MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Management's Discussion and Analysis of Financial Condition and Results of Operations ("MD&A") should be read in conjunction with the condensed unaudited interim financial statements of Helix BioPharma Corp. (the "Company" or "Helix") for the three-month periods ended October 31, 2020 and 2019 and the accompanying notes thereto. 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) changes in the application of accounting standards and interpretations; (x) 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; (xi) the Company's technology and research and development objectives, including development milestones, estimated costs, schedules for completion and probability of success; (xii) the Company's expectation that it can in a timely manner, or at all, produce the appropriate preclinical, and if necessary, clinical data required; (xiii) 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); (xiv) the Company's intentions with respect to initiating marketing activities following receipt of the applicable regulatory approvals; (xv) the Company's seeking of licensing opportunities to expand its intellectual property portfolio; (xvi) the Company's expectation that it will be able to finance its continuing operations by accessing public markets for its securities; (xvii) the Company's intended use of proceeds of any offering of its securities; and (xviii) the Company's intention with respect to not paying any cash dividends on its common shares ("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", "2020", "2021", "2022", "2023", "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;
- 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 COVID-19 pandemic, and their potential effect on the Company's business, operations and financial condition;
- 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, 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 (together 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 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 which 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, being L-DOS47 and V-DOS47.

L-DOS47 is currently under clinical study for the treatment of non-small cell lung cancer ("NSCLC") and previously treated advanced pancreatic cancer. The Company completed extensive preclinical testing and manufacturing development of L-DOS4, 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.

V-DOS47 drug candidate uses the Company's proprietary DOS47 technology conjugated to anti-VEGFR2 antibody targeting a wide range of cancers. In 2016, V-DOS47 was licensed to the Company's then wholly-owned Polish subsidiary, HIO, for pre-clinical and clinical development activity. HIO entered into a grant funding agreement with the Polish National Centre for Research and Development ("PNCRD") to fund the V-DOS47 research project. On January 30, 2020, HIO conveyed to the PNCRD that it wished to terminate the grant funding program for V-DOS47. To date the Polish subsidiary under the grant funding agreement received approximately $1,457,000. As part of the debt cancellation agreements, announced by the Company on June 26, 2020, the Company and HIO have agreed to terminate both the V-DOS47 license agreement. As a result, all transferred assets related to V-DOS47 have been automatically reassigned and transferred from HIO back to the Company without any formality. As a result, the Company will now assess what next steps to take with the V-DOS47 antibody.

In NSCLC, L-DOS47 is shown to be safe and well tolerated as a monotherapy pursuant to the Company's LDOS002 study ("LDOS002"). L-DOS47 is also shown to be safe and well tolerated when used in combination with pemetrexed and carboplatin pursuant to the Company's LDOS001 study ("LDOS001"). LDOS001 was conducted in University Hospital's Case Medical Center in Cleveland, Ohio, Penn State's Cancer Institute in Hershey, Pennsylvania and at the University of Texas MD Anderson Cancer Center in Houston, Texas. As reported at the June 2020 conference of the American Society of Clinical Oncology, an objective response rate of 41.7% based on tumour burden and a clinical benefit rate of 75% inclusive of stable diseases were observed in the LDOS001 study. The Company believes the data supports the continuing development of L-DOS47 for NSCLC. As of the date of this MD&A, the Company is contemplating a new study in NSCLC using L-DOS47 in combination with immunotherapy. The Company is also seeking a partner to further its Phase II study of L-DOS47 in combination with vinorelbine and cisplatin ("LDOS003").

In December 2019, the Company announced the start of enrollment and screening for its Phase Ib/II clinical development program for previously treated patients with advanced pancreatic cancer. The study center is located at HonorHealth in Scottsdale, Arizona. 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 is not able to meet the previously forecasted patient enrollment timeline for this clinical study. The Company is attempting to add new clinical sites in other U.S. jurisdictions in order to facilitate patient enrollment. Provided the additional clinical sites can be up and running by the end of December 2020, the Company believes patient enrollment in the Phase Ib portion of the study may be completed by the end of the second quarter of calendar year 2021. 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's collaboration with Moffitt continues to expand with the recent announcement of a new animal model research project involving the use of L-DOS47 in combination with immunotherapy in pancreatic cancer. Pancreatic cancer is known to be a disease that is resistant to immunotherapy treatment and shown in animal models to be highly acidic. The Company believes the ability of L-DOS47 to modulate tumour acidity may be key to enable immunotherapy treatment for pancreatic cancer. This new research collaboration project will also build on data already obtained from imaging techniques performed by Moffitt that demonstrated the ability of L-DOS47 to affect tumour acidity. Translation of this 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. On August 12, 2020, the Company announced that it had extended its collaboration agreement with Moffitt Cancer Center for an additional year

In addition to DOS47, the Company has also developed antibodies that may be suitable for novel chimeric antigen receptor T-Cell therapeutic ("CAR-T") for solid tumours. In March 2018, the Company announced a scientific research collaboration with ProMab Biotechnologies Inc. ("ProMab") to co-develop novel antibody and CAR-T's for various hematological malignancies and solid tumours. The first scientific research collaboration between the two parties involves a co-development program for a cell-based therapy in multiple myeloma. The aim was for both parties to perform various tasks with the objective of filing an IND for testing in humans by early 2019. The Company's working capital deficiency through August 2019 pushed out the originally planned timeline for IND filing. Under the scientific research collaboration agreement with ProMab, the Company retained the rights for the multiple myeloma CAR-T in Canada and Europe and then sublicensed the European rights to its then wholly-owned subsidiary, HIO, to further develop and commercialize these technologies in return for future milestone payments and royalty fees. The Company will provide certain technical and funding support in the early preclinical stages of the multiple myeloma scientific research collaboration program with ProMab. Under the sublicense agreement between the Company and HIO, HIO was expected to fully support the clinical development of cell therapy products and has recently applied for government grant assistance in Poland.

In December 2016, the Company signed an exclusive out-license agreement with Xisle Pharma Ventures Trust ("Xisle") for the Company's late-stage, Biphasix™ technology platform, including the lead product candidate, interferon alpha. Under the terms of the agreement, Xisle paid an up-front fee and agreed to pay subsequent milestone payments and royalties to the Company as

Xisle advances the technology. As part of the agreement, the Company retained marketing rights for Belarus, Bulgaria, the Czech Republic, former Eastern Germany, Hungary, Moldova, Poland, Romania, Russia, Slovakia and Ukraine and non-exclusive rights for co-promotion in Canada. The Company subsequently assigned the foregoing marketing rights which it retained to HIO, its then wholly-owned subsidiary in Poland, pursuant to an agreement between the Company and HIO.

On June 26, 2020, the Company announced that it had approved, in its capacity as a shareholder of HIO, a direct investment in HIO by an investor which resulted in the Company's ownership in HIO being reduced to approximately 42.51% on July 8, 2020. The direct investment in HIO permitted HIO to apply for a new government grant for the development of the multiple myeloma CAR-T program in Poland. On September 3, 2020, HIO closed another direct private placement resulting in a dilution of the Company's holding in HIO to 29.89%.

