

ANNUAL INFORMATION FORM

October 20, 2014

HELIX BIOPHARMA CORP.

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FORWARD-LOOKING STATEMENTS

This Annual Information Form ("AIF") 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 tumortargeting 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 AIF 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 *Risk Factors* and elsewhere in this AIF or identified in the Company's other public filings under the Company's profile on SEDAR at www.sedar.com (together the "Helix Risk Factors"), any of which could cause actual results to vary materially from current results or the Company's anticipated future results. Certain material factors, estimates or assumptions have been applied in making forward-looking statements in this AIF, 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 AIF. 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.

CORPORATE STRUCTURE

Name, address and incorporation

Helix BioPharma Corp. ("**Helix**" or the "**Company**") is a Canadian corporation which was originally formed upon the amalgamation of International Helix Biotechnologies Inc. and Intercon Pharma Inc. on July 31, 1995. On April 30, 2008, the Company further amalgamated by way of short-form vertical amalgamation under the *CBCA* with Helix Product Developments Inc., 6933912 Canada Ltd., Sensium Technologies Inc. and 6965954 Canada Inc.

The Company's principle corporate offices are located at 305 Industrial Parkway South, #3, Aurora, Ontario, Canada L4G 6X7. The Company's phone number is (905) 841-2300. The Company's website is www.helixbiopharma.com.

Inter-corporate relationships

The following table summarizes the Company's wholly owned subsidiaries as at July 31, 2014:

	Date of Incorporation	Jurisdiction	Ownership
Helix BioPharma Inc. Helix Product Development	December 4, 2000	USA	100% by Helix BioPharma Corp
(Ireland) Limited Helix Polska sp.z o.o	March 24, 2004 July 6, 2013	Ireland Poland	100% by Helix BioPharma Corp 100% by Helix BioPharma Corp

In fiscal 2014, the Company dissolved one of its wholly-owned subsidiaries in Ireland, Intercon Pharma Limited.

There were no material amendments to the Company's articles or other constating or established documents in the 2014 fiscal year.

GENERAL DEVELOPMENT OF THE BUSINESS

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 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^{TM¹}, Orthovisc^{®¹}, Monovisc^{®¹}, Immunovir^{®¹} and Normacol^{®¹}. 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 initiates 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.

THREE YEAR HISTORY

Important events which have occurred in the last three fiscal years and the period subsequent to July 31, 2014 up to the date of filing this AIF under the Company's profile on SEDAR at www.sedar.com include the following:

July 31, 2014 to the date of this AIF

- ➤ On September 30, 2014, the Company announced the completion of a second interim review of data collected to date in its ongoing European Phase I/II clinical study of L-DOS47 in Poland;
- ➤ On September 26, 2014, the Company announced the commencement of enrollment for the tenth cohort in the Polish Phase I/II clinical study of its lung cancer drug candidate L-DOS47.

Fiscal year ended July 31, 2014

- ➤ On July 21, 2014, the Company announced the appointment of Mr. Yvon Bastien as new independent Chairman of the Board of Directors, effective July 17, 2014.
- ➤ On July 15, 2014, the Company announced the commencement of enrollment for the ninth cohort in the Polish Phase I/II clinical study of its lung cancer drug candidate L-DOS47.

¹ Klean-PrepTM 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. Imunovir® is a U.S. and Canadian registered trademark of Norgine Limited.

- ➤ On July 11, 2014, the Company announced the completion of a private placement with net proceeds in excess of \$5.4 million. The terms of the Private Placement are for the purchase of common shares at \$1.60 per share and include one warrant per share at an exercise price of \$2.24 and have an expiry of five years from the date of issue.
- ➤ On May 14, 2014, the Company announced the submission of a clinical trial application with Health Canada for approval to initiate a phase I clinical trial with L-DOS47.
- ➤ On April 22, 2014, the Company announced that it had received approval from the FDA to initiate a phase I clinical study of L-DOS47 previously announced by the Company on April 3, 2014.
- ➤ On April 7, 2014, the Company announced the commencement of enrollment for the eighth cohort in the Polish Phase I/II clinical study of its lung cancer drug candidate L-DOS47.
- ➤ On April 3, 2014, the Company announced the submission of an investigational new drug with the FDA for approval to initiate a phase I clinical study of L-DOS47 entitled, "A phase 1, open label, dose escalation study of immunoconjugate L-DOS47 in combination with standard doublet therapy of Pemetrexed/Carboplatin in patients with Stage 4 (TNM M1a and M1b) recurrent or metastatic non-squamous non-small-cell lung cancer".
- ➤ On March 11, 2014, the Company announced the appointment of Mr. Sylwester Cacek to the Board of Directors following the Board's acceptance of Mr. Slawomir Ludwikowski resignation from the Board. In addition, the Company also announced, that Mr. Andreas Kandziora would be acting as observer to the Board of Directors.
- ➤ On February 18, 2014, the Company announced the commencement of enrollment for the seventh cohort in the Polish Phase I/II clinical study of its lung cancer drug candidate L-DOS47.
- ➤ On January 22, 2104, the Company announced the commencement of enrollment for the sixth cohort in the Polish Phase I/II clinical study of its lung cancer drug candidate L-DOS47.
- ➤ On January 10, 2014, the Company announced that Mr. Orlowski, a director of the Company purchased an additional 1,000,000 common shares of the Company.
- ➤ On December 18, 2013, at the Company's annual general meeting, Messrs. Yvon Bastien and Sven Rohmann were elected to the Board by shareholders.
- ➤ On December 17, 2013, the Company announced the resignation of Mr. Mario Gobbo from the Board of Directors.
- ➤ On December 6, 2013, the Company announced the termination of Mr. John Docherty, the Company's former President and COO, effective immediately.
- ➤ On October 28, 2013, the Company announced receipt of subscription agreements agreements for net proceeds of approximately \$4,600,000. The terms of the Private Placement are for the purchase of common shares at \$1.15 per share and include one warrant per share at an exercise price of \$1.61 and have an expiry of five years from the date of issue. The Company, on November 4, 2013 announced the closing of the private placement.

- ➤ On October 15, 2013, the Company announced the completion of an interim review of data collected to date in its ongoing European Phase I/II clinical study of L-DOS47 in Poland;
- ➤ On August 23, 2013, the Company announced the extension of the expiry date for those warrants issued on September 8, 2009 for an additional 12 months, from September 7, 2013 to September 7, 2014 and an increase in the exercise price of such warrants from \$2.87 to \$3.51.
- ➤ On August 9, 2013, the Company announced the extension of the expiry date for those warrants issued on August 6, 2010 for an additional 18 months, from August 5, 2013 to February 5, 2015 and an increase in the exercise price of such warrants from \$3.40 to \$4.16.

