Zacks Small-Cap Research

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Resverlogix Corp. (RVX - TSX)

Maintaining CAD$5.00 Target: Awaiting First BETonMACE Futility Readout.

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 other orphan indications.

Current Price (9/16/2016)	$1.53
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 2018. With a potential impact on multiple markers for CVD we are optimistic on a materially significant impact on MACE.

The company has begun dosing patients in its PK renal study which may provide for a more rapid approval and access to market through the orphan drug pathway.

At the current price, we view Resverlogix shares as undervalued, and in a position to provide long-term upside potential. We maintain our target price of CAD$5.00 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	**2.52**
52-Week Low	**1.10**
One-Year Return (%)	**-20.7**
Beta	**1.25**
Average Daily Volume (sh)	**20,950**
Shares Outstanding (mil)	**105.2**
Market Capitalization ($mil)	**166.5**
Short Interest Ratio (days)	**1.94**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
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 E	$0.0 E	$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	-$0.06 E	-$0.06 E	-$0.05 E	-$0.23 E
2018					-$0.21 E
2018					-$0.22 E

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WHAT'S NEW

Resverlogix Reports First Quarter Fiscal Year 2017 Results

On September 14, Resverlogix Corp. (TSX: RVX) submitted its financial filings for its first quarter of fiscal year 2017 ending July 31, 2016 to the Alberta Securities Commission. The company reported no revenues and a net loss of ($6.5)[1] million or ($0.06) per share. This compares to our estimates also of zero revenues and a net loss of ($4.4) million or ($0.04) per share. Total operational expenses for 1Q:17 were $7.1 million, increasing from $3.5 million in the same quarter of the prior year. First quarter research & development expenses rose 183%, while general & administrative fell 27%. Costs related to the BETonMACE clinical trial drove the overall increase.

Clinical costs totaled approximately $4.1 million with $3.7 million of the total allocated to the BETonMACE clinical trial and $0.2 million for the renal pharmacokinetic clinical trials. This compares to clinical costs of $1.1 million in 1Q: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 $0.8 million in 1Q:17 compared to $0.3 million in 1Q:16 due to shipment costs of supplies for the BETonMACE trial. Preclinical costs of $0.5 million were up from $0.1 million on higher expenses attributable to various small studies related in part to additional indications. R&D compensation costs rose modestly to $0.5 million from $0.4 million in the previous year period. Overall, the higher expenses are related to the commencement of the BETonMACE trial in October 2015.

General and administrative costs of $1.0 million declined in the first quarter from $1.3 million due to decreases in professional fees and business development costs, and other corporate costs. This reflected the inclusion of costs in the comparative period associated with the Hepalink license.

As of July 31, 2016, cash of $24.2 million was held on the balance sheet and long-term debt totaled $47.1 million. A transaction with former subsidiary Zenith related to the cancellation of a royalty agreement resulted in a $5.6 million cash payment by Zenith to Resverlogix in 1Q:17 offsetting much of the operating expense in the quarter. Operating cash burn was ($2.9) million in 1Q:17. Cash burn for the quarter, after adjusting for changes in non-cash working capital was ($7.7) million, or approximately $2.6 million per month. This compares to a $1.4 million monthly cash burn rate in 1Q:16.

Our Estimates

Resverlogix has increased the pace of investment into its portfolio of indications for apabetalone in recent quarters, launching a Phase 1 PK study with patients suffering from severe renal impairment and accelerating the pace of its BETonMACE study. We anticipate that the company will continue to launch studies in other neighboring indications as funding permits. Due to this acceleration in research and clinical activity, we have increased our estimates of research and development costs for FY:17 and FY:18. We also initiate on FY:19 estimates which are provided in our income statement at the end of this report. We maintain our target price of CAD$5.00.

We note that at current cash burn rates, Resverlogix does not have sufficient cash to complete the fiscal year. The company will need to raise additional funds and we anticipate that they will issue equity shares to fund operations for the subsequent year. While management has not provided any indication on timing, our model assumes a share issuance in the fiscal fourth quarter that will raise an additional $30 million increasing shares outstanding by 22.5 million.

Key Milestones

As of April 30, 2016, all planned countries, including Argentina, Belgium, Bulgaria, Croatia, Germany, Hungary, Israel, Mexico, Poland, Serbia, and Slovakia had received regulatory approval to open clinical investigator sites and were recruiting patients.