On June 26, 2020, the Company also announced the cancellation of intercompany debt in the total aggregate amount of approximately $2,700,000 owed to the Company by HIO. As part of the debt cancellation, both the V-DOS47 and Biphasix™ agreements between the Company and HIO described above were terminated with immediate effect.

Also, on June 26, 2020, the Company announced the receipt of a non-binding offer from CAIAC Fund Management AG ("CAIAC"), as designated trustee of an alternative investment fund to be established, to purchase the Company's remaining shares in HIO. The transaction was initially expected to close no later than August 31, 2020 but has since been deferred, subject to the satisfaction of certain conditions, including, but not limited to, the negotiation of binding documentation, the receipt of a minimum of PLN7,300,000 by CAIAC pursuant to a financing, and the receipt of all required regulatory approvals. On November 9, 2020, the Company announced that it has signed a definitive share purchase agreement with CAIAC to purchase the Company's remaining holdings in its Polish subsidiary, HIO, for gross proceeds of PLN 6,700,000 (approximately $2,300,000)

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.

The Company's investment in HIO was classified as held for sale and was presented as discontinued operations at July 31, 2020. At September 3. 2020 HIO completed a direct financing with an arm's length party. As a result of the financing the Company's ownership in HIO was diluted down to 29.89% and as a result, the Company has determined that it has lost control of HIO. As the Company's interest allows the Company to exert significant influence over HIO, the Company's remaining interest is now accounted for as an interest in associate using the equity method. The Company's remaining interest in HIO was recognized at its fair value as at September 3, 2020 based on the post financing valuation. The difference between the carrying value of the net assets of HIO and non-controlling interest and the value assigned to the shares of $2,231,000 was recognized as a gain on loss of control of subsidiary. See below - *Gain from loss of control in subsidiary*

The Company currently believes that its growth and future prospects are mainly dependent on the success of its DOS47 drug product candidates.

During the year, the Company has been in discussions with various capital market firms, both in the U.S. and Canada, with the goal of raising additional capital to qualify the Company for a listing on a U.S. stock exchange such as NASDAQ.

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.

Tumours 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, tumours contain an abnormal network of blood vessels. Because of this, tumours are hypoxic (receive 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, tumour 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 tumour microenvironment. Thus, the tumour microenvironment is acidic.

The acidic microenvironment helps promote tumour survival and metastasis in a number of ways. The genes expressed by the tumour are affected by the acidic microenvironment, which allows tumour cells to adapt. One of these acid-induced changes is to

increase production and release of proteases by tumour cells. The proteases destroy the protein matrix that surrounds the tumour cells, which makes it easier for the tumour cells to invade local tissues – a first step to metastasis. In addition, the acidic tumour microenvironment has been shown to impair the activity of immune cells in the tumour, which allows the tumour cells to avoid destruction by the immune system.

The acidic tumour 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 tumour cells, where they perform their function, is greatly reduced at acidic pH compared to neutral pH. Radiation therapy also is 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 effect. 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 response 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. In order to deliver alkalization therapy to tumours, 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 tumours 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 outcome. 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 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 pancreatic cancer tissues, but not to normal 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 for 12-72 hours after injection, L-DOS47 was localized at the tumour.

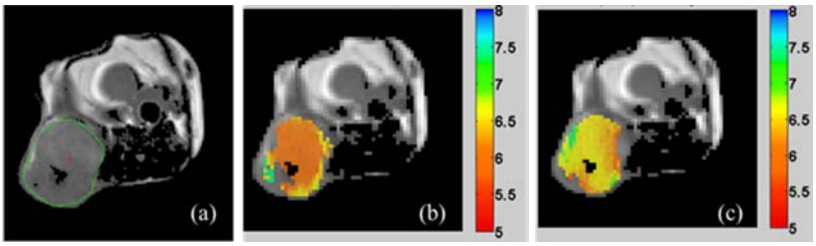
L-DOS47 has been shown to control tumour growth, reduce metastases, and enhance the effect of chemotherapy in animal models

L-DOS47 was tested in two mouse models: one lung cancer and one pancreatic cancer. In both cases, administration of L-DOS47 reduced tumour growth 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 L-DOS47 reduced the ability of the tumour cells to colonize the lungs. The ability of L-DOS47 to improve chemotherapy efficacy 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 in mice bearing a CEACAM6-positive pancreatic tumour.

L-DOS47 has been shown to raise the pH of the tumour microenvironment and restore immune-cell activity

Numerous experiments have been performed by the Company which monitored the production of ammonia and increase in pH when L-DOS47 was combined with urea *in vitro.* For examples, see Tian et al and Uger**Error! Bookmark not defined.**. The ability of L-DOS47 to raise the pH of the tumour microenvironment *in vivo* has been observed in both lung and pancreatic cancer models using multiple imaging methods including ^{31}P-MRS and MRI-CEST. The Company has performed *in vitro* experiments with human $CD8^+$ T cells and has observed that culture at acidic pH increased the expression of the immune-downregulatory molecule programmed cell death protein 1 (PD-1) on the T cells, and that the T cells in acidic conditions reduced their production of the pro-immune cytokine interferon-gamma (IFN-γ)**Error! Bookmark not defined.**. L-DOS47 successfully restored the activity of these cells, as observed by reduced expression of PD-1 and increased production of IFN-γ and another pro-immune cytokine, interleukin-2 (IL-2)**Error! Bookmark not defined.**. In one preliminary preclinical experiment, treatment with L-DOS47 enhanced the ability of an anti-PD1 antibody to control growth of a pancreatic tumour in a mouse model.



CEST MRI of iopamidol for pH imaging [1] of a Panc02 clone 38 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 pHs 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 is able to improve the efficacy of chemotherapy and immunotherapies. L-DOS47 is currently being tested in clinical trials of both lung and pancreatic cancers. See “Clinical Programs” s been published.

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.

CAR-T for solid tumours and hematological malignancies

CEACAM6 specific CARs

Expression of CEACAM6 protein has been reported in a variety of normal human tissues including granulocytes. However, its expression is elevated in many types of solid tumours such as breast, pancreatic, ovarian, lung and colon. CEACAM6 is envisaged as a biomarker and potential therapy target for pancreatic ductal adenocarcinoma and pancreatic intraepithelial neoplasia (Duxbury et al., 2004a, 2004c, 2004d). Recently CEACAM6 is suggested to be check point molecule in multiple myeloma.

The Company believes CEACAM6 specific CAR immune cells may have broad applications in a number of cancer types. The Company is working on two camelid single domain antibodies that target CEACAM6.

2A3 is a camelid single domain antibody isolated from a whole cancer cell immunized llama library. The antibody binds specifically to the CEACAM6 antigen with high affinity and inhibits the proliferation of CEACAM6-expressing cancer cells *in vitro*. The efficacy of CEACAM6-CAR-T cells in xenograft model was examined *in vivo*. The results strongly support that CEACAM6-CAR-T cells can be used as an effective immunotherapy agent against CEACAM6-expressing cancers, and that camelid single domain antibodies can be easily adopted for CAR-T type therapies.

