

# 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 years ended July 31, 2014, and 2013 and the accompanying notes thereto, which have been prepared in accordance with International Financial Reporting Standards ("IFRS") and depict values that are 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, 2014, which is available on SEDAR at [www.sedar.com](http://www.sedar.com).

## FORWARD-LOOKING STATEMENTS AND INFORMATION

This Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements and information (collectively, "forward-looking statements") within the meaning of applicable Canadian securities laws. Forward-looking statements are statements and information that are not historical facts but instead include 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 its two drug candidates, L-DOS47 and Topical Interferon Alpha-2b (cervical lesions indication) and other information relating to future periods. Forward-looking statements include, 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 one or both of L-DOS47 and Topical Interferon Alpha-2b; (iii) the Company's priority continuing to be L-DOS47; (iv) the Company's development programs for Topical Interferon Alpha-2b, DOS47 and L-DOS47, including but not limited to, extension of the drug candidates 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 trial for L-DOS47 in Poland, including the number of cohorts required to reach Maximum Tolerable Dose ("MTD"); (vi) the Company's planned future U.S. Phase I clinical trial for L-DOS47 and the Company's anticipated resubmission of its Clinical Trial Application ("CTA") in Canada or possible similar submissions in other jurisdictions, (vii) U.S. Phase II/III and European Phase III clinical trials for Topical Interferon Alpha-2b (low-grade cervical dysplasia); (viii) seeking strategic partner support and therapeutic and market opportunities for the two drug candidates; (ix) the nature, design and timing of future clinical trials and commercialization plans; (x) future expenditures, insufficiency of the Company's current cash resources and the need for financing; and (xi) future financing requirements, the seeking of additional funding and anticipated future operating losses. Forward-looking statements can further be identified by the use of forward-looking terminology such as "expects", "plans", "designed to", "potential", "believe", "intended", "continues", "opportunities", "anticipated", "2015", "next", "ongoing", "to seek", "proceed", "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 statements are 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 statements are reasonable, such statements involve risks and uncertainties, and undue reliance should not be placed on such statements. Forward-looking statements, 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 statements contained in this Management's Discussion and Analysis of Financial Condition and Results of Operations 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 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;
- the possibility of dilution of current shareholders from future equity financings;
- the possibility of a change of control of the Company, which could impact the Company's plans and result in existing key personnel leaving the Company;
- 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;
- uncertainty as to whether Topical Interferon Alpha-2b or L-DOS47 will be successfully developed and marketed;
- intellectual property risks, including the possibility that patent applications may not result in issued patents, that issued patents may be circumvented or challenged and ultimately struck down, that any expiry of an issued patent, may

negatively impact the further development or commercialization of the underlying technology, and that the Company may not be able to protect its trade secrets or other confidential proprietary information;

- research and development risks, including without limitation, the fact that L-DOS47 and Topical Interferon Alpha-2b are complex compounds and the Company faces difficult challenges in connection with the manufacture of clinical batches of L-DOS47 and Topical Interferon Alpha-2b, 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, including without limitation, the need for strategic partner support prior to initiating our planned clinical trials for Topical Interferon Alpha-2b, which is not assured, and the need to secure new strategic relationships, which are not assured, to commercialize L-DOS47 and any other drug candidates which may arise out of DOS47;
- the Company's dependence on its contractors, consultants, clinical trial investigators, advisors and licensees, 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 products;
- 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 candidates;
- product liability and insurance risks;
- the risk of lawsuits and other legal proceedings against the Company;
- the effect of competition;
- 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 limited 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,

and other risk factors that are discussed under *Risks and Uncertainties* and elsewhere in this Management's Discussion and Analysis of Financial Condition and Results of Operations 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 statements in this Management's Discussion and Analysis of Financial Condition and Results of Operations, including, but not limited to, the safety and efficacy of L-DOS47 and Topical Interferon Alpha-2b (low-grade cervical lesions); the Company's ability to commence the Phase I U.S. clinical trial for L-DOS47; the success of the Company's anticipated resubmission of its Canadian CTA application or possible similar submissions in other jurisdictions; 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, including Interferon Alpha-2b raw materials, 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 statements.

For all of the reasons set forth above, which do not represent an exhaustive list of factors that may affect the forward-looking statements, investors should not place undue reliance on forward-looking statements. These forward-looking statements are 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 statement should those beliefs, assumptions, opinions or expectations, or other circumstances change, except as required by law.

Data relevant to estimated market sizes and penetration for the Company's lead products under development are presented in this Management's Discussion and Analysis of Financial Condition and Results of Operations. 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 actively 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 and Topical Interferon Alpha-2b BiPhasix platforms for creating new drug candidates. Two clinical stage drug candidates have been developed; L-DOS47, which is currently under study in a European Phase I/II clinical trial in Poland for the treatment of non-small cell lung cancer ("NSCLC") and Topical Interferon Alpha-2b for the treatment of cervical lesions associated with HPV infection. The Company believes that its growth and future prospects are largely dependent on the success of its DOS47 drug product candidates.

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 European Phase I/II clinical study in Poland continues to enrol patients and the U.S. Phase I study in NSCLC, involving L-DOS47 in combination with pemetrexed/carboplatin chemotherapy, is currently under development.

