Zacks Small-Cap Research

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John D. Vandermosten, CFA
312-265-9588 / jvandermosten@zacks.com
scr.zacks.com
10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606

Resverlogix Corp. (RVX - TSX)

2Q:19 Results

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 (12/27/2018)	$3.00
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 yield a topline readout in 1H:19. Apabetalone provides a potential impact on multiple markers for CVD and we are optimistic on a materially significant impact on MACE.

The company has announced several successful early phase studies in cognition, 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 return 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	**4.31**
52-Week Low	**1.11**
One-Year Return (%)	**50**
Beta	**1.14**
Average Daily Volume (sh)	**109,017**
Shares Outstanding (mil)	**193**
Market Capitalization ($mil)	**579**
Short Interest Ratio (days)	**4.83**
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 2018 Estimate	**N/A**
P/E using 2019 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)
2018	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2019	$0.0 A	$0.0 A	$0.0 E	$0.0 E	$0.0 E
2020					$0.0 E
2021					$14.2 E

Earnings per Share

	Q1 (Jul)	Q2 (Oct)	Q3 (Jan)	Q4 (Apr)	Year (Apr)
2018	-$0.14 A	-$0.10 A	-$0.15 A	-$0.05 A	-$0.42 A
2019	-$0.28 A	-$0.21 A	-$0.05 E	-$0.04 E	-$0.56 E
2020					-$0.24 E
2021					-$0.23 E

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WHAT'S NEW

Second Quarter 2019 Results

Resverlogix Corp (TSX: RVX) filed its fiscal year 2019 second quarter financial results with SEDAR on December 13, 2018. The company participated in several conferences and raised a modest amount of capital in the quarter as the remaining events in the BETonMACE trial to take place. Trial results are expected in the first half of calendar year 2019, but are dependent on MACE events which are unpredictable.

Operating expenses were $10.9[1] million in the second quarter, a rise of 14% over the prior year. The total was comprised of $8.9 million in research and development expense and $2.0 million of general and administrative expense. Both categories were higher in 2Q:19 as compared to 2Q:18. Higher share-based payments contributed to the higher levels of general and administrative expenses. No revenues were reported in the quarter.

Net finance costs in the third quarter were $28.3 million with $26.8 million of the total attributable to loss of fair value of warrants and royalty preferred shares. The increase in the share price over the quarter was the primary contributor to the accounting change in value. The remaining portion of finance costs were comprised of interest, fees and accretion offset by foreign exchange. Net loss for the quarter was ($32.9) million or ($0.21) per share.

Cash and equivalents stood at $5.9 million as of October 31, 2018 and debt was carried at $18.5 million. Following the close of the quarter, Resverlogix issued $10.3 million in shares in a private placement. $5.15 million of this total was used to repay a portion of the Third Eye loan.

Operating cash burn was ($9.3) million for the quarter or ($3.1) million per month in 2Q:19 compared to ($4.1) for the second quarter of 2018 or ($1.4) million per month. Resverlogix also calculates cash burn; relative to our formula it removes changes in non-cash working capital and excludes capital expenditures yielding ($9.6) million for the quarter and ($3.2) million on a monthly basis.

Despite a raise in cash, Resverlogix has continued to catch up with payables, pay down debt and assume higher quarterly expenditures, resulting in only a modest increase in cash compared to the first quarter.

Additional Capital

After the end of the reporting period, on November 2nd, Resverlogix closed a CAD$13.5 million (US$10.3 million) placement at a share price of $3.00. This is equivalent to 4.5 million shares and includes an additional 2.25 million warrants at an exercise price of $3.10. The warrants have a duration of three years and require a four month holding period.

On August 30th, Resverlogix announced the close of a private placement raising CAD$26 million (US$20 million). 10.4 million shares were issued at a price of $2.50 with an additional 5.2 million warrants. Warrants are exercisable at $3.10, have a three year life and are subject to a four month hold.

