Zacks Small-Cap Research

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Resverlogix Corp. (RVX - TSX)

Apabetalone: A Potential Alzheimer's Play?

Based on our DCF model and a 15% discount rate, RVX is valued at approximately CAD$5.00 per share. Our model applies a 64% probability of apabetalone sales for indications in the BETonMACE trial. Our valuation only includes BETonMACE indication contributions from the US, Europe, & Latin America, as well as royalties from the Hepalink arrangement. It does not recognize potential from renal or orphan indications.

Current Price (8/17/2018)	$3.04
Valuation	**$5.00**

OUTLOOK

Resverlogix Corp. (RVX.TO) began recruiting and dosing participants in the Phase 3 BETonMACE trial of its lead candidate apabetalone (RVX-208) in high-risk CVD patients with diabetes in November 2015. We believe the trial will take approximately 3 years to complete, targeting topline readout in 1H:19. With a potential impact on multiple markers for CVD we are optimistic on a materially significant impact on MACE.

The company has announced several successful early phase studies in diabetes mellitus and chronic kidney disease that are supportive of apabetalone's safety profile and point to expanded indications.

At the current price, we view Resverlogix shares as undervalued, and in a position to provide long-term upside potential. We see additional upside from the realization of expansion into new geographies, cognitive impairment, the orphan disease program, and renal disease.

SUMMARY DATA

52-Week High	**3.77**
52-Week Low	**1.11**
One-Year Return (%)	**133.8**
Beta	**0.84**
Average Daily Volume (sh)	**169,280**
Shares Outstanding (mil)	**177**
Market Capitalization ($mil)	**538**
Short Interest Ratio (days)	**5.35**
Institutional Ownership (%)	**0.0**
Insider Ownership (%)	**69.5**
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 2017 Estimate	**N/A**
P/E using 2018 Estimate	**N/A**
Zacks Rank	**N/A**

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

ZACKS ESTIMATES

Revenue

(In millions of US$)

	Q1 (Jul)	Q2 (Oct)	Q3 (Jan)	Q4 (Apr)	Year (Apr)
2017	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2018	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2019					$0.0 E
2020					$0.0 E

Earnings per Share

	Q1 (Jul)	Q2 (Oct)	Q3 (Jan)	Q4 (Apr)	Year (Apr)
2017	-$0.06 A	-$0.14 A	-$0.12 A	-$0.11 A	-$0.44 A
2018	-$0.14 A	-$0.10 A	-$0.15 A	-$0.05 A	-$0.42 A
2019					-$0.25 E
2020					-$0.25 E

WHAT'S NEW

In the Home Stretch

Resverlogix Corp. (TSX: RVX) launched its Phase III BETonMACE trial in the fall of 2015 and for the last three years has steadily recruited patients now exceeding its targeted 2,400 patient target and completing enrollment. The trial is event-driven and will end when 250 MACE events have occurred. Based on management commentary we believe the trial will generate a readout in 1H:19. BETonMACE is not only important due to the anticipated benefit for high risk cardiovascular patients, but also for other related diseases including chronic kidney disease, renal disease, diabetes and cognitive dysfunction. The last of these, cognitive dysfunction, is of particular importance given the multiplicity of failures that have occurred in Alzheimer's Disease in recent years and the lack of a cure. Apabetalone inhibits bromodomain and extraterminal domain (BET) causing release from chromatin and downregulation of gene expression which may be associated with neuroinflammation. This association as well as favorable impact of apabetalone treatment on biomarkers that indicate chronic kidney disease, MACE and diabetes which are also associated with cognitive decline suggest that there may be a positive association between apabetalone and prevention of dementia. The BETonMACE trial contains several sub-studies that will examine these related diseases as part of the larger study.

With multiple failures in amyloid beta and BACE inhibitor directed therapies, a favorable response in the BETonMACE trial for patients could bring apabetalone to the forefront in Alzheimer's Disease (AD). The cognitive impairment focused sub-study that is taking place will use the Montreal Cognitive Assessment (MoCA), which can measure cognitive impairment, including attention, concentration, executive functions, memory, language and other elements. The group is comprised of all patients in the BETonMACE study over 70 years of age, and management has indicated that there are approximately 250 individuals in each of the active and placebo groups. If the small sub-study yields a favorable result, a further, larger study will be pursued. A follow-on cognition trial could enroll from 800 to 1,000 participants over 12 – 24 months to confirm the sub-study results.

