

First Read

Akebia Therapeutics Inc

Why We See Potential for Re-Rating in 1Q15

Conclusion: Phase-2b hard to interpret, but arguably good risk-reward here

Unfavorable imbalances in serious adverse events (SAEs) or deaths on drug such as these are always hard to get comfortable with, so we're not surprised with the pullback in the stock. That said, we believe the additional color provided on the call better supports the view that the drug is safe and will put up favorable data in phase-3, principally because there is no relationship between SAE's and Hb level, and because the overall rate of AE's are comparable (although adjudication of seriousness differed: even advancement to dialysis was not always considered serious on placebo). Hence we see an opportunity for the stock to re-rate with full data (March 2015 at ISN) and potentially on feedback from the end-of-ph2 talks with the FDA/EMA in early 2015.

Key takeaways from the call and our conversation with management

[1] Akebia reported no baseline imbalances that could explain differences seen in SAE's. [2] Although the rate of total AE's were comparable in the 2 arms, the categorization of SAEs were not consistent. Management saw several AE's in the placebo arm that arguably could/should have been adjudged serious. [3] Although worsening disease was the largest cause of SAE's on drug, the markers of renal function were in line to better than placebo. One example is the progression to dialysis, which favored drug (9.7% on placebo vs, 7.2% on drug). [4] SAEs were not correlated to hemoglobin level, which gets us more comfortable with the HIF stabilization mechanism. [5] The patient death that was "possibly drug-related" had multiple risk factors for heart disease and complications including atherosclerotic disease. The death was ruled as ischemic heart disease, but since an autopsy was not performed, the investigator took a conservative stance and reported it as possibly related. We aren't particularly worried about the implications since death amid several risk-factors is highly confounded.

Potential re-rating into full data / advancement into phase-3

We est at the current intraday level, AKBA shares reflect ~15% probability of success.

Valuation: Buy, \$28 PT by SOTP supported by DCF (assumes 40% POTS)

Dialysis data (3Qe) are likely required for PT, March ph2b data should drive re-rating.

Equities

Americas
Biotechnology

12-month rating **Buy**

12m price target **US\$28.00**

Price **US\$14.11**

RIC: AKBA.O BBG: AKBA US

Trading data and key metrics

52-wk range	US\$29.17-14.11
Market cap.	US\$0.28bn
Shares o/s	19.7m (COM)
Free float	32%
Avg. daily volume ('000)	128
Avg. daily value (m)	US\$2.7
Common s/h equity (12/14E)	US\$0.09bn
P/BV (12/14E)	2.5x
Net debt / EBITDA (12/14E)	2.0x

EPS (UBS, diluted) (US\$)

	12/14E	
	UBS	Cons.
Q1	-	(4.35)
Q2	-	(0.39)
Q3E	-	(0.45)
Q4E	-	(0.62)
12/14E	(44.90)	(4.72)
12/15E	0.42	(1.10)
12/16E	(0.62)	(0.51)

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Highlights (US\$m)	-	-	12/13	12/14E	12/15E	12/16E	12/17E	12/18E
Revenues	-	-	0	0	85	84	87	102
EBIT (UBS)	-	-	(16)	(41)	12	(16)	(29)	(46)
Net earnings (UBS)	-	-	(13)	(693)	12	(15)	(29)	(46)
EPS (UBS, diluted) (US\$)	-	-	(1.30)	(44.90)	0.42	(0.62)	(1.13)	(1.51)
DPS (US\$)	-	-	0.00	0.00	0.00	0.00	0.00	0.00
Net (debt) / cash	-	-	21	81	187	172	145	282
Profitability/valuation	-	-	12/13	12/14E	12/15E	12/16E	12/17E	12/18E
EBIT margin %	-	-	-	-	13.6	-18.5	-33.2	-45.1
ROIC (EBIT) %	-	-	-	<-500	380.0	>500	>500	>500
EV/EBITDA (core) x	-	-	-	-5.5	12.2	-6.4	-4.2	-1.4
P/E (UBS, diluted) x	-	-	-	(0.3)	33.8	(22.8)	(12.5)	(9.4)
Equity FCF (UBS) yield %	-	-	-	(45.5)	4.5	(5.3)	(10.1)	(16.2)
Net dividend yield %	-	-	-	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\$14.11 on 27 Oct 2014 11:42 EDT

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Forecast returns

Forecast price appreciation	+98.5%
Forecast dividend yield	0.0%
Forecast stock return	+98.5%
Market return assumption	5.4%
Forecast excess return	+93.1%

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 ¹	IB Services ²
Buy	FSR is > 6% above the MRA.	47%	34%
Neutral	FSR is between -6% and 6% of the MRA.	42%	28%
Sell	FSR is > 6% below the MRA.	11%	21%
Short-Term Rating	Definition	Coverage ³	IB Services ⁴
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 30 September 2014.

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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
Akebia Therapeutics Inc ^{2, 4, 6, 16}	AKBA.O	Buy	N/A	US\$19.72	24 Oct 2014

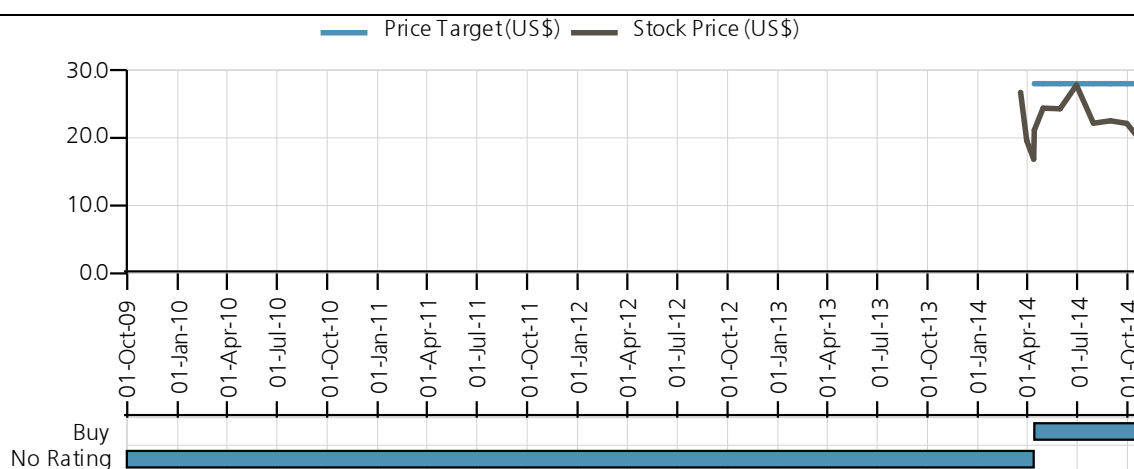
Source: UBS. All prices as of local market close.

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Akebia Therapeutics Inc (US\$)



Source: UBS; as of 24 Oct 2014

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