

# Management's Discussion & Analysis

October 31, 2021

This Management's Discussion and Analysis ("MD&A") of Zenith Capital Corp.'s ("Zenith" or the "Company") operations and financial position should be read in conjunction with the unaudited condensed interim consolidated financial statements and the notes thereto for the three and six months ended October 31, 2021 and 2020 and the audited consolidated financial statements and the notes thereto and the Management's Discussion and Analysis for the years ended April 30, 2021 and 2020. Our financial statements have been prepared by management in accordance with International Financial Reporting Standards ("IFRS") and comprise Zenith and its wholly-owned subsidiaries, Zenith Epigenetics Ltd. and Zenith Epigenetics Inc. An advisory with respect to the use of non-IFRS measures is set out in this MD&A under "Non-IFRS Measures". All amounts in the following MD&A are stated in US dollars unless otherwise stated. References to "we", "us" or "our" mean Zenith 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: our belief that our small molecules inhibit Bromodomain and ExtraTerminal Domain ("BET") proteins (or "bromodomains"); our intention to use our epigenetic drug development platform to develop compounds that potentially impact multiple diseases including cancer, autoimmune and others; our belief that our patent applications will protect our ideas and inventions related to composition of matter, methods and treatments in our core areas of science and business; our expectation that sufficient cash will be available to fund contractual commitments; and our expectation that we will be able to raise capital through external financing or partnering to provide funds for our programs.

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:

- BET proteins play a critical role in the epigenetic regulation of transcription of particular genes.
- BET proteins all contain highly conserved bromodomains that play a key role in their epigenetic control of gene expression.
- Our small molecules function via inhibition of BET bromodomains and, therefore, specifically modulate transcription of particular targets.
- We believe our BET inhibitors are differentiated from competing molecules.
- We believe that targeting BET proteins will have clinical applications in oncology and potentially other therapeutic areas.
- We anticipate our patents and patent applications will protect our ideas and inventions related to composition of matter, methods and treatments in our core areas of science and business.
- We anticipate that we will be able to raise capital through external financing or partnering (which could be impacted by the COVID-19 outbreak described herein) to provide funds for our programs; and
- We believe we have accurately estimated the expenditures required to complete research and development.

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 those discussed on page 12 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.

## Non-IFRS Measures

To supplement our consolidated financial statements presented in accordance with IFRS, we use the non-IFRS measure average monthly cash burn rate. This measure is provided to enhance readers' overall understanding of our current use of cash resources and is included to provide investors and management with an alternative measure for assessing our operating results in a manner that is focused on the use of cash for operations and to provide a more consistent basis for comparison between quarters. This measure is based on the cash flow used in operations prior to changes in non-cash working capital from the Consolidated Statements of Cash Flows, as presented on page 6 herein. The average monthly amount is determined using the applicable period total divided by the

number of months in the period. This measure is not in accordance with and does not have a standardized meaning under IFRS and is unlikely to be comparable to a similar measure used by other entities.

## Going Concern

Our success is dependent on the continuation of our research and development activities, progressing the core technologies through clinical trials to commercialization and our ability to finance our cash requirements. It is not possible to predict the outcome of future research and development programs, our ability to fund these programs in the future, or the commercialization of products. We have incurred significant losses to date, and with no assumption of revenues (other than the unearned licensing revenue), 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 October 31, 2021, we had \$0.1 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 October 31, 2021, we were committed to pay \$2.0 million of trade and other payables, \$0.9 million due to Resverlogix Corp. (“Resverlogix”), \$1.9 million of promissory notes, \$1.5 million of debt, \$1.1 million for research and development commitments and an additional \$0.8 million for National Cancer Institute funding (for studies to develop ZEN-3694) over the next twelve months. In addition, estimated expenditures over the next twelve months under cancellable agreements with contract research organizations conducting work related to our clinical trials total approximately \$0.5 million.

Subsequent to October 31, 2021, we received \$3.2 million from Newsoara Biopharma Co., Ltd. (“Newsoara”) pursuant to a licensing agreement. Our cash as at October 31, 2021, in combination with the \$3.2 million received subsequent to October 31, 2021, 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 alternatives to raise additional capital including issuing additional equity and/or debt and/or from other sources such as partnering and/or licensing; 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. We will also require additional capital to fund its planned research, development and corporate activities beyond the next year. The COVID-19 outbreak may impact our ability to raise additional capital and/or impact our ability to continue its clinical trials.

## Overview

Zenith Capital Corp. is a biotechnology investment company. Zenith Epigenetics Ltd., a wholly-owned subsidiary of Zenith Capital Corp., is a clinical stage biotechnology company focused on the discovery and development of novel therapeutics. Zenith Epigenetics Ltd.’s BET bromodomain inhibitors are being advanced in several oncology indications and have the potential to impact multiple additional diseases as well. Our lead compound, ZEN-3694, is in clinical development for metastatic Castration Resistant Prostate Cancer (“mCRPC”). In collaboration with Pfizer Inc. (“Pfizer”), Zenith conducted a Phase 1b/2 clinical trial evaluating ZEN-3694 in combination with talazoparib in triple negative breast cancer (“TNBC”). Zenith and Pfizer shared costs for the TNBC trial and Zenith retains all rights to ZEN-3694.

We have used ZEN-3694 in four clinical trials, a single agent trial, and a Phase 1b/2a combination trial in mCRPC with enzalutamide, which both have been completed, and a Phase 1b/2a combination trial in TNBC with talazoparib, which is ongoing, and a Phase 2b randomized mCRPC trial which dosed its first patient in December 2021. These trials are described below. Zenith announced in July 2020 the participation in a University of California San Francisco (“UCSF”) principal investigator led Phase 2 clinical trial in androgen receptor (“AR”) independent and AR dependent mCRPC patients who have progressed on an AR signaling inhibitor (“ARSi”). For this trial, UCSF is also collaborating with Merck who is providing financial support and Keytruda. Patients will be dosed with a triple combination of ZEN-3694, Merck’s PD-1 antibody, pembrolizumab, and Pfizer’s ARSi, enzalutamide. The first patient was dosed in March 2021.

Also, Zenith entered into a cooperative research and development agreement (“CRADA”) with the National Cancer Institute (“NCI”) in October 2020 to develop ZEN-3694 for multiple oncology indications. The first clinical study is in resistant ovarian cancer combining ZEN-3694 with Bristol Myers Squibb (“BMS”) checkpoint inhibitors nivolumab and ipilimumab. BMS is a co-collaborator for this study and dosing for this study is expected to start by calendar Q1 2022. The second NCI sponsored study in collaboration with the Dana-Farber Cancer Institute will evaluate the combination of ZEN-3694 plus chemotherapy in patients with nut midline carcinoma and is expected to start in calendar Q1 2022. The third NCI sponsored study combining ZEN-3694 with entinostat, a HDAC inhibitor, in patients with lymphoma or solid tumors is expected to start in Q1 2022. Syndax Pharmaceuticals Inc. (“Syndax”) is a co-collaborator for this study and is providing entinostat. Furthermore, Zenith also expects to enter into multiple additional clinical studies under the CRADA over the coming year.

We have also entered into an agreement with Astellas Pharma Inc. to evaluate ZEN-3694 in combination with enzalutamide in patients with metastatic castration resistant prostate cancer (mCRPC). Zenith and Newsoara will conduct a Phase 2b randomized study in the US, China and possibly elsewhere to evaluate the combination relative to single agent enzalutamide in mCRPC patients who have

progressed on a prior androgen receptor signaling inhibitor (ARSi). Astellas will supply enzalutamide for the trial and Zenith will retain all rights to ZEN-3694.

In addition, we conduct research and development related to our epigenetics platform technology, supporting the development of ZEN-3694. We also hold royalty preferred shares of Resverlogix, as described on page 6 under “Resverlogix Royalty Preferred Shares”.