Fiscal year ended July 31, 2013

- ➤ On July 12, 2013, the Company announced its intention to change the Company's auditors from KPMG LLP to BDO Canada LLP, effective following the completion of the Company's fiscal 2013 audit by KPMG LLP, with a transition period having commenced on June 21, 2013.
- ➤ On June 13, 2013, the Company announced the appointment of Mr. Stacy L. Wills to the Board and the voluntary resignation of Mr. Andrew J. MacDougall as a director. Mr. MacDougall had agreed to serve on the board on an interim basis pending the appointment of a resident Canadian director to satisfy the statutory requirement for resident Canadians to comprise at least 25% of the Board.
- ➤ On March 7, 2013, the Company announced the extension of the expiry date for those warrants issued on September 8, 2009 for an additional six months, from March 7, 2013 to September 7, 2013.
- ➤ On February 25, 2013, the Company announced the voluntary resignation of Mr. William White from the Board, effective February 22, 2013.
- ➤ On February 21, 2013, the Company announced the appointment of Mr. Andrew J. MacDougall to the Board.
- ➤ On February 10, 2013, the Company announced that John A. Rogers had voluntarily resigned from the Board, effective February 8, 2013.
- > On January 25, 2013, the Company announced the closing of the Rivex Transaction.
- ➤ On January 24, 2013, the Company announced that Mario Gobbo had been elected as the new Chair of the Board.
- ➤ On December 17, 2012, the Company announced the voluntary resignations of Mr. Jack Kay and Mr. Tom Hodgson from the Board, effective December 14, 2012.
- ➤ On December 14, 2012, the Company announced the termination of the Merck material transfer and license agreement for the Topical Interferon Alpha-2b development program.
- ➤ On December 10, 2012, the Company announced that it had entered into a definitive agreement for the sale of the Rivex Pharma division to Pharmascience Inc.

- ➤ On October 25, 2012, the Company announced the appointment of Professor Sławomir Majewski as a director of the Company, effective October 19, 2012 along with the staff reductions and the planned closure of the Saskatoon laboratory, which was closed at the end of November 2012.
- ➤ On October 23, 2012, the Company announced that the first patient in the Company's European Phase I/II clinical study of lung cancer drug candidate L-DOS47 in Poland was enrolled and that the first dose had been administered.
- ➤ On September 7, 2012 the Company announced the extension of the expiry date for those warrants issued on September 8, 2009 for an additional six months, from September 7, 2012 to March 7, 2013.

Fiscal year ended July 31, 2012

- ➤ On July 19, 2012, the Company announced the intention to file a Form 15F with the U.S. Securities and Exchange Commission, which took place on the same day of the announcement. Upon making the Form 15F filing, the Company's reporting obligations with the U.S. Securities and Exchange Commission were immediately suspended and the Company's reporting obligations were terminated effective on October 17, 2012, being ninety days after the Form 15F filing.
- ➤ On June 25, 2012, the Company announced the appointment of Robert Verhagen as chief executive officer. In addition, the Company announced board of director approval to voluntarily delist the Company's common stock from the NYSE MKT and to voluntarily deregister the Company's common shares under the Securities Exchange Act of 1934, as amended, after which the Company ceased filing reports with the U.S. Securities and Exchange Commission. The Company also announced that the baseline report by the independent advisors on the Company's operations and financial situation was received and reviewed by the Board and that the summary report and managements actions in response to the report had been filed on SEDAR.
- ➤ On May 18, 2012, the Company announced the receipt of regulatory approval to conduct a European Phase III clinical trial of Topical Interferon Alpha-2b in patients with low-grade cervical lesions.
- ➤ On May 14, 2012, the Company announced the commencement of its European Phase I/II clinical study of its lung cancer drug candidate L-DOS47 in Poland.
- ➤ On May 7, 2012, the Company announced that it had obtained an order of the Ontario Superior Court of Justice approving the settlement that the Company entered into with the concerned shareholders and others on March 14, 2012 and dismissed any related court proceedings. Among other things, the approved settlement specified the constitution of Helix's reconstituted board of directors and provided that Helix's next annual general meeting of shareholders would not take place prior to January 15, 2013.
- ➤ On May 3, 2012, the Company announced that it was seeking an Order of the Ontario Superior Court of Justice to approve the settlement entered into by the Company with the concerned shareholders and others on March 14, 2012 and dismissing the related court proceedings. The settlement specified, among other things, specified the constitution of Helix's reconstituted board of directors and provided that Helix's next annual general meeting of shareholders would not take place prior to January 15, 2013.

- ➤ On April 5, 2012, the Company announced that the reconstituted board of directors met and commenced a detailed review with independent advisors of the Company's operations and financial situation. In addition the reconstituted board approved the initiation of the European Phase I/II clinical trial of L-DOS47 in Poland. Mr. William White was appointed interim Chief Executive Officer, replacing Mr. Donald H. Segal, who resigned, while Professor Sławomir Majewski joined the board as an observer, given his expertise and clinical knowhow.
- ➤ On March 14, 2012, the Company announced the settlement of the proxy contest with the concerned shareholders named in the dissident proxy circular dated January 13, 2012, in connection with the company's annual general meeting held on Jan. 30, 2012, and agreed on a reconstituted board of directors of Helix. As a result of the settlement, Donald H. Segal, John Docherty, Kenneth Cawkell, Gordon Lickrish, and Roszkowski-Sliz resigned from the board of directors and were replaced by William White, Robert Verhagen, Marek Orlowski and Mario Gobbo. Jack Kay and W. Thomas Hodgson remained on the board and agreed to support the appointment of Mr. William White as the new chairman of the board.
- ➤ On January 31, 2012, the concerned shareholders announced their challenge to the chairman's decision at the annual general shareholders meeting held on January 30, 2012 to disallow all proxies and votes for the election of directors.
- ➤ On January 30, 2012, the Company announced an update on the result of the annual general shareholders meeting. The chairman of the meeting concluded that there were serious concerns that shareholders had not been properly and fully informed in making their voting decisions with respect to the election of directors and that proxies had been solicited through misrepresentation. As a result, the Company announced that the then board of directors would continue on in their capacity until a new meeting could be scheduled. On the recommendation of the chairman of the meeting and subsequent approval of the then board, a formal invitation was extended to two of the director nominees of the concerned shareholder group, offering them seats on the board.
- ➤ On January 27, 2012, the concerned shareholders announced that they had received proxies from 65.5% of shareholders favouring the concerned shareholders proxy for a new board of directors.
- ➤ On January 25, 2012 the Company announced an update to shareholders by the Special Committee on the ongoing investigation by Ernst & Young.
- ➤ On January 13, 2012, concerned shareholders of the Company filed their own proxy circular to effect change on the board of directors in connection with the annual general meeting of shareholders to be held on January 30, 2012.
- ➤ On January 9, 2012, the Company announced the proposal of a new board slate of directors for the upcoming annual general meeting of shareholders to be held on January 30, 2012. The Company also announced the appointment of Mr. Jack Kay as Chairman of the Board and Professor Kazimierz Roszkowski-Sliz as European Medical Director.
- ➤ On December 12, 2011, the Company announced the filing of a clinical trial application in both Germany and the United Kingdom, with the Bundesinstitut für Arzneimittel und Medizinprodukte ("BfArM") and the Medicines and Healthcare Regulatory Authority ("MHRA") respectively, seeking approval to perform a European phase III efficacy trial of Topical Interferon Alpha-2b in patients with low-grade cervical lesions in one or both jurisdictions. On May 18, 2012, the Company announced the receipt of regulatory approval to conduct a European Phase III clinical trial of Topical Interferon Alpha-2b in patients with low-grade cervical lesions.