Topical Interferon Alpha-2b is a clinical stage drug candidate that has undergone Phase II level clinical testing for two prospective therapeutic indications, low-grade cervical dysplasia and ano-genital warts. Of these, efficacy was demonstrated only against low-grade cervical dysplasia. Due to a lack of funding, a decision was made by the Company to downsize and eventually close the Saskatoon laboratory which supported the Topical Interferon Alpha-2b drug development program and to 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.

Prior to January 25, 2013, the Company had product revenue from the distribution in Canada of Klean-Prep™<sup>1</sup>, Orthovisc®<sup>1</sup>, Monovisc®<sup>1</sup>, Immunovir®<sup>1</sup> and Normacol®<sup>1</sup>. On January 25, 2013, the Company completed the sale of its distribution business and as a result will no longer have any revenue from product distribution activities (nor will it incur the associated expenses). See "*Drug Distribution Business in Canada*" below.

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 recently completed a private placement on July 10, 2014 for net proceeds of approximately \$5,481,000. However, the Company does not have sufficient cash reserves to meet anticipated cash needs for working capital and capital expenditures through the next twelve months. Since the Company's cash and cash equivalents as at July 31, 2014 of \$6,980,000 are not sufficient to see the current research and development initiatives through to completion, the Company will require additional financing in the near term. Securing additional financing continues to be of utmost importance to the Company.

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<sup>1</sup> Klean-Prep™ is a registered trademark in the U.S. and Canada owned by Pharmascience Inc. Orthovisc® is a U.S. and Canadian registered trademark of Anika Therapeutics Inc. Monovisc® is a Canadian registered trademark of Anika Therapeutics Inc. Immunovir® is a U.S. and Canadian registered trademark of Newport Pharmaceuticals Ltd. Normacol® is a Canadian registered trademark of Norgine Limited.

## 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 vinca alkaloid 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***

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, effectively reversing the acidic extra-cellular conditions that are known to be necessary 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.

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 has prioritized the European Phase I/II clinical study with L-DOS47 in Poland while deferring the commencement of previously-approved U.S. Phase I clinical study with L-DOS47. The Company has since received approval for a new Phase I study from the FDA but, as of the date of this Management's Discussion and Analysis of Financial Condition and Results of Operations, the Company does not have sufficient cash resources to see either the remainder of the European Phase I/II clinical study through to completion or to commence enrolment into the U.S. Phase I clinical study.

### ***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 three 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 Ramlaou, 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.

Doses of 0.12, 0.21, 0.33, 0.46, 0.59, 0.78, 1.04, 1.38 and 1.84 micrograms of L-DOS47 per kilogram of patient body weight have been successfully administered to study patients with no dose limiting toxicities. 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 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, the Company has now enrolled 29 patients, and intends to enrol further patients in additional cohorts until MTD is reached. 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.

On May 20, 2014 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 1.38 µg/kg administered to patients in Cohort 8. The additional four approved dose levels include 1.84, 2.45, 3.26 and 4.33 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 interview 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. A formal PK analysis will be conducted pending the collection of all PK data at the completion 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 dose limiting toxicities 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.

The Company continues to have insufficient cash resources to see the entire European Phase I/II clinical study in Poland nor any part of the U.S. Phase I study or, if approved by Health Canada, the Canadian Phase I study (as discussed below), through to completion. The Company previously disclosed that it did expect to have sufficient cash to complete the Phase I portion of the European Phase I/II clinical study, provided the Company did not experience any unforeseen challenges and/or expenditures. However, because the Company is dosing patients in Cohort 10, exceeding the originally estimated number of cohorts required to reach MTD, the Company no longer has sufficient funds to complete the European Phase I trial for L-DOS47 in Poland.

### *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 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. Commencement of the Phase I L-DOS47 study in the United States is now dependent on the Company’s ability to raise sufficient capital.

### *Phase I clinical study (“LDOS003”)*

On May 14, 2014, the Company announced the submission, for approval by Health Canada, of a new CTA in Canada and commencement of a Phase I study for L-DOS47 in combination with the chemotherapy drug vinorelbine in patients with metastatic NSCLC and metastatic breast cancer. In discussions with Health Canada additional information regarding the proposed trial was requested, and in order to properly address Health Canada’s questions in the most efficient manner, the Company voluntarily withdrew the CTA submission on June 11, 2014 and intends to resubmit the CTA, including the additional information requested by Health Canada. The Company met with Health Canada on October 2, 2014 to discuss questions submitted as part of a pre-CTA meeting. Commencement of the LDOS003 study in Canada depends on the feedback received from Health Canada and on the Company’s ability to raise sufficient capital. The Company is also considering the possible submission of applications to conduct the LDOS003 study in other jurisdictions.

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

The Company is also actively engaged in *in vivo* animal efficacy testing of L-DOS47 for other potential therapeutic applications beyond NSCLC, including colorectal and breast cancers. *In vitro* testing showed promising results in these indications. If the outcome of the *in vivo* experiments is positive, and subject to the availability of sufficient cash and other resources, the Company intends to evaluate the possibility of expanding its clinical testing program of L-DOS47 to include patients with these cancers.