### **Epigenetics**

The selective production of the proteins encoded by genes contained in cells within our body gives rise to the differences between cells. When cellular protein levels deviate from normal, this can lead to disease. Epigenetics is a cellular mechanism for regulating gene expression arising from the interplay between nuclear proteins and DNA that does not alter the genetic code. Specifically, the epigenetic processes refer to the function or modifications to DNA or the proteins (such as histones) that are associated with DNA, which in turn determine whether a gene is on or off or whether its activity is high or low. The activity level of a gene can in many cases mean the difference between a healthy normal physiological effect and a disease.

### **Our Epigenetic Drug Development Platform**

Our epigenetics drug development platform has the potential to impact multiple diseases including cancer and other disorders with significant unmet medical need. This platform targets BET proteins that play a critical role in the epigenetic regulation of transcription of particular genes. BET proteins are often called “readers” of the histone/chromatin structure because they recognize a particular modification (acetylated lysine moieties) of proteins that may be associated with the DNA upon a BET protein ‘reading’, in other words binding to an acetylated lysine, the BET protein can recruit other proteins essential to the regulation of gene transcription. All BET proteins contain highly conserved bromodomains that play a key role in their epigenetic control of gene expression. Our small molecules function via inhibition of BET bromodomains and therefore specifically modulate transcription of particular target genes. We are focused on the development of these inhibitors for the treatment of patients with defined cancers and other disease indications.

### **Research and Development**

We continue to expand our knowledge in drug research, including significantly expanding our oncology drug discovery and development program with new epigenetic targets, each comprised of research performed by contract research organizations as well as our internal discovery group. Based on novel scaffolds discovered by Zenith, we advanced several differentiated BET inhibitor programs through preclinical development.

#### *Oncology*

Small molecule inhibition of BET bromodomain containing proteins is an exciting new epigenetic approach to treat cancer. BET bromodomain inhibitors have shown promising preclinical efficacy in multiple models of hematological malignancies and solid tumors and clinical validation is emerging. Our oncology program centers around developing best in class BET inhibitors for the treatment of cancers with significant unmet need.

BET bromodomain inhibitors are part of a novel and emerging class of epigenetic regulators that target cancer in a fundamentally different way than most other chemotherapeutic drugs and existing targeted therapies, including kinase inhibitors, hormone modulators, and immunotherapies. BET inhibitors act by repressing expression of oncogenes, including MYC and BCL-2, that are abnormally and highly expressed in many cancer cells, resulting in inhibited cell proliferation and induction of apoptotic cell death.

Additionally, it has recently been shown that cancer progression may arise from tumor cells acquiring super-enhancers as a mechanism for overexpressing specific hallmark oncogenes. BET inhibitors may selectively suppress the activity of super-enhancers underlying gene expression, and we have shown this mechanism may be selective towards tumor cells. BET proteins also play a central role in the transcriptional program of oncogenes arising from gene fusions, translocations and mutations.

Drug resistance is a critical limitation across all therapeutic modalities and there is a broad preclinical dataset demonstrating that the treatment of drug resistant cancers with BET inhibitors renders them sensitive to the other therapies. This offers significant clinical potential for the treatment of resistant cancers with BET inhibitors, either as a single agent or in combination with other therapeutic agents.

Our current goal is to advance BET inhibitors, that are well-differentiated from competing BETi programs, into clinical development. Our 2<sup>nd</sup> generation inhibitors, compared to competing BET inhibitors, have shown good preclinical and clinical efficacy, favorable drug-like properties, and a superior on-target safety profile, combinability with other targeted drugs, providing us with the opportunity to develop best-in-class inhibitors with potentially better efficacy and safety profiles. We may identify and explore new epigenetic targets that will complement our current platform in the future.

Our lead compound, ZEN-3694, is well differentiated and has shown a superior safety and efficacy profile in clinical studies as compared to other BET bromodomain inhibitors; we believe ZEN-3694 places us at the forefront of development of BET combination therapies for the treatment of mCRPC and triple negative breast cancers in patient populations with a high unmet need and most likely to benefit from BET inhibitor combination therapies.

## *Clinical Development*

Our Phase 1 single agent clinical trial with ZEN-3694 in mCRPC patients, initiated in April 2016, met its primary safety endpoints, identified a maximum tolerated daily dose of 60 mg for the single agent (ZEN-3694), and provided valuable safety, pharmacokinetic and pharmacodynamic data.

Next, in our Phase 1b/2a combination clinical trial in metastatic Castration Resistant Prostate Cancer (“mCRPC”) patients, dosing ZEN-3694 in combination with enzalutamide, initiated in December 2016, we evaluated the safety, pharmacokinetics, and efficacy of ZEN-3694 in combination with enzalutamide in mCRPC patients that have progressed on first line standard of care androgen receptor signaling inhibitors (“ARSi”). The trial encompassed a dose escalation phase and an expansion phase, designed to potentially demonstrate early proof of concept.

On June 4, 2018, we announced that we had initiated the Phase 2 portion of our mCRPC clinical trial in patients that had progressed on an ARSi. The trial was completed in October 2019. In Phase 2, we focused on continuing the evaluation of efficacy and safety of ZEN-3694 in combination with enzalutamide (“Xtandi”). The associated translational program, measuring target modulation, and the effect of ZEN-3694 on resistance markers of ARSi, allowed us to identify patients that benefited the most from the combination treatment. The clinical data demonstrate that ZEN-3694 is active, safe, and well differentiated and most effective in patients whose tumors no longer rely on androgen signaling for growth. In April 2019, we presented a poster titled “A phase 1b/2a study of the BET bromodomain inhibitor ZEN-3694 in combination with enzalutamide in patients with metastatic castration-resistant prostate cancer” at the American Association for Cancer Research (“AACR”) Annual Meeting at Atlanta, Georgia, USA. Subsequently, the data from the completed clinical trial was published online in *Clinical Cancer Research* in August 2020.

On November 20, 2018, we announced that we had entered into a clinical trial collaboration with Pfizer to evaluate the safety and efficacy of a novel anti-cancer combination of Zenith’s investigational bromodomain and extra-terminal domain inhibitor (“BETi”), ZEN-3694, and Pfizer’s poly ADP ribose polymerase inhibitor (“PARPi”), talazoparib, in patients with locally advanced or metastatic triple negative breast cancer (“TNBC”) and without a germline mutation in BRCA1/2. The preclinical data indicate that combining talazoparib with ZEN-3694 is a rational combination to test in patients that are proficient in homologous DNA repair. BETi have been shown pre-clinically to modulate homologous DNA repair genes and can thus potentially sensitize BRCA1/2 proficient patients to talazoparib. The Phase 1b part of the trial (initiated in calendar Q1 2019 and completed in calendar Q2 2020) evaluated the safety, pharmacokinetics, and pharmacodynamics of the combination and identified a dose for the Phase 2 part of the trial. On December 19, 2019, we announced that the TNBC collaboration with Pfizer was progressing well with clinical activity in some patients. The Phase 2 part of the trial evaluating efficacy of the combination, with overall response rate plus disease stabilization (clinical benefit rate) being the primary endpoint, began in April 2020. Interim clinical data from our TNBC study was presented in December 2020 at the San Antonio breast cancer symposium. Pfizer is providing talazoparib, Zenith is providing ZEN-3694 and executing the study, and both parties are funding the study, with Pfizer funding up to \$2.9 million, or approximately 50%, of the shared study costs. Patient accrual has been completed and future plans for this program will be announced in the first half of calendar 2022.

