Zacks Small-Cap Research

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Viking Therapeutics, Inc. (VKTX-NASDAQ)

VKTX: Phase 2 Study of VK5211 for Hip Fracture Ongoing; Phase 2 Study of VK2809 for Hypercholersterolemia to Commence in mid-2016…

Based on our probability adjusted DCF model that takes into account potential future revenues of VK5211, VK2809, and VK0214, VKTX is valued at $8/share. This model is highly dependent upon continued clinical success of those compounds and will be adjusted accordingly based upon future clinical results.

Current Price (05/16/16)	$1.18
Valuation	**$8.00**

OUTLOOK

On May 10, 2016, Viking Therapeutics, Inc. announced financial results for the first quarter of 2016 and provided a business update. The company exited the first quarter with approximately $11.3 million. Subsequent to the end of the quarter, Viking raised gross proceeds of approximately $10.8 million. We believe Viking has sufficient capital to fund operations for at least the next 12 months.

The Phase 2 clinical trial of VK5211 for hip fracture is ongoing, with all 16 clinical sites in the U.S. expected to be open and enrolling patients by the end of the second quarter of 2016. In addition, the company is expected to initiate a clinical trial of VK2809 for hypercholesterolemia in mid-2016.

SUMMARY DATA

52-Week High	**$9.35**
52-Week Low	**$1.06**
One-Year Return (%)	**-87.47**
Beta	**N/A**
Average Daily Volume (sh)	**472,268**
Shares Outstanding (mil)	**19**
Market Capitalization ($mil)	**$23**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**20**
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 2016 Estimate	**-0.9**
P/E using 2017 Estimate	**-1.1**

Risk Level	**High,**
Type of Stock	**Small-Blend**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	0 A	0 A	0 A	0 A	0 A
2016	0 A	0 E	0 E	0 E	0 E
2017					0 E
2018					0 E

Earnings per Share
(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015	-$1.40 A	- $1.07 A	-$0.53 A	-$0.57 A	-$3.68 A
2016	-$0.40 A	-$0.27 E	-$0.28 E	-$0.24 E	-$1.12 E
2017					-$0.89 E
2018					-$0.93 E

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WHAT'S NEW

Business Update

VK5211 Update

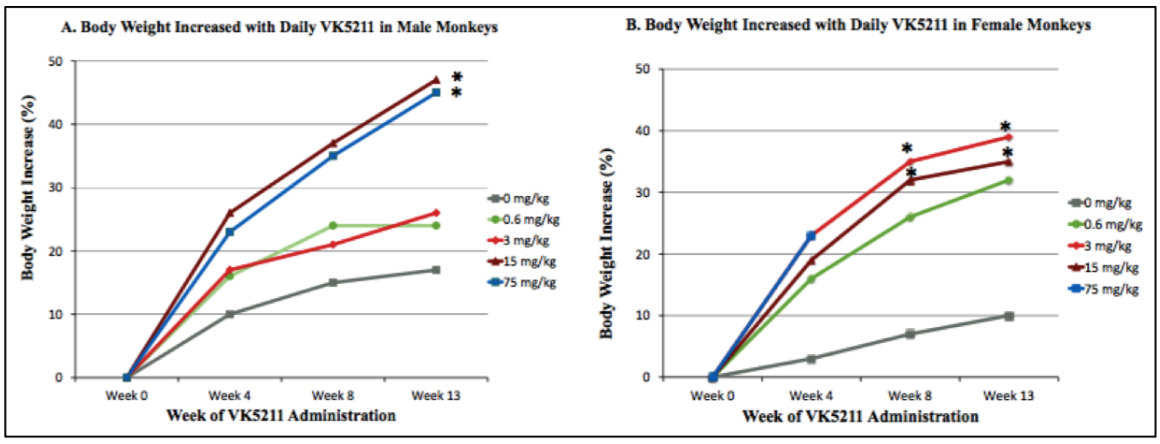
Viking's lead drug candidate is VK5211, a third-generation non-steroidal Selective Androgen Receptor Modulator (SARM) that is being developed for maintenance or improvement of lean body mass (LBM), bone mineral density (BMD), and function in patients recovering from non-elective hip fracture surgery. Hip fracture is associated with a number of morbidities, the majority of which are the result of deleterious changes in body composition following the injury. In the first year after a hip fracture, fat mass increases by up to 7% (Karlsson *et al*., 1996) while lean mass decreases by up to 11% (Fox *et al*., 2000). This is in comparison to healthy older females who lose approximately 1% of lean mass per year and gain approximately 1.7% in fat mass (Karlsson *et al*., 2000).

