

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

The following discussion should be read in conjunction with the consolidated financial statements of Helix BioPharma Corp. (the "Company" or "Helix") for the three-month periods ended October 31, 2015, and 2014 and the accompanying notes thereto, which have been prepared in accordance with International Financial Reporting Standards ("IFRS") and does not include all the information required for full annual financial statements. The following discussion should also be read in conjunction with the consolidated financial statements of Helix for the years ended July 31, 2015 and 2014 and accompanying notes thereto. 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 for the fiscal year ended July 31, 2015, which is available on SEDAR at [www.sedar.com](http://www.sedar.com).

## FORWARD-LOOKING INFORMATION

This Management's Discussion and Analysis of Financial Condition and Results of Operations this ("MD&A") contains forward-looking information (collectively, "forward-looking information") within the meaning of applicable Canadian securities laws. 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 on L-DOS47 which is the Company's primary drug candidate, Topical Interferon Alpha-2b and other information relating to future periods. Forward-looking information includes, without limitation, statements concerning (i) the Company's ability to operate on a going concern being dependent mainly on obtaining additional financing; (ii) the Company's growth and future prospects being dependent 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 tumor-targeting antibodies for DOS47; (v) the anticipated timeline for completion of enrolment and other matters relating to the Company's European Phase I/II clinical study for L-DOS47 in Poland, including the number of cohorts required to reach Maximum Tolerable Dose ("MTD") and the Company's U.S. Phase I clinical study for L-DOS47, (vi) seeking strategic partner support and therapeutic market opportunities; (vii) the nature, design and timing of future clinical trials (including the Company's anticipated reassessment of the re-design of the LDOS003 study to focus on advanced stage lung cancer patients by combining L-DOS47 with Vinorelbine/Cisplatin ("VIN/CIS") and commercialization plans; (viii) future expenditures, insufficiency of the Company's current cash resources and the need for financing and the Company's possible response for such matters; (ix) future financing requirements, the seeking of additional funding (including the possible receipt of grants or listings on the Warsaw Stock Exchange) and anticipated future operating losses; (x) changes in the application of accounting standards and interpretations; and (xi) industry performance, competition (including potential developments relating to immunotherapies and the Company's possible response to such developments), prospects, and general prevailing business and economic conditions. 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", "2016", "2017", "2020", "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 need for additional capital which may not be available in a timely manner or at all (whether from additional issuances of the Company's securities, grant applications or otherwise) and which, if not obtained, will have a material adverse impact on the Company and its ability to continue as a going concern;
- the risk that the Company may have to suspend or terminate one or more of its clinical trials for lack of funding, as the Company does not have sufficient funds to complete them and will need to raise additional funding, which is not assured;
- uncertainty as to whether the Company's drug product candidate(s), especially L-DOS47, will be successfully developed and marketed;
- developments in immunotherapies may result in significant changes in 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 L-DOS47;
- the possibility of dilution of current shareholders from future equity financings;

- the impact of the ongoing volatility in the economic environment which has negatively affected the availability and terms of debt and equity financings and may have a negative effect on the Company's ability to raise further financing and its research and development initiatives;
- 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 trade secrets or other confidential proprietary information;
- 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;
- partnership/strategic alliance risks and the need to secure new strategic relationships, which are both not assured;
- 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 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;
- the need for future clinical 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;
- 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;
- uncertainty as to the size and existence of a market opportunity for, and market acceptance of the Company's drug product candidate(s) including as a result of possible changes in the market for the Company's drug candidates resulting from development in immunotherapies;
- 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);
- product liability and insurance risks;
- the risk of lawsuits and other legal proceedings against the Company;
- the effect of competition, especially from the new immunotherapy treatments for non-small cell lung cancer ("NSCLC");
- the risk of unknown side effects arising from the development, manufacture or use of the Company's products;
- the need to attract and retain key personnel;
- that the Company has no sales, marketing and distribution experience;
- government regulation, including drug price regulation, and the need for regulatory approvals for both the development and profitable commercialization of products, which are not assured;
- risks associated with the fact that the U.S. Food and Drug Administration (the "FDA") and any other regulatory agency that the Company has consulted are not bound by their scientific advice, nor are any approvals given by one regulatory body binding on another;
- rapid technological change and competition from pharmaceutical companies, biotechnology companies and universities, which may make the Company's technology or products obsolete or uncompetitive;
- risks associated with claims, or potential claims, of infringement of third party intellectual property and other proprietary rights;
- the risk of unanticipated expenses;
- the impact on the Company's finances resulting from shifts in foreign exchange rates, credit risk and interest rate risk,

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](http://www.sedar.com), including under the headings "*Forward-Looking Statements*" and "*Risk Factors*" in the Company's most recent Annual Information Form (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. Certain material factors, estimates or assumptions have been applied in making forward-looking information in this MD&A, including, but not limited to, the safety and efficacy of the Company's drug product candidate(s); the Company's cost and timing in connection with the Phase I U.S. clinical trial for L-DOS47; the cost and timing for achieving MTD in the Company's European Phase I/II clinical trial for L-DOS47 in Poland; that sufficient financing will be obtained in a timely manner to allow the Company to continue operations; the timely provision of services and supplies or other performance of contracts by third parties; future costs; the absence of any material changes in business strategy or plans, the timely receipt of required regulatory approvals, strategic partner support; and

that the Helix Risk Factors will not cause the Company's actual results or events to differ materially from the forward-looking information.

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 foregoing data is reliable, the Company has not independently verified the accuracy and completeness of this data.

## **OVERVIEW**

Helix is a biopharmaceutical company mainly focused in the field of cancer therapy.

The Company is developing products for the treatment and prevention of cancer based on its proprietary technologies.

The Company's product development initiatives are focused primarily on its DOS47 new drug candidate. L-DOS47 is currently under study for the treatment of NSCLC. The Company currently believes that its growth and future prospects are mainly dependent on the success of its DOS47 drug product candidate.

L-DOS47 has completed extensive preclinical testing and manufacturing development, following which, regulatory approvals were obtained in Poland and the U.S. to conduct Phase I/II and Phase I clinical studies, respectively. The LDOS002 European Phase I/II clinical study in Poland continues to enroll patients and three sites have been initiated in the U.S. Phase I study in NSCLC involving L-DOS47 in combination with pemetrexed/carboplatin.

