



## MANAGEMENT'S DISCUSSION & ANALYSIS – Year Ended December 31, 2022

This Management's Discussion and Analysis ("MD&A") of Resverlogix Corp.'s operations and financial position should be read in conjunction with the audited consolidated financial statements and the notes thereto for the years ended December 31, 2022 and 2021. This MD&A is dated March 31, 2023. Our financial statements have been prepared by management in accordance with International Financial Reporting Standards ("IFRS") and comprise Resverlogix Corp. ("Resverlogix" or the "Company") and its wholly-owned subsidiary Resverlogix Inc. (together referred to as the "Group"). All amounts in the following MD&A are stated in US dollars unless otherwise stated. References to "we", "us" or "our" mean Resverlogix Corp. and its subsidiary unless the context otherwise requires.

### Cautionary Statement Regarding Forward-Looking Information

This MD&A contains forward-looking information within the meaning of applicable Canadian securities legislation. Forward-looking information is often, but not always, identified by the use of words such as "believes", "anticipates", "plans", "intends", "will", "should", "expects", "continue", "estimate", "forecasts" and other similar expressions. In particular, this MD&A includes forward-looking information related to:

- aim to commercialize or license to a pharmaceutical partner our products for the treatment of unmet medical needs related to prevention of: major adverse cardiovascular events in patients with diabetes mellitus and chronic kidney disease; post COVID-19 conditions and additional indications;
- aim to carry out trials on our products for the treatment of unmet medical needs related to major adverse cardiovascular events in patients with higher risk such as acute coronary syndrome, diabetes mellitus and chronic kidney disease, post COVID-19 conditions and additional indications, and the timing of such trials;
- plans related to our post COVID-19 conditions, cardiovascular disease and other programs and the planning and design of clinical trials as part of each of these programs;
- expectations relating to the timing of significant clinical trial milestones;
- the function and effectiveness of apabetalone, also referred to as RVX-208;
- the development of new compounds and the potential impact of these compounds on multiple diseases;
- aim to obtain regulatory approval for our products;
- expectations with respect to the cost of clinical trials and commercialization of our products;
- projected competitive conditions with respect to our products;
- anticipated sources of revenue and the estimated market for our products;
- expectations regarding the protection of our intellectual property;
- business strategy;
- intentions with respect to dividends; and
- potential milestone payments and royalties pursuant to the license agreements with Shenzhen Hepalink Pharmaceutical Co., Ltd. ("Hepalink") and Medison Pharma Ltd.

Readers are cautioned that our expectations, beliefs, projections, and assumptions used in preparation of such information, although considered reasonable at the time of preparation, may prove to be wrong, and as such, undue reliance should not be placed on forward-looking statements. With respect to forward-looking statements contained in this MD&A, we have made key assumptions including:

- general business and economic conditions;
- interest rates;
- the timing of the receipt of regulatory and governmental approvals for research and development projects;

- the availability of financing for research and development projects, or the availability of financing on reasonable terms;
- the ability to refinance existing indebtedness on reasonable terms upon maturity;
- the impact of changes in Canadian dollar-US dollar and other foreign exchange rates on our costs and results;
- market competition;
- our ability to attract and retain skilled staff; and
- ongoing relations with employees and with business partners.

Our actual results, events or developments could be materially different from those expressed or implied by these forward-looking statements. We can give no assurance that any of the events or expectations will occur or be realized. By their nature, forward-looking statements are subject to numerous known and unknown risks and uncertainties including but not limited to:

- risks related to the early stage of our products;
- uncertainties related to clinical trials and product development;
- uncertainties related to current economic conditions;
- risks related to rapid technological change;
- uncertainties related to forecasts and timing of clinical trials and regulatory approval;
- competition in the market for therapeutic products to treat cardiovascular disease, neurodegenerative diseases, diabetes mellitus and other high risk vascular diseases;
- risks related to potential product liability claims;
- availability of additional financing and access to capital for research and development, clinical trials, and regulatory approval;
- market acceptance and commercialization of our products;
- the availability and supply of raw materials, including supplies of sufficient active pharmaceutical ingredients for large clinical trials and future commercial production;
- risks related to the effective management of our growth;
- potential reliance on partnering agreements to provide support for discovery and development efforts, and on corporate sponsors, pharmaceutical companies, and others to successfully develop and commercialize our technology;
- the willingness of health care insurers and other organizations to pay for our products;
- risks related to our reliance on key personnel;
- risks related to the regulatory approval process for the manufacture and sale of non-therapeutic and human therapeutic products; and
- our ability to secure and protect our intellectual property, and to operate without infringing on the proprietary rights of others or having third parties circumvent the rights owned or licensed by us.

You should also carefully consider the matters discussed under “Risk Factors” in our Annual Information Form and other documents we file from time to time with securities authorities, which are available through SEDAR at [www.sedar.com](http://www.sedar.com). Additionally, risks and uncertainties are discussed on page 14 of this MD&A.

The forward-looking statements contained in this MD&A are expressly qualified by this cautionary statement. We disclaim any intention and have no obligation or responsibility, except as required by law, to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

## Going Concern

Our success is dependent on the continuation of our research and development activities, progressing the core technologies through clinical trials to commercialization or a strategic partnership, and our ability to obtain additional financing. It is not possible to predict the outcome of future research and development programs, our ability to fund these programs in the future, or to secure a strategic partnership, or the commercialization of products. To date, we have not generated any product revenue. We have incurred significant losses to date, and with no assumption of revenues, we are dependent on our ability to raise additional financial capital by continuing to demonstrate the successful progression of our research and development activities if we are to remain as a going concern.

As at December 31, 2022, we had \$0.04 million of cash. We need to raise additional capital to fund research, development and corporate activities over the next year or we may be forced to cease operations. As at December 31, 2022, we were committed to pay \$14.1 million of current trade and other payables, \$1.5 million for research and development over the next twelve months, and \$0.4 million of lease liabilities over the next twelve months. Furthermore, our \$6.0 million secured convertible debenture with Hepalink is due on May 13, 2024. As at December 31, 2022, the Group is also party to a commercialization partnership; the parties have mutually

agreed to temporarily pause services and the Group is not obligated as at December 31, 2022 to incur pre-commercialization costs over the next twelve months. The parties may or may not resume services over the next twelve months.

Our cash as at December 31, 2022 is not sufficient to fund our contractual commitments or our planned business operations over the next year. Therefore, we will have to raise additional capital to fund our contractual commitments and our planned business operations. We continue to pursue and/or examine several sources of additional capital including co-development, licensing, rights or other partnering arrangements, procurement arrangements, private placements and/or public offerings (equity and/or debt). However, there is no assurance that any of these measures will be successfully completed.

The Company will also require additional capital to fund research, development, and corporate activities beyond the next year. The Company will continue to explore alternatives to generate additional cash including raising additional equity and/or debt and/or partnering; however, there is no assurance that these initiatives will be successful.

These conditions result in a material uncertainty which may cast significant doubt on our ability to continue as a going concern. If we are not able to raise capital, we may be forced to cease operations.

## Overview

### Company Overview

Resverlogix is a late-stage clinical biotechnology company dedicated to improving the lives of patients with chronic illnesses. We focus on the development of a new class of therapeutics, bromodomain and extraterminal domain (“BET”) protein inhibitors. BET proteins play a central role in epigenetics and enable the transcription of disease-causing genes. Our small-molecule BET inhibitors are designed to exploit this central epigenetic role to regulate gene expression and tackle the root causes of chronic diseases.

Due to the extensive role of BET proteins in many cell types throughout the human body, BET inhibitors can simultaneously benefit multiple pathological processes. Several complex chronic conditions, including cardiovascular disease (“CVD”), diabetes mellitus (“DM”), chronic kidney disease (“CKD”), vascular cognitive impairment (“VCI”), non-alcoholic fatty liver disease (“NAFLD”), post COVID-19 conditions (“PCC”), and pulmonary arterial hypertension (“PAH”), share common underlying biological processes that drive disease progression and are associated with negative patient outcomes. Combinations of inflammation, calcification, fibrosis, dyslipidemia, metabolism, and cell proliferation contribute to these conditions, and many others.

Most conventional pharmaceuticals target single proteins, based on the expectation of interrupting a critical step in the development of a disease. This has been the template for decades: one disease, one target, one compound. While this approach can be very effective in treating diseases that result from the dysregulation of a single gene or protein, we believe it is limited in its ability to combat diseases with many contributing factors – such as CVD, CKD, and DM. By aiming upstream of typical pharmaceuticals, and targeting gene transcription, we can effectively regulate expression of entire signaling pathways. Our goal is to define a new drug development template: one compound, multiple signaling pathways, shared by multiple complex diseases.

### Apabetalone (RVX-208)

Apabetalone, the first BET inhibitor in advanced clinical trials outside of oncology, is our lead compound and a selective inhibitor of the second bromodomain (BD2) on BET proteins. With robust intellectual property protection (extending to 2040), over 40 peer-reviewed scientific publications, 4200 patient-years of Food & Drug Administration (“FDA”) reviewed safety data, detailed proteomic and transcriptomic analysis, as well as FDA breakthrough therapy designation, apabetalone is a thoroughly characterized and de-risked asset.

The largest study of apabetalone to date, BETonMACE, was a Phase 3, multi-centered, placebo-controlled, clinical trial, investigating apabetalone for the secondary prevention of major adverse cardiac events (“MACE”), in a high-risk population. Trial participants treated with apabetalone saw reduced incidence of MACE (10.9%), a composite endpoint of cardiovascular (“CV”) death, non-fatal myocardial infarction (“MI”), and stroke, compared to the patients receiving a placebo (12.4%)<sup>1</sup>. The cardioprotective benefit of apabetalone was more pronounced in the prespecified subgroup of trial participants with CKD comorbidity, where apabetalone treatment was associated with a 50% hazard reduction in MACE<sup>2</sup>. Apabetalone also significantly reduced the hazard of hospitalization for congestive heart failure (“CHF”) <sup>3</sup>, a key secondary endpoint in the trial. Patients receiving apabetalone saw a 41% hazard reduction in first occurrence of hospitalization for CHF compared to those receiving standard of care treatment alone.

Another significant finding that emerged from BETonMACE is the potentially synergistic benefit seen in trial participants who were administered sodium-glucose cotransporter-2 (“SGLT2”) inhibitors concomitantly with apabetalone. Among patients receiving SGLT2

<sup>1</sup> <https://jamanetwork.com/journals/jama/fullarticle/2763951>

<sup>2</sup> [https://journals.lww.com/cjasn/Abstract/2021/05000/Effect\\_of\\_Apabetalone\\_on\\_Cardiovascular\\_Events\\_in.9.aspx](https://journals.lww.com/cjasn/Abstract/2021/05000/Effect_of_Apabetalone_on_Cardiovascular_Events_in.9.aspx)

<sup>3</sup> <https://cardiab.biomedcentral.com/articles/10.1186/s12933-020-01199-x>

inhibitors a 65% hazard reduction in a composite of MACE and hospitalization for CHF was observed in those treated with apabetalone compared to placebo. This finding, along with other benefits seen in this group, contributed to filing three new patents related to the combination of SGLT2 inhibitors and BET inhibitor for the treatment of CVD, type 2 DM, and CKD.

Indication	Phase 1	Phase 2	Phase 3
<b>High-Risk Cardiovascular Disease</b> <i>Type 2 Diabetes Mellitus, Low HDL-C, and Recent ACS</i>		ASSERT [2b] SUSTAIN [2b] ASSURE [2b]	BETonMACE (Completed) BETonMACE2 (Ready)
<b>High-Risk Chronic Kidney Disease</b> <i>Type 2 Diabetes Mellitus, CVD, and CKD</i>			BETonCKD (Ready)
<b>Post COVID-19 Conditions</b>			Phase 2/3 (Planned)
<b>Pulmonary Arterial Hypertension</b>	APPRoACh-p (Completed)	APPRoACh-2 (Planned)	
<b>Vascular Cognitive Impairment</b>			BETonMACE (Subgroup)
<b>Combined Patient-years of Safety</b>			<b>4200</b>

#### Development stage overview for apabetalone in targeted clinical indications

Following the outcomes of BETonMACE, the FDA granted breakthrough therapy designation for apabetalone in combination with top standard of care, including high-intensity statins, for the secondary prevention of MACE in patients with type 2 DM and recent acute coronary syndrome. According to the FDA, this designation is intended to expedite the development and review of new drugs to address the unmet medical need in the treatment of serious or life-threatening conditions. As a result, apabetalone is eligible for intensive guidance and expedited review of clinical trial design and protocols along with planning to accelerate the manufacturing development strategy of the drug.