Vascular epithelial growth factor receptor 2 (VEGFR2) CARs

Most solid tumours and some hematologic malignancies are characterized by an angiogenic phenotype that is an absolute requirement for tumour survival, progression, and metastasis. Therapeutic approaches targeting molecules involved in tumour angiogenesis can inhibit tumour growth. Proliferating endothelial cells in the vessels within solid Tumours aberrantly express high levels of angiogenic growth factors, receptors, and adhesion molecules that are absent or barely detectable in established blood vessels, which are normally quiescent. Among these, VEGF and its receptors appear to be the dominant regulators of angiogenesis responsible for the vascularization of normal and neoplastic tissues. Overexpression of VEGF and its receptors is associated with tumour angiogenesis, survival, invasion, metastasis, recurrence, and prognosis in human cancers. VEGF stimulates angiogenesis mainly through VEGFR-2 (also known as Flk1 in mice and KDR in humans), a tyrosine kinase receptor that is overexpressed in tumour endothelial cells and on some tumour cells. Pharmacologic approaches to inhibit VEGF, using monoclonal antibodies or small molecules, are of value in cancer treatment, though the cytostatic rather than cytotoxic nature of these interventions and the redundancy of angiogenic pathways have limited the curative potential of these treatments. The Company believes VEGFR2 specific CAR immune cells may have broad applications in a number of cancer types. Helix is working on two camelid single domain antibodies that target VEGFR2.

The Company is also leveraging its know-how in manipulating the tumour microenvironment, and its expertise in developing unique single domain antibody therapeutics to develop CAR-T novel cell-based treatments. Helix intends to develop CARs for ACT for solid and hematological malignancies. The Company has selected CEACAM6 and VEGFR2 specific CARs for solid tumour. For hematological malignancies the Company has selected CD19, CD22 and BCMA as potential targets.

ProMab Biotechnologies Inc. ("ProMab")

On March 16, 2018 the Company entered into a collaboration agreement with ProMab to co-develop novel antibody and chimeric antigen receptor T-cell therapy ("CAR-T") that target BCMA to treat multiple myeloma. In this collaboration, the Company retains commercial rights for this CAR-T in Canada and Europe. The Company entered into a sublicense agreement for BCMA with HIO whereby the Company will assist in preclinical and early phase clinical planning of the BCMA project. The Company's assistance includes funding a certain portion(s) of the preclinical development stage while HIO leads the regulatory and clinical development of the product in Europe. These activities are expected to be coordinated with ProMab who will be developing the product for Asia and the U.S.A. The Company retains the rights for Canada.

The Biphasix™ Topical Formulation System

The Biphasix™ Topical Formulation System is a platform technology which the Company acquired and further developed for microencapsulating therapeutic compounds in multilayered, lipid-based microvesicles. These microvesicles have complex structures that include a variety of compartments into which drug molecules can be integrated. The principal application of the technology is in the preparation of topical dosage forms for the dermal (into the skin) or mucosal (into the mucosal tissues) delivery of large molecular weight drug compounds.

Clinical Programs

The Helix clinical program for L-DOS47 currently includes four clinical trials. 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 trial, a Phase Ib/II study (LDOS006) investigating the treatment of metastatic pancreatic adenocarcinoma, received regulatory approval and is currently being conducted in the U.S.

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 clinical benefit rate of 75.0%.

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%)

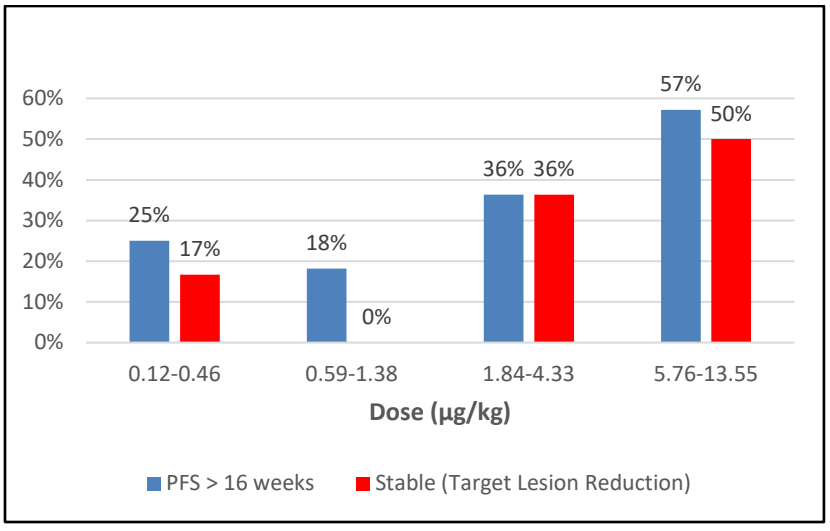
[1] Number of patients used as denominator to calculate percentages.

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 was 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 (where one treatment cycle is 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.



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. Based on the efficacy

results of the Phase I/II monotherapy study, Helix is pursuing Phase II studies in combination with therapies that may benefit from the pH-modulating effects of L-DOS47 on solid Tumours that express CEACAM6.

LDOS003 – A Phase II Combination Therapy Trial in Lung Cancer

LDOS003 is a Phase II, open-label, randomized study of L-DOS47 in combination with vinorelbine/cisplatin vs vinorelbine/cisplatin alone in patients with lung adenocarcinoma. Vinorebine/cisplatin chemotherapy combination in the U.S. has become 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 vinorebine/cisplatin chemotherapy combinations in Eastern European and Asian markets.

Patients who receive L-DOS47 will 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 is divided into two parts. Part I applies 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 will be recruited into three dosing cohorts (6, 9 and 12 µg/kg). All patients at a given dosing cohort must complete the first treatment cycle (3-week period) before escalation in subsequent patients can proceed. The decision for escalation to the next dose level will be made after the safety data have been reviewed by the Trial Steering Committee (TSC). If a patient in any cohort experiences a DLT, an additional three patients will 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 will be randomized (1:1) to receive L-DOS47 in combination with vinorelbine/cisplatin, or vinorelbine/cisplatin alone. Efficacy will 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 will include radiological evaluations every second cycle. Safety and tolerability of L-DOS47 in combination will also continue to be evaluated.

For all patients, treatment will 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. To date, the first two cohorts (6 and 9 µg/kg) in Part I of the study have been completed. Two (2) patients have also been dosed at 12 µg/kg. The third cohort has not been completed due to a hold on recruitment due to a shortage in the required vinorelbine dosages from the manufacturer. As shortages of required vinorelbine dosages from the manufacturer are expected to continue through to 2021, the Company has made the decision to terminate further recruitment and proceed to data analysis. The Company has therefore determined that it will not be moving forward with Part II of the study unless certain clinical objectives are met in Part I of the study and sufficient capital is obtained, or the Company enters into a co-development partnership with a third party.

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 increasing weekly dose levels of L-DOS47 in combination with a fixed dose of 20 mg/m2 of doxorubicin weekly, 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. 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.

The Phase II part of the study will 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 will 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, 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.

Currently a total of seven (7) patients have been dosed, 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. One patient experienced a chemo-related dose limiting toxicity and as a result, three (3) additional patients will need to be enrolled to close cohort 1. Due to slower enrolment related to challenges resulting from COVID-19 pandemic measures, an additional two sites are engaged in study start-up activities,

with plans to be open for patient recruitment in Q1/2021. A protocol amendment is also planned for submission to FDA this month (December 2020).

