Zacks Small-Cap Research

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Resverlogix Corp. (RVX - TSX)

Price Target Up; More BETonMACE Sites Opening

Based on our DCF model and a 15% discount rate, RVX is valued at approximately CAD$6.50 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 (3/24/2017)	$2.18
Valuation	**$6.50**

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 2018. With a potential impact on multiple markers for CVD we are optimistic on a materially significant impact on MACE.

The company announced successful PK study results for its Phase I renal trial and should commence Phase II studies in 1H:17.

At the current price, we view Resverlogix shares as undervalued, and in a position to provide long-term upside potential. We increase our target price to CAD$6.50 per share and believe that expansion into new geographies, the orphan disease program, and renal disease, could provide further upside to our valuation.

SUMMARY DATA

52-Week High	**2.47**
52-Week Low	**1.10**
One-Year Return (%)	**73.0**
Beta	**0.8**
Average Daily Volume (sh)	**43,440**
Shares Outstanding (mil)	**105.5**
Market Capitalization ($mil)	**230.0**
Short Interest Ratio (days)	**4.16**
Institutional Ownership (%)	**0.0**
Insider Ownership (%)	**42.0**
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)
2016	$0.0 A	$0.0 A	$0.0 A	$0.0 A	$0.0 A
2017	$0.0 A	$0.0 A	$0.0 A	$0.0 E	$0.0 E
2018					$0.0 E
2019					$0.0 E

Earnings per Share

	Q1 (Jul)	Q2 (Oct)	Q3 (Jan)	Q4 (Apr)	Year (Apr)
2016	$0.03 A	-$0.04 A	-$0.08 A	-$0.09 A	-$0.20 A
2017	-$0.06 A	-$0.14 A	-$0.12 A	-$0.06 E	-$0.38 E
2018					-$0.26 E
2018					-$0.28 E

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WHAT'S NEW

Resverlogix Reports Third Quarter Fiscal Year 2017 Results

On March 17, Resverlogix Corp. (TSX: RVX) posted its financial statements and management discussion and analysis for its third quarter of fiscal year 2017 ending January 31, 2016. The company reported no revenues and a net loss of ($13.0)[1] million or ($0.12) per share. This compares to our estimates also of zero revenues and a net loss of ($7.3) million or ($0.07) per share. Total operational expenses for 3Q:17 were $13.0 million, increasing from $8.9 million in the same quarter of the prior year. Second quarter research & development expenses rose 120%, while general & administrative increased 21%. Costs for the Renal PK and the BETonMACE clinical trials related to recruiting and clinical supply shipments were important drivers behind the increase.

Clinical costs, which include investigator grants, project and site management and monitoring costs and laboratory costs, totaled approximately $5.4 million with $5.1 million of the total allocated to the BETonMACE clinical trial and $0.1 million for the renal pharmacokinetic clinical trials. This compares to clinical costs of $2.3 million in 3Q:16. Regulatory costs comprised $0.1 million of the total and $0.1 million was spent on other clinical costs including sample analysis, consultants and insurance. Chemistry costs were $1.6 million in the third quarter compared to $0.5 million in in the same quarter of the prior year due to shipment costs of supplies for the BETonMACE trial. Preclinical costs of $0.8 million were up from $0.2 million on higher expenses attributable to higher research, pharmacology, toxicology and drug metabolism, and pharmacokinetics spend. R&D compensation costs were flat year over year at $0.5 million.

General and administrative costs fell just below $1.0 million up 21% from $0.8 million as a payment for a cardiovascular continuing education grant was made. Net finance costs fell in 3Q primarily due to lower loss from change in value of royalty preferred shares offset by higher foreign exchange loss and interest accretion. The warrant liability shifted from a gain in 3Q:16 to a slight loss in 3Q:17 due to the increase in stock price.

As of January 31, 2017, cash of $4.9 million was held on the balance sheet and long-term debt increased sequentially by $2.6 million to $49.7 million. Operating cash burn was ($7.4) million in 3Q:17 and ($19.3) million for the first nine months of the year. This compares to cash burn of ($10.5) million in 3Q:16 and ($17.9) million in the first nine months of FY:16.

