

MediciNova, Inc.

(MNOV-NASDAQ)

MNOV: Phase 3 Trial Initiated for MN-166 in ALS

Based on our probability adjusted DCF model that takes into account potential future revenues from MN-166 in ALS, progressive MS and addiction and MN-001 in NASH and IPF, MNOV is valued at \$22/share. This model is highly dependent upon continued clinical success of both MN-166 and MN-001 and will be adjusted accordingly based upon future clinical results.

Current Price (10/30/19) **\$7.44**
Valuation **\$22.00**

OUTLOOK

MediciNova, Inc. (MNOV) has initiated a Phase 3 trial of MN-166 (ibudilast) in patients with amyotrophic lateral sclerosis (ALS). The randomized, double blind, placebo-controlled trial is anticipated to enroll approximately 230 patients with a primary outcome of mean change in the ALSFRS-R following 12 months of treatment.

The company is also preparing for a Phase 3 trial of MN-166 in patients with progressive multiple sclerosis (MS). A single Phase 3 trial is planned with a primary endpoint of time to 3-month confirmed disability progression as measured by the Expanded Disability Status Scale (EDSS), which is the same primary endpoint used to evaluate other recently approved MS therapies.

SUMMARY DATA

52-Week High **\$13.22**
52-Week Low **\$6.82**
One-Year Return (%) **-19.74**
Beta **1.25**
Average Daily Volume (sh) **104,003**

Shares Outstanding (mil) **44**
Market Capitalization (\$mil) **\$326**
Short Interest Ratio (days) **N/A**
Institutional Ownership (%) **22**
Insider Ownership (%) **15**

Annual Cash Dividend **\$0.00**
Dividend Yield (%) **0.00**

5-Yr. Historical Growth Rates
Sales (%) **N/A**
Earnings Per Share (%) **N/A**
Dividend (%) **N/A**

P/E using TTM EPS **N/A**
P/E using 2018 Estimate **N/A**
P/E using 2019 Estimate **N/A**

Risk Level **Above Avg.**
Type of Stock **Small-Growth**
Industry **Med-Biomed/Gene**

ZACKS ESTIMATES

	Revenue (In millions of \$)				
	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	0 A	0 A	0 A	0 A	0 A
2019	0 A	0 A	0 A	0 E	0 E
2020					0 E
2021					0 E

	Earnings per Share				
	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-\$0.12 A	-\$0.08 A	-\$0.16 A	-\$0.00 A	-\$0.36 A
2019	-\$0.11 A	-\$0.09 A	-\$0.05 A	-\$0.08 E	-\$0.34 E
2020					-\$0.56 E
2021					-\$0.56 E

WHAT'S NEW

Business Update

Phase 3 Trial of MN-166 in ALS Underway

In April 2019, MediciNova, Inc. (MNOV) [announced](#) that following review of the protocol the U.S. Food and Drug Administration (FDA) determined that the company may proceed with the Phase 2b/3 clinical trial of MN-166 (ibudilast) in amyotrophic lateral sclerosis (ALS). If successful, results from this trial are expected to support a New Drug Application (NDA) for MN-166 in ALS. The company officially launched the trial earlier this year and we expect updates as the trial progresses.

The Phase 2b/3 clinical trial is a multi-center, two-arm, randomized, double blind, placebo controlled trial that will compare MN-166 to placebo in approximately 230 patients with ALS ([NCT04057898](#)). Participants in the trial will be randomized 1:1 between placebo and 100 mg/day of MN-166 for 12 months of treatment. The primary endpoint of the trial is the mean change in ALS functional rating scale-revised (ALSFRS-R) ([Cedarbaum et al., 1999](#)). The ALSFRS-R consists of a series of 12 questions on basic tasks (speech, salivation, swallowing, handwriting, cutting food, dressing and hygiene, turning in bed, walking, climbing stairs, dyspnea, orthopnea, and respiratory insufficiency) that are rated on a five-point scale where 0 = can't do and 4 = normal ability. The individual items are summed to produce a score of between 0 = death and 48 = best. The ALSFRS-R score is utilized to keep track of the health of all ALS patients, and is a common outcome measure in ALS clinical trials as well as an established FDA-approvable endpoint. Secondary endpoints in the trial include the mean change from baseline in muscle strength and quality of life, time to survival, and safety and tolerability.

