AEGIS CAPITAL CORP

Biotechnology
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Initiating Coverage

November 15, 2016

Key Metrics

AKBA - NASDAQ	$8.90
Pricing Date	Nov 14 2016
Price Target	$18.00
52-Week Range	$13.20 - $7.00
Shares Outstanding (mm)	38.0
Market Capitalization (mm)	$338.2
3-Mo Average Daily Volume	147,337
Institutional Ownership	36%
Book Value/Share	$2.66
Price/Book	3.3x

EPS FY: December

	2015E	Prior 2016E	Curr. 2016E	Prior 2017E	Curr. 2017E
1Q-Mar	(0.53)	--	(0.70)A	--	(1.24)E
2Q-Jun	(0.40)	--	(0.95)A	--	(1.23)E
3Q-Sep	(0.68)	--	(0.96)A	--	(0.86)E
4Q-Dec	(0.66)	--	(1.20)E	--	(0.81)E
FY	(2.30)	--	(3.81)E	--	(4.13)E
P/E	NM		NM		NM

REVENUE

	2015E	Prior 2016E	Curr. 2016E	Prior 2017E	Curr. 2017E
1Q-Mar	0.0E	--	0.0E	--	0.0E
2Q-Jun	0.0E	--	0.0E	--	0.0E
3Q-Sep	0.0E	--	0.0E	--	8.0E
4Q-Dec	0.0E	--	0.0E	--	10.0E
FY	0.0E	--	0.0E	--	18.0E

Company Description:
Akebia Therapeutics, Inc. is a biopharmaceutical company focused on the development of novel proprietary therapeutics based on hypoxia inducible factor, or HIF, biology and the commercialization of these products for patients with serious unmet medical needs. HIF is the primary regulator of the production of red blood cells, or RBCs, in the body and a potentially novel mechanism for the treatment of anemia secondary to chronic kidney disease, or CKD.

Akebia Therapeutics, Inc.

Rating: Buy

Novel Mechanism of Action for Anemia Treatment related to CKD, Initiate with a BUY and $18 PT.

Investment Highlights:

- **Vadadustat is in development as an oral therapy.** Meant to be taken once daily, Vadadustat is designed to aid in the regulation of hemoglobin levels in patients with anemia induced by chronic kidney disease (CKD). Vadadustat's novel mechanism of action, HIF Prolyl-hydroxylase (HIF-PH) inhibition, works by activating critical pathways for hemoglobin and red blood cell production (RBC) in a manner mimicking the body's natural physiological adjustments made when exposed to lower oxygen levels experienced at higher altitudes. After reporting positive phase II results showing safe and predictable elevation of hemoglobin levels in patients afflicted with anemia related to CKD, Vadadustat is now in two phase III trials, enrolling patients with non-dialysis dependent CKD (ND-CKD) and dialysis dependent CKD (DD-CKD).
- **Two global Vadadustat phase III trials underway.** The first trial, PRO_2TECT, is indicated for ND-CKD and is expected to complete enrollment of 3,100 patients in 2H17. PRO_2TECT has primary and secondary non-inferiority endpoints of mean change in hemoglobin measured from baseline at a primary evaluation period, week 36, and a secondary evaluation period, week 52. The second trial, $INNO_2VATE$, is indicated for DD-CKD and is expected to complete enrollment of 2,600 patients in 1H18. Both groups for $INNO_2VATE$, which is divided into Correction and Conversion trials, are 1:1 randomized, active controlled, open-label safety and efficacy studies, with primary and secondary non-inferiority endpoints of mean change in hemoglobin measured from baseline at a primary evaluation period, week 36, and a secondary evaluation period, week 52. Key elements from both trials have been vetted with the FDA.
- **AKBA is seeking EU partnership for Vadadustat similar to MTPC agreement.** The MTPC agreement, entered into on December 11, 2015, provides MTPC with exclusive development and commercialization rights to Vadadustat in Japan and Asia. Pursuant to the agreement, Akebia is receiving funding for their global phase III trials and is eligible to receive up to a total of $350 mill in milestone payments, of which $100 mil has been received to date. We expect a similar partnership to materialize and be signed in Europe in 2017.
- **$163 mil cash runway to 2Q17 and projected 2022 sales of ~$502 mil.** Not including cash from the MTPC partnership or contributions from a potential EU partner, Akebia's current cash and cash equivalents of $163 mil should fund operations through 2Q17.
- **Valuation.** Our Target price of $18 was determined by DCF analysis. We used DCF based on 2016-2022 EBITDA to determine our target price. We applied a multiple of 6x to our terminal value of estimated 2022 EBITDA and assumed a 60% probability of clinical success for Vadadustat. The discount rate is 8%.
- **Risks.** Other than typical risks associated with investing in companies in the healthcare industries, such as R&D, regulatory, manufacturing, and commercialization risks, investing in Akebia Therapeutics , Inc. carries several firm-specific risks: 1) potential multiple binary events; 2) intense competition; 3) pricing and reimbursement pressures; 4) The company has not shown a history of profitability; and 5) additional funding may be required to successfully develop and commercialize its products.