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 carcinoembryonic antigen-related cell adhesion molecule 6 (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. Helix has extensively characterized L-DOS47 and maintains a comprehensive analytical program for the drug substance, drug product, and the urease and antibody intermediates.

Helix also manufactures its own 1% Polysorbate 80 diluent, which is co-mixed with L-DOS47 in order 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 1% Polysorbate diluent is currently conducted by contract manufacturing organizations ("CMO") and contract testing laboratories ("CTL") in Canada and the U.S. Helix requires all CMO and CTL's to maintain compliance with current Good Manufacturing Practice ("cGMP") and to be licensed by the national regulatory authority in their jurisdiction. Helix employees and consultants provide technical, quality, and regulatory oversight for all operations related to L-DOS47 production. Currently, Helix has service and quality agreements with several CMO/CTL for clinical-stage manufacturing, testing, and release of the L-DOS47 drug substance and drug product and the 1% Polysorbate diluent.

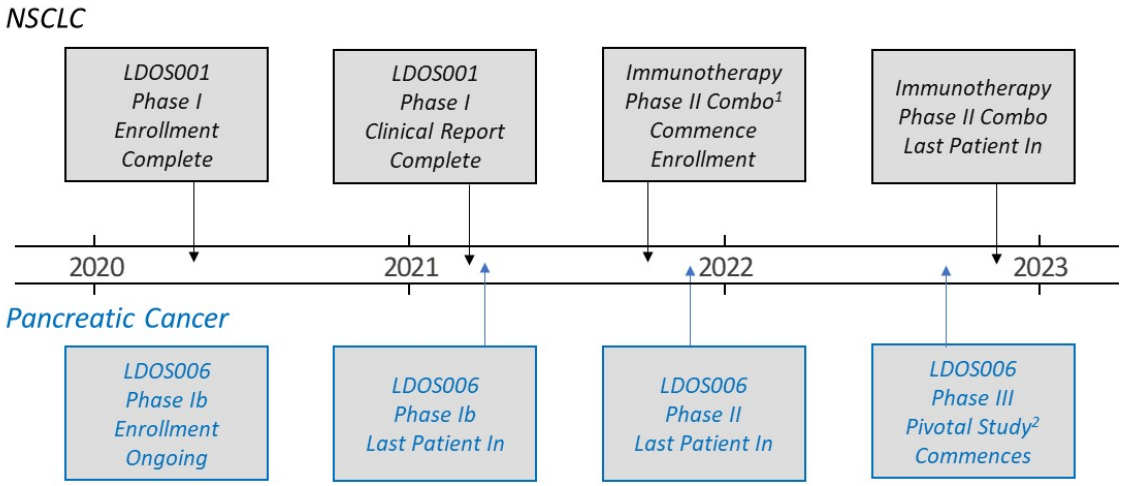
The Company's current supply of L-DOS47 drug product continues to be subjected to stability assays every six months. The next stability assay has been scheduled for November 2020 with a final batch testing scheduled for May 2021 after which time the Company will not have any additional stability samples available to further extend the current L-DOS47 drug product batch beyond May 2021. The CMO that manufactured the current L-DOS47 drug substance 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 repurpose a drug substance batch the Company had kept in reserve. The Company completed the reprocessing of a drug substance batch in June 2020 and, subject to the approval of various quality assurance tests which are expected to be completed in November 2020., the drug substance will be transferred to another CMO for lyophilization. The Company expects the lyophilization process to be completed December 2020, pending final approval of various quality assurance tests after which time the new batch of L-DOS47 drug product will be labelled and packed for use in the Company's ongoing clinical studies.

The Company has also been in discussion with the new CMO to plan out a technology transfer to manufacture a new batch of L-DOS47 drug product. No commitment has been made to date.

In the event that any of the stability assays (current batch or new production batch) do not pass quality assurance tests, 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.

Product Focus

The following table sets forth the current status and future research and clinical development activities relating to L-DOS47 and the anticipated timing thereof:



1) subject to preclinical data support, financial constraints, and possible third-party collaboration
2) Subject to favourable Phase I/II and financing constraints.

Strategy

We are focused on the development and commercialization of L-DOS47 as a potential therapy for NSCLC and pancreatic cancer. The key elements of our strategy, our expected timelines to achieve our strategic objectives, and the assumptions upon which such statements are made are as follows:

- Last patient enrollment for the Company's L-DOS47 Phase Ib pancreatic study is anticipated by the second quarter of calendar year 2021 with new clinical sites added and provide the study is not impeded by the COVID-19 pandemic, a potential severe adverse event that requires an increased number of patients to be enrolled from what is currently planned and/or dose limiting toxicities;
- Provided the Phase Ib portion of the Company's L-DOS47 pancreatic study is completed as planned, the Company expects patient enrollment for the Phase II portion of the study to then commence immediately with the last patient enrolled by November 2021 (unlike the Phase Ib study where new patient enrollment must be completed sequentially, the Phase II portion of the trial allows for multiple patient enrollment all at once);

- The initiation of a Phase III pivotal study of the Company's L-DOS47 in pancreatic late in 2022 (assumes the successful completion of the Phase Ib/II study and the achievement of all study objectives);

- Provided current pre-clinical research activity, both inhouse and in collaboration with Moffit Cancer Center show sufficient evidence, the Company will look to apply for a new NSCLC Phase II clinical study with L-DOS47 in combination with immunotherapy;

- Provided current pre-clinical research activity, both inhouse and in collaboration with Moffit Cancer Center show sufficient evidence, the Company will look to expand the utility of L-DOS47 not only in combination with immunotherapy in pancreatic cancer some time in early 2023 but for other possible indications;

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 Company has retained Deloitte Corporate Finance as its strategic advisor to explore partnering and licensing opportunities. 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.

Market and Competition

Non small cell lung cancer

Treatment options for metastatic NSCLC have changed significantly in the last few years due to the clinical success of Immunotherapies such as immune checkpoint inhibitors that target PD-1 or its ligands. On March 4, 2015 the FDA approved

Nivolumab, the generic name for the trade drug named Opdivo®, which targets PD-1 for the treatment of metastatic squamous NSCLC with progression on or after platinum-based chemotherapy. On October 2, 2015, the FDA granted accelerated approval for Pembrolizumab, the generic name for the trade drug named Keytruda®, which targets PD-1 to treat patients with advanced metastatic NSCLC with Tumours that express PD-L1 whose disease has progressed after treatment.

As of March 2017, the FDA had approved five checkpoint inhibitor drugs: ipilimumab (Yervoy®), pembrolizumab (Keytruda®), nivolumab (Opdivo®), atezolizumab (Tecentriq®) and avelumab (Bavencio®).

On May 10, 2017, the FDA granted accelerated approval to pembrolizumab (Keytruda®, Merck and Co., Inc.) in combination with pemetrexed and carboplatin for the treatment of patients with previously untreated metastatic NSCLC. Approval was based on a cohort (G1) of patients enrolled in an open-label, multicenter, multi-cohort study (KEYNOTE-021).