Important inclusion criteria include onset of ALS no more than 18 months prior to screening, the use of riluzole for at least 30 days prior to initiation of the study drug, slow vital capacity at least 70% of predicted, and an ALSFRS-R score of at least 35 at screening. Patients currently taking Radicava[®] (edaravone) or Nuedexta[®] (dextromethorphan/quinidine) may be eligible as long as they cease taking those treatments three months prior to entering the trial.

Radicava[®] Most Recently Approved ALS Treatment

Radicava (edaravone) was [approved](#) for the treatment of ALS by the FDA in May 2017. Edaravone is a potent scavenger of oxygen radicals. While the underlying mechanisms responsible for causing ALS are unknown, it is believed that oxidative stress plays some role in the development of the disease. This is supported by the fact that mutations in superoxide dismutase 1 (SOD1) cause familial ALS. SOD1 is responsible for converting superoxide radicals to oxygen and hydrogen peroxide.

In an ALS mouse model that involves a mutation in SOD1, administration of edaravone resulted in reduced motor decline and preserved motor neurons in the spinal cord ([Ito et al., 2008](#)). Similar results were seen in a rat model of ALS ([Aoki et al., 2011](#)). Based on these results, edaravone was tested in ALS patients in three different clinical trials.

Edaravone Clinical Trials

Edaravone was originally tested in a Phase 2 clinical trial involving 20 ALS patients ([Yoshino et al., 2006](#)). The study was an open-label comparison study that evaluated patients before and after treatment with edaravone. Results showed a statistically significant difference in the change in ALSFRS-R before treatment (4.7 points) compared to during the treatment period (2.3 points; $P=0.036$).

The first Phase 3 clinical trial of edaravone was conducted in 205 patients randomized to receive edaravone (n=101) or placebo (n=104) ([Abe et al., 2014](#)). Treatment consisted of intravenous infusions given over 60 min for the first 14 days of cycle 1 (followed by 14 days off drug), and then 10 of the first 14 days during cycles two through six, with 14 days off drug following treatment in each cycle. The primary endpoint was the change in ALSFRS-R during the 24-week treatment period. Results showed that the change in ALSFRS-R scores were -5.70 and -6.35 in the edaravone and placebo groups, respectively, which did not represent a statistically significant difference ($P=0.411$). No serious adverse events were reported and the level and frequency of adverse events were similar between the two treatment groups. A post-hoc analysis suggested that edaravone could be efficacious in a

restricted subgroup that includes recently diagnosed patients with milder disease symptoms.

Based on the post-hoc analysis, a second Phase 3 clinical trial was conducted that was restricted to patients with a disease duration of <2 years and independent activity of daily living (Tanaka *et al.*, 2015). A total of 134 patients were randomized to receive edaravone (n=68) or placebo (n=66) for six months, with treatment given the same as in the first Phase 3 clinical trial. The change in ALSFRS-R score from baseline at six months was -5.01 in the edaravone group and -7.50 in the placebo group (P=0.001). Once again, adverse events were similar between the edaravone and the placebo groups.

Positive Results from Phase 2 Trial of MN-166 in ALS

MediciNova previously studied MN-166 in a Phase 2 trial in ALS. This was a single center, double blind, placebo controlled six-month study with patients randomized 2:1 to receive riluzole (100 mg/day) plus either MN-166 (60 mg/day) or placebo. The six-month double blind portion was followed by a six-month open label extension phase during which all patients received MN-166. The intent-to-treat (ITT) population consisted of 51 patients who were randomized to placebo (n=17) or MN-166 (n=34) for the double-blind portion of the study. The per protocol (PP) population consisted of 44 patients that completed the double-blind portion of the study (n=15 for placebo; n=29 for MN-166) and 35 patients that completed the open label extension (n=12 for placebo; n= 23 for MN-166). The results shown below were presented at the 28th International Symposium on ALS/MND in Dec. 2017.

Since this was the first time MN-166 was tested in ALS patients the primary outcome of the study was safety and tolerability of the drug when administered along with riluzole (100 mg/day), the standard of care for ALS patients. The study achieved the primary outcome with no serious or life-threatening treatment-related adverse events (TRAEs). There were six subjects that had a total of seven serious adverse events (five for MN-166 group and one for placebo group), however none of them were related to treatment.