The Company is also exploring the potential of other combinations that can expand the use of L-DOS47, either in NSCLC as an alternative to current first-line therapies or use as adjuvant/neoadjuvant, or as a mechanism to show potential for accessing other tumour types.

### *New potential DOS47 drug candidates*

Several new potential DOS47 conjugates have been advanced by the Company. These potential new drug candidates may have application in pancreatic, colorectal, ovarian, and breast cancer. However, there is no assurance at this time that the research work can be completed successfully or whether any of these research candidates are suitable for development. The Company has prepared laboratory-scale DOS47 immunoconjugate product candidates and continues to conduct *in vitro* and pilot animal efficacy research studies with these product candidates. If these studies are positive, the Company intends to request a pre-IND meeting with the FDA in calendar 2015 to devise a development program. The Company has not yet initiated any formal preclinical investigations with these new DOS47 immunoconjugate product candidates, pending the research outcome, a potential meeting with the FDA and the need for further capital before doing so.

The Company also has separate arrangements with the NRC and is in discussion with third parties for the identification of additional tumor-targeting antibodies for conjugation with DOS47 and testing of the resultant immunoconjugates. In the event that antibody candidates worthy of further development are identified, the Company will need to discuss development and licensing with a third party, which licenses may not be available on terms acceptable to the Company or at all.

In fiscal 2012, the Company also entered into a collaborative research agreement with Amorfix Life Science Inc. (“Amorfix”) to develop therapeutics against cancers associated with misfolded prion protein. As part of this collaboration, Amorfix will provide tumour specific antibodies identified and developed with its ProMIS discovery technology while the Company will utilize its technology to produce antibody-urease conjugates which are toxic to cells. Amorfix has announced preliminary efficacy results in animal studies of an ovarian cancer conjugate and the Company understands work is ongoing to confirm these results and optimize the conjugate.

### *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*

Histological subtype mutation testing in choosing first and second line treatments for advanced or metastatic NSCLC are becoming increasingly important. 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.

Based on information published in "Cancer Facts and Figures 2014" by the American Cancer Society ([www.cancer.org](http://www.cancer.org)), lung cancer remains the leading cause of death for both females and males in the U.S. and it is estimated that in 2014 there will be over 180,000 new cases of NSCLC diagnosed.

Treatment strategies today for patients with advanced stage NSCLC are of limited effectiveness. 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.

As a result, the Company believes that there is a substantial market opportunity for L-DOS47 given that (a) its target therapeutic indication, inoperable, locally-advanced, recurrent or metastatic NSCLC, represents a significant and unmet medical need worldwide; and (b) leading therapeutics for such oncology applications have commonly been high revenue generators for the pharmaceutical sector.

However, technological competition from pharmaceutical companies, biotechnology companies and university researchers is intense and is expected to increase. 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 Biphaxis™ Topical Formulation System***

The Biphaxis™ 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.

The Company's issued patents relating to Biphaxis™ technology have expiration dates ranging from 2017 through 2020 in the United States. Without patent protection, Biphaxis™ could be genericized by others interested in copying the technology for other uses which could further limit the Company's ability to advance the Topical Interferon Alpha-2b program and/or other prospective Biphaxis™ initiatives, and fuel divestiture of any assets associated with the Biphaxis™ technology.

### *Topical Interferon Alpha-2b*

Topical Interferon Alpha-2b is a developmental product candidate for the treatment of certain skin/mucosal lesions caused by human papilloma virus ("HPV"), based on the Company's proprietary Biphaxis™ technology (see "*Biphaxis™ Topical Formulation System*" above). To date, the Company has completed three Phase II clinical studies with Topical Interferon Alpha-2b; two in patients with HPV-positive, low-grade cervical dysplasia and one in patients with HPV-positive ano-genital warts.

The Company has received 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 CTA approval by the Bundesinstitut für Arzneimittel und Medizinprodukte ("BfArM") and conditional CTA approval by the Medicines and Healthcare Regulatory Authority ("MHRA") 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 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.

## Market and Competition

Merck and GlaxoSmithKline, two large pharmaceutical companies, have developed and commercialized vaccines (Gardasil® and Cervarix®, respectively) that are designed to protect against infection from several specific subtypes of HPV. Merck is also developing a new broad spectrum HPV vaccine, V503, which is presently under advanced clinical development.

The Company is not aware of any other interferon alpha-2b cream product under development but is aware of other companies having also recognized the need for effective therapies for HPV-induced lesions. The following is a non-exhaustive list of some of the companies which are, based on publicly available information, developing products which offer a competitive alternative to the Company's Topical Interferon Alpha-2b: Photocure Inc., Erimos Pharmaceuticals LLC, Foamix Pharmaceuticals Ltd., BioMAS Ltd. and Nanovir LLC.

## DRUG DISTRIBUTION BUSINESS IN CANADA

On December 10, 2012, the Company announced that it had entered into a definitive agreement for the sale of the Company's Rivex Pharma division for gross cash proceeds of up to \$8.5 million (the "Rivex Transaction"). The Rivex Transaction was approved at the annual general and special meeting of the Company's shareholders on January 24, 2013 and the Rivex Transaction closed on January 25, 2013.