On December 19, 2019, we also announced that we had completed the Phase 1b/2, ZEN-3694 + enzalutamide combination trial in mCRPC patients who had progressed on an androgen receptor (AR) antagonist, abiraterone and/or enzalutamide. In these poor prognosis patients, where there is no standard of care, the data demonstrated that ZEN-3694 + enzalutamide provided a significant and meaningful radiographic progression-free survival benefit of approximately 39 weeks compared to approximately 12-24 weeks for patients receiving only the AR antagonist. Furthermore, the benefit was particularly significant in low AR signaling and/or AR independent tumors, which do not respond to AR antagonist monotherapy. Detailed results of the Phase 1b/2 mCRPC study were published online in *Clinical Cancer Research* in August 2020.

As part of our clinical program, we have implemented a rich translational biology program to support further clinical development. The program encompasses our in-house developed pharmacodynamic assay to monitor target engagement in whole blood, correlative biomarkers for insight into mechanism of action and for developing future patient pre-selection approaches, and immuno-oncology pharmacodynamic markers.

On July 29, 2020, we announced our participation in a University of California San Francisco (“UCSF”) principal investigator led Phase 2 clinical trial in collaboration with Zenith and Merck in mCRPC patients who have progressed on an ARSi and includes patients whose tumors are no longer dependent on androgen receptor signaling. These ARSi independent patients do not benefit from a second ARSi and are in need for alternate therapies. In this study patients will be dosed with a triple combination of ZEN-3694, Merck’s PD-1 antibody, pembrolizumab, and Pfizer’s ARSi, enzalutamide. Pre-clinical data has shown that ZEN-3694 has synergistic immune-oncologic activity with pembrolizumab in various pre-clinical models. On March 15, 2021, we announced dosing of the first patient with the triple combination of ZEN-3694, pembrolizumab, and enzalutamide.

On October 5, 2020, we announced we entered into a cooperative research and development agreement (“CRADA”) with the National Cancer Institute (“NCI”) (part of the U.S Department of Health and Human Services) to develop ZEN-3694 for multiple oncology indications. Under the CRADA, ZEN-3694 will be included in clinical studies in combination with other therapies for cancers with a significant unmet medical need. In the first clinical study under the CRADA, NCI, Zenith, and Bristol Myers Squibb will investigate the combination of ZEN-3694 with checkpoint inhibitors nivolumab and ipilimumab in resistant ovarian cancer. Dosing is expected to start

during calendar Q1 2022. The second NCI sponsored study in collaboration with the Dana-Farber Cancer Institute will evaluate the combination of ZEN-3694 plus chemotherapy in patients with midline carcinoma and is expected to start in calendar Q1 2022. The third NCI sponsored study combining ZEN-3694 with entinostat, a HDAC inhibitor, in patients with lymphoma or solid tumors is expected to start in Q1 2022. Syndax is a co-collaborator for this study and is providing entinostat. Zenith expects to enter into additional NCI led clinical studies under the CRADA over the coming year to significantly broaden the indications and combination therapies in which ZEN-3694 is explored. As at October 31, 2021, we are committed to provide funding totaling up to an estimated \$2.1 million (excluding the cost of ZEN-3694), anticipated over the next five years, including up to an estimated \$0.8 million over the next twelve months.

On April 22, 2021, we announced we entered into an agreement with Astellas Pharma Inc. (“Astellas”) to evaluate ZEN-3694, Zenith’s leading BET inhibitor, in combination with Astellas and Pfizer’s androgen receptor inhibitor, XTANDI (enzalutamide), in patients with metastatic castration resistant prostate cancer (mCRPC). Under the terms of the agreement, Zenith and Newsoara are conducting a Phase 2b randomized study to evaluate the efficacy of the combination of ZEN-3694 and enzalutamide relative to single agent enzalutamide in mCRPC patients who have progressed on a prior androgen receptor signaling inhibitor (ARSi). The trial dosed its first patient in December 2021. Astellas is supplying enzalutamide for the trial and Zenith has retained all rights to ZEN-3694.

### **Private Placements**

In June, July and August 2021, we issued a total of 120,334 equity units pursuant to private placements at a price of \$1.50 per unit for gross proceeds of \$0.2 million. Each equity unit consisted of one common share and one-half common share purchase warrant. Each warrant granted in June, July and August 2021 is exercisable at a price of \$2.00 per underlying common share for a period of two years from the closing of the private placements. As described in Note 8 “Financing rights” in our unaudited condensed interim consolidated financial statements, under certain conditions, the subscribers of the June, July and August 2021 private placements are entitled to receive additional shares.

Subsequent to October 31, 2021, Newsoara entered into a subscription agreement to subscribe for 1.5 million units of Zenith at a price of \$1.00 per unit, and Newsoara also agreed to subscribe for an additional 10 million units of Zenith by way of completing ZEN-3694 development programs with a budget of \$10 million over the next 15 months. Each unit shall be comprised of one common share and one-half of a common share purchase warrant. Each whole warrant shall be exercisable into one common share at \$1.00 for a period of two years from the date of the subscription agreement.

### **Newsoara License Agreements**

In July 2019, Zenith Epigenetics Ltd. entered into a license agreement with Newsoara for our lead compound, ZEN-3694, in China, Hong Kong, Taiwan, and Macau (the “Territories”). Under the terms of the agreement, Newsoara will have the rights to develop, market, and distribute ZEN-3694 for all indications in the Territories. If the results from ZEN-3694 are not satisfactory to Newsoara, Newsoara is entitled to replace ZEN-3694 with another of our compounds to which the license agreement will apply, however we would not necessarily develop, market and/or distribute the replacement compound (outside the Territories). Pursuant to the License Agreement, Newsoara agreed to pay Zenith Epigenetics Ltd. upfront and near-term development milestone payments totaling \$15.0 million. Initial non-refundable upfront payments of \$1.0 million and \$2.5 million (less applicable tax withholdings) were received in July and September 2019, respectively. In December 2019, we received a development milestone payment of \$5.0 million, less applicable tax withholdings, from Newsoara upon completion of our Phase 2 clinical study with ZEN-3694 in metastatic castration-resistant prostate cancer to Newsoara’s satisfaction and election to continue development. The \$7.7 million of unearned licensing revenue at October 31, 2021 is comprised of the upfront payments and development milestone payments (less applicable tax withholdings).

Pursuant to the License Agreement, Newsoara also agreed to pay us a \$6.5 million development milestone payment for/upon completion of either a Phase 3 clinical trial or a clinical study which results in Zenith receiving accelerated approval by the US Food and Drug Administration (“FDA”) (subject to Newsoara’s satisfaction with the study’s results). In addition, Zenith is eligible to receive tiered royalty payments on sales of products once commercialization commences and Newsoara achieves sales. No amounts have been recognized for these milestone or royalty payments at October 31, 2021 as the conditions described above have not yet been met. During the year ended April 30, 2021, Zenith and Newsoara amended the License Agreement, removing the \$6.5 million milestone payment.

Subsequent to October 31, 2021, Zenith Epigenetics Ltd. entered into a licensing agreement with Newsoara for ZEN-3694 in Asia excluding Middle East and North Africa (“MENA”), India, and ten Eurasian countries (the “Territories”). Under the terms of the agreement, Newsoara will have the rights to develop, market, and distribute ZEN-3694 for all indications in the Territories. Zenith received an upfront payment of \$3.2 million (\$3.5 million less applicable tax withholdings) in November 2021. Zenith will also receive sales-based milestones and single digit royalties.



## Beyond Therapeutics License Agreement

In December 2020, Zenith Epigenetics Ltd. entered into an agreement with Beyond Therapeutics Corp. (the "Licensee") for an outlicense of one of our compounds (excluding ZEN-3694) worldwide excluding China, Hong Kong, Taiwan and Macau. Within one year of the effective date of the license agreement, the Licensee must select one compound to license, from up to three compounds that it shall select. In connection with the license agreement, we received a non-refundable upfront payment of \$0.5 million. The \$0.5 million received is included in unearned licensing revenue at October 31, 2021.