AD afflicts almost six million Americans and over 30 million people worldwide.[1] The prevalence of the disease is increasing and these numbers are expected to almost double and triple by 2030 and 2050 respectively. AD is also distinguished in that it is the only major disease where deaths have increased over the last decades. Between 2000 and 2013, a report from the Alzheimer's Association found that deaths resulting from stroke, heart disease, and prostate cancer decreased 23%, 14%, and 11%, respectively, while Alzheimer's deaths increased 71%. According to the CDC[2] AD is the 6th leading cause of death in the United States, after stroke and before diabetes. While there are almost 6 million individuals in the US diagnosed with AD, there are many more who are in earlier stages of the disease called mild cognitive impairment (MCI), suggesting an even larger target market.

With no other therapies that can halt or reverse the disease, strong evidence of a benefit from apabetalone could add tremendous value to Resverlogix. We are eagerly awaiting the results of the BETonMACE trial to determine if there is support for the primary endpoint of MACE, but also other associated disease such as diabetes, chronic kidney disease and dementia.

Fiscal Year 2018

2018 is the final stretch for Resverlogix as the BETonMACE trial approaches the finish line and expenses should peak this year, followed by regulatory related efforts and expenses in 2019. The company posted its financial statements and management discussion and analysis for the fiscal year 2018 ending April 30, 2018 at the end of July. No revenues were recognized and a net loss of ($58.3)[3] million or ($0.42) per share was reported. This compares to our estimates of zero revenues and a net loss of ($60.5) million and ($0.44) per share with the difference attributable to a favorable change in warrant liability. For operational costs alone, overall expenses were higher than our estimate due to greater R&D expense reflecting greater levels of BETonMACE enrollment and associated shipments of clinical supplies to trial sites. Total operational expenses for FY:18 were $41.9 million, increasing from $34.1 million in the prior year. FY:18 research & development expenses rose 26% while general & administrative expenses contracted 5% on a comparable basis with FY:17.

[1] WHO Dementia Fact Sheet. December 2017. 60% to 70% of the 50 million people who have dementia have Alzheimer's. http://www.who.int/mediacentre/factsheets/fs362/en/

[2] Center for Disease Control Age Adjusted Death Rates 2016 https://www.cdc.gov/nchs/products/databriefs/db293.htm

[3] Note that financial statements are prepared in US Dollars and our commentary on revenues expenses and earnings is also in US Dollars, while our target price is in Canadian Dollars.

As of April 30, 2018, Resverlogix held $0.1 million in cash and zero debt. Operating cash burn was ($25.7) million for the year or ($2.1) per month in FY:18 rising due to higher R&D. Resverlogix also calculates cash burn; relative to our formula it includes changes in non-cash working capital and excludes capital expenditures yielding a ($3.5) million average monthly burn rate for the fiscal year. Using our definition of cash from operations less capital expenditures, this compares to monthly cash burn of ($2.1) million in FY:18.

Resverlogix's cash has been at minimal levels during FY:18. The company has been successful obtaining additional financing by raising equity in various deals and using the proceeds to pay down outstanding debt and provide additional cash for operations. Following the end of the fiscal year discussed above, Resverlogix raised USD$30.0 million from Third Eye Capital on May 7. The loan carries an interest rate of 10% and requires a minimum cash balance of $5.0 million as well as other constraints. We believe that this will be sufficient cash to cover operations until the topline readout from BETonMACE is available. The majority of the expenses for the trial have peaked as full enrollment has been reached. We forecast a decline in R&D spend in coming quarters which should temper the cash burn burden.

On August 30, 2018, an additional financing of US$20 million (CAD$26 million) was announced. This was a private placement that issued 10.4 million units at a price of CAD$2.50. 5.2 million warrants were attached at an exercise of $3.00. Funds are intended to support R&D and other corporate purposes.