Due to a lack of funding, a decision was made by the Company in fiscal 2013 to downsize and eventually close the Saskatoon laboratory which supported the Topical Interferon Alpha-2b drug development program and to focus any ongoing activities associated with this program to sourcing and qualifying alternative interferon alpha-2b raw material samples and finding suitable strategic partner(s) who would be willing to license or acquire the product and support the remaining development costs through to commercial launch. The Company has since ceased all activities related to Topical Interferon Alpha-2b, other than maintaining existing intellectual property associated with Topical Interferon Alpha-2b.

On January 25, 2013, the Company completed the sale of its distribution business and as a result has any revenue from product distribution activities (nor does it incur the associated expenses).

The Company expects to incur additional losses for the foreseeable future and will require additional financial resources to fund the Company's ongoing research and development activities. The Company finances its research and development programs primarily from the issuance of its securities.

The Company continues to have insufficient cash reserves to meet anticipated cash needs for working capital and capital expenditures through the next twelve months. Since the Company's cash reserves as at October 31, 2015 of \$5,008,000 are not sufficient to see the current research and development initiatives through to completion, the Company will require additional financing in the near term.

The Company is considering alternative sources of securing additional financing. First, the Company is actively seeking grant money from European authorities for research and development activities in Poland. Secondly, the Company may apply to list the Company's common shares on the Warsaw Stock Exchange. There can be no assurance that the Company will be successful in receiving any grant money or that it will ultimately pursue a listing on the Warsaw Stock Exchange.

The Company intends to continue to actively explore means of securing additional financing and securing additional financing continues to be of utmost importance to the Company. However, 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 trials along with further reductions in overhead, any of which could impair the current and future value of the business.

## RESEARCH AND DEVELOPMENT ACTIVITIES

### *DOS47 – A broad anti-cancer therapeutic platform*

DOS47 is based upon a naturally occurring enzyme called urease which breaks down urea into ammonia. DOS47 candidates are produced by conjugating urease with a targeting antibody or antibody fragment that can specifically direct the urease to the surface of a cancer cell. Once docked to the cell, the urease produces ammonia enzymatically through the conversion of urea found throughout the body. These conjugates of antibodies to urease are called DOS47 candidates. By selecting antibodies that are selective to different tumour cell surface receptors, the Company believes that DOS47 candidates can be used in several types of solid tumours.

The Company believes that its DOS47 candidates may have potential anti-cancer activity because it stimulates an increase in the pH of the microenvironment surrounding the cancerous cells. The local production of ammonia at the site of cancerous tissues is thought to readily diffuse into the cancer cells and may exert a potent cytotoxic effect by interfering with their critical metabolic functions. In addition, the Company believes that the use of DOS47 candidates may also have a synergistic effect on the efficacy of other marketed chemotherapeutics, such as vinka alkylid analogues, where low pH can inhibit the cellular uptake of these agents. The Company believes the enzymatic action of urease to increase the pH at the site of cancerous cells is repetitive and sustainable due to the plentiful supply of urea that is furnished by the body.

L-DOS47 is the Company's first targeted therapeutic immunoconjugate under development based on the DOS47 technology.

L-DOS47 is an antibody protein conjugate where the urease component enzymatically converts naturally occurring urea to ammonia. The L-DOS47 drug molecule includes a highly specialized camelid-derived single domain antibody, designed to identify a unique CEACAM6 antigenic site associated with NSCLC cells. By delivering the conjugate in a targeted manner, the Company believes L-DOS47 stimulates an increase in the pH of the microenvironment surrounding the NSCLC cells, reversing the acidic extra-cellular conditions that are shown to be favourable for cancer cell survival.

L-DOS47 is intended to offer an innovative approach to the first-line treatment of inoperable, locally advanced, recurrent or metastatic NSCLC. However, other emerging therapies, including immunotherapy, may alter the treatment paradigm in NSCLC. Therefore, the eventual approval for L-DOS47 as a first-line treatment for NSCLC will depend on both successful clinical trials and on the treatment landscape shaped by these new therapies. The Company continues to monitor developments in this area and to consider their effect on its L-DOS47 program, including its focus on L-DOS47 as a first-line treatment for NSCLC.

In 2005, the Company entered into a worldwide exclusive license with the National Research Council of Canada ("NRC"), through which it obtained the rights to combine this highly specialized camelid-derived single domain antibody with Helix's DOS47 technology. As a result, the Company has certain royalty and milestone payment obligations pursuant to the license agreement. The license agreement with the NRC has been filed under the Company's profile on SEDAR at [www.sedar.com](http://www.sedar.com). The NRC filed patent applications in respect of the antibody in Canada, the United States and other countries. On March 2, 2011, the NRC was issued a U.S. patent in respect of the antibody.

The Company had prioritized the LDOS002 European Phase I/II clinical study with L-DOS47 in Poland and had previously deferred the commencement of the previously-approved U.S. Phase I clinical study with L-DOS47. The Company has since received approval for a new LDOS001 U.S. Phase I study for L-DOS47 from the FDA and has initiated three sites in connection with their study. However, as of the date of this MD&A, the Company continues to have insufficient cash resources to see either the LDOS002 European Phase I/II clinical study or the LDOS001 U.S. Phase I clinical study through to completion.

#### *U.S. Phase I clinical study ("LDOS001")*

On February 7, 2011, the Company announced it received approval by the FDA to conduct a U.S. Phase I clinical study with L-DOS47. The Company originally planned to commence the L-DOS47 U.S. Phase I study during fiscal 2012 but, given the Company's limited cash resources, the Company has prioritized the LDOS002 European Phase I/II clinical study with L-DOS47 in Poland while deferring the previously planned commencement of the U.S. Phase I clinical study with L-DOS47.

On April 22, 2014, the Company announced an IND approval by the FDA to commence a study for an L-DOS47 Phase I, open label, dose escalation study in combination with standard doublet therapy of pemetrexed/carboplatin in patients with Stage IV recurrent or metastatic non-squamous NSCLC. The Company has initiated three U.S. sites: Dr. Sarina Piha-Paul at the MD Anderson Cancer Center, Dr. Chandra Belani at Penn State University and the Milton S., Hershey Medical Center, and Dr. Afshin Dowlati at University Hospitals Case Medical Center. The first patient was dosed in the US Phase I clinical study on April 20, 2015 at the MD Anderson Cancer Center. Three patients have been dosed at the first L-DOS47 dose level 0.59 µg/kg and a third patient is currently being screened.

