

# Management's Discussion & Analysis

# January 31, 2014

This Management's Discussion and Analysis ("MD&A") of Zenith Epigenetics 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 nine months ended January 31, 2014 and 2013 and the audited consolidated financial statements and the notes thereto and the Management's Discussion and Analysis for the period from incorporation on April 10, 2013 to April 30, 2013. Our financial statements have been prepared by management in accordance with International Financial Reporting Standards ("IFRS"). 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 will impact multiple diseases including cancer, autoimmune and others; our intention to move drug candidates into IND-enabling studies and first-in-man clinical studies; 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 is available to fund contractual commitments; 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 have secured intellectual property covering a host of molecules all discovered using our epigenetics drug development platform.
- 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.
- We anticipate that we will be able to raise capital through external financing or partnering to provide funds for our programs; and
- 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 10 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 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 Statements of Cash Flows. 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.

# Overview

Zenith currently conducts research and development related to its epigenetics platform technology through RVX Therapeutics Inc., its wholly-owned subsidiary, and holds royalty preferred shares of Resverlogix Corp.

#### **Epigenetics**

The selective production of the proteins encoded by our genes leads to differences between cells, and the alteration of their levels can contribute to disease. Epigenetics is a cellular mechanism for regulating gene expression arising from the interplay between proteins and DNA without altering the genetic code, referring to modifications to DNA or the proteins associated with DNA, such as histones, which in turn determine whether a gene is on or off or whether its activity is high or low. The level of activity of a gene will in many cases mean the difference between a healthy normal physiological effect and a disease. An understanding of this system will allow for the discovery and development of targeted medicines that may treat specific diseases in specific individuals.

## Our Epigenetic Drug Development Platform

Our epigenetics drug development platform has the potential to impact multiple diseases including autoimmune, cancer and others. This platform targets Bromodomain and ExtraTerminal Domain ("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 of proteins, associated with the DNA where they can bind and 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 creation of novel small molecule BET inhibitors, a new class of therapeutics, for the treatment of patients with defined cancers, inflammatory disorders and other therapeutic indications. Our research is based on breakthroughs in the field of epigenetics.

## Research

We continue to expand our knowledge in important drug research, including significantly expanding our oncology drug discovery program, and performing further BET inhibition research. Each of these programs are comprised of both research performed by contract research organizations and our internal discovery group. Based on novel scaffolds identified from virtual screening of a 28 million compound library, we have advanced compounds into late lead optimization and have commenced IND enabling studies for the our lead compound (ZEN-3365). We continue to advance our medicinal chemistry operations with leading global contract research organizations and have synthesized over 1,000 small molecules related to BET bromodomain inhibition. These molecules are the foundation for our growing intellectual property estate, covering composition and use claims related to BET bromodomain inhibition.

# Research Programs

## Oncology

Our oncology program builds upon the recent discovery that BET inhibitors may have therapeutic potential in certain human cancers, and might lead to a class of more effective oncology drugs. Based on our research and the published work of others, these inhibitors can inhibit several known drivers of tumor cell growth. These include c-Myc and Bcl-2. c-Myc is a well-known oncogene that drives the growth of multiple hematological cancers and solid tumors, a role which has been studied for more than 30 years. Despite the critical function this oncogene has in the development of cancer, treatments that target its activity have eluded discovery. Bcl-2 is a gene known to enhance survival of other cancer cells. Recent research has shown that BET inhibition can result in the suppression of transcription of the c-Myc and Bcl-2 genes in certain cancer cell types and the resulting loss of c-Myc and Bcl-2 protein leads to inhibition of tumor cell proliferation and cell death.



We have developed highly potent compounds with good drug properties for orally delivered therapy. We have demonstrated that our lead compounds inhibit the proliferation of tumor cells derived from acute myelogenous leukemia ("AML") and multiple myeloma ("MM"), and also inhibit the growth of an AML derived tumor in a mouse xenograft model.

We have completed lead optimization and selected an IND candidate ZEN-3365 for IND enabling studies and further drug development. In addition, we continue to build on our highly efficient and rapid drug discovery platform to identify additional drug candidates in the area of oncology. We are also exploring approaches to identify the best cancer patients to target based on analyses of tumor cell sensitivity and the ability to combine BET bromodomain inhibitors with standard of care.