The Disclosure section may be found on pages 4 - 5 of this report.

- **Vadadustat is in development as an oral therapy.** Meant to be taken once daily, Vadadustat is designed to aid in the regulation of hemoglobin levels in patients with anemia related to chronic kidney disease (CKD). Vadadustat's novel mechanism of action, HIF Prolyl-hydroxylase (HIF-PH) inhibition, works by activating critical pathways for hemoglobin and red blood cell production (RBC) in a manner mimicking the body's natural physiological adjustments made when exposed to lower oxygen levels experienced at higher altitudes. The current standard of care in treating CKD lies in injectable recombinant erythropoiesis-stimulating agents (rESA's), which carry high associated costs and the potential for adverse side effects of thromoembolic complications and hypertension, which occurs in about 20 -30% of patients undergoing ESA therapy. After reporting positive phase II results showing safe and predictable elevation of hemoglobin levels in patients afflicted with anemia related to CKD, Vadadustat is now in two phase III trials, enrolling patients with non-dialysis dependent CKD (ND-CKD) and dialysis dependent CKD (DD-CKD).
- **Two global Vadadustat phase III trials underway.** The first trial, PRO_2TECT, is indicated for ND-CKD and is expected to complete enrollment of 3,100 patients in 2H17, about 22 to 24 months after the first patient was enrolled in December 2015. PRO_2TECT is a 1:1 randomized, active controlled, open-label safety and efficacy study, with primary and secondary non-inferiority endpoints of mean change in hemoglobin measured from baseline at a primary evaluation period, week 36, and a secondary evaluation period, week 52. The second trial, $INNO_2$VATE, is indicated for DD-CKD and is expected to complete enrollment of 2,600 patients in 1H18 after being initiated in August, 2016. Both groups for $INNO_2$VATE, which is divided into Correction and Conversion trials, are 1:1 randomized, active controlled, open-label safety and efficacy studies, with primary and secondary non-inferiority endpoints of mean change in hemoglobin measured from baseline at a primary evaluation period, week 36, and a secondary evaluation period, week 52. Key elements from both trails have been vetted with the FDA.
- **AKBA is seeking EU partnership for Vadadustat similar to MTPC agreement.** The MTPC agreement, entered into on December 11, 2015, provides MTPC with exclusive development and commercialization rights to Vadadustat in Japan and Asia. MTPC will fund up to $100 mil of the global phase III PRO_2TECT and $INNO_2$VATE programs, including the $40 mil paid in January 2016. If Japanese patients are not included in either phase III program, $20 mil of the $40 mil will potentially be refunded to MTPC. Akebia is eligible to receive up to an additional $250 mil ($350 mil total) in milestone payments. The partnership is supported with data from an ethno-bridging trial released earlier this year that showed Vadadustat's PK and PD in both Caucasian and Japanese across all ascending doses tested. As of September 30, 2016 the company had recorded $40 mil in deferred revenue related to the collaboration agreement. We expect a similar partnership to materialize and be signed in Europe in late 2016/ early 2017.
- **$163 mil cash runway to 2Q17 and projected 2022 sales of ~$502 mil.** Not including cash from the MTPC partnership or contributions from a potential EU partner, Akebia's current cash and cash equivalents of $163 mil should fund operations through 2Q17. Our valuation is based solely on projected US and Rest of World (ROW) Vadadustat sales ending with ~$515 mil sales in 2022.
- **Third Quarter EPS in line with estimates.** For 3Q16, Akebia reported a loss per share of $(0.96), coming in just 2 cents below street estimates of $(0.94). The company reported no revenue for the quarter and as a clinical stage development company, we align our views with the potential value of Vadadustat, currently in phase III trials, and its path to potential FDA approval and less concerned about quarterly financial performance.

