Management's Discussion and Analysis of Financial Condition and Results of Operations
For the three months ended October 31, 2023, and 2022

This Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") is prepared as of December 14, 2023, and should be read in conjunction with the financial statements of Helix BioPharma Corp. (the "Company" or "Helix") for the three months ended October 31, 2023, and 2022 and the accompanying notes thereto and the annual audited financial statements of Helix BioPharma Corp. for the years ended July 31, 2023, and 2022. This MD&A is based on financial statements which have been prepared in accordance with International Financial Reporting Standards ("IFRS"). All amounts are depicted in Canadian currency unless otherwise noted.

Additional information relating to the Company can be found in the Company's Annual Information Form, which is available on SEDAR at www.sedar.com.

FORWARD-LOOKING INFORMATION

This MD&A contains "forward-looking statements" and "forward-looking information" within the meaning of applicable Canadian securities laws (collectively, "forward-looking information"). Forward-looking information means disclosure regarding possible events, conditions or financial performance that is based on assumptions about future economic conditions and courses of action and includes financial projections and estimates; statements regarding plans, goals, objectives, intentions and expectations with respect to the Company's future business, operations, research and development, including the focus of the Company's primary drug product candidate L-DOS47 and other information relating to future periods. Forward-looking information includes, without limitation, statements concerning: (i) the Company's ability to continue to operate on a going concern basis being dependent mainly on obtaining additional financing; (ii) the Company's growth and future prospects being dependent mainly on the success of L-DOS47; (iii) the Company's priority continuing to be L-DOS47; (iv) the Company's development programs, including but not limited to, extension of the current drug candidate(s) to other indications and the identification and development of further tumour-targeting antibodies for DOS47; (v) the nature, design and anticipated timeline for completion of enrollment and other matters relating to the Company's ongoing clinical study programs such as the recently approved Investigational New Drug ("IND") Phase Ib/II combination study combination with doxorubicin for previously treated advanced pancreatic cancer patients by U.S Food and Drug Administration ("FDA"); (vi) the Company seeking strategic partner support and therapeutic market opportunities; (vii) future expenditures, insufficiency of the Company's current cash resources and the need for financing and the Company's possible response for such matters; (viii) future financing requirements, the seeking of additional funding and anticipated future operating losses; (ix) further evaluation and changes to the Company's disclosure controls and procedures related to internal controls over financial reporting and informing the public of such changes, including the timeline for achieving such changes; (x) changes in the application of accounting standards and interpretations; (xi) industry performance, competition (including potential developments relating to immunotherapies and the Company's possible response to such developments), prospects, and general prevailing business and economic conditions; (xii) the Company's technology and research and development objectives, including development milestones, estimated costs, schedules for completion and probability of success; (xiii) the Company's expectation that it can in a timely manner, or at all, produce the appropriate preclinical, and if necessary, clinical data required; (xiv) the Company's plans to develop L-DOS47 and the estimated incremental costs (including the status, cost and timing of achieving the development milestones disclosed herein); (xv) the Company's intentions with respect to initiating marketing activities following receipt of the applicable regulatory approvals; (xvi) the Company's seeking of licensing opportunities to expand its intellectual property portfolio; (xvii) the Company's ability to identify and appoint a permanent Chief Executive Officer; (xviii) the Company's expectation that it will be able to finance its continuing operations by accessing public markets for its securities; (xix) the Company's intended use of proceeds of any offering of its securities; and (xv) the Company's intention with respect to not paying any cash dividends on its common shares in the capital of the Company ("Common Shares") in the foreseeable future. Forward-looking information can further be identified by the use of forward-looking terminology such as "expects", "plans", "designed to", "potential", "believe", "intended", "continues", "opportunities", "anticipated", "2021", "2022", "2023", "2024", "next", "ongoing", "seek", "objective", "estimate", "future", or the negative thereof or any other variations thereon or comparable terminology referring to future events or results, or that events or conditions "will", "may", "could", "would", or "should" occur or be achieved, or comparable terminology referring to future events or results.

Forward-looking information includes statements about the future and are inherently uncertain and are necessarily based upon a number of estimates and assumptions that are also uncertain. Although the Company believes that the expectations reflected in such forward-looking information are reasonable, such statements involve risks and uncertainties, and undue reliance should not be placed on such statements. Forward-looking information, including financial outlooks, are intended to provide information about management's current plans and expectations regarding future operations, including without limitation, future financing requirements, and may not be appropriate for other purposes. The Company's actual results could differ materially from those anticipated in the forward-looking information contained in this MD&A as a result of numerous known and unknown risks and uncertainties, including, but not limited to:

- the Company's lack of operating income and need for additional capital which may not be available in a timely manner or at all;
- the Company's history of losses and expectations regarding incurring additional losses for the foreseeable future;
- rapid technological change and competition from pharmaceutical companies, biotechnology companies and universities, which may make the Company's technology or products obsolete or uncompetitive;

- the Company's dependence on a single drug product candidate, L-DOS47, uncertainty as to the size and existence of a market opportunity for, and market acceptance of the Company's drug product candidate including as a result of possible changes in the market for the Company's drug candidates resulting from development in immunotherapies or other future cancer treatments;
- the possibility that the market may never accept L-DOS47 or any other drug product candidate the Company successfully develops;
- uncertainty as to product development milestones and, in particular, whether the Company's drug product candidate(s), especially L-DOS47, will be successfully developed and marketed;
- intellectual property risks, including the possibility that patent applications may not result in issued patents, that issued patents may be circumvented or challenged and ultimately struck down, that any expiry of an issued patent, may negatively impact the further development or commercialization of the underlying technology, and that the Company may not be able to protect its confidential proprietary information;
- risks relating to patent litigation;
- risks relating to security breaches and other disruptions which may compromise the Company's information and expose the Company to liability and cause the Company's business and reputation to suffer;
- risks related to the potential infringement by the Company of the intellectual property rights of third parties, and the possibility that such parties may commence legal proceedings to protect or enforce such rights, the outcome of which would be uncertain and could harm the Company's business;
- risks associated with claims, or potential claims, of infringement of third-party intellectual property and other proprietary rights;
- risks relating to lawsuits or other proceedings commenced by the Company to protect or enforce the Company's patents or other intellectual property, and their potential effect on the Company;
- risks relating to potential claims of third parties that the Company's employees, collaborators, consultants, or independent contractors have wrongfully used or disclosed the confidential information of third parties, or that the Company's employees have wrongfully used or disclosed alleged trade secrets of their former employers;
- research and development risks, including without limitation, the fact that the Company's drug product candidate(s) are complex compounds and the Company faces difficult challenges in connection with the manufacture of clinical batches, and the risk of obtaining negative findings or factors that may become apparent during the course of research or development, any of which may result in the delay or discontinuation of the research or development projects;
- regulatory risks, including the lengthy, unpredictable, and costly FDA regulatory approval process and the potential impact on the Company if such approvals are not ultimately obtained;
- the risk of unknown side effects arising from the development, manufacture, or use of the Company's products;
- risk relating to the difficulty in enrolling patients in clinical trials which may result in delays or cancellation of clinical trials;
- the Company's dependence on third parties, including without limitation, contract research organizations, contract manufacturing organizations, clinical trial consultants, collaborative research consultants, regulatory affairs advisors, and others, whose performance and interdependence can critically affect the Company's performance and the achievement of its milestones;
- the Company's significant dependence on licensed intellectual property and the risk of losing or breaching such licenses;
- the Company's dependence on assurances from third parties regarding licensing of proprietary technology owned by others, including the Company's dependence on its license of the L-DOS47 antibody
- risks relating to the marketability of the Company's products arising from regulatory delays or inability to obtain regulatory approval, and ongoing regulatory review and requirements;
- uncertainty as to the availability of raw materials that the Company utilizes to manufacture its products, and in particular, Good Manufacturing Practice ("GMP") grade materials, on acceptable terms or at all, and that the Company may not be able to timely obtain alternative suppliers upon commercially viable terms or at all, which could have a material adverse effect on the further development and commercialization of any or all of the Company's drug product candidate(s);
- manufacturing risks, the need to manufacture to regulatory standards, uncertainty whether the manufacturing process for the Company's drug candidates can be further scaled-up successfully or at all and the risk that clinical batches of the Company's drug candidate may not be able to be produced in a timely manner or at all, which would have a negative effect on the timing and/or occurrence of planned clinical trials and the potential commercialization of the drug candidates;
- risks relating to the Company's potential failure to find third party collaborators to assist or share in the costs of product development and the potential impact on the Company's business, financial condition, and results of operations;
- the need for future preclinical and clinical trials, and the reliance by the Company on third parties to conduct such trials, the occurrence and success of which cannot be assured, and the fact that results seen in earlier clinical trials may not be repeated in later trials;
- product liability and insurance risks;
- the risk of lawsuits and other legal proceedings against the Company;
- uncertainty as to the Company's ability to maintain product liability insurance required by third parties and the risk of the corresponding agreement being terminated;

- the need to attract and retain key personnel and reliance on key personnel;
- the risk of misconduct on the part of employees and consultants, including non-compliance with regulatory standards and requirements;
- the risk that indemnification obligations to directors and officers may adversely affect the Company's finances;
- the impact on the Company's finances resulting from shifts in foreign exchange rates, credit risk and interest rate risk;
- risks related to adverse decisions by tax authorities and changes in law;
- risks relating to the potential financial strain on the Company's resources due to the requirements of being a public company;
- the impact of the ongoing volatility in the economic environment;
- risks relating to compliance with environmental laws;
- risk relating to a failure to maintain an effective system of internal controls;
- risks related to epidemics, pandemics, or other health crises, including the coronavirus ("COVID-19") pandemic, and their potential effect on the Company's business, operations and financial condition;
- risks associated with default of the Company's debts, primarily relating to the Funding Agreement (as defined herein) governing the Convertible Security (as defined herein);
- volatility in the trading price and volume of the Common Shares and potential challenges in maintaining listing requirements;
- the possibility of dilution to current shareholders from future equity or convertible debt financings or through the exercise of stock options ("Options"), warrants ("Warrants") or other securities convertible or exchangeable into Common Shares;
- liquidity of the Common Shares;
- the risk that inaccurate or unfavorable research about the Company's business, or the lack of research about its business, may affect the share price and trading volume of the Common Shares;

and other risk factors that are discussed above and elsewhere in this MD&A or identified in the Company's other public filings under the Company's profile on SEDAR at www.sedar.com (collectively, the "Helix Risk Factors"), any of which could cause actual results to vary materially from current results or the Company's anticipated future results. Forward-looking information in this MD&A is based on certain material factors, estimates or assumptions, which may prove to be incorrect, including, but not limited to assumptions about: general business and current global economic conditions; future success of current research and development activities; achievement of development milestones; inability to achieve product cost targets; competition; changes to tax rates and benefits; the availability of financing on a timely basis; the Company's and competitors' costs of production and operations; the Company's ability to attract and retain skilled employees; receipt of all applicable regulatory approvals/clearances; protection of the Company's intellectual property rights; market acceptance of the Company's product candidates; the Company's ability to meet the continued listing requirements of the Toronto Stock Exchange (the "TSX"); and that the Helix Risk Factors will not cause the Company's actual results or events to differ materially from the forward-looking information. The Company cautions that the foregoing list of important factors and assumptions is not exhaustive.

For all of the reasons set forth above, which do not represent an exhaustive list of factors that may affect the forward-looking information, investors should not place undue reliance on forward looking information. The forward-looking information is based on the beliefs, assumptions, opinions, and expectations of the Company's management at the time they are made, and the Company does not assume any obligation to update any forward-looking information should those beliefs, assumptions, opinions or expectations, or other circumstances change, except as required by law.

Data relevant to estimated market sizes in connection with Company's lead products under development are presented in this MD&A. These data have been obtained from a variety of published resources, including published scientific literature, websites, and information generally available through publicized means. The Company attempts to source reference data from multiple sources whenever possible for confirmatory purposes. Although the Company believes the data is reliable, the Company has not independently verified the accuracy and completeness of this data.

OVERVIEW

Helix is a clinical-stage biopharmaceutical company developing unique therapies in the field of immuno-oncology for the prevention and treatment of cancer based on its proprietary technological platform DOS47.

The Company is pioneering the development of a platform technology targeting the tumour microenvironment. Helix's technology is designed to reduce tumour acidity, an escape mechanism that cancer cells utilize to evade the anti-tumour immune response. Tumour acidity has been shown to correlate with resistance to anti-cancer treatment and poor prognosis for cancer patients.

To date, the Company's proprietary technology platform, DOS47, has yielded two new drug product candidates, L-DOS47 and V-DOS47.

The Company completed extensive preclinical testing and manufacturing development of L-DOS47, following which the Company obtained regulatory approvals to conduct a Phase I/II NSCLC monotherapy clinical study in Poland, a Phase I NSCLC combination study with pemetrexed and carboplatin in the United States, and a Phase II NSCLC combination study with vinorelbine and cisplatin in Ukraine and Poland. In August 2019, the Company also received approval to conduct a Phase Ib/II combination study utilizing L-DOS47 with doxorubicin in patients with previously treated advanced pancreatic cancer in the United States.

In December 2019, the Company announced the start of enrollment and screening for its Phase lb/ll clinical development program for previously treated patients with advanced pancreatic cancer. The study center is located in Scottsdale, Arizona at the Scottsdale Hospital (dba "HonorHealth"). The Company originally forecasted patient enrollment in the Phase Ib portion of the study to be completed by the end of the 2020 calendar year, pending safety outcomes and the impact of the COVID-19 pandemic. As a result of the COVID-19 pandemic, the Company has not met the previously forecasted patient enrollment timeline for this clinical study. The Company added two new clinical sites in other U.S. jurisdictions during the first quarter of 2021 in order to facilitate patient enrollment. Please see "Our results of operations may be negatively impacted by the COVID-19 outbreak" under the heading "Risk Factors".

In 2017, the Company entered into a scientific research collaboration agreement with the Moffitt Cancer Center ("Moffitt") in Tampa, Florida, to perform basic research studies to further investigate the pharmacodynamics of L-DOS47 and to determine the potential benefits of combining L-DOS47 with immune checkpoint inhibitors. The Company is assessing the possibility of expanding the scope beyond its research collaboration program with Moffitt. The Company believes the ability of L-DOS47 to modulate tumour acidity may be key to enable immunotherapy treatment for selected cancers.

A new research collaboration project initiated with the University Hospital of Tübingen builds on data already obtained from imaging techniques performed by Moffitt that demonstrated the ability of L-DOS47 to affect tumour acidity. Extending the scope to further cancer models, and translation of the imaging technique into the clinic may help stratify patients for L-DOS47 and potentially identify patients who may be resistant to certain therapies due to tumour acidity.

The Company has an extensive patent portfolio that includes company owned and licensed patents and pending applications, including, but not limited to, the use of DOS47 as immunoconjugate for cancer treatment. The Company also has licenses with the National Research Council of Canada ("NRC") that cover the use of antibodies for L-DOS47, other DOS47 candidates and cellular therapy products. Issued patents have coverage in all major pharmaceutical markets including North America, Europe, and Asia.

In August 2021, the Company retained the services of Lumanity Healthcare (Lumanity"), a highly experienced oncology consultancy group, to assess the Company's drug product candidate with a focus on identifying value propositions and positioning strategies that would enable clinical adoption of L-DOS47, including broad clinical development key opinion leader input on the positioning of possible combination therapies and the prioritization of current and/or any additional clinical indications.

Interviews conducted by Lumanity with key opinion leaders since its engagement with the Company helped validate the utility of certain of the clinical work completed by Helix to date and has assisted the Company to identify additional opportunities to further strengthen and de-risk the Company's clinical drug candidate program, including optimal selection of patients for trials (stratification) based on objective biomarkers, among other criteria. The Company anticipates that these activities may assist to initiate dialogue with potential market participants in cancer treatment, and that the additional preclinical data obtained could further enhance the Company's clinical program design.
.

RESEARCH AND DEVELOPMENT ACTIVITIES

Background

The pH system, with values ranging from 0 – 14, is used to measure acidity (pH < 7) and alkalinity (pH > 7). In general, the human body exists at a near-neutral pH - neither acidic nor alkaline (basic). In order for cells to function properly, they need the pH both inside and outside the cell to be neutral. There are some examples, however, where this rule is not followed. For example, the inside of the stomach is maintained at an acidic pH, as this helps to digest food. The cells lining the stomach have adapted to live in this acidic environment.