In February 2017, Resverlogix identified two new potential indications for apabetalone including potential in degenerative diseases of the eye and in Facioscapulohumeral Muscular Dystrophy (FSHD). In January the Journal of Neuroinflammation published an article where BET inhibitors, including apabetalone were tested in a murine model of retinal degeneration. The findings indicated that BET inhibition rescues photoreceptor degeneration and suggests that BET interference could treat degenerative retinal diseases. Research at St. Louis University illustrated that BET inhibitors were able to suppress the DUX4 gene which is thought to reduce the severity of FSHD. The research showed that pulsed treatment was more effective than continuous treatment, which is supportive of oral administration of a BET inhibitor.

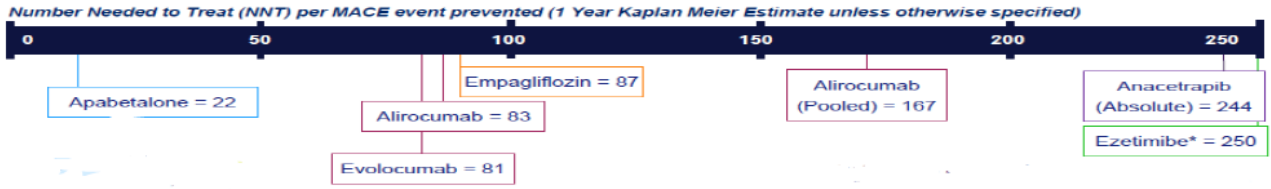
Our Estimates

Resverlogix has increased the pace of investment into its portfolio of indications for apabetalone in recent quarters, launching and completing a Phase 1 PK study with patients suffering from severe renal impairment and accelerating the pace of its BETonMACE study through expansion into additional clinical investigator sites. We anticipate that the company will continue to launch studies in other neighboring indications as funding permits. Due to the rise in research and clinical activity, we increased our estimates of research and development costs over the forecast period. Based on comparisons with other molecules used in cardiovascular health, our estimates assume a very low cost for patients of ~$4,000 per year, compared to other drugs, such as the PCSK9 inhibitors which are running at near $14,000 per year. When examined in terms of its potential economic benefit, the cost for apabetalone to prevent one cardiovascular event is even more striking at under $100,000. This level makes the implicit assumption that the relative risk reduction of apabetalone is greater than 25%. This is a conservative assumption in our view given the pooled analysis performed on the ASSURE and SUSTAIN trials that found a 55% relative risk reduction for CVD patients and even higher reductions for at-risk populations.

[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.

Other drugs, such as anacetrapib, ezetimibe and evolocumab run ICER[2] scores from $360,000 to over $1 million,[3] which provides a high ceiling relative to apabetalone with US payors. Apabetalone is able to achieve this attractive economic benefit due to the low number needed to treat versus competitors.

Exhibit I – Number Needed to Treat for Apabetalone vs. Competitors[4]



To assess the potential value of apabetalone in the market, Resverlogix commissioned a study with Destum Analytics in 2016 to assess the amount that several of the major pharmacy benefit managers in the US market would be willing to pay to prevent one MACE event.[5] The analysis found that an average of $140,000 to prevent one event was seen as appropriate by payors, which is 50% higher than the ICER score for apabetalone at ~$4,000 per annum, assuming a 25% relative risk reduction. Based on this analysis and the potential for apabetalone, we increase our 2020 per annum price estimate for apabetalone from $4,204 to $6,000 to reflect the current pricing environment and maintain the comparative relationship of US pricing with other regions. We also raise R&D expense estimates for the remainder of FY:17 and successive years to reflect management guidance of increased trial activity as new indications are pursued and reflect the sequential increase in net debt. The net impact of these changes raises our price target from CAD$5.00 to CAD$6.50 per share or a 30% increase.

We note that at current cash burn rates, Resverlogix will need to raise cash prior to the end of the fiscal year. Management has outlined several financial options that they are currently exploring which we list below:

- Co-development or follow on compounds with major pharmaceutical company would provide upfront payment and coverage of future expenses.
- Licensing on a regional basis would provide upfront payments
- Licensing certain new or orphan indications to partners for upfront payment
- Partnering and offering first right of refusal in an M&A transaction for an upfront payment
- Private placements with equity and warrants
- Public offering of equity, potentially with an IPO on a US Exchange (less likely)
- Debt financing (less likely)

We anticipate that Resverlogix will favor the options in the order they are presented above and expect execution on one or more in the next months.