Through numerous clinical studies, apabetalone has established a strong track record of clinical safety and tolerability in multiple patient populations. Combined, over 1,800 patients have received apabetalone, and more than 4,200 patient-years of safety data has been accumulated and analysed for increased risk of adverse events and off-target effects. Apabetalone is well tolerated and has an adverse event profile that compares favourably to placebo controls. Selectively targeting BD2 is an important contributor to apabetalone's clinical safety, and a key distinguishing feature from other BET inhibitors, many of which are non-selective. Pan-BET inhibitors – which bind both bromodomains equally – have been found to disrupt the structure of chromatin and alter the fundamental functions of cells, potentially leading to cell death. BD2-selective inhibitors, on the other hand, are able to inhibit gene transcription while maintaining chromatin structure and cell viability.

## Year End 2022 Highlights

### Clinical Development of Apabetalone

#### Cardiovascular Disease

Design and planning activity for BETonMACE2, a planned registration-enabling study of apabetalone in high-risk CVD patients with type 2 DM, was completed throughout 2022. Apabetalone's breakthrough therapy designation has enabled us to work closely with the FDA and receive timely feedback and guidance on the BETonMACE2 study protocol. Trial design has been guided by key findings from BETonMACE, including the strong positive impact of apabetalone on reducing CHF hospitalizations, its cardioprotective benefit in CKD patients, and the potential synergy with SGLT2 inhibitors. BETonMACE's primary endpoint, a composite of MI, stroke, and cardiovascular death, will be expanded to include hospitalizations due to CHF. The populations that experienced the most benefit from apabetalone in BETonMACE will be expanded for the upcoming trial. All patients are expected to receive SGLT2 inhibitor alongside the study drug, and the target proportion of CKD patients is anticipated to be significantly higher than it was for BETonMACE. BETonMACE2 is also expected to enroll more patients than BETonMACE, improving the likelihood of statistically significant findings. We believe these study parameters will best demonstrate apabetalone's benefit in treating cardiovascular disease. Subject to regulatory approval and securing financing, BETonMACE2 is expected to begin recruiting patients in 2023.

#### Post COVID-19 Conditions

Following the conclusion of our Phase 2 study (NCT04894266), Resverlogix was granted a Type C meeting with the FDA to discuss an updated protocol for evaluating apabetalone in COVID-19 and a roadmap towards registration. Based on guidance from this meeting and the compelling opportunity for apabetalone to benefit patients, we announced that future development of apabetalone for COVID-

19 will focus on the treatment of Post COVID-19 Conditions (“PCC”), colloquially known as long-COVID. The US Centers for Disease Control and Prevention (“CDC”) estimates<sup>4</sup> that as many as one-in-three adults will experience PCC symptoms following COVID-19 infection. A growing body of evidence also highlights long-term risk of negative cardiovascular outcomes in COVID-19 survivors<sup>5</sup>. We believe apabetalone is well positioned to treat PCC and reduce cardiovascular risks in high-risk patients. Planning for a Phase 2/3 trial of apabetalone in PCC is underway and expected to be completed in 2023 or 2024, pending all necessary regulatory approval and securing financing.

### **Pulmonary Arterial Hypertension**

In March 2022, results of our pilot study of apabetalone in PAH, APPRoACH-p, were published in the prestigious American Journal of Respiratory and Critical Care Medicine<sup>6</sup>. The article highlighted improvements in key study endpoints, including pulmonary vascular resistance, stroke volume, and cardiac output, among apabetalone-treated trial participants. The encouraging results of this study pave the way for the larger multi-centered APPRoACH-2 trial, in collaboration with researchers at the Quebec Heart and Lung Institute, Laval University, who led the pilot study.

### **Publications and Presentations**

As leaders in the field of epigenetic therapeutics, we believe it is our responsibility to participate in the scientific community and publish our findings in peer-reviewed scientific journals, whenever possible. In 2022, we published several articles on our pre-clinical and clinical work. In June we published a major breakthrough in the understanding of BD2-selective BET inhibitors. A new role for BET protein BRD4 was discovered, in maintaining the structure of chromatin (a compact, densely coiled structure made up of DNA and proteins, and found in the nucleus of our cells). For years it has been understood that both BD2-selective and non-selective (pan) BET inhibitors can both interrupt gene transcription by preventing the formation of transcription complexes at the site of certain genes. However, prior to this research, it was not understood that BD2-selective BET inhibitors prevent transcription while maintaining chromatin structure, while pan-BET inhibitors do not. This finding provides a potential mechanism for the important differences in clinical safety outcomes observed between BD2-selective and non-selective BET inhibitors and highlights the safety of BD2-selective inhibitors like apabetalone.

Additional articles highlighting apabetalone’s potential beneficial impact on Fabry’s disease, NAFLD, and CVD<sup>7</sup> were published in 2022. Fabry disease is a genetic disorder that affects lipid metabolism, resulting in systemic inflammation that contributes to life-threatening consequences in multiple organs – such as the heart and kidneys. Using immune cells donated by Fabry disease patients, our team demonstrated that apabetalone treatment alleviates inflammatory processes and oxidative stress. This finding suggests a potential role for apabetalone in the treatment of Fabry’s disease. Analysis of BETonMACE clinical data, using a validated measure of NAFLD fibrosis score found that apabetalone treatment was associated with reduced incidence of MACE and CHF in NAFLD patients. NAFLD is common among type 2 DM patients and is linked to higher cardiovascular risk. Finally, an article published in early 2023 further detailed the cardiometabolic effects of apabetalone. Using a diet-induced obesity mouse model, our team replicated the pro-inflammatory signaling seen in obese patients, who are at high risk of type 2 DM and CVD. The research demonstrated that apabetalone counters inflammatory signaling, providing mechanistic insight into how it may reduce CVD risk in obese patients.

Members of our R&D and clinical development teams participated in leading scientific conferences during 2022, including American Heart Association Scientific Sessions, American College of Cardiology Scientific Sessions, European Society of Cardiology Congress, and Clinical Trials on Alzheimer’s Disease Congress. These articles and presentations not only showcase apabetalone to the global scientific community and allow us to connect with thought leaders in the space, but also publicizes concrete, peer-reviewed evidence of apabetalone’s safety and efficacy. Our comprehensive body of evidence, and detailed mechanistic understanding of apabetalone, guides our clinical development and lends credibility in our discussions with potential partners.

### **Corporate Developments**

#### **Financing and Partnership Activities**

In 2022, Resverlogix pursued multiple opportunities for financial and development partnerships. We are actively seeking non-dilutive financing options to fund apabetalone’s clinical programs, including co-development, licensing, rights or other partnering arrangements, and procurement arrangements. Given the potential synergistic benefits of apabetalone and SGLT2 inhibitor co-administration seen in BETonMACE, and our subsequent patent applications, there may be mutually beneficial partnering opportunities with pharmaceutical companies that have SGLT2 inhibitors in their portfolio. Although, it should be noted that our

<sup>4</sup> <https://www.cdc.gov/nchs/covid19/pulse/long-covid.htm>

<sup>5</sup> <https://www.nature.com/articles/s41591-022-01689-3>

<sup>6</sup> <https://www.atsjournals.org/doi/abs/10.1164/rccm.202109-2182LE>

<sup>7</sup> <https://www.resverlogix.com/science-and-programs/publications>

partnering efforts are not limited to producers of SGLT2 inhibitors. Our partnering discussions are ongoing. We will provide updates regarding significant developments related to financing and partnering as appropriate.

### Private placements

In March 2022, we issued 4,727,192 equity units at CAD\$0.48 per unit pursuant to a private placement for gross proceeds of \$1.8 million (CAD\$2.3 million). Each equity unit consists of one common share and one common share purchase warrant. Each warrant is exercisable at a price of CAD\$0.50 per underlying common share for a period of either three or five years from the closing of the private placement.

In April 2022, we issued 400,000 equity units at CAD\$0.48 per unit pursuant to a private placement for gross proceeds of \$0.2 million (CAD\$0.2 million). Each equity unit consisted of one common share and one common share purchase warrant. Each warrant is exercisable at a price of CAD\$0.50 per underlying common share for a period of three years from the closing of the private placement.

In June 2022, we issued 2,090,454 equity units (including 1,923,787 equity units issued to a relative of the Chief Executive Officer / Chairman of the Company) at CAD\$0.30 per unit pursuant to a private placement for gross proceeds of \$0.5 million (CAD\$0.6 million). Each equity unit consisted of one common share and one common share purchase warrant. Each warrant is exercisable at a price of CAD\$0.30 per underlying common share for a period of three years from the closing of the private placement.

In August and September 2022, we issued 11,494,256 equity units (including 666,667 equity units issued to an officer of the Company to settle CAD\$0.2 million of promissory notes) at CAD\$0.24 per unit pursuant to a private placement for gross proceeds of \$2.1 million (CAD\$2.8 million). Each equity unit consisted of one common share and one common share purchase warrant. Each warrant is exercisable at a price of CAD\$0.30 per underlying common share for a period of five years from the closing of the private placement.

### Hepalink Convertible Debenture

On May 13, 2021, we closed a \$6.0 million secured convertible debenture (the “Debenture”) with a subsidiary of Hepalink. The Debenture bears interest at 10% per annum. During the year ended December 31, 2022, the maturity date of the Debenture, and the corresponding payment date of interest thereon, were both extended by one year from May 13, 2022 to May 13, 2023. The amendment was accounted for as a debt modification. A modification gain of \$0.4 million, related to the extension of the maturity date, was recognized within accretion on the statement of comprehensive loss. Incremental debt issuance costs of \$5 thousand were added to the carrying value of the convertible debenture. Subsequent to December 31, 2022, the Debenture was further amended to extend the maturity date to May 13, 2024, and to increase the interest rate to 12% per annum effective May 14, 2023.

Hepalink may elect to convert the principal amount of the Debentures and accrued and unpaid interest thereon into common shares of the Company at a conversion price equal to the lesser of CAD\$0.93 per share and the 5-day volume weighted average trading price of the common shares on the date of conversion. The Company granted Hepalink a security interest in all of its assets, including its patents and other intellectual property, as security for its obligations under the Debenture. In addition, Hepalink received 300,000 common share purchase warrants exercisable for a period of four years from the grant date at a price of CAD\$0.93 per share.

### Licensing

Under the terms of a licensing agreement between us and Hepalink, Hepalink has the exclusive rights to distribute and market apabetalone in China, Hong Kong, Taiwan, and Macau (the “Territories”), for all indications.

The license between us and Hepalink provides for certain milestone payments based on net sales of RVX-208 in the Territories. The annual sales milestones range from 500 million renminbi (“RMB”) to 10 billion RMB (US\$72 million to US\$1.4 billion, incorporating the period end spot exchange rate), with Resverlogix being eligible to receive sales-based milestone payments from Hepalink ranging from US\$5 million to US\$90 million. In addition, Hepalink shall pay a royalty of 6% of annual net sales of RVX-208 in the Territories. The royalty is subject to an adjustment mechanism that may reduce the royalty rate to a minimum of 4% in the event that certain annual sales milestones are achieved and applicable regulatory authorities in the Territories reduce the approved selling price of RVX-208. Hepalink will be responsible for all clinical and development costs in the Territories, including a patient population that was included in the Company’s Phase 3 BETonMACE trial. We are contractually obligated to pay a fee to the financial advisor involved with the transaction equal to 3.5% on the first \$10.0 million of payments, if any, received from Hepalink pursuant to the license, and 2.5% on amounts above \$10.0 million, up to a maximum of \$1.0 million of fees. As at December 31, 2022, these potential payments do not satisfy the criteria for recognition as a liability.