The Company continues to have insufficient cash resources to see the entire LDOS001 U.S. Phase I clinical study through to completion.

*European Phase I/II clinical study in Poland (“LDOS002”)*

On July 25, 2011, Helix announced that the Company had received approval from the Central Register of Clinical Trials at the Polish Ministry of Health to perform a European Phase I/II clinical study with L-DOS47 and, on May 14, 2012, announced that clinical site initiation and patient recruitment activities had commenced for its European Phase I/II clinical study of L-DOS47. On October 23, 2012, the Company announced that its first patient had been enrolled and the first dose had been administered in this study.

The study is being conducted at five Polish centers under the direction of Dr. Dariusz Kowalski at The Maria Skłodowska-Curie Memorial Cancer Centre & Institute of Oncology as the overall coordinating investigator, together with four other principal investigators: Prof. Cezary Szczylik, MD, PhD at the Military Medical Institute, Prof. Elzbieta Wiatr, MD, PhD at the National Tuberculosis and Lung Diseases Research Institute, Dr. Aleksandra Szczensa, MD, PhD at the Mazovian Center of Pulmonary Diseases and Tuberculosis in Otwock and Prof. Rodryg Ramlau, MD, PhD at Med. Polonia Hospital Poznan.

The study is being conducted in patients with inoperable, locally advanced, recurrent or metastatic, non-squamous stage IIIb/IV NSCLC.

The study, which is now well underway, recruits patients eligible for inclusion into escalating doses of L-DOS47 given as a monotherapy. The study utilizes an open-label design, allowing for periodic status updates through its course. The study is intended to demonstrate valuable safety and proof-of-concept efficacy data for L-DOS47.

Patients in the study receive weekly doses of L-DOS47, administered as an intravenous infusion over 14 days, followed by seven days' rest (one treatment cycle is three weeks). Once the MTD of L-DOS47 has been determined in Phase I, an estimated 20 patients will be enrolled to evaluate the preliminary efficacy of L-DOS47 in the Phase II portion of the study.

The total number of patients to be enrolled in the Phase I portion of the study will depend on how many escalating dose levels are required to reach MTD. The Company originally estimated that MTD would be reached after enrolling eight cohorts of three patients each. Management also originally assumed that there would be two dose limiting toxicities (“DLT”) events requiring a further six patients to be enrolled, for a total of up to 30 patients by the time the study dosed patients in Cohort 8. However, L-DOS47 continued to display a good safety profile. In clinical study LDOS002, L-DOS47 is approved for dosing up to Cohort 16. This will allow the Company to study the highest safe dose to be administered in the Phase II portion of the study. The Company has now enrolled 52 patients and completed enrollment in the 14th dosing cohort. The Company intends to enroll up to MTD or Cohort 16, whichever event occurs first. Study patients are male or female, at least 18 years of age, with histologically confirmed non-squamous NSCLC. Patients have an Eastern Cooperative Oncology Group performance status of 0 – 2 at the screening visit for this study, and have at least one site of measurable disease per RECIST v1.1.

Efficacy evaluation of L-DOS47 is based upon response rate using the RECIST version 1.1 criteria, disease progression and survival. Monitoring includes radiologic evaluations prior to the first dose to establish a baseline and every six weeks thereafter (“Radiologic Evaluations”). For all patients (Phase I and II), treatment with L-DOS47 will continue until the patient experiences disease progression or unacceptable toxicity, the patient withdraws consent, or the patient has completed four treatment cycles and does not wish to continue with additional cycles, whichever occurs first. After four treatment cycles, at the discretion of the investigator and in consultation with the medical monitor, patients who experience clinical benefit may be eligible to continue L-DOS47 for as long as the treatment is well tolerated and the clinical benefit is sustained.

For Cohorts 1 through 12, doses of 0.12, 0.21, 0.33, 0.46, 0.59, 0.78, 1.04, 1.38, 1.84, 2.45, 3.26, and 4.33 of L-DOS47 per kilogram of patient body weight have been successfully administered to study patients with no DLTs. In Cohort 13, of the three patients that were dosed at 5.76 micrograms, one of these patients experienced an adverse event that met the definition of DLT. After review, the Trial Steering Committee agreed to expand Cohort 13 to an additional three patients per the clinical trial protocol.

On February 10, 2015 the central ethics committee overseeing the Phase I clinical study in Poland approved additional dose levels in the Phase I component of the LDOS002 study in anticipation of continued dose escalation beyond the 4.33 µg/kg administered to patients in Cohort 12. The additional four cohort (Cohorts 13 to 16) approved dose levels include 5.76, 7.66, 10.19 and 13.55 µg/kg. The Phase II component will start after the maximum tolerated dose of L-DOS47 is determined in Phase I and is expected to enrol 20 patients to evaluate the preliminary efficacy of L-DOS47.

The Company has now completed two interim data reviews in connection with the LDOS002 study. On October 15, 2013, the Company announced the completion of an interim data review of the first four cohorts for this study. The release stated that L-DOS47 was well tolerated for all patients treated within all cohorts. None of the treatment related adverse events reported to date has met the definition of a dose-limiting toxicity. Adverse events reported as of that date are those normally expected for the population under study.

A review of available pharmacokinetic (“PK”) and immunogenicity data showed that these data so far, are consistent with trends seen within pre-clinical animal studies of L-DOS47. Results from these reviews, together with safety data will provide guidance on the treatment schedule and dosing for the Phase II portion of the study.

Based on Radiologic Evaluations, patients assigned a status of "Progressive Disease" following any such assessment were withdrawn from the study. At least one patient in each of the four cohorts dosed had a radiological assessment of "Stable Response". Duration of treatment increased with each dose escalation up to Cohort 4. One patient in Cohort 3 was dosed for 6 cycles without disease progression. None of the patients treated to date have had a partial or complete response as defined by RECIST v1.1 definition.