## Autoimmune

BET proteins are a family of proteins which play a critical role in the expression of inflammatory genes which are activated in response to pathogens. Expression of these inflammatory genes results in production of inflammatory mediators such as the cytokines IL-6, IL-17 and the chemokine MCP-1. While this is part of the host's normal response to pathogens, an exaggerated, uncontrolled response can be detrimental to the host, and this represents the medical basis for many serious autoimmune diseases such as rheumatoid arthritis, multiple sclerosis, among others.

We have a research and drug discovery program to develop novel, orally administered, small-molecule drugs which can suppress these aberrant inflammatory responses by inhibition of BET proteins. Both in terms of chemical structure and mechanism, our molecules are distinct from those traditionally used to treat autoimmune diseases, including nonsteroidal antiinflammatory drugs ("NSAID's"), corticosteroids, and older line disease-modifying drugs ("DMARD's") such as methotrexate. Newer DMARD's, such as the cytokine receptor antagonist Enbrel, work through related immunomodulatory mechanisms, by blocking the action of immune mediators. However, as biological agents, these drugs have the disadvantage that they must be administered by injection. In contrast, the pharmaceutical properties of our novel compounds are being optimized for oral administration as a solid dose form.

Our compounds are efficacious in well-established in vivo animal models for rheumatoid arthritis and multiple sclerosis, including the well-known collagen-induced arthritis and murine experimental autoimmune encephalomyelitis models. We have discovered several different chemical approaches to achieve effective inhibition of BET proteins, and we are now in process of optimizing one of these chemical series for clinical development. Lead molecules of this chemical series are characterized by a favorable immunomodulatory profile, including in vitro and in vivo suppression of IL-6, IL-17 and MCP-1 production. We believe that molecules of this new drug class, which will be administered orally, can provide an attractive alternative to protein-based DMARD therapeutics such as Enbrel which are now widely used.

## **Services Agreement**

Pursuant to an Assignment and Services Agreement effective May 1, 2012, we engaged Resverlogix to perform research and administrative services for us. As consideration for the services, we will pay Resverlogix service fees for salary and other compensation related costs allocated to the services and reimbursable expenses incurred by Resverlogix.

## **Resverlogix Royalty Preferred Shares**

Pursuant to the Arrangement, on June 3, 2013 Resverlogix issued 75,202,620 royalty preferred shares to the Company. The holder of the royalty preferred shares is entitled to dividends in the amount of 6-12% of net Apo Revenue from Resverlogix's Apo program, if any. Net Apo revenue is defined as the aggregate of the following amounts: (i) amounts received by Resverlogix or its affiliates (as defined in 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 the Apo products and/or Apo 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 Apo product (other than consideration received by Resverlogix, any licensee or their respective affiliates from a licensee of such Apo 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; and (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); and (iii) amounts received from a third party by Resverlogix or its affiliates in consideration for the sale of any Apo intellectual property right.

The holder of the preferred shares does not have the right to participate in any 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.

We have not recognized the royalty preferred shares because book value accounting has been applied to the assets that have been acquired through the distribution in connection with the Arrangement and they 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.

## **Plan of Arrangement**

From incorporation on April 10, 2013 to June 2, 2013, Zenith was a wholly owned subsidiary of Resverlogix Corp. ("Resverlogix"). We only recently commenced operations. Zenith was incorporated for the purposes of participating in an arrangement under the *Business Corporations Act* (Alberta) (the "Arrangement") between Resverlogix, RVX Therapeutics Inc. ("RVX Therapeutics") and Zenith. On June 3, 2013, we, Resverlogix, and RVX Therapeutics completed the Arrangement which involved the spin-off of all of the issued and outstanding shares of RVX Therapeutics to us. Upon completion of the Arrangement, Resverlogix shareholders owned one new common share of Resverlogix and received one common share of Zenith for each Resverlogix share held immediately prior to the Arrangement becoming effective.

Pursuant to the Arrangement, Resverlogix retained its research and development activities related to the development of compounds for applications with indications involving a therapeutic increase in Apolipoprotein A-I ("ApoA-I"), including the clinical program related to RVX-208. Resverlogix spun-off all other research and development activities related to its epigenetics platform technology to us. Pursuant to the Arrangement, we were also issued royalty preferred shares in the capital of Resverlogix which will provide us with a dividend equal to six to 12 percent of "Net Apo Revenue" as defined above.

Every Resverlogix warrant holder at the effective date of the Arrangement received one warrant in Zenith for every warrant held in Resverlogix immediately prior to the Arrangement becoming effective. The exercise price of Resverlogix warrants was reduced in accordance with the terms of the applicable warrant by an amount on a per share basis to reflect the fair market value of Zenith and the reduction was allocated to the exercise price of the Zenith warrants.

