

## COMPANY NOTE

Target | Estimate Change

USA | Healthcare | Biotechnology

March 27, 2015

# Jefferies

## Minerva (NERV) 4Q14 Update – Phase 2b MIN-101 Trial Kicks Off, Data In Mid-2016

### Key Takeaway

**On its 4Q14 call, NERV highlighted a number of recent developments with its pipeline programs. The critical Phase 2b study for MIN-101 in schizophrenia should be fully enrolled by year-end, with data by mid-2016. We are also encouraged by NERV's advances in its earlier stage pipeline.**

**Updates From Eastern European Regulatory Agencies Bode Well For MIN-101 And MIN-117.** In conjunction with 4Q earnings, NERV noted that regulators in Latvia and Estonia had approved the Phase 2b study of MIN-101 in schizophrenia, a randomized double-blind trial in 234 schizophrenic patients with a history of negative symptoms. The primary efficacy endpoint will be the negative symptom subscale of PANSS evaluated after 3 months of treatment with a further extension for 6 months. The study is powered to demonstrate a 3.5 point improvement relative to placebo. Enrollment is expected to start next quarter and continue until year-end with results in mid-2016. NERV also noted that the Latvia ethical committee had approved a double-blind, placebo and active controlled Phase 2a trial of MIN-117 in 60 patients with major depressive disorder (MDD). The primary endpoint will be to evaluate the 0.5 mg dose of MIN-117 in reducing symptoms of depressive episodes as measured by change from baseline in Montgomery-Asberg Depression Rating Scale (MADRS) over 6 weeks of treatment and to compare safety to 20 mg daily dose of paroxetine. NERV expects to begin enrolling this trial in 2Q15.

**Pipeline Updates: MIN-202 On Track For Two Trials, MIN-301 IND In 2016.** NERV and partner Janssen (JNJ, Hold) are expecting to initiate two trials of MIN-202 by mid-year: a Phase 2a study in primary insomnia and a Phase 1b study in patients with MDD and comorbid insomnia. As a reminder, earlier this year, NERV reported preliminary positive results from a Phase 1 study, in which MIN-202 showed improvements in sleep onset and duration in patients with MDD and comorbid insomnia. Separately, NERV announced it intended to file an Investigational New Drug (IND) with the FDA for MIN-301 for Parkinson's disease in 2016, and begin Phase 1 trials shortly after. Although we do not ascribe value to either MIN-202 or MIN-301, we are encouraged by the progress with internal development efforts.

### Valuation/Risks

We are lowering our price target from \$10 (\$7.50 MIN-101 + \$1.50 MIN-117 + \$1 cash) to \$9 (\$6 MIN-101 + \$1 MIN-117 + \$2 cash) to reflect additional dilution from a recent private placement. Risks include clinical, regulatory, commercial.

USD	Prev.	2013A	Prev.	2014A	Prev.	2015E	Prev.	2016E
Rev. (MM)	--	0.0	--	0.0	25.0	0.0	--	25.0
EV/Rev								3.1x
<b>EPS</b>								
Mar	--	--	--	(0.43)	--	(0.70)	--	--
Jun	--	--	--	(2.32)	--	(0.55)	--	--
Sep	--	--	--	(1.53)	--	(0.55)	--	--
Dec	--	--	(0.53)	(0.49)	--	(0.55)	--	--
FY Dec	--	(0.63)	(4.55)	(4.47)	(2.19)	(2.33)	--	(1.71)
FY P/E		NM		NM		NM		NM

**BUY**

Price target \$9.00

(from \$10.00)

Price \$5.36

### Financial Summary

Net Debt (MM):	(\$18.6)
Long-Term Debt (MM):	\$0.0

### Market Data

52 Week Range:	\$10.00 - \$4.08
Total Entprs. Value (MM):	\$76.8
Market Cap. (MM):	\$95.4
Shares Out. (MM):	17.8
Float (MM):	11.3
Avg. Daily Vol.:	238,772

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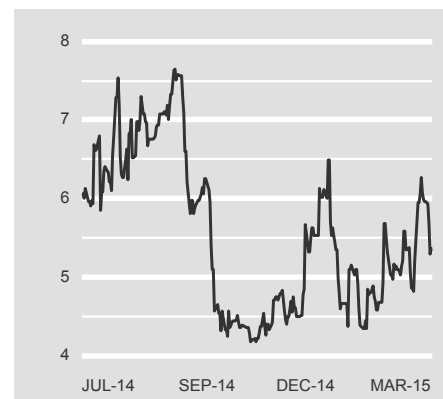
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### Price Performance