- ➤ On December 6, 2011, the Company announced that the Special Committee engaged Ernst & Young LLP to assist the special committee in the investigation of the conduct of certain shareholders and parties related to shareholders that had come to the attention of the special committee.
- ➤ On November 16, 2011, the Company announced the appointment of a special committee of independent directors to advise the board with respect to the Company's annual general meeting of shareholders to be held on January 30, 2012.
- ➤ On November 11, 2011, the Company announced a collaboration with Amorfix Life Sciences Inc. to develop novel therapeutics against cancers associated with misfolded prion protein.
- ➤ On November 11, 2011, the Company announced that the clinical-hold, which was previously placed on its investigational new drug application for its Topical Interferon alpha-2b Phase II/III low-grade cervical lesion efficacy trial, was removed by the FDA.
- ➤ On October 20, 2011, the Company announced the termination of its financial and investor relations agreement with ACM Alpha Consulting Establishment Est.
- ➤ On October 18, 2011, the Company announced the receipt of a shareholder requisition to call a meeting of shareholders to elect and set the number of directors.
- ➤ On October 12, 2011, the Company announced that it had filed its response to the clinical-hold issues previously raised by the FDA relating to a pending Topical Interferon Alpha-2b Phase II/III, low-grade cervical lesion efficacy trial investigational new drug application.

NARRATIVE DESCRIPTION OF THE BUSINESS

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 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-PrepTM, Orthovisc^{®2}, Monovisc^{®1}, Immunovir^{®1} and Normacol[®]. 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 initiates 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.

RESEARCH AND DEVELOPMENT ACTIVITIES

DOS47 – A broad anti-cancer therapeutic platform

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

The Company believes that its DOS47 candidates may have potential anti-cancer activity because it stimulates an increase in the pH of the microenvironment surrounding the cancerous cells. The local production of ammonia at the site of cancerous tissues is thought to readily diffuse into the cancer cells and may exert a potent cytotoxic effect by interfering with their critical metabolic functions. In addition, the Company believes that the use of DOS47 candidates may also have a synergistic effect on the efficacy of other marketed chemotherapeutics, such as vinka alkyloid 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.

¹ 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. Imunovir® is a U.S. and Canadian registered trademark of Newport Pharmaceuticals Ltd. Normacol® is a Canadian registered trademark of Norgine Limited.

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. 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 Annual Report, 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 Sklodowska-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 Ramlau, MD, PhD at Med. Polonia Hospital Poznan.

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

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

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 μ g/kg administered to patients in Cohort 8. The additional four approved dose levels include 1.84, 2.45, 3.26 and 4.33 μ g/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), lung cancer remains the leading cause of death for both female and male 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 BiphasixTM Topical Formulation System

The BiphasixTM 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 BiphasixTM technology have expiration dates ranging from 2017 through 2020 in the United States. Without patent protection, BiphasixTM 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 BiphasixTM initiatives, and fuel divestiture of any assets associated with the BiphasixTM 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 BiphasixTM technology (see "*Biphasix*TM *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 BfArM and conditional CTA approval by the 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.

REVENUE GENERATING ACTIVITIES

Drug Distribution 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:

Gross proceeds	
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)
	8,148,000
Costs	
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
<u> </u>	2,129,000
Gain on sale from discontinued operations	\$ 6,019,000

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).

Royalty and in-licensing commitments

License Agreement with National Research Council

Helix announced on May 2, 2005 that it had begun to develop its lung cancer-specific drug compound L-DOS47. For this purpose, Helix entered into a worldwide exclusive license with the NRC, through which it obtained the right to combine an antibody that binds to NSCLC cells, and predominantly those of the adenocarcinoma type with minimal cross reactivity to other tissues with Helix's DOS47 technology. Unless earlier terminated pursuant to the license agreement, the license terminates when the last patent right related to the licensed technology expires, on a country-by-country basis. The Company is required to pay a royalty of 3% of net sales, with a minimum royalty of \$10,000 per year. The Company is also required to make certain milestone payments as follows: \$25,000 upon successful completion of Phase I clinical trials; \$50,000 upon successful completion of Phase IIb clinical trials; \$125,000 upon successful completion of Phase III clinical trials; and \$200,000 upon receipt of market approval by a regulatory authority. The license was subsequently amended to include an additional patent application which the Company is no longer pursuing. Patent applications in respect of the antibody originally licensed have been filed in Canada, the United States, and other countries. As announced on March 2, 2011, the NRC was issued a U.S. patent in respect of this antibody.

Amended Royalty Agreement with Dr. Foldvari

Certain of the Company's products are subject to the following royalty payments to Dr. Marianna Foldvari, a former director and officer of a former subsidiary of the Company:

- ➤ 2% of the Company's net sales revenue received from the marketing, manufacture, distribution or sale of certain products; or
- in the case of sub-license revenue, 2% of license fees or other revenue received by the Company related to the marketing, manufacture, distribution or sale of certain products which revenue is not allocated by the Company to the further development of the product.

Included in the products subject to the foregoing 2% royalty are PGE1, Alpha Interferon, Gamma Interferon, Acyclovir, Corticosteroids, Methotrexate, Minoxidil, Miconazole, and Tetracycline. Accordingly, any future revenue generated through the commercialization of Topical Interferon Alpha-2b will also be subject to this royalty. The royalty agreement expires on March 27, 2017.

Other Agreements

In addition to the foregoing, the Company also has payment commitments to the University of Saskatchewan Technologies Inc. in respect of the licensing or sale by the Company of any prospective

products which utilize the BiphasixTM technology and contain prostaglandin E_1 . The Company does not currently contemplate developing any such products.

PHARMACEUTICAL REGULATORY ENVIRONMENT

New drug development

Helix conducts drug development within a highly regulated environment. Regional and country-specific laws and regulations define the data required to show safety and efficacy of pharmaceutical products, and govern testing, approval, manufacturing, labeling and marketing of drugs. These regulatory requirements are a major factor in determining whether a marketable product is successfully developed and the amount of time and expense associated with each development process.

A pharmaceutical company launches a new prescription or non-prescription drug, whether innovative (original) or a generic version of a known drug, must demonstrate to the applicable regulatory authority, such as the FDA in the United States and Health Canada in Canada, that the drug is both effective and safe. The regulatory process for new drug approvals in the United States, Canada and Europe are among the most rigorous in the world, and many other jurisdictions follow a similar process. This regulatory process generally comprises the following stages described below.

In general, a potential new drug must first undergo pre-clinical testing in the laboratory ("in vitro studies") and in animal models of the targeted disease or condition ("in vivo studies") before being evaluated in humans ("clinical studies"). Pre-clinical studies primarily involve in vitro evaluations of the therapeutic activity of the drug and in vivo evaluations of the pharmacokinetic, metabolic and toxic effects of the drug in selected animal models.

Based on data generated during pre-clinical studies, extrapolations will be made to evaluate the potential risks versus the potential benefits of use of the drug candidate in humans under specific conditions of use. Upon successful completion of the pre-clinical studies, the drug candidate will undergo a series of evaluations in humans, including healthy volunteers and/or patients with the targeted disease or condition. Before undertaking clinical studies, the pharmaceutical company sponsoring the new drug must submit to the Applicable Regulatory Authority an IND submission (in the United States), a CTA (in most European countries) or the equivalent in other jurisdictions. The application must contain specific, specified, information which generally includes the results of the pre-clinical tests completed up to the time of the application. Since the method of manufacture of a particular drug may affect the efficacy and safety of that drug, information on manufacturing methods and standards and the stability of the drug candidate and dosage form must also generally be presented.