Tumors also exist in an acidic environment. Normal tissues include an extensive network of blood vessels, which deliver oxygen and nutrients to cells and remove waste products. However, tumors contain an abnormal network of blood vessels. Because of this, tumors can become hypoxic (receiving less oxygen than normal tissues) and need to use a non-oxygen requiring form of metabolism to provide energy for their survival and growth. One side effect of this type of metabolism is that it generates an excess of hydrogen ions (H+) inside the cell, and hydrogen ions directly affect pH: the more hydrogen ions there are, the more acidic the inside of the cell becomes. Since a neutral pH inside the cell is essential for a cell to survive, tumor cells pump the excess hydrogen ions out of the cell. Due to the abnormal network of blood vessels, the excess hydrogen ions are not efficiently removed from the tumor microenvironment. Thus, the tumor microenvironment becomes acidic.

The acidic microenvironment helps promote tumor survival and metastasis in a number of ways. The genes expressed by the tumor are affected by the acidic microenvironment, which allows tumor cells to adapt. One of these acid-induced changes is to increase production and release of proteases by tumor cells. The proteases destroy the protein matrix that surrounds the tumor cells, which makes it easier for the tumor cells to invade local tissues – a first step to metastasis. In addition, the acidic tumor microenvironment impairs the activity of immune cells in and around the tumor, which allows the tumor cells to avoid destruction by the immune system.

The acidic tumor microenvironment also reduces the efficacy of common cancer treatments. Some chemotherapy drugs, such as doxorubicin, are weakly basic. The ability of these drugs to enter tumor cells, where they perform their function, is greatly reduced at acidic pH compared to neutral pH. Radiation therapy is also less effective at an acidic pH than at a neutral pH.

It is clear that the acidic tumour microenvironment has a profound effect both on tumour biology and current therapies, and that neutralizing the pH of the tumour microenvironment may have a dramatic impact. One way to reverse extracellular tumour acidity is to inhibit the proteins that pump hydrogen ions out of tumour cells. One advantage of inhibiting these proteins is that not only is acidity of the extracellular tumour microenvironment reduced, but acidity inside the tumour cells increases, which has a negative effect on tumour cell viability. However, targeting these pumps is not easily achieved as many of them exist in multiple forms and some are critical for the function of normal cells. In addition, since there are several different pumps that regulate pH, inhibition of just one is generally insufficient to combat tumour acidity.

A more general and theoretically more effective method to neutralize tumour extracellular pH is to use buffers. A variety of orally administered buffers have been effective in reducing tumour growth and/or metastases in preclinical animal studies. In addition, buffer therapies have been shown to enhance the activities of chemotherapy and immunotherapy. Although oral sodium bicarbonate buffer therapy was tested clinically, these trials failed due to poor compliance and moderate adverse effects. However, improved survival was seen in pancreatic cancer patients undergoing chemotherapy and “alkalization therapy” (produced by changes in diet and consumption of bicarbonate).

Similarly, an alkaline diet likely improved responses to epithelial growth factor receptor – tyrosine kinase inhibitor (EGFR-TKI) therapy in non-small cell lung cancer (NSCLC) patients. Thus, a change in delivery method may allow for successful buffer therapy. Consistent with this hypothesis, administration of iv sodium bicarbonate nanoparticles improved doxorubicin efficacy in a preclinical breast cancer model. In addition, a clinical study was performed in which sodium bicarbonate was administered by local infusion into the tumour. In this study, hepatocellular carcinoma patients were treated with trans-arterial chemoembolization (TACE) with or without local bicarbonate. Patients receiving bicarbonate showed a 6-fold lower viable tumour residue, and a randomized controlled study showed that patients treated with bicarbonate had a higher objective response rate and cumulative overall survival in comparison to the patients treated with TACE alone.

Alkalization using urease - DOS47 platform technology

Although buffer therapies have the potential to neutralize the acidic tumour microenvironment, local administration of buffers is generally not feasible. To deliver alkalization therapy to tumors, the Company has developed DOS47, a proprietary technology platform. DOS47 compounds are conjugates of two components: the plant-based urease enzyme and an antibody that binds to a tumour-specific antigen. The antibody component targets the conjugate to tumors and the urease enzyme converts endogenous urea into metabolites that include ammonia and hydroxyl ions, thus raising the pH of the tumour microenvironment.

L-DOS47

L-DOS47 includes an antibody that targets carcinoembryonic antigen-related cell adhesion molecule 6 (CEACAM6)

Carcinoembryonic antigen-related cell adhesion molecule 6 (CEACAM6) is a cell surface protein found to be upregulated in several types of cancer, including NSCLC and pancreatic cancer. In lung adenocarcinoma, CEACAM6 expression has been significantly associated with adverse clinical outcomes. Similarly, the median survival time of pancreatic adenocarcinoma patients with CEACAM6-positive tumours was significantly shorter than that of patients with CEACAM6-negative disease.

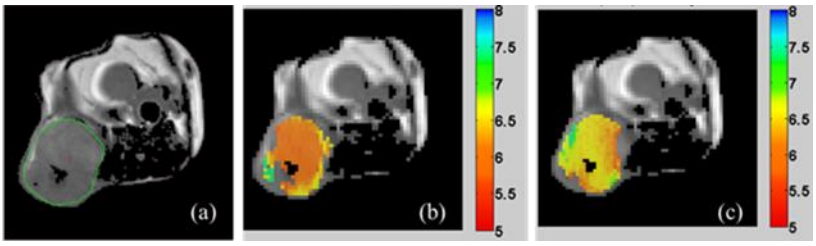
L-DOS47 is composed of the jack bean urease enzyme conjugated to approximately ten (10) copies of a camelid single-chain anti-CEACAM6 antibody. The specificity of L-DOS47 for CEACAM6 was confirmed in *in vitro* binding studies where binding was only observed to cells that express CEACAM6. Immunohistochemistry studies showed binding of L-DOS47 to lung cancer and some pancreatic cancer tissues. The ability of L-DOS47 to specifically target tumours was confirmed using a fluorescently labelled version of L-DOS47. These experiments were performed in a mouse model of lung cancer and showed that L-DOS47 was localized to tumors for at least 72 hours after injection.

L-DOS47 has been shown to control tumour growth, reduce metastases, and enhance the effect of chemotherapy in animal models.

L-DOS47 has been tested in mouse models of lung and pancreatic cancer. Administration of some concentrations of L-DOS47 demonstrated a trend toward tumour stabilization compared to treatment with a control reagent. In addition, when lung cancer cells and L-DOS47 were premixed and injected into mice, the presence of LDOS47 reduced the ability of the tumour cells to colonize the lungs. Enhanced chemotherapy efficacy in the presence of L-DOS47 was observed both in *in vitro* and *in vivo* preclinical experiments. *In vitro* experiments showed that at an acidic pH, L-DOS47 was able to dramatically increase the cytotoxicity of the weakly basic chemotherapeutic drug doxorubicin. In addition, a preliminary preclinical study showed that pre-treatment with L-DOS47 24 hours before doxorubicin delayed tumour growth compared to doxorubicin alone in mice bearing a human CEACAM6-positive pancreatic tumour.

L-DOS47 raises the pH of the tumour microenvironment and restores immune cell activity.

Numerous experiments have been performed by the Company that monitored the production of ammonia and increase in pH when L-DOS47 was combined with urea *in vitro.* The ability of L-DOS47 to raise the pH of the tumour microenvironment *in vivo* has been observed in both lung and pancreatic cancer preclinical models using multiple imaging methods including Phosphorus-31 Magnetic Resonance Spectroscopy (PMRS) and Chemical Exchange Saturation Transfer Magnetic Resonance Imaging (CEST MRI, see images below). In vitro experiments have shown that L-DOS47 successfully restored CD8+ T cell activity, as observed by increased production of the proinflammatory cytokine, interleukin-2 (IL-2). Treatment with L-DOS47 significantly enhanced the ability of an anti-PD1 antibody to control growth of human CEACAM6-expressing pancreatic tumours in mice. A manuscript reporting on this work was uploaded to the preprint server *BioRxiv* on 28 August 2023, and the team is now working on getting a more comprehensive version published in a high-impact journal.



CEST MRI of iopamidol for pH imaging [1] of a Panc02 clone 38 subcutaneous (SC) tumour. (a) T2 weighted image, (b) CEST MRI before L-DOS47 injection, (c) ~30 minutes after 90 µg/ kg L-DOS47 injection. The difference in mean pH is 0.38 units. L-DOS47 was administered iv. Iopamidol was administered SC, next to the tumour.

In summary, these preclinical experiments demonstrate that L-DOS47 successfully targets CEACAM6-expressing tumours, controls tumour growth, increases the pH of the tumour microenvironment, and improves the efficacy of chemotherapy and immunotherapies. L-DOS47 is currently being tested in a clinical trial in patients with metastatic pancreatic cancer. See “Clinical Programs” below.

V-DOS47

V-DOS47 is the second immuno-oncology drug candidate derived from the Company’s DOS47 technology platform. V-DOS47 is an antibody-DOS47 conjugate that targets the vascular endothelial growth factor 2 receptor (VEGFR2). VEGFR2 is overexpressed in breast carcinoma compared with benign breast tissue. In patients with highly estrogen receptor positive (ER^+) forms of breast cancer, the efficacy of tamoxifen treatment negatively correlates with VEGFR2 expression.

Clinical programs

The Company has commenced four clinical studies under the L-DOS47 program. Three clinical studies involve the treatment of NSCLC: A Phase I combination study (LDOS001) conducted in the U.S., a Phase I/II monotherapy study concluded in Poland (LDOS002), and a Phase II combination study running in Eastern Europe (LDOS003). A fourth clinical study, a Phase Ib/II study (LDOS006) investigating the treatment of metastatic pancreatic adenocarcinoma, is currently actively recruiting.

LDOS001 – A Phase I combination therapy trial in lung cancer

LDOS001 was a Phase I, open label, dose escalation study of L-DOS47 in combination with standard doublet therapy of pemetrexed/carboplatin in patients with stage IV (TNM M1a and M1b) recurrent or metastatic non-squamous NSCLC. Patients received standard of care doses of pemetrexed [500 mg/m2] and carboplatin [AUC6], respectively, on Day 1 of a 3-week cycle, in combination with L-DOS47 (starting dose 0.59 µg/kg), administered weekly. The objective of the study design was to evaluate safety and tolerability, as well as determine the maximum tolerated dose ("MTD") of L-DOS47, in combination treatment.

Fourteen (14) patients were enrolled across six dosing cohorts, starting at 0.59 and increasing up to 9.0 µg/kg. The MTD was not achieved as none of the patients experienced any dose-limiting toxicity ("DLT"). Fifty percent (50.0%) of patients experienced at least one treatment emergent adverse event assessed as study drug-related, with 14.3% of patients experiencing at least one grade 3/4 drug-related toxicity. Although the study was not designed specifically to assess efficacy, preliminary results showed that of 12 patients evaluable for efficacy, five patients (41.7%) had a partial response ("PR"), four patients (33.3%) experienced stable disease (SD) and three patients (25.0%) had progressive disease ("PD"). The objective response rate was 41.7%, with a median duration of 187 days, and a clinical benefit rate of 75.0% with a median duration of 141 days. Additional reports on L-DOS47 pharmacokinetics and immunogenicity have been completed, with the final Clinical Study Report issued on December 13, 2021. A manuscript was published online in *Journal of Thoracic Oncology Clinical Research Reports* on September 15, 2022.

L-DOS47, in combination with pemetrexed/carboplatin, was well tolerated with promising anti-tumour activity against non-squamous NSCLC.

LDOS001 Phase I Best Overall Response Summary Efficacy Evaluable(N=12)	
	L-DOS47 (All Dosing Cohorts) + Pemetrexed/Carboplatin
Best Overall Response	Overall
Number of Patients[1]	12
Complete Response (CR)	0 (0%)
Partial Response (PR)	5 (41.7%)
Stable Disease (SD)	4 (33.3%)
Progressive Disease (PD)	3 (25.0%)

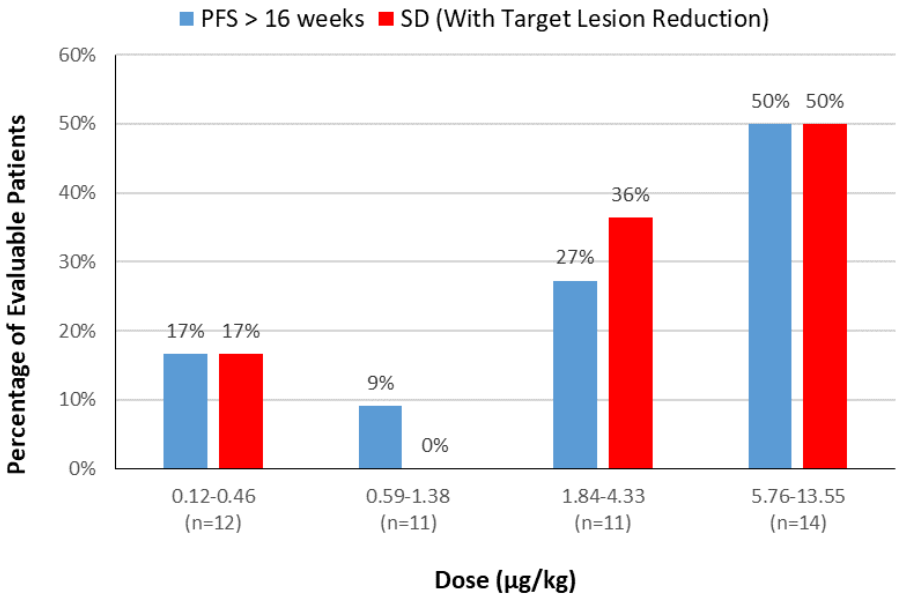
[1] Number of patients used as denominator to calculate percentages.

LDOS002 – A phase I/II monotherapy trial in lung cancer

LDOS002 was a Phase I/II open-label, non-randomized, dose escalation study of L-DOS47 as a monotherapy in adult subjects with inoperable, chemo-naïve, or refractory Stage IIIb or IV non-squamous NSCLC. The primary objectives of the Phase I portion of the study were to evaluate safety and tolerability of ascending doses of L-DOS47 and define the MTD. Patients received weekly doses of L-DOS47, administered as an intravenous infusion over 14 days, followed by seven days rest (with one treatment cycle occurring over three weeks).

Despite a total of 55 patients being dosed across 16 dose levels ranging from 0.12 up to 13.55 µg/kg, the MTD was not reached. There was only one single DLT of spinal/bone pain reported at the 5.76 µg/kg dose level. The weekly dosing schedule of L-DOS47 for all doses up to 13.55 µg/kg was otherwise well tolerated and most adverse events reported were typical of the population under study. L-DOS47 did not elicit a dose-dependent release of cytokines at doses up to13.55µg/kg. Time of maximum observed plasma drug concentration after dosing ("Tmax") was consistent across dose levels and treatment cycles, occurring within the first hour following the L-DOS47 infusion. There were no safety issues beyond those already observed in pre-clinical toxicology studies or expected in the population of patients being studied.

A dose response trend was observed when comparing the percentage of patients who were progression-free at 16 weeks across dose ranges, according to Response Evaluation Criteria in Solid Tumours ("RECIST") version 1.1. A similar trend was observed when comparing the percentage of patients who had stable disease and had a reduction in target lesions. A manuscript is currently in preparation to report the results from this phase of the trial.



. L-DOS47 Monotherapy dose response in cohorts

In the Phase II portion of the study, the objective was to make a preliminary assessment of efficacy for L-DOS47 given as monotherapy. Enrolling subjects in the same patient population as in Phase I, patients were dosed at 13.55µg/kg, twice weekly over 14 days, followed by seven days' rest. A total of 21 patients were dosed in the first stage of the Phase II component of the study.

Despite an intensified L-DOS47 monotherapy dosing regimen, evaluation of initial results did not yield ≥1 partial or complete response at any time point as defined by protocol. The Phase II component of the study did not proceed to Phase II Stage 2, and the development of L-DOS47 as monotherapy treatment of non-squamous NSCLC was discontinued.