On May 24, 2016, the company announced the formation of an International Renal Clinical Advisory Board ("RCAB") for the future development of apabetalone into expanded renal indications. The RCAB is comprised of six physicians including the Chairman Dr. Kamyar Kalantar-Zadeh, Dr. Carmine Zoccali, Dr. Marcello Tonelli, Dr. Vincent Brandenburg, Dr. Srinivasan Beddhu, and Dr. Mathias Haarhaus.

[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.

In June 2016, the company announced that a pre-diabetes mellitus study performed by the Baker IDI Heart and Diabetes Institute was published in the journal 'Metabolism' under the title "Effects of the BET-inhibitor, RVX-208 on the HDL lipidome and glucose metabolism in individuals with prediabetes: A randomized controlled trial." The study concluded that apabetalone treatment impacted glucose metabolism and both the reduction in glucose absorption and its production are expected to be of benefit in patients with prediabetes mellitus.

On July 21, 2016, Resverlogix announced that dosing had commenced in a Phase 1 pharmacokinetics ("PK") study with apabetalone in patients with severe renal impairment. This trial has been initiated and designed in accordance with the company's strategy to expand into new indications such as renal and orphan diseases. The primary objective of the Phase 1 study, based in New Zealand, is to determine if apabetalone treated patients with severe renal impairment have the same favorable PK traits as has been illustrated in previous apabetalone trials. Results are expected in the second half of 2016, and if favorable, will likely allow for us to proceed with more advanced renal impairment and dialysis trials.

On August 11, 2016, RVX announced that the independent Data and Safety Monitoring Board (DSMB) for the BETonMACE trial had completed a planned safety review and verbally recommended that the study should continue as planned without any modifications. The DSMB reviewed available study data and noted that no safety or efficacy concerns were identified. The DSMB will conduct additional periodic reviews and will also perform a futility assessment once 125 adjudicated MACE have been observed. The parties remain blinded to the actual safety and efficacy results.

In May and June 2016, new findings were presented at the Arteriosclerosis, Thrombosis and Vascular Biology (ATVB) Scientific Sessions, EAS Congress and the ADA Scientific Sessions. These presentations summarized studies designed to further understand the reductions in MACE observed in apabetalone treated patients.

On August 28, 2016, Resverlogix hosted the symposium, "A novel approach for high CV risk patients with diabetes: The potential of epigenetics" at the ESC Congress. Speakers included renowned experts in the field of CVD presenting a variety of topics related to diabetes, CVD and BET inhibition. A poster was also presented at the congress containing data demonstrating that apabetalone treatment reduced basal and cytokine-induced expression of complement factors in hepatocytes.

Expanded Renal and Orphan Programs

As mentioned above, in 1Q:16, the company formed the RCAB for the future development of apabetalone into expanded renal indications. Shortly after, on July 21, 2016, Resverlogix announced that it had begun a Phase 1 pharmacokinetic (PK) trial in patients with severe renal impairment with apabetalone. The company is targeting this renal population to address a serious unmet need in an orphan population and may see accelerated development, approval and ultimately market adoption in pursuing this pathway.

The study's primary goal is to confirm the favorable pharmacokinetic traits that have been observed in other apabetalone trials. The study is being conducted in New Zealand and expects to post results in the second half of 2016, after which additional renal impairment and dialysis trials will proceed if positive data is seen. We hope to see a Phase 2 trial begin shortly after the completion of the data analysis and could potentially obtain approval in a renal indication under an orphan designation prior to an approval for high-risk cardiovascular disease.

The study will examine acute changes in Bromodomain and Extra-Terminal (BET) inhibition biomarkers for subjects with severe renal impairment. The company stated in its press release that "Two cohorts, each comprised of eight subjects, will be evaluated in the study. Cohort one will include subjects with end-stage renal disease (ESRD) not on dialysis, with an estimated glomerular filtration rate (eGFR) of less than 30 mL/min/1.73m^2 while cohort two will include healthy individuals whose age, weight and gender will be matched to the renal impaired subjects. All subjects will receive a single oral administration of 100mg of apabetalone."

While we do not currently include a valuation component for an orphan renal indication, we recognize the attractiveness of this pathway, find it to be an unqualified positive and will adjust our model accordingly as development details becomes more certain.