SARMs are a group of compounds designed to act as androgen receptor (AR) agonists in muscle and bone while being partial agonists in other areas of the body (e.g., prostate). The most prominent androgen, testosterone, stimulates the growth of muscle and bone (anabolic effects) as well as the prostate and sebaceous glands (androgenic effects), and is considered a non-tissue-selective androgen.

While androgens inhibit fat accumulation and increase skeletal muscle growth, two properties that make them ideal therapeutic candidates for restoring or preserving body composition following hip fracture, the use of testosterone therapy has a number of side effects including prostate growth (Meikle *et al*., 1997) and polycythemia (Snyder *et al*., 2000) in men and acne, alopecia, and hirsutism in women (Phillips *et al*., 1997) that precludes its use in a large number of patients. Thus, what would be most beneficial would be a product that provided the anabolic effects of androgen therapy with limited androgenic effects.

VK5211 (then known as LGD-4033) was originally developed by Ligand Pharmaceuticals, Inc. (LGND) and was previously tested in preclinical models and early stage clinical trials. Two Phase 1 clinical trials showed the drug to be safe and well-tolerated at all doses following daily oral administration for up to 21 days. The drug selectively activates AR in muscle and bone, stimulating muscle and bone growth, while avoiding undesirable side effects, such as unwanted hair growth, acne, or prostate growth.

To examine the safety and physiological changes that occur after 13 weeks of VK5211 dosing, cynomolgus monkeys were orally administered VK5211 once daily at 0, 0.6, 3, 15, or 75 mg/kg. The following figure shows a significant increase in body weight in both male and female monkeys during the 13 weeks of dosing. The fact that the results were seen in females is important, as the majority of hip fractures occur in females.



Source: Bleavins *et al*., 2015

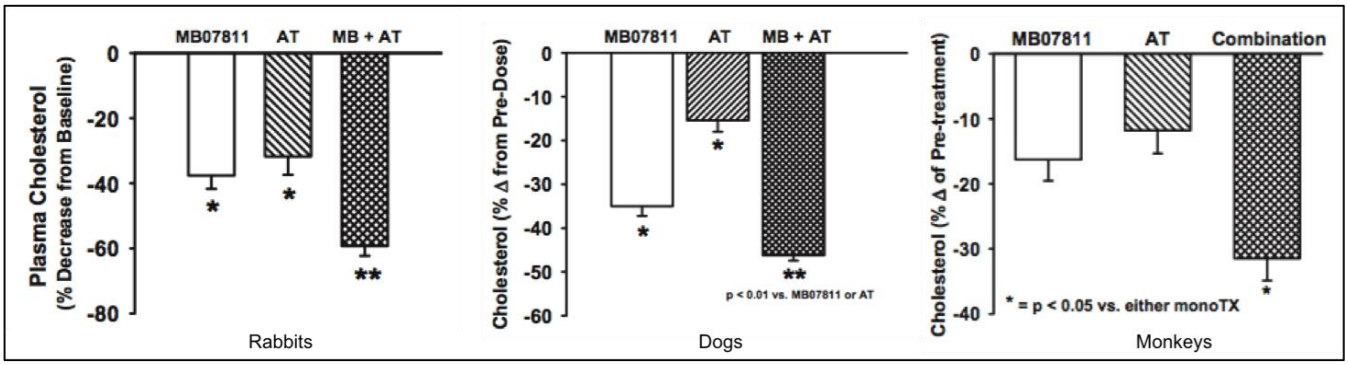
In November 2015, Viking initiated a Phase 2 study in patients ≥ 65 years of age who have suffered a hip fracture within the past three to seven weeks. This is a multicenter, randomized, parallel group, double blind, placebo controlled trial, where patients will be administered placebo or 0.5 mg, 1.0 mg, or 2.0 mg of VK5211 once-daily for 12 weeks (NCT02578095). A total of 120 patients are expected to enroll in the trial evenly split between the four

treatment groups. The primary outcome of the trial is the change in LBM after 12 weeks of treatment. Secondary and exploratory endpoints include assessments of functional performance, quality-of-life, and activities of daily living. All 16 clinical sites in the U.S. are expected to be open and enrolling patients by the end of the second quarter of 2016, and an additional 15 centers will opening in Europe in 2016.

