	*17.93%*
MARKET UNDERPERFORM	Sell	6	*1.38%*	Sell	6	*1.38%*	0	*0%*
COVERAGE IN TRANSITION		43	*9.89%*		43	*9.89%*	0	*0%*
TOTAL:		435	*100%*		435	*100%*	118	*27.13%*

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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