U.S. Listing

As we move into the final stretch of the BETonMACE trial, Resverlogix will seek a listing on a U.S. exchange. To obtain a listing on a U.S. exchange, the company's shares will need to trade at a higher share price to conform to exchange rules. For example, the NASDAQ requires shares to trade above $2.00 if the market value of the company is greater than $50 million. Other considerations need to recognize U.S. institutional investors that many times will only screen for an investible universe with shares that trade above $5.00. While in some cases reverse splits are seen as a negative, when they are undertaken to qualify for a listing on a U.S. exchange, they fall into another category. A listing in the U.S. will help expand the investor base and give additional prestige to a company that trades there. Many times there is a perception of higher quality of companies that trade on a specific exchange because of the accounting and reporting standards that are required to trade there.

To assist with the listing process, Resverlogix has engaged Rothschild & Company as an advisor. We anticipate that management will provide additional details on the path forward in coming months.

Participation in Conferences

Resverlogix presented at the Alzheimer's Association International Conference (AAIC) in late July. The poster at this event focused on the cognition substudy that is part of the BETonMACE trial. As discussed above, there are no approved cures for AD, and there have been countless failures. If apabetalone is able to show promise in the sub-study, we anticipate that there will be substantial interest from large pharma to get involved, which means non-dilutive capital flows. We also anticipate a larger, more focused study will take place to measure the impact of apabetalone on cognition.

In early September, Resverlogix has two presentations awarded at the Clinical Trials in Alzheimer's Disease (CTAD) Asia conference in Shanghai, China. Dr. Jeffrey Cummings, who sits on the organizing committee of the conference, will present a topic in one of the sessions. The topic is "Cognitive Evaluation of Treatment Effects of the Bromodomain and Extra-terminal Inhibitor Apabetalone; Design and Baseline Data of the Cognition Substudy of the BETonMACE Phase 3 Cardiovascular Trial" and his discussion will highlight the design and baseline characteristics of a prespecified substudy of cognition in elderly patients in the Company's ongoing phase 3 BETonMACE clinical trial. He will also present a poster entitled "Effect of the BET Protein Inhibitor Apabetalone on Serum Markers of Potential Importance for Cognitive Decline in Cardiovascular Disease Patients," illustrating new data from the proteomic analysis from the Company's phase 2 ASSURE clinical trial.

BETonMACE Update

The BETonMACE trial contains several sub-studies that examine the impact of apabetalone on cognition, renal function, diabetes and vascular dysfunction in addition to the primary MACE endpoint. The cognition substudy will administer the MoCA which is a series of visuospatial, naming, memory, attention, language and abstraction questions administered to patients 70 years of age and older. Approximately 20% of the anticipated 2,400 enrollees in BETonMACE are anticipated to be 70 years of age or older and will be administered the MoCA test.

Another substudy in the BETonMACE will examine kidney function and will assess the changes in kidney function for patients with an estimated glomerular filtration rate below 60 mL/min at screening. In Phase II work, treatment with apabetalone was associated with a decline in alkaline phosphatase (ALP) and a greater reduction in CVD events was apparent in patients with diabetes, both of which are closely linked to kidney disease. In the BETonMACE trial, 11% (~260) of the currently enrolled patients are screening for eGFR below 60.

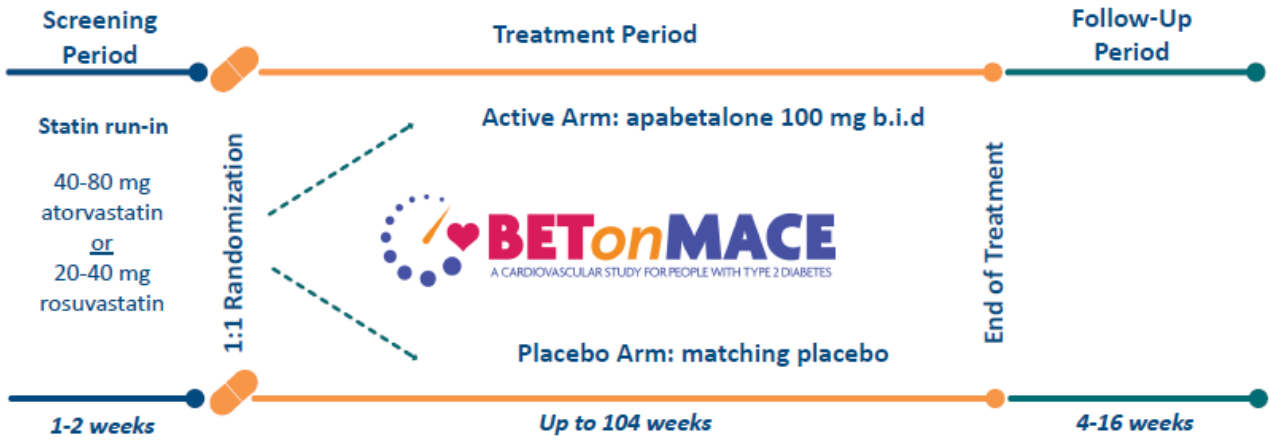
A third area of focus for apabetalone's impact is on the reduction of vascular calcification. In Resverlogix' Phase II study, analysis demonstrated a reduction in circulating proteins associated with vascular calcification in patients with cardiovascular disease. Alkaline phosphatase (ALP) experienced an 11% decline in the trial compared to a 3.2% decline for the placebo. Other biomarkers, including osteoprotegerin and osteopontin were reduced with apabetalone and indicated downregulation of vascular calcification.