Neurodegenerative Disease

Apabetalone has many potential applications as addressed in the company's prolific posters and articles. As we learn more about the leading diseases facing the world today, we find that many are interrelated and are the result of a core dysregulation. For example, there is a close association among diabetes, cardiovascular, kidney and neurodegenerative diseases. An improvement in one pathology may have a beneficial impact on all. Examining Resverlogix's area of focus, we see that apabetalone has a favorable impact on biomarkers correlating to cardiovascular disease, chronic kidney disease, diabetes and dementia. This suggests that a drug that works for one, may help for all and that multiple therapies may be required to fully treat the dysregulation. This holistic approach extends to Alzheimer's Disease (AD), which we highlight here due to the promise of apabetalone and the lack of any disease modifying therapies approved to date.

[1] 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.

Resverlogix's recent poster[2] provided details on the secondary analysis being performed within BETonMACE for cognition. Participants above 70 years of age will be examined to determine the potential for BET inhibition to affect cognitive function. These patients will be given a baseline MoCA[3] exam and be measured against this every twelve months for the duration of their participation in the trial and at termination. There will also be a subgroup of patients with a MoCA score below 25 at baseline that will receive special analysis.

Resverlogix has conducted a number of trials that have examined a broad spectrum of biomarkers and proteins. . Apabetalone has a number of effects on pathways which impact cognition, bringing them back into balance:

- Upregulates apolipoprotein A-I (apoA-I), which is a component of high density lipoprotein (HDL)
- Reduces expression of inflammatory mediators in microglial cells, potentially reverting to resting state
- Favorably modulates multiple processes that contribute to neurodegenerative disease

There are a number of serum biomarkers that have shown favorable movement in response to apabetalone as measured in Phase II trials, when compared to placebo. We list below the most impactful proteins that have implications for cognitive decline. These proteins are implicated in a variety of processes including reduction of reactive oxygen species, to an anti-inflammatory impact and a contribution to the ability for the brain to adapt and grow (plasticity). Below we summarize the various proteins measured in the ASSURE trial and their association with cognitive decline.

Exhibit I - Serum Biomarkers of Vascular Cognitive Impairment[4]

Protein	Neuro Impact	RVX vs. Placebo Treatment Difference (%)	P-Value Rank-ANCOVA (% Difference)	Implications in Cognitive Decline
ATP Synthase Subunit O-Mitochondrial	Energy Oxidative Phosphorylation	+44.6	0.03	→ Reduced expression of certain oxidative phosphorylation genes in blood from people with AD and MCI, including ATP5O → Compromised oxidative phosphorylation efficiency may contribute to the generation of reactive oxygen species
Amyloid Beta A4 Protein	Aβ Production	+32.9	0.01	→ Plasma concentration of soluble amyloid precursor protein β is significantly decreased in AD patients
Brain-Derived Neurotrophic Factor	Plasticity	+28.2	*0.07*	→ Reduced expression implicated in pathogenesis of neurodegenerative disorders (AD,PD, etc.) → Higher serum levels may protect against future occurrence of dementia in AD
Annexin A1	Plasticity	+8.7	0.02	Neuroprotective role with anti-inflammatory activities → Suppresses inappropriate microglial phagocytosis of non-apoptotic cells and the production of inflammatory mediators during the phagocytic reaction → Increases enzymatic degradation of Aβ plaques and stimulates phagocytosis by microglia → Downregulated in serum of AD patients → accelerated BBB breakdown
Gelsolin	Aβ Fibrillization Inhibitor Anti-Oxidant Anti-Apoptotic	+5.3	0.005	→ Plasma gelsolin binds Aβ, inhibits its aggregation into fibrils, and protects cells from apoptosis induced by Aβ → AD patients display significantly lower levels of plasma gelsolin → Plasma gelsolin correlates to AD progression and MMSE decline rate
Serum Amyloid P-Component	Aβ Formation, Deposition	-10.8	0.01	Produced by the liver; travels to the brain →Constituent of amyloid deposits → Stabilises amyloid fibrils, and Enhances amyloid formation, deposition, persistence → SAP may be directly neurocytotoxic
YKL-40 (Chitinase-3-Like Protein 1)	Inflammation Fibrosis	-18.5	*0.06*	→ Biomarker of neuroinflammation, tissue remodelling, and fibrosis in CNS → Mean plasma YKL-40 was found to be higher in very mild and mild AD-type dementia, and correlates with CSF levels
C-reactive Protein	Inflammation	-21.3	0.02	→ Elevated serum levels of high-sensitivity C-reactive protein (hs-CRP) and adhesion molecule in were correlated with MCI in elderly patients with T2D

