

BHVN

Biohaven Pharmaceutical Holding Co Ltd

Healthcare

05/16/2018

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PRESENTED
CURRENT

DATE	05/11/2018		PRICE	\$35.62	MARKET CAP	\$1.43B
PRICE	MARKET CAP	ENT VALUE	Image type unknown Chart http://portal.dmlc.com/storage/ideas/Chart/a08A000001FrXL2IAJ.jpg			
\$27.19	\$0.98B	\$0.84B				
P/E RATIO	BOOK VALUE	DIV YIELD				
N/A	\$3.66	0%				
SHARES O/S	AVE DAILY VOL	SHORT INT				
35.98M	768,919	6.17%				

Biohaven Pharmaceutical Holding Co. Ltd. is a clinical-stage biopharmaceutical company, which engages in the research and development of late-stage product candidates targeting neurological diseases, including rare disorders. It focuses on a pipeline of product candidates that represent mechanistic platforms, calcitonin gene-related peptide receptor antagonists, and glutamate modulators. The company was founded in September 2013 and is headquartered in New Haven, CT.

Publicly traded companies mentioned herein: Alder Biopharmaceuticals Inc (ALDR), Allergan PLC (AGN), Biohaven Pharmaceutical Holding Co Ltd (BHVN), Bristol-Myers Squibb Company (BMY), Eli Lilly and Company (LLY)

Highlights

The presenter is long shares of Biohaven (BHVN), which recently announced positive Phase 3 data for its acute migraine treatment, rimegepant [BHV-3000; a small molecule, oral calcitonin gene-related peptide (CGRP) receptor antagonist]. With the stock at ~\$27, he believes the risk/reward is favorable, as the positive data should de-risk the story. The market opportunity is quite large, as roughly 17MM scripts are expected to be written for triptans - the current standard of care - in the US this year. Given a relatively good tolerability profile, rimegepant could take substantial share, which he estimates will result in \$800MM - \$1B of peak annual sales. Applying a 5x multiple, and using a reasonable rate to discount the value back, results in a fair market value estimate of \$2B - \$2.5B (versus a ~\$1B market cap today).

- At the end of March 2018, BHVN provided updates on two of the Phase 3 rimegepant studies. The stock initially fell on the news (by ~40%), as one of the p-values appeared to be low, and the company faces competition from Allergan (ubrogepant) and LLY (lasmiditan), which are also looking to bring new migraine treatments to the market. Last year (2017), over 16MM scripts were written for triptans in the US. For 2018, the presenter expects the number to be closer to 17MM, and this figure could understate the addressable market due to tolerability issues.
 - Three new oral anti-CGRP pills are being developed to provide alternatives for patients that suffer from migraines. If approved by the FDA, each could launch in 2020. Meanwhile, triptans are the most frequently prescribed therapy for migraines. They generally work, but have a history of tolerability issues (nausea, tiredness, dizziness, contraindicated for coronary artery disease/cardiac issues, etc.).
 - Between Allergan and Biohaven, the presenter said there was "some misinterpretation" of BHVN's Phase 3 data