The BETonMACE trial is event dependent and will conclude upon achieving 250 MACE events. We had expected the 75% sample size re-estimation analysis at 188 patient events to be announced in the spring or summer, however, it appears that this has not yet taken place.[4] We see a few possible scenarios that could contribute to this slower than expected rate of MACE events.

- The population that has enrolled in the study has a much lower than expected event rate overall,
- Apabetalone is effective in reducing the MACE rate,
- A combination of these two factors or other unknown factor.

While the slow pace is delaying the completion of the trial, we do not believe it detracts from a positive outcome. Our best guess is that we will see the full 250 events complete in the first few months of 2019.

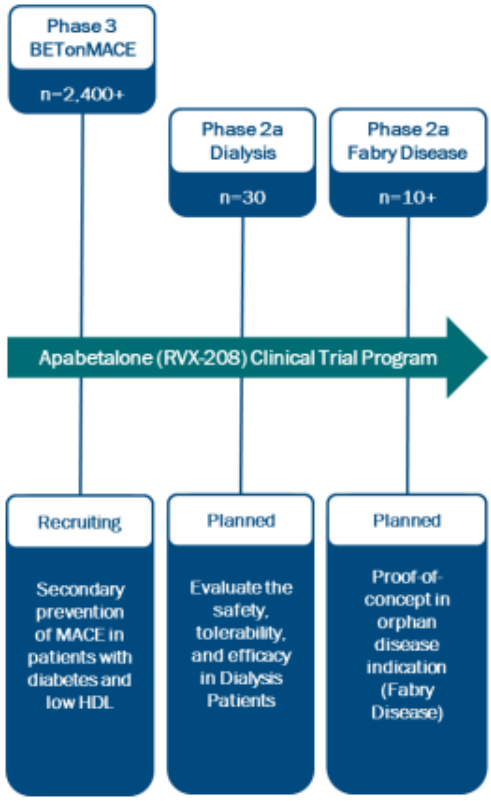
Exhibit I – BETonMACE Trial Design



On July 25, 2017 Resverlogix received a positive Type C written response from the FDA allowing the launch of the BETonMACE study in the United States. The FDA had previously requested updated information on apabetalone with respect to human exposure, clinical dosing and established acceptable safety margins to which Resverlogix satisfactorily responded. In January 2018, the FDA accepted the study protocol amendments, allowing the expansion of the trial into the United States. In June, the FDA provided confirmation that the BETonMACE trial, if successful, is likely to support a New Drug Application. The agency accepts the protocol, statistical analysis plan and endpoints for BETonMACE which should eliminate concern an additional trial would be needed for approval in the United States. As of early April, over 2,400 patients have been enrolled in the BETonMACE trial. Seven Data and Safety Monitoring Board (DSMB) meetings have taken place, all recommending that the trial continue as designed. No safety or efficacy concerns were raised in the reviews. The seventh and latest recommendation came on August 7th where the board had the opportunity to review data from all 2,400 patients recruited. The BETonRENAL Dialysis trial and the Fabry Disease trial are both filed and planned, but have yet to enroll their first patient. We anticipate when sufficient funding is received to complete the BETonMACE trial, initial enrollees will be added to these ancillary trials.