Preclinical work with apabetalone provided evidence of its suppressing pro-inflammatory factors related to activated microglia. Microglia are a type of cell in the brain and spinal cord that function as the active immune response in the brain. They clear plaques, damaged neurons and synapses as well as infectious agents. In both preclinical and clinical studies, apabetalone was shown to suppress expression of specific proinflammatory cytokines in stimulated BV-2 microglia which suppressed expression of proinflammatory factors. These factors drive chronic neuroinflammation and excessive synaptic pruning that can result in neurodegenerative disease and AD. While we will need to see the data from the BETonMACE trial to draw further conclusions, the data generated so far suggests that apabetalone can favorably impact the inflammatory expression of cytokines, chemokines and markers of endothelial and microglial activation associated with neuroinflammation and cognitive dysfunction.

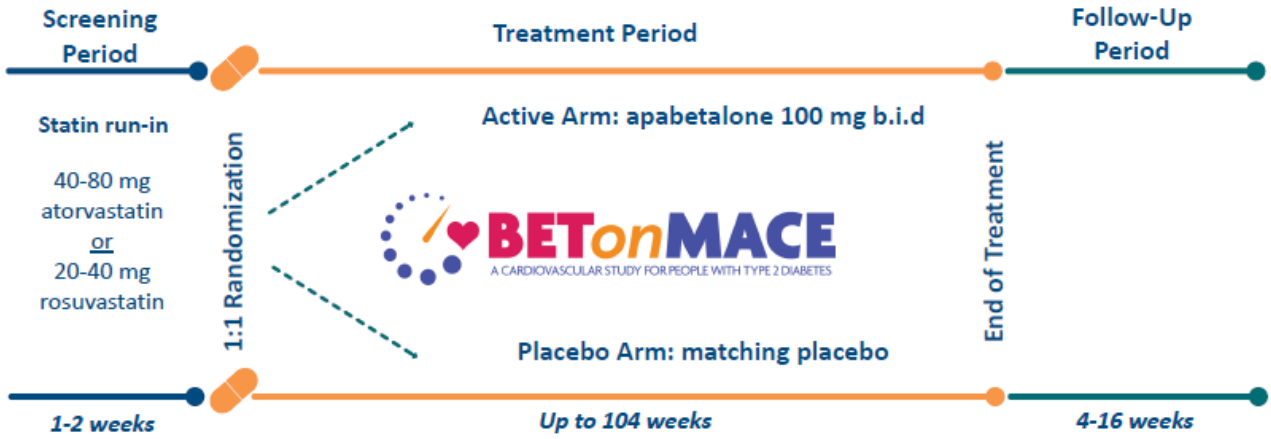
[2] Effects of the Selective BD2/BRD4 BET-Inhibitor Apabetalone in Cognition after Acute Coronary Syndrome In Patients 70 Years And Older With Diabetes.
[3] The Montreal Cognitive Assessment (MoCA) is a widely used screening assessment for detecting cognitive impairment. It was created in 1996 by Ziad Nasreddine and was validated in the setting of mild cognitive impairment, and has subsequently been adopted in numerous other settings clinically.
[4] From Resverlogix May 2016 presentation: Epigenetics and Select BET Inhibition: Apabetalone A Novel Approach to Combating Vascular Cognition Impairment

BETonMACE Status

The BETonMACE trial has been fully enrolled since February 2018 and additional enrollment was allowed at Chinese sites since then to provide for additional flexibility with regulatory authorities. Enrollment in China continued until June. 2,425 patients have been enrolled and dosed in the BETonMACE trial with eight Data and Safety Monitoring Board (DSMB) meetings completed, all of which recommended that the trial continue as designed. The final DSMB review was completed on December 19, 2018 with no safety or efficacy concerns raised in any of the reviews.

