FLASH NOTE

Company Update

USA | Healthcare | Biotechnology

September 22, 2014

Jefferies

Minerva (NERV)

Multiple MIN-202 Phase 1Data Readouts In 4Q14/1Q15

BUY
Price target $10.00
Price $5.80

EQUITY RESEARCH AMERICAS

Key Takeaway

NERV announced it will begin a U.S. study of MIN-202 (partnered with Janssen) for the treatment of insomnia. This will be a bioavailability study of a solid dosage formulation of MIN-202 expected to go into the Phase 2 studies. We continue to expect Phase 1b data from MIN-202 in secondary insomnia in MDD patients by YE14. We reiterate our Buy and $10 PT, noting positive Phase 1 data for MIN-202 could be a catalyst in 2H14 that would be upside to our valuation.

MIN-202 Bioavailablity Study To Begin Shortly. Today, NERV announced it will begin a U.S.-based bioavailability study to advance development of MIN-202, NERV's orexin-2 antagonist being developed for the treatment of primary and secondary insomnia. The bioavailability study will be a randomized, open-label, 3-way crossover study in healthy male volunteers to evaluate the bioavailability, food effect, safety and tolerability of a solid dosage formulation of MIN-202 as compared to a previous formulation. While this is not the expected final dosage form, it is the formulation that is anticipated to be used in the Phase 2 studies. The company expects data from the bioavailability study in 1Q15.

MIN-202 Phase 1b Data In 2H14. In addition to the bioavailability study, NERV and partner Janssen have two ongoing Phase 1 studies with MIN-202, including a Phase 1b study in patients suffering from secondary insomnia and major depressive disorder (MDD) and a randomized, double-blind, placebo-controlled multiple ascending dose (MAD) study in healthy subjects. The primary objective of the MAD study is to investigate pharmacokinetics data for several doses (10, 20, and 40mg) of MIN-202 after repeated dosing and to explore the safety and tolerability of MIN-202 versus placebo during 10 days of consecutive dosing. MIN-202 remains on track to readout Phase 1b data in MDD patients with secondary insomnia by YE14. Further, the company is nearing the end of dosing at the 40mg dose in the MAD trial and expects data in healthy volunteers also by YE14. Following these data readouts, Minerva plans to start either a Phase 1b or Phase 2a trial focusing on primary insomnia.

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Company Description

Minerva is focused on developing neuropsychiatry drugs. Minerva's lead product candidate, MIN-101, is a 5-HT2A/Sigma2 antagonist in Phase 2 development for the treatment of schizophrenia. MIN-101 is thought to be differentiated from conventional antipsychotics as it was developed to be effective against negative symptoms. NERV is also developing MIN-117, an antagonist of 5-HT1A and 5-HTT receptors and both serotonin and dopamine, for major depressive disorder (MDD). NERV believes MIN-117 could be differentiated by fast onset of action and potential to treat patients that have failed previous lines of antidepressants. NERV has two other products in early Phase 1 or preclinical development: MIN-202, an orexin-2 antagonist for primary and secondary insomnia, and MIN-301, an ErbB4 activator for Parkinson's disease.

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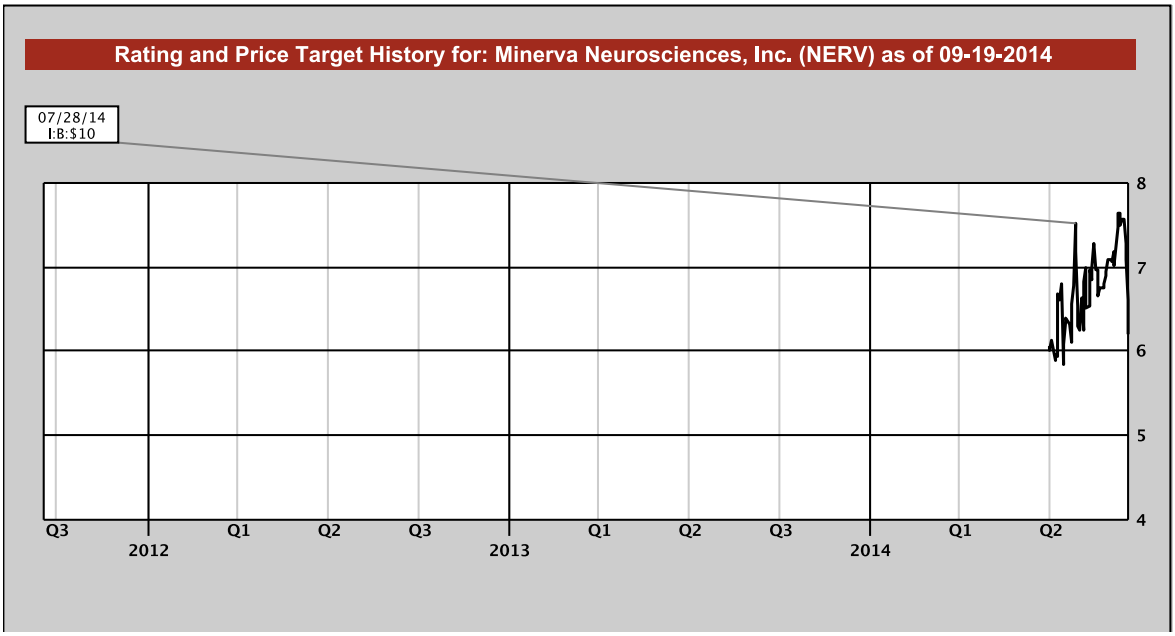

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