Elle Investments Research Report: AKBA

Company: Akebia Therapeutics, Inc.
Symbol: **AKBA**
Analysis Date: 4/25/19 – UPDATE: 11/19/19
Analysis Price: $3.18
PT: $16.41
Upside: 416%
Dividend: NA
Recommendation: **Buy**

AKBA: 1-Year Chart

Source: Seeking Alpha

INVESTMENT THESIS:

Commercialized drug Auryxia (approved in the US for hyperphosphatemia in adults with dialysis-dependent chronic kidney disease (DD-CKD) and iron deficiency anemia (IDA) in adults with non-dialysis-dependent (NDD) CKD) has blockbuster potential, but after several years on the market, annual sales are only about $100M. However, they have another potential blockbuster candidate, vadadustat, which is in several phase-3 trials around the globe. The hope is that it can become the standard of care in the $6B+ market for anemia due to CKD in adults with DD-CKD and NDD-CKD. Our valuation for vadadustat alone justifies a position in AKBA.

LIQUIDITY POSITION: Good

As of 3Q19, AKBA had cash, cash equivalents, and available for sale securities of $146M. Concurrently with earnings they announced a $100M non-dilutive term loan agreement with funds managed by Pharmakon Advisors LP, the investment manager of the BioPharma Credit funds. They expect to draw $80M at closing in late November and can draw the additional $20M tranche at their choosing until December 31, 2020. Additionally, AKBA is eligible to receive over $150M in development and regulatory milestones from its collaboration partners. Management expects this new funding agreement to extend the cash runway into 2021, well past

the major data readout expected in mid-2020. Because of this, we think the chances of additional dilution in the near future are low.

COMMERCIAL PROSPECTS: Very Good

Auryxia (ferric citrate)
Value: not included in valuation

Auryxia has been on the market in the US since late 2014 for hyperphosphatemia in adults with dialysis-dependent (DD) CKD. In early 2018, it also began selling for a second indication: iron deficiency anemia (IDA) in adults with non-dialysis-dependent (NDD) CKD. Auryxia is also marketed in Japan under the trade name Riona for the improvement of hyperphosphatemia in patients with CKD (both DD and NDD). Lastly, it was approved in the EU in 2015 for the control of hyperphosphatemia in adult patients with CKD under the trade name Fexeric (it is not marketed yet in the EU, as the company continues to explore third party commercialization opportunities).

Expectations for Auryxia were very high, with some analysts projecting peak sales of $1B+ in just the US alone. However, almost 5 full years after launch, the annual run-rate remains at a paltry $100M, with AKBA's management unwilling to give any type of sales guidance as of 1Q19 (until they become more familiar with the normalized growth rate). Licensing royalties from Japan also remains at less than $2M per quarter, and the inability/unwillingness of KERX's past management to sign a commercialization partner in the EU several years after approval does not instill much confidence.

While we acknowledge the possibility of Auryxia being able to differentiate itself in the newer IDA indication, the sales results thus far are such that we have chosen to exclude Auryxia from our valuation.

Vadadustat (hypoxia-inducible factor prolyl hydroxylase inhibitor) (HIF-PHI)
Value: $2B

AKBA: Drug Development Pipeline

Source: AKBA website

Vadadustat is currently in various phase-3 trials for anemia due to CKD in adults with DD-CKD and NDD-CKD. AKBA has multiple licensing deals in place around the globe for vadadustat that have already generated over $200M in upfront payments. Additionally, these licensing deals provide for significant assistance in completing the various phase-3 trials being run: over $1B in potential regulatory and commercial milestones, and very generous double-digit royalties on net sales—all of which validate the blockbuster potential of vadadustat.

The reason AKBA's collaborators were so interested in becoming partners is because vadadustat has the potential to set a new oral standard of care for this indication. Anemia due to CKD is currently treated by injectable recombinant human erythropoiesis-stimulating agents (ESAs) such as Epogen (epoetin alfa) and Aranesp (darbepoetin alfa), or blood transfusion. Global sales of injectable ESAs in 2018 were about $6.1B. Though this figure covers all uses, the vast majority of sales were for the treatment of anemia due to CKD.

Injectable ESAs can be very effective in raising hemoglobin levels. However, in addition to requiring a subcutaneous or intravenous injection, they can cause serious side effects such as thrombosis, stroke, myocardial infarction and death. These safety concerns became evident starting around 2006, and have subsequently led to a major reduction in the utilization of injectable ESAs. For example, from 2009 to 2013, it is estimated that the collective injectable ESA treatment rate in NDD-CKD patients in the US decreased by approximately half. Because of this, anemia is either not treated or inadequately treated in the majority of NDD-CKD patients, leaving a high unmet need for a new treatment paradigm (pg. 9, 2018 10-K).
When AKBA announced their expanded licensing deal with Otsuka in the EU, China, and other territories, they valued the addressable market at $3.5B. For our valuation, we therefore assume an addressable market size of $3.5B in both the US and the International territories covered by the Otsuka agreement. We think this is reasonable given that global sales of ESAs in 2018 were

$6.1B, and considering the fact that many patients with anemia due to CKD go untreated because of the harmful side effects.

Below you can see our peak sales estimates for just the Otsuka US and International territories, as well as our valuation for vadadustat. Our calculation uses the following assumptions:

- Addressable Otsuka US and International market size $3.5B (in each territory)
- 50% gross-to-net reduction (2019 guidance for Auryxia gross-to-net reduction)
- 20% International royalty rate to AKBA on net sales
- 97% gross margin
- $250M in commercialization costs
- 21% tax rate
- Target P/E of 5x
- No impact from potentially dilutive securities (given the outstanding share count of 117M, the impact will not be too material)

To be conservative, we have only included the potential commercial milestones from Otsuka, even though AKBA could also receive up to $175M from MTPC (for Japan and other Asian countries) and $25M from Vifor (for sales to select dialysis clinics and third-party dialysis organizations in the US). Also, our choice of $250M in commercialization costs for the US territory might seem a bit high, but we prefer to err on the side of caution. We feel confident saying that AKBA's share of vadadustat is worth somewhere around $2B, which equates to a PT of $16.41/share, representing 416% upside.