The activities which are typically completed prior to obtaining approval for marketing and sale are typically as follows:

- ➤ Pre-clinical studies: Conducted using laboratory *in vitro* testing and testing in animal models of the targeted disease or condition to gain data on the efficacy and metabolism of the therapeutic as well as to identify potential safety issues.
- > Filing of an IND, CTA or equivalent: The pre-clinical results are submitted to the Applicable Regulatory Authority for approval prior to testing in humans.
- ➤ Phase I Trials: Studies are conducted on a small number of human subjects to assess safety and the patterns of drug distribution and metabolism in the body. Normally, the initial human testing is conducted on healthy volunteers. In some cases, Phase I trials will also include patients having the targeted disease or condition: these trials are referred to as Phase I/II trials and may show efficacy results typically obtained in Phase II studies. Upon the completion of Phase I, and every phase

- thereafter, the drug sponsor must submit the results of such phase to, and obtain approval from, the Applicable Regulatory Authority before proceeding to the next phase of the clinical trial.
- ➤ Phase II Trials: Studies are conducted on groups of patients with the targeted disease or condition in order to develop efficacy, dosages and additional safety data. Typically, a Phase IIa trial uses escalating dose groups and a Phase IIb trial uses a specific dosage with a larger number of patients than a Phase IIa trial and adds a placebo arm to the trial.
- ➤ Phase III Trials: Large, multi-center, well-controlled studies are conducted on patients having the targeted disease or condition in order to provide statistically relevant proof of efficacy and safety of the therapeutic. Phase II/III trials refer to a combined trial where efficacy and safety are demonstrated.

Following Phase III, the drug sponsor submits a Marketing Authorization Application or equivalent to the Applicable Regulatory Authority for marketing approval. The application typically includes the results of the preclinical and clinical testing, together with manufacturing and controls information. The application is reviewed by the Applicable Regulatory Authority, and if approved, the drug is authorized for sale in the given country or jurisdiction.

Additional government regulation

In addition to the governmental approvals required in connection with the development of new drugs, governmental regulation in each applicable country or jurisdiction generally regulates research and laboratory procedures (including experimental testing on animals and disposal of potential or actual hazardous materials), clinical studies, manufacturing procedures, marketing, advertising and distribution methods, and industry sponsored scientific and educational activities, all of which significantly increases the level of difficulty and the costs involved in obtaining and maintaining the regulatory approval for marketing new and existing products.

Moreover, once the drug is approved for the market, the Applicable Regulatory Authority may impose restrictions on the marketing and sale of the product, including seizure or recall of the product and suspension or withdrawal of approval, if pre-marketing or post-marketing regulatory standards are not complied with or if there are problems with the product after it reaches the market. The Applicable Regulatory Authority may also require post-marketing studies to monitor the effect of an approved drug, and may impose restrictions on the marketing and sale of such drug based on the results of such studies.

INTELLECTUAL PROPERTY

Patents and other proprietary rights are very valuable to the Company, even though the patent positions of biotechnology companies may be uncertain and involve complex legal and factual issues. The Company has no assurance that any of its patent applications will result in the issuance of any patents. Even issued patents may not provide the Company with a competitive advantage against competitors with similar technologies, or who have designed around the Company's patents. Furthermore, the Company's patents may be struck down if challenged. Intellectual property laws do not protect intellectual property to the same extent from one country to another.

Because of the substantial length of time and expense associated with developing new products, the pharmaceutical, medical device, and biotechnology industries place considerable importance on obtaining patent protection for new technologies, products, and processes. The Company's policy is to file patent applications to protect inventions, technology, and improvements that are important to the development of our business and with respect to the application of our products and technologies to the treatment of a number of disease indications. The Company's policy also includes regular reviews related to the

development of each technology and product in light of its intellectual property protection, with the goal of protecting all key research and developments by patent.

The Company seeks intellectual property protection in various jurisdictions around the world and owns patents and patent applications relating to products and technologies in the United States, Canada, Europe and other jurisdictions. The scope and duration of our intellectual property rights vary from country to country depending on the nature and extent of our intellectual property filings, the applicable statutory provisions governing the intellectual property, and the nature and extent of our legal rights. The Company will continue to seek intellectual property protection as appropriate and require our employees, consultants, outside scientific collaborators, and sponsored researchers to enter into confidentiality agreements with us that contain assignment of invention clauses outlining ownership of any intellectual property developed during the course of the individual's relationship with us.

DOS47

The Company currently owns two U.S. patents in respect of the DOS47 technology, and also has also licensed patent rights from the NRC for the antibody component of L-DOS47. With respect to non-U.S. patents, the Company owns 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.

BiPhasixTM

The Company currently owns four U.S. BiphasixTM 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. BiphasixTM patent applications. The Company is prosecuting these three applications with a view to further strengthening its patent portfolio for BiphasixTM and Topical Interferon 2b.

FACILITIES

General office space

The Company's head office is located in a 6,000-sq. ft. leased office and warehouse space located north of Toronto in Aurora, Ontario, Canada. Administration, sales and marketing functions are located at the Aurora office. The current lease arrangement expires on February 28, 2015.

The Company leases a small office on a month to month basis in Saskatoon, Saskatchewan.

Laboratories

The Company also leases approximately 4,155 sq. ft. in Edmonton, Alberta, Canada under a lease arrangement that originally expired on June 30, 2014. The Company successfully amended the lease terms to expire December 2014 and has since renewed the lease to extend the terms to June 30, 2015. These premises house the Company's oncology research laboratory.

Manufacturing

The Company has no manufacturing capacity and, prior to the sale of its Rivex Pharma division pursuant to the Rivex Transaction, relied on third parties for manufacturing.

EMPLOYEES

The following table depicts the number of full-time equivalent employees as at July 31:

	2014	2013
Research and development	8.0	10.0
Operating, general and administration	3.5	2.5
	11.5	12.5

None of the Company's employees are covered by collective bargaining agreements.

RISK FACTORS

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 AIF, 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 noncore 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.

DIVIDEND POLICY

To date, the Company has not paid any dividends on the outstanding common shares and has no current intention to declare dividends on its common shares in the foreseeable future. Any decision to pay dividends on the common shares in the future will be dependent upon the financial requirements of the Company to finance future growth, the financial condition of the Company and other factors that the Board may consider appropriate in the circumstances. The Company has no restrictions on the payment of dividends other than those provided under the provisions of the *CBCA* and the policies of the TSX.

CAPITAL STRUCTURE

Share capitalization

The Company's Articles of Continuance authorize the issuance of an unlimited number of common shares and 10,000,000 preferred shares issuable in series. As at July 31, 2014, 75,900,337 (July 31, 2013 – 67,226,377) common shares were issued and outstanding. No preferred shares have been issued, nor has any series of preferred shares been designated.

Common shares

The holders of the common shares of our Company are entitled to receive notice of and to attend all meetings of the shareholders of our Company and have one vote for each common share held at all meetings of shareholders.