Key Milestones

The Data and Safety Monitoring Board (DSMB) for the BETonMACE trial has announced its third positive recommendation for the Phase III study as of March 17, 2017. Previous announcements were made on August 11, 2016 and December 5, 2016 and similarly found no safety or efficacy concerns.

RVX announced preliminary results from New Zealand based Phase I trial for severe kidney impaired patients. The study provided evidence of rapid reductions in inflamed protein biomarkers. The results were marked by distinct differences in the impaired patients and the control group where the biomarkers were reduced in the former group Analysis of the changes in protein levels at the 12-hour time point revealed that, in the kidney disease patients, 33 percent of proteins had statistically significant changes ($p<0.05$) compared to only 10 percent in the controls. Of these significant proteins, several established renal biomarkers such as interleukin 6 and osteopontin, were

[2] The incremental cost-effectiveness ratio (ICER) is a statistic used in cost-effectiveness analysis to summarize the cost-effectiveness of a health care intervention. It is defined by the difference in cost between two possible interventions, divided by the difference in their effect.
[3] IMS Health Estimates provided by Resverlogix
[4] Sourced from Resverlogix Presentation
[5] Destum Partners Apabetalone Analysis from top 5 payors in US covering 200 Million Lives. Analysis assessed their perception of appropriate ICER target threshold for high risk T2DM patients with low HDL for reduction of secondary MACE per annum versus the SGLT2 and GLP1 products.

regulated positively with respect to disease severity and progression. This can potentially provide some treatment options for patients that currently have limited options.

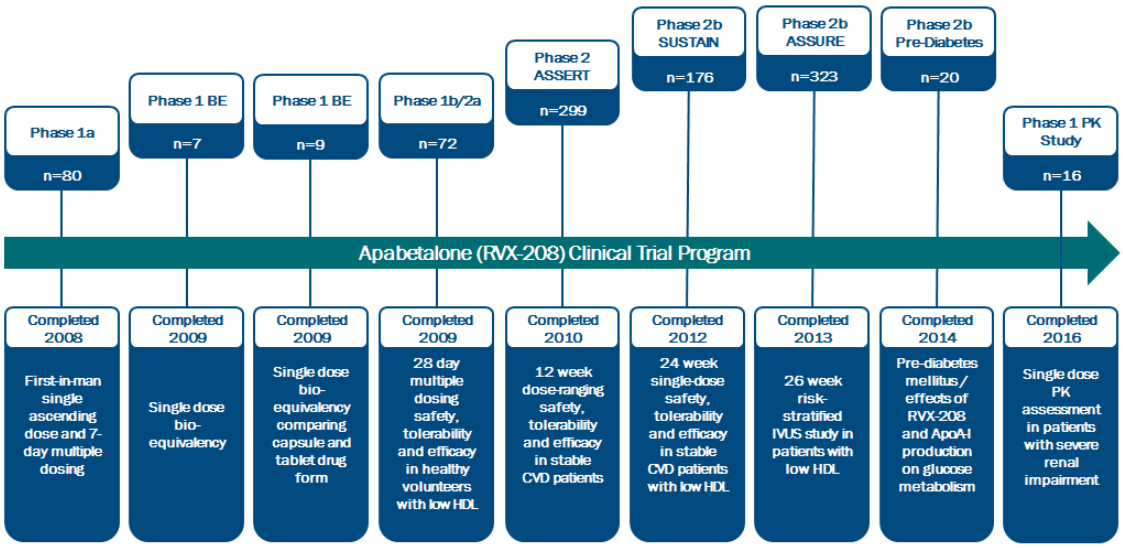
RVX announced that a Notice of Allowance was received for patent claims covering the use of apabetalone with Rosuvastatin in the US. The patent's title is "Compositions and Therapeutic Methods for Accelerated Plaque Regression."

A REVIEW OF RESVERLOGIX'S ASSETS

Clinical Overview of Apabetalone

Resverlogix has completed many clinical trials to date. Apabetalone has been tested in over 1,000 patients in 12 countries, and clinical experience with apabetalone has demonstrated that BET inhibitors can be both safe and effective. Over the years, Resverlogix has gathered information from these studies and shifted focus to target patients with low HDL and diabetes with co-treatment of RVX-208 and rosuvastatin (Crestor) and atorvastatin (Lipitor) in its BETonMACE trial.