The details of the Rivex Transaction are as follows:

| <b>Gross proceeds</b>                            |                     |
|--|---------------------|
| Initial sale price                               | \$ 7,600,000        |
| Add: Inventory assumed by buyer                  | 748,000             |
| Add: Trade accounts receivable assumed by buyer  | 368,000             |
| Less: Accounts payable assumed by buyer          | (363,000)           |
| Less: Accruals assumed by buyer                  | (5,000)             |
| Less: Holdback by buyer                          | (200,000)           |
|  | <hr/>               |
|  | 8,148,000           |
| <b>Costs</b>                                     |                     |
| Supplier contract extension fee                  | 500,000             |
| Transaction advisory fee                         | 425,000             |
| Legal costs                                      | 173,000             |
| Employee termination costs                       | 150,000             |
| Other costs                                      | 133,000             |
| Net assets disposed of at carrying value         | 748,000             |
|  | <hr/>               |
|  | 2,129,000           |
|  | <hr/>               |
| <b>Gain on sale from discontinued operations</b> | <b>\$ 6,019,000</b> |

As security for the fulfillment of certain obligations by the buyer of the Company's distribution business to a key supplier, a holdback amount of \$200,000 was applied to the proceeds upon closing the Rivex Transaction. This holdback amount will be paid to the Company in tranches starting at the end of calendar 2014, subject to the achievement of certain sales objectives by the purchaser of the Rivex Pharma division under a distribution agreement assumed by the purchaser in connection with the Rivex Transaction. The Company has not included the \$200,000 holdback amount as consideration as at the closing date of the Rivex Transaction and will not do so until such amounts are received by the Company.

As a result of the Rivex Transaction, the Company no longer has any revenue from product distribution activities (nor will it incur the associated expenses).

## 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.

Prior to January 25, 2013, the Company earned revenue, primarily from its drug distribution business in Canada. On January 25, 2013, the Company completed the sale of its Rivex Pharma drug distribution business and as a result no longer had any revenue from product distribution activities (nor will it incur the associated expenses). The Company received gross proceeds of \$8,148,000 in the second quarter of 2013 from the sale of the distribution business. See "Drug Distribution Business in Canada" above.

Net loss and total comprehensive loss from continuing operations, over the last eight quarters, ranged from a high of \$2,660,000 in fiscal Q2 2014 to a low of \$1,726,000 in fiscal Q2 of 2013 with fluctuations mainly dependant on the level of research and development activities and lower operating, general and administration expenses. Included in research and development expense for Q2 F2014 is a one-time payout of \$500,000 related to the termination of the Company's former President and Chief Operating Officer.

In fiscal Q4 2014, the Company closed a private placement for net proceeds of \$5,481,000. In fiscal Q4 2014 operating, general and administration expenditures remained in line with previous fiscal quarters while research and development expenditures were slightly lower as a result of the Company recording an investment tax credit totalling \$219,000.

The following table depicts selected quarterly data from continuing operations for the fiscal year ended July 31, 2014:

|  | Q4             | Q3             | Q2             | Q1             |
|--|----------------|----------------|----------------|----------------|
| Revenue                                    | \$ -           | \$ -           | \$ -           | \$ -           |
| Research and development                   | \$ 973,000     | \$ 1,285,000   | \$ 1,649,000   | \$ 1,332,000   |
| Operating, general and administration      | \$ 830,000     | \$ 829,000     | \$ 1,011,000   | \$ 826,000     |
| Special committee and settlement agreement | \$ -           | \$ -           | \$ -           | \$ -           |
| Net loss and total comprehensive loss      | \$ (1,750,000) | \$ (2,114,000) | \$ (2,660,000) | \$ (2,158,000) |
| Basic and diluted loss per common share    | \$ (0.02)      | \$ (0.03)      | \$ (0.04)      | \$ (0.03)      |
| Weighted average number of common shares   | 72,816,467     | 71,904,337     | 71,904,337     | 67,226,337     |
| Cash                                       | \$ 6,980,000   | \$ 2,832,000   | \$ 4,386,000   | \$ 2,482,000   |

The following table depicts selected quarterly data from continuing operations for the fiscal year ended July 31, 2013:

|  | Q4             | Q3             | Q2             | Q1             |
|--|----------------|----------------|----------------|----------------|
| Revenue                                    | \$ -           | \$ -           | \$ -           | \$ -           |
| Research and development                   | \$ 1,072,000   | \$ 1,303,000   | \$ 1,049,000   | \$ 1,608,000   |
| Operating, general and administration      | \$ 817,000     | \$ 911,000     | \$ 704,000     | \$ 764,000     |
| Special committee and settlement agreement | \$ -           | \$ -           | \$ -           | \$ -           |
| Net loss and total comprehensive loss      | \$ (1,844,000) | \$ (2,224,000) | \$ (1,726,000) | \$ (2,400,000) |
| Basic and diluted loss per common share    | \$ (0.03)      | \$ (0.03)      | \$ (0.03)      | \$ (0.03)      |
| Weighted average number of common shares   | 67,226,337     | 67,226,337     | 67,226,337     | 67,226,337     |
| Cash                                       | \$ 4,493,000   | \$ 6,674,000   | \$ 8,478,000   | \$ 3,313,000   |

