Biohaven Ltd.

Key Takeaways from AES 2024 & Mgmt Catch Up

Overweight

BHVN, BHVN US
Price (10 Dec 24):$42.59

SMid Biotechnology

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Over the weekend, we attended the AES Annual Meeting (Dec. 6-10, 2024; Los Angeles, CA) and we wanted to provide our key takeaways from the expanded phase 1 MAD safety results for BHV-7000 including the once-daily extended-release (ER) formulation which were presented in a poster as well as our brief catch up with mgmt (CMO, Irfan Qureshi) wherein we covered a number of topics relevant to the rest of the pipeline. At a high level, the ER formulation of BHV-7000 was safe and well-tolerated in healthy adults which we find important given the extended-release tablets are currently being evaluated in doses up to 75mg once daily in the ongoing phase 2 and 3 studies in focal epilepsy, idiopathic generalized epilepsy, bipolar mania, and major depressive disorder (MDD). In our catch up, mgmt expressed that they are very happy with the phase 1 profile of BHV-7000 and its clean safety and tolerability thus far including the low rates of CNS-related TEAEs and in particular the results with the ER formulation; moreover, they emphasized the potential opportunities for the asset in bipolar disorder and MDD. We agree with mgmt that these findings support the continued clinical development of BHV-7000 with the potential to reduce seizures while minimizing AEs; we have similarly heard from doctors in the past and at the conference that there remains a continued need for efficacious anti-seizure medications (ASMs) with minimal burden around AEs. Net-net, we continue to strongly recommend BHVN for investors looking for growth harboring a diverse set of opportunities and to the extent that some of them are derisked could drive the stock further as we round out 2024 and head into 2025 (see our latest view/further details in our biotech outlook here).

- **Details on the expanded phase 1 MAD safety results for BHV-7000, including the ER formulation.** The update included data on the healthy adults who were randomized to receive the ER formulation of BHV-7000 (25mg, 50mg, or 75mg once daily) or placebo for up to 15 days (Poster 1.486). Of note, there were only 2 nervous system TEAEs reported in one patient each that were mild in severity with one being presyncope at the 25mg ER dose and the other being dysgeusia at the 50mg ER dose; in our catch up, mgmt was unconcerned by these events and stressed that they were mild and self-resolving. Of note, there were no severe or serious AEs and no cases of cognitive/mood disturbances or somnolence reported. Overall, this study demonstrated favorable safety and tolerability of BHV-7000 with no dose-limiting AEs. We have heard in our conversations that at the same time the doctors are eager to better understand how the drug performs with respect to seizure reduction in patients in this context. *We are hosting a call with Dr. Kathryn Davis (University of Pennsylvania) on Dec. 12 at 2pm ET to discuss BHV-7000 clinical results and prospects as well as the epilepsy competitive landscape in more detail (please contact the team for details).*
- **Other pipeline tidbits.** Regarding the recent results from the phase 3 RESILIENT study for taldefgrobep alfa (t-alfa) in spinal muscular atrophy (SMA) which did not meet its primary endpoint (see our prior comments here), mgmt continues to look at the data and plans to engage with the FDA on a

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potential path forward. Despite the primary endpoint miss in RESILIENT, mgmt indicated they were really excited by the dual energy x-ray absorptiometry (DXA)/body composition data (i.e., fat mass, lean muscle mass and bone density) from the study in particular; recall, Biohaven cited the demonstrated target engagement (i.e., myostatin reduction) and taldefgrobep-associated changes in body composition as support for the decision to advance t-alfa into a placebo-controlled phase 2 obesity study in 4Q24. Further, they reaffirmed to us their plan to provide an update on BHV-1300 (see our prior comments here and deep dive here) and submit a total of 4 INDs from the MoDE platform in 2024 as well as re-submit the NDA for troriluzole in spincerebellar ataxia (SCA) in 4Q24. We think the positive topline BHV4157-206-RWE results set troriluzole for a potential broad label encompassing all SCA genotypes in the U.S. and a strong launch around mid-2025, if/when approved. In the EU, EMA marketing authorization remains under review.

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Companies Discussed in This Report (all prices in this report as of market close on 10 December 2024, unless otherwise indicated)
Biohaven Ltd.(BHVN/$42.59/OW)

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Biohaven Ltd. (BHVN, BHVN US) Price Chart

Date	Rating	Price ($)	Price Target ($)
04-Jan-23	OW	13.50	23
25-Apr-23	OW	13.87	20
17-May-23	OW	13.87	21
15-Jun-23	OW	24.38	27
16-Aug-23	OW	20.75	24
06-Sep-23	OW	17.77	26
20-Nov-23	OW	30.09	32
23-Feb-24	OW	47.33	56
07-Mar-24	OW	58.13	57
19-May-24	OW	37.37	55
03-Oct-24	OW	47.99	68

Source: Bloomberg Finance L.P. and J.P. Morgan; price data adjusted for stock splits and dividends.
Initiated coverage Jan 04, 2023. All share prices are as of market close on the previous business day.

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