AKBA: Vadadustat Peak Sales Estimates In Otsuka US Territory

Drug Name	Vadadustat					**Probability Of Approval**		**65%**
Territory	Otsuka US							
Indication	Anemia due to CKD (DD adults)							
Status	Phase 3 INNO$_2$VATE (top-line results 2Q20)							
Market Share	**Commercial Probability**	**Approval-Adjusted Probability**	**Patient Pool**	**Patients Treated**	**Annual Gross Price**	**Gross Sales**	**Gross-to-Net Reduction**	**Net Sales**
10%	30%	20%		45,070		$361M		$180M
20%	10%	7%		90,140		$721M		$361M
30%	15%	10%	450,702	135,211	$8,000	$1,082M	50%	$541M
40%	20%	13%		180,281		$1,442M		$721M
50%	25%	16%		225,351		$1,803M		$901M
Check	**100%**	**65%**					**Expected Net Sales**	**$352M**

Source: Elle Investments

Drug Name	Vadadustat						**Probability Of Approval**	**65%**
Territory	Otsuka US							
Indication	Anemia due to CKD (NDD adults)							
Status	Phase 3 PRO_2TECT (top-line results mid-2020)							
Market Share	**Commercial Probability**	**Approval-Adjusted Probability**	**Patient Pool**	**Patients Treated**	**Annual Gross Price**	**Gross Sales**	**Gross-to-Net Reduction**	**Net Sales**
1%	30%	20%		51,890		$415M		$208M
2%	10%	7%		103,780		$830M		$415M
3%	15%	10%	5,189,000	155,670	$8,000	$1,245M	50%	$623M
4%	20%	13%		207,560		$1,660M		$830M
5%	25%	16%		259,450		$2,076M		$1,038M
Check	**100%**	**65%**				**Expected Net Sales**		**$405M**

Source: Elle Investments

AKBA: Vadadustat Peak Sales Estimate In Otsuka International Territories

Drug Name	Vadadustat							**Probability Of Approval**		**65%**
Territory	Otsuka International (EU, Russia, China, Australia, Canada, Middle East)									
Indication	Anemia due to CKD (DD adults)									
Status	Phase 3									
Market Share	**Commercial Probability**	**Approval-Adjusted Probability**	**Patient Pool**	**Patients Treated**	**Addressable Market Size**	**Gross Sales**	**Gross-to-Net Reduction**	**Net Sales**	**Royalty Rate to AKBA**	**Royalty to AKBA**
10%	30%	20%		-		$350M		$175M		$35M
20%	10%	7%		-		$700M		$350M		$70M
30%	15%	10%	-	-	$3,500M	$1,050M	50%	$525M	20%	$105M
40%	20%	13%		-		$1,400M		$700M		$140M
50%	25%	16%		-		$1,750M		$875M		$175M
Check	**100%**	**65%**						**Expected License Revs**		**$68M**

Source: Elle Investments

AKBA: Price Target Estimate

Territory	**US**	**International**
Drug	**Vadadustat**	**Vadadustat**
Net sales	$756M	$0M
License revs	$0M	$68M
Total revs	**$756M**	**$68M**
Less: COGS	$23M	$0M
Gross profit	**$734M**	**$68M**
Gross margin	*97%*	-
Total gross profit	**$802M**	
Less: Commercialization costs	$250M	
Operating income	**$552M**	
Otsuka ownership	*50%*	
Operating income to AKBA (50%)	**$276M**	
Tax rate	*21%*	
Less: tax	$58M	
Net income	**$218M**	
Target P/E (x)	5x	
Value of sales + license revs to AKBA	**$1,090M**	
COMMERCIAL MILESTONES		
Otsuka US	$575M	
Otsuka International	$525M	
Total commercial milestones	**$1,100M**	
Tax rate	*21%*	
Less: tax	$231M	
Value of commercial miletones to AKBA	**$869M**	
Total vadadustat value to AKBA	**$1,959M**	
Date	11/19/19	
Current price	$3.18	
Fully diluted market cap	$380M	
Upside	**416%**	
PT	**$16.41**	

Source: Elle Investments

CONCLUSION:

AKBA has continued to drift since the merger with KERX was announced in mid-2018. We see this as a buying opportunity. While sluggish sales of Auryxia do not currently offer very much to be hopeful for (and are partially responsible for the downward drift), the value of vadadustat alone is compelling. The decent cash position, along with the potential for vadadustat to disrupt the $6B+ market for anemia due to CKD, makes AKBA a Buy.

GLOSSARY:
CKD: chronic kidney disease
DD: dialysis-dependent
ESA: erythropoiesis-stimulating agent
IDA: iron deficiency anemia
NDD: non-dialysis-dependent
QOQ: quarter-over-quarter

Note: Additional commentary from Elle Investments can be found at http://elle-investments.com. We welcome your feedback. Additionally, we are thinking of launching a subscription service that would offer early access to our research, along with some other features that investors might find useful (i.e. general portfolio management strategies, live blog updates highlighting our reaction to breaking news, etc.). If you would be interested in subscribing to such a service, please let us know.

Published By: Elle Investments Research Team
Phone: (914) 715-8066
Email: info@elle-investments.com