## Resverlogix Royalty Preferred Shares

As at October 31, 2021, we hold all 75,202,620 royalty preferred shares of Resverlogix. We, as the sole holder of the royalty preferred shares of Resverlogix, are entitled to dividends in the amount of 6-12% of Resverlogix's Net Revenue, if any. Net Revenue is defined as the aggregate of the following amounts: (i) amounts received by Resverlogix or its affiliates (as defined in the Plan of Arrangement signed June 3, 2013 ("the Arrangement")) from any person who is not Resverlogix or its affiliate (a "third party") in consideration for granting a license or other rights to the third party which entitle the third party to research, develop, make, manufacture, modify, administer, offer to sell, sell or distribute one or more of Resverlogix's products and/or intellectual property rights or amounts received under the terms of such license or other right that are granted to the third party; (ii) the gross consideration received from a third party by Resverlogix, any licensee or their respective affiliates from the sale of any product (other than consideration received by Resverlogix, any licensee or their respective affiliates from a licensee of such product or its affiliate); less (A) credits or allowances, if any, actually granted; (B) discounts actually allowed; (C) freight, postage, and insurance charges and additional special packaging charges; (D) customs duties, and excise sales taxes, duties or other taxes imposed upon and paid with respect to such sales (excluding what is commonly known as income taxes); (E) rebates and chargebacks or retroactive price reductions made to federal, state or local governments (or their agencies), or any third party payor, administrator or contractor, including managed health organizations; and (F) commissions related to import, distribution or promotion of any product paid to third parties (specifically excluding any commissions paid to sales personnel, sales representatives and sales agents who are employees or consultants of, or members of a contract sales force engaged by or on behalf of, Resverlogix, any licensee or their respective affiliates); and (iii) amounts received from a third party by Resverlogix or its affiliates in consideration for the sale of any intellectual property right.

The holder of the preferred shares does not have the right to participate in additional dividends declared, if any, to common shareholders nor do they carry the right to vote. The holder of the preferred shares does not have any claim on Resverlogix's residual net assets other than an amount equal to the greater of (i) \$1.00 divided by the number of outstanding royalty preferred shares; and (ii) the amount of any accrued, but unpaid royalty dividend payment and additional royalty dividend payment.

The royalty preferred shares have not been recognized in the statement of financial position. We have not recognized the royalty preferred shares for accounting purposes because assets that were acquired through the distribution in connection with the Arrangement were accounted for at Resverlogix's historical carrying values and such assets were not previously recognized in Resverlogix's financial statements. We will recognize a royalty receivable when royalties are reasonably determinable and the economic benefits are probable to flow to us.

## Results of Operations for the Three and Six Months Ended October 31, 2021 and 2020

<i>(in thousands of US dollars unless otherwise noted)</i>	Three months ended October 31,		Six months ended October 31,	
	2021	2020	2021	2020
Expenses	\$ 1,920	\$ 1,770	\$ 4,008	\$ 3,378
Financing costs	159	38	341	176
Loss before income taxes	2,079	1,808	4,349	3,554
Income taxes	8	9	14	15
Net loss and total comprehensive loss	\$ 2,087	\$ 1,817	\$ 4,363	\$ 3,569
<b>Net loss per share</b>				
Basic and diluted	\$ 0.02	\$ 0.01	\$ 0.03	\$ 0.03

## Cash Burn Rate

Our average monthly Cash Burn Rate, a non-IFRS measure as described on page 1 herein, for the three and six months ended October 31, 2021 was \$0.4 million and \$0.4 million, respectively (2020 - \$0.5 million and \$0.4 million, respectively), reflecting continued spending related to our clinical trials.

<i>(in thousands of US dollars unless otherwise noted)</i>	Three months ended October 31,		Six months ended October 31,	
	2021	2020	2021	2020
Cash flow used in operations	\$ (525)	\$ (1,787)	\$ (509)	\$ (5,102)
Changes in non-cash working capital	(707)	333	(1,892)	2,408
	(1,232)	(1,454)	(2,401)	(2,694)
Number of months	3	3	6	6
Average Monthly Cash Burn Rate	(411)	(485)	(400)	(449)

Our historical Cash Burn Rate is not necessarily indicative of our future Cash Burn Rate. Our Cash Burn Rate will be impacted most significantly by the specific nature and timing of our research and development activities including, in particular our clinical trials (including any expansions thereof) and any additional clinical trials. Refer to “Cash and Liquidity” below for further information.

## Research and Development

Research and development (“R&D”) includes product development costs such as clinical development costs, drug development and pharmacology, toxicology and other studies, and costs associated with discovery research such as medicinal chemistry. R&D expenses include compensation and related costs (including service fees paid to Resverlogix) for R&D staff, consulting fees, supplies and general laboratory operating expenses.

During the three and six months ended October 31, 2021, gross R&D expenditures totaled \$0.9 million and \$2.2 million, respectively, net of cost recoveries of \$0.2 million and \$0.4 million, respectively, related to the clinical trial collaboration with Pfizer Inc. (2020 – \$1.2 million and \$2.4 million, respectively, net of cost recoveries of \$0.3 million and \$0.6 million, respectively).

During the three and six months ended October 31, 2021, clinical and regulatory costs totaled \$0.3 million and \$0.5 million, respectively (2020 – \$0.4 million and \$0.8 million, respectively), and included costs for our TNBC and mCRPC trials. The decrease reflects lower spending on our Phase 1b/2 TNBC trial. Clinical costs are comprised primarily of investigator grants, project and site management and monitoring costs, and laboratory costs.

During the three and six months ended October 31, 2021, preclinical research and other activities totaled \$0.1 million and \$0.2 million, respectively (2020 – \$0.1 million and \$0.2 million, respectively). These costs include research, pharmacology, toxicology and DMPK (drug metabolism, and pharmacokinetics). The focus of the preclinical activities continues to be on the understanding and utilizing clinical data for further development activities. Costs in both periods included preclinical support to the translational medicine program for mCRPC, academic collaborations to support the understanding of resistance to BET inhibitors, as well as external studies supporting the expansion of the immuno-oncology program.

Research and development costs were decreased by lower non-cash share-based payments (as described below).

## General and Administrative

General and administrative (“G&A”) expenses include operating costs not directly involved in research and development, as well as professional fees for legal, audit, tax, communications, and business development. During the three and six months ended October 31, 2021, G&A expenditures totaled \$1.0 million and \$1.8 million, respectively (2020 – \$0.6 million and \$1.0 million, respectively), reflecting higher non-cash share-based payments (as described below) and management fees charged by Resverlogix in the current period.

## Share-Based Payments

Our share-based payments are included in research and development and general and administrative.

During the three and six months ended October 31, 2021, we recognized non-cash share-based payments of \$0.7 million and \$1.5 million, respectively (2020 – \$0.3 million and \$0.6 million, respectively). The expense recognized in a given period reflects the fair value of past and newly-granted stock options and restricted stock units (“RSUs”) outstanding during the period, and is impacted by factors such as vesting and fluctuations in the fair market value of our shares. During the six months ended October 31, 2021, we granted 829,000 stock options (2020 – 1,078,400) with a weighted average exercise price of CAD\$1.39 (2020 - CAD\$1.05) and a weighted average fair value of \$0.73 (2020 - \$0.76) per stock option, and 2,512,420 (2020 – 246,823) RSUs, including 1,088,813 RSUs to settle accrued bonuses and director fees from prior years. In addition, directors fees are currently paid by way of the issuance of RSUs in lieu of payment in cash, with \$97 thousand of current period director fees settled with RSUs.

## Change in Fair Value of Financing Rights

Pursuant to the terms of certain private placements closed during the six months ended October 31, 2021 and the year ended April 30, 2021 with anti-dilution rights attached, in the event that we complete an equity financing within the period of time prescribed by the applicable subscription agreement and the price per share is below \$1.50, the price per share paid by the initial subscriber will be adjusted to the lower price per share and they will, accordingly, receive additional common shares for no additional consideration. Unexpired financing rights are adjusted to estimated fair value at each reporting period and any change in fair value during a given period is recorded in the statement of comprehensive loss.

