

## First Read

# Akebia Therapeutics Inc

## Investigator Supportive of AKB-6548 Benefit/Risk

### Conclusion: Incrementally positive based on investigator's view on safety data

Akebia reviewed the full results from the AKB-6548 phase-2b study in non-dialysis anemia with investigator Dr. Bruce Spinowitz. Recall that the key point of debate has been the imbalance in serious adverse events (SAEs), which to some suggested a high level of clinical/regulatory risk to the program. Dr. Spinowitz argued that the imbalance was due to variability in classification, not variability in clinical experience, based on patient-level analysis of data that was not previously available. Overall the update appears to support a favorable view on the risk/reward in AKBA shares. Maintain Buy.

### Key takeaways from the call

**[1]** Dr. Spinowitz argued that the imbalance in SAEs was due to variability in classification and that a comparison of dialysis initiations (8.0% with '6548 vs. 9.7% in placebo) is a more objective measure for severity of renal AEs. Importantly, analysis of patient-level detail shows the drug-treated patients were clinically no worse than placebo patients. Regarding the deaths, the investigator (and expert community) appears unconcerned given the predicted death rate would have been 2-4 based on TREAT and CHOIR, in line with the 3 observed. **[2]** Management expects to begin ph3 later this year, which we think would also lower perceived clinical risk. The briefing package has been shared with FDA and European regulatory agencies, and meetings so far have focused on the ph3 design, not safety concerns. Akebia will provide an update of the trial design after meeting with the FDA, which they expect in 2Q. A formal EMA meeting is expected in 3Q. **[3]** Akebia is planning to partner Japan (possibly by YE15e), and may also partner EU 1H16e. We think partnerships will also lower perceived risk.

### Risk-reward looks better for 2015 now that safety overhang should be lifted

We note that our PT assumes 35% probability of technical success (POTS). Given the investigator's outlook on the safety results, the potential blessing by FDA to advance, further dialysis data this year, and partnership all should improve perception of '6548.

### Valuation: Buy, \$24 PT by SOTP supported by DCF (assumes 35% POTS)

Our upside scenario valuation of \$49 assumes a standard ph3 60% POTS.

## Equities

Americas  
Biotechnology

12-month rating **Buy**

12m price target **US\$24.00**

Price **US\$12.94**

RIC: AKBA.O BBG: AKBA US

### Trading data and key metrics

52-wk range	US\$29.17-8.81
Market cap.	US\$0.26bn
Shares o/s	19.8m (COM)
Free float	32%
Avg. daily volume ('000)	136
Avg. daily value (m)	US\$1.5
Common s/h equity (12/15E)	US\$0.19bn
P/BV (12/15E)	1.6x
Net debt / EBITDA (12/15E)	NM

### EPS (UBS, diluted) (US\$)

	12/15E	
	UBS	Cons.
Q1E	(0.54)	(0.57)
Q2E	(0.74)	(0.64)
Q3E	(0.75)	(0.72)
Q4E	1.94	0.48
12/15E	(0.09)	(1.46)
12/16E	(0.55)	(0.97)
12/17E	(1.04)	(2.07)

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Highlights (US\$m)	-	12/13	12/14	12/15E	12/16E	12/17E	12/18E	12/19E
Revenues	-	0	0	84	83	86	99	469
EBIT (UBS)	-	(16)	(38)	14	(16)	(31)	(57)	201
Net earnings (UBS)	-	(13)	(690)	(2)	(15)	(30)	(56)	196
EPS (UBS, diluted) (US\$)	-	(24.20)	(44.82)	(0.09)	(0.55)	(1.04)	(1.65)	5.35
DPS (US\$)	-	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Net (debt) / cash	-	21	84	193	179	149	277	191
Profitability/valuation	-	12/13	12/14	12/15E	12/16E	12/17E	12/18E	12/19E
EBIT margin %	-	-	-	16.9	-19.8	-36.4	-57.8	42.9
ROIC (EBIT) %	-	-	(481.3)	390.5	>500	>500	>500	<-500
EV/EBITDA (core) x	-	-	-9.0	8.2	-4.4	-3.0	-0.8	0.2
P/E (UBS, diluted) x	-	-	(0.5)	NM	(23.7)	(12.4)	(7.9)	2.4
Equity FCF (UBS) yield %	-	-	(31.5)	6.2	(5.7)	(11.5)	(21.4)	76.9
Net dividend yield %	-	-	0.0	0.0	0.0	0.0	0.0	0.0

