Zacks Small-Cap Research

July 8, 2015
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Resverlogix Corp. (RVX - TSX)

RVX: With Financing Secured, Resverlogix Now Focuses On Moving Forward with Phase 3 BETonMACE…

Current Recommendation	**Hold**
Prior Recommendation	N/A
Date of Last Change	04/17/2015
Current Price (07/08/15)	$2.02
Target Price	**$3.25**

UPDATE

Resverlogix's lead candidate, RVX-208, is currently in mid-stage clinical development and has a proposed multimodal approach of achieving Major Cardiac Adverse Event (MACE) reduction. Resverlogix continues to move forward in the planning and design process for the future Phase 3 trial (BETonMACE) of RVX-208 in high-risk CVD patients with diabetes, and recently attained Phase 3 status with a European Regulatory Authority, in addition to inking a license and financing agreement with Shenzhen Hepalink Pharmaceutical Co., Ltd and Eastern Capital.

We initiated coverage of Resverlogix Corp. (TSX: RVX) in April 2015 with a "Hold" rating and a $3.25 price target, and are maintaining our target price.

SUMMARY DATA

52-Week High	**3.13**
52-Week Low	**0.41**
One-Year Return (%)	**136.9**
Beta	**N/A**
Average Daily Volume (sh)	**156,300**
Shares Outstanding (mil)	**85.3**
Market Capitalization ($mil)	**180**
Short Interest Ratio (days)	**N/A**
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 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**

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

ZACKS ESTIMATES

Revenue

(In millions of $)

	Q1 (Jul)	Q2 (Oct)	Q3 (Jan)	Q4 (Apr)	Year (Apr)
2014	0 A	0 A	0 A	0 A	0 A
2015	0 A	0 A	0 A	0 E	0 E
2016					0 E
2017					0 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Jul)	Q2 (Oct)	Q3 (Jan)	Q4 (Apr)	Year (Apr)
2014	$0.55 A	-$0.02 A	$0.19 A	$0.00 A	$0.70 A
2015	$0.08 A	-$0.04 A	-$0.02 A	-$0.02 E	-$0.01 E
2016					-$0.11 E
2017					-$0.16 E

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WHAT'S NEW

Resverlogix Financial & Business Update

On July 8, 2015, Resverlogix Corp. (TSX: RVX) announced that it closed a license agreement with Shenzhen Hepalink Pharmaceutical Co., Ltd. According to the license agreement, should lead candidate RVX-208 reach specific annual sales milestones in China, Hong Kong, Taiwan, and Macau ranging from 500 million to 10 billion Renminbi ("Chinese Yuan") (approximately $80 million to $1.6 billion), Resverlogix will be eligible to receive sales-based milestone payments from Hepalink, each ranging from USD $5 million to $90 million. Additionally, Hepalink will pay Resverlogix an adjusted royalty of 6% of net sales of RVX-208 in the territories listed above. The license agreement will expire on a region-by-region basis on the later of either the 15th anniversary of the first commercial sale in such region or the expiration date of the last-to-expire of any licensed patent. We would like to point out that Hepalink will be responsible for all clinical and development costs in the territories mentioned above, including a patient population that will be included in the upcoming Phase 3 BETonMACE trial.

Resverlogix and Hepalink also entered into a definitive stock purchase agreement whereby Hepalink will purchase approximately 13.3 million shares of common stock at CAD $2.67per share. Hepalink will also be granted roughly 1.0 million 5-year warrants exercisable at CAD $2.67 per share. The transaction provides gross proceeds of CAD $35 million to Resverlogix. After the transaction is completed, Hepalink will hold approximately 12.63% of Resverlogix's common shares, and the common shares and warrants issued to Hepalink will be subject to a lock-up period of three years. Hepalink will also be able to nominate one representative for election to the board of directors of Resverlogix. Furthermore, If the Hepalink transaction is completed, Eastern Capital Limited will purchase 5.6 million shares and be granted 0.422 million warrants under the same terms, for aggregate consideration of approximately CAD $15 million, or CAD $2.67 per share.

Net proceeds, which we estimate to be in the area of CAD $47 million ($37 million USD) will be used to fund research and development activities including clinical development, non-clinical development, research, discovery, chemistry and regulatory costs in addition to repayment of outstanding indebtedness and/or payment of interest thereon as well as general and administrative expenses, capital expenditures, working capital needs and other general corporate purposes.

At the end of January 2015, Resverlogix had approximately $17 million in cash and cash equivalents. We believe that the cash position as of the end of January 2015 is enough to fund the initial activities related to Phase 3 BETonMACE trial design into the early part of 2016. In our opinion, if all goes according to schedule, the first patient in the Phase 3 program will be dosed at some point in the fourth quarter of this year. Although exact costs will be based on the total number of patients enrolled, we believe the program will cost in the area of $25 million and take about 3 years to complete. In our opinion, the cash being raised from the Hepalink and Eastern Capital Limited will fully fund the Phase 3 BETonMACE trial. Furthermore, this puts the top-line data in 2018, with the goal to file a new drug application (NDA) during the end of 2018 or early part of 2019. We understand that Resverlogix has a lot on its plate with the intricacies of the Phase 3 planning process, but we look forward to learning more about the study design. Resverlogix should be reporting annual results for the year ending April 30, 2015 by the end of July 2015.