LDOS003 – *A Phase II combination therapy trial in lung cancer*

LDOS003 was a Phase II, open-label, randomized study of L-DOS47 in combination with vinorelbine/cisplatin vs vinorelbine/cisplatin alone in patients with lung adenocarcinoma. Vinorelbine/cisplatin chemotherapy combination in the U.S. became infrequent due to the rapidly evolving treatment landscape and the growing prominence of immunotherapies such as Keytruda®. The Company commenced this study based on the use of vinorelbine/cisplatin chemotherapy combinations in Eastern European and Asian markets.

The approved protocol called for patients receiving L-DOS47 to be dosed on days 1 and 8 of each 21-day treatment cycle, along with standard vinorelbine/cisplatin chemotherapy for a total of four treatment cycles. The study was divided into two parts. Part I applied a standard 3 + 3 algorithm for dose escalation to determine the L-DOS47 maximum tolerated dose when given in combination with vinorelbine/cisplatin. Cohorts of three patients were recruited into three dosing cohorts (6, 9 and 12 µg/kg). All patients at a given dosing cohort were to complete the first treatment cycle (3-week period) before escalation in subsequent patients were to proceed. The decision for escalation to the next dose level would be made after the safety data had been reviewed by the Trial Steering Committee ("TSC"). If a patient in any cohort experiences a DLT, an additional three patients would need to be enrolled, for a maximum of up to 18 patients in this initial dose escalation part of the study.

In Part II, after the maximum tolerated dose of L-DOS47 in combination with vinorelbine/cisplatin has been determined, a further 118 patients were to have been randomized (1:1) to receive L-DOS47 in combination with vinorelbine/cisplatin, or vinorelbine/cisplatin alone. Efficacy was to be assessed by time to progression (time from first day of study drug administration to documented disease progression), response rate (proportion of patients with a best overall response of complete response and partial response according to RECIST v. 1.1), and overall survival (time from first day of study drug administration to death due to any cause). Monitoring was to have included radiological evaluations every second cycle. Safety and tolerability of L-DOS47 in combination was also to have been evaluated. For all patients, treatment would continue either until the patient experiences disease progression, unacceptable toxicity, the patient withdraws consent or has completed four treatment cycles.

Patient recruitment began in February 2019 but halted in April 2020. At the time, the first two cohorts (6 and 9 µg/kg) in Part I of the study had been completed. Two (2) patients had also been dosed in the third cohort, 12 µg/kg, but the cohort could not be completed due to a shortage in the required vinorelbine dosages from the manufacturer, which was expected to continue into 2021. Consequently, the Company made the decision to terminate further recruitment, proceed to data analysis and not move forward with Part II of the study. Completion of an abbreviated clinical study report was further delayed due to subsequent covid restrictions and the war in Ukraine. An incomplete clinical study database

was received in spring 2023 and the abbreviated clinical study report was completed September 8, 2023. Final notifications to ethics committees and applicable health authorities were completed fall 2023.

LDOS006 – A Phase Ib/II combination trial in pancreatic cancer

The Company received FDA approval in August 2019 to initiate a new study of L-DOS47 in the treatment of pancreatic cancer. This is an open label, non-randomized study designed to evaluate the safety, tolerability, and preliminary anti-tumour activity of L-DOS47 in combination with doxorubicin in patients aged ≥ 18 years old with metastatic pancreatic cancer who have progressed on at least two prior treatment regimens. The trial was initiated in November 2019 and the first patient dosed in December 2019.

The Phase Ib part of the study applies a standard 3 + 3 algorithm for dose escalation to determine the L-DOS47 maximum tolerated dose to use in combination with doxorubicin for the Phase II part of the study. Patients are recruited into three cohorts where each cohort receives weekly dose levels of L-DOS47, (starting at 3 µg/kg and potentially escalating to 6 and 9 µg/kg), in combination with a fixed dose of 20 mg/m2 of doxorubicin weekly, (or 15 mg/m^2 as per the subsequently amended protocol), with four weeks making up one treatment cycle up to a maximum of six cycles. The decision for escalation to the next dose level will be made after all patients in a cohort have completed four weeks of combination treatment and the safety data have been reviewed by the Safety Review Committee of the Company. If a patient in any cohort experiences a dose limiting toxicity, an additional three patients will be enrolled, for a maximum of up to 18 patients in this initial dose escalation part of the study. A further protocol amendment was submitted to FDA on November 15, 2021, to increase up to 8 treatment cycles at the reduced doxorubicin dose level of 15 mg/m^2, with discretion to continue additional cycles at the discretion of the investigator.

The Phase II part of the study was designed to focus on evaluating preliminary anti-tumour activity, as well as continuing to evaluate safety and tolerability of L-DOS47 in combination with doxorubicin. A further 11 additional patients were scheduled to be enrolled in this phase of the study. Patients will be initiated on the L-DOS47 dose determined in Phase I, in combination with 20 mg/m2 doxorubicin as per the original protocol or 15 mg/m^2 as per the subsequently amended protocol, with tumour marker carbohydrate antigen 19-9 (CA19-9) measurements at each treatment cycle, and radiological assessments every two treatment cycles. Tumour response will be assessed according to RECIST version 1.1. Safety will be assessed by reported adverse events (AEs), serious adverse events (SAEs), physical exams, vital signs, Karnofsky Performance Status, electrocardiogram (ECG), echocardiogram (ECHO)/multi-gated acquisition scan (MUGA), clinical laboratory evaluations (hematology, chemistry, coagulation, and urinalysis), and anti-L-DOS47 antibody levels.

A total of 22 patients have been dosed with L-DOS47 in combination with doxorubicin. Six (6) patients were dosed under the original protocol where patients were initiated on L-DOS47 in combination with 20 mg/m^2 doxorubicin, three (3) of whom withdrew due to disease progression prior to completing the required 4-week cycle in order to be included in the evaluation for dose escalation. Of the remaining three (3) patients, one patient experienced a DLT attributed to doxorubicin and as a result, a protocol amendment adjusting the starting chemotherapy dose was submitted to FDA on December 23, 2020, and patient screening resumed on January 25, 2021. Due to slower enrolment related to challenges resulting from COVID-19 pandemic measures, two additional sites were opened for recruitment in March and April 2021.

Under an amended protocol where patients were initiated on L-DOS47 in combination with 15 mg/m^2 doxorubicin, the first three (3) patients dosed at the lowest L-DOS47 dosing cohort (3 µg/kg) resulted in one patient experiencing a serious adverse event (thromboembolic event – pulmonary emboli). As this event was initially assessed by the investigator as probably related to L-DOS47, thereby meeting the criteria for a DLT, the cohort was expanded and a further 5 patients were subsequently dosed. Two patients discontinued from the trial prior to completing the required 4-week cycle in order to be included in the evaluation for dose escalation due to adverse events unrelated to study treatment. Of the remaining three patients, one discontinued after two treatment cycles due to disease progression, one discontinued in the sixth treatment cycle with stable disease observed for at least 4 treatment cycles, and one patient discontinued after the first treatment cycle due to an SAE (atrial fibrillation) that met criteria for DLT, based on initial investigator assessment. Sponsor physician disagrees with initial causality assessment due to patient's complex medical/cardiac history. Further medical records were compiled and a complete review of all safety data from the first dosing cohort was conducted January 19, 2022. The first event, pulmonary emboli, which was initially identified as a DLT due to causality relationship, was subsequently revised to be unrelated to study treatment due to the emergence of additional relevant medical history prior to study entry. With a total of six (6) patients dosed, one (1) DLT event, the investigator group recommended to move forward with dose escalation to the next dosing level (6 µg/kg)

On March 3, 2022, Helix submitted an additional protocol amendment to the FDA, updating exclusion criteria to further restrict patients with cardiac medical histories that would put them at higher risk of adverse events from doxorubicin treatment, which is a chemotherapy agent with known cardiotoxicities. On May 5, 2022, patient screening re-opened for dosing cohort 2 (6 µg/kg). Four (4) patients were dosed with three patients completing the DLT period without a DLT event and one patient discontinued early due to an adverse event unrelated to study treatment. A safety review conducted by investigators resulted in a recommendation to escalate to the next dosing level (9 µg/kg).

On February 28, 2023, Helix submitted a further protocol amendment to the FDA to include an additional dosing cohort, 13.55 µg/kg, with the possibility of higher dosing cohorts as agreed upon by study investigators and the sponsor. Recruitment for dosing level, 9 µg/kg, opened on December 1st, 2022. Four patients were dosed in total with three patients completing the DLT period. There were no DLT events recorded and following safety review on July 17, 2023, a recommendation was made to escalate to the next dosing level, 13.55 µg/kg. Recruitment for this dosing cohort is currently ongoing.

Given the Company's limited current cash resources and the possibility of not being able to obtain additional financing on a timely basis, the Company may be required to reduce, delay, or cancel one or more of its planned research and development programs, including clinical studies.

Manufacturing

L-DOS47 is an immunoconjugate drug composed of single chain antibody molecules specific for CEACAM6 that are cross-linked with a purified urease derived from the jack bean plant (*Canavalia ensiformis*).

The urease component is extracted from jack beans through a multistage process that yields an enzyme with high activity and purity. The llama-derived recombinant antibody is manufactured in *E. coli* and the purified antibodies are covalently linked to the urease enzyme by a chemical cross-linker into L-DOS47 drug substance. The drug substance is filled and lyophilized into the final L-DOS47 drug product for use in the clinic. The Company has extensively characterized L-DOS47 and maintains a comprehensive analytical program for the drug substance, drug product, and the urease and antibody intermediates.

A Polysorbate 80, 1% w/w in water for injection diluent is co-mixed with L-DOS47 in normal saline prior to administration to prevent protein adsorption to the saline bags and IV tubing that are used to administer the drug to patients in the clinic.

Manufacturing, release, and stability testing of L-DOS47 and the Polysorbate 80, 1% diluent is currently conducted by contract manufacturing organizations ("CMOs") and contract testing laboratories ("CTLs") in the U.S and Canada. The Company requires all CMOs and CTLs to maintain compliance with current GMP and to be licensed by the national regulatory authority in their jurisdiction. Company employees and consultants provide technical, quality, and regulatory oversight for all operations related to L-DOS47 production. Currently, the Company has service and quality agreements with several CMOs/CTLs for clinical-stage manufacturing, testing, and release of the L-DOS47 drug substance and drug product and the Polysorbate 80, 1% diluent.

The Company's supply of L-DOS47 drug product continues to be subjected to stability assays according to ICH Q1A (R2) guidelines. The stability program for the lot in clinical use will be extended as long as the product continues to meet specifications. The batch has been found to be stable at least through the last testing point (102M as of May 2023). If the product goes Out-of-Specification (OOS) at the real-time storage condition (2-8ºC) for two consecutive pulls before the final time point, further stability testing and clinical use may be discontinued.

The CMO that manufactured the L-DOS47 drug substance batch that has been used in the Company's clinical studies informed the Company in early 2019 that it would no longer be able to manufacture L-DOS47. In September 2019, the Company signed an agreement with another CMO to reprocess an older drug substance batch the Company had kept in reserve. The Company completed the reprocessing of the drug substance batch in June 2020, and after quality control testing and release, the drug substance was transferred to another CMO to complete the fill/finish process. After lyophilization, which was completed in early 2021, the drug product lot was placed on a 36M stability program which may be extended if warranted by real-time stability data. If the product goes OOS at the real-time storage condition (2-8ºC) for two consecutive pulls before the final time point, further testing may be discontinued. The new batch completed 24M stability testing in January 2023 with the next time point in progress as of August 2023. The Company has another older batch of L-DOS47 drug substance which requires reprocessing to produce drug product. If this lot is successfully reprocessed it can be used for to produce a new lot of drug product in the event it is needed.

The Company has also been in discussion with various CMOs to plan out a technology transfer program to manufacture batches of L-DOS47 drug substance. As of the date of this MD&A, no commitment has been made.

If any of the stability assays for the current batch or new production batch do not meet acceptance criteria, the Company's clinical studies and any planned research and development programs would likely face delays and possibly be cancelled, which could impair the current and future value of the business. See "Risk Factors".

Product focus and strategy

The Company is evaluating the current clinical strategy to determine if the Company's L-DOS47 pipeline can be expanded into rare diseases, based on feedback from pharmaceutical companies, Key Opinion Leaders, and internal discussions. A focus on rare diseases would facilitate an orphan disease designation from the FDA, allowing the Company to conduct either smaller trials at lower costs or potentially a basket trial, which is a a type of master protocol designed to test a single investigational drug or drug combination in different populations. The company is currently evaluating two rare diseases for pre-clinical studies with regards to technical and clinical feasibility. The long term goal of the rare disease strategy is to allow the Company to expand approval for L-DOS47 into other disease indications with potential for significant revenue growth.

Commercialization

The Company's DOS47 commercialization objective is to eventually enter into a strategic partnering alliance with a large pharmaceutical company, on an individual or multiple drug candidate basis, such as L-DOS47 or any potential new DOS47 drug product candidate. The intention of Company is to enter a structured process that will include preparing the Company to have discussions with potential partners, engaging in dialogue with a targeted group of qualified partners and licensees, and entering

negotiations on a prospective partnership, alliance, or licensing transaction. In the meantime, the Company will continue to gather as much value-adding clinical data/findings, which demonstrate the safety and efficacy of L-DOS47 in patients or any other new potential DOS47 drug candidate, so as to maximize value for shareholders when entering into a strategic partnering alliance.

SUMMARY OF QUARTERLY RESULTS

The Company reported a net loss and total comprehensive loss of $1,254,000 for the three months ended October 31, 2023 (2022 - $1,606,000).

The following table depicts selected quarterly data previously reported for the last eight quarters (thousands of $, except per share data):

	Q1 2024	Q4 2023	Q3 2023	Q2 2023	Q1 2023	Q4 2022	Q3 2022	Q2 2022
Research and development expenses	949	1,661	1,084	1,038	1,300	850	939	1,506
Operation, general and admin expens	303	479	272	207	285	266	363	420
Net loss and total comprehensive loss	(1,254)	(2,153)	(1,337)	(1,194)	(1,606)	(1,386)	(1,345)	(2,019)
Loss per share - basic and fully dilute	(0.01)	(0.01)	(0.01)	(0.01)	(0.01)	-	(0.01)	(0.01)
Cash	1,641	808	1,330	2,824	4,397	3,252	1,882	471
Working capital (deficiency)	580	(877)	877	2,185	(903)	319	(1,015)	(3,110)

Cash increase in Q3 in fiscal year 2022 is due the successful closing of a private placement financing for gross proceeds of $1,001,000 from the issuance of 3,850,000 common shares at a price of $0.26 per common share and the closing of a private placement financing for net proceeds of $2,002,000 from the issuance of 7,700,000 common shares at a price of $0.26 per common share. Cash increase in Q4 F2022 is due to shareholders exercising 12,346,938 warrants at a special reduced price of $0.26 per share which the Company applied and received approval from the Toronto Stock Exchange. The exercise of the warrants generated a total of $3,210,204.

On September 12, 2022, the Company applied to the TSX to price protect a proposed $5 million financing of common shares at a price of $0.18 per share. The TSX granted a price protection letter on September 14, 2022, and the conditional approval of the placement on September 26, 2022. On November 3, 2022, the Company announced that it had closed a private placement financing for net proceeds of CAD $4,629,020 from the issuance of 25,716,777 common shares at a price of $0.18 per common share with insiders subscribing for $270,000. The common shares issued pursuant to the Private Placement are subject to a statutory hold period of four months and one day ending on March 4, 2023, in accordance with applicable securities law. In connection with the closing, the Company paid a cash fee of 10% of gross proceeds raised to an eligible finder.

On July 19, 2023, the Company applied to the TSX to price protect a proposed $3 million financing of common shares at a price of $0.18 per share. The TSX granted the conditional approval of the placement on July 19, 2023. On August 15, 2023, the Company announced that it had closed the private placement financing for gross proceeds of CAD $2,998,000 from the issuance of 16,655,557 common shares at a price of $0.18 per common share.

RESULTS FROM OPERATIONS

Net loss from continuing operations

The Company reported a net loss and total comprehensive loss of $1,254,000 for the three months ended October 31, 2023 (2022 - $1,606,000).and a loss of $0.01 per common share (2022 - $0.01 per common share).

Research & development

Research & development expenses for the three months ended October 31, 2023, totalled $949,000 (2022 –$1,300,000).