Pancreatic Cancer

Treatment options for late stage metastatic pancreatic cancer patients are limited. Surgery and radiation are used only for symptom relief and chemotherapy remains the primary mode of therapy. Gemcitabine is widely used either alone or in combination with erlotinib (Tarceva), capecitabine, cisplatin or nab-paclitaxel. Other chemo-cocktails are also possible depending on patient tolerability to such cocktails and physican choice of best suitable care. If these lines of therapy are not effective, other combinations such as oxaliplatin and fluoropyrimidine may be used.

Technological competition from pharmaceutical companies, biotechnology companies and university researchers is intense and is expected to continue. While the Company is not aware of any other competitors in clinical development of a therapy that targets tumour acidosis, some potential competitors have substantially greater product development capabilities and financial, scientific, marketing and human resources than the Company. See "The Company faces risks in connection with competition and technological change" under the heading "Risk Factors".

SELECTED FINANCIAL INFORMATION

The Company reported a net loss and total comprehensive loss of $222,000 for the three-month periods ended October 31, 2020 (2019 - $2,214,000). The Company recorded a gain from loss of control of a subsidiary in the three-month period ended October 31, 2020 of $2,162,000.

The Company experienced a working capital deficiency throughout fiscal 2018 and 2019 until August 21, 2019 when the Company closed the first of a series of private placements with a more recent financing occurring on December 4, 2020. See *SUBSEQUENT EVENTS* section below.

Fluctuations in total net loss and total comprehensive loss is mainly the result of the Company's cash reserves available to be deployed on ongoing research and development activities and operating, general and administration expenses.

The reduction in research and development expenses in Q1 fiscal 2021 mainly reflects the winding down of two other clinical trials in previous quarters with now only one clinical trial in progress with patient enrollment having been somewhat impacted by COVID-19.

The increase in operating, general and administration spending in Q1 fiscal 2021 mainly reflects higher legal, accounting and investor relation costs as well as the vesting of stock options granted over their vesting period.

At September 3. 2020 HIO completed a direct financing with an arm's length party. As a result of the financing the Company's ownership in Helix Immuno-oncology S.A. ("HIO") was diluted down to 29.89% and as a result, the Company has determined that it has lost control of HIO.

(thousand $, except per share information)								
	Q1 2021	Q4 2020	Q3 2020	Q2 2020	Q1 2020	Q4 2019	Q3 2019	Q2 2019
Research and development expense	1,084	1,246	1,523	1,588	1,446	1,311	1,351	1,330
Operating, general and admin expense	1,303	523	862	654	576	881	699	533
Gain from loss of control of subsidiary	2,231	0	0	0	0	0	0	0
Net loss and total comprehensive loss	-256	-2,114	-2,594	-2,255	-2,214	-2,168	-2,071	-1,908
Loss per share - basic & fully diluted	-0.02	-0.01	-0.02	-0.02	-0.02	-0.02	-0.02	-0.02
Cash	1,428	4,235	4,989	2,094	1,650	206	938	306
Working capital / (deficiency)	2,392	2,735	3,826	873	430	-3,534	-2,209	-1,998

RESULTS FROM OPERATIONS

Net loss from continuing operations

The Company reported a net loss and total comprehensive loss of $222,000 for the three-month period ended October 31, 2020 (2019 - $2,214,000).

Research & development

Research and development expense for the three-month periods ended October 31, 2020 and 2019 totalled $1,084,000 and $1,446,000, respectively.

Components of research and development expenses for the three-month periods ended October 31:

	2020	2019
Research and development programs, excluding the below items	$ 689,000	$ 1,106,000
Salaries and benefits	315,000	257,000
Stock-based compensation expense	4,000	39,000
Amortization of property, plant and equipment	17,000	12,000
Amortization of right of use assets	32,000	32,000
Research and development investment tax credits	27,000	–
	$ 1,084,000	$ 1,446,000

The decrease in research and development expenses for the current quarter, when compared to the prior year's quarter is the result of lower clinical operation expense of $140,000, lower intellectual property maintenance cost of $139,000, lower collaborative scientific research expenditures of $80,000 and lower manufacturing costs of $20,000.

Lower clinical operation expenses are due to spending having occurred in the prior year's quarter related to the Company's LDOS003 Phase II clinical study in Poland and the Ukraine which has since concluded but currently awaiting reporting. The Company's new LDOS006 Phase Ib/II pancreatic clinical study in the U.S. was still in the early stages with U.S. FDA approval only having been received in August 2019.

Lower intellectual property maintenance costs are mainly the result of the Company having occurred higher costs over the previous years and timing related spend which is forecasted for the second fiscal quarter ending January 31, 2021.

Lower collaborative scientific research spend mainly reflects the conclusion of a previous research project with the Moffit Cancer Center. A new collaboration has since been agreed upon with work having commenced in November.

Operating, general and administration

Operating, general and administration expenses for the three-month periods ended October 31, 2020 and 2019 totalled $1,303,000 and $576,000, respectively.

Components of operating, general and administration expenses for the three-month periods ended October 31:

	2020	2019
Operating, general and administration, excluding the below items	$ 776,000	$ 423,000
Salaries and benefits	107,000	120,000
Stock-based compensation expense	420,000	33,000
Amortization of property, plant and equipment	–	–
Amortization of right of use assets	–	–
	$ 1,303,000	$ 576,000

The increase in operating, general and administration expense for the current quarter, when compared to the prior year's quarter is the result of higher legal costs of $148,000, higher audit fees of $65,000 and higher investor relations expenditures of $153,000.

The Company has been in discussions with various groups both in the U.S. and Canada and has been incurring additional legal and audit expenses as part of the Company's objective to raise additional capital to qualify for a listing on a U.S. stock exchange such as NASDAQ. On October 21, 2020 the agreement with ACM Alpha Consulting Management EST ("AGMest") was terminated by mutual agreement of the parties. The agreement included a termination clause which required a ninety-day written notice resulting in a payout of $144,000.

Stock based compensation expense for the three-month period ended October 31, 2020 totalled $420,000 (2019 - $33,000). The amount represents the expense associated with the vesting of stock options that were granted to directors of the Company, over their vesting period.

iGain from loss of control in subsidiary – discontinued operations

The Company's investment in HIO was classified as held for sale and was presented as discontinued operations at July 31, 2020. At September 3. 2020 HIO completed a direct financing with an arm's length party. As a result of the financing the Company's ownership in HIO was diluted down to 29.89% and as a result, the Company has determined that it has lost control of HIO. As the Company's interest allows the Company to exert significant influence over HIO, the Company's remaining interest is now accounted for as an interest in associate using the equity method. The Company's remaining interest in HIO was recognized at its fair value as at September 3, 2020 based on the post financing valuation. The difference between the carrying value of the net assets of HIO and non-controlling interest and the value assigned to the shares of $2,231,000 was recognized as a gain on loss of control of subsidiary.