…Recent Resverlogix Headlines…

In other news, on June 22, 2015, Resverlogix announced that following various meetings with European regulatory bodies, the company officially attained Phase 3 status with a European Regulatory Authority. With this regulatory confirmation in place, Resverlogix plans to provide a Phase 3 BETonMACE clinical trial design following approval of additional regulatory bodies. BETonMACE is still set to start at some point in the fall 2015. As a reminder, the primary endpoint of the BETonMACE trial is designed to show a relative risk reduction of Major Adverse Cardiac Events (MACE) in high-risk cardiovascular and diabetes mellitus patients. We look forward to learning more about the trial design as details are made available in the near term.

A Review of Resverlogix & RVX-208

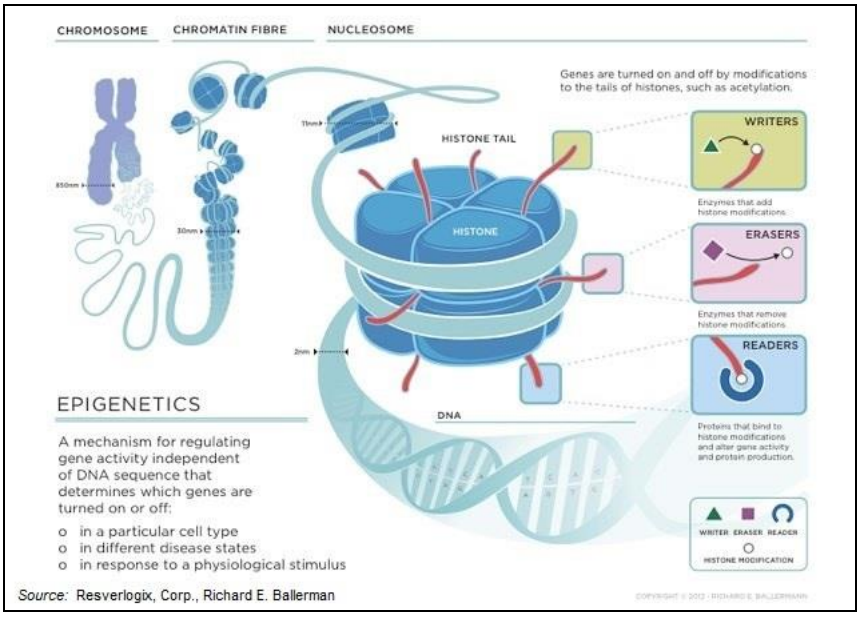
Resverlogix Corp. is a clinical stage cardiovascular company with an epigenetic platform technology that modulates protein production. Novel compounds arising from Resverlogix's epigenetic drug development platform function by inhibiting Bromodomain and Extra Terminal domain (BET) proteins and have the potential to impact multiple diseases. This area of epigenetic research is a new emerging arena of high interest. Resverlogix is engaged in the development of novel therapies for important global medical markets with significant unmet medical needs.

Resverlogix's lead candidate, RVX-208 (apabetalone), is a first-in-class small molecule that inhibits BET proteins and has the potential to impact cardiovascular disease, neurodegenerative diseases, diabetes, cancer, and autoimmune diseases. RVX-208 has a multimodal approach and impacts several key biological processes that play a role in vascular disease risk. These processes include ApoA-I/HDL and reverse cholesterol transport as well as mediation of several vascular inflammatory and metabolic mediators.

Currently, RVX-208 is the first selective BET bromodomain inhibitor in clinical trials for high-risk vascular disease. Resverlogix is the first to test RVX-208 in the reduction of major adverse cardiac events (MACE) in diabetic and chronic kidney disease (CKD) patients, and has a seven-year head start in the arena of epigenetic small molecules for CVD risk reduction. Analysis of prior Phase 2 clinical trials data ("ASSERT", "ASSURE", and "SUSTAIN") showed that RVX-208 significantly reduces coronary atherosclerosis and major adverse cardiac events in patients with CVD who also have a low level of HDL and elevated CRP, and other select populations with unmet medical need. With regulatory confirmation from a European Regulatory Agency now in place, RVX-208 is poised to enter a Phase 3 clinical trial "BETonMACE." We are looking forward to learning more about the study design as more details are made available.

Resverlogix's Epigenetics Platform Technology

Epigenetics refers to the study of heritable changes caused by activation or deactivation of gene expression that do not involve alterations in DNA sequence and is involved in many normal cellular processes (Dupont *et al.*, 2009). A more advanced approach to epigenetics involves the protein-to-protein interaction of "readers," which are proteins that that identify a specific pattern of modifications by binding to them and recruiting other proteins to modulate gene activity.