The following table outlines research and development costs expenses for the current and comparative periods (in thousands of Canadian dollars):

Research and development				
For the three-month periods ended October 31		2023		2022
Research and development programs, excluding the below items	$	803	$	1,017
Salaries and benefits		235		266
Stock-based compensation		14		14
Amortization of property plant and equipment		4		3
Research and development investment tax credits		(106)		-
	$	**949**	**$**	**1,300**

Research and development expenditures for the three months ended October 31, 2023, when compared to the three months ended October 31, 2022, were lower by $351,000 or 27%. The decrease in spending is covered most areas of expenditures including those associated with clinical and pre-clinical research and development activities. Stock-based compensation expenses were similar while salaries and benefits were lower by $31,000 when compared to the three months ended October 31, 2022).

The Company hired biotechnology consultants to assess the Company's drug product candidate with a focus on identifying value propositions and positioning strategies that would enable clinical adoption of L-DOS47. See "*Overview*" above for additional information.

Operating, general and administration

Operating, general and administration expenses for the three months ended October 31, 2023, totalled $303,000 (2022 – $285,000).

The following table outlines operating, general and administration expenses for the current and comparative periods (in thousands of Canadian dollars):

OG&A				
For the three-month periods ended October 31		2023		2022
Operating, general and administration (excluding below items)	$	135	$	272
Wages and benefits		12		-
Director fees and investor relations		136		11
Stock-based compensation		20		2
	$	**303**	**$**	**285**

Operating, general and administration expenditures for the three months ended October 31, 2023, when compared to the three months ended October 31, 2022, were higher by $18,000 or 6%.

Since May 2022, the Company has made significant efforts to control and reduce its overheads expenditures. This included closing its headquarters at Richmond Hill Ontario and moving it to Grove Corporate Services offices "(Grove") in downtown Toronto. The Company hired Grove to perform accounting and corporate secretarial services following the resignation of its previous CFO in May 2022. The savings apply to various activities including salaries, rent, legal, and other operational expenditures. Further measures are being taken which will result in more reductions in the current period.

In general, administrative savings were made in operating expenses ($137,000), Wages were higher by ($12,000) and Director and IR fees were higher by ($136,000). Stock-based compensation was higher by $18,000.

Several factors materialized that resulted in the Company abandoning its plans to list on a U.S. stock exchange. These include but are not limited to the increase in the percentage ownership of the Common Shares by new insiders and a decline in the price of the Common Shares making it extremely challenging for the Company to leverage the Multijurisdictional Disclosure System.

CRITICAL ACCOUNTING ESTIMATES

The preparation of the annual financial statements in conformity with IFRS requires management to make judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets and liabilities, revenue and expenses and the related disclosures of contingent assets and liabilities and the determination of the Company's ability to continue as a going concern. Actual results could differ materially from these estimates and assumptions. The Company reviews its estimates and underlying assumptions on an ongoing basis. Revisions are recognized in the period in which the estimates are revised and may impact future periods.

The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the Company's annual financial statements have been set out in Note 1 of the Company's financial statements for the three months ended October 31, 2023, and 2022.

SIGNIFICANT ACCOUNTING POLICIES

The significant accounting policies used in preparing the Company's financial statements are described in Note 2 of the Company's annual financial statements for the three months ended October 31, 2023, and 2022, except for those related accounting policies and methods of computation related to any new accounting standards and pronouncements.

NEW ACCOUNTING STANDARDS AND PRONOUNCEMENTS NOT YET ADOPTED

There are no new accounting standards and pronouncements issued but not yet effective up to the date of issuance of the Company's annual financial statements that are expected to have a material impact on the Company.

LIQUIDITY AND CAPITAL RESOURCES

Since inception, the Company has mainly relied on financing its operations from public and private sales of equity. The Company does not have any credit facilities and is therefore not subject to any externally imposed capital requirements or covenants. The Company manages its liquidity risk by continuously monitoring forecasts and actual cash flow from operations and anticipated investment and financing activities.

The Company reported a net loss and total comprehensive loss of $1,254,000 for the three months ended October 31, 2023, (2022 - $1,606,000) and a loss of $0.01 per common share (2022 - $0.01 per common share). As of October 31, 2022, the Company had a working capital deficiency of $877,000, shareholders' equity deficiency of $844,000 and a deficit of $201,407,000.

On July 19, 2023, the Company applied to the TSX to price protect a proposed $3 million financing of common shares at a price of $0.18 per share. The TSX granted the conditional approval of the placement on July 19, 2023. On August 15, 2023, the Company announced that it had closed the private placement financing for gross proceeds of CAD $2,998,000 from the issuance of 16,655,557 common shares at a price of $0.18 per common share.

On September 12, 2022, the Company applied to the TSX to price protect a proposed $5 million financing of common shares at a price of $0.18 per share. The TSX granted a price protection letter on September 14, 2022, and the conditional approval of the placement on September 26, 2022. On November 3, 2022, the Company announced that it had closed a private placement financing for net proceeds of CAD $4,629,020 from the issuance of 25,716,777 common shares at a price of $0.18 per common share with insiders subscribing for $270,000. The common shares issued pursuant to the Private Placement are subject to a statutory hold period of four months and one day ending on March 4, 2023, in accordance with applicable securities law. In connection with the closing, the Company paid a cash fee of 10% of gross proceeds raised to an eligible finder.

On April 13, 2022, the Company announced that it has received conditional approval from the Toronto Stock Exchange to extend its previously announced Early Warrant Exercise Incentive Program from April 28, 2022, to May 31, 2022. The Incentive Program is a period during which holders of the Company's eligible common share purchase warrants ("Eligible Warrants") may take advantage of a temporary reduction in the exercise price of the Eligible Warrants to a price of C$0.26. The Eligible Warrants include an aggregate of 49,806,469 warrants that if exercised at the Incentive Exercise Price will result in the Company receiving gross proceeds of up to $12,949,682. During the three-month period ended October 31, 2022, 12,346,938 warrants were exercised for a total subscription amount of $3,210,204.

On March 11, 2022, the Company closed a private placement financing for gross proceeds of $1,001,000 from the issuance of 3,850,000 common share at a price of $0.26 per common share. On April 21, 2022, the Company closed a private placement financing for net proceeds of $2,002,000 from the issuance of 7,700,000 common shares at a price of $0.26 per common share.

On May 11, 2021, the Company entered into a definitive convertible security funding agreement ("the Funding Agreement") with Lind Global Macro Fund, LP, a New York based institutional investment fund managed by The Lind Partners, LLC (collectively "Lind"). The Company closed the first tranche under the Funding Agreement on May 13, 2021, for gross proceeds of $3,500,000 (the "First Tranche"). In connection with the closing of the First Tranche, the Company issued (i) an 8.75% convertible note (a "Convertible Security") with a two-year term and a fair value of $4,112,500 and (ii) an aggregate of 1,957,056 Warrants exercisable into Common Shares until May 12, 2025, at an exercise price of $1.0283 per Common Share and classified as equity instruments. The Convertible Security issued under the First Tranche accrues a simple interest rate obligation of 8.75% per annum on the amount funded, being $3,500,000, which interest is prepaid and attributed to the face value of the Convertible Security. The Company also paid Lind a 3% commitment fee on the amount funded under the First Tranche, as well as under any second tranche, which as of the date of this MD&A has not yet been completed.

Each Convertible Security issuable under the Lind Agreement has a two-year term from the date of issuance and accrues a simple interest rate obligation of 8.75% per annum on the amount funded, where interest is prepaid and attributed to the face value of each Convertible Security upon issuance. Lind is entitled to convert the Convertible Securities into Common Shares over the term of the applicable Convertible Security, subject to certain limitations, at a conversion price equal to 85% of the five-day trailing volume-weighted average price ("VWAP") of the Common Shares prior to the notice date of conversion provided to the Company by Lind. The Lind Agreement includes certain restrictions on the maximum face value of each of the Convertible Securities that may be converted in any particular month. In addition, the Company has the option to buy-back 66.7% of the Convertible Securities in cash at any time with no penalty, subject to the option of Lind to convert up to 1/3 of the face value of the applicable Convertible Security into Common Shares at the time of such buy-back. If the Convertible Security is repaid by the Company within 180 days of issuance, the face value amount owed will be reduced pursuant to the terms of the Lind Agreement. Lind will also be entitled to accelerate its conversion right to the full amount of the face value or demand repayment of the face value in cash upon a default and other designated events as set out in the Lind Agreement. To the extent that the full-face value of a Convertible Security has not been converted at the maturity date of the applicable Convertible Security, the outstanding balance of such face value shall be to be repaid to Lind by the Company in cash.

The Funding Agreement contains certain ongoing covenants of the Company typical of an agreement of its nature. In the event of certain defaults by the Company under the Funding Agreement, Lind has the right, upon notice to the Company, to accelerate the conversion of the face value of any outstanding Convertible Security or demand repayment of such face value in cash and terminate the Funding Agreement. No such notice has been delivered to the Company as at the date of these consolidated financial statements. A copy of the Funding Agreement is available on SEDAR at www.sedar.com.

From September 13, 2021, to August 26, 2022, Lind converted $2,050,625 of the face value of the Convertible Security issued under the First Tranche into 9,272,127 common shares of the Company at an average deemed price of $0.19 per common share. On August 30, 2022, the Company announced that it had completed the buyback of the outstanding amount of the convertible security funding agreement with Lind at a cost of C$2,061,875.

See Note 7 – Convertible note payable for additional information.

Date	Lind Conversion	Share price	Shares	Amount of conversion
September 13, 2021	Conversion 1	$ 0.6686	307,545	$ 205,625
October 11, 2021	Conversion 2	$ 0.4014	512,269	$ 205,625
December 3, 2021	Conversion 3	$ 0.3967	518,338	$ 205,625
January 11, 2022	Conversion 4	$ 0.2368	868,348	$ 205,625
February 22, 2022	Conversion 5	$ 0.2076	990,486	$ 205,625
April 12, 2022	Conversion 6	$ 0.1791	1,148,101	$ 205,625
May 12, 2022	Conversion 7	$ 0.1661	1,237,959	$ 205,625
June 27, 2022	Conversion 8	$ 0.1740	1,181,752	$ 205,625
August 2, 2022	Conversion 9	$ 0.1652	1,244,703	$ 205,625
August 26, 2022	Conversion 10	$ 0.1584	1,262,626	$ 200,000
			9,272,127	**$ 2,050,625**

In order for the Company to advance the currently planned preclinical and clinical research and development activities, its collaborative scientific research programs and pay for its overhead costs, the Company will need to raise approximately $11,000,000 through to the end of fiscal 2025. The Company projects an average monthly fixed overhead spend of approximately $120,000. This amount does not include the costs related to any of the Company's third-party activities such as clinical studies, collaborative research activities and contract manufacturing.

The Company currently has three clinical studies (see *Research and Development Activities* above for additional information) in various stages. The Company has completed the clinical study report for LDOS001 and submitted a final annual report to the FDA

in April 2022 and update the result into the www.clinicaltrials.gov portal in June 2022. The Company is forecasting approximately $10,000 to finalize reporting.

The Company previously forecasted LDOS003 as a large, randomized study but concluded that it would not move forward with the randomized portion of the study unless the Company entered into a co-development partnership with a third party. The Company was working to complete the study and report which has been delayed due to administrative disagreement as a result of overbilling by the clinical research organization overseeing the program. The recent escalation of war in Ukraine, where the Company enrolled virtually all its patients in this clinical study, has complicated matters. As at the date of this MD&A, it is uncertain as to when the clinical study reports will be completed, if at all. The Company is currently projecting $486,000 to complete and wind up the clinical study.

The Company received IND approval by the FDA to conduct a Phase Ib/II study (LDOS006) in the U.S., L-DOS47 in combination with doxorubicin, for previously treated advanced pancreatic cancer. Patient enrollment commenced December 2019. COVID-19 impacted patient enrollment resulting in the Company adding two additional clinical sites this year. The Company is forecasting a cost of approximately $5,855,000 through to December 2025 to complete both the Phase Ib and Phase II portion of the trial. Certain conditions need to be achieved in order for the Company to be able to progress through to the Phase II portion of the trial. Of the forecasted $5,500,000, the portion attributable to the Phase II is estimated to be approximately $1,000,000.

The Company is forecasting manufacturing expenditures of approximately $400,000 through to the end of fiscal 2025 in support of the Company's drug development program. The Company previously forecasted a manufacturing technology transfer to a new manufacturer with a scaled-up production in anticipation of having sufficient supply for a contemplated pivotal trial and a new clinical study of L-DOS47 in combination with an immune-oncology drug. The Company has since produced a new batch of drug product from previous drug substance providing additionally sufficient supply for the Company's current clinical program, provided stability assays continue to meet protocol standards.

Collaborative research expenditures are estimated at $966 through to the end of fiscal 2025.

The Company's cash reserves of $1,641,000 as of October 31, 2023, are insufficient to meet anticipated cash needs for working capital and capital expenditures through the next twelve months, nor are they sufficient to see planned research and development initiatives through to completion. Additional funds are required to advance the Company's clinical and preclinical programs and deal with future working capital requirements. To the extent that the Company does not believe it has sufficient liquidity to meet its current obligations, management considers securing additional funds, preferably through the issuance of equity securities of the Company, to be critical for its development needs. The Company may also consider other forms of raising funds, such as the issuance of debt which may or may not include a conversion of equity in the Company.

The Company's long-term liquidity depends on its ability to raise funds from various sources, which depends substantially on the success of its ongoing research and development programs, economic conditions, and the state of the biotech industry.

Accessing the capital markets can be particularly challenging for companies that operate in the biotechnology industry. While the Company has been able to raise equity financing in recent years, there can be no assurance that additional funding by way of equity financing will continue to be available. Any additional equity financing, if secured, would result in dilution to the existing shareholders and such dilution may be significant. The Company may also seek additional funding from or through other sources, including technology licensing, co-development collaborations, mergers and acquisitions, joint ventures, and other strategic alliances, which, if obtained, may reduce the Company's interest in its projects or products or result in significant dilution to existing shareholders. The Company may also seek additional funding from government grants. There can be no assurance, however, that any alternative sources of funding will be available. The failure of the Company to obtain additional financing on a timely basis may result in the Company reducing, delaying, or cancelling one or more of its planned research, development and/or marketing programs, including clinical trials, further reducing overhead, or monetizing non-core assets, any of which could impair the current and future value of the business or cause the Company to consider ceasing operations and undergoing liquidation.

Given the Company's conclusion about the insufficiency of its cash reserves, significant doubt is cast about the Company's ability to continue operating as a going concern. The continuation of the Company as a going concern for the foreseeable future depends mainly on raising sufficient capital, and in the interim, reducing, where possible, operating expenses (including making changes to the Company's research and development plans), including the delay of one or more of the Company's research and development programs, further reducing overhead and the possible disposition of assets.

The Company needs to raise additional capital to further advance its clinical development program.

Use of proceeds from the sale of securities in the past have been used for working capital, including funding the Company's ongoing research and development activities.

CONTRACTUAL OBLIGATIONS

The Company's commitments as of October 31, 2023, are summarized as follows (in thousands of Canadian dollars):

	2024	2025	2026	2027	2028	2029+	Total
Clinical research organizations	$ 2,766	$ 3,090	$ -	$ -	$ -	$ -	$ 5,856
Collaborative Research Organizations	966	-	-	-	-	-	966
Royalty and in-licensing	20	20	10	10	10	50	120
Operating leases	13	-	-	-	-	-	13
	$ 3,765	$ 3,110	$ 10	$ 10	$ 10	$ 50	$ 6,955

Notes:

(1) The Company has clinical research organization supplier agreements in place for clinical research services and passthrough costs related to the Company's clinical stage programs.

(2) Represents future minimum royalties.

(3) The Company is committed to pay $13,000 under two facility lease agreements.

RELATED PARTY TRANSACTIONS

During the three months ended October 31, 2023, the Company entered into various transactions with related parties. The related parties consist of officers, directors and shareholders or companies controlled directly or indirectly by them. Details of the transactions and balances owing, or receivables for the three months ended October 31, 2023 are as follows:

(i) The Company recorded management fees to the executive officers of $25,000 (October 31, 2022 - $38,000) as well as consulting fees paid to the directors of the company in the amount of $Nil (October 31, 2022 – $Nil).

(ii) Since June 2021, the Company has retained Grove Corporate Services Ltd. ("Grove") to provide accounting, governance, and administrative services (the "Services"), including those provided by the Chief Financial Officer ("CFO"). During the three months ended October 31, 2023, the Company recorded the CFO fees to Grove in the amount of $77,000.