The aforementioned license agreement between us and Hepalink was amended effective June 17, 2022 such that we agreed to pay up to CAD\$8.0 million of clinical development costs associated with apabetalone, including a global Phase 3 clinical trial (which we intend to perform in any event), in the Territories and if the costs incurred by Resverlogix after May 1, 2020 and up to December 31, 2023 total less than CAD\$8 million, then Resverlogix and Hepalink shall negotiate a mutually-agreeable timeframe regarding any difference, in principle by not later than June 30, 2024.

Under the terms of a licensing agreement between us and Medison Pharma Ltd., Medison has the exclusive rights to distribute and market apabetalone in Israel. Resverlogix is eligible to receive from Medison, ascending double digit royalties based on future net sales of the product in the licensed territory. Medison will be responsible for all regulatory, sales and marketing costs for apabetalone in the licensed territory.

### **Commercialization Partnership with EVERSANA**

In June 2021, we entered into a partnership with EVERSANA Life Science Services, LLC (“EVERSANA”). EVERSANA supported the planned commercialization of apabetalone for the treatment of COVID-19 in the United States, Canada and any other countries agreed upon in the future as Emergency Use Authorization and/or a New Drug Application or equivalent if issued or approved in said countries. EVERSANA provides fully integrated commercialization services including market access, agency services, clinical and commercial field teams, medical science liaisons, channel management, patient services, health economics and outcomes research, and compliance. For providing its services, EVERSANA shall be entitled to receive fees (of which 25% (possibly increasing to up to 50% in the future, at EVERSANA’s discretion) shall be initially deferred and are due when we generate subsequent apabetalone sales in applicable indications) and profit sharing in the amount of 3.0 - 4.5% of apabetalone sales in applicable indications in the United States and Canada during the five-year term of the partnership (commencing upon commercial launch). The Company and EVERSANA have mutually agreed to temporarily pause services until additional capital is raised. The partnership may be expanded to include additional global markets, should additional approvals be issued.

In April 2022, Resverlogix and EVERSANA expanded its partnership to include cardiovascular and pulmonary arterial hypertension indications (the “Amendment”). In connection with the Amendment, if Resverlogix and EVERSANA have not launched a product by July 1, 2022, the Company will make monthly payments to EVERSANA, commencing in July 2022, equal to 50% of the deferred fees for the corresponding month twelve months prior. Resverlogix has not yet made any such payments.

During the year ended December 31, 2022, EVERSANA completed pre-commercialization activities in the amount of \$3.6 million (2021 – \$7.2 million), with 25% (and up to 50% in the future) of the fees earned, \$0.9 million (2021 – \$1.8 million), being deferred. A total discount of \$0.2 million on the pre-commercialization fees incurred in the year ended December 31, 2022 has been recognized as an offset to the long-term deferred fees liability and to pre-commercialization expenses to reflect the financing component of the deferred fees. The discount will be accreted over the term that is projected until settlement. \$1.3 million of deferred fees (\$1.0 million, net of a cumulative \$0.3 million discount) is included as Other long-term liability on the statement of financial position and are due when the Company generates subsequent COVID-19-related sales of apabetalone. As at December 31, 2022, Trade and other payables includes \$10.1 million (2021 – \$5.5 million) owing to EVERSANA; amounts owing to EVERSANA bear interest at 7.25% per annum.

### **Global Business Landscape**

Certain world events and external factors, including COVID-19, have impacted our business operations and created an environment of uncertainty. The constantly evolving COVID-19 pandemic, including newly emergent variants of concern, resulted in challenges affecting our clinical activities, including patient enrolment, and requiring study design amendments. There were also shifts in the regulatory environment as governments around the world adapted to changing pandemic conditions and reacted to declining appetites for pandemic controls and emergency measures.

Biotechnology stock prices saw a broad decline in the first half of 2022, continuing the trend experienced throughout 2021. Though some recovery occurred in the second half of 2022, many biotechnology stocks closed the year significantly below where they began the year<sup>8</sup>. We believe these market conditions impacted our stock price and affected our ability to raise capital.

Despite challenges posed by the current global business landscape, we are confident in our long-term strategy for the clinical development of apabetalone.

### **2023 Outlook**

Our long-term strategy remains consistent for 2023; we are focused on the development of apabetalone, and on securing the necessary financing and/or partnerships to drive that development. Our clinical development efforts in 2023 will concentrate primarily on our two highest priority indications: high-risk CVD and PCC. BETonMACE2, our planned Phase 3, registration-enabling trial of apabetalone in patients with T2DM, recent-ACS and low high-density lipoprotein cholesterol (“HDL-C”), is expected to begin in 2023. A Phase 2/3 clinical study of apabetalone for PCC is currently being planned, and a revised trial protocol is being submitted to the FDA. The start-up of both trials is pending all necessary regulatory approvals and securing financing. We are in active discussions with multiple parties in respect of funding including various potential clinical trials.

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<sup>8</sup> <https://finance.yahoo.com/quote/XBI/>

As at December 31, 2022, we had \$0.04 million of cash. Our cash as at December 31, 2022 is not sufficient to fund our contractual commitments or our planned business operations over the next year. We will have to raise additional capital. If we are not able to raise capital, we may be forced to cease operations. We continue to pursue and explore a range of opportunities including partnering and regional licensing as well as equity offerings. However, there is no assurance that these arrangements will be completed. Delays in securing funding could potentially delay future clinical trials and obtaining regulatory approvals necessary for the commercialization of apabetalone.

Volatility and uncertainty in the global business landscape will most likely continue well into 2023. Inflation and rising interest rates in 2022 have driven concerns of potential recessions beginning as soon as this year. While governments and central banks are striving for “soft landings”, it is yet to be seen whether they will be able to successfully rein in inflation without triggering a recession. It is impossible to predict future economic developments, and ultimately, they could affect our ability to finance and execute our planned business operations.

## Results of Operations for the Years Ended December 31, 2022 and 2021

*(in thousands of US dollars unless otherwise noted)*

	2022	2021
Expenses	\$ 12,712	\$ 15,847
Finance (income) costs	(9,120)	8,912
Loss before income taxes	3,592	24,759
Income taxes	18	12
Net and total comprehensive loss	\$ 3,610	\$ 24,771
<b>Net loss per share</b>		
Basic and diluted	\$ 0.01	\$ 0.10

### Research and Development

In addition to the costs associated directly and indirectly with clinical programs, research and development includes other product development costs such as drug development and manufacturing, pharmacology, toxicology and other studies, and costs associated with discovery research. R&D expenses also include salaries and benefits for R&D staff, consulting fees, supplies and general laboratory operating expenses.

During the year ended December 31, 2022, gross R&D expenditures totaled \$5.6 million (2021 – \$4.6 million). The increase is primarily due to a \$1.3 million impairment recognized within R&D expenditures, relating to an impairment of certain intangible assets (unrelated to the Company’s lead compound, apabetalone). Clinical costs in the year ended December 31, 2022 totaled approximately \$1.1 million (2021 – \$1.0 million). The current year includes costs for our Phase 2 COVID-19 trial. The prior year clinical costs include startup costs for the Phase 2 COVID-19 trial and sample storage fees related to the BETonMACE clinical trial.

Research and development compensation and related costs (related primarily to our research, nonclinical and clinical teams) for the year ended December 31, 2022 were approximately \$1.5 million (2021 – \$1.6 million).

During the year ended December 31, 2022, chemistry costs (comprised of CMC, or chemistry, manufacturing and controls) totaled \$0.2 million (2021 – \$0.2 million). The costs in both years are comprised primarily of storage and shipping fees of clinical supplies (drug product) being used in our research and development. The current year included the cost of a portion of the drug product that was utilized in our Phase 2 COVID-19 trial.

During the year ended December 31, 2022, nonclinical costs were approximately \$0.1 million (2021 – \$0.1 million). Nonclinical costs include research, pharmacology, toxicology and DMPK (drug metabolism, and pharmacokinetics) costs including those related to the potential broadening of indications.

### Pre-commercialization, General and Administrative

General and administrative expenses includes compensation and related costs, operating costs not directly involved in research and development, as well as professional fees for legal, audit, communications, medical affairs, and business development services.

During the year ended December 31, 2022, general and administrative expenditures totaled \$7.2 million (2021 – \$11.3 million). The pre-commercialization activities completed by EVERSANA, net of discounts discussed above, during the year ended December 31, 2022 totaled \$3.4 million (2021 – \$6.7 million). The pre-commercialization activities relate to the planned commercialization of apabetalone for the treatment of COVID-19 in the United States and Canada as Emergency Use Authorization and/or a New Drug



Application or equivalent if issued or approved in these two countries. Resverlogix and EVERSANA have mutually agreed to temporarily pause services until additional capital is raised.

### Share-based Payments

Share-based payments are included in research and development and general and administrative rather than being presented separately in the statements of comprehensive income.

During the year ended December 31, 2022, we recognized share-based payments of \$2.4 million (2021 – \$2.6 million). The expense recognized in a given period reflects the fair value of past and newly-granted stock options outstanding during the period and is impacted by factors such as vesting and fluctuations in share price. Share-based payments are a non-cash expense which does not impact operating cash flows.

During the year ended December 31, 2022, we granted 1,180,000 stock options with a weighted-average exercise price of CAD\$0.43 and a weighted-average fair value of \$0.18 per option (2021 – 550,000 stock options with a weighted-average exercise price of CAD\$0.86 and a weighted-average fair value of \$0.35 per option), and we granted 7,038,454 restricted stock units (2021 – 3,116,500 restricted stock units), including 1,000,000 restricted stock units granted primarily in settlement of outstanding compensation.

### Change in Fair Value of Warrant Liability

We have issued warrants in connection with various securities offerings. Warrants issued as part of an equity unit, or in connection with a debt financing, with an exercise price denominated in a foreign currency are reported as a liability until they are exercised or expire. These warrants are adjusted to fair value at each reporting period and any change in fair value between reporting periods is recorded in the statement of comprehensive loss (income).

During the year ended December 31, 2022, we recognized a \$3.9 million gain on the change in the fair value of our warrant liability (2021 – \$4.8 million gain). The changes in fair value were based on several factors including changes in the market price of our shares to CAD\$0.14 on December 31, 2022 from CAD\$0.51 on December 31, 2021 and CAD\$0.94 on December 31, 2020, as well as decreases in the remaining terms of the various series of warrants, and changes in estimated future volatility of our common shares. Gains and losses resulting from the revaluation of warrant liability are non-cash and do not impact our cash flows.

### Change in Fair Value of Royalty Preferred Shares

During the year ended December 31, 2022, we recognized a \$7.0 million gain on the change in the estimated fair value of our royalty preferred shares (2021 – \$12.7 million loss). For fair value measurement purposes, the royalty preferred shares liability has been categorized within level 3 of the fair value measurement hierarchy. The estimated 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 the Company's discounted future net cash flows. The estimate incorporates the following assumptions: an average cumulative probability rate of generating forecasted future cash flows of 42% as at December 31, 2022 (42% as at December 31, 2021) reflecting in each case, among other factors, our clinical results, in particular the results of BETonMACE, and communication with the FDA (including Breakthrough Therapy Designation) and other regulatory bodies; a discount rate of 26.1% as at December 31, 2022 (December 31, 2021 – 23.7%); projected commencement of revenue between late-2026 and mid 2027 (based on projected clinical development paths across various jurisdictions, which is based substantially on securing the requisite funding from a partnership or other source(s) of capital in the first half of 2023), as at December 31, 2022 (as at December 31, 2021 – between early 2026 and late 2026); and projected apabetalone market shares percentages and projected product pricing. The estimated fair value of royalty preferred shares in the current period was affected by the change in the projected commencement of revenue and an increase to the discount rate during the year ended December 31, 2022, offset by the passage of time (to future cash flows based on the estimated timing and commencement of revenue).