A REVIEW OF RESVERLOGIX'S ASSETS

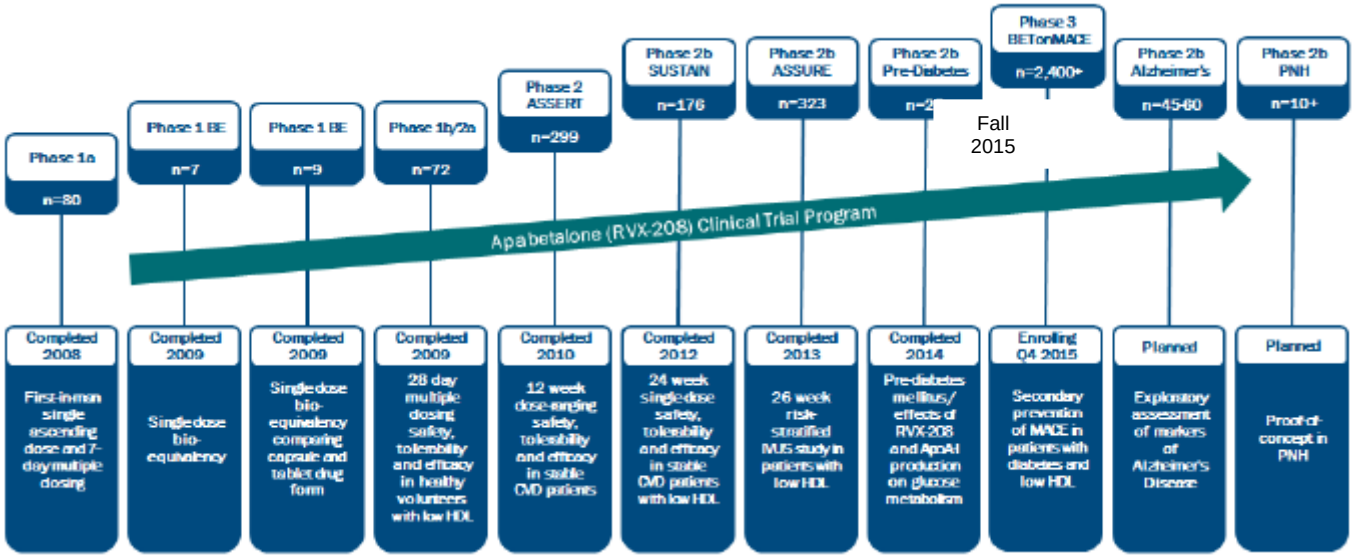
Clinical Overview of Apabetalone

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.

Prior to the BETonMACE trial, apabetalone has completed two Phase 2b trials named SUSTAIN and ASSURE in collaboration with the Cleveland Clinic. Furthermore, Resverlogix has performed thorough analysis of MACE in the Phase 2b clinical program; 35 MACE events were reported in both the SUSTAIN and ASSURE trials. This analysis demonstrated that treatment with apabetalone was associated with a 55% reduction in MACE. Apabetalone treated patients had a lower level of cumulative events of 6.7% vs. 15.1% (p=0.02) in the placebo treated group.

Furthermore, a beneficial effect of apabetalone on patients with diabetes mellitus was accentuated with a reduction in MACE that was lowered by 77% (p=0.01). BETonMACE will continue to focus on MACE reduction as the primary endpoint for the registration study.

Exhibit I – Summary of Resverlogix's Clinical Trials[2]



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.

[2] Source: Resverlogix Clinical Trials Summary

Secondary endpoints include time to first occurrence of the composite broad MACE which includes the addition of hospitalization for CVD events (unstable angina and revscularization procedures), changes in lipoprotein concentrations (HDL and apolipoprotein A-1), changes in diabetes mellitus variables (glucose and glycated hemoglobin), change in alkaline phosphatase ("ALP"), changes in kidney function and additional safety and tolerability of apabetalone.

In order to be eligible to participate in the study, patients must have documented history of type 2 Diabetes Mellitus, experienced a recent (defined as 7-90 days prior to randomization) coronary artery disease ("CAD") event including unstable angina, revascularization procedure or MI and have low levels of HDL (<40 mg/dL for males and <45 mg/dL for females). Standard of care high potency statin therapy shall consist of daily dose of either atorvastatin 40-80 mg or rosuvastatin 20-40 mg. After an initial screening period of 1 to 2 weeks during which subjects will be treated with standard of care statin therapy, subjects will be randomized to either apabetalone 100 mg twice daily or matching placebo with continued statin treatment. This combination treatment period will continue for up to 104 weeks.