Akebia Therapeutics, Inc.
Income Statement
Fiscal Year ends December
(in $000, except per share items)

	2012A	2013A	2014A	1Q15	2Q15	3Q15	4Q15	2015A	1Q16A	2Q16A	3Q16A	4Q16E	2016E	1Q17E	2Q17E	3Q17E	4Q17E	2017E
Vadadustat revenue in non-dialysis patients		-	-	-	-	-	-	-					-					-
Vadadustat revenue in dialysis patients		-	-	-	-	-	-	-					-					-
Other revenue		-	-	-	-	-		-					-			8,000	10,000	18,000
Total Revenue	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**8,000**	**10,000**	**18,000**
COGS																		
R&D	5,632	10,782	25,399	7,505	7,182	15,790	14,244	44,721	20,235	30,877	31,238	40,609	122,959	42,640	42,640	36,244	36,244	157,768
SG&A	2,891	5,152	12,541	3,391	3,707	3,888	5,806	16,792	5,811	5,311	4,944	5,191	21,257	5,295	5,401	5,509	5,784	21,989
Total Operating Expenses	**8,523**	**15,933**	**37,940**	**10,896**	**10,889**	**19,678**	**20,050**	**61,513**	**26,046**	**36,188**	**36,182**	**45,801**	**144,217**	**47,935**	**48,041**	**41,753**	**42,028**	**179,757**
Operating Income	**(8,523)**	**(15,933)**	**(37,940)**	**(10,896)**	**(10,889)**	**(19,678)**	**(20,050)**	**(61,513)**	**(26,046)**	**(36,188)**	**(36,182)**	**(45,801)**	**(144,217)**	**(47,935)**	**(48,041)**	**(33,753)**	**(32,028)**	**(161,757)**
Interest income, net	(1,645)	(704)	206	201	116	203	193	713	248	409	(126)	(113)	418	(102)	(92)	(83)	(74)	(351)
Extinguishment of debt and other liabilities		2,420	-	-	-	-	-	-	-	-	-	-	-					-
Reimbursements from Aerpio	1,971	1,050	700		84			84										
Pretax income	**(8,196)**	**(13,167)**	**(37,034)**	**(10,695)**	**(10,689)**	**(19,475)**	**(19,857)**	**(60,716)**	**(25,798)**	**(35,779)**	**(36,308)**	**(45,914)**	**(143,799)**	**(48,037)**	**(48,133)**	**(33,836)**	**(32,103)**	**(162,108)**
Provision for income tax (benefit)			-					-					-					-
Net Income	**(8,196)**	**(13,167)**	**(37,034)**	**(10,695)**	**(10,689)**	**(19,475)**	**(19,857)**	**(60,716)**	**(25,798)**	**(35,779)**	**(36,308)**	**(45,914)**	**(143,799)**	**(48,037)**	**(48,133)**	**(33,836)**	**(32,103)**	**(162,108)**
Accretion on preferred stock	3,323	55,886	86,900					-										
Net Income to common stockholders	**(11,519)**	**(69,053)**	**(123,934)**	**(10,695)**	**(10,689)**	**(19,475)**	**(19,857)**	**(60,716)**	**(25,798)**	**(35,779)**	**(36,308)**	**(45,914)**	**(143,799)**	**(48,037)**	**(48,133)**	**(33,836)**	**(32,103)**	**(162,108)**
EPS	**(27.82)**	**(126.94)**	**(8.04)**	**(0.53)**	**(0.40)**	**(0.68)**	**(0.66)**	**(2.30)**	**(0.70)**	**(0.95)**	**(0.96)**	**(1.20)**	**(3.81)**	**(1.24)**	**(1.23)**	**(0.86)**	**(0.81)**	**(4.13)**
EPS diluted, GAAP	**(27.82)**	**(126.94)**	**(8.04)**	**(0.53)**	**(0.40)**	**(0.68)**	**(0.66)**	**(2.30)**	**(0.70)**	**(0.95)**	**(0.96)**	**(1.20)**	**(3.81)**	**(1.24)**	**(1.23)**	**(0.86)**	**(0.81)**	**(4.13)**
Basic shares outstanding	414	544	15,406	20,030	26,615	28,784	30,309	26,434	36,874	37,811	37,899	38,278	37,715	38,661	39,047	39,438	39,832	39,244
Diluted shares outstanding	414	544	15,406	20,030	26,615	28,784	30,309	26,434	36,874	37,811	37,899	38,278	37,715	38,661	39,047	39,438	39,832	39,244