## Scenarios

## Target Investment Thesis

- MIN-101 could offer benefit for negative schizophrenia symptoms
- Negative symptoms represent a major unmet need – modest penetration could yield \$1.1b in peak U.S. sales
- MIN-101 exclusive through 2026
- MIN-117 is a high-risk / high-reward opportunity in addressing antidepressant failures
- Price Target: \$9 (\$6 MIN-101 + \$1 MIN-117 + \$2 cash)

## Upside Scenario

- With strong benefit on positive and negative symptoms, MIN-101 could be multi-billion opportunity
- Vast market opportunity for MIN-117 if it shows differentiating characteristics
- MIN-101 exclusive through 2031
- Takeout potential if either drug works
- Price Target: \$19 (\$20 MIN-101 + \$4 MIN-117 + \$2 cash)

## Downside Scenario

- MIN-101 trial design changes could be negative
- MIN-101 may not show benefit for positive symptoms limiting opp
- MIN-117 may not find partner and is too costly for NERV to develop
- High likelihood MIN-117 fails
- MIN-101 exclusive through 2021
- Price Target: \$2 (\$2 cash)

## Long Term Analysis

## Revenue (millions)

N/A

Source: Company Reports, Jefferies LLC

## Long Term Financial Model Drivers

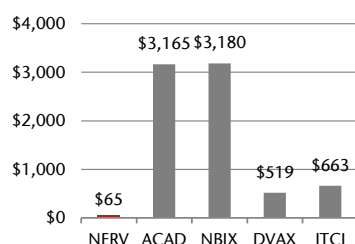
<b>Earnings CAGR</b>	<b>+45%</b>
Revenue Growth (2019-2022 CAGR)	<b>+53%</b>

## Other Considerations

With several eagerly anticipated product launches, anemic pipelines at large cap pharma, and an increasingly conservative FDA stance, we believe small and mid-cap biotech could lead sector performance in 2015. We see a premium placed on late-stage and marketed products. M&A interest could also factor into the performance of the sector, particularly among small-cap and mid-cap companies with later stage programs.

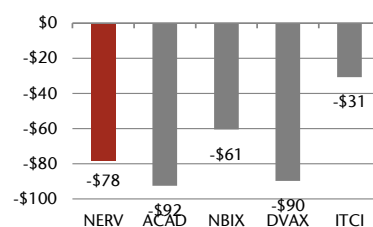
## Peer Group

## Group EV



Source: Jefferies LLC

## Net Income



Source: Jefferies LLC

## Recommendation / Price Target

Ticker	Recommendation	PT
NERV	BUY	\$9
ACAD	BUY	\$47
NBIX	BUY	\$39
DVAX	BUY	\$30
ITCI	NC	NA

## Catalysts

- 1H16: MIN-117 Phase 2 data
- 1H16: MIN-101 Phase 2b data

## Company Description

Minerva Neurosciences Inc. (NERV, \$10) is a Cambridge, MA-based company focused on developing neuropsychiatry therapeutics. Minerva's lead product candidate MIN-101 is a 5-HT<sub>2A</sub>/Sigma2 antagonist in Phase 2 development for the treatment of schizophrenia. NERV is also developing MIN-117, an antagonist of 5-HT<sub>1A</sub> and 5-HT<sub>2A</sub> receptors and both serotonin and dopamine, for major depressive disorder (MDD).

## NERV

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**Financials.** NERV reported a net loss of \$7.4m for 4Q14. As of December 31, NERV had a cash position of \$18.6m. In March, the company issued 6.3m shares and 6.3m warrants – resulting in net proceeds of \$28.8m. The company expects to have enough cash to get through 2016.