The change in fair value of financing rights impacted our reported loss. During the three and six months ended October 31, 2021, we recognized a \$33 thousand gain and a \$32 thousand gain, respectively, on the change in the fair value of financing rights (2020 – \$Nil and \$0.1 million loss, respectively). Gains and losses resulting from the revaluation of financing rights are non-cash and do not impact our cash flows from operations.

## Interest and Accretion

Accretion on the Newsoara loan in the three and six months ended October 31, 2021 totaled \$54 thousand and \$0.1 million, respectively. During the three and six months ended October 31, 2020, interest on the \$0.5 million unsecured convertible debenture with NGN BioMed Opportunity II, LP and another shareholder totaled \$12 thousand and \$23 thousand, respectively, and accretion of the debt issuance costs totaled \$11 thousand and \$22 thousand, respectively.

## Liquidity and Capital Resources

### Debt

#### Newsoara Loan

In March 2021, we closed a \$1.5 million loan with Newsoara. The loan is non-interest bearing, unsecured and has a maturity date of March 5, 2022. In connection with the loan, we canceled the reversionary right in the Newsoara license agreement that previously entitled Zenith, for no additional consideration, to re-acquire ownership of patents in the Territories previously assigned to Newsoara. Recognizing the loan initially at fair value resulted in a \$0.2 million gain within financing costs during the year ended April 30, 2021.

### Cash and Liquidity

As at October 31, 2021, we had \$0.1 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 October 31, 2021, we were committed to pay \$2.0 million of trade and other payables, \$0.9 million due to Resverlogix, \$1.9 million of promissory notes, \$1.5 million of debt, \$1.1 million for research and development commitments and an additional \$0.8 million for National Cancer Institute funding (for studies to develop ZEN-3694) over the next twelve months as described below under “Contractual Obligations”. In addition, estimated expenditures over the next twelve months under cancellable agreements with contract research organizations conducting work related to our clinical trials total approximately \$0.5 million.

Subsequent to October 31, 2021, we received \$3.2 million from Newsoara pursuant to a licensing agreement. We believe our cash as at October 31, 2021, in combination with the \$3.2 million received subsequent to October 31, 2021, is not sufficient to fund our contractual commitments over at least the next year and is not sufficient to fund our planned business operations over the next year. We must raise additional capital. We will continue to pursue alternatives to raise additional capital including issuing additional equity and/or debt and/or from other sources such as partnering and/or licensing; 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. The COVID-19 outbreak may impact the Company’s ability to raise additional capital and/or impact the Company’s ability to continue its clinical trials.

### Cash Flows

During the six months ended October 31, 2021, cash flows used by operating activities totaled \$0.5 million. This included \$0.85 million funding received from Pfizer Inc. for the TNBC trial collaboration (which was applied to Other assets and Unearned deposit in the six months ended October 31, 2021) (2020 - \$5.1 million used in operating activities, including a \$2.0 million decrease in trade and other payables). Cash flows generated from financing activities totaled \$0.7 million, comprised primarily of proceeds from promissory notes and the June, July and August 2021 private placements (2020 – \$5.1 million, comprised primarily of proceeds from the June 2020 private placement with Newsoara and the May 2020 convertible debenture). Cash flows used in investing activities totaled \$0.2 million (2020 – \$0.2 million).



## Commitments

As at October 31, 2021, we were party to cancellable agreements with contract research organizations conducting work related to our clinical trials. Corresponding estimated aggregate expenditures over the next twelve months total approximately \$0.5 million (April 30, 2021 – \$1.4 million).

As at October 31, 2021, we were committed to expenditures over the next twelve months of \$1.1 million (April 30, 2021 – \$1.2 million), pursuant to various research and development contracts.

We are also party to a Cooperative Research and Development Agreement (“CRADA”) with the National Cancer Institute (part of the U.S Department of Health and Human Services) to develop ZEN-3694, our lead compound, for multiple oncology indications. As at October 31, 2021, we are committed to provide funding totaling up to an estimated \$2.1 million, anticipated over the next five years, including up to an estimated \$0.8 million over the next twelve months.

We have agreed to pay Resverlogix for our proportionate share of operating rental payments and operating costs (for a laboratory and offices that Resverlogix shares with Zenith) of an estimated \$0.2 million and \$0.1 million, respectively, for the next twelve months.

## Significant Accounting Policies and Estimates

Note 4 to our consolidated financial statements for the years ended April 30, 2021 and 2020 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 share-based payment transactions, financing rights, derivative liability and taxes.

There is estimation uncertainty with regards to the possible impact of the COVID-19 outbreak on our financial results and our condition over the next twelve months.

The outbreak of the novel strain of coronavirus, SARS-CoV-2, has caused a pandemic identified as “COVID-19” and has resulted in governments worldwide enacting emergency measures to combat the spread of the virus. These measures, which include the implementation of travel bans, self-imposed quarantine periods and social distancing, have caused material disruption to businesses globally resulting in an economic slowdown. Global equity markets have experienced significant volatility and weakness. Governments and central banks have reacted with significant monetary and fiscal interventions designed to stabilize economic conditions. The introduction of vaccines has led to optimism and an easing of restrictions; however, the situation continues to evolve (including the prevalence of virus variants), and the duration and impact of the COVID-19 outbreak remains unknown at this time, as is the efficacy of the government and central bank interventions. It is not possible to reliably estimate the length and severity of these developments and the impact on the financial results and condition of the Company and its operating subsidiaries in future periods. The COVID-19 outbreak may impact our ability to raise additional capital and/or impact our ability to continue our clinical trials.

## Off-Balance Sheet Arrangements

As of October 31, 2021, we had 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 interim consolidated financial statements for each of the eight most recently completed quarters.

(in thousands of US dollars except as otherwise noted)	For the three months ended			
	October 31, 2021	July 31, 2021	April 30, 2021	January 31, 2021
Revenue	-	-	-	-
Total comprehensive (loss)	(2,087)	(2,276)	(1,586)	(1,758)
Net (loss) per share (\$) - basic and diluted	(0.02)	(0.02)	(0.01)	(0.01)

**For the three months ended**

(in thousands of US dollars except as otherwise noted)	October 31, 2020	July 31, 2020	April 30, 2020	January 31, 2020
Revenue	-	-	-	-
Total comprehensive (loss)	(1,817)	(1,752)	(2,283)	(2,876)
Net (loss) per share (\$) - basic and diluted	(0.01)	(0.01)	(0.02)	(0.02)

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

- the nature of our research and development programs during specific reporting periods including the timing of various studies (including our clinical trials) and discovery research;
- additional administration associated with expanded research;
- interest and accretion were impacted by entering into the \$0.5 million Debenture in the six months ended October 31, 2020 period and the \$1.5 million non-interest bearing Newsoara loan being outstanding in the current period;
- financing rights 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 loss, resulting in volatility in quarterly income (loss); and
- share-based payments fluctuate from quarter to quarter based on the timing and fair value of stock option and RSU grants. Share-based payments are a non-cash expense.

## Related Party Transactions

### Related Party Transactions with Resverlogix

We have a majority of our directors in common with Resverlogix, and thus are considered related parties. We receive management and administrative services from Resverlogix pursuant to a Management Services Agreement dated June 3, 2013 between us and Resverlogix. The purpose of the agreement is to allow us to utilize Resverlogix's resources on a cost-effective basis and enable Resverlogix to achieve greater utilization of its resources. As consideration for the services, we pay Resverlogix 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.

We are party to a Services Agreement with Resverlogix whereby we supply limited research services to Resverlogix. The purpose of the agreement is to enable Resverlogix to obtain access to specialized research services on a more cost-effective basis than other alternatives.