The following table summarizes key management personnel compensation for the three months ended October 31:

	2023	2022
Salary and management consulting	$ 102	$ 38
Stock-based compensation	18	-
	$ 120	**$ 38**

The following table summarizes non-management directors' compensation for the three months ended October 31:

	2023	2022
Directors' fees	$ -	$ -
Stock-based compensation	6	2
	$ 6	**$ 2**

FINANCIAL INSTRUMENTS

Fair value hierarchy

Financial instruments recorded at fair value on the balance sheet are classified using a fair value hierarchy that reflects the significance of the inputs used in making the measurements. The fair value hierarchy has the following levels:

- Level 1 reflects valuation based on quoted prices observed in active markets for identical assets or liabilities;
- Level 2 reflects valuation techniques based on inputs that are quoted prices of similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; inputs other than quoted prices used in a valuation model that are observable for that instrument; and inputs that are derived principally from or corroborated by observable market data by correlation or other means; and
- Level 3 reflects valuation techniques with significant unobservable market inputs.

A financial instrument is classified to the lowest level of the hierarchy for which a significant input has been considered in measuring fair value. The financial instrument in the Company's annual financial statements, measured at fair value, is cash.

Fair value

The fair value of financial instruments as of October 31, 2023, approximates their carrying value because of the near-term maturity of these instruments.

INTELLECTUAL PROPERTY

The Company protects its intellectual property rights through a robust combination of patent, copyright, trademark, and trade secrets as well as with confidentiality and invention assignment agreements.

The Company seeks intellectual property protection in various jurisdictions around the world and owns patents and patent applications relating to products and technologies in the United States, Canada, Europe, and other jurisdictions.

As of October 31, 2023, the Company had rights to 4 issued U.S. patents, which will expire between July 16, 2023, and January 22, 2036, assuming all required fees are paid, 5 pending U.S. patent applications, 64 issued foreign patents, and 42 pending foreign patent applications. The Company's patents and patent applications cover aspects of its current and future product concepts. Some of the pending foreign patent applications preserve an opportunity to pursue patent rights in multiple countries. As of October 31, 2023, the Company had one registered trademark in Canada.

The Company also relies, in part, upon unpatented trade secrets, know-how and continuing technological innovation, and may in the future rely upon licensing opportunities, to develop and maintain our competitive position. The Company protects its proprietary rights through a variety of methods, including confidentiality and assignment agreements with suppliers, employees, consultants, and others who may have access to the Company's proprietary information.

While there is no active litigation involving any of the Company's patents or other intellectual property rights and the Company has not received any notices of patent infringement, the Company may be required to enforce or defend its intellectual property rights against third parties in the future.

Patents and other proprietary rights are very valuable to the Company and involve complex legal and factual issues. The Company has no assurance that any of its patent applications will result in the issuance of patents. Even issued patents may not provide the Company with a competitive advantage against competitors with similar technologies, or who have designed around the Company's patents. Furthermore, the Company's patents may be invalidated or found enforceable if challenged. Intellectual property laws vary from country to country which may result in varying levels of intellectual property protection.

Because of the substantial length of time and expense associated with developing new products, the pharmaceutical, medical device, and biotechnology industries place considerable importance on obtaining patent protection for new technologies, products, and processes. The Company's policy is to file patent applications to protect inventions, technology, and improvements that are important to the development of its business and with respect to the application of our products and technologies to the treatment of several diseases. The Company's policy also includes regular reviews related to the development of each technology and product considering its intellectual property protection, with the goal of protecting all key research and developments by patent. The Company will continue to seek intellectual property protection as appropriate and require our employees, consultants, outside scientific collaborators, and sponsored researchers to enter into confidentiality agreements with the Company that contain assignment of invention clauses outlining ownership of any intellectual property developed during the course of the individual's relationship with the Company.

Patents

The Company currently owns several patents in respect of the DOS47 technology and has licensed patent rights from the NRC for the antibody component of L-DOS47. In addition to issued patents, the Company has filed several new patent applications around the world.

OFF-BALANCE SHEET ARRANGEMENTS

The Company has no material off-balance sheet arrangements.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company's main objectives when managing capital are to ensure sufficient liquidity to finance research and development activities, clinical trials, ongoing administrative costs, working capital and capital expenditures. The Company includes cash and components of shareholders' equity, in the definition of capital. The Company endeavours not to unnecessarily dilute shareholders when managing the liquidity of its capital structure.

Market risk

Market risk is the risk that changes in market prices, such as interest rates and foreign exchange rates, will affect the Company's income or the value of its financial instruments.

Currency risk

The Company has international transactions and is exposed to foreign exchange risks from various currencies, primarily the Euro and U.S. dollar. In addition, foreign exchange risks arise from purchase transactions, as well as recognized financial assets and liabilities denominated in foreign currencies.

Balances in foreign currencies as at October 31 are as follows (in thousands of Canadian dollars):

	October 31, 2023		July 31, 2023	
	USD	EUR	USD	EUR
Cash	2	347	2	18
Accounts payable	(394)	(210)	(305)	–
Accruals	(26)	–	(85)	–
Net foreign currencies	(418)	–	(388)	(18)
Closing exchange rate	1.3969	1.4828	1.3225	1.4580
Impact of 1% change in exchange rate	+/- 5	+/- 2	+/- 4	+/- 1

Any fluctuation in the exchange rates of the foreign currencies listed above could have an impact on the Company's results from operations; however, they would not impair or enhance the ability of the Company to pay its foreign-denominated expenses.

Credit risk

Credit risk is the risk of a financial loss to the Company if a customer or counterparty to a financial instrument fails to meet its contractual obligation.

The table below breaks down the various categories that make up the Company's accounts receivable balances, in thousands of Canadian dollars, as at:

	October 31, 2023	July 31, 2023
Government related – GST/HST	$ 36	$ 29
Research and development investment tax credits	18	18
Patent costs recoverable from HIO	15	15
	$ 69	$ 62

Interest rate risk

Interest rate risk is the risk that future cash flows of a financial instrument will fluctuate because of changes in interest rates, which 9are affected by market conditions. The Company is exposed to interest rate risk arising from fluctuations in interest rates received on its cash. The Company is not subject to any debt related interest rate risk.

The Company manages its interest rate risk by maximizing the interest income earned on excess funds while maintaining the liquidity necessary to conduct its operations on a day-to-day basis. Any investment of excess funds is limited to risk-free financial instruments. Fluctuations in the market rates of interest do not have a significant impact on the Company's results of operations due to the relatively short-term maturity of any investments held by the Company at any given point in time and the low global interest rate environment. The Company does not use derivative instruments to reduce its exposure to interest rate risk.

Liquidity risk

Liquidity risk is the risk that the Company will not be able to meet its obligations as they come due. Since inception, the Company has mainly relied on financing its operations from public and private sales of equity. The Funding Agreement is subject to certain ongoing covenants of the Company that could affect the Company's liquidity.

The Company manages its liquidity risk by continuously monitoring forecasts and actual cash flow from operations and anticipated investing and financing activities.

The Company's cash reserves of $1,641,000 as of July 31, 2023, are insufficient to meet anticipated cash needs for working capital and capital expenditures through the next twelve months, nor are they sufficient to see the current research and development initiates through to completion. To the extent that the Company does not believe it has sufficient liquidity to meet its current obligations, management considers securing additional funds primarily through equity arrangements to be of utmost importance.

The Company's long-term liquidity depends on its ability to access the capital markets, which depends substantially on the success of the Company's ongoing research and development programs, as well as economic conditions relating to the state of the capital markets generally. Accessing the capital markets is particularly challenging for companies that operate in the biotechnology industry.

The following are the contractual maturities of the undiscounted cash flows of financial liabilities (in thousands of Canadian dollars) as at:

	October 31, 2023			**July 31, 2023**		
	Carrying amount	Less than one year	Greater than one-year	Carrying amount	Less than one year	Greater than one-year
Accounts payable	$ 984	$ 984	$ -	$ 493	$ 493	-
Accrued liability	289	289	-	383	383	-
	$ 1,273	**$ 1,273**	**$ -**	**$ 876**	**$ 876**	**-**

This table only covers liabilities and obligations relative to financial instruments and does not anticipate any income associated with assets.

OUTSTANDING SHARE DATA

The Company is authorized to issue 10,000,000 preferred shares. As of the date of this MD&A, the Company has nil preferred shares issued and outstanding.

The Company is authorized to issue an unlimited number of Common Shares without par value. As at the date of this MD&A, the Company has 216,674,416 Common Shares issued and outstanding.

As at the date of this MD&A, the Company had the following securities convertible into common shares outstanding:

1. Warrants to purchase up to 34,024,556 Common Shares**:**
2. Options to purchase up to 5,725,000 Common Shares.

DISCLOSURE CONTROLS AND PROCEDURES AND INTERNAL CONTROL OVER FINANCIAL REPORTING

Management has designed the Company's disclosure controls and procedures ("DC&P") to provide reasonable assurance that all relevant information is gathered, recorded, processed, summarized and reported to the Chief Executive Officer and the Chief Financial Officer of the Company so that appropriate decisions can be made within the time periods specified in securities legislation regarding public disclosure by the Company in its annual filings, interim filings or other documents or reports required to be filed or submitted by it under securities legislation.

Management has also designed internal controls over financial reporting ("ICFR") to provide reasonable assurance regarding the reliability of the Company's financial reporting and the preparation of its financial statements for external purposes, as applicable, in accordance with IFRS. Because of its inherent limitations, ICFR can provide only reasonable assurance and may not prevent or detect misstatements. Further, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies or procedures may deteriorate.

Management Report on ICFR and DC&P

Management is responsible for establishing and maintaining adequate ICFR and has designed such ICFR to provide reasonable assurance regarding the reliability of financial reporting and the preparation and fair presentation of annual consolidated financial statements for external purposes in accordance with IFRS.

Management, including the Chief Executive Officer and Chief Financial Officer, do not expect that the Company's ICFR will prevent all error and all fraud. A control system can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving our stated goals under all potential future conditions. Because of the inherent limitations in /a cost-effective control system, misstatements due to error or fraud may occur and not be detected. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As at July 31, 2021, the Company's Chief Financial Officer and Chief Executive Officer evaluated the effectiveness of the Company's internal controls over financial reporting and identified a material weakness resulting from the Company's limited accounting resources and technical expertise to ensure complex and non-routine transactions are addressed during the financial statement close process. As a result, the control deficiency created a reasonable possibility that a material misstatement of interim and annual financial statements may not be prevented or detected on a timely basis. The CFO and the Financial Controller have worked to resolve the issue that had created a material weakness and will keep watching for any other material weaknesses that may arise. Management and the Board have been assessing the effectiveness of the Company's internal controls in the current period and have since appointed three new Board members.

Management believes, based on its knowledge, that (i) this MD&A does not contain any untrue statements of a material fact or omit to state a material fact necessary to make the statements not misleading, in light of the circumstances under which they were made, with respect to the period covered by this MD&A and, (ii) the annual financial statements and other financial information included in this MD&A, fairly present in all material respects the financial condition, results of operations and cash flows at, and for, the fiscal periods presented in this MD&A.

Management is confident that the Company will be able to address any material weakness in ICFR in fiscal 2024.

SUBSEQUENT EVENTS

There are no subsequent events at this time.

RISKS AND UNCERTAINTIES

The Company is subject to risks, events and uncertainties, or "risk factors", associated with being a publicly traded company operating in the biotechnology industry, with research and development stage projects in pre-clinical discovery and clinical development and with no expectation of revenue or profits in the foreseeable future and, as such, is heavily dependent on raising sufficient capital on a timely basis in order to advance the Company's drug development programs. As a result of these risk factors, reported information and forward-looking information may not necessarily be indicative of future operating results or of future financial position, and actual results may vary from the forward-looking information or reported information. The Company cannot predict all of the risk factors, nor can it assess the impact, if any, of such risk factors on the Company's business or the extent to which any factor, or combination of factors, may cause future results or financial position to differ materially from either those reported or those projected in any forward-looking information. Accordingly, reported financial information and forward-looking information should not be relied upon as a prediction of future actual results. Some of the risks and uncertainties affecting the Company, its business, operations, and results which could cause actual results to differ materially from those reported or from forward-looking information include, either wholly or in part, those described elsewhere in this MD&A, as well as the following:

Risks Related to the Company's Business

The Company does not have any source of operating income and is dependent solely on outside sources of financing

The Company's operations consist of research and development activities, which do not generate any revenue. Accordingly, the Company has no source of revenue, positive operating cash flow or operating earnings to subsidize its ongoing research and development and other operating activities and the ability of the Company to continue as a going concern is dependent upon the Company's ability to rely on cash on hand, and on outside sources of financing to fund its ongoing research and development and other operating activities. Such sources of financing involve risks, including that the Company will not be able to raise such financing on terms satisfactory to the Company or at all, and that any additional equity and/or any convertible debt financing, if secured, would result in dilution to existing shareholders, and that such dilution may be significant. The Company may also seek additional funding from or through other sources, including technology licensing, co-development collaborations, mergers and acquisitions, joint ventures, and other strategic alliances, which, if obtained, may reduce the Company's interest in its projects or products or result in significant dilution to existing shareholders. The Company may also seek additional funding from government grants. There can be no assurance, however, that any alternative sources of funding will be available. The failure of the Company to obtain additional financing on a timely basis may result in the Company reducing, delaying, or cancelling one or more of its planned research and development programs, including clinical trials, further reducing overhead, or monetizing non-core assets, any of which could impair the current and future value of the business or cause the Company to consider ceasing operations and undergoing liquidation.

The Company has a history of losses and expects to continue to incur additional losses for the foreseeable future

The Company's primary focus continues to be on its research and development of drug product candidates. The research and development of drug product candidates require the expenditure of significant amounts of cash over a relatively long-time period. The Company expects to continue to incur losses from continuing operations for the foreseeable future. The Company's accumulated deficit as of October 31, 2023, is $202,661,000. There can be no assurance that the Company will record earnings in the future or that the drug product candidates under development by us will be approved for sale in Canada, the United States, or elsewhere. Furthermore, there can be no assurance that if such products are approved, they will be successfully commercialized, and the extent of our future losses and the timing of our profitability are highly uncertain. If we are unable to achieve profitability, we may be unable to continue our operations.

The Company faces risks in connection with competition and technological change

The biotechnology industry is subject to rapid and substantial technological change. Technological competition from pharmaceutical companies, biotechnology companies and university researchers are intense and is expected to continue to be intense.

The rapid advancement of immunotherapies has and likely will continue to significantly change the treatment of cancer and may result in a reduction, which may be significant, in the potential patient population and/or treatment protocols available to chemotherapies and other treatments currently in development, such as the Company's primary drug product candidate, L-DOS47. Developments in immunotherapies have resulted in the Company repositioning its L-DOS47 lead drug product candidate away from a front-line monotherapy protocol towards second and third-line combination therapies with existing chemotherapy drugs and possibly in combination with immunotherapies, resulting in additional expenditures and delays in previously anticipated development timelines for L-DOS47. Advancements in technology can impact the Company at any time and as such, any further repositioning, would likely result in additional expenses being incurred by the Company and in further delays in the anticipated development timeline for L-DOS47, or in the Company determining that its L-DOS47 drug product candidate is no longer viable. The Company is currently heavily dependent on the success of its lead drug product candidate L-DOS47, which is the only drug candidate currently in clinical development.

The Company cell-based therapies initiative may face significant hurdles. The Company's effort is mainly at research proof-of-concept stage. It is possible that the selected targets or choice of antibodies are not optimal. This can delay the initiation of formal preclinical and clinical development significantly. The Company has chosen to develop cell-based therapy for solid tumour. While there are many successful examples of cell-based therapy treatment in hematological malignancies, similar success in solid tumour is less certain.

Many of the Company's competitors have substantially greater financial, technical, and human resources and significantly greater experience in conducting preclinical testing and human clinical trials of product candidates, scaling up manufacturing operations and obtaining regulatory approvals of products. Accordingly, the Company's varying competitors may succeed in obtaining regulatory approval for products more rapidly. The Company's ability to compete successfully will largely depend on:

- the efficacy and safety profile of our product candidates relative to marketed products and other product candidates in development;
- our ability to develop and maintain a competitive position in the product categories and technologies on which we focus;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- our ability to obtain required regulatory approvals;
- our ability to commercialize any of our product candidates that receive regulatory approval;
- our ability to establish, maintain and protect intellectual property rights related to our product candidates; and
- acceptance of any of our product candidates that receive regulatory approval by physicians and other healthcare providers and payers.