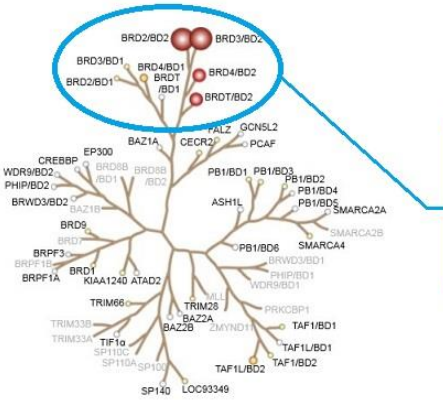


The basis of Resverlogix's epigenetics drug development platform involves targeting Bromodomain and Extra Terminal Domain (BET) proteins with the potential to impact cardiovascular disease, neurodegenerative diseases, diabetes, cancer, and autoimmune diseases. Acetylated lysine, a modified amino acid that is found in histones, binds to the two small bromodomain regions of BET proteins. Resverlogix has discovered BET protein inhibitors that specifically bind to BET bromodomains, thereby preventing them from binding to histones. This leads to modifications in certain gene activity involved in disease processes. Resverlogix is focusing the majority of its research efforts on the BRD2, BRD3, BRD4, and BRDT proteins.

Resverlogix is in the process of identifying and developing compounds for additional clinical indications with proprietary platform activities continuing to add to its growing portfolio of intellectual property needed to support the development of these assets.

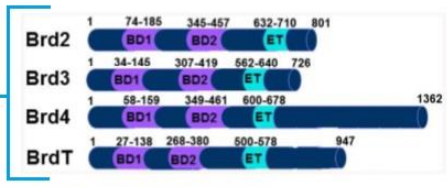
RVX-208 is a BET antagonist

Resverlogix's lead candidate, RVX-208 (apabetalone), is a first-in-class, orally active small molecule that selectively inhibits BET proteins. RVX-208 works by binding to the two specialized areas of BET proteins known as bromodomains (BD1 and BD2, *below middle*). Both of these bromodomains can recognize and bind an acetylated lysine, which is a modified amino acid found on histones bound to DNA. This process is referred to as "reading", which refers to the protein-to-protein interaction of a BET protein finding and binding an acetylated lysine through the actions of the bromodomain. RVX-208 acts via an epigenetic mechanism on BET proteins, specifically BRD2, BRD3, BRD4 and BRDT with increased selectivity for BRD4-BD2 (*below left and below middle*).



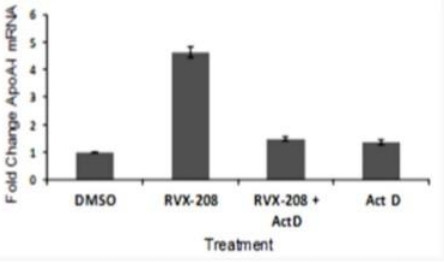
Selectivity of RVX-208 within the human bromodomain family determined using a thermal shift assay.

Source: Picaud et al., 2013



Schematic of domain structure of the human BET proteins.

Source: McLure et al., 2013



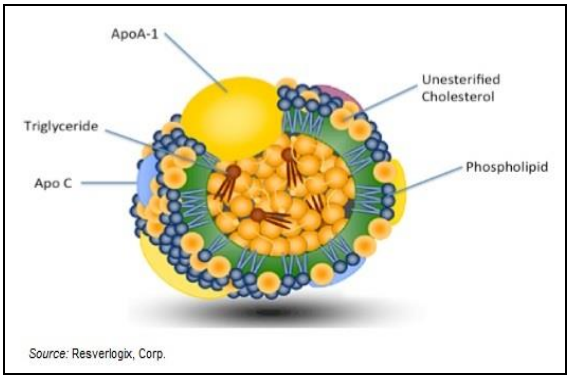
Induction of ApoA-I in the human hepatoma cell line Huh7 by 30 μM RVX-208 is inhibited by Actinomycin D (Act D).

Source: McLure et al., 2013

By targeting BET bromodomains, RVX-208 has a multimodal approach and impacts several key biological processes that play a role in vascular disease risk. First off, when RVX-208 binds to the BET protein, it triggers a cascade of events. RVX-208 induces ApoA-I mRNA production in human hepatocyte cell lines leading to an increase in ApoA-I gene transcription and eventually an increase in endogenous ApoA-I protein production (*above right*) (McLure *et al*., 2013). This results in the subsequent synthesis of new HDL particles.

RVX-208 Targeting ApoA-I, HDL, & Reverse Cholesterol Transport

Apolipoprotein A-I (ApoA-I) makes up approximately 70% of the protein found in HDL particles ("good cholesterol") and is secreted by the intestines and liver. ApoA-I is crucial for the synthesis and function of HDL (Zannis *et al*., 2006), and greater production of ApoA-I results in the formation of new HDL molecules. The newly formed HDL molecules have increased functionality because they are unfilled and flat, and thus have a greater ability to remove cholesterol out of plaques from arteries and reduce and/or prevent atherosclerosis. These HDL particles can effectively remove plaque via reverse cholesterol transport (RCT), which is a natural physiologic process by which cholesterol is transported out of arteries and subsequently to the liver for excretion out of the body in bile.



