

# Minerva Neurosciences, Inc. (NERV)

MIN-101 Set for Phase 2b Initiation in the Near Term

## MARKET DATA

Price	\$4.56
52-Week Range:	\$4.08 - \$7.90
Shares Out. (M):	17.8
Market Cap (\$M):	\$81.2
Average Daily Vol. (000):	10.0
Cash (M):	\$24
Cash/Share:	\$1.33
LT Debt (M):	\$0

Source: Thomson Reuters and JMP Securities LLC

**MARKET OUTPERFORM** | Price: \$4.56 | Target Price: \$16.00

## INVESTMENT HIGHLIGHTS

**MIN-101 once-daily formulation ready for near-term advancement into Phase 2b development; reiterate our Market Outperform rating and \$16 price target on Minerva Neurosciences.** This morning, Minerva announced that it has completed selection of a once-daily formulation of MIN-101 for advancement into the planned Phase 2b trial in schizophrenia patients. The formulation demonstrated optimal pharmacokinetic parameters in Phase 1 development. The Phase 2b trial remains on track to begin in 1H15 and we continue to believe the drug candidate has attractive potential given the previously demonstrated improvements in schizophrenia patients, specifically in negative symptoms which represent an important unmet medical need, in our view. Our \$16 price target is derived through a sum-of-the-parts NPV analysis of MIN-101 and MIN-202.

**PK parameters support potential for optimal clinical profile.** The final once-daily formulation of MIN-101 was selected based on a Phase 1 trial intended to assess single- and multiple-dose cohorts of multiple lead candidates. Importantly, the formulation selected for advancement into Phase 2b development optimizes the pharmacokinetic profile of MIN-101, as well as its two active metabolites (BFB-520 and BFB-999). The Phase 2b formulation enables once-daily formulation of MIN-101, which acts as an antagonist on both 5-HT<sub>2A</sub> and Sigma2 receptors to provide antipsychotic efficacy, while minimizing levels of BFB-520, which has previously been associated with prolongation of QT intervals at supra-therapeutic levels.

**Phase 2b remains on track for 1H15 initiation.** The Phase 2b trial is designed to enroll ~234 patients with schizophrenia aged 18-60 years. Patients are required to be stable for positive and negative symptoms on the gold standard PANSS assessment. All patients enrolled are required to exhibit negative symptoms of schizophrenia. The primary endpoint will compare treatment with MIN-101 to placebo over an initial 12-week treatment period for improvement in the negative symptoms of schizophrenia, after which all patients will be eligible to receive MIN-101 in a six-month extension study.

**MIN-202 progress likely provides additional near-term catalysts.** The company is also making solid progress with MIN-202, its selective orexin-2 receptor antagonist for the treatment of primary and secondary insomnia. Recall this candidate is being developed in collaboration with Janssen Pharmaceuticals. We look to multiple Phase 1 read outs in the coming two months including a bioavailability study in healthy volunteers (YE2014), a multiple-ascending dose study in healthy volunteers and a Phase 1b trial in patients with major depressive disorder.

FY DEC		2013A	2014E	2015E
Revenue (\$M)	1Q	\$0.0	\$0.0A	--
	2Q	\$0.0	\$0.0A	--
	3Q	\$0.0	\$0.0A	--
	4Q	\$0.0	\$0.0	--
	<b>FY</b>	<b>\$0.0</b>	<b>\$0.0</b>	<b>\$0.0</b>
EPS	1Q	--	(\$0.34)A	--
	2Q	--	(\$2.55)A	--
	3Q	--	(\$1.53)A	--
	4Q	--	(\$0.34)	--
	<b>FY</b>	<b>(\$0.78)</b>	<b>(\$4.76)</b>	<b>(\$1.72)</b>

Source: Company reports and JMP Securities LLC

## STOCK PRICE PERFORMANCE



## Company Description

Minerva Neurosciences is a clinical-stage biopharmaceutical company, headquartered in Cambridge, MA, focused on the development and commercialization of novel drug candidates to treat patients suffering from CNS diseases. The company has four novel clinical stage candidates with validated mechanisms of action, each having the potential to differentiate in important unmet medical needs. Its lead product candidates are MIN-101, for the treatment of schizophrenia, and MIN-202, which Minerva is co-developing with Jansen Pharma for the treatment of patients suffering from primary and secondary insomnia. In addition, the portfolio includes MIN-117, for the treatment of patients suffering from major depressive disorder, or MDD, and MIN-301, for the treatment of patients suffering from Parkinson's disease. Based on its current capital, the company intends to focus resources on the development of MIN-101 and MIN-202; however, development of pipeline candidates could be accelerated should additional funds, including from non-dilutive sources or partnerships, become available.