The estimated fair value of the royalty preferred shares is subject to significant volatility. Small changes in the aforementioned assumptions may have a significant impact on the estimated fair value of the royalty preferred shares. For instance, holding all other assumptions constant: a 1% increase in the discount rate would result in a \$3.3 million decrease in the estimated fair value of the royalty preferred shares; assuming commencement of revenue one year later would result in a \$11.9 million decrease in the estimated fair value of the royalty preferred shares; and a 1% increase in the probability rate of generating forecasted future cash flows would result in a \$1.2 million increase in the estimated fair value of the royalty preferred shares.

### Change in Fair Value of Derivative Liability

On May 13, 2021, we closed the US\$6.0 million Debenture with Hepalink. The Debenture bears interest at 10% per annum. On April 1, 2022, the maturity date of the Debenture, and the corresponding payment date of interest thereon, were both extended by one year from May 13, 2022 to May 13, 2023. Subsequent to December 31, 2022, the Debenture was further amended to extend the

maturity date to May 13, 2024, and to increase the interest rate to 12% per annum effective May 14, 2023. Hepalink may elect to convert the principal amount of the Debentures and accrued and unpaid interest thereon into common shares of the Company at a conversion price equal to the lesser of CAD\$0.93 per share and the 5-day volume weighted average trading price of the common shares on the date of conversion. The secured convertible debenture is a hybrid instrument consisting of a financial instrument and an embedded derivative, being the conversion option. The embedded derivative is separated from the host contract and accounted for separately as the economic characteristics and risks of the host contract and the embedded derivative are not closely related. The conversion option contains a variable conversion price, and the conversion price is denominated in a foreign currency. As a result, conversion will result in a variable number of our shares being issued at conversion; as such, the conversion feature has been classified as a derivative liability at fair value through profit or loss.

During the year ended December 31, 2022, we recognized a \$0.1 million loss on the change in estimated fair value of the derivative liability (related to the conversion option on the Hepalink convertible debenture). The \$0.1 million loss on change in estimated fair value of derivative liability during the year ended December 31, 2022 relates to a \$0.1 million decrease in the fair value of the conversion option derivative of the Hepalink convertible debenture between December 31, 2021 and the April 1, 2022 maturity date extension amendment, a \$0.5 million increase in the fair value of the conversion option derivative at the April 1, 2022 maturity date extension amendment, and a \$0.2 million decrease in the fair value on the conversion option derivative after the maturity date extension up to the December 31, 2022 reporting date. Gains and losses resulting from the revaluation of derivative liability are non-cash and do not impact our cash flows.

### Interest and Accretion

Interest and accretion for the years ended December 31, 2022 and 2021 relate to the Hepalink Debenture noted above and the accretion of the discounts related to the EVERSANA deferred fees. The Debenture bears interest at 10% per annum. During the year ended December 31, 2022, interest on the Debenture and amounts owing to EVERSANA totaled \$1.3 million (2021 – \$0.4 million).

During the year ended December 31, 2022, accretion of the debt issuance costs and the EVERSANA deferred fees discounts totaled \$0.3 million (2021 – \$0.3 million). During the year ended December 31, 2022, the maturity date of the Debenture, and the corresponding payment date of interest thereon, were both extended by one year from May 13, 2022 to May 13, 2023. The amendment was accounted for as a debt modification. A modification gain of \$0.4 million, related to the extension of the maturity date, was recognized within accretion on the statement of comprehensive loss.

## Liquidity and Capital Resources

### Cash

As at December 31, 2022, we had \$0.04 million of cash and \$14.1 million of current trade and other payables. Our cash and liquidity are described further under “Liquidity”.

### Liquidity

As at December 31, 2022, we had \$0.04 million of cash. We need to raise additional capital to fund research, development and corporate activities over the next year which include continued clinical development, or we may be forced to cease operations. As at December 31, 2022, we were committed to pay \$14.1 million of current trade and other payables, \$1.5 million for research and development commitments, and \$0.4 million of lease liabilities over the next twelve months. Furthermore, our \$6.0 million debenture with Hepalink is due on May 13, 2024.

Our cash as at December 31, 2022 is not sufficient to fund our contractual commitments and/or our planned business operations over the next year.

We are in active discussions with multiple parties in respect of funding including various potential clinical trials.

We will have to raise additional capital. If we are not able to raise capital, we may be forced to cease operations. These conditions result in a material uncertainty which may cast significant doubt on our ability to continue as a going concern. Refer to Note 3 to our consolidated financial statements for the year ended December 31, 2022 for our going concern note disclosure.

We have not complied fully with the payment terms associated with certain amounts owing to certain vendors. Until we fully satisfy our obligations, it is possible that the vendors could assert that we are in default and could pursue any remedies available to them.

We are a development stage company; our primary capital requirements relate to funding research and development activities, including preclinical and clinical trials, and for general working capital purposes. Our operations have been financed in recent years primarily through the sale of common shares or units (consisting of common shares and warrants) and secured indebtedness.

Our primary objective when managing capital is to ensure we have sufficient funds available to carry out our research, development, and commercialization programs.

We will continue to pursue and examine both non-dilutive and dilutive arrangements including co-development, licensing, rights or other partnering arrangements, procurement arrangements, private placements and/or public offerings (equity and/or debt). However, there is no assurance that these arrangements will be completed.

We will also require additional capital to fund research, development, and corporate activities beyond the next year. We will continue to explore alternatives to generate additional cash including raising additional equity and product licensing; however, there is no assurance that these initiatives will be successful. We intend to raise capital from equity and/or debt offering and/or partnering in the future.

As described herein, we intend to perform additional human clinical trials and such trials and regulatory approvals may require significant expenditures by us and likely require several years to complete. We may not generate operating cash inflows in the foreseeable future, and we will require additional financial resources to ensure that we have sufficient capital to fund our long-term research, development, and corporate activities. Our long-term capital requirements will depend on, among other considerations, whether we commence additional clinical trials, the size of any trials, and whether the trials are funded entirely by us or, partially or entirely, by a strategic partner.

We continuously investigate and assess financing alternatives and expect to be able to raise additional capital to fund our capital requirements. However, there is no assurance that initiatives to raise additional capital will be successful. If we are unable to raise additional capital, we may need to defer or discontinue some or all of our research and development activities.

### Cash Flows Used in Operating Activities

Cash flows used in operating activities for the year ended December 31, 2022 totaled \$3.5 million (2021 – \$8.0 million), comprised primarily of \$8.3 million of operating expenditures and a net increase of trade and other payables of \$4.7 million in the period.

### Cash Flows from Financing Activities

During the year ended December 31, 2022, cash flows provided by financing activities totaled \$4.1 million (2021 – \$8.8 million). Cash flows from financing activities during the year ended December 31, 2022 included issuing a total of \$4.6 million (CAD\$5.8 million) of equity units pursuant to private placements (2021 – \$4.0 million (CAD\$4.9 million) of equity units issued pursuant to private placements and \$6.0 million pursuant to the Debenture), offset by \$0.6 million of lease liability repayments (2021 – \$0.8 million). During the year ended December 31, 2022, 101,356 warrants were exercised for proceeds of \$0.1 million.

### Cash Flows Used in Investing Activities

During the year ended December 31, 2022, additions to intangible assets (patent-related costs), along with net payments for past additions, totaled \$0.5 million (2021 – \$0.8 million).

### Commitments and Contingencies

As at December 31, 2022, the Group is committed to expenditures over the next twelve months of \$1.5 million (December 31, 2021 – \$1.6 million) under various research and development contracts.

As at December 31, 2022, the Group is also party to a commercialization partnership. The Company and EVERSANA have mutually agreed to temporarily pause services and the Group was not obligated as at December 31, 2022 to incur pre-commercialization costs over the next twelve months. The parties may or may not resume services over the next twelve months.

The Group is, or was previously, party to agreements with contract research organizations and central laboratories that conducted clinical trials. The Group relies on contract research organizations and a contract laboratory to conduct its clinical trials in compliance with regulations and standards, commonly referred to as good clinical practices, for conducting, monitoring, recording, and reporting the results of clinical trials, to ensure that data and reported results are accurate and that the clinical trial participants are adequately protected. In addition, the Group relies on global drug manufacturers to produce the active pharmaceutical ingredient (“API”) and the drug product for patient use.

The completion of certain remaining activities associated with the BETonMACE trial could potentially be delayed, potentially preventing the Group from obtaining regulatory approvals necessary for the commercialization of apabetalone. Similarly, if the Group’s contracts with drug manufacturers were cancelled or delayed, manufacturing of API and drug product in the quantities and manner required by regulatory authorities may be delayed and development, approval, and commercialization of apabetalone may be delayed.

The July 2015 License Agreement between us and Hepalink was amended effective June 17, 2022 such that we agreed to pay up to CAD\$8.0 million of clinical development costs associated with apabetalone, including a global Phase 3 clinical trial (which we intend

to perform in any event), in the Territories and if the costs incurred by Resverlogix after May 1, 2020 and up to December 31, 2023 total less than CAD\$8 million, then Resverlogix and Hepalink shall negotiate a mutually-agreeable timeframe regarding any difference, in principle by not later than June 30, 2024.

In July 2020, we entered into an agreement with a supplier to settle amounts owing by us, whereby we agreed to pay a reduced amount in three instalments of \$200,000, \$550,000, and \$550,000 on August 1, 2020, September 1, 2020, and October 1, 2020 respectively. We paid the August 1, 2020 instalment, and have paid an additional \$825,000, but have not yet paid the remaining balance of \$275,000. Until we pay the remaining \$275,000, thereby satisfying our obligations pursuant to the agreement, it is possible that the supplier could assert that we are in default and could pursue any remedies that may be available to them.

The Company has not complied fully with the payment terms associated with certain amounts owing to certain vendors. Until the Company fully satisfies its obligations, it is possible that the vendors could assert that the Company is in default and could pursue any remedies available to them.

In 2021, we acquired certain intellectual property for: (a) \$400,000 paid in cash and (b) a \$600,000 milestone payment payable upon submission of a New Drug Application for apabetalone to the US Food and Drug Administration.

## Significant Accounting Policies and Estimates

Note 4 to our consolidated financial statements for the year ended December 31, 2022 includes a summary of our significant accounting policies.

The preparation of financial statements requires management to use estimates and assumptions that they believe are reasonable based upon the information available. These estimates and assumptions affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods presented. These estimates and assumptions are subject to inherent risk of uncertainty and actual results may differ from these estimates and assumptions.

Significant estimates are used for, but not limited to, the measurement of the fair value of the royalty preferred shares, share-based payment transactions, warrant liability, derivative liability, and taxes.

## Off-Balance Sheet Arrangements

As of December 31, 2022, we have not entered into any off-balance sheet arrangements.

## Summary of Quarterly Results

The following is a summary of selected financial information derived from our unaudited condensed interim consolidated financial statements for each of the eight most recently completed quarters.

<i>(in thousands of US dollars except as otherwise noted)</i>	December 31, 2022	September 30, 2022	June 30, 2022	March 31, 2022
Revenue	-	-	-	-
Total comprehensive income (loss)	801	(1,676)	(403)	(2,332)
Net earnings (loss) per share (\$)				
- basic	0.01	(0.01)	(0.00)	(0.01)
- diluted	0.01	(0.01)	(0.00)	(0.01)

<i>(in thousands of US dollars except as otherwise noted)</i>	December 31, 2021	September 30, 2021	June 30, 2021	March 31, 2021
Revenue	-	-	-	-
Total comprehensive (loss) income	(16,896)	(5,286)	(2,609)	20
Net (loss) income per share (\$)				
- basic	(0.07)	(0.02)	(0.01)	0.00
- diluted	(0.07)	(0.02)	(0.01)	0.00

Items that impact the comparability of quarterly results of operations presented above include:

- Research and development was impacted by the particular stage of our clinical trials during each particular quarter.