**NERV: Historical and Projected Revenue and Earnings**

December 31 Fiscal Year (\$000s, except per share)	2012A	2013A	1Q14A	2Q14A	3Q14A	4Q14A	2014A	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
MIN-101 Sales	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	15,479	221,239	751,234	1,589,771
U.S.	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	11,150	161,607	550,462	1,173,029
EU	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	4,328	58,550	186,135	370,208
ROW	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1,082	14,637	46,534
U.S. Royalties to Minerva	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	2,676	38,786	136,129	317,369
ROW Royalties to Minerva	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1,039	14,312	48,185	100,018
MIN-117 Sales	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	189,406	629,527	1,278,142
U.S.	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	189,406	512,823	943,290
ROW	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	116,704	334,852
U.S. Royalties to Minerva	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	17,047	46,667	102,628
ROW Royalties to Minerva	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	8,169	23,440
Total Royalties	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	3,715	70,144	239,151	543,455
Milestones	-	-	-	-	-	-	-	-	-	-	-	-	25,000	15,000	100,000	175,000	150,000	100,000	100,000
Other	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Total Revenue</b>	-	-	-	-	-	-	-	-	-	-	-	-	<b>25,000</b>	<b>15,000</b>	<b>100,000</b>	<b>178,715</b>	<b>220,144</b>	<b>339,151</b>	<b>643,455</b>
Payments to Mitsubishi	-	-	-	-	-	-	-	-	-	-	-	-	2,500	1,500	10,000	19,601	45,983	113,217	232,230
R&D	550	501	485	1,589	24,638	3,097	29,809	6,000	6,000	6,000	6,000	24,000	35,000	45,000	40,000	55,000	75,000	100,000	125,000
SG&A	443	1,799	1,836	1,547	1,613	2,466	7,462	2,239	2,239	2,239	2,239	8,954	9,402	10,530	11,794	13,209	14,794	16,570	18,558
Income from Operations	(993)	(2,300)	(2,321)	(3,136)	(26,251)	(5,563)	(37,271)	(8,239)	(8,239)	(8,239)	(8,239)	(32,954)	(21,902)	(42,030)	38,206	90,904	84,366	109,364	267,666
Other Income	0	2	-	10	11	(2)	19	30	55	44	33	162	287	317	485	1,169	2,042	2,711	3,439
Other Expenses	(1)	(89)	(315)	-	(15)	(1,720)	(2,050)	(650)	(650)	(650)	(650)	(2,600)	(2,600)	(2,600)	-	-	-	-	-
Pre-Tax Income	(994)	(2,387)	(2,636)	(3,126)	(26,255)	(7,285)	(39,302)	(8,858)	(8,833)	(8,845)	(8,856)	(35,392)	(24,215)	(44,314)	38,691	92,074	86,408	112,075	271,105
Tax Expense	-	-	-	-	-	-	-	-	-	-	-	-	-	-	14,316	34,067	31,971	41,468	100,309
Tax Rate	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	37%	37%	37%	37%	37%
Net Income	(994)	(2,387)	(2,636)	(3,126)	(26,255)	(7,285)	(39,302)	(8,858)	(8,833)	(8,845)	(8,856)	(35,392)	(24,215)	(44,314)	24,376	58,006	54,437	70,608	170,796
Diluted shares outstanding	3,381	4,838	6,903	7,605	17,752	18,652	12,724	19,799	25,134	25,234	25,334	23,875	27,721	34,962	39,797	40,286	40,760	41,225	41,686
Net Loss per share	\$ (0.29)	\$ (0.49)	\$ (0.38)	\$ (0.41)	\$ (1.48)	\$ (0.39)	\$ (3.09)	\$ (0.45)	\$ (0.35)	\$ (0.35)	\$ (0.35)	\$ (1.48)	\$ (0.87)	\$ (1.27)	\$ 0.61	\$ 1.44	\$ 1.34	\$ 1.71	\$ 4.10
Options Expense	588	656	302	14,514	900	1,884	17,600	5,060	5,060	5,060	5,060	20,240	23,276	26,767	30,783	35,400	40,710	46,816	53,839
EPS with Options Expense	\$ (0.47)	\$ (0.63)	\$ (0.43)	\$ (2.32)	\$ (1.53)	\$ (0.49)	\$ (4.47)	\$ (0.70)	\$ (0.55)	\$ (0.55)	\$ (0.55)	\$ (2.33)	\$ (1.71)	\$ (2.03)	\$ (0.16)	\$ 0.56	\$ 0.34	\$ 0.58	\$ 2.81