Every Resverlogix stock option and restricted stock unit holder at the effective date of the Arrangement received one stock option or restricted stock unit, respectively, in the Company for every stock option or restricted stock unit held in Resverlogix. The exercise price of each stock option in the Company was calculated as approximately 9.1% of the exercise price of each corresponding stock option of Resverlogix at the effective time of the Arrangement, to reflect the fair market value of the Company.

Pursuant to the Arrangement, Resverlogix advanced CAD\$10 million to us to provide working capital. The promissory notes and aggregate advances from Resverlogix to RVX Therapeutics immediately prior to the Arrangement becoming effective were transferred from Resverlogix to us such that, subsequent to the Arrangement, RVX Therapeutics is indebted to us in respect of these liabilities.

## **Amended and Restated License Agreement**

On June 3, 2013, RVX Therapeutics and Resverlogix entered into an Amended and Restated License Agreement (the "Amendment"), effective January 31, 2013, which amended a License Agreement dated August 1, 2005. Pursuant to the License Agreement, Resverlogix granted an irrevocable, worldwide license to RVX Therapeutics under certain licensed patents and licensed know-how to develop, commercialize and sell licensed products in any field other than the ApoA-I therapeutic field (the prevention, treatment or mitigation of any disease via the administration of a pharmaceutical agent that results in a specified therapeutic elevation in the plasma levels of ApoA-I).

As ongoing consideration for the grant of the License, RVX Therapeutics shall pay Resverlogix a royalty from 1% to 5% of gross amounts received by RVX Therapeutics from the sale of any product in any field other than the ApoA-I therapeutic field which is encompassed within a patent licensed from Resverlogix.

#### **Waiver Agreement**

On March 17, 2014, Resverlogix and RVX Therapeutics Inc. entered into a Waiver Agreement whereby Resverlogix agreed to waive its right under the Amended and Restated License Agreement dated June 3, 2013 (the "License Agreement") to license any method or pharmaceutical agent within the scope of certain Licensee Patents owned or controlled by RVX Therapeutics Inc. that may be determined to come within the ApoA-I Therapeutic Field (as defined in the License Agreement), and RVX Therapeutics Inc. agreed not to develop any patents for any indication within the ApoA-I Therapeutic Field for a period of five years and granted to Resverlogix a right of first refusal for a period of three years thereafter in respect of the license or sale of such patents and or compounds that are determined to come within the ApoA-I Therapeutic Field. RVX Therapeutics Inc. agreed to pay Resverlogix \$2.5 million in cash.

Entering into the Waiver Agreement significantly enhanced our freedom to operate and was achieved at a fair cost. The \$2.5 million paid by us to Resverlogix was a negotiated amount agreed upon by the two parties as the fair value and, having received independent financial advice, we concluded that the Waiver Agreement was fair from a financial point of view.



# Results of Operations for the Three and Nine Months Ended January 31, 2014 and 2013

	Three months ended January 31,		Nine months ended January 31,	
(in thousands of US dollars)	2014	2013	2014	2013
Expenses:				
Research and development	\$ 3,454	\$ 2,566	\$ 10,592	\$ 7,100
Investment tax credits	(66)	(101)	(188)	(305)
Net research and development	3,388	2,465	10,404	6,795
General and administrative	283	200	1,275	586
	3,671	2,665	11,679	7,381
Finance costs:				
Loss (gain) on change in fair value of				
warrant liability	266	-	(835)	-
Interest income	(4)	-	(21)	-
Foreign exchange loss	88	-	154	-
Net finance costs (income)	350	-	(702)	-
Neteritoria	<b>*</b> 4.004	Φ 0.005	<b>*</b> 40.077	h 7.004
Net and total comprehensive loss	\$ 4,021	\$ 2,665	\$ 10,977	\$ 7,381
Net loss per share				
Basic and diluted	\$ 0.05		\$ 0.17	

In the current period, the operational results for RVX Therapeutics Inc. for the pre-acquisition period of May 1, 2013 to June 2, 2013 have been included in our results of operations to present complete information about the acquired entity. For comparative purposes, the pre-acquisition operational results for RVX Therapeutics Inc. have been included in our results of operations.

## **Cash Burn Rate**

The average monthly Cash Burn Rate, a non-IFRS measure as described on page 2 herein, for the three and nine months ended January 31, 2014 was \$1.2 million and \$1.1 million, respectively (2013 - \$0.9 million and \$0.8 million, respectively). This increase reflects a significant net increase in monthly R&D and G&A spending including, in particular, the initiation of IND-enabling studies.