VK2809 Update

VK2809 is a novel, orally available, selective thyroid hormone receptor (TR) agonist that is in development for lipid disorders such as hypercholesterolemia and fatty liver disease. It was originally developed by Metabasis Therapeutics, Inc., which was acquired by Ligand in 2009. The compound has been tested in multiple preclinical models as well as two Phase 1 clinical trials.

There are two major isoforms of TR, TRα and TRβ, which are encoded by separate genes. TRα and TRβ also have markedly different expression patterns, with TRα expression highest in the heart and brain while TRβ expression is highest in the liver (Bookout *et al*., 2006). VK2809 is a prodrug of a potent TRβ agonist that is converted to the active compound through cleavage by the liver specific cytochrome P450 isoenzyme CYP3A4 (Erion *et al*., 2007). The activated form of the drug has approximately 16-fold higher affinity for TRβ (Ki = 2.2 nM) than for TRα (Ki = 35.2 nM). The cholesterol lowering properties of VK2809 were exhibited in multiple studies in rabbits, dogs, and monkeys (Ito *et al*., 2009). The following figures show that VK2809 (MB07811) was at least as effective in lowering plasma cholesterol as atorvastatin (Lipitor®) in all three species, and an additive effect exists with the combination of VK2809 and atorvastatin.



Adapted from: Ito *et al*., 2009

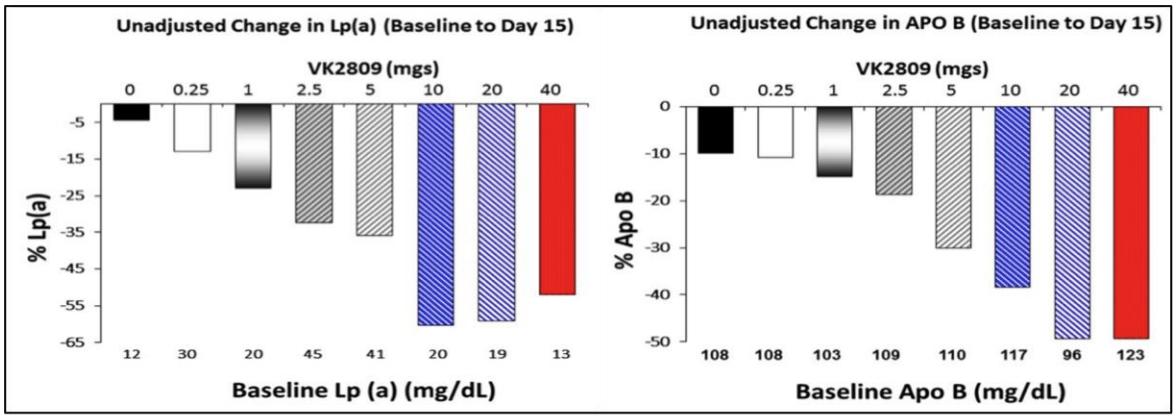
On April 8, 2016, Viking presented positive Phase 1b clinical data for VK2809 in patients with hypercholesterolemia in a poster session at the 65th Annual Scientific Session and Expo of the American College of Cardiology. The Phase 1b trial was a 14-day, placebo controlled trial in patients with mild hypercholesterolemia (defined as baseline LDL cholesterol of at least 100 mg/dL). VK2809 was shown to be safe and well tolerated in doses ranging from 0.25 mg to 40 mg per day. No serious adverse events were reported and the frequency of adverse events in VK2809-treated subjects was similar to placebo-treated subjects. There were also no differences in heart rate, heart rhythm, or blood pressure between VK2809 and placebo-treated patients.