Resverlogix believes that the Phase 3 MACE trial may confirm health benefits in CVD, diabetes, and CKD. The main objective of the trial is to confirm MACE reduction by apabetalone as observed in SUSTAIN and ASSURE pooled analysis and also expand safety assessment. The study is conducted in a larger prospective setting with high-risk patients that have diabetes mellitus and low HDL-C (< 40 mg/dL for males and < 45 mg/dL for females who are post events). Management also plans to further explore the potential impact that apabetalone may have on inflammation, the complement and coagulation pathways, vascular calcification, metabolism, and reverse cholesterol transport.

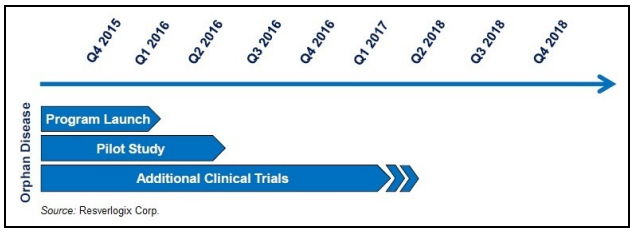
As part of the BETonMACE trial, the study will examine a subset of the patients to test for impact on neuro-degenerative diseases and test for cognition. The subset will include patients over the age of 70 and perform a Montreal Cognitive Assessment (MoCA) test. The company anticipates that this could 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 potential 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. As of April 30, 2016, Argentina, Belgium, Bulgaria, Croatia, Germany, Hungary, Israel, Mexico, Poland, Serbia, and Slovakia had received regulatory approval to open clinical investigator sites and were recruiting patients.

Orphan Disease Program

On September 24, 2015, Resverlogix announced the commencement of an Orphan Disease Program for Complement Mediated Diseases.

Exhibit II – Orphan Disease Timeline



Management believes that new data suggests that apabetalone downregulates different components of the complement and coagulations pathways, which are important to cardiovascular disease as well several orphan diseases. Resverlogix would like to further explore the potential of apabetalone in humans with overactive complement pathways. We believe that apabetalone will be tested in a Phase 2 proof-of-concept pilot study in a small group of patients with Paroxysmal Nocturnal Hemoglobinuria (PNH).

We believe there is potential for Resverlogix to study other complement mediated diseases, such as atypical hemolytic uremic syndrome (aHUS), and glomerulonephritis in conjunction with apabetalone as well as other pre-clinical BET inhibitors/follow-on compounds (*below*), but we are not exactly sure the path the company wishes to pursue. Resverlogix does not currently have an orphan drug designation at this point, but we anticipate that the current Phase 1 PK study in renal has a good chance of securing an orphan designation if data are supportive.

Management believes that the orphan drug route will allow for the drug to reach the market before that for the indications in the BETonMACE trial.

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 3 BETonMACE trial, Apabetalone is targeting a very specific patient population with low HDL, type 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 3 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.

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 orphan diseases, PNH and aHUS. 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.

We believe that 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 recently announced complement-mediated orphan disease program could also provide further upside to our valuation, however at this time it is too early to include in our model. Additionally, apabetalone's multimodal mechanism of action has led to the announcement of the current Phase 1 trial in renal disease, which may provide additional upside to our valuation. Currently, we believe the company is undervalued and maintain our price target of CAD$5.00 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	$5.2	$5.3	$5.5	$22.2	$23.0	$24.0
G&A Expense	$4.3	$1.0	$1.3	$1.3	$1.4	$5.0	$5.2	$6.8
Operating Income	($20.0)	($7.1)	($6.5)	($6.6)	($7.0)	($27.2)	($28.2)	($30.8)
Operating Margin	-					-	-	-
Net Finance Activities	$0.3	$0.7	$0.1	$0.1	$0.1	$1.0	$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)	($6.4)	($6.5)	($6.9)	($26.2)	($27.7)	($30.2)
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)	($6.4)	($6.5)	($6.9)	($26.2)	($27.7)	($30.2)
Reported EPS	**($0.20)**	**($0.06)**	**($0.06)**	**($0.06)**	**($0.05)**	**($0.23)**	**($0.21)**	**($0.22)**
YOY Growth						-	-	-
Diluted Shares Outstanding	101.0	106.8	107.0	107.5	130.0	112.8	131.0	135.0

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

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