On September 30, 2014, the Company announced the completion of a further interim data review for the first eight cohorts for the LDOS002 study. The review included all available data, including patient demographics, safety assessments, PK data, immunogenicity and radiological tumour assessments. The following observations were made:

- adverse events reported are those expected for investigational product and population under study;
- no DLTs have been reported;
- stable disease observed in radiological assessments of 12 of 24 (50%) of patients treated; and
- two patients completed six cycles of treatment each.

On September 8, 2015, the Company announced the presentation and update of the ongoing clinical study LDOS002 for the Company's drug candidate L-DOS47 during the 16th World Conference on Lung Cancer held in Denver Colorado. The presentation included the following data:

- forty (40) patients were enrolled in the first twelve dosing cohorts;
- L-DOS47 was well tolerated at the dose levels up to 4.33 µg/kg;
- No Dose Limiting toxicities ("DLT") were reported for Cohorts 1-12;
- One (1) DLT was reported for Cohort 13;
- adverse events reported to date were expected for the population under study;
- twenty-one (21) of the forty (40) patients had an overall response of stable disease based on radiological assessment after completing two cycles of L-DOS47;
- eleven (11) of these 21 patients continued with a response of stable disease based on radiological assessment after completing four cycles of L-DOS47;
- one patient in cohort 9 was dosed for ten 10 cycles (approximately seven (7) months) without disease progression;
- the study is currently enrolling patients in the thirteen dosing cohort (5.76 µg/kg).

On November 4, 2015, the Company announced the initiation of enrollment of Cohort 14 after the Trial Steering Committee's safety review of Cohort 13. During the dosing of the thirteenth cohort, one patient experienced a serious adverse event that meets the definition of a DLT. The patient was withdrawn from further dosing and subsequently recovered from the event. In accordance with the protocol, Cohort 13 was expanded to enroll three new patients. No new DLT was observed.

Based on safety information provided by Helix, the Central Ethics Committee and the Polish Competent Authority have previously approved the dosing of patients up to Cohort 16. This allows the Trial Steering Committee to recommend dose escalation of 7.66 µg/kg for Cohort 14, 10.19 µg/kg for Cohort 15 and 13.55 µg/kg for Cohort 16, assuming there are no safety issues. It is the Company's intention not to dose beyond Cohort 16. Rather, the Company will consider moving into the Phase II portion of the study as soon as MTD is observed or when Cohort 16 is completed.

The Company continues to have insufficient cash resources to see the entire LDOS002 European Phase I/II clinical study in Poland through to completion. 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 trials along with further reductions in overhead, any of which could impair the current and future value of the business.

#### *Phase I/II clinical study ("LDOS003")*

The Company continues to assess the viability of an LDOS003 clinical study of L-DOS47 in combination with VIN/CIS in patients with metastatic or advanced solid tumours. Following discussions with key advisors, the Company is considering a re-design of the LDOS003 study to focus on advanced stage lung cancer patients by combining L-DOS47 with VIN/CIS.

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 trials along with further reductions in overhead, any of which could impair the current and future value of the business.

#### *Additional potential therapeutic applications of L-DOS47*

The Company is evaluating L-DOS47 for other potential therapeutic applications beyond NSCLC, such as in colorectal, breast and pancreatic cancer types as well as other alternatives to current first-line therapies or in the use as adjuvant/neoadjuvant therapies. In addition, the Company is also exploring the interaction of L-DOS47 with the human immune system. Subject to positive outcomes from these evaluations and the availability of sufficient cash and other resources, the Company intends to

evaluate the possibility of expanding its clinical testing program of L-DOS47 beyond NSCLC, and the potential of combining L-DOS47 with immunotherapies in the future.

#### *New potential DOS47 drug candidates*

The Company continues to reach out to third parties in order to identify and test additional tumor-targeting antibodies for conjugation with DOS47. In the event that antibody candidates worthy of further development are identified, the Company will need to discuss development and licensing arrangements, which may not be available on terms acceptable to the Company or at all.

In fiscal 2012, the Company entered into a collaborative research agreement with Amorfis Life Science Inc. (“Amorfis”) to develop therapeutics against cancers associated with misfolded prion protein.

In January 2015, Amorfis announced the closing of their laboratory in Mississauga and plans to relocate to San Francisco. The Company has suspended all research activity in this project. Amorfis has also announced a name change to ProMIS Neurosciences in July 2015. In fiscal 2015, the Company entered into a collaborative research agreement with Affillogic to assess proprietary anti-tumor targeting agents in combination with DOS47. The agreement calls for a feasibility study using a targeting agent in conjugation with DOS47. Continuing development of these new conjugates is subject to a successful feasibility study, execution of a formal development and licensing agreement, and the availability sufficient financial resources.

#### *Commercialization*

The Company's commercialization objective with DOS47 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. In the meantime, the Company's objective is to continue generating value-adding clinical 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*

Based on information published in “Cancer Facts and Figures 2015” by the American Cancer Society ([www.cancer.org](http://www.cancer.org)), lung cancer accounts for about 27% of all cancer deaths and is by far the leading cause of cancer death among men and women in the U.S. It is estimated that in 2015 there will be over 221,200 new lung cancer cases.

If detected early, surgical removal of the cancerous tissue is currently a patient's best option. However, in the vast majority of cases, the cancer is not typically identified until it has advanced to a level at which surgical intervention is no longer an option. In the cases of inoperable, locally advanced, recurrent or metastatic NSCLC and with no known targetable mutations, treatment strategies consist of one or more of today's leading chemotherapeutic drug regimens for lung cancer (e.g. platinum therapy together with certain leading chemotherapeutic drugs). Typically, these regimens relieve symptoms and, at best, delay progression of the disease.

Disease progression, even with targeted therapies, is highly likely to occur, and there are no clear guidelines and/or indications once such therapies fail. Maintenance therapy following the induction of first-line therapy is also a treatment strategy gaining support.

Immunotherapies such as immune checkpoint inhibitors that target Programmed Death 1 (“PD-1”) or its ligands, Programmed Death Ligand 1 or 2 (“PD-L1” and “PD-L2”) are showing significant clinical successes in NSCLC. 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. More recently, 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 whose disease has progressed after other treatments and with tumors that express PD-L1. Anti-PD-L1 drugs such as MPDL3280A from Roche are also advancing rapidly through late stage clinic trials. The company anticipates some of these approved drugs will eventually be approved as front line therapies for advanced stage NSCLC.

