

# Akebia (AKBA)

COMMENT

# Rating OUTPERFORM\* [V] Price (15 Apr 14, US\$) 22.26 Target price (US\$) 25.00¹ 52-week price range 26.70 - 16.86 Market cap. (US\$ m) 451.05 Enterprise value (US\$ m) 345.38

\*Stock ratings are relative to the coverage universe in each analyst's or each team's respective sector.

[V] = Stock considered volatile (see Disclosure Appendix).

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# Topline PIIb readout remains on track for Q4

- Topline PIIb data for AKB-6548 in CKD-ND remains on track for Q4'14, as previously guided. Enrollment of the CI-0007 PIIb trial for AKB-6548 has been completed as of today. The final visit of the last enrolled patient will likely occur in September 2014, setting up a data release in early Q4.
- We view topline CI-0007 PIIb data due in Q4'14 as the key valuation-inflection catalyst. CI-0007 is a 200-patient trial examining AKB-6548 as a treatment for anemia in CKD-ND patients. It is important to note that CI-0007 will enroll CKD-ND patients with (Hemoglobin) Hb ≤ 10.5g/dL, which is slightly above the FDA's recommended Hb < 10g/dL. Patients will be started at 450mg QD, followed by dose adjustments based on Hb responses. The primary endpoint is the percentage of patients who: (1) achieve or maintain Hb ≤ 11.0g/dL, or (2) increase Hb ≥ 1.2g/dL over pre-dose average Hb between screening and baseline.</p>
- We reiterate our view that AKB-6548 could offer a more effective way to maintain/modulate Hb and improve upon cardiovascular safety. The highly effective ESAs are currently relegated to treat more severe anemia because of FDA/EMA restrictions on their use due to cardiovascular safety concerns. Despite these concerns, the WW ESA market for anemia is still substantial at ~\$6B, of which the majority (~\$4B) is generated from CKD-ND and CKD-D. The current PIIa data have shown that AKB-6548 can increase Hb levels gradually in a clinically meaningful way without highly elevated levels of EPO, improves iron metabolism allowing for the potential to remove iron supplementation, and appears to be generally safe and well-tolerated.
- Valuation. Our target price of \$25 is based AKB-6548 revenues (sales and royalties) in anemia in CKD-ND and CKD-D, 10% discount rate, 50% risk-weighting, and no terminal value.



On 04/15/14 the S&P 500 INDEX closed at 1842.27

Quarterly EPS	Q1	Q2	Q3	Q4
2013A	_	_	_	_
2014E	-0.74	-0.54	-0.79	-1.10
2015E	_	_	_	_

Financial and valuation metrics				
Year	12/13A	12/14E	12/15E	12/16E
EPS (CS adj.) (US\$)	-0.70	-1.48	0.17	1.49
Prev. EPS (US\$)	_	<del>-</del>	_	_
P/E (x)	-31.7	-15.1	131.6	14.9
P/E rel. (%)	-184.9	-95.2	924.3	116.3
Revenue (US\$ m)	_	<del></del>	40.0	80.0
EBITDA (US\$ m)	-15.2	-28.0	3.8	35.6
OCFPS (US\$)	-0.60	-1.36	0.36	1.70
P/OCF (x)		-16.3	61.2	13.1
EV/EBITDA (current)	-28.3	-12.3	68.3	6.0
Net debt (US\$ m)	-21	-106	-193	-239
ROIC (%)	-167.02	-374.09	136.28	-1,737.60
Number of shares (m)	20.26	IC (current, US\$ m)		9.54
BV/share (Next Qtr., US\$)	_	EV/IC (x)		_
Net debt (Next Qtr., US\$ m)	_	Dividend (current, US\$)		_
Net debt/tot cap (Next Qtr., %)	_	Dividend yield (%)		_
Source: Company data, Credit Suisse estimates.				

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<sup>&</sup>lt;sup>1</sup>Target price is for 12 months.



# Companies Mentioned (Price as of 15-Apr-2014)

Akebia (AKBA.OQ, \$22.26, OUTPERFORM[V], TP \$25.0)

# **Disclosure Appendix**

# Important Global Disclosures

I, Ravi Mehrotra PhD, certify that (1) the views expressed in this report accurately reflect my personal views about all of the subject companies and securities and (2) no part of my compensation was, is or will be directly or indirectly related to the specific recommendations or views expressed in this report.

# 3-Year Price and Rating History for Akebia (AKBA.OQ)

AKBA.OQ	Closing Price	Target Price	
Date	(US\$)	(US\$)	Rating
14-Apr-14	21.14	25.00	0 *

<sup>\*</sup> Asterisk signifies initiation or assumption of coverage.



The analyst(s) responsible for preparing this research report received Compensation that is based upon various factors including Credit Suisse's total revenues, a portion of which are generated by Credit Suisse's investment banking activities

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**Underweight:** The analyst's expectation for the sector's fundamentals and/or valuation is cautious over the next 12 months.

\*An analyst's coverage sector consists of all companies covered by the analyst within the relevant sector. An analyst may cover multiple sectors.

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Price Target: (12 months) for Akebia (AKBA.OQ)

Method: Our DCF-derived TP for AKBA of \$25 is based on annual cash flows through 2027, a 10% discount rate, 50% probability of success, and no terminal value. The cash flows are based solely on revenues (direct sales in the US as well as royalties in the EU and Japan) form AKB-6548 as a treatment for anemia in chronic kidney disease on dialysis (CKD-D) and not on dialysis (CKD-ND) and add-back of all R&D expenses not associated with AKB-6548.

Risk: The risks to our TP of \$25 for AKBA are: (1) AKB-6548 is not approved or significantly delayed. (2) AKB-6548 does not demonstrate efficacy and/or safety expected from data on studies to date. (3) AKB-6548 could underperform our expectations for the product launch ramp and/or peak sales. (4) Anemia in CKD market may not become as large as expected.

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See the Companies Mentioned section for full company names

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