Subject to the rights, privileges, restrictions and conditions attaching to any other class or series of shares of the Company, the holders of common shares are entitled to receive dividends as and when declared by the Board, in such amount and in such form as the Board may from time to time determine, and subject to the limitations on declaration of dividends prescribed in the *CBCA*. All dividends which the Board may declare on the common shares must be declared and paid in equal amounts per share on all common shares at the time outstanding.

In the event of the dissolution, liquidation or winding-up of the Company, whether voluntary or involuntary, or in the event of any other distribution of the Company's assets among its shareholders for the purpose of winding-up its affairs, the holders of the common shares shall, subject to the rights of the holders of any other class of shares of the Company, be entitled to receive such assets of the Company upon such distribution.

Preferred shares

The preferred shares of the Company may at any time or from time to time be issued in one or more series. The directors may alter by resolution the Articles of the Company, to fix or change the number of shares in, and to determine the designation, rights, privileges, restrictions and conditions attaching to the shares of each series of preferred shares. The directors may also confer on the holders of any series of preferred shares the right to notice of or to be present or to vote, at any general meeting of the shareholders of the Company. Preferred shares shall be entitled to preference over the common shares and any other shares of the Company ranking junior to the preferred shares in the event of any liquidation, dissolution or winding-up of the Company or any distribution of its assets for the purpose of winding-up its affairs, whether voluntary or involuntary. The preferred shares of each series will rank in parity with the preferred shares of every other series with respect to priority in the payment of dividends and in the distribution of assets in the event of liquidation, dissolution or winding-up of the Company. No preferred

shares have been issued by the Company and no series of preferred shares have been designated by the Company.

Warrants

Warrants have been issued by the Company in connection with the sale of units. Each unit issued to date consists of one common share and one common share purchase warrant (each a "Warrant"). All of the issued Warrants are subject to certain restrictions on transfer as set out in the applicable warrant certificates. These certificates provide that any rights under such certificates, including any beneficial interest therein, are not transferrable or assignable to any other person by the holder of such certificate without the prior written consent of the Company. Warrants were issued by the Company on the dates set out below.

On September 8, 2009, the Company announced the completion of a private placement, issuing 6,625,000 units at \$2.05 per unit, for gross proceeds of \$13,581,250. Each unit consists of one common share and one common share purchase warrant. Each common share purchase warrant entitled the holder to purchase one common share at a price of \$2.87 until 5 pm (Toronto time) on September 7, 2012. On September 7, 2012 the Company announced that it had extended the expiry date of warrants issued on September 8, 2009 for an additional six months, from September 7, 2012 to March 7, 2013. The Company did not amend any other provisions of the affected warrants. On February 21, 2013 the Company announced a further extension of the expiry date of these warrants, from March 7, 2013 to September 7, 2013. The Company did not amend any other provisions of the affected warrants as part of this extension. On August 23, 2013, the Company announced that it extended the expiry date of these warrants from September 7, 2013 to September 7, 2014, which in this case, included an increase in the exercise price of the these warrants from \$2.87 to \$3.51. The warrants expired unexercised on September 7, 2014.

On August 6, 2010, the Company announced the completion of a private placement, issuing 4,530,000 units at \$2.43 per unit, for gross proceeds of \$11,007,900. Each unit consists of one common share and one common share purchase warrant. Each common share purchase warrant entitles the holder to purchase one common share at a price of \$3.40 until August 5, 2013. On August 9, 2013, the Company announced that, effective August 5, 2013, it had extended the expiry date of these warrants from August 5, 2013 to February 5, 2015 and to increase the exercise price of the these warrants from \$3.40 to \$4.15. The Company did not amend any other provisions of these warrants.

On March 28, 2011, the Company completed a private placement, issuing 1,652,719 units at \$2.39 per unit, for gross proceeds of \$3,949,998. Each unit consists of one common share and one common share purchase warrant. Each common share purchase warrant entitles the holder to purchase one common share at a price of \$3.35 until March 27, 2016.

On March 30, 2011, the Company completed a private placement, issuing 918,365 units at \$2.39 per unit, for gross proceeds of \$2,194,892. Each unit consists of one common share and one common share purchase warrant. Each common share purchase warrant entitles the holder to purchase one common share at a price of \$3.35 until March 29, 2016.

On November 1, 2013, the Company completed a private placement, issuing 4,678,000 units at \$1.15 per unit, for gross proceeds of approximately \$5,380,000. Each unit consists of one common share and one common share purchase warrant. Each common share purchase warrant entitles the holder to purchase one common share at a price of \$1.61 until October 31, 2018.

On July 10, 2014 the company completed a private placement, issuing 3,996,000 units at \$1.60 per unit, for gross proceeds of \$6,393,600. Each unit consists of one common share and one common share purchase warrant. Each common share purchase warrant entitles the holder to purchase one common share at a price of \$2.24 until July 09, 2019.

MARKET FOR SECURITIES

Trading Price and Volume

The Company's common shares began trading on the TSX on June 3, 1996. The current stock symbol is "HBP". The following table lists the monthly high-low share price and daily average volume on the TSX for the Company's common shares for the respective period:

	High	Low	Volume
August 2013	\$1.20	\$0.92	115,050
September 2013	\$1.55	\$1.19	199,374
October 2013	\$1.50	\$1.01	233,067
November 2013	\$1.77	\$1.25	110,193
December 2013	\$1.55	\$1.36	68,034
January 2014	\$1.55	\$1.32	89,725
February 2014	\$1.55	\$1.30	257,714
March 2014	\$1.52	\$1.41	84,167
April 2014	\$1.99	\$1.40	525,882
May 2014	\$2.25	\$1.76	132,948
June 2014	\$2.27	\$1.84	156,458
July 2014	\$2.10	\$1.70	191,971
August 2014	\$2.00	\$1.66	65,383
September 2014	\$1.95	\$1.58	23,958

The Company's common shares continue to be quoted on the Frankfurt, Stuttgart, Munich and Berlin Stock Exchanges, under the trading symbol "HBP".

DIRECTORS AND OFFICERS

Name, Occupation and Securities Holding

The Directors of the Company are elected at each annual general meeting of the Company and hold office until the next annual general meeting or until their successors are elected.

The following table represents the composition of the Company's board of director committees:

Audit Committee	Governance &	Science & Business
Audit Committee	Compensation Committee	Development Committee
Sven Rohmann (1)	Yvon Bastien (1)	Sven Rohmann (1)
Marek Orlowski	Sławomir Majewski	Robert Verhagen
Stacy L. Wills	Marek Orlowski	Marek Orlowski

(1) Chairs of the individual committees

The following is a list of Directors and Officers of the Company, as of the date of this Annual Information Form, along with a brief biography:

Yvon Bastien

Chair of the Board

Director since December 2013 (independent director)

Residence: Montreal, Québec, Canada

Mr. Bastien has served in health care leadership positions throughout his career. He has served as the Chairman for Trillium Health Care Products Inc. since 2007 and of the St. Bernard Soap Company since 2008. He was also the Chairman of Enobia Pharma Corp. from 2006 to 2009 and Chairman of PainCeptor Pharma Corporation from 2008 to 2009. In November 2013 Mr. Bastien was elected as a director of Bioniche Life Sciences Inc. From 1995 to 2006, Mr. Bastien served as President and General Manager of Sanofi Synthelabo Canada Inc. based in Markham, Ontario, Canada. Prior to joining Sanofi, Mr. Bastien was Founder and President of Delta Healthcare, an early stage Canadian biotechnology company. Prior to Delta, Mr. Bastien served as President of Montreal based Jouveinal, European Marketing Manager of CibaGeigy in Basel, Switzerland, Vice-President, International Marketing and Sales of Laboratoire Debat in Paris, France, General Manager of IMS Canada (Montreal), and as a Hospital Sales Representative with Ely Lilly (Montreal). He serves, or has served, as Chair of the board of directors for four companies and has also served on the boards of directors for various companies in the fields of biotechology, pharmaceuticals and health care. Mr. Bastien trained in medicine at Louvain University in Belgium, conducted MBA coursework at Sir George William University in Montreal and completed an Executive Management Program at CibaGeigy/INSEAD in France.