Exhibit I – Summary of Resverlogix's Clinical Trials[6]



Phase 3 "BETonMACE"

In October 2015, Resverlogix launched its Phase 3 "Effect of RVX-208 on Time to Major Adverse Cardiovascular Events in High-Risk Type 2 Diabetes Mellitus Subjects with Coronary Artery Disease" (BETonMACE) trial with lead drug apabetalone in high-risk patients with coronary artery disease (CAD) and type 2 diabetes mellitus (DM). The study is a large international multi-center, double-blind, randomized, parallel group, placebo-controlled clinical trial to determine whether treatment with apabetalone in combination with rosuvastatin or atorvastatin increases the time to MACE compared to treatment with rosuvastatin or atorvastatin alone.

The primary endpoint of the BETonMACE trial is designed to show a relative risk reduction of MACE, narrowly defined as a single composite endpoint of CV death, non-fatal myocardial infarction ("MI") and stroke. The study is an event-based trial and will continue until at least 250 MACE events have occurred. MACE will be adjudicated by an independent committee and the study will be monitored by a data safety monitoring board. The trial is seeking a 30% reduction in MACE as compared to the placebo arm.

Secondary endpoints include time to first occurrence of the composite broad MACE which includes the addition of hospitalization for CVD events (unstable angina and revascularization procedures), changes in lipoprotein concentrations (HDL and apolipoprotein A-1), changes in diabetes mellitus variables (glucose and glycated

[6] Source: Resverlogix MD&A

hemoglobin), change in alkaline phosphatase ("ALP"), changes in kidney function and additional safety and tolerability of apabetalone.

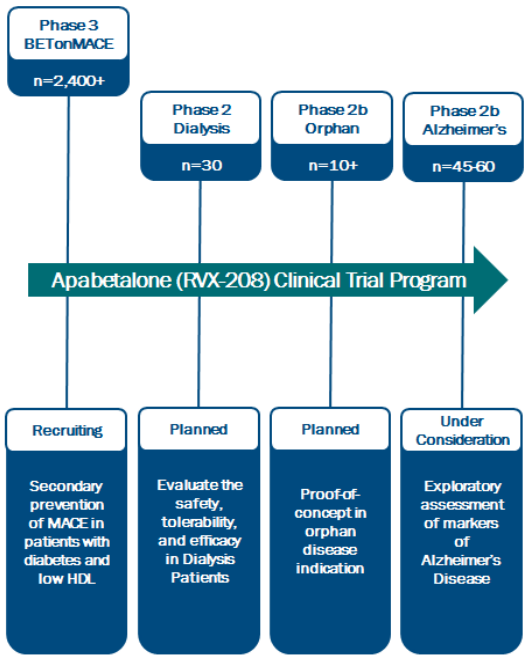
As part of the BETonMACE trial, the study will examine a subset of the patients to test for impact on neuro-degenerative diseases and test for cognition. The subset will include patients over the age of 70 and perform a Montreal Cognitive Assessment (MoCA) test. The company anticipates that this could be from 200 to 300+ participants in the trial. This population group is the equivalent of conducting a Phase 2 dementia trial as part of BETonMACE.

BETonMACE will initially be conducted in Argentina, Mexico and various European cities with expansion into Asia through the partnership with Hepalink. U.S. sites are also a consideration as Resverlogix looks towards FDA approval in this adaptive trial that will target a minimum of 2,400 patients. Argentina, Belgium, Bulgaria, Croatia, Germany, Hungary, Israel, Mexico, Poland, Serbia, and Slovakia have already received regulatory approval to open clinical investigator sites and are recruiting patients. Meetings to launch in Taiwan took place in March 2017 and meetings for a Russian launch are set to take place in April, anticipating June site openings.