Competitors have developed and may develop technologies that could be the basis for products that challenge the differentiated nature and potential for best-in-class product development programs and discovery research capabilities of the DOS47 platform technology. Some of those products may have an entirely different approach or means of accomplishing the desired therapeutic effect than our product candidates and may be more effective or less costly than our product candidates. The success of our competitors and their products and technologies relative to our technological capabilities and competitiveness could have a material adverse effect on the future preclinical studies a nd clinical trials of our product candidates, including our ability to obtain the necessary regulatory approvals for the conduct of such clinical trials. This may further negatively impact our ability to generate future product development programs with improved pharmacological properties.

If we are not able to compete effectively against our current and future competitors, our business will not grow, and our financial condition and operations will substantially suffer.

The Company is heavily dependent on the success of a single drug product candidate

The Company's future success is dependent primarily on the regulatory approval and commercialization of a single drug product candidate, L-DOS47, which is the Company's only drug candidate currently in clinical development. The Company does not have any products that have obtained regulatory approval. The Company is conducting early-stage research and development initiatives and is currently in the process of developing L-DOS47, which will require further time-consuming and costly research and development. There can be no assurance that L-DOS47 or any other drug product candidate that the Company undertakes to develop will ever be successfully developed or commercialized. As a result, the Company's near-term prospects, including its ability to finance its operations and generate revenue, are substantially dependent on its ability to obtain regulatory approval for, and, if approved, to successfully commercialize L-DOS47 in a timely manner.

The Company's single lead drug product candidate, L-DOS47, may not be accepted by the market and may never generate revenue and the Company has limited sales, marketing, and distribution experience

Even with regulatory approval, the Company may not achieve market acceptance of its lead drug product candidate, L-DOS47, which depends on a number of factors, including the establishment and demonstration in the medical community of the clinical utility of the Company's products, and their potential advantage over alternative treatment methods. There is also the risk that the actual market size or opportunity for any drug candidate developed by the Company is uncertain. Failure to gain market acceptance of the Company's products or an incorrect estimate in the nature and size of the markets for the Company's products could have a material adverse effect on the Company.

The Company has limited sales, marketing and distribution experience, and there is no assurance that the Company will be able to establish adequate sales, marketing, and distribution capabilities or make arrangements with any collaborators, strategic partners, licensees, or others to perform such activities, or that such efforts will be successful. The Company's objective for L-DOS47 is to enter into strategic alliances with appropriate pharmaceutical partners. There can be no assurance that any such strategic alliance will be maintained or achieved, or if achieved, that it will result in revenue to the Company.

The timing of the Company's internal goals and projected timelines may not be met

The Company sets internal goals for and makes public statements regarding its expected timing of meeting the objectives material to its success, including the commencement, duration, and completion of clinical trials, and anticipated regulatory approvals. The actual timing of these forward-looking events can vary dramatically due to a number of factors, including, without limitation, delays in scaling-up of drug product candidates, delays or failures in clinical trials, additional data requirements from the regulators, the Company failing to obtain required financing, and other risks referred to herein. Without limiting the generality of the foregoing, it is possible that required regulatory approvals may be delayed or denied, including those related to undertaking or continuing clinical trials, manufacturing of drug products, and marketing such products.

A failure to obtain necessary financing or a change in the schedule of a clinical trial (which may occur for many reasons, including due to factors beyond the Company's reasonable control, such as scheduling conflicts, the occurrence of serious adverse events, interruption of supplies of study drugs, withdrawals of regulatory approvals, or slow patient recruitment) could delay the commencement or completion of the clinical trial, or result in its suspension or early termination, which could have a material adverse effect on the Company.

We will have significant additional future capital needs in 2023 and beyond and there may be uncertainties as to our ability to raise additional funding in the future to meet these needs

We will require significant additional capital resources to expand our business, in particular the further development of our product candidate, L-DOS47. Advancing our product candidate, marketing for our product, or acquisition and development of any new products or product candidates will require considerable resources and additional access to capital markets. In addition, our future cash requirements may vary materially from those now expected. For example, our future capital requirements may increase if:

- we experience unexpected or increased costs relating to preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims, or other lawsuits, brought by either us or our competition;
- we experience scientific progress sooner than expected in our discovery, research, and development projects, if we expand the magnitude and scope of these activities, or if we modify our focus as a result of our discoveries;
- we are required to perform additional pre-clinical studies and clinical trials; or
- we elect to develop, acquire, or license new technologies, products, or businesses.

The Company could potentially seek additional funding through corporate collaborations and licensing arrangements or through public or private equity or debt financing. However, if capital market conditions in general, or with respect to life sciences companies such as ours, are unfavorable, our ability to obtain significant additional funding on acceptable terms, if at all, will be negatively affected. Additional financing that we may pursue may involve the sale of Common Shares which could result in significant dilution to our shareholders. If sufficient capital is not available, we may be required to delay our research and development projects, which could harm our business, financial condition, prospects, or results of operations.

The Company may not obtain adequate protection for its products through its intellectual property

The Company's success depends, in large part, on the Company's ability to protect its competitive position through patents, trade secrets, trademarks, and other intellectual property rights. The Company's success, competitive position, and future revenues with respect to its product candidates will depend, in part, on the Company's ability to protect its intellectual property. The Company will be able to protect its proprietary rights from unauthorized use by third parties only to the extent that its proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. The Company seeks intellectual property protection in various jurisdictions around the world and owns patents and patent applications relating to biological products and technologies in the United States, Canada, Europe, and other jurisdictions. The scope and duration of the Company's intellectual property rights vary from country to country depending on the nature and extent of the Company's intellectual property filings, the applicable statutory provisions governing the intellectual property, and the nature and extent of the Company's legal rights. The Company's failure to do so may adversely affect the Company's business and competitive position.

The patent positions of pharmaceutical and biopharmaceutical firms, including the Company's, are uncertain and involve complex questions of law and fact for which certain important legal issues remain unresolved. The patents issued or to be issued to the Company may not provide the Company with any competitive advantage. The Company may not be able to protect its intellectual property rights throughout the world. The Company's patents may be challenged by third parties in patent litigation. In addition, it is possible that third parties with biological products that are very similar to the Company's may circumvent the Company's patents by means of alternate designs or processes. The Company may have to rely on method of use patent protection for its biological products in development and any resulting biological products, which may not confer the same level of protection as protection of the Company's biological products per se. The Company may be required to disclaim part of the term of certain patents in the United States. There may be prior art of which the Company is not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which the Company is aware, but which the Company does not believe affects the validity or enforceability of a claim, which may, nonetheless ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that the

Company's patents would, if challenged, be held by a court to be valid or enforceable or that a competitor's technology or drug would be found by a court to infringe the Company's patents.

Patent terms may be inadequate to protect the Company's competitive position on its product candidates for an adequate amount of time. Patents have a limited lifespan, in most jurisdictions inclusive of the United States, if all maintenance fees are timely paid, the term of protection is a period of 20 years from the filing date of the application. Patent term extensions of up to 5 years may be available in certain countries for patents pertaining to new medicinal ingredients or new combinations of medicinal ingredients for human or veterinary use based upon the delay in regulatory review. Even if patents covering the Company's product candidates are obtained, once the patent life and any patent term extension have expired, the Company may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, the Company's owned and licensed patent portfolio may not provide the Company with sufficient rights to exclude others from commercializing products similar or identical to the Company's.

Patent applications relating to or affecting the Company's business may have been filed by a number of pharmaceutical and biopharmaceutical companies and academic institutions. The technologies in these applications or patents may cover the Company's technologies, and such conflict could create freedom to operate issues. The Company's granted patents could be challenged, invalidated, or found unenforceable in interference and derivation proceedings, and post grant proceedings including re-examination, *Inter Parte* Review and Post-Grant Review, in the United States. The Company's granted patents could also be challenged and revoked in opposition proceedings in certain countries outside of the United States such as in Europe. In addition to patents, the Company relies on trade secrets and proprietary know-how to protect its intellectual property. The Company generally requires employees, consultants, outside scientific collaborators, and sponsored researchers and other advisors to enter into confidentiality agreements. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with the Company is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all of the technology that is conceived by the individual during the course of employment is the Company's exclusive property. These agreements may not provide meaningful protection or adequate remedies in the event of unauthorized use or disclosure of proprietary information. In addition, it is possible that third parties could independently develop proprietary information and techniques substantially similar to the Company's or otherwise gain access to the Company's trade secrets.

The Company may obtain the right to use certain technology under license agreements with third parties. The Company's failure to comply with the requirements of material license agreements could result in the termination of such agreements, which could cause the Company to terminate the related development program and cause a complete loss of investment in that program. As a result of the foregoing factors, the Company may not be able to rely on its intellectual property to protect the Company's products in the marketplace.

Patent litigation is costly and time consuming and may subject the Company to liabilities

The Company's involvement in any patent litigation, opposition, or other administrative proceedings will likely cause the Company to incur substantial expenses, and the efforts of technical and management personnel will be significantly diverted. In addition, the Company may not have the financial means defend its patents and in the event it does, an adverse determination in litigation could subject the Company to significant liabilities, including, but not limited to, monetary damages.

Security breaches and other disruptions could compromise the Company's information and expose the Company to liability, which would cause the Company's business and reputation to suffer

In the ordinary course of our business, the Company collects and stores sensitive data, including intellectual property, proprietary business information and that of our suppliers and business partners, and personally identifiable information of our collaborators and employees, on our networks and on shared cloud services. The secure processing, maintenance and transmission of this information is critical to our operations. Despite our security measures, our information technology and infrastructure may be exposed to malware, cyberattacks, attacks by hackers or breached due to employee error, malfeasance, or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation, which could adversely affect our business and competitive position.

Further, some of our partners may store personal or confidential information that we share with them. If these third parties fail to implement adequate data-security practices or fail to comply with our terms and policies, sensitive data may be

improperly accessed, acquired, or disclosed. And even if these third parties take all these steps, their networks and information technology systems may still suffer a security breach, which could compromise our data.

The Company may infringe the intellectual property rights of others

The Company's commercial success depends significantly on the Company's ability to operate without infringing on the patents and other intellectual property rights of third parties. There could be issued patents of which the Company is not initially aware that the Company's products infringe or patents that the Company believes it does not infringe, but that the Company may ultimately be found to infringe. Patent applications are maintained in secrecy from the time of filing until publication. The publication of discoveries in the scientific or patent literature frequently occurs later than the date on which the underlying discoveries were made, and patent applications were filed. There may be currently pending patent applications of which the Company is unaware that may later result in issued patents that the Company's products infringe.

The biopharmaceutical industry has produced a proliferation of patents in jurisdictions around the world. The coverage of patents is subject to interpretation by the courts of a particular jurisdiction, and the interpretation is not always uniform. The Company believes that the sale or use of its primary biological product candidate, L-DOS47 would not infringe any valid claim of patents, although there can be no assurances of this. In the event of an infringement or violation of another party's patent, the Company may not be able to enter into licensing arrangements or make other arrangements at a reasonable cost. Any inability to secure licenses or alternative technology could result in delays in the introduction of drugs or lead to prohibition of the manufacture or sale of drugs by the Company.

Third parties may initiate legal proceedings alleging that the Company is infringing their intellectual property rights, the outcome of which would be uncertain and could harm the Company's business

Third parties may assert patent or other intellectual property infringement claims against the Company or its other licensors arising from the manufacture, use, or sale of the Company's current or future product candidates. An unfavorable outcome could result in loss of patent rights and require the Company to cease using the related technology or to attempt to license rights to it from the prevailing party. The Company's business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. The Company may not have the financial means and wherewithal to defend against third party claims and in the event it does, defense of litigation proceedings may fail and, even if successful, may result in substantial costs and distract the Company's management and other employees. In the event of a successful claim of infringement against the Company, the Company may have to pay substantial damages, including treble damages and legal fees for willful infringement, pay royalties, redesign its infringing products, or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

The Company may become involved in lawsuits or other proceedings to protect or enforce the Company's patents or other intellectual property, which could be expensive, time consuming and unsuccessful

Competitors may infringe the Company's patents or other intellectual property. The Company may not have the financial means and wherewithal to defend its patents or other intellectual properties and in the event the Company was to initiate legal proceedings against a third party to enforce a patent covering the Company's product candidates, the defendant could counterclaim that the patent covering the Company's product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description, enablement, or clarity. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the United States Patent and Trademark Office, or "USPTO", or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. The validity of the Company's current or future patents or patent applications or those of the Company's licensors may also be challenged in interference or derivation proceedings, opposition, post grant review, inter partes review, or other similar enforcement and revocation proceedings, provoked by third parties or brought by the Company. The Company's patents could be found invalid, unenforceable, or their scope significantly reduced.

The Company may be subject to claims challenging the inventorship of the Company's patents and other intellectual property

The Company or its licensors may be subject to claims that former employees, collaborators or other third parties have an interest in the Company's owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, the Company or its licensors may have inventorship disputes arise from conflicting obligations of employees, collaborators, consultants, or others who are involved in developing the Company's product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship of the Company's or its licensors' ownership of the Company's owned or in-licensed patents, trade secrets or other intellectual property. The Company may not have the financial means to defend such claims and in the event the Company or its licensors fail in defending any such claims, in addition to paying monetary damages, the Company may lose valuable intellectual property

rights, such as exclusive ownership of, or right to use, intellectual property that is important to the Company's product candidates. Even if the Company is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on the Company's business, financial condition, results of operations and prospects.

The Company may be subject to claims that its employees, collaborators, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties or that the Company's employees have wrongfully used or disclosed alleged trade secrets of their former employers

As is common in the biotechnology and pharmaceutical industry, the Company employs individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including the Company's competitors or potential competitors. Although the Company tries to ensure that its employees, collaborators, consultants and independent contractors do not use the proprietary information or know-how of others in their work for the Company, the Company may be subject to claims that the Company or its employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of the Company's employees' former employers or other third parties. Litigation may be necessary to defend against these claims. The Company may not have the financial means to defend such claims and in the event the Company fails in defending any such claims, in addition to paying monetary damages, the Company may lose valuable intellectual property rights or personnel, which could adversely impact the Company's business. Even if the Company is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and the Company's patent protection could be reduced or eliminated for non-compliance with these requirements

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. The Company has systems in place to remind the Company to pay these fees, and the Company employs an outside firm and relies on its outside counsel to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. The Company employs reputable law firms and other professionals to help the Company comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, the Company's competitors might be able to enter the market and this circumstance would have a material adverse effect on the Company's business.

The Company faces research and development risks, including the need to prove the Company's drug candidates are safe and effective in clinical trials

The Company's drug candidates are complex compounds, and the Company faces difficult challenges in connection with the manufacture of clinical batches of each of them, which could further delay or otherwise negatively affect the Company's planned clinical trials or required regulatory approvals.

There is also the risk that the Company could obtain negative findings or factors that may become apparent during the course of research or development. The results from preclinical and clinical trials may not be predictive of results obtained in any ongoing or future clinical trials. A number of companies in the biotechnology and pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier trials and pre-clinical trials.

The timing and success of the Company's clinical trials also depend on a number of other factors, including, but not limited to: (a) obtaining additional financing, which is not assured; (b) sufficient patient enrolment, which may be affected by the incidence of the disease studied, the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the eligibility criteria for a patient to participate in the study and the rate of patient drop-out; (c) regulatory agency policies regarding requirements for approval of a drug, including granting permission to undertake proposed human testing; (d) the Company's capacity to produce sufficient quantities and qualities of clinical trial materials to meet the trial schedule; (e) performance by third parties, on whom the Company relies to carry out its clinical trials; and (f) the approval of protocols and/or protocol amendments.

Clinical trials are complex, expensive, and uncertain, and have a high risk of failure, which can occur at any stage. Data obtained from pre-clinical and clinical trials may be interpreted in different ways, or be incorrectly reported, which could delay or prevent further development of the drug candidate studied. Failure to complete clinical trials successfully and to obtain successful results on a timely basis could have a material adverse effect on the Company.

Even if the Company's drug candidates successfully complete the clinical trials and receive the regulatory approval necessary to market the drug candidates to the public, there is also the risk of unknown side effects, which may not appear until the drug candidates are on the market and may result in delay or denial of regulatory approval or withdrawal of previous approvals, product recalls or other adverse events, which could materially adversely affect the Company.