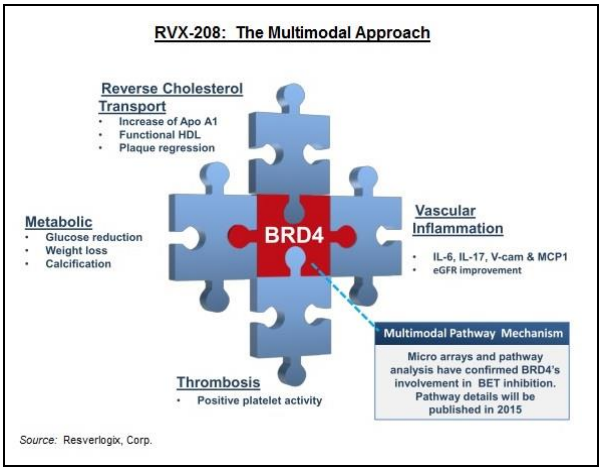
Source: Resverlogix, Corp.

RVX-208 Targeting Inflammatory & Metabolic Biomarkers

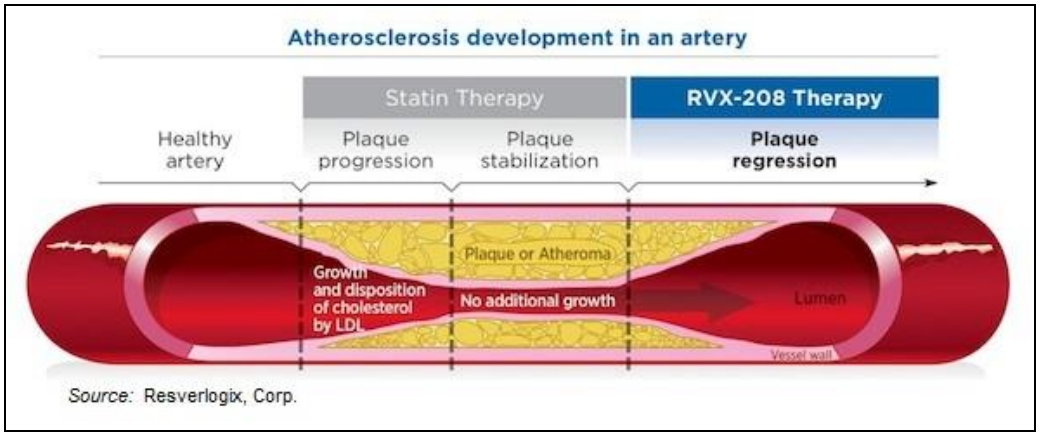
For the first several years of RVX-208 development, Resverlogix focused solely on the RCT mechanism for MACE reduction, and although it is plays an important role in the process, management has now shifted the company's focus to address other aspects of the drug's mechanism of action. Resverlogix has the only epigenetic bromodomain blood bank in the world. As of right now, we are still trying to figure out just what it means in terms of a strategic asset, but nevertheless, through microassays and pathway analyses conducted there, it was found that RVX-208 does indeed have a multimodal approach. Resverlogix believes that RVX-208:

- ✓ Reduces vascular inflammatory markers such as C-reactive protein (CRP), interleukin-6 (IL-6), interleukin-17 (IL-17), vascular cell adhesion molecule-1 (VCAM-1), monocyte chemotactic protein-1 (MCP1);
- ✓ Reduces metabolic risk markers of alkaline phosphatase (ALP) and glucose, and;
- ✓ Plays a part in platelet activity of thrombosis.

These multimodal aspects of RVX-208 explain the overall MACE reduction observed in certain populations within back-to-back clinical trials (*below*).



RVX-208's ability to increase ApoA-I production and thus enhance RCT activity could set itself apart from other HDL medications, making it an intriguing candidate for the treatment of atherosclerotic CVD. While the jury is still out on RVX-208, management believes that the drug is positioned to be one of the most promising drugs in development for the prevention and reduction of atherosclerotic related CVDs.



Addressing the Unmet Need in CVD

Cardiovascular disease is the most common cause of death in the world and future projections illustrate that the prevalence of CVD and associated expenses are anticipated to rise dramatically over the next several years. The need for new therapeutics that lower the CV risk is crucial to addressing the unmet clinical need and could alter the face of medicine. With the growing knowledge and insight into disease mechanisms, new approaches are being evaluated with the hopes of the discovery of novel therapeutic options for CVD.

Resverlogix is addressing the major problem of the unmet need in cardiovascular management. Over the last several years, there has been a great movement forward in cardiovascular care with statins and other therapies, but these only take up 30% of the market. There are some of new medications coming along such as the novel LDL modulators like PCSK9 that are designed to lower LDL, yet they only have a small impact on the unmet need in CV management and take up only a small part of the market.