These and other rapidly advancing immunotherapy treatments, currently in development, have the potential to significantly alter the treatment of cancer, not in just one cancer type but across many cancer types. As a result of these developments in immunotherapies, and in particular with the success of immunotherapies in the treatment of NSCLC, the Company is currently reassessing its L-DOS47 clinical program given that: (a) its target therapeutic indication, being inoperable, locally-advanced, recurrent or metastatic NSCLC, may be a good candidate to combine with the emerging best-in-class immunotherapies; and (b) leading therapeutics for such oncology applications have commonly been high revenue generators for the pharmaceutical sector.

Technological competition from pharmaceutical companies, biotechnology companies and university researchers is intense and is expected to continue to be very intense. Many competitors and potential competitors have substantially greater product development capabilities and financial, scientific, marketing and human resources than the Company, providing them with a competitive advantage over the Company.

### *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.

### *Topical Interferon Alpha-2b*

The Company received investigational new drug (“IND”) approval by the FDA to conduct a U.S. Phase II/III clinical trial of Topical Interferon Alpha-2b in low-grade cervical dysplasia patients, as well as Clinical Trial Application (“CTA”) approval by the Bundesinstitut für Arzneimittel und Medizinprodukte and conditional CTA approval by the Medicines and Healthcare Regulatory Authority to conduct an identical European Phase III confirmatory trial in Germany and/or the United Kingdom, respectively.

Due to a lack of funding, a decision was made by the Company in fiscal 2012 to downsize and eventually close the Saskatoon laboratory which supported the Topical Interferon Alpha-2b drug development program, and focus any ongoing activities to sourcing and qualifying alternative interferon alpha-2b raw material samples, and finding suitable strategic partner(s) who would be willing to license or acquire the product and support the remaining development costs through to commercial launch. The Company has since ceased all activities related to Topical Interferon Alpha-2b, other than maintaining existing intellectual property associated with Topical Interferon Alpha-2b.

## **SELECTED FINANCIAL INFORMATION AND SUMMARY OF QUARTERLY RESULTS**

The tables below reflect only selected annual and quarterly financial information of the Company’s continuing operations.

Net loss and total comprehensive loss from continuing operations, over the last eight quarters, ranged from a high of \$2,665,000 in fiscal Q2 2015 to a low of \$1,804,000 in fiscal Q4 of 2014 with fluctuations mainly dependant on the level of research and development activities and operating, general and administration expenses.

Included in the research and development expense for fiscal Q2 2014 is a one-time payout of \$500,000 related to the termination of the Company’s former President and Chief Operating Officer. Lower research and development expenses in both Q4 2015 and 2014 are mainly the result of the Company recording investment tax credits.

The higher operating, general and administration expenditures in Q1 2016 reflects higher legal, investor and media relations and other consulting arrangements associated mainly with ongoing efforts by the Company to raise financing. Increased costs in Q2 of fiscal 2015 and Q2 of fiscal 2014 were mainly the result of stock-based compensation expense for options granted to directors of the Company. In addition Q4 2015 and Q2 2015 also included various expenditures associated with the Company’s exploration of growth alternatives. In late fiscal 2014, the Company’s board of directors (the “Board”) approved a new policy regarding awarding options to directors, after a peer review with other comparable companies in the biotechnology sector.

In fiscal Q3 2015, the Company closed two private placements for net proceeds of \$8,243,000. In fiscal 2014, the Company closed two private placements for net proceeds of \$5,481,000 in Q4 2014 and \$4,672,000 in Q2 2014, respectively.

The following table depicts selected quarterly data from continuing operations for the last eight fiscal quarters:

(thousand \$, except per share information)								
	Q1 2016	Q4 2015	Q3 2015	Q2 2015	Q1 2015	Q4 2014	Q3 2014	Q2 2014
Research and development	1,339	983	1,216	1,442	1,244	973	1,285	1,649
Operating, general and administration	1,259	1,138	687	1,181	886	830	829	1,011
Net loss and total comprehensive loss	(2,592)	(2,119)	(1,871)	(2,665)	(2,125)	(1,804)	(2,109)	(2,632)
Loss per share - basic & fully diluted	(0.03)	(0.02)	(0.03)	(0.03)	(0.03)	(0.02)	(0.03)	(0.04)
Cash	5,008	6,792	9,151	2,723	4,814	6,980	2,832	4,386



## RESULTS FROM OPERATIONS

### *Net loss and total comprehensive loss from continuing operations*

The Company recorded a net loss and total comprehensive loss of \$2,592,000 (\$0.03 loss per common share) and \$2,125,000 (\$0.03 loss per common share) for the three-month periods ended October 31, 2015 and 2014, respectively.

### *Research & development*

Research and development costs for the three-month periods ended October 31, 2015 and 2014 totalled \$1,339,000 and \$1,244,000, respectively. The following table outlines research and development costs expensed and investment tax credits for the Company's significant research and development projects for the three-month periods ended October 31:

	2015	2014
L-DOS47	\$ 1,094,000	\$ 950,000
Corporate research and development expenses	142,000	165,000
Trademark and patent related expenses	73,000	80,000
Stock-based compensation expense	—	15,000
Depreciation expense	30,000	34,000
	<b>\$ 1,339,000</b>	<b>\$ 1,244,000</b>

L-DOS47 research and development expenses for the three-month periods ended October 31, 2015 and 2014 totalled \$1,094,000 and \$950,000, respectively. The higher L-DOS47 research and development expenses in the three-month period ended October 31, 2015 relate primarily to expenditures associated with the ongoing expansion of European Phase I/II clinical study in Poland.

Corporate research and development expenses for three-month periods ended October 31, 2015 and 2014 totalled \$142,000 and \$165,000, respectively, with the decrease mainly related to lower travel expenses.

Trademark and patent related expenses for the three-month periods ended October 31, 2015 and 2014 totalled \$73,000 and \$80,000, respectively.

### *Operating, general and administration*

Operating, general and administration expenses for the three-month periods ended October 31, 2015 and 2014 totalled \$1,259,000 and \$886,000, respectively. The increase in operating, general and administration expenses reflects higher legal, investor and media relations and other consulting arrangements associated mainly with ongoing efforts by the Company to raise financing.

## SIGNIFICANT ACCOUNTING POLICIES

The accounting policies set out below have been applied consistently to all periods presented in these consolidated financial statements.