	# of Subjects or # of Events	
	Placebo N=17	Ibutilast N=34
# of Subject with at Least one TRAEs	n= 3	n= 4
Total events # of TRAEs	5	8
Severe or Life-threatening TRAEs	0	0
Serious TRAEs	0	0
	# of Subjects	
	Placebo N = 17	Ibutilast N = 34
At Least one TEAEs	n = 17	n = 34
Severe or Life threatening TEAEs	n = 2	n = 4
Serious Adverse Events	n = 1	n = 5
Treatment Related Adverse Events	n = 10	n = 13

Source: Brooks *et al.*, 2017

In addition to the primary endpoint of safety and tolerability, the study also evaluated secondary efficacy endpoints. These secondary endpoints, which included an analysis of ALSFRS-R, were not powered for statistical significance but were evaluated to look for positive trends that could help guide the design of future clinical trials. For this study, a responder was defined as someone who had a ≤1 point decline in the ALSFRS-R during the six-month double blind period while a non-responder was defined as someone who had >1 point decline in ALSFRS-R. For the ITT population, the following table shows that 29.4% (10/34) of MN-166-treated patients were responders, compared to 17.6% (3/17) of placebo-treated patients. The third and fourth columns in the table show the percentage of patients who were responders in the open-label six-month extension phase during which all patients received MN-166. In the open-label extension, 35.3% (6/17) of the patients who had received placebo during the double blind portion of the study were responders when taking MN-166. This compares quite favorably with the 29.4% of patients who were responders with MN-166 during the double blind portion of the study.

Double-Blind Phase		Open Label Phase		Overall
Placebo	Ibudilast	Ibudilast 0-6 mon treatment	Ibudilast 6-12 mon treatment	Ibudilast 0-12 mon treatment combined
(N = 17)	(N = 34)	(N = 17)	(N = 34)	(N = 51)
3 / 17 (17.6 %)	10 / 34 (29.4 %)	6 / 17 (35.3 %)	3 * / 34 (8.8 %)	19 * / 51 (37.3 %)

Source: Brooks et al., 2017

For the PP population, the following table shows that 34.5% (10/29) of MN-166-treated patients were responders, compared to 20.0% (3/15) of placebo-treated patients. Again, the open-label extension results showing 50.0% (6/12) of patients who had received placebo during the double blind portion of the study were responders when taking MN-166 compared well with the 34.5% of patients that were responders when taking MN-166 in the double blind portion of the study.

Double-Blind Phase		Open Label Phase		Overall
Placebo	Ibudilast	Ibudilast 0-6 mon treatment	Ibudilast 6-12 mon treatment	Ibudilast 0-12 mon treatment combined
(N = 15)	(N = 29)	(N = 12)	(N = 23)	(N = 35)
3 / 15 (20.0 %)	10 / 29 (34.5 %)	6 / 12 (50.0 %)	3 * / 23 (13.0 %)	19 * / 35 (54.3 %)

Source: Brooks et al., 2017

We believe these results show that MN-166 was having a positive effect on ALSFRS-R and that this effect is likely to increase in the Phase 3 trial, as the company will be testing a 100 mg/day dose, compared to the 60 mg/day dose that was utilized in the Phase 2 trial.

Planning for a Phase 3 Trial in Progressive Multiple Sclerosis

In July 2019, MediciNova [announced](#) plans for a Phase 3 clinical trial for MN-166 (ibudilast) in progressive multiple sclerosis (MS) following feedback received from the U.S. Food and Drug Administration (FDA). The company is planning to conduct a single Phase 3 trial in patients with secondary progressive MS (SPMS) without relapses with the primary endpoint being the time to 3-month confirmed disability progression as measured by Expanded Disability Status Scale (EDSS). The EDSS is the 'gold standard' for assessing disability progression in patients with MS ([Kurtzke, 1983](#)). The EDSS consists of 19 disease steps on a scale between 0 and 10 and measures impairment or activity limitation in eight functional systems along with ambulation. The most commonly used method for determining disability progression is through repeat measurements of EDSS.

We believe there is ample justification for the company's decisions for each of the three main points of the trial:

- 1) **A single Phase 3 trial to support a regulatory filing for MN-166 in SPMS.** The FDA has recently approved two new therapies for the treatment of relapsing forms of MS (including RRMS and relapsing SPMS) and SPMS with relapses. Mayzent® (siponimod) was approved for SPMS with relapses based on the results of the EXPAND Phase 3 clinical trial ([Kappos et al., 2018](#)). Mavenclad® (cladribine) was approved for relapsing forms of MS based on the results of a 2010 Phase 3 clinical trial ([Giovannoni et al., 2010](#)). Thus, we believe that positive results from a single Phase 3 trial will suffice to support an NDA for MN-166 in SPMS patients without relapses.