The following information summarizes the consolidation of HIO as at September 3, 2020, which is the date of deconsolidation:

Fair value of retained interest		$ 2,715,000
Net assets of HIO		
Cash	966,000	
Receivables	25,000	
Due from intercompany	2,000	
Prepaids	10,000	
Capital assets	69,000	
Accounts payable	(46,000)	
Accrued liabilities	(3,000)	
Net assets of HIO		(1,023,000)
Deconsolidation of non-controlling interest in HIO		587,000
Deconsolidation of accumulated foreign exchange amount		138,000
Book value of investment in HIO		(186,000)
Gain on loss of control of subsidiary		$ 2,231,000

The continuity of the Company's investment in associate related to HIO is as follows:

Balance - September 3, 2020	$ –
Fair value in retained interest in associate	2,715,000
Share of net loss for the period	(69,000)
Balance – October 31, 2020	$ 2,646,000

CRITICAL ACCOUNTING ESTIMATES

The preparation of 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 Company has also assessed the impact of COVID-19 on estimates and critical judgement. Although the Company expects COVID-19 related disruptions to continue, the Company believes that the long-term estimates and assumptions do not require significant revisions. Although the Company determined that no significant revisions to such estimates, judgements or assumptions were required, the pandemic is fluid and given the inherent uncertainty at this time, revisions may be required in future periods to the extent that the negative impacts on the Company's business operations arising from COVID-19 continue or become worse. Any such revision could result in a material impact on the Company's financial performance and financial condition.

The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the Company's financial statements have been set out in Note 1 of the Company's consolidated financial statements for the fiscal year ended July 31, 2020.

SIGNIFICANT ACCOUNTING POLICIES

The significant accounting policies used in preparing the Company's consolidated financial statements are described in Note 2 of the Company's audited consolidated financial statement for the fiscal year ended July 31, 2020, 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 interim 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 investing and financing activities.

The Company reported a net loss and total comprehensive loss of $222,000 for the three-month period ended October 31, 2020 (October 31, 2019 - $2,214,000). As at October 31, 2020 the Company had working capital of $2,426,000, shareholders' equity of $2,596,000 and a deficit of $180,738,000. As at July 31, 2020 the Company had working capital of $2,735,000, shareholders' equity of $2,981,000, a deficit of $180,516,000.

The Company experienced a working capital deficiency throughout fiscal 2018 and 2019 until August 21, 2019 when the Company closed the first of a series of private placements with a more recent financing occurring on December 4, 2020. See *SUBSEQUENT EVENTS* section below. A portion of the private placement financings in the fiscal year ending July 31, 2020, included the total disposition of a 49.0% stake in HIO. HIO completed two direct private placements which reduced the Company's holding in HIO to 29.89% as at October 31, 2020. On November 9, 2020, the Company announced that it has signed a definitive share purchase agreement with CAIAC to purchase the Company's remaining holdings in its Polish subsidiary, HIO, for gross proceeds of PLN 6,700,000 (CAD2,308,000).

In addition, the Company has been in discussions with various capital market firms, both in the U.S. and Canada, with the goal of raising additional capital to qualify the Company for a listing on a U.S. stock exchange such as NASDAQ and further advance the Company's clinical development programs.

In order for the Company to advance the various 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 $15,000,000 to $20,000,000. The Company projects an average monthly fixed overhead spend of approximately $360,000. This amount does not include the costs related to any of the Company's third-party activities such as clinical studies, collaborative research activities, contract manufacturing and any of the additional costs associated with the Company's objective to list on the Nasdaq.

The Company currently has several clinical studies (see *Clinical Study Initiatives* above for details) in various stages of development. Due to slow enrollment, the Company stopped LDOS001 enrollment and has been working on the final clinical study report. The Company is forecasting approximately $370,000 to fully complete the study and report. 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 is forecasting approximately $337,000 to fully complete the study and report.

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. The Company is forecasting a cost of approximately $4,500,000 through to the end of fiscal 2022.

The Company is forecasting approximately $2,400,000 in manufacturing activity through to the end of fiscal 2022 in support of the Company's clinical study programs. Originally the Company determined that it would likely need an entirely new manufacturing batch but has since determine that a current drug substance batch could be repurposed and ready for use in early 2021. The manufacturing is just about complete. The forecast for manufacturing includes technology transfer of L-DOS47 to a new manufacturer with the transfer projected to be complete in late 2021.

The Company is currently forecasting to spend approximately $1,071,000 in collaborative research initiatives with both ProMab and the Moffit Cancer Centre.

The Company's cash reserves of $4,679,000 as at October 31, 2020 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. Though the funds raised have assisted the Company in dealing with its working capital deficiency, additional funds are required to advance the Company's clinical and preclinical programs and deal with 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, primarily through the issuance of equity securities of the Company, to be critical for its development needs.

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. The Company is also assessing the possibility of a Nasdaq listing in order to reach the U.S. capital markets for funding. 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 may be 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 had a total number of 132,933,017 common shares issued and outstanding as at October 31, 2020 (July 31, 2020 – 132,933,017). Use of proceeds from the sale of securities have been used for working capital, including funding the Company's ongoing research and development activities.

RELATED PARTY TRANSACTIONS

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

	2020	2019
Compensation	$ 147,000	$ 147,000
Stock-based compensation	–	53,000
	$ 147,000	$ 1,058,000

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

	2020	2019
Directors' fees	$ 62,000	$ 42,000
Stock-based compensation	420,000	7,000
	$ 482,000	$ 49,000

The following table summarizes the total compensation for both ACMest and ACMag for the three-months ended October 31:

	2020	2019
Finder's fee commissions	$ –	$ 875,000
Investor relations consulting fee	287,000	132,000
	$ 287,000	$ 1,007,000

The Company has agreements with both ACM Alpha Consulting Management EST ("ACMest") and ACM Alpha Consulting Management AG ("ACMag"). The agreements are both effective July 2, 2018 and can be terminated upon ninety days notice. Mr. Kandziora is President of ACMest and acted as Observer on the Board of Directors of the Company up until August 22, 2019 in addition to also being on the Supervisory Board of the Company's Polish subsidiary, Helix Immuno-Oncology S.A. Mrs. Kandziora is President of ACMest and was Corporate Secretary up until August 22, 2019. On October 21, 2020 the agreements with both ACMag and ACMest were terminated by mutual agreement of the parties.

Related party transactions are at arm's length and recorded at the amount agreed to by the related parties.

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 financial statements, measured at fair value, is cash.

Fair value

The fair value of financial instruments as at October 31, 2020 and July 31, 2020 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, trade-mark 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 at October 31, 2020, the Company had rights to 5 issued U.S. patents, which will expire between July 16, 2023 and January 22, 2036 assuming all required fees are paid, 6 pending U.S. patent applications, 64 issued foreign patents, and 42 pending foreign patent applications. Our patents and patent applications cover aspects of our current and future product concepts. Some of the pending foreign patent applications preserve an opportunity to pursue patent rights in multiple countries. As at October 31, 2020, the Company had one registered trademark in Canada.

We also rely, 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. We protect our proprietary rights through a variety of methods, including confidentiality and assignment agreements with suppliers, employees, consultants, and others who may have access to our proprietary information.

While there is no active litigation involving any of our patents or other intellectual property rights and we have not received any notices of patent infringement, we may be required to enforce or defend our 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 all 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 our business and with respect to the application of our products and technologies to the treatment of a number of diseases. The Company's policy also includes regular reviews related to the development of each technology and product in light of 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.