The following table depicts selected annual data from continuing operations for the fiscal years ended July 31:

|  | 2014           | 2013           | 2012           |
|--|----------------|----------------|----------------|
| Revenue  | \$ -           | \$ 1,868,000   | \$ 4,260,000   |
| Research and development expense                   | \$ 5,239,000   | \$ 5,032,000   | \$ 7,450,000   |
| Operating, general and administration expense      | \$ 3,496,000   | \$ 3,196,000   | \$ 4,580,000   |
| Special committee and settlement agreement expense | \$ -           | \$ -           | \$ 6,536,000   |
| Net loss and total comprehensive loss              | \$ 8,682,000   | \$ 8,194,000   | \$ 18,854,000  |
| Deficit, end of year                               | \$ 126,926,000 | \$ 118,244,000 | \$ 116,699,000 |
| Basic and diluted loss per common share            | \$ 0.12        | \$ 0.12        | \$ 0.28        |
| Weighted average number of common shares           | 70,955,132     | 67,226,337     | 67,213,802     |
| Cash   | \$ 6,980,000   | \$ 4,493,000   | \$ 4,862,000   |
| Working capital                                    | \$ 6,363,000   | \$ 4,243,000   | \$ 4,754,000   |
| Total assets                                       | \$ 7,853,000   | \$ 5,868,000   | \$ 7,616,000   |

In fiscal 2012, the Company agreed to reimburse the reasonable costs and expenses incurred by the Concerned Shareholders in respect of all matters in connection with the Special Committee and the 2012 AGM, including costs associated with the shareholder proposal and requisition for a shareholder meeting by such shareholders, the Special Committee's investigation and the Respondents' proxy solicitation. The total expenses associated with the 2012 AGM, the Special Committee and the Settlement totalled \$6,536,000 in fiscal 2012.

## RESULTS FROM OPERATIONS

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

The Company recorded a net loss and total comprehensive loss of \$8,682,000 (\$0.12 loss per common share) and \$1,545,000 (\$0.12 loss per common share) for the fiscal years ended 2014 and 2013, respectively.

Excluding the gain on sale and the net income and total comprehensive income from discontinued operations, the Company realized a net loss and total comprehensive loss from continuing operations of \$8,194,000 (\$0.12 loss per common share) for

the fiscal year ended 2013. On January 25, 2013, the Company announced the sale of its distribution business in Canada. See “Drug Distribution Business in Canada”, above.

### **Research & development**

Research and development costs for fiscal 2014 and 2013 totalled \$5,239,000 and \$5,032,000, 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 fiscal years ended July 31:

|  | 2014            | 2013            |
|--|-----------------|-----------------|
| L-DOS47  | \$ 2,730        | \$ 2,771        |
| Topical Interferon Alpha-2b                    | 383             | 774             |
| Corporate research and development expenses    | 1,407           | 1,081           |
| Trademark and patent related expenses          | 612             | 278             |
| Stock-based compensation expense               | 83              | 130             |
| Depreciation expense                           | 222             | 336             |
| Research and development investment tax credit | (198)           | (338)           |
|  | <b>\$ 5,239</b> | <b>\$ 5,032</b> |

L-DOS47 research and development expenses for fiscal 2014 and 2013 totalled \$2,730,000 and \$2,771,000, respectively. L-DOS47 research and development expenditures relate primarily to expenditures associated with the ongoing European Phase I/II clinical study in Poland and costs associated with the preparation of an IND and CTA applications with the FDA and Health Canada.

Topical Interferon Alpha-2b research and development expenses for fiscal 2014 and 2013 totalled \$383,000 and \$774,000, respectively. Beginning in June 2012, the Company initiated a downsizing of the staff in the Saskatoon laboratory which resulted in the closure of the Saskatoon laboratory at the end of November 2012. In fiscal 2014, the Company focused ongoing activities with respect to its Topical Interferon Alpha-2b program to sourcing and qualifying alternative interferon alpha-2b raw material samples, strengthening the BiPhasix™ patent portfolio and finding a suitable strategic partner(s) who would be willing to license or acquire the product and support the remaining development costs.

Corporate research and development expenses for fiscal 2014 and 2013 totalled \$1,407,000 and \$1,081,000, respectively. Included in corporate research and development expense for fiscal 2014 is a one-time payout of \$500,000 related to the termination of the Company’s former President and Chief Operating Officer.

Trademark and patent related expenses for fiscal 2014 and 2013 totalled \$612,000 and \$278,000, respectively. The increase reflects additional efforts taken by the Company to strengthen the DOS47 and Biphax™ patent portfolio.

The Company is entitled to claim 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 research and development expenditures incurred. These investment tax credits resulted in a reduction of research and development expenditures of \$198,000 and \$338,000 for fiscal periods 2014 and 2013, respectively.

### **Operating, general and administration**

Operating, general and administration expenses for the fiscal 2014 and 2013 totalled \$3,496,000 and \$3,196,000, respectively. Lower director and audit fees were offset by higher legal fees in defense of a legal claim which management believes is without merit, higher stock based compensation expense and higher consulting fees.

## **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**

The consolidated financial statements include the assets and liabilities and results of operations of all subsidiaries after elimination of intercompany transactions and balances.