The large market opportunity lies in the 70% unmet need of unmanaged cardiovascular issues that extend to other indications such as diabetes. According to the International Diabetes Federation, there are 387 million patients worldwide with diabetes, and this number is expected to rise to 592 million by 2035. While the majority of current therapies aim to manage glucose levels in diabetic patients, Resverlogix is taking a unique approach by looking at it from the point of view of reducing Major Adverse Cardiac Event (MACE) – the primary killer in both men and women. In a multinational study, 50% of people with diabetes died of cardiovascular disease, primarily heart disease and stroke (Moorish *et al*., 2001). Other sources cite up to 80% of patients with diabetes will develop and possibly die from CVD (Narayan *et al*., 2003 and Hogan *et al*., 2003). Furthermore, chronic kidney disease (CKD) is an extension of diabetes and also results in high CVD death rates, which Resverlogix is also looking to address.

Major Adverse Cardiac Events (MACE)

Many scientists, key opinion leaders and physicians believe that of all the biomarkers that are analyzed for providing prognostic predictability for cardiovascular risk, Major Adverse Cardiac Event (MACE) is the most crucial. Payer groups and health systems carefully assess MACE when looking at the potential reimbursement of a novel CVD drug. MACE includes several key markers of cardiovascular risk including worsening angina, worsening of peripheral artery pain and ischemia, prevention of percutaneous stent procedures, hospitalization for cardiac-related incidents, stroke, myocardial infarction and death. According to the 2015 AHA Statistics report, an estimated 85.6 million American adults (greater than 1 in 3) have one or more types of CVD. Many of these CVD patients will have some type of MACE during or after they have been diagnosed with heart disease. On average, more than 2,150 Americans die of CVD daily, which is approximately 1 death every 40 seconds (Mozaffarian *et al*., 2015).

The term MACE (major adverse cardiac events) came into use in the mid-1900s in reference to complications related strictly to percutaneous coronary interventions (PCIs) in hospital settings (Hermans *et al*., 1993 and Keane *et al*., 1994). Although there is no standard definition of MACE, it has become the most commonly utilized end point in cardiovascular clinical research today, and is reported for both short and long term outcomes involving various treatment regimens. MACE is used today as a composite of clinical events that typically include safety and effectiveness endpoints. There has been some controversy over the last decade within the medical community regarding the true value of MACE in clinical trials, as there is no standard definition for MACE and individual outcomes vary per study and inconsistencies often arise (Kip *et al*., 2008).

Clinical Overview of RVX-208

Resverlogix has completed many clinical trials to date (*below*). RVX-208 has been tested in nearly 1,000 patients in 12 countries, and clinical experience with RVX-208 has demonstrated that BET inhibitors can be both safe and efficacious. 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®).

Most recently, RVX-208 has completed two Phase 2b trials called 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 with RVX-208 treated patients reporting 6.5% MACE events while placebo group patients reported a total of 13.4% MACE events ($p<0.05$). This is a 44% reduction of events. Further analysis of patients with elevated vascular inflammation of CRP >2.0 mg/dL, a known risk marker for vascular inflammation, reported a 65% reduction of MACE. In September 2014, it was reported that CVD patients when treated with RVX-208 had a 55% ($p=0.02$) relative risk reduction (RRR) in MACE. Furthermore, this effect of RVX-208 on patients with diabetes mellitus was accentuated with a RRR in MACE that was reduced by 77% ($p=0.01$). This information is guiding Resverlogix in the planning and design of Phase 3 clinical study BETonMACE. As mentioned above, RVX-208 is on the verge of entering this Phase 3 clinical trial with final planning discussions underway. The Phase 3 trial (BETonMACE) will continue to focus on MACE reduction as the primary endpoint for the registration study.

Summary of RVX-208 Clinical Trials

Trial	Summary	Patients	Status	Initiated	Data Release
Phase 3	MACE Reduction BETonMACE	2000-4000	Pending	TBD	TBD
Phase 2b	Alzheimer's disease	45-60	Pending	TBD	TBD
Phase 2b	Pre-diabetes mellitus / effects of RVX-208 and ApoA-I production on glucose metabolism	20	Completed	Q4 2012	Q3 2014
Phase 2b ASSURE	26 week risk-stratified IVUS study in patients with low HDL	323	Completed	Q2 2011	Q2 2013
Phase 2b SUSTAIN	24 week single-dose safety, tolerability and efficacy in stable CVD patients with low HDL	176	Completed	Q3 2011	Q3 2012
Phase 2 ASSERT	12 week dose-ranging safety, tolerability and efficacy in stable CVD patient	299	Completed	Q4 2009	Q4 2010
Phase 1b/2a	28 day multiple dosing safety, tolerability and efficacy in healthy volunteers with low HDL	72	Completed	Q3 2008	Q3 2009
Phase 1 BE	Single dose bio-equivalency comparing capsule and tablet drug form	9	Completed	Q3 2009	N/A
Phase 1 BE	Single dose bio-equivalency	7	Completed	Q3 2009	Q4 2009
Phase 1a	First-in-man single ascending dose and 7-day multiple dosing	80	Completed	Q4 2007	Q1 2008

Source: Adapted from Resverlogix, Corp.