Source: Company accounts, Thomson Reuters, UBS estimates. Metrics marked as (UBS) have had analyst adjustments applied. Valuations: based on an average share price that year, (E): based on a share price of US\$12.94 on 16 Mar 2015 10:12 EDT

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### Forecast returns

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Forecast price appreciation	+85.4%
Forecast dividend yield	0.0%
Forecast stock return	+85.4%
Market return assumption	5.7%
Forecast excess return	+79.7%

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### Statement of Risk

We see several risks to AKBA shares, including clinical, regulatory, IP, competitive, and commercial. Clinical risks include if AKB-6548 results in unforeseen safety, tolerability, or toxicity signals, or fails to yield positive clinical results. Regulatory risks include the regulatory agencies not approving the drug candidate after completing clinical trials. Competitive risks include Akebia not being the only company developing treatments for anemia secondary to chronic kidney disease, and new treatments coming to market will all compete with currently available erythropoiesis-stimulating agents. Branded and generic competitors could challenge Akebia's patent estate.

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12-Month Rating	Definition	Coverage <sup>1</sup>	IB Services <sup>2</sup>
Buy	FSR is > 6% above the MRA.	47%	37%
Neutral	FSR is between -6% and 6% of the MRA.	42%	32%
Sell	FSR is > 6% below the MRA.	11%	21%
Short-Term Rating	Definition	Coverage <sup>3</sup>	IB Services <sup>4</sup>
Buy	Stock price expected to rise within three months from the time the rating was assigned because of a specific catalyst or event.	less than 1%	less than 1%
Sell	Stock price expected to fall within three months from the time the rating was assigned because of a specific catalyst or event.	less than 1%	less than 1%

Source: UBS. Rating allocations are as of 31 December 2014.

1:Percentage of companies under coverage globally within the 12-month rating category. 2:Percentage of companies within the 12-month rating category for which investment banking (IB) services were provided within the past 12 months.

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**UBS Securities LLC:** Matthew Roden, PhD; Jeffrey Hung; Charles Shi, PhD.

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Company Name	Reuters	12-month rating	Short-term rating	Price	Price date
<b>Akebia Therapeutics Inc</b> <sup>2, 4, 6, 16</sup>	AKBA.O	Buy	N/A	US\$13.24	13 Mar 2015

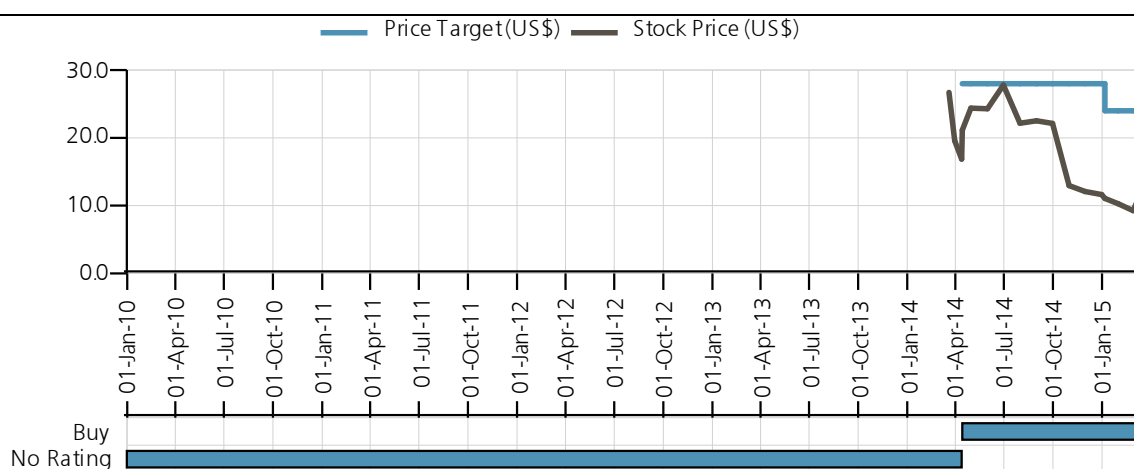
Source: UBS. All prices as of local market close.

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### Akebia Therapeutics Inc (US\$)



Source: UBS; as of 13 Mar 2015

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