- 2) **Focusing on SPMS patients without relapse.** In April 2019, MediciNova [announced](#) the results of a subgroup analysis of the Phase 2b SPRINT-MS trial of MN-166 in patients with progressive MS. The subgroup analysis was done to better understand which type of progressive MS responds best to treatment with MN-166 in regards to confirmed disability progression as measured by EDSS. The following table shows that the greatest treatment effect for MN-166 occurred in patients with SPMS without relapse, as demonstrated by a 46% risk reduction and a hazard ratio of 0.538.

Subgroup	# subjects		Hazard Ratio	Risk Reduction
	MN-166	Placebo		
PPMS	68	66	0.707	29%
SPMS with relapse	9	6	1.153	-15%
SPMS without relapse	52	54	0.538	46%

Source : MediciNova, Zacks SCR

There are only three drugs currently approved for the treatment of progressive MS. Ocrevus® is only approved for PPMS while Mayzent® and Mavenclad® are approved for both RRMS and SPMS with relapse, while no medications are currently approved for the treatment of SPMS without relapses.

- 3) **Primary endpoint will be the time to 3-month confirmed disability progression as measured by EDSS.** The primary endpoints in the Phase 3 clinical trials for Mayzent® and Ocrevus® was the time to 3-month confirmed disability progression as measured by EDSS. The Phase 3 trial for Mavenclad® used that endpoint as a secondary outcome. Based upon this, the FDA agreed that it was an acceptable primary endpoint for a Phase 3 trial of MN-166 in SPMS patients without relapse.

How MN-166 Compares to Other Progressive MS Treatments

We believe that the data presented thus far for MN-166 from the Phase 2b clinical trial compare quite favorably to the data presented for both ocrelizumab and siponimod, potentially making MN-166 a best in disease treatment for patients with both primary and secondary MS, as shown in the following table. Treatment with MN-166 results in a 46% reduction in disability progression in SPMS patients without relapse, compared to siponimod's study which showed only a 13% reduction in disability progression in SPMS patients without relapse (and a 21% reduction for all SPMS subjects) in those treated with siponimod (Mayzent® prescribing information). The weak trend shown by siponimod in SPMS patients without relapse is the reason the FDA limited its approved indication to relapsing SPMS.

Drug	Type of Progressive MS	Route of Administration	Phase / Study Size	Reduction in Brain Atrophy after 2 Years	Reduction in Disability Progression
ocrelizumab	PPMS	intravenous infusion	Phase 3 n=732	17.5%	24%
siponimod	SPMS	oral	Phase 3 n=1651	15%	21%
MN-166	PPMS and SPMS	oral	Phase 2b n=255	48%	PPMS: 29% SPMS without Relapse: 46%

Source: MediciNova, Inc.

In addition to exhibiting better efficacy than already approved products, MN-166 had a very favorable safety and tolerability profile as shown by no increases in serious adverse events and no safety signals. In contrast to the excellent safety profile for MN-166, treatment with ocrelizumab resulted in an increase in malignancies, serious infusion reactions, and infections, while treatment with siponimod increased infections, bradyarrhythmias, macular edema, respiratory effects, liver injury, increased blood pressure, and fetal risk. We don't believe that Mavenclad® will ever command more than 1-2% of the total market for SPMS with relapses due to a black box warning about an increased risk of malignancies.

Drug	Safety Issues	Most Common Adverse Reactions
ocrelizumab (OCREVUS)	<ul style="list-style-type: none"> • malignancies including breast cancer • serious infusion reactions • Infections 	<ul style="list-style-type: none"> • upper respiratory tract infections • infusion reactions • skin infections • lower respiratory tract infections
siponimod (MAYZENT)*	<ul style="list-style-type: none"> • infections • macular edema • bradyarrhythmia • respiratory effects • liver injury • increased blood pressure • fetal risk 	<ul style="list-style-type: none"> • headache • hypertension • transaminase increased • falls • edema peripheral
MN-166	• None	• gastrointestinal side effects

Source: MedicNova, Inc.

How Large is the SPMS Without Relapse Market?

Three recent papers in the journal *Neurology* attempted to accurately estimate the prevalence of MS in the U.S. (Nelson *et al.*, 2019; Culpepper *et al.*, 2019; Wallin *et al.*, 2019). The methodology described in those papers resulted in an estimate of approximately 700,000 individuals in the U.S. with MS. Up until then, most estimates of the number of individuals in the U.S. with MS suggested there were approximately 300,000 to 400,000 (Dilokthornsakul *et al.*, 2016). While the new, larger estimate is certainly interesting, we will continue to use what we view as a more conservative estimate of 400,000 MS patients in the U.S., which we believe is supported by total sales of MS drugs (discussed below).