	Three months ended January 31,		Nine months ended January 31,	
(in thousands of US dollars unless otherwise noted)	2014	2013	2014	2013
Cash flow used in operations	\$ (3,962)	\$ (2,560)	\$ (9,858)	\$ (7,239)
Changes in non-cash working capital	272	(100)	128	(133)
	(3,690)	(2,660)	(9,730)	(7,372)
Number of months	3	3	9	9
Average Monthly Cash Burn Rate	(1,230)	(887)	(1,081)	(819)

Our historical Cash Burn Rate is not necessarily indicative of our future Cash Burn Rate. Our short term cash burn rate will be impacted by, among other factors, the completion of further IND-enabling studies.

## **Research and Development**

Research and development includes product development costs such as drug development and pharmacology, toxicology and other studies, and costs associated with discovery research such as medicinal chemistry. R&D expenses include service fees paid to Resverlogix for salaries and benefits for R&D staff, consulting fees, supplies and general laboratory operating expenses.



During the three and nine months ended January 31, 2014, gross R&D expenditures totaled \$3.5 million and \$10.6 million, respectively (2013 - \$2.6 million and \$7.1 million, respectively). The increase was due primarily to a significant incremental deployment of internal and external resources to perform discovery research related to lead optimization and profiling of candidates for IND enabling studies. This includes medicinal chemistry, pharmacology, external profiling of lead compounds, and preliminary toxicology. R&D for the three and nine months ended January 31, 2014 also included \$nil and \$0.4 million, respectively (2013 - \$nil) of share-based payments related to stock options and restricted stock units granted on June 3, 2013 in connection with the Arrangement.

## **General and Administrative**

During the three and nine months ended January 31, 2014, general and administrative ("G&A") expenditures totaled \$0.3 million and \$1.3 million, respectively (2013 - \$0.2 million and \$0.6 million, respectively). General and administrative expenses includes service fees paid to Resverlogix for compensation and related costs, operating costs not directly involved in research and development, as well as professional fees for legal, audit, tax, communications, and business development. The increase in G&A for nine months ended January 31, 2014 is primarily attributable to the inclusion of \$0.5 million of share-based payments related to stock options and restricted stock units granted on June 3, 2013 in connection with the Arrangement and the inclusion of professional fees and communications costs associated with the Company's commencement of operations.

#### **Share-based Payments**

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

During the three and nine months ended January 31, 2014, we recognized share-based payments of \$41 thousand and \$0.9 million, respectively (2013 - \$nil). The expense recognized in a given period reflects the fair value of past and newly-granted stock options and restricted stock units outstanding during the period, and is impacted by factors such as vesting and fluctuations in the fair market value of our shares. During the nine months ended January 31, 2014, we granted 5,198,070 stock options (5,123,070 of these stock options were granted in connection with the Plan of Arrangement) with a weighted average exercise price of CAD\$0.24 and a weighted average fair value of \$0.15 per option, and 753,000 restricted stock units. Share-based payments are a non-cash expense which does not impact operating cash flows.

## Change in Fair Value of Warrant Liability

We issued warrants on June 3, 2013 in connection with the Plan of Arrangement. Warrants with an exercise price denominated in a foreign currency are reported as a liability until they are exercised or expire. These warrants are adjusted to fair value at each reporting period and any change in fair value between reporting periods is recorded in the statement of comprehensive loss.

The change in fair value of warrant liability has significantly impacted our reported loss (income). During the three and nine months ended January 31, 2014, we recognized a \$0.3 million loss and a \$0.8 million gain, respectively, on the change in the fair value of our warrant liability (2013 - \$nil). The changes in fair value were based primarily on the change in the estimated fair market value of our shares, which fluctuated during the periods. Gains and losses resulting from the revaluation of warrant liability are non-cash and do not impact our cash flows from operations.

# **Liquidity and Capital Resources**

#### Cash

As at January 31, 2014, we had \$2.1 million of cash. Pursuant to the Arrangement, on June 3, 2013, CAD\$10 million of cash was transferred from Resverlogix to us. Our average monthly Cash Burn Rate, a non-IFRS measure as described on page 2 herein, for the three and nine months ended January 31, 2014 was \$1.2 million and \$1.1 million, respectively.

## Promissory Notes Payable to Resverlogix and Advances from Resverlogix

As at April 30, 2013 promissory notes totaling US\$7.6 million were payable to Resverlogix from RVX Therapeutics. The promissory notes are non-interest bearing, repayable sixty days subsequent to demand, and unsecured. Pursuant to the Arrangement, on June 3, 2013 the promissory notes were transferred from Resverlogix to us.