> Mr. Sylwester Cacek

Director since March 2014 (independent director)

Residence: Zurich, Switzerland

Sylwester Cacek is currently president of Sfinks Polska SA, and was the founder of Dominet Capital Group, which included a nationwide retail bank Dominet Bank SA. As CEO of the group, Mr. Cacek created a nationwide financial institution with a wide range of products and services dedicated to individual clients and small and medium enterprises. In 2007, Dominet SA was successfully sold to Fortis Group. In his career, Mr. Cacek has served as a member of supervisory boards in such companies as Dominet Bank SA, Impel SA, OrsNet Sp. z o.o., SportLive24 SA and KS Widzew Łódź SA. He is a shareholder of the Polish professional football club RTS Widzew Łódź.

Sławomir Majewski

Director since October 2012 (independent director)

Residence: Warsaw, Poland

Prof. Majewski has been the Head of the Department of Dermatology and Venereology, Center of Diagnostics and Treatment of STD, Warsaw Medical University, Poland, since 1998, Deputy Rector for Science and International Relations at the Medical University of Warsaw since 2008, Coordinator of the Polish Center of Preclinical Studies and Technology since 2008 and a member of the scientific advisory board at the Polish Ministry of Health. Prof. Majewski is also a member of several national and international societies and scientific institutions including the Polish Academy of Sciences, European Society of Dermatological Research, European Academy of Dermatology and Venereology, European Association for Cancer Research, American Association for Cancer Research, International Advisory Committee of the Archives of

Dermatology and the International Editorial Committee of the Journal of American Academy of Dermatology. He was also member of the board of the European Society for Dermatological Research from 2000 to 2004 and from 2003 to 2008, Prof. Majewski was a member of the International Steering Committee of the FUTURE II Study on the quadrivalent HPV vaccine. He is also a former member of the Board, having served from 2008 to 2009.

> Marek Orlowski

Director since March 2012 (independent director)

Residence: Warsaw, Poland

Mr. Orlowski is currently a consultant for Sanofi-Aventis for portfolio development and globalization of brands, a position he has held since 2010. Mr. Orlowski is the co-founder of the Polish pharmaceutical company, Nepentes S.A., which was acquired by Sanofi-Aventis in 2010. Mr. Orlowski's experience at Nepentes S.A., from the time he co-founded it in 1991 until its acquisition in 2010, included extensive experience in all aspects of marketing, supervision of sales, creation of the company's portfolio and development strategy. His responsibilities included the supervision of strategy of product placement on the market and research and development, the sale of a number of significant brands, creation of new products, and involvement in clinical trials of products. He negotiated distribution contracts and coordinated product launches in Eastern Europe, from Russia through to Poland to Romania. He was also a member of the Management Board of Nepentes S.A. until 2010, where he was responsible for marketing, sales, portfolio creation, strategic development and research and development.

Mr. Orlowski also oversaw the listing of Nepentes S.A. on the Warsaw Stock Exchange and negotiated its subsequent acquisition by Sanofi-Aventis. Mr. Orlowski established and co-owned a direct marketing company, Pelargos Sp. z o.o., as well as a pharmaceutical company, Mexigem Polska Sp. z.o.o., both of which were later acquired. He is a board member and Chief Executive Officer of Airway Medix Sp. z.o.o., a Polish-Israeli company that produces ventilation assistance devices for intensive care units. Mr. Orlowski holds a MD (Medical Director) degree from the Medical Academy of Warsaw.

Mr. Orlowski holds a MD (Medical Director) degree from the Medical Academy of Warsaw.

> Dr. Sven Rohmann

Director since December 2013 (independent director)

Residence: Zurich, Switzerland

Dr. Rohmann is an experienced life science venture capitalist with more than 25 years hands-on experience in pre-clinical & clinical research as well as marketing, business & corporate development, especially in the field of oncology. Since July 2010, Dr. Rohmann has served as General Manager, Europe with Burrill & Company, a leading global Venture Capital firm with \$1.5 billion under management, and during that same period he has served as Chief Medical Officer and Advisor to the President of Immudyne Inc. During the period from April 2007 to October 2008, Dr. Rohmann served as a Venture Fund Capital Fund Manager for Novartis Pharma AG, and for part of that time also served as Head of Partnering, General Medicine and Mature Products with Novartis. Prior to his service with Novartis, Dr. Rohmann served as General Partner of Nextech Venture AG from 2002 to April 2007. Before his career as venture capitalist, Dr. Rohmann spent 10 years with Merck Serono, where he served as the Global Head, Strategic Marketing, Oncology, and was involved in the licensing of Erbitux, an oncology blockbuster drug, from Imclone and he led the establishment of Merck Oncology. In addition, Dr. Rohmann was the founding CEO of Ganymed Pharmaceuticals, a German oncology start-up

company. Mr Rohmann obtained his medical degree, PhD and MBA from the University of Rotterdam.

> Stacy L. Wills

Director since June 2013 (independent director)

Residence: Calgary, Alberta, Canada

Mr. Wills has over 20 years of experience in working with early to mid-stage Canadian technology companies. Since 2011, Mr. Wills has worked with Innovate Calgary, the commercialization arm of the University of Calgary and one of Alberta's largest and longeststanding technology incubators. Mr. Wills is Innovate Calgary's Vice President, Company Creation, and he oversees a portfolio of 10 public and private investee companies, primarily in the life sciences and biotechnology sectors. From 2005 to 2010, prior to joining Innovate Calgary, Mr. Wills served as the Senior Director of Corporate Development at Elluminate Inc., where he was involved in growing the company from a start-up to having over 140 employees and annual revenues in excess of \$20 million. Mr. Wills was also actively involved in Elluminate's sale process, which resulted in its acquisition by Blackboard Inc., a leading educational technology firm. Mr. Wills had previously co-founded and served as a board member of the Accolade Private Companies Fund which made seed-level investments in start-up technology companies. Since 2001, Mr. Wills has also been involved in a number of equity financing transactions in the technology sector, including SYNSORB Biotech. Mr. Wills holds a Chartered Investment Manager designation and obtained a B.Comm (with distinction) from the University of Calgary.