**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.

**Foreign currency translation**

The Company's currency of presentation is the Canadian dollar, which is also the Company's functional currency. Foreign currency-denominated items are translated into Canadian dollars. Monetary assets and liabilities in foreign currencies are translated into Canadian dollars at the rates of exchange in effect at the balance sheet dates. Non-monetary items are translated at historical exchange rates. Revenue and expenses are translated at the exchange rates prevailing at their respective transaction dates. Exchange gains and losses arising on translation are included in income.

**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**

Standards 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 were issued by the International Accounting Standards Board ("IASB") or International Financial Reporting Interpretations Committee that are mandatory for annual periods beginning on or after January 1, 2011 or later periods. Many of these updates are not applicable or are inconsequential to the Company and have been excluded from the discussion below.

### ***IFRS 7, Financial Instruments: Disclosures***

The IASB has issued amendments to the disclosure requirements in IFRS 7, Financial Instruments: Disclosures ("IFRS 7"). The amendments require information about all recognized financial instruments that are set off in accordance with paragraph 42 of IAS 32, Financial Instruments: Presentation ("IAS 32"). The amendments also require disclosure of information about recognized financial instruments subject to enforceable master netting arrangements and similar agreements even if they are not set off under IAS 32. These amendments are effective for annual periods beginning on or after January 1, 2015. The Company has yet to assess 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"). IFRS 9 uses a single approach to determine whether a financial asset or liability is measured at amortized cost or fair value. The approach in IFRS 9 is based on how an entity manages its financial instruments in the context of its business model and the contractual cash flow characteristics of the financial assets. The new standard also requires a single impairment method to be used, replacing the multiple impairment methods in IAS 39. IFRS 9 is effective for annual period beginning on or after January 1, 2015. Early adoption is permitted. The Company is evaluating the impact of the new standard on its results of operations, financial position and disclosures.

### ***IAS 32, Financial Instruments: Presentation***

The IASB has issued amendments to IAS 32. The amendments require entities to disclose gross amounts subject to rights of set-off, amounts set off in accordance with the accounting standards followed, and the related net credit exposure. This information will help investors understand the extent to which an entity has set off in its balance sheet and the effects of rights of set-off on the company's rights and obligations. These amendments are effective for annual periods beginning on or after January 1, 2014 and are required to be applied retrospectively. The Company is evaluating the impact of the amendment 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 \$6,980,000 as at July 31, 2014 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 of the 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 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.

At July 31, 2014 and 2013, the total number of common shares issued was 75,900,337, respectively and the Company's working capital was \$6,363,000 and \$4,243,000, respectively.

## PROPERTY, PLANT AND EQUIPMENT EXPENDITURES

There were no major purchases of capital equipment in fiscal 2014 and 2013. Any purchases of property, plant and equipment in fiscal 2015 is expected to be limited.

The following table summarizes the capital expenditures made by the Company in the fiscal years ended July 31:

|             | Amount    | Type                 |
|-------------|-----------|----------------------|
| Fiscal 2014 | \$ 3,000  | General IT purchases |
| Fiscal 2013 | \$ 24,000 | General IT purchases |

## RELATED PARTY TRANSACTIONS

The key management personnel of the Company are the President and Chief Executive Officer, former President and Chief Operating Officer, Chief Scientific Officer, Chief Financial Officer and Director of Clinical Development.

The following table summarizes for key management personnel compensation for the fiscal years ended:

|                          | 2014     | 2013     |
|--------------------------|----------|----------|
| Compensation             | \$ 1,750 | \$ 1,324 |
| Stock-based compensation | 238      | 291      |

Included in compensation expense in the above table is a one-time payout of \$500,000 related to the termination of the Company's former President and Chief Operating Officer.

The following table summarizes Directors' compensation for the fiscal years ended:

|                          | 2014   | 2013   |
|--------------------------|--------|--------|
| Directors' fees          | \$ 291 | \$ 369 |
| Stock-based compensation | 182    | 16     |

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:

|      | 2014       |                      | 2013       |                      |
|------|------------|----------------------|------------|----------------------|
|      | Fair Value | Fair value hierarchy | Fair Value | Fair value hierarchy |
| Cash | \$ 6,980   | Level 1              | \$ 4,493   | 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 July 31, 2014 and 2013 approximates their carrying value because of the near-term maturity of these instruments.

### **CASH FLOWS**

The following table presents the Company's consolidated statement of cash flows:

|   | 2014           | 2013           |
|---|----------------|----------------|
| Used in operating activities                      | \$ (7,692,000) | \$ (7,814,000) |
| Provided by in financing activities               | 10,153,000     | –              |
| Used in investing activities                      | (3,000)        | (6,000)        |
| Impact of foreign exchange on cash balances       | 29,000         | (9,000)        |
| Net decrease in cash from continuing operations   | 2,487,000      | (7,829,000)    |
| Net increase in cash from discontinued operations | –              | 7,460,000      |
| Cash, beginning of period                         | 4,493,000      | 4,862,000      |
| Cash, end of period                               | \$ 6,980,000   | \$ 4,493,000   |

Cash used in operating activities of \$7,692,000 in fiscal 2014 includes a net loss and total comprehensive loss from continuing operations of \$8,682,000 with significant adjustments in operating activities related to depreciation of property, plant and equipment of \$232,000; stock-based compensation of \$420,000; and a net increase to non-cash working capital of \$390,000.