As at April 30, 2013, advances from Resverlogix to RVX Therapeutics totaling US\$9.8 million were payable on demand and non-interest bearing. On June 3, 2013, advances from Resverlogix were transferred from Resverlogix to us.



## Liquidity

Zenith is a development stage company; its primary capital requirements relate to funding research and development activities and for general working capital purposes. Under the terms of the Arrangement, Resverlogix advanced CAD\$10 million to Zenith to provide it with additional working capital.

As at January 31, 2014, we had \$2.1 million of cash and \$2.0 million of trade and other payables, and we were committed to pay \$2.7 million for research and development and \$0.3 million of lease obligations over the following twelve months. As well, we are committed to pay our proportional share of the cost of tenant improvements to be completed (based on either proportionate square footage or specific use), net of a tenant improvement allowance, estimated to be approximately \$0.4 million. On March 14, 2014 we closed a private placement of 8 million common shares at a price of \$1.00 per share for gross proceeds of \$8 million. We received \$2 million on January 30, 2014 and \$6 million on March 14, 2014 in connection with the private placement. On March 17, 2014, we paid Resverlogix \$2.5 million pursuant to a Waiver Agreement. We believe our cash as at January 31, 2014, in combination with the \$8 million received from the private placement and the \$2.5 million paid to Resverlogix, each subsequent to January 31, 2014, is not sufficient to fund our contractual commitments over the next year and is not sufficient to fund our planned business operations over the next year. We will have to raise additional capital and intend to do so through equity or debt financing and/or from other sources. If we are not able to raise capital, we will have to reduce our cash requirements by eliminating or deferring spending on research, development and corporate activities, or may be forced to cease operations.

RVX Therapeutics has historically been economically dependent on and has relied entirely on Resverlogix, its previous parent company, for funding to support its operations. We intend to raise capital from equity and/or debt offering (such as private placements) and partnering in the future. Our ability to continue as a going concern is dependent on continued funding.

## **Cash Flows**

During the nine months ended January 31, 2014, cash flows used in operating activities totaled \$9.9 million (2013 - \$7.2 million); cash flows generated from financing activities totaled \$12.5 million (2013 - \$7.4 million), comprised of advances from Resverlogix and subscriptions received in advance; and cash flows used in investing activities totaled \$0.5 million (2013 - \$0.1 million).

# **Contractual Obligations**

The table below summarizes our contractual obligations related to research and development, by due date, as at January 31:

(in thousands of US dollars)	2014	2013
Less than one year	2,651	1,638
Between one and five years	-	-
More than five years	-	-
	2,651	1,638

The table below summarizes our contractual obligations related to operating leases for office and laboratory premises, by due date, as at January 31:

(in thousands of US dollars)	2014	2013
Less than one year	291	135
Between one and five years	1,082	46
More than five years	1,421	-
	2,794	181

As at January 31, 2014, Resverlogix was committed to pay \$0.7 million for tenant improvements to be completed, net of a tenant improvement allowance. We agreed to pay Resverlogix for our proportionate share of operating lease payments and operating costs for office and laboratory premises of an estimated \$0.4 million for the next twelve months, as well as the cost of tenant improvements (based on either proportionate square footage or specific use), net of a tenant improvement allowance, estimated to be approximately \$0.4 million.



# Significant Accounting Policies and Estimates

Note 4 to our unaudited condensed consolidated financial statements for the three and nine months ended January 31, 2014 and 2013 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, warrant liability and taxes.

# **Recent Accounting Pronouncements**

The Company has adopted the following new standards and amendments to standards, with a date of initial application of May 1, 2013:

IFRS 10 - Consolidated Financial Statements - supersedes IAS 27 "Consolidation and Separate Financial Statements" and SIC-12 "Consolidation - Special Purpose Entities". This standard provides a single model to be applied in control analysis for all investees including special purpose entities. The adoption of IFRS 10 did not have a material impact on the condensed interim consolidated financial statements.

IFRS 11 - Joint Arrangements - divides joint arrangements into two types, joint operations and joint ventures, each with their own accounting model. IFRS 11 replaces the guidance in IAS 31 Interest in Joint Ventures, and essentially carves out of previous jointly controlled entities, those arrangements which although structured through a separate vehicle, such separation is ineffective and the parties to the arrangement have rights to the assets and obligations for the liabilities and are accounted for as joint operations in a fashion consistent with jointly controlled assets/operations under IAS 31. In addition, under IFRS 11, joint ventures must now use the equity method of accounting. The adoption of IFRS 11 did not have a material impact on the condensed interim consolidated financial statements.