Robert A. Verhagen

Chief Executive Officer

Director since March 2012 (non-independent director)

Residence: Toronto, Ontario, Canada

Mr. Verhagen is Helix's Chief Executive Officer, a position he has held since July 2012. He has more than 20 years of business development experience in the pharmaceutical and diagnostics industries, including experience working with small-cap biotechnology companies as well as multinational corporations. He has extensive knowledge of corporate development and business planning including licensing arrangements, strategic alliances, partnerships, mergers and acquisitions and subsidiary structuring as well as strategic planning experience in areas including pharmaceutical and medical devices product development, capital equipment and reagent markets and life sciences service lines.

Prior to his appointment as Chief Executive Officer, Mr. Verhagen was employed at Spectral Diagnostics Inc., a company focused on the development and commercialization of key diagnostics in several disease areas, with particular emphasis on the combination of diagnostics and therapeutics in disease management. Mr. Verhagen served as Spectral Diagnostics' Vice President, Business Development from 2006 to July 2012, with responsibility for licensing and corporate strategic alliances, as well as Co-Chair of the Clinical Operations Committee, tasked with running a multi-national pivotal trial in Sepsis.

➤ Between 2000 and 2006 he was Senior Director, Corporate Development of MDS Inc., where he created and launched a consortium of biotechnology and technology companies in genomics, proteomics, imaging and clinical development while leading the integration of acquired operations into the company. He has also held a senior position at SYNSORB Biotech, and founded and developed INH Technologies Inc., a life sciences company focused on drug

discovery technologies, overseeing all aspects of growth, including financing, operations, management and business development, and ultimately negotiated the acquisition of the company by a large multi-divisional life sciences company, providing premium shareholder value for investors. Mr. Verhagen holds an MBA and B.Sc. (Spec), both from the University of Alberta.

Photios (Frank) Michalargias

Chief Financial Officer

Residence: Richmond Hill, Ontario, Canada

Photios (Frank) Michalargias, CA, possesses over 20 years of senior management experience in both public and private industry; and is experienced in transition and growth management, strategic planning and the raising of debt and equity financing. From 2004 to mid-2005, he was Chief Financial Officer of AP Plasman Corporation, a tier one North American automotive parts supplier controlled by Schroder Ventures International. From 2002 through to mid-2004, he was Senior Finance Director for CFM Corporation, a public company listed on the TSX. Mr. Michalargias' previous tenures include senior financial roles with Trailmobile Corporation, Huhtamaki Oyi and Unilever. He holds a Commerce and Economics degree from the University of Toronto and is a Chartered Accountant. Mr. Michalargias' business functions, as Chief Financial Officer, include financial administration; responsibility for accounting and financial statements; liaising with auditors, the financial community and shareholders; and coordination of expenses/tax activities of the Company.

➤ Heman Chao

Chief Scientific Officer

Residence: Aurora, Ontario, Canada

Heman Chao, Ph.D., is a biochemist with expertise in proteomics technologies. He has been President of Sensium Technologies Inc., a Company subsidiary, since November 2004 until it was wound up into the Company in April 2008. From 1999 to June 2002, he was Manager of Sensium Technologies Inc. From June 2002 to 2004, he was Vice President of Technology for the Company; his title was changed from Vice President of Technology to Vice President of Research for the Company in late 2004. Prior to joining the Company, he was a research fellow in the federally funded Protein Engineering Network of Centres of Excellence coordinating multicenter research.

To the best of the Company's knowledge, the number and percentage of issued common shares of the Company beneficially owned, directly or indirectly, by the Directors and Officers of the Company, as a group and individually, are as set out in the following table:

Designation of Class	Number of Shares Held	Percentage of Class	
Yvon Bastien	0	0.00%	
Sylwester Cacek	6,997,200	9.22%	
Slawomir Majewski	1,705,700	2.25%	
Marek Orlowski	1,710,000	2.25%	
Sven Rohmann	0	0.00%	
Stacy L. Wills	0	0.00%	
Robert A. Verhagen	67,400	0.09%	
Photios (Frank) Michalargias	0	0.00%	
Herman Chao	0	0.00%	
Total Common Shares	10,480,300	13.81% ⁽¹⁾	

⁽¹⁾ Based on 75,900,337 common shares issued and outstanding as at September 30, 2014 and information filed on the System for Electronic Disclosure by Insiders at www.sedi.com.

Cease Trade Orders, Bankruptcies, Penalties and Sanctions

To the knowledge of the directors and officers of the Company:

- a) no director or officer of the Company is, as at the date of this AIF or has been, within the 10 years before the date of the AIF, a director or executive officer of any company (including the Company) that:
 - (i) while such person was acting in such capacity, was the subject of a cease trade or an order similar to a cease trade order or an order that denied the relevant company access to any exemption under securities legislation, that was in effect for a period of more than 30 consecutive days (an "order"); or
 - (ii) was subject to an order that was issued after such person ceased to act in such capacity and which resulted from an event that occurred while such person was acting in such capacity; or
- b) no director or officer of the Company or a shareholder holding a sufficient number of securities of the Company to affect materially the control of the Company is, at the date of this AIF or has been, within the 10 years before the date of the AIF, a director or executive officer of any company (including the Company) that:
 - (i) while such person was acting in such capacity or with a year of such person ceasing to act in such capacity, became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold its assets; or
 - (ii) has, within the 10 years before the date of this AIF, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or become subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold such person's assets.

To the knowledge of the directors and officers of the Company, no director or officer of the company: (a) has been subject to any penalties or sanctions imposed by a court relating to Canadian securities legislation or by a Canadian securities regulatory authority or has entered into a settlement agreement

with a Canadian securities regulatory authority, or (b) has been subject to any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable investor in making an investment decision.

LEGAL PROCEEDINGS

Chapman, Spira & Carson, LLC ("Chapman, Spira") has made a claim against the Company in the Supreme Court of the State of New York for damages of US\$500,000, punitive damages of US\$1,500,000, plus costs, for breach of contract and *quantum meruit* pursuant to a complaint dated May 2, 2012. The court has now denied Chapman, Spira's claim for breach of contract, but permitted its claim for *quantum meruit* to continue. The Company continues to contest this remaining claim and believes it to be without merit. The matter is currently in the discovery phase, which is expected to continue until December 2014.

No penalties or sanctions have been imposed on the Company by a court relating to securities legislation or by a securities regulatory authority during the fiscal year.

INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

To the Company's knowledge, none of its directors, executive officers, or other insiders, nor any associate or affiliate of any of them, has any material interest, direct or indirect, in any transaction within the three most recently completed financial years or during the current financial year that has materially affected or will materially affect the company.

TRANSFER AGENT AND REGISTRAR

The Company's transfer agent and registrar for its common shares is:

Computershare Trust Company of Canada 100 University Avenue Toronto, Ontario, Canada, M5J 2Y1

MATERIAL CONTRACTS

The Company did not enter into any other new material contracts outside the ordinary course of the Company's business during the fiscal year ended July 31, 2014.