Cash used in operating activities of \$7,814,000 in fiscal 2013 includes a net loss and total comprehensive loss from continuing operations of \$8,194,000 with significant adjustments in operating activities related to depreciation of property, plant and equipment of \$396,000; stock-based compensation of \$241,000; and a net decrease to non-cash working capital of \$223,000.

Cash provided from financing activities in fiscal 2014 of \$10,153,000 is the result of closing two private placements (2013 – nil).

Investing activities in fiscal 2014 and 2013 represent a use of cash of \$3,000 and \$6,000, respectively which mainly represent purchases of property, plant and equipment.

In fiscal 2013, as a result of the Rivex Transaction, (See "*Drug Distribution Business in Canada*" above), the Company recorded a net increase in cash from discontinued operations of \$7,460,000.

### **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-US patents, the Company owns 18 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 also filed by the Company during fiscal 2013.

### **Biphasix™**

The Company currently owns four U.S. Biphasix™ patents which includes one application claiming a priority date of 2007. This application was subject to a final office response received in May 2012 and a "Request for a Continuing Application" amendment with prioritized examination (track1) was filed with the United States Patent Trademark Office ("USPTO") in July 2012. Final correspondence from the Company was filed in September 2014 with an expectation that an allowance will be granted by the USPTO if the Company's response is satisfactory. The Company has three other U.S. Biphasix™ patent applications. The Company is prosecuting these three applications with a view to further strengthening its patent portfolio for Biphasix™ and Topical Interferon 2b.

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

The Company has no material off-balance sheet arrangements.

### **TABULAR DISCLOSURE OF CONTRACTUAL OBLIGATIONS**

The Company's commitments are summarized as follows:

|  | 2015         | 2016        | 2017      | 2018      | 2019      | 2020 and beyond | Total       |
|--|--------------|-------------|-----------|-----------|-----------|-----------------|-------------|
| Royalty and in-licensing (1)             | \$ 10,000    | \$ 10,000   | \$ 10,000 | \$ 10,000 | \$ 10,000 | \$ 40,000       | \$ 90,000   |
| Clinical research organizations (2)      | 2,527,000    | 1,828,000   | –         | –         | –         | –               | 4,355,000   |
| Contract manufacturing organizations (3) | 96,000       | 113,000     | 76,000    | 16,000    | –         | –               | 301,000     |
| R&D distribution services (4)            | 72,000       | 48,000      | –         | –         | –         | –               | 120,000     |
| Operating leases (5)                     | 84,000       | –           | –         | –         | –         | –               | 84,000      |
| Financial and investor relations (6)     | 119,000      | –           | –         | –         | –         | –               | 119,000     |
|  | \$ 2,908,000 | \$1,999,000 | \$ 86,000 | \$ 26,000 | \$ 10,000 | \$ 40,000       | \$5,069,000 |

- (1) Represents future minimum royalties.
- (2) The Company has a Clinical Research Organization supplier agreement in place for clinical research services related to the management of the Company's Phase I clinical studies in both Europe and the U.S. of L-DOS47.
- (3) The Company has three separate contract manufacturing organization supplier agreements related to the Company's L-DOS47 program, all of which are interdependent in the manufacturing of L-DOS47.
- (4) The Company has a distribution services agreement associated with the fulfillment of L-DOS47 and ancillary medical items in support of the Company's Phase I clinical studies in both Europe and the U.S. of L-DOS47.
- (5) The Company owes \$84,000 under various operating lease agreements with remaining terms of up to February 2015 for office and warehouse and research premises.
- (6) The Company has a non-exclusive financial and investor relations agreement. The financial and investor relations agreement expired on May 1, 2013 with provisions to continue on a month-to-month basis where notice to terminate requires a ninety day written notice.

## 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 July 31, 2014 and 2013 are as follows:

|                                      | 2014   |            | 2013   |            |
|--------------------------------------|--------|------------|--------|------------|
|                                      | Euros  | US Dollars | Euros  | US Dollars |
| Cash                                 | 102    | 162        | 314    | 3          |
| Accounts payable                     | (64)   | (242)      | (35)   | (39)       |
| Accruals                             | (65)   | –          | (3)    | –          |
| Net foreign currencies               | (27)   | (80)       | 276    | (36)       |
| Closing exchange rate                | 1.4581 | 1.0890     | 1.3665 | 1.0272     |
| Impact of 1% change in exchange rate | +/- 1  | +/- 1      | +/- 4  | +/- 1      |

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

### Credit risk

Credit risk is the risk of a financial loss to the Company if a customer or counterparty to a financial instrument fails to meet its contractual obligation. The Company sold its distribution business on January 25, 2013 resulting in a reduction in customer credit risk going forward. See "Drug Distribution Business in Canada" above.

The table below breaks down the various categories that make up the Company's accounts receivable balances as at July 31:

|   | 2014   | 2013   |
|---|--------|--------|
| Accounts receivable                             |        |        |
| Government related – HST/VAT                    | 51     | 121    |
| Research and development investment tax credits | 288    | 434    |
| Other   | 4      | 4      |
|   | \$ 343 | \$ 559 |

### 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 balances. 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 \$6,980,000 as at July 31, 2014 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, 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 July 31, 2014, the Company had outstanding 75,900,337 common shares; warrants to purchase up to 22,400,084 common shares; and incentive stock options to purchase up to 3,338,084 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 and the Chief Financial Officer 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.