**IFRS 12** - **Disclosure of Interests in Other Entities** - combines in a single standard the disclosure requirements for subsidiaries, associates and joint arrangements as well as unconsolidated structured entities. The adoption of IFRS 12 did not have a material impact on the condensed interim consolidated financial statements.

IFRS 13 - Fair Value Measurement – replaces the fair value measurement guidance contained in individual IFRSs with a single source of fair value measurement guidance. It defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, i.e. an exit price. The standard also establishes a framework for measuring fair value and sets out disclosure requirements for fair value measurement to provide information that enables financial statement users to assess the methods and inputs used to develop fair value measurements and, for recurring fair value measurements that use significant unobservable inputs (Level 3), the effect of the measurements on profit or loss or other. Due to the nature of the Company's financial assets and liabilities, the adoption of IFRS 13 did not have a material impact on the condensed interim consolidated financial statements. The adoption of IFRS 13 resulted in the inclusion of certain fair value disclosures which were previously applicable to annual financial statements only.

**Amendments to IAS 1 - Presentation of Financial Instruments** - requires an entity to present separately the items of other comprehensive income that may be reclassified to profit or loss in the future from those that would never be reclassified to profit or loss. As the amendments only required changes in the presentation of items in other comprehensive income, the new standard did not have a material impact on the condensed interim consolidated financial statements.

Amendments to IFRS 7 – Offsetting Financial Assets and Liabilities – contains new disclosure requirements for offset financial assets and liabilities and netting arrangements. The amendments to IFRS 7 did not have a material impact on the condensed interim consolidated financial statements.

## **Off-Balance Sheet Arrangements**

As of January 31, 2014, we have not entered into any off-balance sheet arrangements, other than operating leases.



# **Summary of Quarterly Results**

## For the Three Months Ended

(in thousands of US dollars except as otherwise noted)	January 31, 2014	October 31, 2013	July 31, 2013	April 30, 2013
Revenue	-	-	-	-
Total comprehensive loss	(4,021)	(3,527)	(3,429)	(3,240)
Net earnings (loss) per share (\$) - basic and diluted	(0.05)	(0.05)	(0.07)	

## For the Three Months Ended

(in thousands of US dollars except as otherwise noted)	January 31, 2013	October 31, 2012	July 31, 2012	April 30, 2012
Revenue	-	-	-	-
Total comprehensive loss	(2,665)	(2,430)	(2,287)	(1,020)

Zenith was incorporated on April 10, 2013. Financial information for periods prior to the three months ended July 31, 2013 is that of RVX Therapeutics. No comparative net loss per share has been included as there were no shares outstanding in the comparative period since Zenith was incorporated on April 10, 2013.

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

- the expansion of our research programs and the timing of various studies and chemistry-related research;
- additional administration associated with significantly expanded research;
- warrants with an exercise price denominated in a currency other than an entity's functional currency are remeasured to
  reflect the change in fair value as at the end of the reporting period, with changes in fair value recognized in the statement
  of comprehensive 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 grants. Share-based payments are a non-cash expense.

# **Related Party Transactions**

Pursuant to the Assignment and Services Agreement dated June 3, 2013 and effective May 1, 2012 between us and Resverlogix, we engaged Resverlogix to perform research and administrative services on our behalf. As consideration for the services, we will pay Resverlogix service fees for salary and other compensation related costs allocated to the services and reimbursable expenses incurred by Resverlogix. In addition, pursuant to a Management Services Agreement dated June 3, 2013 between us and Resverlogix, we engaged Resverlogix to perform all management and administrative services pertaining to us as are required. We will pay Resverlogix a management fee based on the cost of its personnel and the proportionate time worked on behalf of us. Resverlogix will also be reimbursed for general and administrative costs.



# **Outstanding Equity Instruments**

As at March 17, 2014, we had authorized an unlimited number of common shares and preferred shares.

	As at March 17, 2014	As at January 31, 2014
Common Shares	83,671,987	75,381,587
Warrants	10,690,754	10,698,754
Stock Options	3,634,970	3,914,970
Restricted Stock Units	696,600	699,000
	98,694,311	90,694,311

2,528,640 of 3,634,970 stock options are vested and exercisable; 350,135 of 696,600 restricted stock units are vested.