Cell-Based Therapy

The Company has recently filed a joint patent application with NRC to protect the use of an antibody for use in cell-based therapies. In addition, the Company filed a new patent application covering the use of anti-VEGFR2 antibodies in cell-based therapy in July 2017.

OFF-BALANCE SHEET ARRANGEMENTS

The Company has no material off-balance sheet arrangements.

SUBSEQUENT EVENT

On November 9, 2020, the Company announced that it has signed a definitive share purchase agreement with CAIAC Fund Management AG ("CAIAC") to purchase the Company's remaining 29.89% holdings in HIO, for gross proceeds of PLN 6,700,000 (~$2,308,000). The funds were wired by CAIAC on November 13, 2020. Closing of the transaction is to occur upon finalizing administrative reporting requirements and evidence of share registry changes in Poland. COVID-19 has had an impact on closing the transaction. Upon closing of the transaction, the Company is committed to paying ACMest a transaction fee equal to 12.5% of the gross proceeds.

On December 4, 2020, the Company closed a private placement financing of 2,200,00 units at a price of $0.50 per unit, for aggregate gross proceeds of $1,100,000. Each unit consisted of one common share and one common share purchase warrant. Each common share purchase warrant entitles the holder to purchase one common share of the Company at a price of $0.70 and have an expiry of five years from the date of issuance.

TABULAR DISCLOSURE OF CONTRACTUAL OBLIGATIONS

The Company's commitments as October 31, 2020 are summarized as follows:

	2021	2022	2023	2024	2025	2026 and beyond	Total
Clinical research organizations [1]	$ 1,797,000	$1,314,000	$ 96,000	$ –	$ –	$ –	$ 3,207,000
Collaborative research organization[2]	1,363,000	–	–	–	–	–	1,363,000
Contract manufacturing organizations [3]	89,000	–	–	–	–	–	89,000
Royalty and in-licensing [4]	20,000	20,000	20,000	20,000	10,000	60,000	150,000
Financial & investor relations (5)	138,000	–	–	–	–	–	138,000
Facility leases [6]	41,000	–	–	–	–	–	41,000
	$ 3,448,000	$1,334,000	$ 116,000	$ 20,000	$ 10,000	$ 60,000	$ 4,988,000

(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) The Company has collaborative research organization agreements relating to its L-DOS47 program.
(3) The Company has contract manufacturing organization supplier agreements related to its L-DOS47 program, all of which are inter-dependant with the manufacturing of L-DOS47.
(4) Represents future minimum royalties.
(5) The Company amended a financial advisory agreement dated July 2, 2018 which includes a termination clause which requires a ninety-day written notice. On October 21, 2020 the agreements with both ACM Alpha Consulting Management EST and ACM Alpha Consulting Management AG were terminated by mutual agreement of the parties. (also see *RELATED PARTY TRANSACTIONS* section above).
(6) The Company is committed to pay $41,000 under three facility lease agreements.

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.

Currency risk

The Company operates internationally and is exposed to foreign exchange risks from various currencies, primarily the U.S. dollar and Euro. Foreign exchange risks arise from the foreign currency translation of the Company's integrated foreign operation in Poland. 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, 2020		July 31, 2020	
	USD	EUR	USD	EUR
Accounts payable	(723,000)	(255,000)	(622,000)	(257,000)
Accruals	–	–	(44,000)	–
Net foreign currencies	(723,000)	(255,000)	(666,000)	(257,000)
Closing exchange rate	1.3310	1.5550	1.3404	1.5831
Impact of 1% change in exchange rate	+/- 7	+/- 4	+/-9	+/- 6

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 as at:

	October 31, 2020	July 31, 2020
Government related – HST/VAT	$ 73,000	$ 46,000
Research and development investment tax credits	93,000	121,000
Other	–	13,000
	$ 166,000	$ 180,000

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 are affected by market conditions. The Company is exposed to interest rate risk arising from fluctuations in interest rates received on its cash. The Company does not have any credit facilities and is therefore 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 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 investing and financing activities.

The Company's cash reserves of $4,679,000 as at October 31, 2020 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 initiatives 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 as at:

	October 31, 2020			July 31, 2020		
	Carrying amount	Less than one year	Greater than one-year	Carrying amount	Less than one year	Greater than one-year
Accounts payable	$ 1,685,000	$ 1,685,000	$ –	$ 1,416,000	$ 1,416,000	$ –
Accrued liabilities	198,000	198,000	–	301,000	301,000	–

This table only covers liabilities and obligations relative to financial instruments and does not anticipate any income associated with assets nor does it include liabilities related to assets held for sale.

OUTSTANDING SHARE DATA

As at December 15, 2020, the Company had outstanding 135,133,017 common shares; warrants to purchase up to 60,534,413 common shares; and incentive stock options to purchase up to 7,275,000 common shares. As at July 31, 2020, the Company had outstanding 132,933,017 commons shares; warrants to purchase up to 65,080,413 common shares; and incentive stock options to purchase up to 5,225,000 common shares.

DISCLOSURE CONTROLS AND PROCEDURES AND INTERNAL CONTROL OVER FINANCIAL REPORTING

Management has designed the Company's disclosure controls and procedures to provide reasonable assurance that all relevant information is gathered, recorded, processed, summarized and reported to the Chief Executive Officer ("CEO") and the Chief Financial Officer ("CFO") 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 financial statements for external purposes 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.

Material weakness previously disclosed but not yet remediated

The termination of the Company's controller in fiscal 2017, whose position to this day has not been filled, resulted in a lack of resources and has in turn impacted segregation of duties associated with the financial close and reporting process.

Management has concluded and the board has agreed, that when taking into account the Company's size and financial resources, the Company does not have sufficient scale of resources to warrant the hiring of additional staff to address this concern at this time and, accordingly, that there is a material weakness in the design of the Company's ICFR that has the potential to result in material misstatements in the Company's financial statements and that this should also be considered a weakness in the design and operating effectiveness of the Company's disclosure controls and procedures. This material weakness is considered to be a common area of deficiency for many smaller listed companies in Canada. With the Company's objective to list on the Nasdaq management will be taking steps to cure the material weakness for the Company's fiscal quarter ending January 31, 2021.

Although the CEO and CFO are not aware of the above deficiency having actually resulted in a material misstatement of a financial statement amount or disclosure, they have determined that, the deficiency could result in business and accounting practices that could put both the Company's reputation and its financial reporting at risk and lead to uncertainty whether control procedures are being carried out such that the Company's ICFR may fail to prevent or detect a material misstatement of a financial statement amount or disclosure on a timely basis or fail to disclose material information required to be disclosed under securities legislation within the time periods specified in securities legislation. However, there are several mitigating procedures and other factors which reduce the risk of a material misstatement in the financial statements, including substantive review of the financial statements by the Company's audit committee and day-to-day management involvement in operations and reporting.

RISKS AND UNCERTAINTIES

Helix 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 dependant on raising sufficient capital on a timely bases 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:

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. 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 and/or debt 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 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. Given the Company's conclusion about the insufficiency of its cash reserves, significant doubt may be 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 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 cumulative deficit as at October 31, 2020 is $183,738,000. There can be no assurance that the Company will record earnings in the future.