Results from the trial showed that treatment with VK2809 resulted in statistically significant placebo-adjusted reductions in low-density lipoprotein (LDL) cholesterol of 15.2% at the 5 mg dose to 41.2% at the 20 mg dose ($p<0.05$ for both doses). In addition, decreases in triglycerides of as much as 78.6% were seen at the 40 mg dose. The following table summarizes the placebo-adjusted percentage decreases in LDL cholesterol, triglycerides, total cholesterol, high-density lipoprotein (HDL) cholesterol, and non-HDL cholesterol.

Dose	Placebo-Adjusted LSM (SE)				
	LDL-C	Triglyceride	TC	HDL-C	Non-HDL-C
0.25 mg (N=6)	10.5 (6.6)	-9.6 (17.5)	4.0 (4.9)	2.3 (7.0)	6.0 (7.1)
1 mg (N=6)	-9.2 (6.6)	9.7 (17.1)	-2.4 (5.0)	-2.2 (6.9)	-2.6 (7.1)
2.5 mg (N=6)	-0.7 (6.6)	-36.6 (17.3)	-1.1 (4.9)	11.2 (6.9)	-4.5 (7.0)
5 mg (N=6)	-15.2 (6.6)	-34.8 (17.4)	-15.7 (4.9)	-4.1 (6.9)	-19.9 (7.0)
10 mg (N=5)	-27.1 (7.0)	-61.0 (18.5)	-24.2 (5.4)	-3.0 (7.5)	-32.0 (7.5)
20 mg (N=6)	-41.2 (6.6)	-62.1 (17.2)	-29.8 (5.0)	16.5 (6.9)	-44.2 (7.1)
40 mg (N=5)	-36.6 (7.0)	-78.6 (18.7)	-32.1 (5.3)	-2.7 (7.3)	-42.2 (7.5)

Source: Lian *et al.*, 2016

In addition to the results shown above, statistically significant reductions of lipoprotein a (Lp(a)) and apolipoprotein B (Apo(B)), which are believed to be positively associated with a patient's risk of developing cardiovascular disease, were observed in certain cohorts as shown in the following figure.



Source: Lian *et al.*, 2016

Lastly, the table below gives a comparison of the Phase 1b efficacy results of VK2809 and data from existing hyperlipidemia treatments.

Drug	Class	LDL-C[1]	Triglycerides	Lp(a)	Apo-B	Safety, Tolerability, Other
VK2809, 10 mg	**TR-β**	**-27**	**-61**	**-55**	**-29**	**Expect safe, additive efficacy with statins; efficacy in statin-intolerant**
Niacin, 1500 mg	Nicotinic acid	-13	-25	-17	-13	Flushing, increased plasma glucose, liver toxicity, skeletal muscle toxicity
Ezetimibe, 10 mg	Cholesterol absorption inhibitor	-19	-8	-10	-14	Modest efficacy
Colesevelam, 3.8 g	Bile acid sequestrant	-15	+5	-	-12	Modest efficacy, gastrointestinal tolerability
Atorvastatin 20 mg	Statin	-47	-36	-	-38	Skeletal muscle toxicity/pain, potential elevation in diabetes risk
Fenofibrate, 145 mg	Fibrate	-18	-36	-	-28	Gallstones, risk of kidney dysfunction, skeletal muscle toxicity

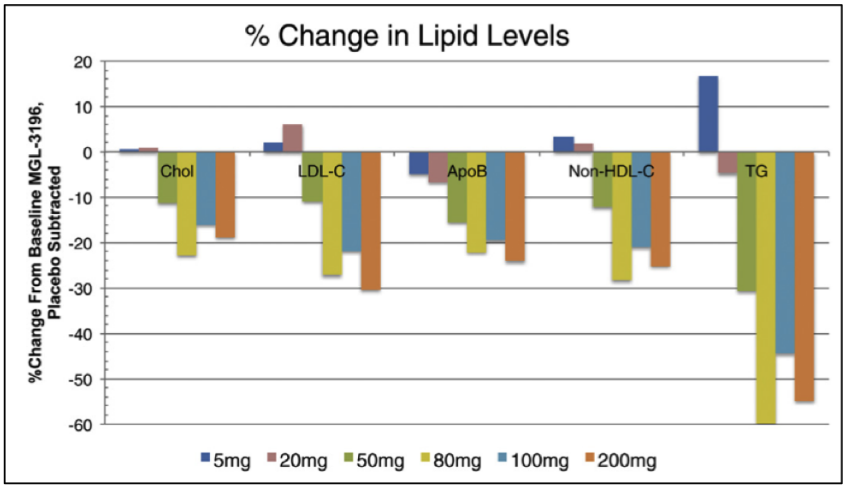
Source: Viking Therapeutics, Inc.

