

Jefferies

January 22, 2015

Minerva (NERV) Positive MIN-202 Data In Insomnia

Key Takeaway

Minerva and partner INI (Hold) reported positive data for MIN-202 in insomnia. We see this as positive validation of NERV's management team, although we expect the company to streamline its focus onto MIN-101 for schizophrenia and MIN-117 for depression. We reiterate our Buy rating and \$10 price target.

Positive Top-Line Results For MIN-202. NERV reported top-line results from its three Phase 1 trials for MIN-202, its orexin-2 antagonist for the treatment of sleep disorders. The key trial was the Phase 1b in patients with major depressive disorder and insomnia. All three doses (10, 20 and 40mg) showed a significant improvement on latency to persistent sleep. Further, total sleep duration was increased by ~45 minutes. In a multiple ascending dose trial (5mg to 60mg) in healthy volunteers, it was shown that doses ≥20mg induced daytime somnolence when administered in the morning. The lowest dose still elicited sedation. The third trial tested a solid dose formulation, compared to a liquid formulation for the prior two trials. This solid formulation would likely be used in further trials.

NERV Is Committed To Reaching Tangible Trial Results With MIN-101 And MIN-117. NERV believes that the most prudent strategy to maximize value is to continue full-scale development of MIN-101 for schizophrenia. MIN-101 could have a unique profile and be the first antipsychotic with proven efficacy in treating negative symptoms of schizophrenia (social withdrawal, isolation). The Phase 2b protocol has been submitted in 3 countries already and should enroll first patient in 1H15. Top-line trial results are expected by mid-2016. For MIN-117 for depression, the market for antidepressants is large and dominated by generic drugs, but NERV believes that results from a MIN-117 Phase 2a trial could show differentiated results in several key areas, including less sexual dysfunction, faster onset, and cognition improvement. The trial would only cost \$2m-\$3m and could lead to a significant monetization event. For MIN-202, while we see the data as positive validation of the NERV neuroscience team, NERV has to pay 40% of development costs for '202 and only has European rights and a royalty on U.S. sales from [N], and thus, we believe this opportunity could be limited. While near-term costs are capped under the partnership, we see the other pipeline products as a more productive use of resources at this time. If NERV returns rights back to JNJ within 45 days of completion of the Phase 1b trial and certain tox studies in animals, it would need to pay a termination fee of \$3.0m.

Price target \$10.00 Price \$4.37

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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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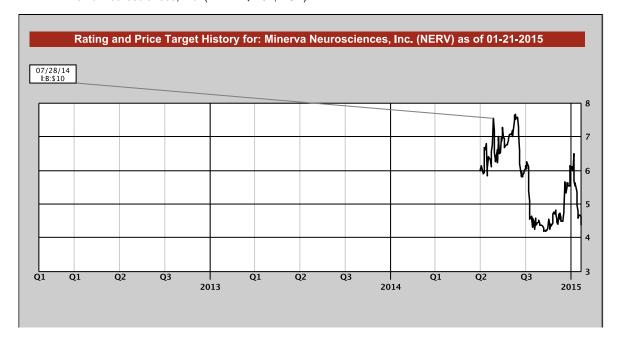
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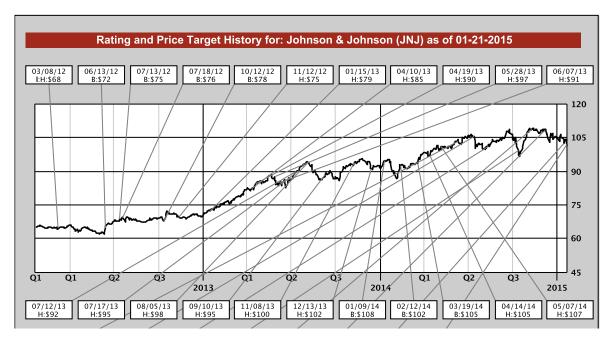
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Other Companies Mentioned in This Report

- Johnson & Johnson (JNJ: \$101.90, HOLD)
- Minerva Neurosciences, Inc. (NERV: \$4.37, BUY)



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IB Serv./Past 12 Mos.

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Rating	Count	Percent	Count	Percent
BUY	1055	52.02%	285	27.01%
HOLD	818	40.34%	145	17.73%
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