### Promissory Notes

At October 31, 2021, promissory notes totaling \$1.9 million are due to four related party lenders and one third party. During the six months ended October 31, 2021:

- the Chief Executive Officer / Chairman of the Company lent an additional CAD\$0.2 million and was repaid CAD\$0.1 million (the outstanding \$0.6 million (CAD\$0.8 million) promissory note bears interest at 5%, is payable on demand and is secured);
- another director of the Company lent an additional CAD\$0.1 million to the Company (the outstanding \$0.3 million (CAD\$0.4 million) promissory note bears interest at 5% per annum, is unsecured and is payable on demand);
- a relative of the Chief Executive Officer / Chairman of the Company lent an additional \$0.3 million (the outstanding \$0.9 million promissory note bears interest at 11% per annum, is payable on demand and is secured);
- the Chief Financial Officer lent CAD\$20 thousand (the outstanding promissory notes bears interest at 8% per annum, is unsecured and is payable on demand); and
- a third party lent \$63 thousand (the outstanding promissory notes bears interest at 8% per annum, is unsecured and is payable on demand).

In connection with the \$0.3 million promissory note advanced by a relative of the Chief Executive Officer / Chairman of the Company, we issued 150,000 warrants. Each warrant is exercisable at a price of \$0.75 per underlying common share for a period of five years from the grant date. The fair value of the 150,000 warrants was determined to be \$0.1 million and was recognized as a financing cost during the six months ended October 31, 2021.

## Outstanding Equity Instruments

As at December 16, 2021, we had authorized an unlimited number of common shares and preferred shares.

	As at December 16, 2021	As at October 31, 2021	As at April 30, 2021
Common Shares	135,623,077	135,434,077	135,302,493
Equity-classified Warrants	1,567,699	1,577,699	7,491,282
Liability-classified Warrants	100,000	100,000	100,000
Stock Options	4,777,534	4,777,534	5,123,900
Restricted Stock Units	9,158,374	9,158,374	6,665,453
	<b>151,226,684</b>	<b>151,047,684</b>	<b>154,683,128</b>

As at December 16, 2021, 3,271,824 of 4,777,534 stock options are vested and exercisable; 6,254,748 of 9,158,374 RSUs are vested. Additional information relating to our securities can be found in Note 9 to the condensed interim consolidated financial statements for the three and six months ended October 31, 2021.

## Outlook

We have developed a robust drug discovery platform in the area of epigenetics. Focusing on the inhibition of BET bromodomains, we are developing novel small molecules for indications in the areas of oncology and other disorders with significant unmet medical need. Our Phase 1 clinical trial with ZEN-3694 in mCRPC patients met its primary safety endpoints, identified a maximum tolerated daily dose of 60 mg for the single agent (ZEN-3694), and provided valuable pharmacokinetic data. ZEN-3694 is well differentiated and has shown a superior safety and efficacy profile. In our Phase 1b/2a combination clinical trial in mCRPC patients, we evaluated the safety, pharmacokinetics, and efficacy of ZEN-3694 in combination with enzalutamide in mCRPC patients that have progressed on first line standard of care anti-androgen therapy. The trial encompassed a dose escalation phase and an expansion phase, designed to potentially demonstrate early proof of concept. We believe this positions us at the forefront of development of BET Bromodomain inhibitors for the treatment of cancer. The phase 2 portion of this trial has now been completed. The data show that ZEN-3694 + enzalutamide provided a significant and meaningful radiographic progression-free survival benefit of approximately 39 weeks compared to approximately 24 weeks for patients receiving only the AR antagonist. Based on the Phase 1b/2a study data, we have met with the FDA and received positive feedback on potential development paths for our mCRPC program. As a next step in the development of ZEN-3694 + enzalutamide, we are executing a randomized Phase 2b mCRPC study in collaboration with our partner Newsoara. The first patient was dosed in December 2021.

In March 2019, we initiated a clinical trial evaluating a combination of ZEN-3694 and talazoparib (PARP inhibitor developed by Pfizer) in patients with locally advanced or metastatic triple negative breast cancer and without a germline mutation in BRCA1/2. Interim clinical data from the ongoing triple negative breast cancer (TNBC) study was presented in December 2020 at the San Antonio breast cancer symposium. We also look to expand the development of ZEN-3694 into immuno oncology combinations, as well as other solid tumor cancers beyond mCRPC and TNBC.

As part of this expansion, we are participating in a University of California San Francisco (“UCSF”) principal investigator led Phase 2 clinical trial in collaboration with Merck in mCRPC patients who have progressed on an androgen receptor signaling inhibitor (“ARSi”). Patients are dosed with a triple combination of ZEN-3694, Merck’s PD-1 antibody, pembrolizumab, and Pfizer’s ARSi, enzalutamide. Also, we have entered into a cooperative research and development agreement (“CRADA”) with the National Cancer Institute (“NCI”) (part of the U.S Department of Health and Human Services) to develop ZEN-3694 for multiple oncology indications. The first clinical study is in resistant ovarian cancer combining ZEN-3694 with BMS’s check point inhibitors and dosing in the study is expected to start in calendar Q1 2022. The second NCI sponsored study in collaboration with the Dana-Farber Cancer Institute will evaluate the combination of ZEN-3694 plus chemotherapy in patients with nut midline carcinoma and is expected to start in calendar Q1 2022. The third NCI sponsored study combining ZEN-3694 with entinostat, a HDAC inhibitor, in patients with lymphoma or solid tumors is expected to start in Q1 2022. Syndax is a co-collaborator for this study and is providing entinostat. Furthermore, we also expect to enter into additional clinical studies under the CRADA over the coming year. As at October 31, 2021, we are committed to provide funding totaling up to an estimated \$2.1 million (excluding the cost of ZEN-3694), anticipated over the next five years, including up to an estimated \$0.8 million over the next twelve months.

In parallel, we will continue to advance other aspects of our discovery platform. We will continue to discuss these specific development opportunities with potential partners to enable the advancement of these novel therapies. As described above, subsequent to October 31, 2021, we and Newsoara entered into an Asia license, for which we received \$3.2 million upfront, and concurrently entered into a private placement for a total of \$11.5 million over 15 months, strengthening our financial position and contributing substantial capital towards our development programs. Further information about our financial position is provided herein under “Cash and Liquidity”.

## Risks and Uncertainties

The biotechnology industry generally may be regarded as uncertain given the nature of the industry. Accordingly, investments in biotechnology companies should be regarded as speculative. Biotechnology research and development involves a significant degree of risk. An investor should carefully consider the risks and uncertainties described below, as well as other information contained in this Management's Discussion and Analysis. The risks and uncertainties described below is not an exhaustive list. Additional risks and uncertainties not presently known to us or that we believe to be immaterial may also adversely affect our business. If any one or more of the following risks occur, our business, financial condition and results of operations could be seriously harmed.

### Risks Relating to Our Business

**Due to the COVID-19 outbreak, we could experience supply, logistics or other disruptions, which could have a negative impact on our ability to conduct research and development (including clinical development) or commercialize products; the COVID-19 outbreak could also have a negative impact on our ability to raise additional capital.**

The outbreak of the novel strain of coronavirus, SARS-CoV-2, has caused a pandemic identified as "COVID-19" and has resulted in governments worldwide enacting emergency measures to combat the spread of the virus. These measures, which include the implementation of travel bans, self-imposed quarantine periods and social distancing, have caused material disruption to businesses globally resulting in an economic slowdown. Global equity markets have experienced significant volatility and weakness. Governments and central banks have reacted with significant monetary and fiscal interventions designed to stabilize economic conditions. The introduction of vaccines has led to optimism and an easing of restrictions; however, the situation continues to evolve (including the prevalence of virus variants), and the duration and impact of the COVID-19 outbreak remains unknown at this time, as is the efficacy of the government and central bank interventions. It is not possible to reliably estimate the length and severity of these developments and the impact on the financial results and condition of the Company and its operating subsidiaries in future periods. If the COVID-19 outbreak continues or increases in severity and results in expanded or prolonged travel, commercial or other similar restrictions, we could experience supply, logistics or other disruptions, which could have a negative impact on our ability to conduct research and development (including clinical development) or commercialize products. The COVID-19 outbreak may impact our ability to raise additional capital and/or impact our ability to continue our clinical trials.