RVX has also been working with the FDA on adding the United States to the BETonMACE study. Several meetings, including a Type C meeting took place between Resverlogix and the FDA over the late summer and fall. Following comments provided by the FDA, RVX made modifications to trial design in preparation for an IND in support of a Phase II kidney dialysis trial. Based on FDA input, the Phase IIa study design will be separated in two parts. Part A will involve a single-dose pharmacokinetic (PK) study in eight patients receiving hemodialysis. The PK results from Part A will influence the dose selection for Part B. Part B will be a double-blind, randomized, placebo-controlled, sequential cross-over study with apabetalone, and is designed to evaluate biomarker changes and safety parameters with apabetalone in up to 30 patients with end-stage renal disease treated with hemodialysis.

Other Programs

Exhibit II – Current and Planned Clinical Trials



Summary

Resverlogix's lead product candidate, apabetalone, is the first selective BET bromodomain inhibitor in clinical trials for high-risk vascular disease. In the current Phase III BETonMACE trial, apabetalone is targeting a very specific patient population with low HDL, type 2 diabetes mellitus and chronic kidney disease with a high cardiovascular risk for increased MACE. The trial is progressing with patient recruitment and trial site activation in Phase III BETonMACE. Currently, all planned countries including Argentina, Belgium, Bulgaria, Croatia, Germany, Hungary, Israel, Mexico, Poland, Serbia, and Slovakia have received regulatory approval to open clinical investigator sites and are recruiting patients and expansion into Taiwan, China and Russia is underway.

As a reminder, our investment thesis for Resverlogix is based on a large and growing underserved market in cardiovascular disease. With a growing older population in the world, and in many cases a less healthy one than in previous generations, the addressable market for therapies that reduce cardiovascular risk is increasing. Apabetalone has shown an ability to positively impact major adverse cardiac events in early trials and we expect the current BETonMACE trial to confirm this hypothesis. There is also potential for the compound to address a number of other indications, including renal and orphan diseases. With a substantially large market and an anticipated high degree of efficacy, we forecast a rapid uptake of apabetalone following regulatory approval and forecast robust pricing ability given the anticipated pharmacoeconomics of the drug.

Based on a study conducted by Destum Partners' DP Analytics division, and pricing for other cardiovascular medicines in the market, we increase our pricing estimates for apabetalone. The increase in NPV value is partially offset by anticipated higher R&D expenses and increases in net debt as Resverlogix pursues additional trials in renal and advanced chronic kidney disease

We believe that a durable patent position and the forecasted pricing of apabetalone, combined with a management skill set surrounding CVD and diabetes and a novel approach to addressing the residual risk in high need CVD patients, support our price target. We highlight that data from the BETonMACE trial will not likely be available until mid to late-2018, but we look forward to see results from the interim futility analysis which will provide a first look after 125 MACE events. The anticipated start of Phase II work for renal may provide additional upside, however at this time it is too early to include in our model. We increase our price target to CAD$6.50 per share.

PROJECTED FINANCIALS

Resverlogix Corp. - Income Statement

Resverlogix Corp. (millions of $US)	Apr. 2016 FY-16 A	Jul. 2016 Q1 A	Oct. 2016 Q2 A	Jan. 2017 Q3 A	Apr. 2017 Q4 E	Apr. 2017 FY-17 E	Apr. 2018 FY-18 E	Apr. 2019 FY-19 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)	$15.7	$6.1	$6.3	$8.7	$7.0	$28.2	$30.0	$32.0
G&A Expense	$4.3	$1.0	$1.3	$1.0	$1.4	$4.6	$5.2	$6.8
Operating Income	($20.0)	($7.1)	($7.6)	($9.7)	($8.4)	($32.8)	($35.2)	($38.8)
Operating Margin	-					-	-	-
Net Finance Activities	$0.3	$0.7	($7.6)	($3.3)	$0.1	($10.1)	$0.5	$0.6
Other Gain / (Loss)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($19.7)	($6.4)	($15.2)	($13.0)	($8.3)	($42.9)	($34.7)	($38.2)
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	($19.7)	($6.5)	($15.2)	($13.0)	($8.3)	($42.9)	($34.7)	($38.2)
Reported EPS	**($0.20)**	**($0.06)**	**($0.14)**	**($0.12)**	**($0.06)**	**($0.38)**	**($0.26)**	**($0.28)**
YOY Growth						-	-	-
Diluted Shares Outstanding	101.0	106.8	105.3	105.5	130.0	111.9	131.0	135.0

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

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