### *Use of estimates and assumptions*

The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the year. Actual results could differ from those estimates. Significant areas requiring the use of estimates include research and development tax credits associated with research and development expenditures, the determination of fair value of stock options granted for estimating stock-based compensation, the allocation of proceeds to share purchase warrants, estimates related to the determination of useful lives and assessment of impairment of long-lived assets such as property, plant and equipment. In determining these estimates, the Company relies on assumptions regarding applicable industry performance and prospects, as well as general business and economic conditions that prevail and are expected to prevail. These assumptions are limited by the availability of reliable comparable data and the uncertainty of predictions concerning future events. Actual results could differ from these estimates.

### *Functional and presentation currency*

The functional and presentation currency of the Company is the Canadian dollar.

### *Basis of consolidation*

These consolidated financial statements include the accounts of the Company and its subsidiaries listed below. Control is achieved when the Company has the power to govern the financial and operating policies of an entity so as to obtain benefits from its

activities. Subsidiaries are fully consolidated from the date on which control is acquired by the Company. Inter-company transactions and balances are eliminated upon consolidation. They are de-consolidated from the date that control by the Company ceases. The consolidated financial statements include the assets and liabilities and results of operations of all subsidiaries after elimination of intercompany transactions and balances.

As at October 31, 2015, the subsidiaries of the Company include: Helix BioPharma Inc., incorporated in the USA, Helix Polska sp.z.o.o incorporated in Poland and Helix Product Development (Ireland) Limited, incorporated in Ireland. All these subsidiaries are 100% owned by Helix BioPharma Corp.

**Cash**

The Company considers cash on hand, deposits in banks and bank term deposits with maturities of 90 days or less as cash.

**Property, plant and equipment**

Property, plant and equipment are recorded at cost less accumulated depreciation. Impairment charges are included in accumulated depreciation. Depreciation is provided using the following methods and estimated useful life:

Asset	Basis	Rate
Computer equipment and software	Straight line	3 years
Furniture and fixtures	Straight line	5 years
Research and manufacturing equipment	Straight line	10 years
Leasehold improvements	Straight line	Lease term

**Research and development costs**

Research costs are expensed as incurred. Development costs are expensed as incurred except for those which meet the criteria for deferral, in which case, the costs are capitalized and amortized to operations over the estimated period of benefit. No costs have been deferred to date.

**Investment tax credits**

The Company is entitled to Canadian federal and provincial investment tax credits, which are earned as a percentage of eligible research and development expenditures incurred in each taxation year. Investment tax credits are accounted for as a reduction of the related expenditure for items of a current nature and a reduction of the related asset cost for items of a capital nature, provided that the Company has reasonable assurance that the tax credits will be realized.

**Stock-based compensation**

The Company accounts for stock-based compensation and other stock-based payments made in exchange for goods and services provided by employees and non-employees in accordance with the fair value method. The fair value of stock options granted is determined at the appropriate measurement date using the Black-Scholes option pricing model, and generally expensed over the options' vesting period for employee awards and non-employee awards. Awards with graded vesting are considered multiple awards for fair value measurement and stock-based compensation calculation. In determining the expense, the Company accounts for forfeitures using an estimate based on historical trends.

**Income taxes**

The Company follows the asset and liability method of accounting for income taxes. Under this method, deferred income tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of certain existing assets and liabilities and their respective tax bases. Deferred income tax assets and liabilities are measured using enacted or substantively enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the date of substantive enactment. Given the Company's history of net losses and expected future losses, the Company is of the opinion that it is probable that these tax assets will not be realized in the foreseeable future and therefore, the deferred tax asset has not been recognized.

**Financial instruments**

Financial assets and financial liabilities are initially recorded at fair value and their subsequent measurements are determined in accordance with their classification. The classification depends on the purpose for which the financial instruments were acquired or issued and their characteristics. Cash and cash equivalents are classified as held-for-trading assets and are accounted for at fair value. Accounts receivable are classified as loans and receivables, and after initial recognition are recorded at amortized cost. Accounts payable and accrued liabilities are classified as other financial liabilities, and after initial recognition are recorded at amortized cost.

## **Impairment**

### *(i) Financial assets:*

A financial asset not carried at fair value through profit or loss is assessed at each reporting date to determine whether there is objective evidence that it is impaired. A financial asset is impaired if objective evidence indicates that a loss event has occurred after the initial recognition of the asset, and that the loss event had a negative effect on the estimated future cash flows of that asset that can be estimated reliably.

An impairment test is performed, on an individual basis, for each material financial asset. Other individually non-material financial assets are tested as groups of financial assets with similar risk characteristics. Impairment losses are recognized in income.

An impairment loss in respect of a financial asset measured at amortized cost is calculated as the difference between its carrying amount and the present value of the estimated future cash flows discounted at the asset's original effective interest rate. Losses are recognized in income and reflected in an allowance account against the respective financial asset. Interest on the impaired asset continues to be recognized through the unwinding of the discount. When a subsequent event causes the amount of impairment loss to decrease, the decrease in impairment loss is reversed through income for all financial assets except available-for-sale equity securities.

### *(ii) Non-financial assets:*

The carrying amounts of the Company's non-financial assets are reviewed at each reporting date to determine whether there is any indication of impairment. If such an indication exists, the recoverable amount is estimated.

The recoverable amount of an asset or a cash-generating unit is the greater of its value in use and its fair value less costs to sell. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset or cash-generating unit. For the purpose of impairment testing, assets that cannot be tested individually are grouped together into the smallest group of assets that generates cash inflows from continuing use that are largely independent of cash inflows of other assets or cash-generating units. An impairment loss is recognized if the carrying amount of an asset or its related cash-generating unit exceeds its estimated recoverable amount.

Impairment losses recognized in prior periods are assessed each reporting date for any indications that the loss has decreased or no longer exists. An impairment loss is reversed if there has been a change in the estimates used to determine the recoverable amount. An impairment loss is reversed only to the extent that the asset's carrying amount does not exceed the carrying amount that would have been determined, net of depreciation, if no impairment loss had been recognized.