- Research and development was also impacted by the timing of costs related to our chemistry and nonclinical studies.
- Liability-classified warrants issued pursuant to unit offerings with an exercise price denominated in a currency other than an entity's functional currency are remeasured to reflect the change in fair value as at the end of the reporting period, with changes in fair value recognized in the statement of comprehensive (income) loss, resulting in volatility in quarterly income (loss).
- Royalty preferred shares are remeasured to reflect the change in estimated fair value at the end of the reporting period, with changes in estimated fair value recognized in the statement of comprehensive (loss) income, resulting in volatility in quarterly (loss) income.
- Interest and accretion was impacted by entering into the US\$6.0 million Hepalink Debenture in May 2021 and amending the maturity date of the Hepalink Debenture in April 2022 and interest on amounts owing to EVERSANA. Accretion is also impacted by the the discounts related to the EVERSANA deferred fees.
- Share-based payments fluctuate from quarter to quarter based on the timing and fair value of restricted stock unit and stock option grants. Share-based payments are a non-cash expense.
- The recognition of foreign currency gains and losses resulting from fluctuations in Canadian denominated assets and liabilities and Canadian / US dollar exchange rates.

## Related Party Transactions

### Related party transactions with Zenith Capital Corp. ("Zenith")

We have several directors in common with Zenith, and thus are considered related parties. We provide management and administrative services to Zenith pursuant to a Management Services Agreement dated June 3, 2013 between us and Zenith. The purpose of the agreement is to enable the Company to achieve greater utilization of its resources. As consideration for the services, Zenith pays us a service fee, consisting of salary and other compensation costs attributable to the services and reimbursable expenses incurred by Resverlogix in connection with the services.

### Hepalink Convertible Debenture

In May 2021, we closed the \$6.0 million Debenture with a subsidiary of Hepalink. The Debenture bears interest at 10% per annum. During the year ended December 31, 2022, the maturity date of the Debenture, and the corresponding payment date of interest thereon, were both extended by one year from May 13, 2022 to May 13, 2023. Subsequent to December 31, 2022, the Debenture was further amended to extend the maturity date to May 13, 2024, and to increase the interest rate to 12% per annum effective May 14, 2023. Hepalink may elect to convert the principal amount of the Debentures and accrued and unpaid interest thereon into common shares of the Company at a conversion price equal to the lesser of CAD\$0.93 per share and the 5-day volume weighted average trading price of the common shares on the date of conversion. The Company granted Hepalink a security interest in all of its assets, including its patents and other intellectual property, as security for its obligations under the Debenture. In addition, Hepalink received 300,000 common share purchase warrants exercisable for a period of four years from the grant date at a price of CAD\$0.93 per share.

As at December 31, 2022 Hepalink held 32.1% (December 31, 2021 – 35.1%) of Resverlogix outstanding common shares and is considered to have significant influence over us.

## Outstanding Equity Instruments

As at March 31, 2023, we had authorized an unlimited number of common shares and preferred shares and 75,202,620 royalty preferred shares.

	As at March 31, 2023	As at December 31, 2022	As at December 31, 2021
Common Shares	267,798,628	265,673,607	243,210,022
Warrants	29,807,425	29,207,425	16,562,588
Stock Options	1,845,000 (1)	1,405,000	625,000
Restricted Stock Units	20,081,146 (2)	15,959,071	12,258,513
Deferred Share Units	1,672,091	1,672,091	926,570
<b>Total</b>	<b>321,204,290</b>	<b>313,917,194</b>	<b>273,582,693</b>
Royalty Preferred Shares	75,202,620	75,202,620	75,202,620

(1) 965,000 of 1,845,000 stock options are vested and exercisable.

(2) 17,151,014 of the 20,081,146 restricted stock units are vested.

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In addition, the Company had a \$6 million secured convertible debenture as at December 31, 2022 and March 31, 2023. Additional information relating to our securities can be found in Notes 11, 12 and 13 to the consolidated financial statements for the year ended December 31, 2022.

## Disclosure Controls and Procedures

We are required to comply with National Instrument 52-109 “Certification of Disclosure in Issuers’ Annual and Interim Filings” (“NI 52-109”). Our Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”) are responsible for establishing and maintaining disclosure controls and procedures (“DC&P”) for the Company. Our designed DC&P provides reasonable assurance that material information is made known to the certifying officers, and that information disclosed by the Company is done in the time period specified in securities legislation. In accordance with the requirements of NI 52-109, an evaluation of the effectiveness of our disclosure controls and procedures was carried out under the supervision and with the participation of management, including our President and Chief Executive Officer (“CEO”) and our Chief Financial Officer (“CFO”). Based on this evaluation, the CEO and CFO concluded that, as at December 31, 2022, the design and operation of our disclosure controls and procedures were effective.

## Internal Controls Over Financial Reporting

As defined within NI 52-109, our CEO and CFO are responsible for establishing and maintaining internal control over financial reporting (“ICFR”). Our designed ICFR provides reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with Generally Accepted Accounting Principles (“GAAP”). The framework behind the design of the Company’s ICFR was the Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”). Based on the COSO Framework, an evaluation of the effectiveness of the Company’s ICFR was carried out under the supervision of the CEO and CFO. Based on this evaluation, the CEO and CFO have concluded that the Company’s ICFR is effectively designed and operating as at December 31, 2022.

While the CEO and CFO have concluded that ICFR is effective, a control system, no matter how well conceived or operated, can provide only reasonable, not absolute, assurance that the objectives of the control system will be met, and it should not be expected that the control system will prevent all errors or fraud.

There have been no changes in our existing DC&P or ICFR during the period ended December 31, 2022, which have materially affected or are reasonably likely to materially affect the Company’s ICFR.

## Risks and Uncertainties

An investment in the Company should be considered highly speculative due to the nature of its activities and the stage of its development. Biotechnology research and development involves a significant degree of risk. The risks and uncertainties set forth below are not the only ones we will face. Additional risks and uncertainties not presently known to us or that we currently consider immaterial may also impair our business and operations and cause the price of the Common Shares to decline. If any of the following risks actually occur, our business may be harmed, and our financial condition and results of operations may suffer significantly. In that event, the value of the Common Shares could decline and purchasers of the Common Shares or securities convertible into Common Shares may lose all or part of their investment. Readers should carefully consider the following risk factors in addition to the other information contained herein before investing in the Company.

### Risks Relating to Our Business

**We have a history of net losses and negative cash flow. We expect to continue to incur substantial net losses for the foreseeable future, and we may never achieve or maintain positive cash flow.**

To date, we have not recorded any revenues from the sale of biopharmaceutical products and have incurred significant negative cash flows in many periods since our inception. As at December 31, 2022, we had a deficit of US\$445.7 million. We expect to incur substantial net losses and negative cash flow for the foreseeable future. Such losses and negative cash flow have had, and will continue to have, an adverse effect on our shareholders’ equity and working capital.

The process of developing and commercializing our products requires significant preclinical testing and clinical trials as well as regulatory approvals for commercialization and marketing before we could begin product sales. In addition, commercialization of our products would require us to establish a sales and marketing organization or contractual relationships to enable product manufacturing and other related activities. Because of the numerous risks and uncertainties associated with pharmaceutical product development and commercialization, we are unable to accurately predict the timing or amount of future expenses or when, or if, we will be able to achieve or maintain positive cash flow. Currently, we have no products approved for commercial sale, and to date we have not generated any product revenue. We have financed our operations primarily through the sale of equity securities and advances pursuant to credit facilities. The size of our future negative cash flow will depend, in part, on the rate of growth or contraction of our

expenses and the level and rate of growth, if any, of our revenues. We expect to report net losses and negative cash flow unless and until such time as payments, if any, from corporate collaborations, product sales and/or royalty payments generate sufficient revenues to fund our continuing operations. Quarter to quarter fluctuations in revenues, expenses, net losses, and cash flow are also expected. Even if we do achieve profitability, we may not be able to sustain positive cash flow on an ongoing basis.

**We will need to raise additional capital in the future to fund our operations. If we cannot raise additional capital, we will have to delay, reduce, or cease operations.**

We will need to raise additional capital to fund our operations and to develop our products. We expect to raise additional funds through public or private equity or debt financing and/or from other sources. Our future capital requirements will be substantial and will depend on many factors, such as the following:

- the scope, rate of progress, results, and costs of any clinical and nonclinical programs;
- timing, costs, and outcomes of regulatory proceedings;
- the cost and timing of developing sales and marketing operations or partnerships;
- payments received under any future partnerships;
- prosecution or defense of patent claims;
- the cost and timing of developing manufacturing capacity;
- costs associated with commercialization of our products; and
- competing technological and market developments, including the introduction by others of new therapies in our market.

Our cash as at December 31, 2022 is not sufficient to fund our contractual commitments or our planned business operations over the next year. We will have to raise additional capital. If we are not able to raise sufficient capital to fund our operations, we may be forced to cease operations. These conditions result in a material uncertainty which casts significant doubt on our ability to continue as a going concern.

The Company has not complied fully with the payment terms associated with certain amounts owing to certain vendors. Until the Company fully satisfies its obligations, it is possible that the vendors could assert that the Company is in default and could pursue any remedies available to them.

We will also require additional capital to fund research, development, and corporate activities beyond the next year. We will continue to explore alternatives to generate additional cash including raising additional equity and product licensing; however, there is no assurance that these initiatives will be successful. We intend to raise capital from equity and/or debt offering and/or partnering in the future.

Further, changing circumstances may cause us to consume capital significantly faster or slower than we currently anticipate. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available financial resources sooner than we currently expect.

There can be no guarantee that we will be able to access capital markets in the future to fund our ongoing operations. If we cannot access capital markets in the future, we may be forced to cease operations. Any financing transaction may contain unfavourable terms. If we raise additional funds by issuing equity securities, our stockholders' equity will be diluted. If we raise additional funds through strategic partnerships, we may be required to relinquish rights to our products, or to grant licenses on terms that are not favourable to us.

**There is no certainty that insiders will make further investments in the Company.**

In recent years, we have often raised additional capital to fund repayment of indebtedness and operating activities through private placements of equity and debt securities to insiders of the Company. However, there is no certainty that insiders will continue to make further investments in the Company or that any further investments will be sufficient to fund the Company's existing obligations or ongoing research and development activities. In addition, there are restrictions relating to the amount that insiders may invest in the Company pursuant to stock exchange policies and applicable securities laws, without the Company obtaining the prior approval of shareholders. There is no certainty that all necessary approvals could be obtained to enable insiders to make further investments in the Company or that the Company will be able to obtain such approvals in a timely manner.

**We are a development stage company. If we do not develop commercially successful products, we may be forced to cease operations.**

We are a development stage company, which may require significant additional investment for research and development, manufacturing, clinical testing, and regulatory submissions prior to commercialization. Investors must evaluate our business

considering the uncertainties and complexities affecting a development stage biotechnology company and there can be no assurance that any such product will eventually be developed. Any product would be unsuccessful if it:

- does not demonstrate acceptable safety and efficacy in preclinical studies and clinical trials or otherwise does not meet applicable regulatory standards for approval;
- does not offer therapeutic or other improvements over existing drugs used to treat the same or similar conditions;
- is not capable of being produced in commercial quantities at an acceptable cost, or at all; or
- is not accepted by patients, the medical community or third-party payors.

A commitment of substantial time and resources is required to conduct research and clinical trials if we are to complete the development of any product. We have not proven our ability to develop and commercialize products. It is not known whether any of these products will meet applicable health regulatory standards and obtain required regulatory approvals, or (i) whether such products can be produced in commercial quantities at reasonable costs and be successfully marketed, (ii) whether our products will achieve market acceptance, or (iii) if our investment in any such products will be recovered through sales or royalties. Problems frequently encountered in connection with the development and utilization of new and unproven technologies and the competitive environment in which we operate might limit our ability to develop commercially successful products.