The Company requires additional funding

The Company's cash reserves will not be sufficient for the Company to fully fund the Company's ongoing research and development programs, operating activities, working capital or capital expenditures for the next twelve months. The Company has no sources of external liquidity, such as a bank loan or line of credit. The Company is therefore in need of additional equity and/or debt financings in order to fund its ongoing research and development programs and other operating expenses for the foreseeable future.

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, including any 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 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 is 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.

With the recent FDA approval of pembrolizumab (Keytruda®) as first line treatment for NSCLC with PD-L1>1%, either as first line or in combination with carboplatin/pemetrexed, there is an urgent need for data to demonstrate the safety of L-DOS47 in combination with accepted standard chemotherapies, and also in combination with immunotherapies that are being offered with growing frequency. In addition, the rapidly evolving treatment landscape and growing prominence of immunotherapies, along with the infrequent use of vinorebine/cisplatin chemotherapy combination in the U.S., the potential relevance of data from the Company's LDOS003 study may be limited.

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 conducting early stage research and development initiatives for products under development which may not be accepted by the market and may never generate revenue and the Company has limited sales, marketing and distribution experience

The Company is conducting early stage research and development initiatives and is currently in the process of developing new products that require further time consuming and costly research and development. It will be a number of years, if ever, before its products in development begin to generate revenues, if at all. There can be no assurance that any of the drug product candidates will ever be successfully developed or commercialized.

Even with regulatory approval, the Company may not achieve market acceptance, 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 the Company's drug candidates is not certain. Failure to gain market acceptance of either of the

Company's products currently under development or an incorrect estimate in the nature and size of their respective markets 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 its drug candidate products 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.

The Company has expressed certain estimated timelines for its European Phase I//II clinical trials for L-DOS47 in Poland, the U.S. Phase I study. The timeline for the European Phase I/II trials and any future timelines are contingent on the Company having adequate financing to complete the trials and the assumption that the trials will be completed according to the current schedules. A failure to obtain necessary financing or a change in the schedule of the trials (which may occur if certain cost-deferral measures are taken, or 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 their commencement or completion, or result in their suspension or early termination, which could have a material adverse effect on the Company.

The Company faces intellectual property risks, including the loss of patent protection, the potential termination of licences, the inability to protect proprietary property, and possible claims of infringement against the Company or against a third-party from whom the Company licenses intellectual property

The Company's success depends, in part, on its ability to secure and protect its intellectual property rights and to operate without infringing on the proprietary rights of others or having third parties circumvent the rights owned or licensed by the Company. However, the Company cannot predict the enforceability of its patents or its ability to maintain trade secrets that may not be protected by patents. Patent risks include the fact that patent applications may not result in issued patents, issued patents may be circumvented, challenged, invalidated or insufficiently broad to protect the Company's products and technologies; blocking patents by third parties could prevent the Company from using its patented technology; it may be difficult to enforce patent rights, particularly in countries that do not have adequate legal enforcement mechanisms, and enforcing such rights may divert management attention and may cause the Company to incur significant expenses; and any expiry of an issued patent may negatively impact the underlying technology.

To protect its trade secrets, the Company enters into confidentiality undertakings with parties that have access to them, such as the Company's current and prospective distributors, collaborators, employees and consultants, but a party may breach the undertakings and disclose the Company's confidential information or competitors might learn of the information in some other way, which could have a material adverse effect on the Company.

The Company uses processes, technology, products, or information, the rights to certain of which are owned by others, such as a license from the NRC of the lung antibody used by the Company for L-DOS47. Termination or expiry of any licenses or rights during critical periods, and an inability to obtain them on commercially favourable terms or at all could have a material adverse effect on the Company and its drug candidates' development.

The Company operates in an industry that experiences substantial litigation involving the manufacture, use and sale of new products that are the subject of conflicting proprietary rights. The Company or one or more of its licensors may be subject to a claim of infringement of proprietary rights by a third party. It is possible that the Company's products and technologies do infringe the rights of third parties, and the Company or such licensor could incur significant expenses, and diversion of management attention, in defending allegations of infringement of proprietary rights, even if there is no infringement. Furthermore, the Company or such licensors may be required to modify its products or obtain licenses for intellectual property rights as a result of any alleged proprietary infringement. The inability to modify products or obtain licenses on commercially reasonable terms, in a timely manner or at all, could adversely affect 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.

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 for the production of 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 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.

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 our 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 five 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 one or more of its three current resident Canadian directors in the future and is unable to find a sufficient number of resident Canadian directors to fill the resulting vacancy(ies), the Board will be prevented from taking any action other than appointing additional resident Canadian directors until such time as a sufficient number of new resident Canadian directors have 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. The Novel Coronavirus ("COVID-19") imposes a high risk to all the Companies 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-man 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 Company's 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 and the Euro.

Unanticipated changes in the Company's tax rates could affect its future results

Since the Company operates in different countries and is subject to taxation in different jurisdictions, its future effective tax rates could be impacted by changes in such countries' tax laws or their interpretations. Both domestic and international tax laws are subject to change as a result of changes in fiscal policy, changes in legislation, evolution of regulation and court rulings. The application of these tax laws and related regulations is subject to legal and factual interpretation, judgment and uncertainty.

Shareholders of the Company may face dilution through exercise of stock options, warrants and future equity financings

To attract and retain key personnel, the Company has granted options to its key employees, directors and consultants to purchase common shares and share awards 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 share awards and the exercise of a significant number of such options and warrants may result in significant dilution of 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 and warrants may also result in significant dilution to the shareholders of the Company.

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

The 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 Company's 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: quarterly variations in results of operations; announcements of technological innovations or new products by the Company, its customers or competitors; changes in securities analysts' recommendations; announcements of acquisitions; changes in earnings estimates made by independent analysts; general fluctuations in the stock market; or revenue and results of operations below the expectations of public market securities analysts or investors. Any of these could result in a sharp decline in the market price of the common shares.

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 Toronto Stock Exchange ("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.

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

As a public company, the Company is subject to the reporting requirements of Canadian securities regulators, the listing requirements of the Exchange 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.

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 Company's 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.

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 our financial statements or cause us to fail to meet our reporting obligations or fail to prevent fraud; and in that case, our shareholders could lose confidence in our financial reporting, which would harm our business, could negatively impact the price of our 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 our financial reporting, which would harm our business, negatively impact the price of the Company's common shares and also prevent the Company from raising additional capital. Even if we were to conclude that our internal control over financial reporting provides reasonable assurance regarding the reliability of financial reporting and the preparation of 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 financial statements, harm our business**,** negatively impact the trading price of our common shares and prevent the Company from raising additional capital.

Novel Coronavirus ("COVID-19")

The World Health Organization has declared COVID-19 a pandemic. The Company is actively assessing and responding where possible to the potential impact of the COVID-19 pandemic. The risk to the Company, the health of its employees and to those third-party vendors that support the Company and its operations is high. Any impact on the Company arising from the pandemic could have a material adverse effect on the Company's business, results of operations and financial condition.

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 filings is available under the Company's profile on SEDAR at www.sedar.com.

December 15, 2020