VK2809 Clinical Development Plan

The preceding data is the basis for Viking to conduct a Phase 2 trial to evaluate VK2809 as a treatment for both hypercholesterolemia and fatty liver disease. The company is planning to target patients with elevated cholesterol, fatty liver disease, and at least three risk factors for metabolic syndrome, which is considered a major driver for the onset of nonalcoholic steatohepatitis (NASH). The primary endpoint will assess changes in LDL, with exploratory endpoints evaluating changes in liver fat content, inflammatory markers, and histological changes. Upon conclusion, the company hopes to be in a position to move forward in either hypercholesterolemia or NASH. Thus, it could be viewed as a two-in-one study – confirmatory on LDL and exploratory for fatty liver disease. We anticipate the study initiating in mid-2016.

Synta Merger with Madrigal Shows Viking is Significantly Undervalued

On April 14, 2016, Synta Pharmaceuticals Corp. (SNTA) announced a merger agreement with Madrigal Pharmaceuticals, Inc., a privately held company developing treatments for metabolic and cardiovascular diseases. Madrigal's lead compound, MGL-3196, is a TRβ agonist similar to VK2809. A 2013 publication reported results from a Phase 1b study of MGL-3196 in patients with mildly elevated LDL cholesterol (>110 mg/dl) (Taub *et al*., 2013). The multi-dose study took place over two weeks and was a randomized, double blind, placebo controlled trial to examine the safety and tolerability of various doses of MGL-3196 along with the effect on lipid levels. As shown in the following figure, MGL-1396 does appear to be effective at decreasing LDL, ApoB, and triglycerides.



Source: Taub *et al*., 2013

However, when taking a closer look at some of the lipid values, it appears that MGL-1396 may not be as effective as VK2809. For triglycerides, of the six cohorts tested with MGL-3196, only one of them was statistically significantly different from the placebo cohort. In comparison, VK2809 was statistically significantly different from placebo in multiple cohorts for triglycerides. In addition, treatment with MGL-3196 resulted in decreases in Lp(a) of between +2.7% to -20%, compared to decreases in Lp(a) from treatment with VK2809 of -15% to -60%. Lastly, treatment with MGL-3196 resulted in decreases in ApoB of -4.9% to -24%, compared to decreases in ApoB from treatment with VK2809 of -10% to -50%. As mentioned earlier, reductions in both Lp(a) and ApoB are associated with increased cardiovascular health, thus the data so far would indicate that VK2809 is superior to MGL-1396 in this regard.

Even with a potentially superior TRβ agonist compound, the valuation for Viking in comparison to Madrigal does not reflect this fact. Following the recent public offering, Viking has approximately 19.3 million common shares outstanding. The stock has recently traded near $1.25, putting the company's valuation at approximately $24 million. Following the merger with Synta, Madrigal will have approximately 392 million shares outstanding. Synta's stock recently traded at $0.40, which would give Madrigal a valuation of approximately $157 million, almost six times as much as Viking! MGL-3196 has not yet entered a Phase 2 clinical trial, thus it is at the same development stage as VK2809. In addition, Viking has VK5211, which is currently in a Phase 2 clinical trial for the prevention of loss of lean body mass following hip fracture in elderly patients. Thus, based upon the valuation assigned to Madrigal following the announcement of the merger with Synta we believe that Viking is significantly undervalued.

Financial Update

On May 10, 2016, Viking announced financial results for the first quarter of 2016. The company reported a net loss of $3.6 million, or $0.40 per share, which was comprised of $1.9 million in R&D expenses and $1.4 million in G&A expenses. The company exited the first quarter with approximately $11.3 million in cash and cash equivalents.