## **Basic and diluted loss per common share**

Basic loss per share is computed by dividing the net loss available to common shareholders by the weighted average number of shares outstanding during the reporting period. Diluted loss per share is computed similarly to basic loss per share, except that the weighted average shares outstanding are increased to include additional shares for the assumed exercise of stock options and warrants, if dilutive. The number of additional shares is calculated by assuming that outstanding stock options and warrants were exercised and that the proceeds from such exercises were used to acquire common stock at the average market price during the reporting periods. The inclusion of the Company's stock options and warrants in the computation of diluted loss per share has an anti-dilutive effect on the loss per share and, therefore, they have been excluded from the calculation of diluted loss per share.

## **NEW ACCOUNTING STANDARDS AND PRONOUNCEMENTS NOT YET ADOPTED**

New accounting standards and pronouncements issued but not yet effective up to the date of issuance of the Company's consolidated financial statements are listed below. This listing includes standards and interpretations issued, which the Company reasonably expects to be applicable at a future date. The Company intends to adopt those standards when they become effective.

Certain pronouncements have been issued by the IASB or International Financial Reporting Interpretations Committee. Many of these updates are not applicable or are inconsequential to the Company and have been excluded from the discussion below:

### **IFRS 1, Presentation of Financial Statements**

In December 2014, the IASB issued amendments to IAS 1, Presentation of Financial Statements as part of the IASB's disclosure initiative. These amendments encourage entities to apply professional judgment regarding disclosures and presentation in their financial statements. The amendments are effective for annual periods beginning on or after January 1, 2016 with early adoption permitted. The Company is evaluating the impact of the new standard on its results of operations, financial position and disclosures.

### ***IFRS 9, Financial Instruments***

The IASB has issued a new standard, IFRS 9, Financial Instruments ("IFRS 9"), which will ultimately replace IAS 39, Financial Instruments: Recognition and Measurement ("IAS 39"). The project had three main phases: classification and measurement, impairment and general hedging. The standard becomes effective for annual periods beginning on or after January 1, 2018 and is to be applied retrospectively. Early adoption is permitted. The Company is evaluating the impact of the new standard on its results of operations, financial position and disclosures.

### ***IFRS 15, Revenue from Contracts with Customers***

The IASB has issued a new standard, IFRS 15, Revenue from Contracts with Customers ("IFRS 15"). IFRS 15 contains a single model that applies to contracts with customers and two approaches to recognizing revenue: at a point in time or over time. The model features a contract-based five-step analysis of transactions to determine whether, how much and when revenue is recognized. New estimates and judgmental thresholds have been introduced, which may affect the amount and/or timing of revenue recognized. The standard becomes effective for annual periods beginning on or after January 1, 2017. The Company is evaluating the impact of the new standard on its results of operations, financial position and disclosures.

## **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's cash reserves of \$5,008,000 as at October 31, 2015 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 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 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 can be particularly challenging for companies that operate in the biotechnology industry.

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

Given the Company's conclusion about the insufficiency of its cash reserves, significant doubt 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 total number of 84,663,837 common shares issued and outstanding as at October 31, 2015 and the Company's working capital on October 31, 2015 was \$4,003,000.

## **RELATED PARTY TRANSACTIONS**

The key management personnel of the Company include the Interim Chief Executive Officer, Chief Financial Officer and Chief Scientific Officer. In addition to the aforementioned key management personnel, the table below also includes compensation for the former President and Chief Executive Officer and former Director of Clinical Development.

The following table summarizes for key management personnel compensation for the three month periods ended:

	October 31 2015	October 31 2014
Compensation	\$ 268,000	\$ 325,000
Stock-based compensation	11,000	52,000
	\$ 279,000	\$ 377,000

The following table summarizes total directors' compensation for the three month periods ended:

	October 31 2015	October 31 2014
Directors' fees and expense reimbursement	\$ 113,000	\$ 84,000
Stock-based compensation	63,000	31,000
	\$ 176,000	\$ 115,000

During the second quarter of fiscal 2014, a consultancy agreement was entered into with a current director of the Company to provide consulting services. The consultancy agreement has an initial term lasting three months and automatically renews for an additional three months unless the Company gives written notice not less than thirty days prior to the end of the initial term.

The following table summarizes the Board Observer's compensation for the three month periods ended:

	October 31 2015	October 31 2014
Financial and investor relations agreement	\$ 136,000	\$ 158,000
Expense reimbursement	3,000	–
	\$139,000	\$ 158,000

The Company entered into a non-exclusive financial and investor relations agreement with ACM Alpha Consulting Management EST ("ACMest"), effective May 1, 2012. On March 7, 2014, Mr. Andreas Kandziora was appointed as an Observer to the Board. Mr. Kandziora is President and Chief Executive Officer of ACMest.

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

## FINANCIAL INSTRUMENTS

The Company has classified its financial instruments as follows:

	October 31, 2015		July 31, 2015	
	Fair Value	Fair value hierarchy	Fair Value	Fair value hierarchy
Cash	\$ 5,008,000	Level 1	\$ 6,792,000	Level 1

### *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, 2015 and July 31, 2015 approximates their carrying value because of the near-term maturity of these instruments.

### **INTELLECTUAL PROPERTY**

Patents and other proprietary rights are very valuable to the Company, even though the patent positions of biotechnology companies may be uncertain and involve complex legal and factual issues. The Company has no assurance that any of its patent applications will result in the issuance of any 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 struck down if challenged. Intellectual property laws do not protect intellectual property to the same extent from one country to another.

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 disease indications. 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 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. The scope and duration of our intellectual property rights vary from country to country depending on the nature and extent of our intellectual property filings, the applicable statutory provisions governing the intellectual property, and the nature and extent of our legal rights. 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 us that contain assignment of invention clauses outlining ownership of any intellectual property developed during the course of the individual's relationship with us.

### ***DOS47***

The Company currently owns two U.S. patents in respect of the DOS47 technology, and also has also licensed patent rights from the NRC for the antibody component of L-DOS47. With respect to non-U.S. patents, the Company owns 52 DOS47 related patents in other jurisdictions with a number of patent applications in countries around the world. The Company has recently filed a joint patent application in the U.S. with Amorfix to cover the antibody-DOS47 conjugates derived from their collaboration (see "*New potential DOS47 Candidates*" above). A new U.S. patent application to cover new features of the DOS47 technology was filed by the Company during fiscal 2013. During January 2014, an additional U.S. patent application covering specific L-DOS47 manufacturing and novel features was filed.