Of the patients diagnosed with MS, approximately 85% will be initially diagnosed with RRMS while approximately 15% will be diagnosed with primary progressive MS (PPMS). Of those diagnosed with RRMS, we estimate that at least 50% of them will go on to develop SPMS, although over a longer period of time (20+ years) that number may be much higher. Of those with SPMS, we estimate that approximately 20% will have relapses (based on a 19% rate of relapse in placebo patients in the Mayzent® Phase 3 clinical trial). Based on a total of 400,000 MS patients in the US, this represents a potential market of >130,000 patients with SPMS without relapse.

According to EvaluatePharma, the MS market was approximately \$23 billion in 2018. The following table shows the leading MS drugs according to 2018 worldwide sales. Tecfidera® was the highest-grossing MS drug in 2018 with approximately \$4.3 billion in sales out of a total of 18 drugs available to treat those with RRMS. While there are a large number of drugs available for patients with RRMS, as previously mentioned there are only three drugs currently approved for treating progressive MS: Ocrevus® (only approved for PPMS), Mayzent® (approved for RRMS and SPMS with relapse), and Mavenclad® (approved for RRMS and SPMS with relapse), and none that are approved for treating SPMS without relapses.

Company	Product	Indication	WW 2018 Sales (Millions)
Biogen	Tecfidera	RRMS	\$4,274
Novartis	Gilenya	RRMS	\$3,341
Roche	Ocrevus	RRMS/PPMS	\$2,406
Teva	Copaxone	RRMS	\$2,366
Sanofi	Aubagio	RRMS	\$1,945
Biogen	Avonex	RRMS	\$1,915
Biogen	Tysabri	RRMS	\$1,864
Merck KGaA	Rebif	RRMS	\$1,699
Bayer	Betaseron	RRMS	\$643
OTHER			\$2,616
TOTAL			\$23,069

Source: EvaluatePharma

Patent Updates

In 2019, MediciNova has received additional intellectual property coverage for MN-001 (tipelukast) for the treatment of fibrosis and fibrotic diseases, lipid disorders, idiopathic pulmonary fibrosis (IPF), nonalcoholic fatty liver disease (NAFLD), and nonalcoholic steatohepatitis (NASH) along with additional patent protection for MN-166 for glioblastoma, ALS, and other neurodegenerative diseases:

- On Jan. 7, 2019, the company **received** a notice of allowance from the Japan Patent Office for a pending patent application that covers MN-001 and MN-002 (a major metabolite of MN-001) for the treatment of fibrosis which includes a broad range of fibrotic diseases. The patent is expected to have an expiration date no earlier than June 2035.
- On Jan. 21, 2019, the company **received** a notice of allowance from the U.S. Patent and Trademark Office for a pending patent application that covers the combination of MN-166 and riluzole for the treatment of ALS and a wide range of other neurodegenerative diseases including Alzheimer's disease, Parkinson's disease, multiple sclerosis, Huntington's disease, Lewy body disease, motor neuron disease, spinal muscular atrophy, myelopathy, traumatic brain injury, spinal cord injury, and many others. The patent is expected to have an expiration date no earlier than November 2035.
- On April 3, 2019, the company **received** a notice of allowance from the Chinese Patent Office for a pending patent application that covers MN-001 for the treatment of hypertriglyceridemia, hypercholesterolemia, and hyperlipoproteinemia. The patent is expected to have an expiration date no earlier than July 2034.
- On April 23, 2019, the company **received** a notice of allowance from the U.S. Patent and Trademark Office for a pending patent application that covers MN-166 for the treatment of glioblastoma. The patent is expected to expire no earlier than December 2037.
- On Sep. 30, 2019, the company **received** a notice of allowance from the Chinese Patent Office for a pending patent application that covers MN-001 for the treatment of IPF. The patent is expected to have an expiration date no earlier than May 2035.
- On Oct. 7, 2019, the company **received** a notice of allowance from the Japan Patent Office for a pending patent application that covers MN-001 and MN-002 (a major metabolite of MN-001) for the treatment of IPF. The patent is expected to have an expiration date no earlier than May 2035.
- On Oct. 23, 2019, the company **received** a notice of allowance from the Japan Patent Office for a pending patent application that covers MN-001 for the treatment of NAFLD and NASH. The patent is expected to have an expiration data no earlier than December 2032.
- On Oct. 28, 2019, the company **received** a notice of allowance from the Canadian Intellectual Property Office for a pending patent application that covers MN-166 for the treatment of ALS. The patent is expected to expire no earlier than July 2028.