Additional information relating to our securities can be found in note 10 to the condensed interim consolidated financial statements for the three and nine months ended January 31, 2014.

## 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 autoimmune disease. We are advancing these small molecules from discovery to early development and have already demonstrated in-vivo proof of concept with a number of our novel BET inhibitors for both oncology and autoimmune disease.

More specifically, our drug discovery platform allows us to efficiently identify novel orally active BET bromodomain inhibitors. Through biochemical and cell based assays, and *in vivo* efficacy models in combination with a strong medicinal chemistry program and X-ray crystallography, we are able to rapidly advance compounds from hit to lead and through lead optimization.

In the area of oncology, we have demonstrated that several of our compounds inhibit the proliferation of tumor cells derived from acute myelogenous leukemia ("AML") and multiple myeloma ("MM"), and also inhibit the growth of an AML and MM derived tumors in mouse orthotopic models. We also continue to explore approaches to identify the best cancer patients to target based on analyses of primary tumor cell sensitivity and the ability to combine BET inhibitors with standard of care. We have identified our first IND candidate for hematological malignancies (ZEN-3365) and initiated IND enabling studies. We intend to file an IND in calendar 2014 and, subject to raising additional capital, commence clinical trials shortly after IND acceptance and site initiations. Therefore, we are actively pursuing various sources of capital.

In the area of autoimmune disease we have demonstrated that our compounds are efficacious in well-established *in vivo* animal models for rheumatoid arthritis and multiple sclerosis, including the established collagen-induced arthritis and murine experimental autoimmune encephalomyelitis. We have discovered several different chemical approaches to achieve effective inhibition of BET bromodomains, Lead molecules of this chemical series are characterized by a favorable immunomodulatory profile, including *in vitro* and *in vivo* suppression of IL-6, IL-17 and MCP-1 production. We believe that molecules of this new drug class, which will be administered orally, can provide an attractive alternative to current therapeutics.

We will continue to discuss these specific opportunities with potential licensing partners to enable the advancement of these novel therapies.

# **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**

The Resverlogix royalty preferred shares held by Zenith may fluctuate in value based on factors that are not within our control.

Zenith holds royalty preferred shares of Resverlogix which entitle Zenith to dividends based on a percentage of net Apo Revenue, if any, received by Resverlogix, its affiliates or licensees. The royalty preferred shares of Resverlogix that are held by Zenith represent a significant asset of Zenith. 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 the control of Zenith. 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 the Zenith common shares and may impact the ability of Zenith to access additional capital required to fund its research and development activities.

We are a development stage 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. We have not commenced clinical development and 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 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. 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. Historically RVX Therapeutics' operations have been financed exclusively by Resverlogix. 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 RVX Therapeutics' operations have been financed exclusively by 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; and
- costs associated with commercialization of any products;
- the cost and timing of developing sales and marketing operations or partnerships;
- competing technological and market developments, including the introduction by others of new therapies in our markets.

We believe our cash as at January 31, 2014, in combination with the \$8 million received from the private placement and the \$2.5 million paid to Resverlogix, each subsequent to January 31, 2014, is not sufficient to fund our contractual obligations for the next twelve months and is not sufficient to fund all of our currently planned operations over the next twelve months. We intend to raise additional capital. Any equity financing transaction would result in our existing common stockholders experiencing immediate dilution. Any financing transaction may 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 has made the business climate more volatile and more costly. Our business strategy may be adversely affected by unpredictable and unstable market conditions. If the current equity and credit markets deteriorate it may make any necessary equity or debt financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on 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 in the preclinical stage and have not filed an Investigational New Drug for any product candidates.

Preclinical studies involving the evaluation of toxic effects and pharmacokinetics and metabolism of a drug in animals must be performed to provide evidence of the safety, efficacy and bioavailability of the drug prior to its administration to humans in clinical studies. The results of the preclinical studies as well as the comprehensive descriptions of proposed human clinical studies are then submitted as part of the Investigational New Drug ("IND") application to the FDA and TPD. There can be no assurance that preclinical studies will be completed successfully within any specified period of time, if at all.



#### We have not conducted 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, the TPD or foreign regulatory authorities if it is determined that the subjects or patients are being exposed to unacceptable risks. We may encounter delays or rejections based on varying regulatory interpretations or changes in regulatory agency policies, during the period in which we develop a product.

## 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 United States Federal Drug Administration ("FDA"), Health Canada's Therapeutic Products Directorate (the "TPD"), 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, the TPD or foreign regulatory authorities could suspend or terminate a clinical trial due
  to adverse side effect of a drug on subjects or patients in the trial;
- we may decide, or regulators may require us, to conduct additional preclinical testing or clinical trials;
- enrollment in our clinical trials may be slower than anticipated;
- the cost of our clinical trials may be greater than anticipated;
- our 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.