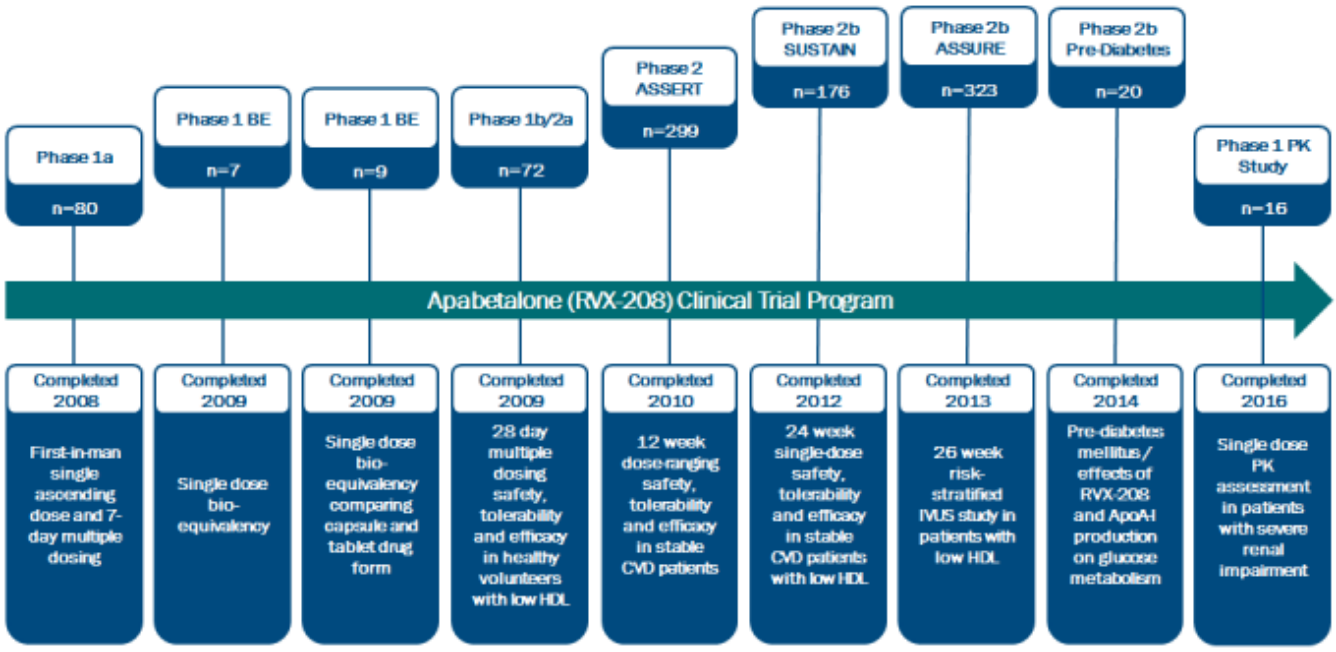
[4] The MACE event rate for the untreated population in the 3-year BETonMACE study was estimated to be approximately 8% per year. At full enrollment, this would suggest 192 events per year (8% x 2,400 patients).

Exhibit II – Current or Planned Apabetalone Trials



Over its history, Resverlogix has completed trials providing treatment with apabetalone in over 1,000 patients, providing a substantial set of safety and efficacy data supportive of the current efforts in the BETonMACE trial.

Exhibit III – Completed Apabetalone Trials



Key Events

During fiscal year 2018 Resverlogix has experienced several milestones and anticipates several more in the coming year. Below we summarize the key events over these periods for the company.

