First Read

Akebia Therapeutics Inc

Implications of Downsized Competitor Phase-3 Program

Conclusions: Competitor's revised trial sizes now in line with Akebia's plans

A read of competitor Fibrogen's S-1 filing reveals protocol changes to the roxadustat phase-3 clinical trial program, whereby the non-dialysis program appears to be downsized to a similar scope as those planned by Akebia. These changes are also reflected in updated listings on clinicaltrials.gov. Recall that we previously wrote about the implications of the surprisingly large phase-3 roxadustat program by AstraZeneca (n>5000 in non-dialysis alone; see HERE). *In our view, these changes reduce the risk to Akebia's end-of-phase-2 regulatory meetings (1H15e), and reinforce the credibility of the Akebia management team and its strategy.* We remain positive on the phase-2b data (4Qe) as a value creating event. See HERE for more on the trial and the oppty.

Specifics on the changes; Smaller program (as planned) reduces need to partner

Fibrogen and its partners now plan to enroll fewer patients for their ph3 studies, from 5,200 prior to 2,600 in non-dialysis (see HERE) and from 2,850 to 1,425 in dialysis (HERE). Also, the initial roxadustat dosing in the non-dialysis study was changed from weight-based dosing to 70mg TIW. Although the reasons for the changes are not clear, in our view it reflects some level of uncertainty in Fibrogen and partner AstraZeneca's initial strategy and knowledge of optimal dosing for roxadustat. We note that Akebia has consistently communicated its intent to conduct a non-dialysis ph3 with an Omontys-like trial size of about 2,600 patients, dependent on the ph2b data and post-ph2 discussions with the FDA. We spoke with Akebia, who reports that nothing has changed operationally following Fibrogen's protocol changes. Management continues to believe that a non-inferiority margin of 1.5 makes sense, and they haven't heard anything from the FDA to suggest otherwise.

Near term opportunity to raise probability of success (POTS) with 4Q data

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 believe that HIF activators could become the standard in anemia, and that '6548 is well-positioned with once-daily dosing and restoration of physiological epo response.

Equities

Americas
Biotechnology

12-month rating	**Buy**
12m price target	**US$28.00**
Price	**US$20.49**

RIC: AKBA.O **BBG:** AKBA US

Trading data and key metrics

52-wk range	US$29.17-16.86
Market cap.	US$0.40bn
Shares o/s	19.7m (COM)
Free float	32%
Avg. daily volume ('000)	113
Avg. daily value (m)	US$2.5
Common s/h equity (12/14E)	US$0.09bn
P/BV (12/14E)	3.7x
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	-	-	-	-8.6	22.9	-14.7	-8.6	-4.2
P/E (UBS, diluted) x	-	-	-	(0.5)	49.1	(33.1)	(18.2)	(13.6)
Equity FCF (UBS) yield %	-	-	-	(31.3)	3.1	(3.6)	(6.9)	(11.1)
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$20.49 on 17 Oct 2014 16:42 EDT

Forecast returns

Forecast price appreciation	+36.7%
Forecast dividend yield	0.0%
Forecast stock return	+36.7%
Market return assumption	5.3%
Forecast excess return	+31.4%

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.

Company Disclosures

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$20.49	17 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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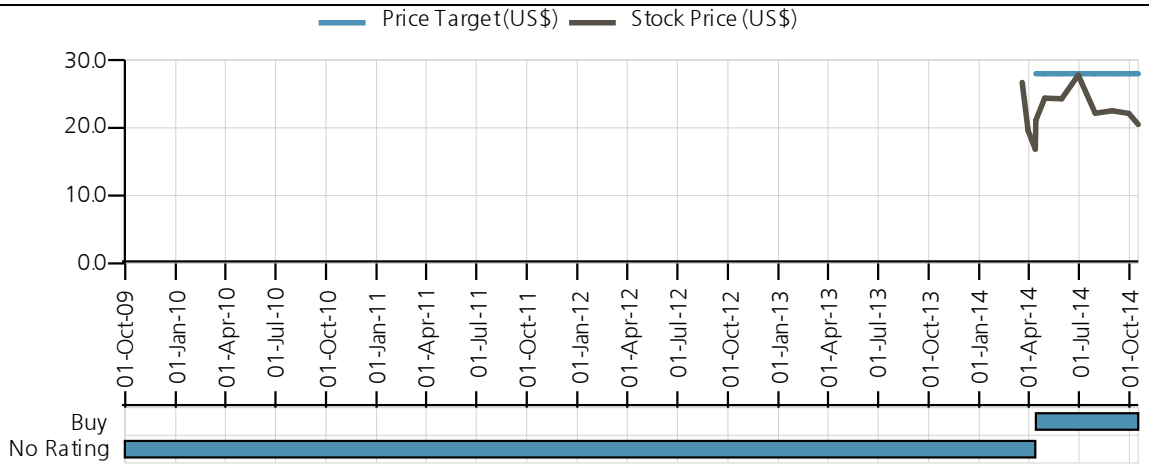
Akebia Therapeutics Inc (US$)



Source: UBS; as of 17 Oct 2014

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