## Investment Risks

**Clinical risk.** Minerva may not be successful in the full development and launch of its product candidates. There may be enrollment, dosing, efficacy, or safety issues that would preclude development. It is possible that drug candidates may fail to reach endpoints or statistical significance in respective clinical trials. Any of the aforementioned issues would cause a delay, or potential discontinuation of development. If product candidates make it through clinical trials, the company may encounter manufacturing issues including challenges with the scale-up to commercial quantities. All of the above circumstances should be taken into consideration when assessing clinical risk.

**Regulatory risk.** The company's drug candidates may not receive approval from the FDA or from ex-U.S. agencies. The FDA may request additional pre-clinical or clinical trials to provide validation for approval that would likely delay approval timelines and increase expenses. If approval is granted, the regulatory agency may impose restrictions on the label, or may require a REMS program for a drug candidate; this could limit commercial uptake and delay commercial progress.

**Market risk.** The market opportunity for products may not accurately reflect current estimates and there may be challenges with market adoption. This would impact the ability to reach revenue and profitability projections. The company must obtain and protect its intellectual property rights in order to effectively compete in the marketplace. Minerva could get involved in patent lawsuits that would likely be time-consuming and expensive.

**Financial risk.** Minerva has no commercial products generating revenue, thus, it has not been, and is not yet, profitable. It has incurred losses each year since inception due to research and development expenses. These expenses are expected to increase in the near future as product candidates advance through the pipeline. The company will likely need to raise additional capital to fund these trials and continue operations. If there are any issues with acquiring needed financing, commercializing its product candidates, or achieving sales revenue, the company may not reach profitability.

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JMP Securities currently makes a market in the security of Minerva Neurosciences, Inc.

JMP Securities was manager or co-manager of a public offering of securities for Minerva Neurosciences, Inc. (NERV) in the past 12 months, and received compensation for doing so.

JMP Securities expects to receive OR intends to seek compensation for investment banking services from Minerva Neurosciences, Inc. in the next 3 months.

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Market Outperform (MO): JMP Securities expects the stock price to outperform relevant market indices over the next 12 months.

Market Perform (MP): JMP Securities expects the stock price to perform in line with relevant market indices over the next 12 months.

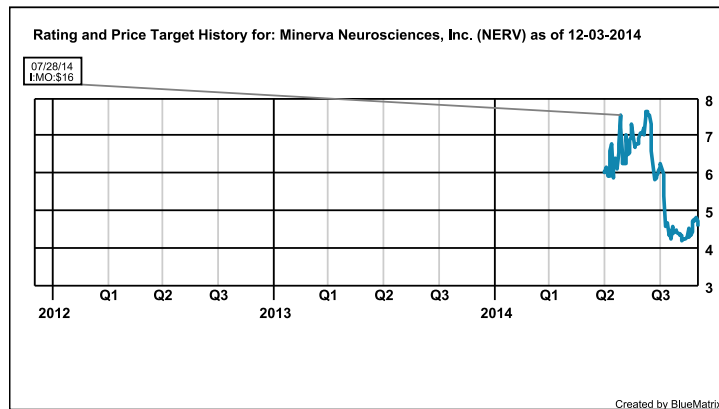
Market Underperform (MU): JMP Securities expects the stock price to underperform relevant market indices over the next 12 months.

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JMP Rating	Regulatory Equivalent	# Co's Under Coverage	% of Total	# Co's Receiving IB Services in Past 12 Months				
				Regulatory Equivalent	# Co's Under Coverage	% of Total	% of Co's With This Rating	
MARKET OUTPERFORM	Buy	289	65.24%	Buy	289	65.24%	103	35.64%
MARKET PERFORM	Hold	142	32.05%	Hold	142	32.05%	16	11.27%
MARKET UNDERPERFORM	Sell	3	0.68%	Sell	3	0.68%	0	0%
COVERAGE IN TRANSITION		6	1.35%		6	1.35%	0	0%
TOTAL:		443	100%		443	100%	121	27.31%

### Stock Price Chart of Rating and Target Price Changes:

Note: First annotation denotes initiation of coverage or 3 years, whichever is shorter. If no target price is listed, then the target price is N/A. In accordance with NASD Rule 2711, the chart(s) below reflect(s) price range and any changes to the rating or price target as of the end of the most recent calendar quarter. The action reflected in this note is not annotated in the stock price chart. Source: JMP Securities.

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