Future Clinical Development Plan for Phase 3 "BETonMACE"

Future development for Phase 3 "BETonMACE" trial planning is in progress. Resverlogix believes that a Phase 3 MACE trial could confirm health benefits in CVD, diabetes, and CKD, and that confirmation of this trial would establish a very strong value proposition for a Phase 3 registration trial. The main objective of the trial will be to confirm MACE reduction by RVX-208 as seen in SUSTAIN and ASSURE pooled analysis and also expand safety assessment. The study will be in a larger prospective setting with high-risk patients that have diabetes mellitus and low HDL-C (< 40 mg/dL who are post events). Management also plans to further explore the potential impact that RVX-208 may have on inflammation, the complement and coagulation pathways, as well as on platelet improvement in these high-risk patients in the future Phase 3 trial.

Resverlogix reiterates that RVX-208 is designed to increase ApoA-I and HDL, and through previous studies, it has been found that the drug is most successful in these types of patients. Treatment will be randomized 1:1 and patients will receive either placebo or 100 mg of RVX-208 twice daily added to standard of care rosuvastatin (Crestor®) therapy for an average of 18 months. A once daily formulation will be available in the future, but economically, the cost for formula conversion at this point does not make sense. BETonMACE will be conducted in 80-100 European and (potentially) U.S. sites and will be an adaptive trial with a minimum of 2,000 patients and the ability to go up to 4,000 patients if necessary.

The primary endpoint for the trial will be a 25-30% MACE reduction with RVX-208 as compared to the placebo. Resverlogix has defined MACE as the endpoint for the trial as: (1) death, including suddenly with no other reasonable explanation, (2) ischemic stroke, (3) non-fatal myocardial infarction, (4) hospitalization for worsening of angina, (5) revascularization with evidence of progressive anatomy or symptoms, and (6) congestive heart failure of ischemic etiology.

Clinical trial sites as well as the contract research organization (CRO) that will handle BETonMACE are already lined up. If all goes according to schedule, the first patient will be dosed at some point in the fourth quarter of this year. Resverlogix had meetings in April 2015 with the EMA (European Medicines Agency), followed by a meeting with the FDA in May 2015. As of June 22 2015, the company officially attained Phase 3 status with a European Regulatory Authority. We believe the program will cost in the area of $25 million and take about 3 years to complete. We note that exact costs will depend on how many patients are ultimately enrolled since the trial is currently setup to be adaptive. We look forward to learning more about the BETonMACE trial design and learning more about what the various regulatory bodies have to say regarding the proposed Phase 3 trial.

New Paradigm / Development Strategy for RVX-208

It is worth mentioning that cardiovascular disease Phase 3 clinical trials typically take two to five years to complete and require testing of a much greater population pool of patients, anywhere from several hundred to several thousand patients. Last year, Resverlogix was in discussions with various parties regarding the sale of RVX-208 in the context of acute coronary disease in a Phase 3 trial. This was projected to cost around $600 million, which was a difficult deal to close. Currently, Resverlogix has repositioned itself for Phase 3 clinical trial planning involving patients with diabetes, decreased levels of HDL with coronary artery disease. There is an unmet need in these high-risk patients as they are more likely to suffer from MACE than CVD patients. Resverlogix believes, and we agree, that this is a much more manageable Phase 3 process. This presents as a large savings in both time and cost related expenses. The Phase 3 clinical trial planning is partly based on existing FDA guidance for Diabetes CVD Safety.

It is also important to mention that RVX-208 has the potential to expand to other indications, and Resverlogix plans on conducting parallel or subsequent Phase 3 trials in the future. For instance, Resverlogix plans on embedding a sub-study of CKD patients within "BETonMACE" and a future Phase 3 peripheral artery disease (PAD) study may be on the horizon. Additionally, we anticipate that Resverlogix will file for an Orphan indication in the next few months, but we are not exactly sure the path they plan to go down at this point.