- ▶ and regulatory endpoints when data were first released. However, looking at the full data set, and comparing rimegepant to ubrogepant, he sees better durability for the prior, and noted that its secondary endpoints look good as well. Other “bothersome” symptoms of migraines include light and/or sound sensitivity, and rimegepant looks like the better option, in his opinion.
- ▶ Eli Lilly’s lasmiditan was reacquired when it bought CoLucid for over \$900MM. With only one Phase 3 candidate at the time, and poorer safety/tolerability, the presenter doesn’t view it as a good comp from a valuation standpoint. He explained that lasmiditan has a different mechanism of action (MOA; a 5-HT antagonist, but it does not constrict the blood vessels) compared to rimegepant and ubrogepant, and is more similar to triptans.
- To think through rimegepant’s commercial potential, the presenter said he looks at the total number of triptan scripts and assumes the total market value is \$8B. Using round numbers, ~30% of people either don’t respond to or can’t tolerate triptans. This initial figure - \$2.5B - \$3B - can be carved up among BHVN, AGN, and LLY. Indiscriminately ascribing 1/3 share to each would suggest that peak sales could be ~\$800MM - \$1B for rimegepant.
 - This figure could be conservative, as it is based on just non-responders and the acute market. The tolerability profiles of the new drugs, regardless of MOA, should allow more patients to try them.
 - Additionally, there is the potential for BHVN to have the best-in-class drug. Biohaven has not seen any liver function test elevation throughout its trials (said differently, there has been no imbalance). However, in Allergan’s Phase 3 study, six people saw their liver enzymes spike. While the presenter noted that there were reasonable explanations in each case, liver function has been an overhang for years for this class of drugs.
 - ▶ Commercially, the presenter can envision MDs showing a preference for rimegepant due to the tolerability profile, and a perception that Allergan’s and LLY’s drugs are not different enough from the prior generation. This could lead to BHVN’s share being closer to 50%.
 - ▶ To be fair, the presenter noted that the overall tolerability of ubrogepant is also much better than triptans on measures of chest pain, flushing, dizziness, etc. However, lasmiditan has showed higher rates of dizziness.
 - ▶ Large pharma had issues with the previous class of anti-CGRPs. For example, Merck stopped developing an older, similar drug called telcagepant in 2011 due to worries about high liver enzyme levels. This is why longer-term safety data, which is expected later in 2018, could be a key catalyst for these stocks.
- BHVN has another formulation in Phase 3, and while the shift in PK formulation “doesn’t matter a lot”, it could improve the overall perception of rimegepant if the 2-hour endpoint looks good as well.
- The presenter noted that BHVN may need capital, but that the management team is good and recognizes the challenge of potentially commercializing a “primary care drug” such as rimegepant. He believes the company may be open to a partnership, which could be another catalyst.
 - BHVN raised \$50MM via a PIPE in early March, before the Phase 3 data were released. The market was skeptical, but the money was used to amend the license agreement with Bristol-Myers Squibb (the royalty rate was reduced). In concert, the non-compete was changed. The presenter said he is “not trying to infer too much”, but BHVN was precluded from doing a transaction with any company with a CGRP, including monoclonal antibodies. There are 4 - 5 of these drugs in development for preventive measures, and changes to contracts such as this are “usually with intent (it is reasonable to think that a larger player might want an oral complement to an injectable)”.
- Valuation:
 - At 5x peak sales, BHVN is worth \$4bn. Discounting this back using a reasonable rate results in a \$2B - \$2.5B market cap.
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- Risks:

- Safety is a risk, until long-term data are published. The safety trial is open-label, and management must have a “decent sense” about what’s going on (e.g. if liver enzymes are getting too high in patients). However, Biohaven’s trial is large, with 1,200 patients, and a potential partner/acquirer would be able to see that data.
 - A participant noted that a BMY abstract from ~5 - 6 years ago showed no increase in liver enzymes or related warning signals during a dose escalation study with a substantially higher dose.
- Could Amgen’s CGRP launch impact BHVN shares? Not likely, in the presenter’s opinion, as the injectable is on the preventive side (a smaller market, limited to the most severe patients). If these [preventive] antibodies don’t work, it could be perceived to be negative. And, if the data are positive, it could be good. Separately, Allergan could have data out on a Phase 2b study, with a different molecule, over the summer (2018).

- Is there a good hedge?

- In the presenter’s opinion, Alder can be used to hedge the long position in BHVN. It has an anti-CGRP called eptinezumab in Phase 3 for migraine prevention, and he is long both stocks at this time (rimegepant’s failure would likely be a catalyst for Alder’s stock).

For questions regarding DeMatteo Research Events and Services, please contact:

Hans Noering, Co-Director of Research, 212-833-9932, hnoering@dmlc.com

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