On April 13, 2016, Viking Therapeutics, Inc. (VKTX) announced the closing of a previously announced public offering of 7.5 million shares of its common stock and warrants to purchase up to 7.5 million shares of common stock at a public offering price of $1.25 per share. The warrants have an exercise price of $1.50 and are exercisable until Apr. 13, 2021. This resulted in gross proceeds to the company of approximately $9.4 million before deducting underwriting discounts, commissions, and other offering expenses. The warrants will trade on the Nasdaq under the ticker symbol 'VKTXW'.

Per the company's $2.5 million loan agreement with Ligand Pharmaceuticals, Inc. (LGND), Viking was required to repay $1.5 million of the loan following the company raising at least $2.0 million, with $300,000 due in cash and the rest payable in equity. On April 14, 2016, Viking issued to Ligand 960,000 shares of common stock and a warrant to purchase 960,000 shares of common stock with an exercise price of $1.50 per share and expiration date of April 13, 2021. According to the loan agreement, Ligand will not sell any securities of Viking before January 23, 2017.

As of April 29, 2016, Viking had approximately 19.3 million shares of common stock outstanding, with Ligand owning approximately 40% of the total number of outstanding shares. When factoring in the outstanding shares of restricted stock, stock options, and warrants the company has a fully diluted share count of approximately 34.2 million shares.

Valuation

For valuation purposes, we have constructed a probability adjusted discounted cash flow model that takes into account potential revenues from VK5211 in hip fracture, VK2809 in NASH, and VK0214 in adrenoleukodystrophy (ALD).

The pre-clinical and clinical data for VK5211 are quite encouraging, particularly the magnitude of the effect, the durability of response, and the lack of any serious adverse events. We model for peak revenues of VK5211 of approximately $600 million in the U.S. and $1 billion in the E.U.

Viking has presented compelling data for VK2809, particularly given the low level of adverse events coupled with data that rivals many of the current treatment options for dyslipidemia. We estimate potential peak worldwide revenues for VK2809 of $2.5 billion.

For ALD, since it is an orphan indication we believe the drug would likely command premium pricing, thus we model for a yearly cost of $150,000 in the U.S. and $120,000 in Europe, leading to estimated peak worldwide sales of approximately $450 million.

Based on these numbers, and using an 18% discount rate, leads to a valuation of $8/share. The fact that Viking has a market cap of only $23 million is quite perplexing, particularly given the valuation of Madrigal and its TRβ agonist of approximately $150 million following the announcement of its merger with Synta Pharmaceuticals. There is no discernable reason that Viking, with a TRβ agonist with potentially superior efficacy to Madrigal's, should have a market cap approximately 1/6th that of Madrigal and we believe it is only a matter of time until Viking's valuation matches the company's potential. In the meantime, we believe Viking's current valuation presents investors with a valuable opportunity to acquire shares or add to a position in a very promising small-cap biotechnology company.

PROJECTED FINANCIALS

Viking Therapeutics, Inc.
Income Statement

Viking Therapeutics, Inc.	2015 A	Q1 A	Q2 E	Q3 E	Q4 E	2016 E	2017 E	2018 E
VK5211 (Hip Fracture)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
VK2809 (Hypercholesterolemia)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
VK2809/VK0214 (ALD)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
Grants & Collaborative Revenue	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
Research & Development	$7.0	$1.9	$3.2	$3.4	$2.9	$11.4	$13.5	$16.0
General & Administrative	$5.0	$1.4	$1.4	$1.5	$1.4	$5.7	$5.8	$6.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($12.0)	($3.3)	($4.6)	($4.9)	($4.3)	($17.1)	($19.3)	($22.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	($11.4)	($0.3)	($0.5)	($0.5)	($0.5)	($1.8)	($2.0)	($3.0)
Pre-Tax Income	($23.4)	($3.6)	($5.1)	($5.4)	($4.8)	($18.9)	($21.3)	($25.0)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($23.4)**	**($3.6)**	**($5.1)**	**($5.4)**	**($4.8)**	**($18.9)**	**($21.3)**	**($25.0)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($3.68)**	**($0.40)**	**($0.27)**	**($0.28)**	**($0.24)**	**($1.12)**	**($0.89)**	**($0.93)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	6.356	9.016	19.000	19.500	20.000	16.879	24.000	27.000

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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WEEKLY PRICE CHART



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