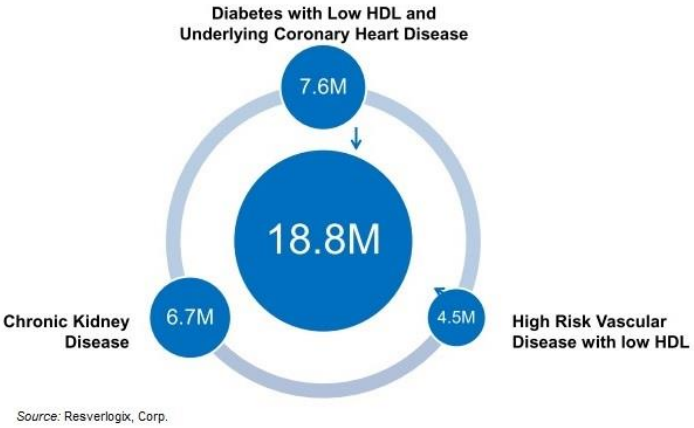
Resverlogix applied for NIH funding for a Phase 2 Alzheimer's Study of 60 patients, but did not receive the first round of funding. Management plans to reapply in June 2015 and will include additional data to support their trial design. Each patient in the study will require two lumbar punctures for CSF analysis of Apo-I levels at initiation and six months following treatment, as it has been discussed that Apo-AI has profound impacts in the brain. Resverlogix is also pursuing a parallel path regarding the ability of RVX-208 to destroy β-amyloid plaques potentially via the complement pathway and non-toxic rendering of Apo-AI/ Aβ40. Management is currently in discussions with Cleveland Clinic's Dr. Jeff Cummings regarding a future trial to explore this effect in more depth. We believe that pursuing this path would lead to a shorter, much more affordable trial, anticipated to cost around $1 million, and would not have to rely on NIH funding.

Resverlogix hopes that a successful pharmaceutical partnership or licensing agreement for RVX-208 will help overcome the cost burden, lengthy development time, and high attrition rates, while helping to advance the drug through future clinical trials and drug development stages. We are hopeful that this will ultimately lead to commercialization of the drug. Through extensive modeling and ongoing outreach to key opinion leaders (KOLs), management believes that if RVX-208 shows a 25% relative risk reduction of MACE in the Phase 3 trial, the pharmaco-economics of RVX-208 could be quite appealing for the near future. The company believes it will cost around $2,200-$2,500 per year once it hits the market, similar to AstraZeneca's Brilinta® (ticagrelor). It's important to remember that this is a sliding scale and that numbers needed to treat (NNT) and the cost to prevent an event must also be taken into consideration. For example, the ODYSSEY LONG TERM trial showed that alirocumab (Sanofi/Regeneron Pharmaceuticals), an investigational monoclonal antibody that inhibits PCSK9 (proprotein convertase subtilisin/kexin type 9), was significant in lowering LDL cholesterol by 62% and also illustrated a 50-55% reduction in MACE. These results appear to be promising, but with a reported $5,000-$8,000 per year treatment cost per patient, some would argue that the cost to prevent an event could be in the area of $500,000-$700,000 per event as per the analysis of the NNT, in this case 90-92 for alirocumab (vs. 21 for RVX-208 from the SUSTAIN and ASSURE trials), based on annualized treatment therapy. If approved, and if RVX-208 costs mirror what management is currently predicting, we believe this could be a game changer from the viewpoint of payer groups.

Resverlogix is confident that RVX-208 is now well-positioned to move forward on an expedited and more affordable registration path. Resverlogix believes there are early revenue opportunities that include regional licensing deals, with discussions underway in high need areas such as China, Russia and the Middle East. By pursuing this parallel development program, Resverlogix hopes to expand and speed up revenue streams.

Conclusion & Valuation Methodology

Resverlogix's only clinical stage candidate, RVX-208, is the first selective BET bromodomain inhibitor in clinical trials for high-risk vascular disease. RVX-208 is targeting a very specific patient population with low HDL, diabetes and chronic kidney disease with a high cardiovascular risk for increased MACE. Based on pooled Phase 2 data, patients who respond best to RVX-208 are also taking AstraZeneca's Crestor® (rosuvastatin), but we do not suspect that will be included in the final label. According to internal analysis conducted by Resverlogix, there is a minimum high-risk market for RVX-208 of 18.8 million patients.



Source: Resverlogix, Corp.

To value Resverlogix, we use metrics directly out of the January 2015 financial statements and the methods for which management values the existing 75.2 million royalty preferred shares. These are preferred shares that are entitled to dividends in the amount of 6-12% of net RVX-208 revenue.

> For fair value measurement purposes, the royalty preferred shares liability has been categorized within level 3 of the fair value measurement hierarchy. The fair value of the royalty preferred shares is based on management's judgments, estimates and assumptions which include significant unobservable inputs including the timing and amounts of discounted risk adjusted future net cash flows derived from the Apo-A-I applications rights. The estimate incorporates the following assumptions: a cumulative probability rate as at January 31, 2015 of generating forecasted future cash flows of 21% for high risk vascular disease with low HDL excluding diabetes mellitus and 14% for diabetes mellitus, and a cumulative probability rate as at April 30, 2014 of generating forecasted future cash flows of 21% (reflecting in each case, among other factors, the Company's clinical results including those of the ASSURE trial); a discount rate of 25.0% as at April 30, 2014 and 24.0% as at January 31, 2015; commencement of revenue in 2020 as at April 30, 2014 and between 2020 and 2023 (based on various possible probability-weighted clinical development paths) as at January 31, 2015; RVX-208 market shares percentages; and product pricing.