The BETonMACE trial had originally intended to run until 250 major adverse cardiovascular events occurred. However, the pace has been slower than that indicated by historical event rates in this population, delaying the 250 event milestone by a few months. This may be interpreted as a favorable result for the apabetalone arm in the trial or it could be a healthier population overall contributing to the slower death rate. Resverlogix has also decided to continue dosing until 250 events have occurred, which suggests that there could be ~270 events when the trial closes, improving the statistical powering in comparison with the original protocol. These historical numbers suggest that the trial can begin the adjudication process around the beginning of the year. While clinical events are independently assessed over an anticipated two month period, additional events will be added providing a topline readout in the first half 2019.

Exhibit II – BETonMACE Trial Design



Key Events

During fiscal year 2018 Resverlogix has experienced numerous 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
- August 30, 2018 – CAD$26 million private placement
- September 12, 2018 – Annual Meeting of Shareholders
- October/November 2018 – Participation in various Kidney, AD and cardiovascular conferences
- November 2, 2018 – CAD$13.5 million private placement
- December 2018 – Eighth and final DSMB recommendation
- 1H:19 (Calendar year) – Topline readout from BETonMACE
- 2H:19 (Calendar year) – New Drug Application with major regulatory agencies

Summary

We are in the final stretch for Resverlogix's Phase III BETonMACE trial and should achieve the target event rate around the turn of the year. To increase the power of the trial, Resverlogix will allow BETonMACE to run a couple months after 250 events occur. The company will also skip the sample size re-estimation analysis, which will remove a statistical penalty and improve p-values. While the trial will extend several months beyond what was originally anticipated, we see this as a risk reduction technique that is well worth the additional time investment. Now that we are very close to the end of the trial, we anticipate interest will increase in the stock as we close on the read out date.

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 Alzheimer's Disease. Resverlogix's lead compound has shown promise in addressing many of the key biomarkers underlying CVD and other related diseases and potentially has applications in other therapeutic areas.

We updated our model for 2Q:19 actuals and the issuance of additional shares and warrants following the end of the reporting period. There was no net impact on our target valuation with the read out of BETonMACE serving as the next anticipated catalyst driving our numbers. R&D expenses are forecast to fall in FY:19 vs. FY:18 reflecting the end of the enrollment phase of the study and G&A is expected to see a slight rise. 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 in what we expect to be autumn 2019.

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 forecasts and discounted cash flow model. We maintain our price target at CAD$5.00 per share.

PROJECTED FINANCIALS

Resverlogix Corp. - Income Statement

Resverlogix Corp (millions of $US)	Apr. 2018 FY-18 A	Jul. 2018 Q1 A	Oct. 2018 Q2 A	Jan. 2019 Q3 E	Apr. 2019 Q4 E	Apr. 2019 FY-19 E	Apr. 2020 FY-20 E	Apr. 2021 FY-21 E
RVX-208	$0	$0	$0	$0	$0	$0	$0	$14.2
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)	$37.8	$6.7	$8.9	$7.0	$6.0	$28.6	$30.0	$30.0
G&A Expense	$4.1	$1.0	$2.0	$1.1	$1.1	$5.2	$7.0	$7.0
Operating Income	($41.9)	($7.7)	($10.9)	($8.1)	($7.1)	($33.8)	($37.0)	($37.0)
Operating Margin	-					-	-	-
Net Finance Activities	($16.4)	($41.8)	($28.3)	($0.8)	($0.8)	($71.6)	($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	($58.3)	($49.5)	($39.2)	($8.9)	($7.9)	($105.4)	($45.8)	($45.8)
Taxes & Other	$0.0	$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	($58.3)	($49.5)	($39.2)	($8.9)	($7.9)	($105.4)	($45.8)	($45.8)
Reported EPS	**($0.42)**	**($0.28)**	**($0.21)**	**($0.05)**	**($0.04)**	**($0.56)**	**($0.24)**	**($0.23)**
YOY Growth	-					-	-	-
Diluted Shares Outstanding	137.7	177.3	185.2	192.5	193.0	187.0	190.0	195.0

Source: Company Filing // Zacks Investmer

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HISTORICAL STOCK PRICE

Resverlogix, Corp. – Five Year Price Chart[5]



[5] Chart provided courtesy of barchart.com

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