Source: Company data, Jefferies Group LLC estimate  
March 27, 2015

## NERV: Historical and Projected Changes in Financial Position

December 31 Fiscal Year (\$000s)	2012A	2013A	2014A	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
<b>Cash flows from operating activities</b>											
Net loss	(994)	(2,387)	(38,935)	(35,392)	(24,215)	(44,314)	24,376	58,006	54,437	70,608	170,796
Adjustments to reconcile used in operating activities:											
Depreciation/Amortization	-	-	34	-	-	-	14,316	34,067	31,971	12,762	-
Amortization of debt discount recorded as interest expense	-	36	1,952	-	-	-	-	-	-	-	-
Change in fair value of derivative	-	0	(10)	-	-	-	-	-	-	-	-
Unrealized foreign exchange loss	-	20	-	-	-	-	-	-	-	-	-
Interest expense	-	23	-	-	-	-	-	-	-	-	-
Changes in operating assets and liabilities											
Accounts receivable			-	-	-	-	-	-	(11,837)	(34,002)	(86,944)
Prepaid expenses	25	(6)	(713)	-	-	-	-	-	-	-	-
Accounts payable	-	538	369	-	-	-	-	-	-	-	-
Accrued expenses and other liabilities	59	(383)	1,342	-	-	-	-	-	-	-	-
Net cash used in operating activities	(909)	(2,159)	(35,961)	(35,392)	(24,215)	(44,314)	38,691	92,074	74,571	49,368	83,852
<b>Cash flows from investing activities:</b>											
Equipment purchases	-	(3)	(46)	(10)	(20)	(20)	(20)	(20)	(20)	(20)	(20)
Cash acquired in business acquisition	-	631	1,168	-	-	-	-	-	-	-	-
Net cash provided by investing activities	-	628	1,122	(10)	(20)	(20)	(20)	(20)	(20)	(20)	(20)
<b>Cash flows from financing activities</b>											
Proceeds from issuance of convertible promissory notes	-	1,300	-	-	-	-	-	-	-	-	-
Proceeds from options exercises and warrant exercises			-	-	-	1,898	2,610	3,445	4,421	5,558	6,878
Proceeds from follow on offerings	900	1,850	55,041	28,800	37,718	54,874	-	-	-	-	-
Debt issuance/repayment				10,000		(20,000)					
Stock issuance costs	-	-	(3,440)	-	-	-	-	-	-	-	-
Net cash provided by financing activities	900	3,150	51,601	38,800	37,718	36,772	2,610	3,445	4,421	5,558	6,878
Net (decrease) increase in cash and cash equivalents	(9)	1,619	16,762	3,398	13,483	(7,561)	41,281	95,498	78,972	54,906	90,710
<b>Beginning of period</b>	<b>209</b>	<b>200</b>	<b>1,818</b>	<b>18,581</b>	<b>21,979</b>	<b>35,461</b>	<b>27,900</b>	<b>69,181</b>	<b>164,680</b>	<b>243,652</b>	<b>298,558</b>
<b>End of period</b>	<b>200</b>	<b>1,818</b>	<b>18,581</b>	<b>21,979</b>	<b>35,461</b>	<b>27,900</b>	<b>69,181</b>	<b>164,680</b>	<b>243,652</b>	<b>298,558</b>	<b>389,268</b>

Source: Company data, Jefferies Group LLC estimate  
March 27, 2015

**NERV: Historical Condensed Balance Sheets**

(000s)	12/31/2013	3/31/2013	6/30/2014	9/30/2014	12/31/2014
<b>Assets</b>					
Cash and cash equivalents	1,818	2,141	480	23,640	18,581
Prepaid expenses	1	46	33	584	757
Total current assets	1,819	2,187	513	24,224	19,338
Equipment	3	31	27	35	44
In-process research and development	19,000	34,200	34,200	34,200	34,200
Goodwill	7,918	15,104	15,104	14,869	14,869
Deferred public offering costs	434	-	3,112	-	-
Other assets	-	1,615	-	-	-
<b>Total assets</b>	<b>29,175</b>	<b>53,138</b>	<b>52,956</b>	<b>73,328</b>	<b>68,451</b>
<b>Liabilities</b>					
Accounts payable, accrued expenses, and other current liabilities	1,348	5,052	8,046	3,179	3,509
Convertible promissory notes	58	333	2,007	-	-
Total current liabilities	1,407	5,384	10,053	3,179	3,509
Deferred tax liability	7,589	13,669	13,669	13,434	13,442
<b>Total liabilities</b>	<b>8,995</b>	<b>19,053</b>	<b>23,722</b>	<b>16,613</b>	<b>16,951</b>
<b>Stockholders' equity</b>	<b>20,180</b>	<b>34,085</b>	<b>29,235</b>	<b>56,715</b>	<b>51,500</b>
<b>Total liabilities and stockholders' equity</b>	<b>29,175</b>	<b>53,138</b>	<b>52,956</b>	<b>73,328</b>	<b>68,451</b>