# We rely on Resverlogix for performing certain research and administrative services.

We are dependent on Resverlogix to provide research and administrative services required to carry on certain of our research and development activities. Research and administrative 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 will be primarily responsible for the provision of research and administrative services to us have extensive 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 January 31, 2014 including the \$2.5 million received from us subsequent to January 31, 2014, was not sufficient to fund its contractual commitments and net working capital liability over the next year, and was not sufficient to fund substantially all of its planned business operations over the next year, and would, therefore, have to raise additional capital.



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 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 preclinical studies are conducted in accordance with applicable regulations. The FDA requires us to comply with regulations and standards, commonly referred to as good laboratory practices, or GLP, for conducting and recording the results of our preclinical studies. Our reliance on third parties does not relieve us of these responsibilities. If the third parties conducting clinical trials do not perform their contractual duties or obligations, do not meet expected recruitment or other deadlines, fail to comply with the FDA's good clinical practice regulations, do not adhere to 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, or 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.

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.

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

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



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

As a result of the costs and risks associated with commercializing a product candidate, we intend to seek 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.

# 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 Canada, 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, Canada 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 Canada, 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 Canada, 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, the TPD or foreign regulatory



authorities if it is determined that the subjects or patients are being exposed to unacceptable risks. We may encounter delays or rejections based on varying regulatory interpretations or changes in regulatory agency policies, during the period in which we develop a product.

No assurance can be given that 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, the TPD and other foreign regulatory agencies can delay, limit or deny marketing approval for many reasons, including finding a product may not be considered safe and effective; the manufacturing processes or facilities may not meet applicable requirements; or changes in approval policies or regulations. 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, Canadian or other foreign regulatory authority could condition approval on conducting additional costly post-approval studies or could limit the scope of approved uses. In addition, the product may later cause adverse effects that limit or prevent its widespread use, force us to withdraw it from the market or prevent or delay our ability to obtain regulatory approvals in additional countries. In addition, we will continue to be subject to regulatory review and periodic inspections to ensure adherence to applicable regulations. After receiving marketing approval, the FDA imposes extensive regulatory requirements on the manufacturing, labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping related to the product. Failure to comply with the regulatory requirements could result in:

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

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

The manufacture and sale of pharmaceutical products involve an inherent risk of product liability claims and associated adverse publicity. We 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 autoimmune disorders, our small molecules would potentially compete with novel autoimmune agents in preclinical development.

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 and Resverlogix's scientific staff, the loss of whose services might significantly delay or prevent the achievement of research, development or business objectives and would materially adversely affect our business, financial condition and results of operations. 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 our potential expansion into additional areas and activities requiring additional expertise will place additional requirements on our management, operational and financial resources. We expect these demands will require an increase in management and scientific personnel and the development of additional expertise by existing management personnel. There is currently aggressive competition for employees who have 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 polices 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.

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 license intellectual property from Resverlogix.

Certain intellectual property utilized by us has been obtained under licenses from Resverlogix and we expect to rely on these licenses for the development of our own product candidates. Licenses have been granted by Resverlogix to us pursuant to an Amended and Restated License Agreement dated June 3, 2013, whereby Resverlogix permits us to develop compounds covered by the licensed patents and patent applications for applications other than indications involving an increase in ApoA-I. We cannot assure that these licenses will remain in good standing or that the technology we have licensed under these agreements has been adequately protected or is free from claims of infringement of the intellectual property rights of third parties. We may in the future be obligated to make royalty payments on the sales, if any, of product candidates resulting from licensed technology and, in some instances, may be responsible for the costs of filing and prosecuting patent applications. Any breach or termination of the Amended and Restated License Agreement could have a material adverse effect on our business, financial condition, and results of operations.

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 or Resverlogix's key employees, which could result in loss of intellectual property, our or Resverlogix's key employees or both.

Many of our and Resverlogix's 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 Zenith's common shares may be sold and it is not anticipated that Zenith's 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 Zenith's common shares or that a trading market for any of Zenith's common shares will develop. Even if a trading market develops for Zenith common shares, there is no guarantee at what prices such Zenith's common shares will trade. The value for Zenith's common shares may also be affected by Zenith's 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 the control of Zenith.



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 will need to 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. As a result, our existing common shareholders will 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 maintain 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.