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

We are in an early stage of development, which may require significant additional investment for research and development, manufacturing, clinical testing, and regulatory submissions prior to commercialization. Investors must evaluate our business in light of the uncertainties and complexities affecting a development stage pharmaceutical company. There can be no assurance that any products will 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 products. We have not proven our ability to develop and commercialize products. It is not known whether such 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 such 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 may not be indicative of the results that will be obtained in later stages of research. If regulatory authorities do not approve the products or if regulatory compliance is not maintained, we would have limited ability to commercialize such 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 products commercially available, we will not generate product revenues, and we may be forced to cease operations.

**We have been advanced funds by Newsoara under an unsecured promissory note and failure to pay all amounts when they become due could result in legal action by Newsoara.**

In March 2021, we obtained a \$1.5 million loan from Newsoara; we issued an unsecured promissory note which does not bear interest and matures on March 5, 2022.

We do not currently have sufficient cash available to repay the loan when it becomes due. We will have to raise additional capital to repay the loan on the maturity date. If we are unable to repay the promissory note, Newsoara could pursue legal action to obtain and enforce a judgment for the amount of the indebtedness, which could have a material adverse effect on our business and operations and our ability to continue as a going concern.

**We have been advanced funds under secured promissory notes and failure to repay all amounts upon demand could result in a loss of all of our assets.**

In May 2021, the promissory notes (and potentially any future promissory notes) due to the Chief Executive Officer / Chairman of the Company and a relative of the Chief Executive Officer / Chairman of the Company were amended to be secured by a general security interest in all of our assets, rather than unsecured.

We do not currently have sufficient cash available to repay the principal amount of the promissory notes upon demand. We will have to raise additional capital to repay the promissory notes. If we are unable to repay amounts owing under the promissory notes, the lenders could proceed to foreclose or otherwise realize upon all of our assets, including our intellectual property, that is security for the indebtedness.

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

To date, we have not recorded any revenues from the sale of biopharmaceutical products (other than the unearned licensing revenue from Newsoara and Beyond Therapeutics Corp.). We expect to incur substantial net losses and negative cash flow for the foreseeable future. Such losses will 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 profitability. Currently, we have no products approved for commercial sale, and to date we have not generated any product revenue. The size of our future net losses 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 incur losses 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 and losses are also expected. Even if we do achieve profitability, we may not be able to sustain or increase profitability 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 products. Historically operations have been financed exclusively by private placements and, initially, Resverlogix. We intend to raise additional funds through 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 our discovery research, preclinical studies, clinical trials and developmental programs;
- timing, costs and outcomes of regulatory proceedings;
- payments received under any future partnerships;
- prosecution or defense of patent claims;
- costs associated with commercialization of any products;
- the cost and timing of developing sales and marketing operations or partnerships; and
- competing technological and market developments, including the introduction by others of new therapies in our markets.

Subsequent to October 31, 2021, we received \$3.2 million from Newsoara pursuant to a licensing agreement. We believe our cash as at October 31, 2021, in combination with the \$3.2 million received subsequent to October 31, 2021, is not sufficient to fund our contractual commitments and is not sufficient to fund our planned business operations for the next year. We need to raise additional capital. Any equity financing transaction would result in our existing common stockholders experiencing immediate dilution. Any financing transaction may also contain unfavorable terms. If we raise additional funds, we may be required to relinquish rights to our products, or to grant licenses on terms that are not favorable to us.

There can be no guarantee that we will be able to raise additional funds. If we are not able to raise additional funds, we may not have sufficient capital to fund all of our currently planned operations. We would have to reduce our cash requirements by eliminating or deferring spending on research, development and corporate activities, and we may be forced to cease operations.



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.

**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. Market conditions have been particularly impacted by the COVID-19 outbreak. 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 favorable terms could have a material adverse effect on our growth strategy, financial performance and could require us to delay or abandon clinical development plans. There is a risk that one or more of our current or future business partners, such as contract research organizations and contract laboratories, may encounter difficulties during challenging economic times, which may directly affect our ability to attain our operating goals on schedule and on budget.

**We are conducting Phase 2/2b human clinical trials.**

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 any 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 many 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 or other 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.

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

Drug discovery and development has inherent risk and the historical failure rate is high. To obtain regulatory approval to market and sell any of our products, we must satisfy the FDA and other regulatory authorities, through extensive clinical trials and preclinical studies, that our products are safe. If we cannot demonstrate that our drugs 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, or other 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 products may have unfavorable 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 drugs do not show sufficient efficacy in patients with the targeted indication in clinical trials, it could negatively impact our development and commercialization or goals for our drugs and, as a result, materially adversely affect our business, financial condition and results of operations.

**The Resverlogix royalty preferred shares we hold may fluctuate in value based on factors that are not within our control.**

We hold royalty preferred shares of Resverlogix which entitle us to dividends based on a percentage of net Revenue, if any, received by Resverlogix, its affiliates or licensees. The royalty preferred shares of Resverlogix that we hold represent a significant asset. However, there is no assurance that dividends will ever be paid in respect of the royalty preferred shares. The royalty preferred shares may fluctuate significantly in value based on developments relating to the business of Resverlogix and other events that are not within

our control. In addition, there is no market through which the royalty preferred shares may be sold. Accordingly, developments relating to the business of Resverlogix may affect the value of our common shares and may impact our ability to access additional capital required to fund its research and development activities.

**We utilize Resverlogix for performing certain functions.**

We utilize Resverlogix to perform certain financial and administrative functions. Services are provided by Resverlogix to us pursuant to an agreement that may be terminated by Resverlogix upon six months prior notice. In addition, the employees of Resverlogix who are primarily responsible for the provision of services to us have specialized knowledge and experience and there is no certainty that such individuals will continue to be employees of Resverlogix. Resverlogix believed its cash as at September 30, 2021 is not sufficient to fund its contractual commitments and its planned business operations over the next year. Therefore, Resverlogix will have to raise additional capital to fund its contractual commitments and its planned business operations. If Resverlogix is not able to raise capital, the Company may be forced to cease operations.

**We are dependent on third parties 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 and contract laboratories to conduct our clinical 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 studies, 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 clinical and preclinical studies are conducted in accordance with applicable regulations. The FDA requires us to comply with regulations and standards, commonly referred to as good clinical practices (“GCP”) and good laboratory practices (“GLP”), for conducting and recording the results of our clinical and preclinical studies. Our reliance on third parties does not relieve us of these responsibilities. If the third parties conducting clinical or preclinical studies do not perform their contractual duties or obligations, do not meet expected recruitment or other deadlines, fail to comply with the FDA’s regulations, do not adhere to clinical trial protocols or otherwise fail to generate reliable clinical data, development, approval and commercialization of products 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 production of the active pharmaceutical ingredient (“API”), used in our drug compounds. 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 any 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 a product candidate. We are ultimately responsible for confirming that the APIs used in 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.