While the Company continues to explore opportunities to expand its drug product pipeline with new DOS47-based therapeutics pending the identification of further tumour targeting agents, there can be no assurance that any such tumour targeting agents will be identified or that any new DOS47-based therapeutics will be developed.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, expensive, and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. It is not uncommon for companies in the biopharmaceutical industry to suffer significant setbacks in advanced clinical trials due to nonclinical findings made while clinical studies were underway and safety or efficacy observations made in clinical studies, including previously unreported adverse events. Our future clinical trial results may not be successful, and notwithstanding any potential promising results in earlier studies, we cannot be certain that we will not face similar setbacks. The historical failure rate for product candidates in our industry is high. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a New Drug Application, or NDA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

We may not have the necessary capabilities, including adequate staffing, to successfully manage the execution and completion of any future clinical trials we initiate in a way that leads to our obtaining marketing approval for our product candidates in a timely manner, or at all. This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate or may restrict its distribution. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

We have not previously submitted an NDA to the FDA or similar drug approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patients that we are targeting for our product

candidates are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval to commercialize our product candidates both in the United States and the European Union and in additional foreign countries. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials, and commercial sales, pricing, and distribution of our product candidates, and we cannot predict success in these jurisdictions.

Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. The clinical evaluation of our product candidates in patients is still in the early stages and it is possible that there may be side effects associated with their use. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, we, the FDA, the IRBs at the institutions in which our studies are conducted, or the DSMB could suspend or terminate our clinical trials, or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the clinical trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may harm our business, financial condition, and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such products;
- we may be required to recall a product or change the way such a product is administered to patients;
- additional restrictions may be imposed on the marketing or distribution of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require additional warnings on the label, such as a “black box” warning or contraindication;
- we may be required to implement Risk Evaluation and Mitigation Strategies, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- our product may become less competitive; and
- our reputation may Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate or for particular indications of a product candidate, if approved, and could significantly harm our business, results of operations and prospects.

Difficulty in enrolling patients in the Company’s clinical trials, could result in delays or cancellation of clinical trials

As the Company’s product candidates advance from preclinical testing to clinical testing, and then through progressively larger and more complex clinical trials, the Company will need to enroll an increasing number of patients that meet various eligibility criteria. There is significant competition for recruiting cancer patients in clinical trials, and the Company may be unable to enroll the patients it needs to complete clinical trials on a timely basis or at all. The factors that affect the Company’s ability to enroll patients is largely uncontrollable and include, but are not limited to, the following:

- size and nature of the patient population;
- eligibility and exclusion criteria for the trial;
- design of the study protocol;
- competition with other companies for clinical sites or patients;
- the perceived risks and benefits of the product candidate under study;
- the patient referral practices of physicians; and
- the number, availability, location, and accessibility of clinical trial sites.

The Company is dependent on a number of third parties and the failure or delay in the performance of one of these third parties' obligations may adversely affect the Company

The Company is dependent on third parties to varying degrees in virtually all aspects of its business, including without limitation, on contract research organizations, contract manufacturing organizations, clinical trial consultants, raw material suppliers, collaborative research consultants, regulatory affairs advisers, medical and scientific advisors, clinical trial investigators, business service providers and other third parties. Critical supplies may not be available from third parties on acceptable terms, or at all, including GMP grade materials. Service providers may not perform, or continue to perform, as needed, or be available to provide the required services on acceptable terms or at all. Any lack of or interruption in supplies of raw materials or services, or any change in supply or service providers or any inability to secure new supply or service providers, would have an adverse impact on the development and commercialization of the Company's products. For example, the Company has previously experienced delays in the manufacturing of both engineering and clinical batches of L-DOS47, which have in turn caused delays in the progression of its development program, and there may be further delays. The Company relies on a third party for its supply of urease and if the contract with the third-party urease supplier is terminated early, the Company will have to find a new supplier of urease, as well as a new manufacturer of bulk drug product for future clinical testing programs. There can be no assurance that a new supplier or manufacturer can be contracted in a timely manner or at all, and this could negatively impact the Company's development plans for L-DOS47.

With respect to L-DOS47, the Company is currently dependent on, in addition to third party suppliers, manufacturers and consultants, the NRC and its license to the Company of a lung cancer antibody in order to develop and commercialize L-DOS47. Early termination of the license with NRC would have a material adverse effect on the further development of L-DOS47 and may require the cessation of such development, which would have a material adverse effect on the Company.

Given the Company`s lack of financing, expertise, infrastructure, and other resources to support a new drug product from clinical development to marketing, the Company also requires strategic partner support to develop and commercialize its drug candidates. There can be no assurance that such strategic partner support will be obtained upon acceptable terms or at all.

The Company relies heavily on contract manufacturers to produce product required for its clinical trials, product formulation work, scaling-up experiments, and commercial production. The Company may not be able to obtain new, or keep its current, contract manufacturers to provide these services. Even if the Company does, contract manufacturers may not be reliable in meeting its requirements for cost, quality, quantity or schedule, or the requirements of any regulatory agencies. The Company may not be able to manufacture products in quantities or qualities that would enable the Company to meet its business objectives, and failure to do so would materially adversely affect the Company's business.

If the Company can successfully develop markets for its products, the Company would have to arrange for their scaled-up manufacture. There can be no assurance that the Company will, on a timely basis, be able to make the transition from manufacturing clinical trial quantities to commercial production quantities successfully or be able to arrange for scaled-up commercial contract manufacturing. Any potential difficulties experienced by the Company in manufacturing scale-up, including recalls or safety alerts, could have a material adverse effect on the Company's business, financial condition, and results of operations.

The Company relies significantly on licensed intellectual property. If the Company were to lose its rights to licensed intellectual property, the Company would not be able to continue developing or commercializing L-DOS47. If the Company breaches the agreement with NRC under which it licenses the use, development, and commercialization rights to a lung cancer antibody to develop and commercialize L-DOS47 or any other future product candidate or technology from third parties or if certain insolvency events were to occur, the Company could lose license rights that are critical to its business

The Company has an exclusive worldwide license to a lung cancer antibody necessary to develop and commercialize L-DOS47 pursuant to a license agreement with NRC that is critical to the Company's business, which is subject to termination for breach of certain terms and, therefore, the Company's rights may only be available for as long as the Company's development and commercialization activities are sufficient to meet the terms of the license. In addition, the Company may need to enter into additional license agreements in the future. The Company's existing license agreements impose, and any future license agreements may impose on the Company, various developments, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If the Company fails to comply with its obligations under these agreements, or the Company is subject to a bankruptcy, the licensor may have the right to terminate the license, in which event the Company would not be able to market products covered by the license, which would have a material adverse effect on the Company's business, financial condition, results of operations and prospects. Moreover, the Company's current or future licenses may provide for a reversion to the licensor of the

Company's rights in regulatory filings or other intellectual property or data that the Company regards as its own in the event the license terminates under certain circumstances, such as due to breach.

Licensing of intellectual property is of critical importance to the Company's business and involves complex legal, business, and scientific issues. Disputes may arise between us and the Company's licensors regarding intellectual property subject to a license agreement, including with respect to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the rights of the Company's licensors under the license agreements; and
- the Company's diligence obligations with respect to the use of the licensed technology in relation to the Company's development and commercialization of L-DOS47 and any future product candidates, and what activities satisfy those diligence obligations.

Any disputes with the Company's licensors over intellectual property that the Company has licensed from them may prevent or impair the Company's ability to maintain its current licensing arrangements on acceptable terms. Termination or expiry of the Company's license agreements could result in the loss of significant rights and could materially harm the Company's ability to further develop and commercialize L-DOS47 or other future product candidates.

In addition, the agreements under which the Company currently licenses intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what the Company believes to be the scope of its rights to the relevant intellectual property or technology or increase what the Company believes to be its financial or other obligations under the relevant agreement, either of which could have a material adverse effect on the Company's business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that the Company has licensed prevent or impair the Company's ability to maintain its current licensing arrangements on commercially acceptable terms, the Company may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on the Company's business, financial conditions, results from operations and prospects.

The marketability of the Company's products may be affected by delays and the inability to obtain necessary approvals, and following any market approval, the Company's products will be subject to ongoing regulatory review and requirements which may continue to affect their marketability, including but not limited to regulatory review of drug pricing, healthcare reforms or the payment and reimbursement policies for drugs by the various insurers and other payors in the industry

The research, development, manufacture, and marketing of pharmaceutical products are subject to regulation by the FDA, and comparable regulatory authorities in other countries. These agencies and others regulate the testing, manufacture, safety, and promotion of the Company's products. The Company must receive applicable regulatory approval of a product candidate before it can be commercialized in any particular jurisdiction. Approval by a regulatory authority of one country does not ensure the approval by regulatory authorities of other countries. Changes in regulatory approval policies or regulations during the development period may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval, or require additional preclinical, clinical, or other trials and place the Company's IND submissions on hold for an indeterminate amount of time. The development and regulatory approval process in each jurisdiction takes many years, requires the expenditure of substantial resources, is uncertain and subject to delays, and can adversely affect the successful development and commercialization of our drug candidates.

Even if the Company obtains marketing approval in a particular jurisdiction, there may be limits on the approval and the Company's products likely will be subject to ongoing regulatory review and regulatory requirements in that jurisdiction. Pharmaceutical companies are subject to various government regulations, including without limitation, requirements regarding occupational safety, laboratory practices, environmental protection, and hazardous substance control, and may be subject to other present and future regulations.

The availability of reimbursement by governmental and other third-party payors, such as private insurance plans, will affect the market for any pharmaceutical product, and such payors tend to continually attempt to contain or reduce the costs of healthcare. Significant uncertainty exists with respect to the reimbursement status of newly approved healthcare products.

We are substantially dependent on third parties for the manufacture of our clinical supplies of our product candidates, and we intend to rely on third parties to produce commercial supplies of any approved product candidate. Therefore, our development of our products could be stopped or delayed, and our commercialization of any future product could be

stopped or delayed or made less profitable if third party manufacturers fail to obtain approval of the FDA or comparable regulatory authorities or fail to provide us with drug product in sufficient quantities or at acceptable prices

The manufacture of biotechnology and pharmaceutical products is complex and requires significant expertise, capital investment, process controls and know-how. Common difficulties in biotechnology and pharmaceutical manufacturing may include: sourcing and producing raw materials, transferring technology from chemistry and development activities to production activities, validating initial production designs, scaling manufacturing techniques, improving costs and yields, establishing and maintaining quality controls and stability requirements, batch lot expiries, eliminating contaminations and operator errors, and maintaining compliance with regulatory requirements. We do not currently have, nor do we plan to acquire the infrastructure or capability internally in accordance with cGMP prescribed by the FDA or to produce an adequate supply of compounds to meet future requirements for clinical trials and commercialization of our products. Drug manufacturing facilities are subject to inspection before the FDA will issue an approval to market a new drug product, and all of the manufacturers that we intend to use must adhere to the cGMP regulations prescribed by the FDA.

We expect therefore to rely on third-party manufacturers for clinical supplies of our product candidates that we may develop. These third-party manufacturers will be required to comply with current good manufacturing practices, or GMPs, and other applicable laws and regulations. We will have no control over the ability of these third parties to comply with these requirements, or to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any other applicable regulatory authorities do not approve the facilities of these third parties for the manufacture of our other product candidates or any products that we may successfully develop, or if it withdraws any such approval, or if our suppliers or contract manufacturers decide they no longer want to supply or manufacture for us, we may need to find alternative manufacturing facilities, in which case we might not be able to identify manufacturers for clinical or commercial supply on acceptable terms, or at all. Any of these factors would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates and adversely affect our business.

We and/or our third-party manufacturers may be adversely affected by developments outside of our control, and these developments may delay or prevent further manufacturing of our products. Adverse developments may include labor disputes, resource constraints, shipment delays, inventory shortages, lot failures, unexpected sources of contamination, lawsuits related to our manufacturing techniques, equipment used during manufacturing, or composition of matter, unstable political environments, acts of terrorism, war, natural disasters, and other natural and man-made disasters. If we or our third-party manufacturers were to encounter any of the above difficulties, or otherwise fail to comply with contractual obligations, our ability to provide any product for clinical trial or commercial purposes would be jeopardized. This may increase the costs associated with completing our clinical trials and commercial production. Further, production disruptions may cause us to terminate ongoing clinical trials and/or commence new clinical trials at additional expense. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications or pass safety inspections. If production difficulties cannot be solved with acceptable costs, expenses, and timeframes, we may be forced to abandon our clinical development and commercialization plans, which could have a material adverse effect on our business, prospects, financial condition, and the value of our securities.

We, or third-party manufacturers on whom we rely, may be unable to successfully scale-up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any

In order to conduct clinical trials of our product candidates and commercialize any approved product candidates, we, or our manufacturers, will need to manufacture them in large quantities. We, or our manufacturers, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. If we, or any of our manufacturers, are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing, and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. If we are unable to obtain or maintain third-party manufacturing for commercial supply of our product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully.

Our failure to find third party collaborators to assist or share in the costs of product development could materially harm our business, financial condition, and results of operations

Our strategy for the development and commercialization of our proprietary product candidates may include the formation of collaborative arrangements with third parties. Existing and future collaborators have significant discretion in determining the efforts and resources they apply and may not perform their obligations as expected. Potential third-party

collaborators include biopharmaceutical, pharmaceutical and biotechnology companies, academic institutions, and other entities. Third-party collaborators may assist us in:

- funding research, preclinical development, clinical trials and manufacturing;
- seeking and obtaining regulatory approvals; and
- successfully commercializing any future product candidates.

If we are not able to establish further collaboration agreements, we may be required to undertake product development and commercialization at our own expense. Such an undertaking may limit the number of product candidates that we will be able to develop, significantly increase our capital requirements and place additional strain on our internal resources. Our failure to enter into additional collaborations could materially harm our business, financial condition, and results of operations.

In addition, our dependence on licensing, collaboration, and other agreements with third parties may subject us to a number of risks. These agreements may not be on terms that prove favorable to us and may require us to relinquish certain rights in our product candidates. To the extent we agree to work exclusively with one collaborator in a given area, our opportunities to collaborate with other entities could be curtailed. Lengthy negotiations with potential new collaborators may lead to delays in the research, development, or commercialization of product candidates. The decision by our collaborators to pursue alternative technologies or the failure of our collaborators to develop or successfully commercialize any product candidate to which they have obtained rights from us could materially harm our business, financial condition, and results of operations.

We rely on third parties to conduct our preclinical and clinical trials. If these third parties do not successfully perform their contractual legal and regulatory duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed

We have relied upon and plan to continue to rely upon third-party medical institutions, clinical investigators, contract laboratories and other third party CROs to monitor and manage data for our ongoing preclinical and clinical programs. We rely on these parties for execution of our preclinical and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with cGCPs, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all of our products in clinical development.

Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of our CROs fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with cGCP regulations. In addition, our clinical trials must be conducted with product produced under current good manufacturing practices, or cGMP, regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going clinical, nonclinical, and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If the third parties conducting our GLP preclinical studies or our clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical trial protocols or to GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter

similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects.

The Company operates in an industry that is more susceptible than others to legal proceedings and, in particular, liability claims

The Company operates in an industry that is more susceptible to legal proceedings than firms in other industries, due to the uncertainty involved in the development of pharmaceuticals. Defense and prosecution of legal claims can be expensive and time consuming and may adversely affect the Company regardless of the outcome due to the diversion of financial, management and other resources away from the Company's primary operations. Negative judgments against the Company, even if the Company is planning to appeal such a decision, or even a settlement in a case, could negatively affect the cash reserves of the Company, and could have a material negative effect on the development of its drug products.

The Company may be exposed, in particular, to liability claims which are uninsured or not sufficiently insured, and any claims may adversely affect the Company's ability to obtain insurance in the future or result in negative publicity regarding the efficacy of its drug products. Such liability insurance is expensive, its ability is limited, and it may not be available on terms that are acceptable to the Company, if at all.

The use of any of the Company's unapproved products under development, the use of its products in clinical trials, and, if regulatory approval is received, the sale of such products, may expose the Company to liability claims which could materially adversely affect the Company's business. The Company may not be able to maintain or obtain commercially reasonable liability insurance for future products, and any claims under any insurance policies may adversely affect its ability to maintain existing policies or to obtain new insurance on existing or future products. Even with adequate insurance coverage, publicity associated with any such claim could adversely affect public opinion regarding the safety or efficacy of the Company's products. As a result, any product liability claims or recall, including in connection with products previously sold by the Company through its former distribution business, could materially adversely affect the Company's business.