As of July 31, 2014, management evaluated the effectiveness of the Company's ICFR and disclosure controls and procedures and concluded that such ICFR and disclosure controls and procedures are not effective for the reasons set out below.

A change in the Company's ICFR occurred during fiscal 2013 that has materially affected, or is reasonably likely to materially affect the Company's ICFR and is due to the resignation of the Company's controller. The resignation of the Company's controller during the period has resulted in a lack of resources and has in turn impacted the segregation of duties associated with the financial close and reporting process.

Since the resignation of the controller in 2013, management had concluded, and the board had agreed, that, when taking into account the Company's size and financial resources, the Company has not had sufficient scale of resources to warrant the hiring of additional staff to address this concern and, accordingly, that there is a material weakness in the design of the Company's ICFR that has the potential to result in material misstatements in the Company's financial statements and that this should also be considered a weakness in the design and operating effectiveness of the Company's disclosure controls and procedures.

This material weakness is considered to be a common area of deficiency for many smaller listed companies in Canada. However, there are several mitigating procedures and other factors which reduce the risk of a material misstatement in the financial statements, including substantive review of the financial statements by the Chief Executive Officer and Audit Committee, day-to-day management involvement in operations and reporting, the fact that the Company has a limited number of transactions and the Company's access to third party experts to address the reporting of complex or non-routine transactions when they occur.

With the recent change in the board of directors of the Company, the new board concluded that it was important to eliminate the material weakness resulting from the lack of segregation of duties due to limited staff, by hiring a full-time controller. The Company is in the process of searching for a full-time controller.

## **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 statements may not necessarily be indicative of future operating results or of future financial position, and actual results may vary from the forward-looking statements 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 statement. Accordingly, reported financial information and forward-looking statements 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 statements include, either wholly or in part, those described elsewhere in this Management's Discussion and Analysis of Financial Condition and Results of Operations, 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 July 31, 2014 was \$126,926,000. 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 initiate its planned U.S. Phase I, or, if approved, Canadian Phase I, clinical trials, or to fully fund its existing European Phase I/II clinical trial with L-DOS47 in Poland and 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, development and marketing programs, 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**

The biotechnology and pharmaceutical industries are subject to rapid and substantial technological change. The Company faces competition from pharmaceutical companies, biotechnology companies and universities. This competition is intense and is expected to increase.

Many competitors and potential competitors of the Company have substantially greater product development capabilities and financial, scientific, marketing and human resources than the Company. Developments by others may render the Company's products and/or technologies non-competitive, and the Company may not be able to keep pace with technological developments or its competition.

### ***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 planned U.S. Phase I study and, if approved, the Canadian 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: (i) obtaining additional financing, which is not assured; (ii) 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; (iii) regulatory agency policies regarding requirements for approval of a drug, including granting permission to undertake proposed human testing; (iv) the Company's capacity to produce sufficient quantities and qualities of clinical trial materials to meet the trial schedule; (v) performance by third parties, on whom the Company relies to carry out its clinical trials; and (vi) 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 for products such as urease and interferon alpha-2b, 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 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.

In the case of Topical Interferon Alpha-2b, the Company had been dependent on Merck for its supply of interferon alpha-2b raw material until the termination of its agreement with Merck on December 14, 2012. The Company is now searching for additional funding through other strategic partner support and additional interferon alpha-2b raw material from other manufacturers. There can be no assurance that additional funding through other strategic partner support and additional interferon alpha-2b raw material from other manufacturers can be arranged. Even if a new source of supply is obtained, there may be challenges from a regulatory perspective in adequately demonstrating the bioequivalence of such new supplier's raw material with the interferon alpha-2b previously provided by Merck.

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***

The Company's ability to continue its development of potential products depends on its ability to attract and maintain qualified key management personnel. Competition for such personnel is intense and the Company may not be able to attract and retain such personnel. In addition, the Company does not carry key-man insurance on any individuals. If the Company loses and is unable to replace key personnel, its business could be negatively affected.

***Indemnification obligations to directors and officers of the Company may adversely affect its 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 claims made in connection with the Company's contested 2012 AGM may adversely affect the Company's ability to procure satisfactory insurance for its directors and officers in the future at reasonable rates, which may adversely affect the Company's finances***

The claims made in connection with the Company's contested annual general meeting for 2012 may have an adverse impact on the Company's ability to procure insurance for its current directors and senior management in the future at reasonable rates, and these increased costs may adversely affect Company's finances.

***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 Euro and U.S. dollar.

***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 stockholders 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 stockholders 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 statements. Other than any obligation to disclose material information under applicable securities laws, the Company undertakes no obligation to revise or update any forward-looking statements after the date hereof.

Data relevant to estimated market sizes and penetration for the Company’s lead products under development are presented in this Management’s Discussion and Analysis of Financial Condition and Results of Operations. 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.

## **ADDITIONAL INFORMATION**

Additional information relating to the Company’s fiscal year ended July 31, 2014, is available under the Company’s profile on SEDAR at [www.sedar.com](http://www.sedar.com).

Dated October 20, 2014