Source: Aegis Capital Analysis

Required Disclosures

Price Target

$18

Valuation Methodology

Our Target price of $18 was determined by DCF analysis. We used DCF based on 2016-2022 EBITDA to determine our target price. We applied a multiple of 6x to our terminal value of estimated 2022 EBITDA and assumed a 60% probability of clinical success for Vadadustat. The discount rate is 8%.

Risk Factors

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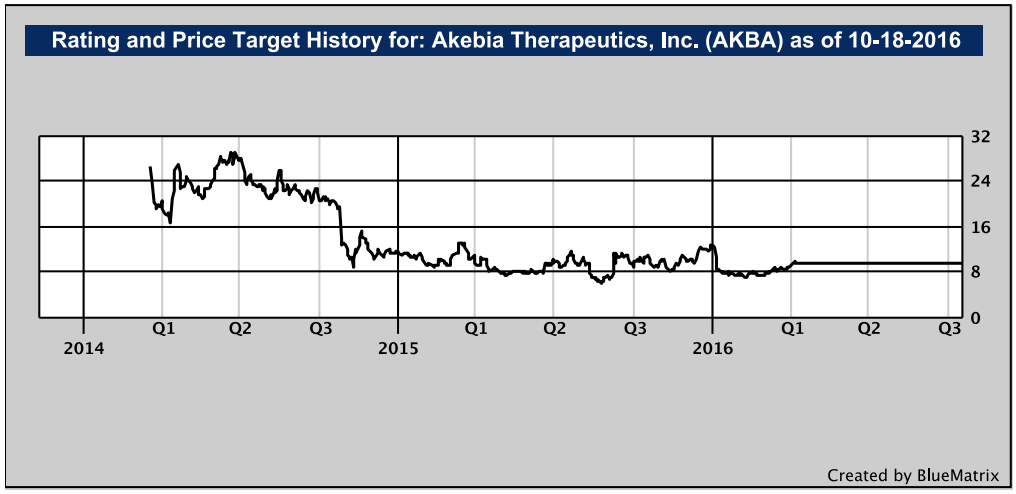

Rating	Percent	Investment Banking Services/Past 12 Mos. Percent
BUY [BUY]	89.01	41.98
HOLD [HOLD]	10.99	30.00
SELL [SELL]	0.00	0.00

Meaning of Ratings

A) A Buy rating is assigned when we do not believe the stock price adequately reflects a company's prospects over 12-18 months.

B) A Hold rating is assigned when we believe the stock price adequately reflects a company's prospects over 12-18 months.

C) A Sell rating is assigned when we believe the stock price more than adequately reflects a company's prospects over 12-18 months.

Other Disclosures

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