If the Company were unable to maintain product liability insurance required by third parties, the corresponding agreements would be subject to termination, which could have a material adverse impact on our operations.

Some of our licensing and other agreements with third parties require or might require us to maintain product liability insurance. If the Company cannot maintain acceptable amounts of coverage on commercially reasonable terms in accordance with the terms set forth in these agreements, the corresponding agreements would be subject to termination, which could have a material adverse impact on the Company's operations.

The Company is dependent upon key personnel; Director residency requirements.

The Company's ability to continue its development of potential products depends on its ability to attract and maintain qualified key individuals to serve in management and on the Board. However, the Company does not currently have a formal succession plan for members of its senior management team or for its Board and, because competition for qualified key individuals with experience relevant to the industry in which the Company operates is intense, the Company may not be able to attract and/or retain such personnel. Additionally, applicable corporate law requires that at least 25% of the Company's directors be resident Canadians, and the Company's articles provide that the Company cannot have fewer than four directors at any time.

Consequently, if the Company is unable to attract and/or loses and is unable to replace key personnel, its business could be negatively affected and, in particular, if the Company loses its current resident Canadian director in the future and is unable to find a resident Canadian director to fill the resulting vacancy, the Board will be prevented from taking any action other than appointing an additional resident Canadian director until such time as a new resident Canadian director has been appointed such that at least 25% of the Company's directors are resident Canadians.

The Company employs a small number of employees who have many years of technical knowledge of the Company's technology and two senior officers, the CEO and CFO. COVID-19 imposes a high risk to all of the Company's activities. The Company has established a policy to diligently monitor developments. Because the situation is fluid, the Company will be updating its staff whenever necessary. The Company has implemented and communicated a policy to all staff in order mitigate any potential risk.

In addition, the Company does not carry key-person insurance on any individuals.

The Company's employees and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could have a material adverse effect on the Company's business.

The Company is exposed to the risk of employee and consultant fraud or other misconduct. Misconduct by employees and consultants could include but are not limited to the following: failure to comply with regulators, failure to provide accurate information, failure to comply with manufacturing standards the Company has established, jurisdictional healthcare fraud and abuse of laws and regulations, failure to report financial information or data accurately or disclose unauthorized activities. For example, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee and consultant misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to the Company's reputation. If any such actions are instituted against the Company, and the Company is not successful in defending itself or asserting its rights, those actions could have a substantial impact on the Company's business and operating results, including the imposition of substantial fines, halt in trading of the Common Shares, possible delisting and/or other sanctions.

Indemnification obligations to directors and officers of the Company may adversely affect the Company's finances.

The Company has entered into agreements pursuant to which the Company has agreed to indemnify its directors and senior management in respect of certain claims made against them while acting in their capacity as such. If the Company is called upon to perform its indemnity obligations, its finances may be adversely affected.

The Company's finances may fluctuate based on foreign currency exchange rates.

The Company operates internationally and is exposed to foreign exchange risks from various currencies, primarily the U.S. dollar, the Euro, and the Polish Zloty. Fluctuations in the value of foreign currencies relative to the Canadian dollar could cause us to incur currency exchange losses.

The Company may incur losses due to adverse decisions by tax authorities or changes in law.

The Company's income tax reporting is subject to audit by tax authorities. The effective tax rate may change from year to year based on the mix of income; non-deductible expenses; changes in tax law; and changes in the estimated values of future income tax assets and liabilities.

The Company may enter into transactions and arrangements in the ordinary course of business in which the tax treatment is not entirely certain. The Company must therefore make estimates and judgments in determining its consolidated tax provision. The final outcome of any audits by taxation authorities may differ from estimates and assumptions used in determining the consolidated tax provisions and accruals. This could result in a material effect on the Company's scientific research and experimental development tax credits, income tax provision, financial position, and the net income/loss for the period in which such determinations are made.

The Company is subject to taxation in Canada. The Company's effective tax rate and tax liability are determined by a number of factors, including the amount of taxable income, the tax rates, The application of these tax laws and related regulations is subject to legal and factual interpretation, judgment, and uncertainty. An adverse interpretation or ruling by a taxing authority in a jurisdiction in which the Company operates or a change in law could increase the Company's tax liability or result in the imposition of penalty payments, which could adversely impact the Company's operating results.

The requirements of being a public company may strain the Company's resources, divert management's attention, and affect its ability to attract and retain qualified board members.

The Company's Common Shares are publicly traded on the TSX. As a public company, the Company is subject to the reporting requirements of Canadian securities regulators, the listing requirements of any stock exchange on which its Common Shares are listed for trading and other applicable securities rules and regulations. Compliance with these rules and regulations may increase the Company's legal and financial compliance costs, may make some activities more difficult, time-consuming, or costly and may increase the demand on the Company's systems and resources. Being a public company requires that the Company file continuous disclosure documents, including, among other things, annual and quarterly financial statements. Management's attention may be diverted from other business concerns, which could have a material adverse effect on the Company's business, financial condition, and results of operations. The Company may need to hire more employees in the future, which will increase its costs and expenses.

In addition, changing laws, regulations and standards relating to corporate governance and public disclosure create uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. The Company may invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If the

Company's efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory authorities, legal proceedings may be initiated against the Company and its business may be harmed.

General economic conditions may have an adverse effect on the Company and its business.

Continuing global economic volatility and uncertainty may have an adverse effect on the Company and its business, including without limitation the ability to raise additional financing, to obtain strategic partner support or commercialization opportunities and alliances for the Company's new drug candidates, and to obtain continued services and supplies.

The Company's business involves environmental risks that could result in accidental contamination, injury, and significant capital expenditures in order to comply with environmental laws and regulations.

The Company and its commercial collaborators are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of materials and certain waste products. Although the Company believes that its safety procedures comply with the regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. In the event of such an accident, the Company could be held liable for any damages that result and any such liability could exceed the resources of the Company. The Company is not specifically insured with respect to this liability. The Company (or its collaborators) may be required to incur significant costs to comply with environmental laws and regulations in the future; and the operations, business or assets of the Company may be materially adversely affected by current or future environmental laws or regulations.

Any failure to maintain an effective system of internal controls may result in material misstatements of the Company's consolidated financial statements or cause us to fail to meet the Company's reporting obligations or fail to prevent fraud; and in that case, the Company's shareholders could lose confidence in the Company's financial reporting, which would harm the Company's business, could negatively impact the price of the Common Shares and prevent the Company from raising additional capital

Effective internal controls are necessary for the Company to provide reliable financial reports and prevent fraud. If the Company fails to maintain an effective system of internal controls, the Company may not be able to report its financial results accurately or prevent fraud; and in that case, the Company's shareholders could lose confidence in the Company's financial reporting, which would harm the Company's business, negatively impact the price of the Common Shares and also prevent the Company from raising additional capital. Even if the Company were to conclude that its internal control over financial reporting provides reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with IFRS as issued by the IASB, because of its inherent limitations, internal control over financial reporting may not prevent or detect fraud or misstatements. Failure to achieve and maintain effective internal control over financial reporting could prevent the Company from complying with its reporting obligations on a timely basis, which could result in the loss of investor confidence in the reliability of the Company's consolidated financial statements, harm the Company's business**,** negatively impact the trading price of the Common Shares, and prevent the Company from raising additional capital.

Our results of operations may be negatively impacted by the COVID-19 outbreak.

The Company's business, operations and financial condition could be materially and adversely affected by the outbreak of epidemics or pandemics or other health crises, including the COVID-19 pandemic. As a result of the COVID-19 outbreak, the Company may experience disruptions that could severely impact its business, preclinical studies, and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials.
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff.
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal, provincial, or state governments, employers and others or interruption of clinical trial subject visits and study procedures, which may impact the integrity of subject data and clinical study endpoints.
- interruption or delays in the operations of the FDA, which may impact approval timelines.
- interruption of, or delays in receiving supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems; and
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people.

In addition, the trading prices for the Common Shares and the securities of other biopharmaceutical companies have been highly volatile as a result of the COVID-19 epidemic. As a result, the Company may face difficulties raising capital through sales of our securities, and such sales may be on unfavorable terms, if at all. The COVID-19 outbreak continues to rapidly evolve. The extent to which the outbreak may impact our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate

geographic spread of the disease, the duration of the outbreak, travel restrictions and other measures implemented in Canada, the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the Canada, the United States and other countries to contain the disease.

The spread of COVID-19 has resulted in a sharp decline in global economic growth as well as causing increased volatility and declines in financial markets. If the COVID-19 pandemic is prolonged, or further diseases emerge that give rise to similar effects, the adverse impact on the global economy could deepen and result in further declines in global economic growth and financial markets. Accordingly, the full impact of the COVID-19 pandemic on the global economy and financial markets is uncertain and may have an adverse effect on the Company.

To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this AIF. Because of the highly uncertain and dynamic nature of events relating to the COVID-19 pandemic, it is not currently possible to estimate the impact of COVID-19 on the Company. However, these effects could have a material impact on our business, operations, and financial condition.

The Russia Ukraine war

The recent escalation of war in Ukraine, where the Company enrolled virtually all its patients in a clinical study, has complicated matters. As at the date of this MD&A, it is uncertain as to when the clinical study reports will be completed, if at all.

Risks Related to the Common Shares

The Company's share price and trading volumes are volatile, and the Company may have difficulty maintaining listing requirements

The market price of the Company's Common Shares, as well as market prices for securities of biopharmaceutical and drug delivery companies generally, have historically been highly volatile, and have from time-to-time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies.

The trading price of the Common Shares is subject to change and could in the future fluctuate significantly. The fluctuations could be in response to numerous factors beyond the Company's control, including but not limited to, the following:

- actual or anticipated fluctuations in the Company's quarterly results of operations;
- recommendations by securities research analysts;
- changes in the economic performance or market valuations of companies in the industry in which the Company operates;
- addition or departure of the Company's executive officers and other key personnel;
- release or expiration of transfer restrictions on outstanding Common Shares;
- sales or perceived sales of additional Common Shares;
- operating and financial performance that vary from the expectations of management, securities analysts and investors;
- regulatory changes affecting the Company's industry generally and its business and operations;
- announcements of developments and other material events by the Company or its competitors;
- fluctuations to the costs of vital production materials and services;
- changes in global financial markets and global economies and general market conditions, such as interest rates and pharmaceutical product price volatility;
- significant acquisitions or business combinations, strategic partnerships, joint ventures, or capital commitments by or involving the Company or its competitors;
- operating and share price performance of other companies that investors deem comparable to the Company or from a lack of market comparable companies;
- news reports relating to trends, concerns, technological or competitive developments, regulatory changes and other related issues in the Company's industry or target markets; and the outbreak of epidemics, pandemics or other health crises including COVID-19.

The Internet offers various avenues for the dissemination of information. The Company has no control over the information that is distributed and discussed on electronic bulletin boards and investment chat rooms. The intention of the people or organizations that distribute such information may not be in the Company's best interest and the best interests of its shareholders. This, in addition to other forms of investment information including newsletters and research publications, could result in a sharp decline in the market price of the Common Shares.

In addition, stock markets have occasionally experienced extreme price and volume fluctuations. The market prices for high-technology companies have been particularly affected by these market fluctuations and such effects have often been unrelated to the operating performance of such companies. These broad market fluctuations may cause a decline in the market price of the Common Shares.

Sales of substantial numbers of the Company's Common Shares could cause a decline in the market price of such Common Shares. There are minimum listing requirements for an issuer to maintain its listing on the TSX, and if the Company fails to maintain these listing requirements, it may be involuntarily delisted from the TSX. De-listing the Company or the Company shares from any securities exchange could have a negative effect on the liquidity of the Company shares and/or the ability of a shareholder to trade in shares of the Company, and could have an adverse effect on the Company's ability to raise future equity financings. The Company's Common Shares trade in a very low volume compared to the number of Common Shares outstanding. This means a shareholder could have difficulty disposing of Common Shares, especially if there are other shareholders of the Company trying to sell their shares in the Company at the same time. Volatility in share price and trading volumes could have an adverse effect on the Company's ability to raise future equity financings.

Shareholders of the Company may face dilution from future equity or convertible debt financings or through the exercise of stock options, warrants or other securities convertible or exchangeable into Common Shares

To attract and retain key personnel, the Company has granted options to its key employees, directors, and consultants to purchase Common Shares as non-cash incentives. In addition, the Company has a significant number of warrants to purchase Common Shares outstanding. The issuance of shares pursuant to the exercise of a significant number of such options and/or warrants may result in significant dilution to other shareholders of the Company.

As noted above, the Company needs additional funding and has historically turned to the equity markets to raise this funding. The future sale of equity securities and warrants may also result in significant dilution to the shareholders of the Company.

The Company cannot predict the size or nature of future sales or issuances of securities or the effect, if any, that such future sales and issuances will have on the market price of the Common Shares. Sales or issuances of substantial numbers of Common Shares or other securities that are convertible or exchangeable into Common Shares, or the perception that such sales or issuances could occur, may adversely affect prevailing market prices of the Common Shares. With any additional sale or issuance of Common Shares or other securities that are convertible or exchangeable into Common Shares, investors will suffer dilution to their voting power and economic interest in the Company. Furthermore, to the extent holders of the Company's stock options or other convertible securities convert or exercise their securities and sell the Common Shares they receive, the trading price of the Common Shares may decrease due to the additional amount of Common Shares available in the market.

Trading in the Company's Common Shares outside of Canada may be subject to restrictions on trading under foreign securities laws, and purchasers of securities under private placements by the Company will be subject to certain restrictions on trading

The Company's Common Shares trade on the TSX and are freely tradeable only in Canada. As such, shareholders trading the Common Shares outside of Canada may be subject to restrictions imposed by foreign securities laws that may restrict their ability to transfer shares freely or at all. Certain securities offered by the Company pursuant to its private placements, including the unlisted warrants issued by the Company, are subject to certain initial hold periods and other restrictions on trading imposed by applicable securities laws and, in the case of the warrants, pursuant to the terms of the applicable warrant certificates. These restrictions may affect the liquidity of the investment of certain shareholders in the securities of the Company.

The Company does not expect to pay any cash dividends for the foreseeable future

Investors should not rely on an investment in the Common Shares to provide dividend income. The Company does not anticipate that it will pay any cash dividends to holders of the Common Shares in the foreseeable future. Instead, the Company plans to retain any earnings to maintain and expand its operations. In addition, any future debt financing arrangement may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on the Common Shares. Accordingly, investors must rely on sales of their Common Shares after price appreciation, which may never occur, as the only way to realize any return on their investment. As a result, investors seeking cash dividends should not purchase Common Shares.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research about the Company's business, the share price and trading volume of the Common Shares could decline

The trading market for the Common Shares will depend, in part, on the research and reports that securities or industry analysts publish about the Company or its business. If one or more of the analysts who cover the Company downgrade the Common Shares or publish inaccurate or unfavorable research about the Company's business, the Company's share price would likely decline. In addition, if the Company's operating results fail to meet the forecast of analysts, the Company's share price would likely decline. If one or more of these analysts cease coverage of the Company or fail to publish reports on the Company regularly, demand for the Common Shares could decrease, which might cause the share price and trading volume of the Common Shares to decline.

RISK FACTORS IN OTHER PUBLIC FILINGS

For all of the reasons set forth above, together with those additional risk factors identified under the headings *"Forward-Looking Statements"* and "*Risk Factors*" in the Company's most recent Annual Information Form filed under the Company's profile on SEDAR at www.sedar.com, investors should not place undue reliance on forward-looking information. Other than any obligation to disclose material information under applicable securities laws, the Company undertakes no obligation to revise or update any forward-looking information after the date hereof.

Data relevant to estimated market sizes and penetration for the Company's lead products under development are presented in this MD&A. This data has been obtained from a variety of published resources including published scientific literature, websites, and information generally available through publicized means. The Company attempts to source reference data from multiple sources whenever possible for confirmatory purposes. Although the Company believes the foregoing data is reliable, the Company has not independently verified the accuracy and completeness of this data.

ADDITIONAL INFORMATION

Additional information relating to the Company's three months financials for the quarter ended October 31, 2023, is available under the Company's profile on SEDAR at www.sedar.com.