Financial Update

On October 25, 2019, MediciNova filed form 10-Q with financial results for the third quarter of 2019. As expected, the company did not report any revenues for the third quarter of 2019. Net loss for the third quarter of 2019 was \$2.4 million, or \$0.05 per share, compared to a net loss of \$6.8 million, or \$0.16 per share, in the third quarter of 2018. R&D expenses for the third quarter of 2019 were \$1.2 million compared to \$2.4 million in the third quarter of 2018. The decrease was due to lower stock-based compensation. G&A expenses in the third quarter of 2019 were \$1.5 million compared to \$4.7 million in the third quarter of 2018. The decrease was primarily due to lower stock-based compensation.

Total operating cash burn for the third quarter of 2019 was approximately \$2.0 million and the company exited the third quarter of 2019 with approximately \$62.9 million in cash and cash equivalents. As of Oct. 23, 2019, the company had approximately 43.8 million shares outstanding and when factoring in the approximately 6.8 million stock options a fully diluted share count of approximately 50.6 million.

Valuation and Conclusion

The treatment of ALS is a potential blockbuster opportunity. With only two drugs approved to treat the disease there is a huge unmet medical need for better treatment options. Given the limited therapeutic options and high costs associated with patient care, if shown to be safer or more effective than the existing drugs, we believe MN-166 would command a premium price, which is supported by the yearly list price of \$145,000 for Radicava®. We estimate this could lead to worldwide sales of approximately \$2 billion annually for MN-166 for ALS.

For MS, we believe Tecfidera®, with sales of \$4.3 billion in 2018, is a good example of the type of revenues that a safe and successful MS drug can generate (and that is in a very crowded market with 18 approved drugs for RRMS), thus we estimate for \$5 billion in peak worldwide sales for MN-166 for SPMS without relapse.

Our valuation for MediciNova is \$22 per share, and investors could use the recent weakness in the stock price as an opportunity to initiate or add to a position ahead of full patient enrollment in the ALS Phase 3 trial and initiation of the progressive MS Phase 3 trial.

PROJECTED FINANCIALS

MediciNova Inc. Income Statement

MediciNova, Inc.	2018 A	Q1 A	Q2 A	Q3 A	Q4 E	2019 E	2020 E	2021 E
MN-166 (Multiple Sclerosis)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
MN-166 (ALS)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
MN-166 (Addiction)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
MN-001 (NASH)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
MN-001 (IPF)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Grants & Collaborative Revenue	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Total Revenues	\$0							
Cost of Sales	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
<i>Product Gross Margin</i>	-	-	-	-	-	-	-	-
Research & Development	\$5.626	\$1.634	\$1.466	\$1.151	\$1.800	\$6.050	\$15.500	\$17.000
General & Administrative	\$9.961	\$3.345	\$2.717	\$1.495	\$2.000	\$9.557	\$11.000	\$11.500
Other Expenses	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Operating Income	(\$15.6)	(\$5.0)	(\$4.2)	(\$2.6)	(\$3.8)	(\$15.6)	(\$26.5)	(\$28.5)
<i>Operating Margin</i>	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	\$0.9	\$0.3	\$0.3	\$0.3	\$0.1	\$0.9	\$0.4	\$0.4
Pre-Tax Income	(\$14.7)	(\$4.7)	(\$3.9)	(\$2.4)	(\$3.7)	(\$14.7)	(\$26.1)	(\$28.1)
Income Taxes Paid	(\$0)	\$0	\$0	\$0	(\$0)	\$0	\$0	\$0
<i>Tax Rate</i>	0%	0%	0%	0%	0%	0%	0%	0%
Net Income	(\$14.7)	(\$4.7)	(\$3.9)	(\$2.4)	(\$3.7)	(\$14.7)	(\$26.1)	(\$28.1)
<i>Net Margin</i>	-	-	-	-	-	-	-	-
Reported EPS	(\$0.36)	(\$0.11)	(\$0.09)	(\$0.05)	(\$0.08)	(\$0.34)	(\$0.56)	(\$0.56)
<i>YOY Growth</i>	-	-	-	-	-	-	-	-
Basic Shares Outstanding	41.125	42.468	43.069	43.343	44.000	43.220	47.000	50.000

Source: Zacks Investment Research, Inc.

David Bautz, PhD

HISTORICAL STOCK PRICE



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