Source: Company Reports, Jefferies Group LLC

March 27, 2015

## Company Description

Minerva is focused on developing neuropsychiatry drugs. Minerva's lead product candidate, MIN-101, is a 5-HT<sub>2A</sub>/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-HT<sub>1A</sub> 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.

## Analyst Certification:

I, Thomas Wei, certify that all of the views expressed in this research report accurately reflect my personal views about the subject security(ies) and subject company(ies). I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views expressed in this research report.

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## Company Specific Disclosures

Rebecca Forest holds a long, equity position in DVAX.

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Jefferies Group LLC, its affiliates or subsidiaries expect to receive or intend to seek compensation for investment banking services from Minerva Neurosciences, Inc. within the next three months.

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Within the past twelve months, Minerva Neurosciences, Inc. has been a client of Jefferies LLC and investment banking services are being or have been provided.

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Buy - Describes stocks that we expect to provide a total return (price appreciation plus yield) of 15% or more within a 12-month period.

Hold - Describes stocks that we expect to provide a total return (price appreciation plus yield) of plus 15% or minus 10% within a 12-month period.

Underperform - Describes stocks that we expect to provide a total negative return (price appreciation plus yield) of 10% or more within a 12-month period.

The expected total return (price appreciation plus yield) for Buy rated stocks with an average stock price consistently below \$10 is 20% or more within a 12-month period as these companies are typically more volatile than the overall stock market. For Hold rated stocks with an average stock price consistently below \$10, the expected total return (price appreciation plus yield) is plus or minus 20% within a 12-month period. For Underperform rated stocks with an average stock price consistently below \$10, the expected total return (price appreciation plus yield) is minus 20% within a 12-month period.

NR - The investment rating and price target have been temporarily suspended. Such suspensions are in compliance with applicable regulations and/or Jefferies policies.

CS - Coverage Suspended. Jefferies has suspended coverage of this company.

NC - Not covered. Jefferies does not cover this company.

Restricted - Describes issuers where, in conjunction with Jefferies engagement in certain transactions, company policy or applicable securities regulations prohibit certain types of communications, including investment recommendations.

Monitor - Describes stocks whose company fundamentals and financials are being monitored, and for which no financial projections or opinions on the investment merits of the company are provided.

## Valuation Methodology

Jefferies' methodology for assigning ratings may include the following: market capitalization, maturity, growth/value, volatility and expected total return over the next 12 months. The price targets are based on several methodologies, which may include, but are not restricted to, analyses of market risk, growth rate, revenue stream, discounted cash flow (DCF), EBITDA, EPS, cash flow (CF), free cash flow (FCF), EV/EBITDA, P/E, PE/growth, P/CF, P/FCF, premium (discount)/average group EV/EBITDA, premium (discount)/average group P/E, sum of the parts, net asset value, dividend returns, and return on equity (ROE) over the next 12 months.

### Jefferies Franchise Picks

Jefferies Franchise Picks include stock selections from among the best stock ideas from our equity analysts over a 12 month period. Stock selection is based on fundamental analysis and may take into account other factors such as analyst conviction, differentiated analysis, a favorable risk/reward ratio and investment themes that Jefferies analysts are recommending. Jefferies Franchise Picks will include only Buy rated stocks and the number can vary depending on analyst recommendations for inclusion. Stocks will be added as new opportunities arise and removed when the reason for inclusion changes, the stock has met its desired return, if it is no longer rated Buy and/or if it triggers a stop loss. Stocks having 120 day volatility in the bottom quartile of S&P stocks will continue to have a 15% stop loss, and the remainder will have a 20% stop. Franchise Picks are not intended to represent a recommended portfolio of stocks and is not sector based, but we may note where we believe a Pick falls within an investment style such as growth or value.

