Acceleron Pharma Inc. (XLRN)

ACE-536 Data Update in Beta-thalassemia

MARKET OUTPERFORM | Price: $46.31 | Target Price: $53.00

MARKET DATA

Price	$46.31
52-Week Range:	$16.78 - $49.33
Shares Out. (M):	26.5
Market Cap ($M):	$1,227.2
Average Daily Vol. (000):	533.0
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

INVESTMENT HIGHLIGHTS

The recent S-1 filing by Acceleron Pharma discloses encouraging Phase II results for ACE-536 in non-transfusion dependent beta-thalassemia on par with those of sotatercept, which were presented at ASH in December; we reiterate our Market Outperform rating and $53 price target based on our DCF, SOTP, and CAGR valuation methodologies. Data from the Phase II dose escalation study thus far show a clear dose-dependent effect on hemoglobin (Hgb) levels, patients treated in the third cohort of 0.6mg/kg achieving a mean Hgb increase of ~1.5mg/dL. Further details from the study, including results from additional dose cohorts, are expected to be presented at EHA in June. In our view, these data underscore the therapeutic potential of the sotaercept/ACE-536 TGF-beta franchise as well as a high level of optionality afforded by the "pick-a-winner" development strategy across a spectrum of anemic disorders.

Phase II data already puts ACE-536 over the threshold for success. Recall, ACE-536 is being evaluated for its ability to stimulate erythrocyte production and alleviate anemia for patients with non-transfusion dependent (NTD) and transfusion dependent (TD) beta-thalassemia in a Phase II dose escalation study. Data to date reported in the S-1 describe mean Hgb increases of 0.0, 0.8, and ~1.5g/dL from baseline across dosing cohorts of 0.2, 0.4, and 0.6mg/kg, respectively, in NTD patients (six patients per cohort). Hgb increase of ≥ 1.5g/dL from baseline within a two-week period has been described as the threshold for demonstrating efficacy in NTD disease. Dose escalation continues, with the trial recently completing enrollment of a 0.8mg/kg cohort and proceeding with a fifth cohort of 1.0mg/kg. On the safety front, ACE-536 continues to be well tolerated, yielding one DLT event of bone pain observed at 0.8mg/kg in a patient with similar preexisting symptoms, according to management.

Encouraging progress also noted in ESRD. Updated language in the recent S-1 filing also refers to progress in the first of two Phase II trials of subcutaneously administered sotatercept in patients with end stage renal disease on hemodialysis. Specifically, the S-1 notes "encouraging early data" characterized by "dose-dependent increases in hemoglobin." While the strength of these data remains to be seen through presentations at the National Kidney Foundation Meeting (April 22 to 26 in Las Vegas), we suspect the use of alternative dose and formulation regimens currently under evaluation in the recently initiated Phase II study could yield further improvement.

Acceleron represents 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, $205PT). In our opinion, the company's first wave of product candidates is 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	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

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, and received compensation for doing so, for Acceleron Pharma Inc. in the past 12 months.

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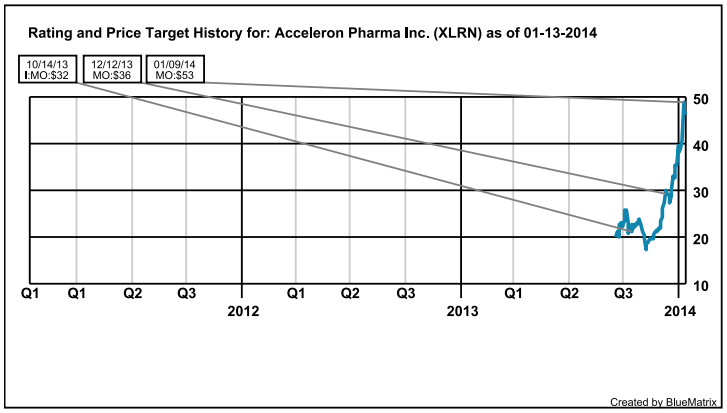
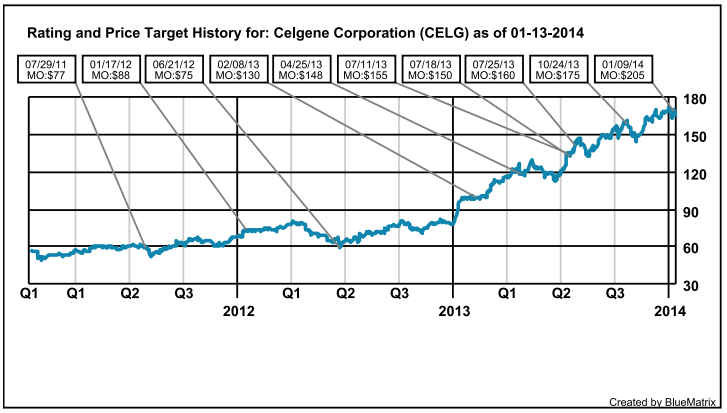
MARKET OUTPERFORM	Buy	243	*55.86%*	Buy	243	*55.86%*	92	*37.86%*
MARKET PERFORM	Hold	143	*32.87%*	Hold	143	*32.87%*	26	*18.18%*
MARKET UNDERPERFORM	Sell	6	*1.38%*	Sell	6	*1.38%*	0	*0%*
COVERAGE IN TRANSITION		43	*9.89%*		43	*9.89%*	0	*0%*
TOTAL:		435	*100%*		435	*100%*	118	*27.13%*

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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