The outbreak of the novel strain of coronavirus, SARS-CoV-2, has caused a pandemic identified as “COVID-19” and has resulted in governments worldwide enacting emergency measures to combat the spread of the virus. These measures, which include the implementation of travel bans, self-imposed quarantine periods and social distancing, have caused material disruption to businesses globally resulting in an economic slowdown. Global equity markets have experienced significant volatility and weakness. Governments and central banks have reacted with significant monetary and fiscal interventions designed to stabilize economic conditions. The duration and impact of the COVID-19 outbreak remains unknown at this time, as is the efficacy of the government and central bank interventions. It is not possible to reliably estimate the length and severity of these developments and the impact on the financial results and condition of the Company and its operating subsidiaries in future periods. If the COVID-19 outbreak continues or increases in severity and results in expanded or prolonged travel, commercial or other similar restrictions, we could experience supply, logistics or other disruptions, which could have a negative impact on our ability to conduct research and development (including clinical

development) or commercialize products. The COVID-19 outbreak may impact our ability to raise additional capital and/or impact our ability to continue our clinical trials.

**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.**

As a result of the costs and risks associated with commercializing a product candidate, we intend to seek strategic partnerships with corporate and academic collaborators, licensors, licensees and others for the research and development, manufacturing, marketing and commercialization of products. There can be no assurance, however, that such collaborations will be established on favourable terms, if at all, or that future collaborations will be successful. 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 commercialize successfully 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.

We may negotiate 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 strategic partnerships on acceptable terms, or at all. We are unable to predict when or if we will enter into any strategic partnerships because of the numerous risks and uncertainties associated with establishing strategic partnerships. If we are unable to negotiate strategic partnerships for our products we may be forced to delay or terminate development or commercialization 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.

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

In addition to our collaboration with Pfizer, as a result of the costs and risks associated with commercializing a product candidate, we intend to seek additional strategic partnerships in order to continue to develop and, if approved, market products. Such strategic partnerships may require us to relinquish control over the timing and manner of clinical trials and commercialization of our products. 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 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.

**Our License Agreements are subject to certain risks and uncertainties related to our dependence on Licensees and doing business in foreign jurisdictions**

On July 25, 2019, we entered into the License Agreement with Newsoara. Under the terms of the agreement, Newsoara will have the rights to develop, market, and distribute ZEN-3694 for all indications in China, Hong Kong, Taiwan, and Macau. Pursuant to the License Agreement, Newsoara agreed to pay Zenith Epigenetics Ltd. upfront and near-term development milestone payments totaling \$15.0 million. During the year ended April 30, 2020, we received \$8.5 million of the milestone payments (less applicable tax withholdings) and during the year ended April 30, 2021, Zenith and Newsoara amended the License Agreement, removing \$6.5 million of the \$15.0 of milestone payments.

Subsequent to October 31, 2021, we entered into a licensing agreement with Newsoara for ZEN-3694 in Asia excluding Middle East and North Africa ("MENA"), India, and ten Eurasian countries. Under the terms of the agreement, Newsoara will have the rights to develop, market, and distribute ZEN-3694 for all indications in these territories.

Under the terms of these license agreements, Newsoara will be responsible for all clinical, regulatory and commercialization activities respecting ZEN-3694 in the aforementioned territories and therefore the Company will be dependent upon Newsoara in successfully undertaking those actions in a timely and economic manner and in compliance with all applicable legal and regulatory requirements within these territories. If Newsoara is unable to fulfill its obligations under the terms of the license agreements and in compliance with all applicable legal and regulatory requirements, including clinical, regulatory and commercialization of ZEN-3694, our prospective

revenue from royalty payments related to the commercialization of ZEN-3694 in these territories may be materially diminished, delayed or never realized, which could negatively affect our operating results and financial condition.

Further, conducting business with Newsoara within these territories, and specifically China, subjects us to certain economic, political, and legal risks and uncertainties regarding, among other things, the development and commercialization of ZEN-3694 and the release and receipt of payments under the terms of the license agreements, including the payment of royalties upon commercialization of ZEN-3694.

In December 2020, Zenith Epigenetics Ltd. entered into an agreement with Beyond Therapeutics Corp. for an outlicense of one of our compounds (excluding ZEN-3694), worldwide excluding China, Hong Kong, Taiwan and Macau.

Beyond Therapeutics Corp. will be responsible for all clinical, regulatory and commercialization activities respecting the licensed compound in the Territories and therefore the Company will be dependent upon Beyond Therapeutics in successfully undertaking those actions in a timely and economic manner and in compliance with all applicable legal and regulatory requirements within the Territories. If Beyond Therapeutics is unable to fulfill its obligations under the terms of the license agreement and in compliance with all applicable legal and regulatory requirements, including clinical, regulatory and commercialization of the licensed compound, our prospective revenue from royalty payments related to the commercialization of the licensed compound in the Territories may be materially diminished, delayed or never realized, which could negatively affect our operating results and financial condition.

Further, conducting business with Beyond Therapeutics subjects us to certain economic, political, and legal risks and uncertainties regarding, among other things, the development and commercialization of the licensed compound and the release and receipt of payments under the terms of the license agreement, including the payment of royalties upon commercialization of the licensed compound.

**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, if we develop any products that are approved, that the products will achieve market acceptance. If our products, 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 the products;
- the products' potential advantages over existing and future treatment methods;
- the price of the 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 the United States or other countries. 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 numerous statutes and regulations in the United States and other countries. We are required to obtain various regulatory approvals prior to being able to study, commercialize and distribute our products. The regulatory review and approval process required to perform a clinical study in the United States and other countries 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 drugs we attempt to develop or to manufacture or market drug products in reasonable time frames, if at all.

Governmental authorities in the United States or other countries may enact regulatory reforms or restrictions on the development of new therapies that could adversely affect our ability to develop drug products. The drugs and processes that we are attempting to develop require significant testing and the investment of significant funds prior to their commercialization. There can be no assurance that any 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 or other 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 any product candidates 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 problems 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 a particular product even if they meet safety and efficacy endpoints in clinical trials.**

The FDA and other 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. A product candidate may not be approved even if it achieves its 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 or other regulatory authorities 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 may enter into human clinical trials that involve inherent risks in the testing of unproven products. We currently do not have clinical trial liability insurance and we do not have product liability insurance. We do not know if we will be able to obtain 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. 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 oncology, our small molecules may be used in conjunction with standard of care oncology therapies to improve on therapeutic outcomes for patients.

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, 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. Neither we nor Resverlogix have employment agreements with any of our respective 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 potential expansion into additional areas and activities requiring additional expertise may place additional requirements on our management, operational and financial resources. These demands may 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 biotechnology experience. 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 collaborators, suppliers, employees 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. 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. 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 or our partners' 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. Health authorities will continue to increase their scrutiny and pharmacoeconomic diligence on new products in all disease areas. 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 over the current standard of care 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 effect service of process within the U.S. 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 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 United States 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 a particular product if competitors devise ways of making these or similar products without legally infringing our patents. The United States 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. Our and Resverlogix's employees, consultants, contractors, outside scientific collaborators and other advisors 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

### No public market for Zenith shares

There is currently no public market through which our common shares may be sold and it is not anticipated that our common shares will be listed on any stock exchange in the near term. There can be no assurance as to the liquidity of the trading market for our common shares or that a trading market for our common shares will develop. Even if a trading market develops for our common shares, there is no guarantee at what prices our common shares will trade. The value for our common shares may also be affected by our results of operations and financial position, changes in general market conditions, fluctuations in the market for equity or debt securities and numerous other factors beyond our control.

**If we sell common shares and/or warrants in the future, existing common shareholders will experience immediate dilution and the value of our stock may decrease.**

We may raise additional capital to fund our operations and to develop our products. We may raise such additional capital through the sale of our common shares and/or warrants from time to time, and our existing common shareholders would experience immediate dilution upon any such issuance.

**If our estimates regarding timing of milestones are incorrect the value of our shares may decline.**

For planning purposes, we estimate and may disclose timing of a variety of research and development, 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 value 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 value 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 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 Zenith will depend on any future appreciation in the value of our common shares. There is no guarantee that our common shares will appreciate in value or even retain the value at which our holders have acquired their common shares.

### **Additional Information**

Additional information relating to Zenith can also be found on SEDAR at [www.sedar.com](http://www.sedar.com).