FLASH NOTE

Company Update

USA | Healthcare | Biotechnology

January 20, 2015

Jefferies

Dicerna Pharmaceuticals (DRNA)
Update Following Recent Management Meeting

BUY
Price target $48.00
Price $20.23

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Key Takeaway

In a recent meeting with management, DRNA provided an update of the ongoing development of its PH1 and pipeline programs. Notably, the company highlighted comparative animal data between its DsiRNA-EX-conjugate platform, which will serve as the foundation for future liver-targeted programs, and competing subcutaneous siRNA delivery technologies. The Phase 1 program for its lead program, DCR-PH1, is anticipated to begin in 2015 with initial data by YE15.

Compelling Data From Subcutaneously Delivery Platform. The company noted that the potency of its recently announced subcutaneous DsiRNA-EX-conjugate delivery platform has dosing comparable to that of Alnylam's (ALNY, not covered) newest subcutaneous delivery. In mice, DRNA has demonstrated knockdown of around 50% at 2mg/kg, comparable to ALNY's data that showed 50% knockdown at 5mg/kg in the subcutaneous delivery being used in its lead SC clinical program, TTR, and 1mg/kg with its newest enhanced SC delivery platform. While DRNA has not measured longer-term duration of the knockdown, the company expects to be competitive with ALNY's duration given the stability of their molecule.

New Programs In Early Development. DRNA has developed a proprietary DsiRNA-EX conjugate-based subcutaneous delivery system that will be used in lieu of Tekmira's LNP and DRNA's EnCore LNP in DRNA's pipeline of four new liver-targeted RNAi candidates. This delivery system allows for subcutaneously delivery and DRNA expects additional targets (beyond the four already in early development) to come in 2015. While the company noted it is targeting both orphan and non-orphan indications with these new targets, we would guess the lead candidate is PH1 given the work done to date to optimize the RNAi dicer sequence being used in the intravenous PH1 program, which can also be used in the subcutaneous delivery technology. DRNA expects to move into primate studies in its new subcutaneous programs in 1H15, followed by a first IND to start human trials in 2016.

DCR-PH1 Phase 1 Trial To Begin In 2015. Recall, DRNA expects to run a two-part, Phase 1/2 study beginning with a single ascending dose (SAD) trial followed by a multiple ascending dose (MAD) portion in PH1 patients who are not on dialysis. The study is expected to begin in 2H15, with initial data from the SAD portion by YE15 and MAD data in 2016. Further, the company expects to start a natural history study in 1Q15 that will enroll 50-75 patients in the US and EU. The study will exclude patients on dialysis and will measure the change in oxalate and glycolate levels (urine and blood) as well as measures of clinical benefit including renal function. Early biomarker data on oxalate and glycolate levels could serve as proof-of-concept and may even serve as eventual surrogate endpoints for FDA approval.

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Company Description

Dicerna Pharmaceuticals is a Watertown, MA-based therapeutics company focused on developing RNA interference (RNAi) technologies targeting liver and cancer. Dicerna has partnered two oncology development programs with the global pharmaceutical company Kyowa Hakko Kirin Co., Ltd. (KHK) targeting KRAS and CKAP5. DRNA's unpartnered programs are DCR-PH1 for Type 1 primary hyperoxaluria, a rare orphan disease resulting in renal failure, and DCR-M1711 targeting MYC for solid tumors.

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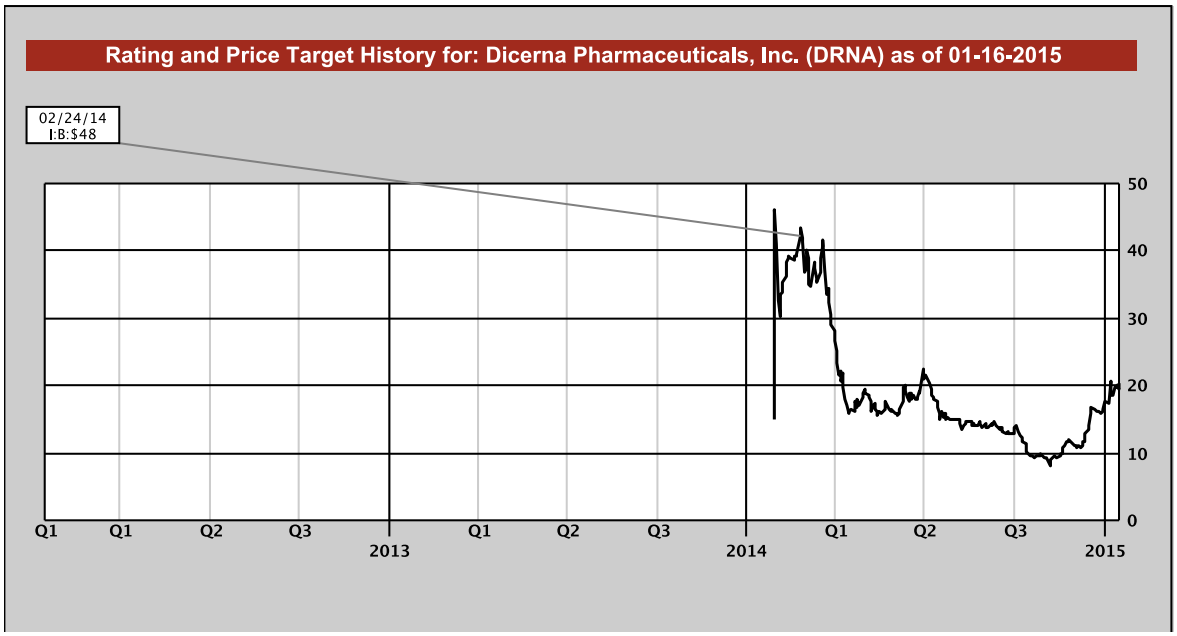

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