Results of early research and development may not be indicative of the results that will be obtained in later stages of research and development. If regulatory authorities do not approve the products or if regulatory compliance is not maintained, we would have limited ability to commercialize our products, and our business and results of operations would be harmed. We may fail to develop any products, to obtain regulatory approvals, to enter clinical trials, or to commercialize any products. If we are unable to make our product candidates commercially available, we will not generate product revenues, and we may be forced to cease operations.

**We have been advanced funds under a secured convertible debenture and failure to pay all amounts when they become due could result in a loss of all of our assets.**

In May 2021, we obtained a US\$6 million Debenture from Hepalink. The Debenture bears interest at a rate of 10% per annum. During the year ended December 31, 2022, the maturity date of the Debenture, and the corresponding payment date of interest thereon, were both extended by one year from May 13, 2022 to May 13, 2023. Subsequent to December 31, 2022, the Debenture was further amended to extend the maturity date to May 13, 2024, and to increase the interest rate to 12% per annum effective May 14, 2023. The loan is secured by all of our assets.

We do not currently have sufficient cash available to repay the principal amount of the Debenture when it becomes due. Unless the Debenture is converted in full into equity or the maturity date is extended, we will have to raise additional capital to repay the Debenture on the maturity date of May 13, 2024.

If an event of default under the Debenture occurs, the lender could elect to declare all principal amounts outstanding under the loan at such time, together with accrued interest and applicable fees, to be immediately due and payable. If we are unable to repay amounts owing under the loan, the lender could proceed to foreclose or otherwise realize upon all of our assets, including our intellectual property, that is security for the indebtedness.

**Unstable market conditions may have serious adverse consequences on our business.**

The economic downturn and market instability made the business climate more volatile and more costly. Our business strategy may be adversely affected by unpredictable and unstable market conditions. If the current equity and credit markets deteriorate it may make any necessary equity or debt financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favourable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. There is a risk that one or more of our current or future strategic partners may encounter difficulties during challenging economic times, which would directly affect our ability to attain our operating goals on schedule and on budget.

**If our clinical trials fail to establish the safety and efficacy of our products, including apabetalone, we will not be able to commercialize our products.**

Drug discovery and development has inherent risk, and the historical failure rate is high. Failures in the HDL cholesterol market by some pharmaceutical companies have highlighted the risk of these types of therapies.

To obtain regulatory approval to market and sell any of our products, we must satisfy the FDA, the TPD, and other regulatory authorities, through extensive clinical trials and preclinical studies, that our products are safe and efficacious. The BETonMACE trial did not meet its primary endpoint and if we cannot demonstrate that our drugs, including apabetalone, are safe and effective for human use, we may need to abandon one or more of our drug development programs.



We may not have conducted or may not conduct in the future the types of testing ultimately required by regulatory authorities, or future tests may indicate that our products are not safe for use in humans. Preclinical testing and clinical trials are expensive, can take many years and have an uncertain outcome. In addition, success in initial preclinical testing does not ensure that later preclinical testing or clinical trials will be successful. There are a number of factors that could cause a clinical trial to fail or be delayed including:

- the clinical trials may produce negative or inconclusive results, which may require us to conduct additional preclinical testing or to abandon product candidates that we believed to be promising;
- the regulators may require that we hold, suspend, or terminate clinical research for noncompliance with regulatory requirements;
- we, our potential partners, the FDA, the TPD or foreign regulatory authorities could suspend or terminate a clinical trial due to adverse side effect of a drug on subjects or patients in the trial;
- we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials;
- enrollment in our clinical trials may be slower than anticipated;
- the cost of our clinical trials may be greater than anticipated;
- our product candidates may have unfavourable pharmacology, toxicology, or carcinogenicity;
- our product candidates may cause undesirable side effects; and
- the supply or quality of our drugs or other materials necessary to conduct clinical trials may be insufficient, inadequate, or delayed.

If any of our product candidates in clinical studies, including apabetalone, do not show sufficient efficacy in patients with the targeted indication, it could negatively impact our development and commercialization or goals for this and other product candidates and, as a result, materially adversely affect our business, financial condition, and results of operations.

**We may be required to conduct additional clinical trials to address concerns that the use of our leading product, apabetalone, might increase the risk of liver injury. This may materially adversely affect our business, financial condition, and results of operations.**

In our Phase 2 ASSERT clinical trial, some patients had elevations in serum enzymes which are sensitive markers of liver injury; however other clinical laboratory tests indicate there was no impairment in liver function and patients were asymptomatic for liver injury. Most of these liver signals occurred between weeks five and ten with fewer occurrences between weeks ten and thirteen. In our subsequent Phase 2b clinical trials, SUSTAIN and ASSURE, increases in ALTs were observed in a small group of patients. Those who had ALT elevations of 3X ULN all dosed through the trial which potentially illustrated adaptability to the drug. Those who had elevation greater than 5XULN, a high number of those patients had pre-existing liver condition such as hepatitis and took known agents that cause ALT elevations such as acetaminophen, clavulanic acid, diclofenac, and Augmentin. These increases were all observed within weeks 12 and 24 of the trial. Upon stopping apabetalone ALT elevations returned to ULN quickly which further illustrates a lack of hepatotoxicity. We also performed the FDA's liver analysis tool ("eDISH") which further illustrated that there were no Hy's Law (elevated ALT and total bilirubin) cases. With these learnings, we believe that the current therapeutic regimen can be safe with regard to effects on the liver. However, if further tests were to determine such risk did exist, the FDA may require us to conduct additional clinical trials to address these concerns prior to receiving FDA or foreign regulatory approval for apabetalone. These clinical trials would be expensive and could delay any commercialization of apabetalone. Adverse results in these trials could delay or prevent commercialization of apabetalone or could jeopardize existing development in other indications.

**If our testing assumptions are incorrect our products may not be approved for marketing.**

The design of our clinical trials is based on many assumptions about the expected effect of our product candidates. If those assumptions prove incorrect, the clinical trials may not produce statistically significant results. We cannot assure you that the design of, or data collected from, the clinical trials of our product candidates will be sufficient to support the FDA and foreign regulatory approvals.

**We are dependent on third parties to conduct our clinical trials and to provide services for certain important aspects of our business. If these third parties do not perform as contractually required or expected, we may not be able to obtain regulatory approval for our products, or we may be delayed in doing so.**

We rely on third parties, such as contract research organizations, medical institutions, academic institutions, independent clinical investigators, and contract laboratories, to conduct our clinical trials and preclinical studies, and we expect to continue to do so in the future. We rely heavily on these parties for successful execution of our clinical trials, but do not control many aspects of their activities. As a result, many important aspects of our product development are outside our direct control. We are responsible for confirming that our preclinical studies are conducted in accordance with applicable regulations and that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. The FDA requires us to comply with regulations and standards, commonly

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referred to as good laboratory practices, or GLP, for conducting and recording the results of our preclinical studies and good clinical practices for conducting, monitoring, recording, and reporting the results of clinical trials, to assure that data and reported results are accurate and that the clinical trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities. If the third parties conducting our clinical trials do not perform their contractual duties or obligations, do not meet expected recruitment or other deadlines, fail to comply with the FDA's good clinical practice regulations, do not adhere to our clinical trial protocols or otherwise fail to generate reliable clinical data, development, approval and commercialization of our products, including apabetalone, may be extended, delayed or terminated or may need to be repeated, and we may not be able to obtain regulatory approval.

We do not currently own or operate manufacturing facilities for clinical or commercial production of the active pharmaceutical ingredient, or API, used in apabetalone. As a result, we rely on third parties to supply the API. We expect to continue to depend on third parties to supply the API for our lead product candidate and any additional product candidates we develop in the foreseeable future. An API manufacturer must meet high precision and quality standards for that API to meet regulatory specifications and comply with regulatory requirements. A contract manufacturer's failure to comply with applicable regulations and requirements could result in refusal to approve or a delay in approval of apabetalone or other product candidates. We are ultimately responsible for confirming that the APIs used in our product candidates are manufactured in accordance with applicable regulations. Furthermore, if our third-party drug suppliers fail to achieve and maintain high manufacturing standards in compliance with applicable regulations, we could be subject to certain product liability claims in the event such failure to comply resulted in defective products that caused injury or harm.

**Natural disasters, public health crises, political crises, and other catastrophic events or other events outside of our control may damage the facilities or disrupt the operations of our strategic partners, third-party manufacturers, suppliers or other third parties upon which we rely, and could delay or impair our ability to initiate or complete our clinical trials or commercialize approved products.**

Our strategic partners, third-party manufacturers, suppliers and other third parties upon which we rely have operations around the world and are exposed to a number of global and regional risks outside of our control. These include, but are not limited to: natural disasters, such as earthquakes, tsunamis, power shortages or outages, floods, or monsoons; public health crises, such as pandemics and epidemics; political crises, such as terrorism, war, political instability or other conflict; or other events outside of our control.

We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including the suppliers, regulators and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.

**We rely on partnerships and strategic relationships for our success. The failure to successfully collaborate with third parties may delay, prevent, or otherwise impair the development or commercialization of our products or revenue expectations.**

In June 2021, we entered into a partnership with EVERSANA. EVERSANA supported the planned commercialization of apabetalone for the treatment of COVID-19 in the United States, Canada and any other countries agreed upon in the future as Emergency Use Authorization and/or a New Drug Application or equivalent if issued or approved in said countries. In the April 2022 Amendment, the Company and EVERSANA expanded its partnership to include cardiovascular and pulmonary arterial hypertension indications. EVERSANA provides fully integrated commercialization services including market access, agency services, clinical and commercial field teams, medical science liaisons, channel management, patient services, health economics and outcomes research, and compliance. The partnership may be expanded to include additional global markets, should additional approvals be issued. There can be no assurance that commercialization of apabetalone for the treatment of any indication will be successful. The Company and EVERSANA have mutually agreed to temporarily pause services until additional capital is raised.

As a result of the costs associated with commercializing a product candidate, we seek strategic partnerships with corporate and academic collaborators, licensors, licensees and others for the research, development, clinical testing, manufacturing, marketing, and commercialization of our products, and we intend to attract corporate partners and enter into additional research collaborations. Our goal is to partner apabetalone so that it may be developed for clinical conditions. There can be no assurance, however, that such collaborations will be established, that such collaborations will be established on favourable terms, if at all, or that future collaborations will be successful. In particular, failures in HDL cholesterol therapies may negatively impact our potential partners' willingness to enter into partnering agreements due to the potential risks in the cholesterol market and the high clinical costs to bring such drugs to market. Failure to attract commercial partners for our products may result in our incurring substantial clinical testing, manufacturing, and commercialization costs prior to realizing any revenue from product sales or result in delays or program discontinuance if funds are not available in sufficient quantities, and this may materially adversely affect our business, financial condition, and results of operations.

Should a collaborative partner fail to develop, manufacture, or successfully commercialize any product to which it has rights, or any partner's product to which we have rights, the business may be adversely affected. Failure of a collaborative partner to continue to participate in any particular program could delay or halt the development or commercialization of products generated from such

program. In addition, there can be no assurance that the collaborative partners will not pursue other technologies or develop alternative products either alone or in collaboration with others, including our competitors, as a means for developing treatments for the diseases targeted by our programs.

Furthermore, we may hold licenses for certain technologies and there can be no assurance that these licenses will not be terminated, or that they will be renewed on conditions acceptable to us. We may negotiate additional licenses in respect of technologies developed by other companies and academic institutions. Terms of license agreements to be negotiated may include, inter alia, a requirement to make milestone payments, which may be substantial. We may also be obligated to make royalty payments on the sales, if any, of products resulting from licensed technology and, in some instances, are responsible for the costs of filing and prosecuting patent applications.

We face significant competition in seeking appropriate strategic partners, and these strategic partnerships can be intricate, and time consuming to negotiate and document. We may not be able to negotiate additional strategic partnerships on acceptable terms, or at all. We are unable to predict when or if we will enter into any additional strategic partnerships because of the numerous risks and uncertainties associated with establishing strategic partnerships. If we are unable to negotiate additional strategic partnerships for our products, we may be forced to delay or terminate development or commercialization of one or more of our products. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us.

