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Spring Bank Pharmaceuticals, Inc.
(SBPH/NASDAQ/$8.02/BUY)
Arrowhead Pharmaceuticals, Inc.
(ARWR/NASDAQ/$4.30/Not rated)

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ARWR Clinical Hold May Benefit SBPH

Arrowhead Pharmaceuticals announced on November 8th it had received verbal notice from the FDA to put the Company's ongoing Heparc-2004 clinical study on hold. The Heparc-2004 is a US multicenter, randomized, double-blind, placebo-controlled, multi-dose study of ARC-520. The study was initiated in 2015 and was slated to enroll up to 12 patients who would receive ARC-520 at a 1mg/kg dose. The FDA put the study on hold for toxicology concerns arising from deaths in an ongoing long-term non-human primate study using EX1, the company's liver-targeted, intravenously administered delivery vehicle. According to Arrowhead, the primate study involved higher doses of EX1 than those used clinically in humans and the doses are higher than those used in the company's previous animal toxicology studies. The cause of the animal deaths is unknown and under investigation. The EX1 delivery vehicle is used in the Company's ARC-520, ARC-521, and ARC-AAT programs. The FDA has not indicated a problem with the ARC-520 Phase II MONARCH trial for which SB9200 is intended to be an immune adjuvant in an ARC-520/SB 9200 combination cohort. We note that the MONARCH trial is evaluating higher doses, 2mg/kg and 4mg/kg, of ARC-520, than the halted Heparc-2004 trial.

This trial halt was prompted by primate study deaths, a significant event, and comes on the heels of the Alnylam's announcement last month of the suspension of its Phase III revusiran study for the treatment of hereditary ATTR amyloidosis, a liver-associated genetic disease that leads to cardiomyopathy. That trial was halted and abandoned after it was found that patients were dying at a higher rate than placebo. Alnylam quickly has pivoted to another RNAi chemistry. We believe the common thread in both of these trials is that fact that the core RNAi technology still has unsolved problems when put into clinical application. Arrowhead's RNAi core technology was originated by Alnylam, but Arrowhead has independently developed a new conjugated delivery system (EX1) for delivery of the RNAi sequences.

Spring Bank's Technology Does Not Have Similar RNAi Issues

In our opinion, Spring Bank's SMNH technology does not have the same technical challenges as RNAi and as such, may become a "sought after" alternative if the antiviral focused RNAi companies continue to experience trial safety issues. Like Alnylam's technology, the ARC-520 technology uses RNAi machinery to direct specific cleavage of RNA transcripts (HBV, in the specific case of ARC-520), thereby effecting a disruption of downstream RNA/DNA activities. Long-standing technical issues with RNAi have been associated with the ability to control the specific cleavage events and to prevent nucleases in the cell cytoplasm from prematurely cleaving or miscleaving the RNA sequence before it has reached its intended target and thereby, creating off-

targeting effects, including triggering high level immune response. In contrast, the dinucleotide SB 9200 binds to and upregulates RIG-1 and NOD2, on a substitution-like basis, not a specific cleavage site mechanism like RNAi, in order to prevent viral integration into the cell's innate immune response machinery. *We believe this is a subtle but extremely important distinction between the two approaches that investors are overlooking as they assess the impact of these two RNAi clinical trial halts.*

Both Spring Bank and Arrowhead are presenting data at a HBV-specific conference being held at Harvard Medical School today and Arrowhead has a number of presentations on the docket at the AASLD, the academic society meeting for liver diseases, that also gets underway today in Boston. We are attending the Harvard Medical School event and hope to have a further update on the RNAi question following the conclusion of the AASLD. **We are maintaining our BUY rating on Spring Bank shares in light of these events**. *SG*

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