### ***Biphasix™***

The Company currently owns seven U.S. Biphasix™ patents.

### **OFF-BALANCE SHEET ARRANGEMENTS**

The Company has no material off-balance sheet arrangements.

### **QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

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

### ***Currency risk***

The Company operates internationally and is exposed to foreign exchange risks from various currencies, primarily the Euro and U.S. dollar. Foreign exchange risks arise from the foreign currency translation of the Company's integrated foreign operation in Ireland. In addition, foreign exchange risks arise from purchase transactions, as well as recognized financial assets and liabilities denominated in foreign currencies.

The Company has maintained minimal cash balances denominated in both Euro and U.S. dollars due to Canadian dollar stability and strength against foreign currencies. Any fluctuation in the exchange rates of the foreign currencies listed 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.

Balances in foreign currencies at are as follows:

	October 31, 2015		July 31, 2015	
	Euros	US Dollars	Euros	US Dollars
Cash	17,000	3,000	8,000	7,000
Accounts payable	(182,000)	(148,000)	(9,000)	(30,000)
Accruals	(173,000)	(71,000)	(162,000)	(2,000)
Net foreign currencies	(338,000)	(216,000)	(163,000)	(25,000)
Closing exchange rate	1.4377	1.3075	1.4388	1.3047
Impact of 1% change in exchange rate	+/- 2,000	+/- 1,000	+/- 1,000	+/- 1,000

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:

	October 31, 2015	July 31, 2015
Accounts receivable		
Government related – HST/VAT	\$ 70,000	\$ 96,000
Research and development investment tax credits	204,000	388,000
Other	4,000	7,000
	\$ 278,000	\$ 491,000

### **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 and cash equivalents. 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 \$5,008,000 as at October 31, 2015 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.

## **OUTSTANDING SHARE DATA**

As at October 31, 2015, the Company had outstanding 84,663,837 common shares; warrants to purchase up to 19,938,584 common shares; and incentive stock options to purchase up to 2,372,084 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.

The CEO and the CFO have identified a number of significant deficiencies in the design and operating effectiveness of the Company's ICFR as at October 31, 2015 that collectively constitute a material weakness relating to the operation of the Company's ICFR:

(a) a failure to adhere to Company standards with respect to the control environment throughout the management structure of the Company and its subsidiaries, including ineffective communication and reporting to the CFO with respect to costs incurred and commitments made by one of the Company's subsidiaries,

(b) a failure by management of one of the Company's subsidiaries to comply with existing Company policies with respect to the opening of bank accounts, including failure to adhere to Company standards for authorizing the opening of subsidiary bank accounts and for designating signing authorities resulting in accounts being opened by that subsidiary with only one signatory without compensating controls (Company policy requires two signatories and/or sufficient compensating controls to ensure the safeguarding of assets),

(c) changes to the directors and officers of one of the Company's subsidiaries being made without compliance with the Company's internal policies respecting such appointments, and

(d) inadequate monitoring of activities of certain consultants retained by the Company on behalf of one of its subsidiaries to confirm that the work of such consultants is being carried out in accordance with management's instructions and the failure of that subsidiary to report on the activities of certain consultants retained by that subsidiary to senior management on a timely basis.

Although the CEO and CFO are not aware of these deficiencies having actually resulted in a material misstatement of a financial statement amount or disclosure, they have determined that, taken together, these deficiencies could result in business and accounting practices that could put both the Company's reputation and its financial reporting at risk and leads 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. This material weakness in the Company's ICFR should also be considered a weakness in the Company's disclosure controls and procedures that is significant.

Management has concluded that it needs to better educate employees including the newly appointed CEO of the Company's Polish subsidiary, certain consultants involved with one of its subsidiaries and the Company agents/representatives regarding Company standards and expectations and is in the process of determining the necessary steps to revise signing authorities and appointment procedures and to improve internal control documentation and communication amongst the various parties.

Initial steps have been taken by the Chairman and in turn followed up by the CEO to communicate the Company's standards to the newly appointed CEO of the Company's Polish subsidiary and the Company's legal advisor in Poland that they report and take direction from the CEO of Helix BioPharma Corp. and not from parties contracted to provide investor relations services to the Company or any other representatives of the Company.



## **RISKS AND UNCERTAINTIES**

Helix is subject to risks, events and uncertainties, or “risk factors”, associated with being both a publicly traded company operating in the biopharmaceutical industry, and as an enterprise with several projects in the research and development stage. 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. As a result, the Company will have 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 financing, if secured, would result in dilution to existing shareholders, and that such dilution may be significant.

### ***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 pharmaceutical product candidates. The research and development of pharmaceutical products requires 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, 2015 is \$138,248,000. 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 its existing European Phase I/II clinical trial with L-DOS47 in Poland or its U.S. Phase I trial or any of the Company's other ongoing research and development, 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 will therefore continue to rely on equity financing to fund its ongoing research and development activities and other expenses for the foreseeable future.

Equity financing has historically been the Company's primary source of funding; however, the market for equity financings for companies such as the Company is challenging. 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 which may be significant. The Company may also seek additional funding from or through other sources, including grants, technology licensing, co-development collaborations, disposition of assets, 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. 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, 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.

### ***Competition and technological change; Immunotherapies***

The biotechnology and pharmaceutical industries are 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 now has the potential 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. Furthermore developments in immunotherapies may require the Company to reposition its L-DOS47 drug product candidate from a front line monotherapy to a combination therapy with immunotherapies or other treatment protocols, and any such repositioning, would likely result in additional expenses being incurred by the Company and in 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 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 clinical trials, manufacturing of drug products, and marketing.

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.

***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.

***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 tumor targeting agents, there can be no assurance that any such tumor targeting agents will be identified or that any new DOS47-based therapeutics will be developed.

***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 our 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 a field whose firms are 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 claim 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.

***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 two 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.

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

***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.

***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.

### ***Volatility of share price and trading volumes***

The price of the Company's 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. 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.

### ***Trading in the Company's 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 shares trade on the TSX and are freely tradable only in Canada. As such, shareholders trading the Company's 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.

## **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](http://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 fiscal year ended July 31, 2015, is available under the Company's profile on SEDAR at [www.sedar.com](http://www.sedar.com).

Dated December 11, 2015