**If we enter into partnerships or other strategic relationships, we may lose important rights to and control over the development of our products.**

As a result of the costs and risks associated with commercializing a product candidate, we will seek strategic partnerships in order to continue to develop and, if approved, market our products. Such strategic partnerships may require us to relinquish control over the timing and manner of clinical trials and commercialization of our product candidates. Strategic partners may experience financial difficulties or choose to terminate the arrangement or independently work on a competing product resulting in the delay or discontinuation of development or commercialization of our product candidates. Furthermore, disputes may arise between us and our strategic partners that result in the delay or termination of the research, development, or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources. Strategic partners may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation.

**We may not receive the full payment of all milestone or royalty payments pursuant to partnerships or strategic relationships.**

We may enter into license agreements and other forms of agreements with third parties regarding the development and commercialization of our product candidates. These agreements generally require that the third party pays to us certain amounts upon the attainment of various milestones and possibly include royalties on the sale of the developed product. There can be no guarantee that we will receive the payments described in those agreements since the development of the products may be cancelled if clinical trials do not yield positive results. Under such circumstances, we would not receive royalties as well. Even if the development of a product yields positive results, all of the risks described herein with respect to the obtaining of regulatory approval and market acceptance of the product are applicable. Finally, if there occurs a disagreement between us and the third party, the payment relating to the attainment of milestones or of royalties may be delayed. The occurrence of any of these circumstances could have a material adverse effect on our financial condition and operating results.

**If our products fail to achieve market acceptance for any reason, such failure may materially adversely affect our business, financial condition, and results of operations.**

There can be no assurance that any of our product candidates, if approved for marketing, will achieve market acceptance. If our product candidates, once approved, do not receive market acceptance for any reason, it will adversely affect our business, financial condition, and results of operations. The degree of market acceptance of any products we develop will depend on a number of factors, including:

- the clinical efficacy and safety of our product candidates;
- our product candidates' potential advantages over existing and future treatment methods;
- the price of our products; and
- reimbursement policies of government and third-party payers, including hospitals and insurance companies.

If after we obtain regulatory approval to sell our products, physicians, and healthcare payors fail to adopt our products or conclude that our products are not safe and effective, physicians could choose not to use them to treat patients. Our competitors may also develop new technologies or products which are more effective or less costly, or that seem more cost-effective than our products.

In addition, regulations affecting the pricing of pharmaceutical products may change in ways adverse to us. While we cannot predict the likelihood of any regulatory proposals, if a government agency were to adopt proposals limiting market or third-party payor pricing for pharmaceutical products, it could materially adversely affect our business, financial condition, and results of operations.

**We cannot be certain that we will ever obtain regulatory approvals in European countries, the United States, Canada, China, or any other jurisdictions. The failure to obtain such approvals may materially adversely affect our business, financial condition, and results of operations.**

Biotechnology, medical device, and pharmaceutical companies operate in a high-risk regulatory environment. The study, manufacture and sale of products are governed by countries' numerous statutes and regulations. We are required to obtain various regulatory approvals prior to being able to study, commercialize and distribute our product candidates. The regulatory review and approval process required to perform a clinical study in any country includes evaluation of preclinical studies and clinical studies, as well as the evaluation of our manufacturing process. This process is complex, lengthy, expensive, resource intensive and uncertain. Securing regulatory approval to market our products also requires the submission of extensive preclinical and clinical data, manufacturing information regarding the process and facility, scientific data characterizing our product and other supporting data to the regulatory authorities in order to establish its safety and effectiveness. We, or our collaborators, may fail to obtain the necessary approvals to commence or continue preclinical or clinical testing of our product candidates, including apabetalone, or to manufacture or market our products in reasonable time frames, if at all.

Governmental authorities in any country may enact regulatory reforms or restrictions on the development of new therapies that could adversely affect our ability to develop our products. Many of the products and processes that are being currently developed by us require significant development, testing and the investment of significant funds prior to their commercialization. There can be no assurance that apabetalone or any other drugs we attempt to develop will actually be developed to a commercial level. Completing clinical testing through late-stage trials and obtaining required approvals is expected to take several years and to require the expenditure of substantial resources. There can be no assurance that clinical trials will be completed successfully within any specified period of time, if at all. Furthermore, clinical trials may be delayed or suspended at any time by us or by the FDA, the TPD or foreign regulatory authorities if it is determined that the subjects or patients are being exposed to unacceptable risks. We may encounter delays or rejections based on varying regulatory interpretations or changes in regulatory agency policies, during the period in which we develop a product.

No assurance can be given that apabetalone or any other product candidate will prove to be safe and effective in clinical trials or that we will receive the requisite regulatory approval. Moreover, any regulatory approval of a drug which is eventually obtained may be granted with specific limitations on the indicated uses for which that drug may be marketed or may be withdrawn if complications occur following initial marketing or if compliance with regulatory standards is not maintained. We have limited experience in filing and pursuing applications necessary to gain these regulatory approvals.

The approval procedures vary among countries and can involve additional product testing and administrative review periods. The time required to obtain approval in various countries vary from one another. Approval in one country does not ensure approval by the regulatory authorities of other countries. The failure to obtain such approvals may materially adversely affect our business, financial condition, and results of operations.

**Regulatory authorities may not approve our products even if they meet safety and efficacy endpoints in clinical trials.**

The FDA, the TPD and other foreign regulatory agencies can delay, limit, or deny marketing approval for many reasons, including finding a product may not be considered safe and effective; the manufacturing processes or facilities may not meet applicable requirements; or changes in approval policies or regulations. Our product candidates may not be approved even if they achieve their endpoints in clinical trials. Regulatory agencies, including the FDA, or their advisors may disagree with our trial design and our interpretations of data from preclinical studies and clinical trials. Regulatory agencies may change requirements for approval even after a clinical trial design has been approved. Regulatory agencies also may approve a product candidate for fewer or more limited indications than requested or may grant approval subject to the performance of post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

**Our products will remain subject to ongoing regulatory review even if they receive marketing approval. If we fail to comply with continuing regulations, we could lose these approvals, and the sale of any future products could be suspended.**

In the event we receive regulatory approval to market a particular product candidate, United States, Canadian or other foreign regulatory authority could condition approval on conducting additional costly post-approval studies or could limit the scope of approved uses. In addition, the product may later cause adverse effects that limit or prevent its widespread use, force us to withdraw it from the market or prevent or delay our ability to obtain regulatory approvals in additional countries. In addition, we will continue to be subject to regulatory review and periodic inspections to ensure adherence to applicable regulations. After receiving marketing approval, the

FDA imposes extensive regulatory requirements on the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion, and record keeping related to the product. Failure to comply with the regulatory requirements could result in:

- civil or criminal penalties or fines;
- injunctions;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- suspension or withdrawal of regulatory approvals; and
- refusal to approve pending applications for marketing approval of new drugs or supplements to approved applications.

**We may be subject to product liability claims if our products harm people, and we do not have product liability insurance.**

The manufacture and sale of pharmaceutical products involve an inherent risk of product liability claims and associated adverse publicity. We have entered into human clinical trials that involve inherent risks in the testing of unproven products. We currently have only clinical trial liability insurance for our products; we do not have product liability insurance. We do not know if we will be able to maintain existing or obtain additional clinical trial liability insurance or obtain product liability insurance on acceptable terms or with adequate coverage against potential liabilities. This type of insurance is expensive and may not be available on acceptable terms. If we are unable to obtain or maintain sufficient insurance coverage on reasonable terms or to otherwise protect against potential clinical trial and product liability claims, we may be unable to commercialize our products. A successful clinical trial liability or product liability claim brought against us in excess of our insurance coverage, if any, may require us to pay substantial amounts. This could have a material adverse effect on our business, financial condition, and results of operations.

**The pharmaceutical industry is extremely competitive. If our competitors develop and market products that are more effective, safer, or less costly than any future products that we may develop, our commercial opportunity will be reduced or eliminated.**

The technological competition we face from new and established pharmaceutical companies, biopharmaceutical companies and universities is intense and is expected to increase, in particular in the market for therapeutic products to treat, mitigate or prevent cardiovascular disease. Competitors may develop products more quickly and obtain regulatory approval for such products more rapidly or develop products which are more effective than those which we intend to develop. Our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects or are less expensive than any future products that we may develop and commercialize. In addition, significant delays in the development of our product candidates could allow our competitors to bring products to market before us and impair our ability to commercialize our product candidates. Research and development by others may render our technology or products obsolete or noncompetitive or produce treatments or cures superior to any therapy developed or to be developed by us.

We anticipate that, if approved for the reduction of MACE in cardiovascular / atherosclerotic disease, apabetalone would be positioned to be used in conjunction with leading standard of care statin treatments such as Lipitor and Crestor to further reduce major adverse cardiac events such as myocardial infarction, stroke, and death and potentially compete with other therapeutic programs in development, such as, the LDL reduction programs (“PCSK9”), sodium-glucose cotransporter-2 inhibitor (“SGLT2”) programs, dipeptidyl peptidase inhibitor (“DPP-4”) programs, peptide programs, ApoA-I infusion treatments, delipidated HDL programs and cholesteryl transfer protein (“CETP”) inhibitors.

We anticipate that, if apabetalone is approved for reduction of CVD risk and MACE and it improves other biomarkers such as eGFR, Albumin and ALP, apabetalone would potentially compete with, or be added to, novel and existing CKD products in clinical development.

We anticipate that, if approved for neurodegenerative disorders, apabetalone would potentially be used in conjunction with standard of care therapies such as Aricept to improve therapeutic outcomes and/or compete with other agents and novel approaches to this disease such as small molecules, Namenda and PBT2, and monoclonal antibody technologies (“MOABs”) such as Bapineuzumab.

We anticipate that, if approved for reduction of CVD risk and MACE in diabetes mellitus patients, apabetalone would potentially be a complimentary agent added to standard of care diabetes mellitus agents in clinical development.

We anticipate that, if approved for the treatment of COVID-19, apabetalone would be used alongside current standard of care therapies to potentially reduce the severity and duration of the disease, shorten related hospitalizations, and limit the need for more serious interventions, such as mechanical ventilation.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Established

pharmaceutical companies may invest heavily to discover quickly and develop novel compounds or drug delivery technology that could make our product candidates obsolete. Smaller or early-stage companies may also prove to be significant competitors, particularly through strategic partnerships with large and established companies. In addition, these third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or discovering, developing and commercializing products before we do. If we are not able to compete effectively against our current and future competitors, our business will not grow, and our financial condition will suffer.

**We are dependent upon retaining and attracting key personnel and others, the loss of which could materially adversely affect our business, financial condition, and results of operations.**

We depend on certain members of our management and scientific staff, the loss of whose services might significantly delay or prevent the achievement of research, development or business objectives and would materially adversely affect our business, financial condition, and results of operations. We do not have employment agreements with any of our senior management that would prevent them from leaving us. In addition, our success depends, in large part, on our ability to improve our management systems and attract and retain qualified management, scientific and medical personnel, and on our ability to develop and maintain important relationships with commercial partners, leading research institutions and key distributors. We face intense competition for such personnel and relationships. We cannot assure that we will attract and retain such persons or maintain such relationships. In addition, failure to succeed in clinical trials may make it more challenging for us to recruit and retain qualified scientific personnel.

**We may not be able to attract, train and retain a sufficient number of qualified employees to maintain and grow our business.**

We expect that our potential expansion into areas and activities requiring additional expertise, such as further clinical trials, governmental approvals, manufacturing, sales, marketing, and distribution will place additional requirements on our management, operational and financial resources. We expect these demands will require an increase in management and scientific personnel and the development of additional expertise by existing management personnel. There is currently aggressive competition for employees who have experience in technology and engineering. The failure to attract and retain such personnel or to develop such expertise could materially adversely affect our business, financial condition, and results of operations.

**Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information. Disclosure of this information may materially adversely affect our business, financial condition, and results of operations.**

We rely on trade secrets, which we seek to protect, in part, through confidentiality and non-disclosure agreements with our employees, collaborators, suppliers, and other parties. There can be no assurance that these agreements will not be breached, that we would have adequate remedies for any such breach or that our trade secrets will not otherwise become known to or independently developed by our competitors. We might be involved from time to time in litigation to determine the enforceability, scope, and validity of our proprietary rights. Any such litigation could result in substantial cost and divert management's attention from our operations.

**We may need to implement additional finance and accounting systems, procedures and controls in the future as we grow and to satisfy new reporting requirements.**

As we grow, we may access capital markets more broadly which could require us to implement additional finance and accounting systems along with enhanced internal control systems. This will result in increased costs to us as we continue to undertake efforts to comply with best practices and applicable rules and requirements applicable to public companies. These rules may make it more difficult and costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage as compared to the policies previously available to public companies. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or our board committees or as executive officers. In addition, we may need to hire additional legal and accounting staff with appropriate experience and technical knowledge, and we cannot assure that if additional staffing is necessary that we will be able to do so in a timely fashion.

**Our products may not be eligible for reimbursement from government or private third-party payors, or may be eligible for reimbursement at lower prices than we currently anticipate, which could materially adversely affect our business, financial condition, and results of operations.**

Our ability to successfully market therapeutic products depends in part on the extent to which reimbursement for the cost of such products and related treatments will be available from government health administration authorities, private health insurers and other healthcare organizations. Significant uncertainty exists as to whether newly approved pharmaceutical products will qualify for reimbursement from these organizations. Furthermore, challenges to the price of medical products continue to grow in frequency due to increased focus on cost containment and pharmacoeconomic issues. These recent changes will become more pronounced as leading therapeutics in the atherosclerosis market such as statins continue to come off patent. Health authorities will continue to

increase their scrutiny and pharmacoeconomic diligence on new products in all disease areas including those for the cardiovascular market. These rapid changes in the healthcare reimbursement marketplace will potentially have a significant impact on the future marketability of new drugs in development and could materially adversely affect our business, financial condition, and results of operations. It is expected that new drug entrants will not only have to be effective and safe but also have to provide a clear value proposal to health systems, such as risk reduction in MACE, over the current standard of care therapy, statin therapy.

In light of these market changes in drug development, pricing of drug therapies has come under significant pressure with government authorities and private health insurers around the world. The top current leading reimbursed markets; USA, Japan, Germany, UK, France, Spain, Italy, and Canada have implemented healthcare reforms that focus specifically on value and reimbursement. Reforms such as reference-based pricing, pharmacoeconomics, and numbers needed to treat are a few of the many instruments that healthcare organizations utilize to ensure maximum value for reimbursed therapeutics. Healthcare reform is underway in these top global markets and there is additional uncertainty about the viability of current pricing methodologies for reimbursement. There can be no assurance that adequate third-party coverage will be available to establish price levels which would allow us to realize an acceptable return on our investment in product development. If we cannot realize an acceptable return on our investment in product development, we may need to delay or cease our product development.

**It may be difficult or impossible for U.S. investors to enforce judgments against us, our directors, or our officers in Canada.**

We were formed under the laws of the Province of Alberta. Some of the members of our board of directors and our officers are residents of countries other than the United States. As a result, it may be impossible for U.S. investors to affect service of process within the United States upon us or these persons or to enforce against us or these persons any judgments in civil and commercial matters, including judgments under U.S. federal or state securities laws. In addition, a Canadian court may not permit U.S. investors to bring an original action in Canada or to enforce in Canada a judgment of a state or federal court in the United States.

**Risks Relating to our Intellectual Property**

**We may not accurately predict the protection afforded by our patents and proprietary technology and if our predictions are wrong, this may materially adversely affect our business, financial condition, and results of operations.**

Our success will depend in part on our ability to obtain, maintain, and enforce patent rights, maintain trade secret protection, and operate without infringing the proprietary rights of third parties, both domestically and internationally.

Our patent positions are highly uncertain, and any future patents we receive for our potential products will be subject to this uncertainty, which may adversely affect our business, financial condition, and results of operations. There can be no assurance that pending patent applications will be allowed and that we will develop additional proprietary products that are patentable, that issued patents will provide any competitive advantage or will not be challenged by any third parties, or that patents of others will not have an adverse effect on the ability to do business. Furthermore, there can be no assurance that others will not independently develop similar products, duplicate any of the products, or design around the products patented by us. In addition, we may be required to obtain licenses under patents or other proprietary rights of third parties. No assurance can be given that any licenses required under such patents or proprietary rights will be available on terms acceptable to us. If such licenses are not obtained, we could encounter delays in introducing one or more of our products to the market, while we attempt to design around such patents, or could find that the development, manufacturing, or sale of products requiring such licenses could be foreclosed. In addition, we could incur substantial costs in defending suits brought against us on such patents or in suits in which we attempt to enforce our own patents against other parties. Such disputes could involve arbitration, litigation or proceedings declared by the U.S. Patent and Trademark Office or International Trade Commission or other foreign patent authorities. Intellectual property litigation can be extremely expensive, and this expense, as well as other consequences should we not prevail, could seriously harm our business. With respect to any infringement claim asserted by a third party, we can give no assurances that we will be successful in the litigation or that such litigation would not have a material adverse effect on our business, financial condition, and results of operation.

Until such time, if ever, that patent applications are filed and/or approved, our ability to maintain the confidentiality of the described technology may be crucial to our ultimate possible commercial success. While procedures have been adopted to protect the confidentiality of our technology through signed invention and service agreements, no assurance can be given that such arrangements will be effective, that third parties will not gain access to trade secrets or disclose the technology, or that we can meaningfully protect our rights to our trade secrets.

**Even if valid and enforceable patents cover our products and technologies, such patents will provide protection only for a limited amount of time.**

Even if patents are issued regarding our product candidates or methods of using them, those patents can be challenged by our competitors who can argue that our patents are invalid and/or unenforceable. Third parties may challenge our rights to, or the scope or validity of, our patents. Patents also may not protect our products if competitors devise ways of making these or similar product

candidates without legally infringing our patents. The Federal Food, Drug and Cosmetic Act and the FDA regulations and policies provide incentives to manufacturers to challenge patent validity or create modified, non-infringing versions of a drug or device in order to facilitate the approval of generic substitutes. These same types of incentives encourage manufacturers to submit new drug applications that rely on literature and clinical data not prepared for or by the drug sponsor.

We also rely on trade secrets to protect our technology, especially where we do not believe that patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. The employees, consultants, contractors, outside scientific collaborators and other advisors of our company and our strategic partners may unintentionally or willfully disclose our confidential information to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time consuming and the outcome is unpredictable. Failure to protect or maintain trade secret protection could adversely affect our competitive business position.

Our research and development collaborators may have rights to publish data and other information in which we have rights. In addition, we sometimes engage individuals or entities to conduct research that may be relevant to our business. The ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to certain contractual limitations. These contractual provisions may be insufficient or inadequate to protect our trade secrets and may impair our patent rights. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our technology and other confidential information, then our ability to receive patent protection or protect our proprietary information may be jeopardized.

**Litigation or other proceedings or third-party claims of intellectual property infringement could require us to spend time and money and could shut down some of our operations.**

Our commercial success depends in part on not infringing patents and proprietary rights of third parties. Others have filed, and in the future are likely to file, patent applications covering products that are similar to our product candidates, as well as methods of making or using similar or identical products. If these patent applications result in issued patents and we wish to use the claimed technology, we would need to obtain a license from the third party. We may not be able to obtain these licenses at a reasonable cost, if at all.

In addition, administrative proceedings, such as interferences and reexaminations before the U.S. Patent and Trademark Office, could limit the scope of our patent rights. We may incur substantial costs and diversion of management and technical personnel as a result of our involvement in such proceedings. In particular, our patents and patent applications may be subject to interferences in which the priority of invention may be awarded to a third party. We do not know whether our patents and patent applications would be entitled to priority over patents or patent applications held by such a third party. Our issued patents may also be subject to reexamination proceedings. We do not know whether our patents would survive reexamination in light of new questions of patentability that may be raised following their issuance.

**We may be subject to claims for intellectual property infringement from former employers of our key employees, which could result in loss of intellectual property, our key employees or both.**

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including competitors or potential competitors. We could be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. In many cases, litigation may be necessary to defend against these claims.

Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying money claims, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper or prevent the ability to commercialize certain product candidates, which could severely harm our business, financial condition, and results of operations.

## **Risks Relating to Owning our Common Shares**

**Our share price has been and may continue to be extremely volatile. It may be difficult to resell our common shares.**

The market price of our common shares has fluctuated substantially in the past and could fluctuate substantially in the future. During the twelve months preceding December 31, 2022, the closing market price of our common shares ranged from CAD\$0.14 to CAD\$0.75 per share. In addition, the trading prices of life science and biotechnology company stocks in general have experienced extreme price fluctuations in recent years. The valuations of many life science companies without consistent product revenues and earnings are high based on conventional valuation standards, such as price-to-revenue ratios. These trading prices and valuations may not be sustained. Any negative change in the public's perception of the prospects of life science or biotechnology companies could depress our stock price regardless of our results of operations. In addition our stock may fluctuate based on a variety of factors, including actual or anticipated regulatory approvals or disapprovals of our products or competing products, actual or anticipated results and timing of our clinical trials, changes in the expected or actual timing of our development programs, changes in our operating



results, conditions or trends in the life science and biotechnology industries, announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments, additions or departures of key personnel, sales and distributions of our common shares by us or our shareholders, changes in general conditions in the economy or other developments affecting us, our clients, or our competitors, some of which may be unrelated to our performance.

Among other things, volatility in our share price could mean that investors will not be able to sell their shares at or above prices at which they were acquired. The volatility also could impair our ability in the future to offer common stock as a source of additional capital. In addition, in the past, stockholders have often instituted securities class action litigation after periods of volatility in the market price of a company's securities. If a stockholder files a securities class action suit against us, we would incur substantial legal fees, and our management's attention and resources would be diverted from operating our business in order to respond to the litigation.

**If we sell common shares in the future, existing common shareholders will experience immediate dilution and our stock price may decrease.**

We will need to raise additional capital to fund our operations and to develop our products. We will likely raise such additional capital through the sale of our common shares and/or warrants from time to time. Any such financing transaction will result in our existing common shareholders experiencing immediate dilution.

**If our estimates regarding timing of milestones are incorrect our share price may decrease.**

For planning purposes, we estimate and may disclose timing of a variety of clinical, regulatory, and other milestones. We base our estimates on present facts and a variety of assumptions. Many underlying assumptions are outside our control such as the ability to recruit patients, obtain access to clinical sites as expected or obtain approval from regulatory bodies such as the FDA to enter into trials. If we do not achieve milestones consistent with investors' expectations, the price of our shares would likely decline.

**We do not currently intend to pay dividends on our common shares and, consequently, investors' ability to achieve a return on investment will depend on appreciation in the price of our common shares.**

We have not to date paid any dividends on our Common Shares. We currently intend to invest our future earnings, if any, to fund the development and growth of our business. The payment of dividends will be at the discretion of our board of directors and will depend on our results of operations, capital requirements, financial condition, future prospects, contractual arrangements, restrictions imposed by applicable law, any limitations on payments of dividends present in any debt agreements we may enter into, the dividends that we may be required to be pay to holders of the royalty preferred shares in accordance with the terms of such securities and other factors our board of directors may deem relevant. If we do not pay dividends, your ability to achieve a return on your investment in the Company will depend on any future appreciation in the market price of our common shares. There is no guarantee that our Common Shares will appreciate in value or even maintain the price at which our holders have purchased their Common Shares.

## **Additional Information**

Additional information relating to Resverlogix, including our Annual Information Form, can also be found on SEDAR at [www.sedar.com](http://www.sedar.com).