First Read

Akebia Therapeutics Inc

Phase-2b Efficacy Good, Need More Info on Safety

First reaction: Ph2b data look positive but several questions on safety

This morning Akebia reported top-line results from the ph2b study of AKB-6548 in non-dialysis patients with anemia related to chronic kidney disease. Efficacy looks good with the primary endpoint achieved of 54.9% of treated patients versus 10.3% of placebo achieving the goal ($p<0.0001$) defined as proportion of subjects achieving or maintaining a mean hemoglobin (Hg) ≥ 11.0 g/dL or increasing Hb by ≥ 1.2 g/dL above baseline. However, we need more information to assess the safety profile, since there is an imbalance in serious adverse events (SAE's) and a death that is possibly related to drug. That said, we acknowledge that the study is in patients who are quite sick with several cardiovascular (and other) co-morbidities. We look forward to clarity on the call, on which mgmt. said that it can speak to each of the safety questions.

Looking for baseline imbalance or other relationships to side effects

The clinical profile of '6548 presented prior is differentiated profile from ESAs, with a more physiological level of Hb correction and no signal for CV risk. The current study shows higher incidence of SAEs (23.9% vs. 15.3% of placebo) and 1 death possibly related to treatment warrants attention. On the call, we will ask whether the data were confounded by baseline imbalance, impact on markers of renal function, and whether there was a relationship between SAE's and Hb level or exposure. Overall, treatment-emergent adverse events (TEAEs) were consistent with previous studies and were well balanced overall between the active and placebo.

Blockbuster potential for '6548 if successful

If successful, we see a blockbuster potential in multi-billion dollar market. We expected '6548 to be well-positioned among competitors due to attractive once-daily dosing and still be ahead of two additional competitors in a multi-billion dollar market. See HERE for more on the trial and the oppty. We think ph2b data could increase POTS to 50-60%, driving the NPV $15-25 higher.

Valuation: $28 price target by SOTP supported by DCF (assumes 40% POTS)

We see HIF activation as a potential multi-billion dollar market.

Equities

Americas
Biotechnology

12-month rating	**Buy**
12m price target	**US$28.00**
Price	**US$19.72**
RIC: AKBA.O **BBG:** AKBA US	

Trading data and key metrics

52-wk range	US$29.17-16.86
Market cap.	US$0.39bn
Shares o/s	19.7m (COM)
Free float	32%
Avg. daily volume ('000)	112
Avg. daily value (m)	US$2.4
Common s/h equity (12/14E)	US$0.09bn
P/BV (12/14E)	3.5x
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)

Matthew Roden, PhD
Analyst
matthew.roden@ubs.com
+1-212-713 2491

Jeffrey Hung
Associate Analyst
jeffrey.hung@ubs.com
+1-212-713 3982

Charles Shi, PhD
Associate Analyst
charles.shi@ubs.com
+1-212-713 4105

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	-	-	-	-8.2	21.6	-13.7	-8.0	-3.8
P/E (UBS, diluted) x	-	-	-	(0.4)	47.3	(31.8)	(17.5)	(13.1)
Equity FCF (UBS) yield %	-	-	-	(32.6)	3.2	(3.8)	(7.2)	(11.6)
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$19.72 on 27 Oct 2014 06:41 EDT

Forecast returns

Forecast price appreciation	+42.0%
Forecast dividend yield	0.0%
Forecast stock return	+42.0%
Market return assumption	5.4%
Forecast excess return	+36.6%

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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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.
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
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.
Ratings in this table are the most current published ratings prior to this report. They may be more recent than the stock pricing date

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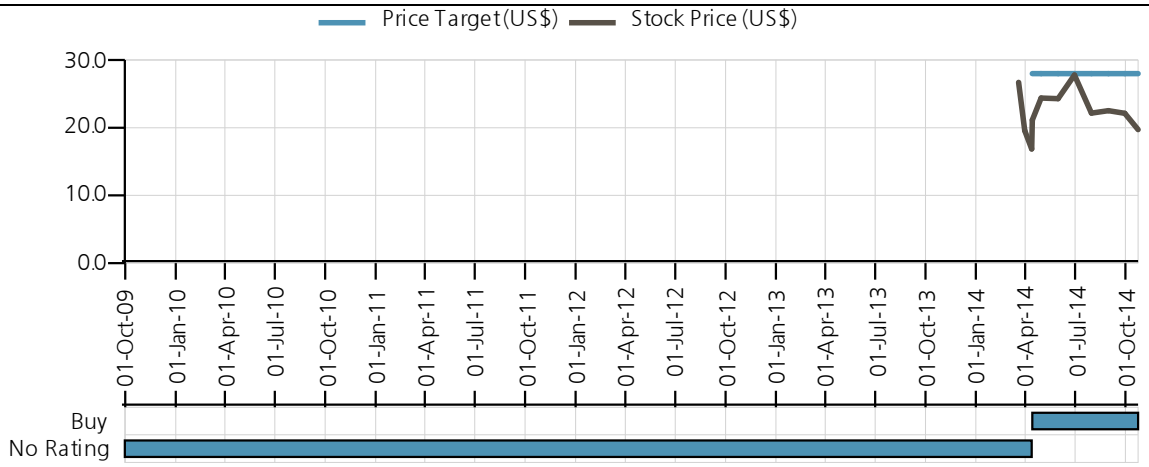
Akebia Therapeutics Inc (US$)



Source: UBS; as of 24 Oct 2014

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