- July 25, 2017 – Type C Response from FDA regarding BETonMACE study protocol
- January 11, 2018 – FDA accepted protocol amendments and US trial sites added
- FY:18/FY:19 - Multiple DSMB safety reviews recommending continuation of trial
- March 19, 2018 – BETonMACE 2,400 patient target exceeded
- May 7, 2018 – Close of USD$30 MM loan from Third Eye Capital
- June 14, 2018 – FDA confirms that BETonMACE trial qualifies for NDA if successful
- August 25, 2018 – Epigenetics Satellite Symposium Presentations
- September 12, 2018 – Annual Meeting of Shareholders
- 1H:19 – Topline readout from BETonMACE

Our Estimates

FY:18, expenses have largely been in line with our estimates; however, R&D did increase due to the launch of the US portion of the apabetalone trial. Trial work has progressed well, and the company has exceeded its 2,400 patient enrollment target. Upcoming events of importance include achieving the 75% mark for the 250 events in the trial. This will occur when 188 MACE events[5] have passed and will be followed by a sample size re-estimation analysis to ensure the trial will generate statistically significant results. We anticipate a first half of calendar year 2019 readout on the trial, at which time the safety and efficacy of apabetalone will be presented. General and administrative expenses have been under control and have not increased materially over the last year

Summary

Our investment thesis on Resverlogix emphasizes the opportunity related to the size of the population impacted by cardiovascular disease (CVD) and the high degree of efficacy and evidence of safety shown so far in clinical investigations. There are additional opportunities in diabetes, chronic kidney disease and importantly Alzheimer's Disease. Resverlogix's lead compound has shown promise in addressing many of the key biomarkers underlying CVD and these other related diseases and potentially has applications in other therapeutic areas as well.

We updated our model for fiscal year end actuals and the issuance of debt following the end of the reporting period. G&A expenses are expected to rise in coming quarters, reflecting increased activity around the completion of the BETonMACE trial. R&D expenses are forecast to fall, reflecting the end of the enrollment phase of the study. We anticipate additional capital raises or access to non-dilutive capital through partnerships that will continue to fund operations until Resverlogix can submit its Phase III data to the FDA and other regulatory authorities.

We believe that a durable patent position, a competence in CVD and diabetes and a novel approach to addressing the residual risk in high need CVD patients combined with our forecasted pricing of apabetalone support Zacks' price target. At current levels, there is substantial upside based on our targets. We highlight that data from the BETonMACE trial will not likely be available until fall 2018, but we eagerly anticipate results from the sample size re-estimation analysis which will provide a first look after 75% of the primary MACE events have been adjudicated. We maintain our price target at CAD$5.00 per share.

[5] As a reminder a MACE (major adverse cardiac event) is the occurrence of any of the following: CV death, non-fatal MI, hospitalization for CVD events, or stroke.

PROJECTED FINANCIALS

Resverlogix Corp. - Income Statement

Resverlogix Corp (millions of $US)	Apr. 2017 FY-17 A	Jul. 2017 Q1 A	Oct. 2017 Q2 A	Jan. 2018 Q3 A	Apr. 2018 Q4 A	Apr. 2018 FY-18 A	Apr. 2019 FY-19 E	Apr. 2020 FY-20 E
RVX-208	$0	$0	$0	$0	$0	$0	$0	$0
Licensing & Collaborative	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
CoGS	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
R&D Expense (net)	$29.9	$8.0	$8.4	$11.9	$9.4	$37.8	$32.0	$30.0
G&A Expense	$4.3	$0.9	$1.1	$1.0	$1.1	$4.1	$4.4	$7.0
Operating Income	($34.1)	($8.9)	($9.6)	($12.9)	($10.5)	($41.9)	($36.4)	($37.0)
Operating Margin	-	-	-	-	-	-	-	-
Net Finance Activities	($12.0)	($6.4)	($1.3)	($11.0)	$2.3	($16.4)	($8.8)	($8.8)
Other Gain / (Loss)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($46.1)	($15.3)	($10.9)	($23.9)	($8.2)	($58.3)	($45.2)	($45.8)
Taxes & Other	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($46.2)	($15.4)	($10.9)	($23.9)	($8.2)	($58.3)	($45.2)	($45.8)
Reported EPS	**($0.44)**	**($0.14)**	**($0.10)**	**($0.15)**	**($0.05)**	**($0.42)**	**($0.25)**	**($0.25)**
YOY Growth	-					-	-	-
Diluted Shares Outstanding	105.4	108.2	113.2	155.1	176.0	137.7	180.0	185.0

Source: Company Filing // Zacks Investment Research, Inc. Es

HISTORICAL STOCK PRICE

Resverlogix, Corp. – Five Year Price Chart[6]

[6] Chart provided courtesy of barchart.com

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