## Risk which may impede the achievement of our Price Target

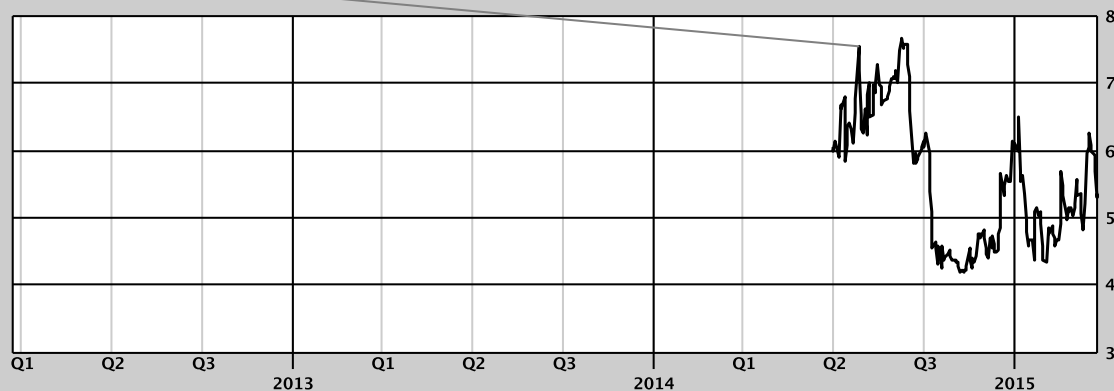
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## Other Companies Mentioned in This Report

- ACADIA Pharmaceuticals Inc. (ACAD: \$30.37, BUY)
- Dynavax Technologies Inc. (DVAX: \$22.37, BUY)
- Neurocrine Biosciences (NBIX: \$37.33, BUY)

Rating and Price Target History for: Minerva Neurosciences, Inc. (NERV) as of 03-26-2015

07/28/14  
FB:\$10

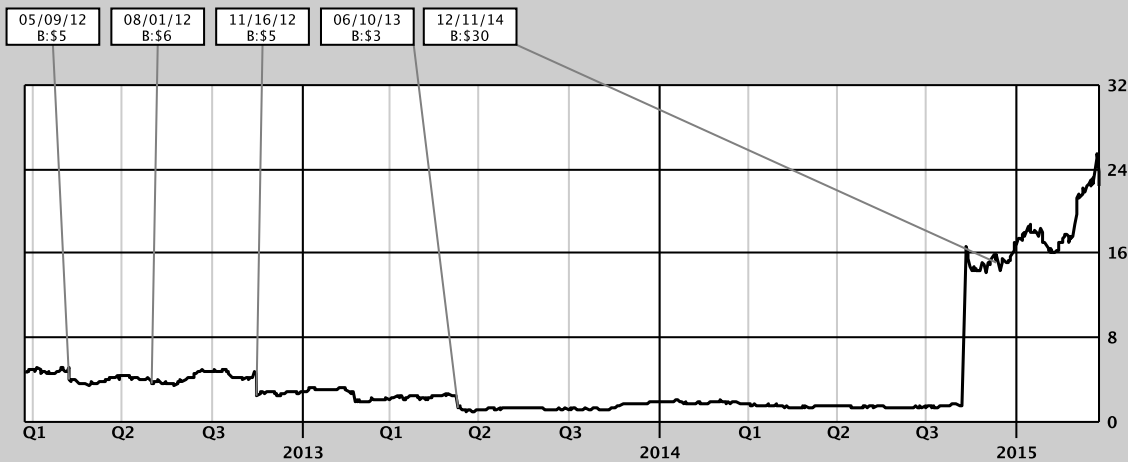




**Rating and Price Target History for: ACADIA Pharmaceuticals Inc. (ACAD) as of 03-26-2015**



**Rating and Price Target History for: Dynavax Technologies Inc. (DVAX) as of 03-26-2015**



**Rating and Price Target History for: Neurocrine Biosciences (NBIX) as of 03-26-2015**



**Distribution of Ratings**

Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY	1065	51.52%	290	27.23%
HOLD	834	40.35%	162	19.42%
UNDERPERFORM	168	8.13%	10	5.95%

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