Management gave us some pretty good inputs for our valuation model – including 21% probability for high-risk CVD and 14% for diabetes mellitus. We are throwing in another indication, chronic kidney disease, with 10% probability. Management told us that the product will likely launch in 2020, with sales ramping up over the next several years. We are assuming peak sales in 2025. Management also gave us the 24% discount rate, which we believe is a fair estimate. We are using a forward price-to-sales multiple of 5.0x (industry average).

The obvious missing variable is peak sales, which we are modeling at $4.75 billion based on $2.5 billion in high-risk CVD, $1.5 billion in DM, and $0.75 billion in CKD. From that $4.75 billion number, we are backing-out 9% royalty (range 6-12%) on the preferred shares. As a reminder, we arrived at these sales figures by taking a look at the existing market for at risk CVD patients, including approved drugs like Lipitor® ($13.7 billion peak in 2006), Crestor® ($6.6 billion peak in 2011, $5.5 billion in 2014), Lovaza® ($1.1 billion peak in 2013). We are also using several estimates we found for late-stage clinical candidates such as Amgen's and Regeneron/Sanofi's PCSK9 inhibitors, evolocumab and alirocumab, respectively. We are also including CETP inhibitors, such as Merck's anacetrapib and Eli Lilly's evacetrapib, on the list of comparable drugs to help us understand the peak sales potential for RVX-208. Wall Street consensus estimates, as well as independent analyst estimates from websites such as TheStreet.com, FierceBiotech, Benzinga, and Seeking-Alpha, for these drugs range between $3 billion to $10 billion. We believe RVX-208, although flying significantly below the radar of these other drugs, has similar peak sales potential.

We are also assuming that the company will issue shares to pay off the CDN $68.8 million in debt due August 28, 2017. We are using the current stock price of $2.02, less 10% discount, to calculate that it would take approximately 37.8 million in new shares required to pay off the existing debt. The current fully diluted share count is 121.2 million. Thus, we are using an adjusted share count of 159 million in our valuation model.

We believe that strong patent position and pharmaco-economics of RVX-208, combined with a management skill set surrounding CVD and diabetes and a novel approach to addressing the residual risk in high need CVD patients, allows for Resverlogix to be in an interesting position. The company recently securing access to approximately $37 million in new capital through licensing and stock purchase agreements with Hepalink and Eastern Capital should fully fund the Phase 3 BETon MACE program.

On the other hand, we still believe that there are certain challenges that Reservlogix will continue to face, and these include the delay in development of RVX-208, ongoing safety analysis of elevated liver signals for RVX-208, and significant operating losses that are building up year after year. We are still not sure what type of cardiovascular clinical trials the FDA and EMA will require of RVX-208, and we are still uncertain regarding the outcome of Phase 3 BETonMACE. As such, although we still see upside to the story, we are maintaining our 'Hold' rating and price target of $3.25 given the potential risks involved and the fact that data from BETonMACE will not likely be available until 2018.

Resverlogix Corp.
Income Statement

ResverLogix	Apr. 2014 FY-14	Jul. 2014 Q1	Oct. 2014 Q2	Jan. 2015 Q3	Apr. 2015 Q4	Apr. 2015 FY-15	Apr. 2016 FY-16	Apr. 2017 FY-17	Apr. 2018 FY-18
RVX-208	$0	$0	$0	$0	$0	$0	$0	$0	$0
Licensing & Collaborative	**$0**	**$0**	**$0**	**$0.0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0.0**	**$0**	**$0**	**$0**	**$0**	**$0**
CoGS	$0	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-	-
R&D Expense (net)	$9.8	$0.7	$0.8	$1.0	$1.2	$3.6	$10.0	$15.0	$20.0
SG&A Expense	$4.2	$1.0	$1.1	$1.0	$1.0	$4.1	$4.5	$5.0	$5.5
Operating Income	($14.0)	($1.8)	($1.8)	($1.9)	($2.2)	($7.7)	($14.5)	($20.0)	($25.5)
Operating Margin	-	-	-	-	-	-	-	-	-
Net finance Activities	$53.1	$8.4	($2.7)	$1.3	$1.0	$8.1	$5.0	$5.0	$5.0
Other Gain / Loss	$16.2	$0.0	$0.0	($1.1)	($0.1)	($1.2)	$0.0	$0.0	$0.0
Pre-Tax Income	$55.2	$6.7	($4.5)	($1.7)	($1.3)	($0.8)	($9.5)	($15.0)	($20.5)
Taxes & Other	$0.1	$0	($1.2)	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*100%*
Net Income	$55.1	$6.7	($3.3)	($1.7)	($1.3)	($0.8)	($9.5)	($15.0)	($20.5)
Reported EPS	**$0.70**	**$0.08**	**($0.04)**	**($0.02)**	**($0.02)**	**($0.01)**	**($0.11)**	**($0.16)**	**($0.21)**
YOY Growth	-	-				-		-	-
Shares Outstanding	78.9	85.3	85.4	85.7	85.7	85.5	90.0	95.0	100.0

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

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