Other material contracts entered into prior to the Company's 2014 fiscal year which are still in effect are listed below:

The Company entered into a Financial and Investor Relations Agreement with ACM Alpha Consulting Management Est. ("ACM") dated May 1, 2012 (the "ACM Agreement") and this agreement remains in force, on a month-to-month basis as of the date of this AIF. The ACM Agreement provides that ACM will provide certain investor and financial advisory services to the Company and may be terminated by either party, effective at any time, after May 1, 2013, upon ninety days written notice. The agreement includes the following provisions:

- (i) a 12.5% fee on the gross proceeds on any capital raised up to six months after the termination of this agreement from an ACMest introduced investor with residency outside Canada and the USA:
- (ii) a 12.5% fee on the value of a transaction up to twelve months after the termination of this agreement from an ACMest introduced strategic partner, including but not limited to, any cash payments to the Company as an up-front payment, any co-development proceeds, any milestone payments and any royalties associated with the transaction;
- (iii) a 12.5% fee on the gross proceeds of any capital raised up to twelve months after the termination of this agreement from an ACMest introduced strategic partner; and
- (iv) a monthly fee for investor relation services of CHF 33,000 and reimbursement of certain expenses.
- ➤ Technology License Agreement with the National Research Council of Canada dated April 28, 2005 and amendment dated December 2, 2009 (described under *Narrative Description of the Business*, above);
- ➤ Clinical Supplies Manufacturing Agreement with BioVectra Inc. dated November 1, 2010. The Company relies on BioVectra for its supply of urease and the manufacturer of bulk drug product for future clinical testing programs.
- The Company entered into an Asset Purchase Agreement with Pharmascience Inc. made as of December 10, 2012 in connection with the Rivex Transaction. Under this agreement, the indemnification obligations, both by and in favour of the Company, survive until January 25, 2015. These obligations are subject to certain thresholds and caps. The Company's indemnification obligations include losses suffered by Pharmascience in connection with a breach of representation or warranty given in the agreement by the Company, a product recall conducted in accordance with the terms of the agreement and non-compliance by Helix with section 6 of the *Retail Sales Act* (Ontario). The Company is indemnified by Pharmascience for losses in connection with, among other things, any liabilities assumed by Pharmascience under the agreement, any breach of representation or warranty given by Pharmascience under the agreement and any tax, interest or penalty imposed on the Company as a result of certain tax elections made in connection with the Rivex Transaction. The agreement is further described under *Drug Distribution Business in Canada*, above.

INTERESTS OF EXPERTS

The Company's auditors for fiscal 2014 were BDO Canada LLP, 60 Columbia Way, Markham, Ontario, Canada, L3R 0C9. As announced on July 12, 2013, the Company's auditors following the completion of the fiscal 2013 audit would change from KPMG LLP for BDO Canada LLP. Both KPMG LLP and BDO Canada LLP are independent of the Company in accordance with the applicable rules of professional conduct/code of ethics of The Institute of Chartered Accountants of Ontario.

AUDIT COMMITTEE DISCLOSURE

Audit Committee Responsibilities

The Company's Audit Committee is responsible for reviewing the Company's financial reporting procedures and internal controls and for the retention and review of the performance of the Company's external auditors, together with reviewing the scope and results of the Company's audits and managing the professional services furnished by the independent auditors. The Audit Committee is also responsible for reviewing the annual and quarterly financial statements and accompanying Management's Discussion

and Analysis prior to their approval by the full Board. The Audit Committee also reviews the Company's financial controls with the auditors of the Company on an annual basis.

The Company's independent auditor is accountable to the Board and to the Audit Committee. The Board, through the Audit Committee, has the ultimate responsibility for evaluating the performance of the independent auditor, and through the shareholders, to appoint, for replacing and compensating the independent auditor.

The Company's Audit Committee has a charter, a copy of which is attached as Schedule "A".

Composition and relevant education and experience

The Audit Committee is currently comprised of three members: Dr. Sven Rohmann, Marek Orlowski and Stacy L. Wills, all of whom are independent directors. Audit Committee members were last appointed on December 18, 2013.

All members of the audit committee are financially literate, meaning they have the ability to read and understand a set of financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of the issues that can reasonably be expected to be raised by the Company's financial statements. A brief description of the education and experience of each of the audit committee members is set under the heading "Directors and Officers", above.

Exemptions Relied Upon

None.

Pre-approval of non-audit services

It is the Company's policy that all audit and non-audit services performed by its external auditors will continue to be pre-approved by the Company's Audit Committee.

Auditor fees

The total fees billed for professional services by BDO Canada LLP for fiscal 2014 and KPMG LLP for fiscal 2013 are as follows:

Item	2014		2013	
	Amount	Percentage	Amount	Percentage
Audit-Fees	\$41,250	89%	\$117,300	87%
Audit-Related Fees	\$0	0%	\$0	0%
Tax Fee	\$0	0%	\$6,750	5%
All Other Fees	\$5,188	11%	\$11,500	8%
Total	\$46,438	100%	\$135,550	100%

As disclosed on July 12, 2013, the Company's Board had initiated the process of changing the Company's external auditor from KPMG LLP to BDO Canada LLP effective as of the completion of the audit for the Company's 2013 fiscal year by KPMG LLP, though a transition period which commenced on June 21, 2013.

ADDITIONAL INFORMATION

Additional information, including directors and officers remuneration and indebtedness, principal holders of the Company's securities, securities authorized for issuance under equity compensation plans, and interests of insiders in material transactions, if applicable, is contained in the Company's Management Proxy Circular for its most recent annual meeting of shareholders that involved the election of directors. Additional financial information is provided in the Company's comparative financial statements, together with the associated management discussion and analysis, for its most recently completed financial year.

Any request for any documents referred to above should be made to the Chief Financial Officer, attention: Frank Michalargias, 305 Industrial Parkway South Unit #3, Aurora, Ontario, L4G 6X7, Canada or by fax to (905) 841-2244.

Additional information relating to the Company can be found under the Company's profile on SEDAR at www.sedar.com and the Company's website at www.helixbiopharma.com.

GLOSSARY

Adenocarcinoma: Cancer that originates in glandular tissue.

BioVectra: BioVectra Inc., a cGMP manufacturer of active pharmaceutical ingredients, advanced intermediates, specialty biochemicals, enzymes and biomolecules.

BiphasixTM **technology**: Helix's proprietary platform technology designed for dermal, mucosal, transdermal and transmucosal delivery of molecules.

Board: The board of directors of the Company.

CBCA: means the Canada Business Corporations Act.

cGMP: Is an acronym for Current Good Manufacturing Practices, a term that is recognized worldwide for the control and management of manufacturing and quality control testing of foods and pharmaceutical products.

CIN: Cervical Intraepithelial Neoplasia. Standard CIN grading of increasing severity is CIN1, CIN2 or CIN3.

Colposcopy: A medical diagnostic procedure to examine the epithelial cells of the cervix, vagina, and vulva, especially for early signs of cancer.

CTA: Clinical Trial Application.

Dermal: Pertaining to the region of skin to the epidermis, consisting of a dense bed of vascular connective tissue. Dermal administration refers to the delivery of substances or compounds into the dermal region.

Dysplasia: A term used in pathology to refer to an abnormal growth or development of cells, tissue or organs. Dysplasia is often an indicator of early stage neoplasia or the abnormal proliferation of cells.

Epithelial: Of, pertaining to, or characterized by the epithelium, which is tissue, consisting of one or more cellular layers separated by very little intercellular substance, that covers most internal and external surfaces of the body.

FDA: United States Food and Drug Administration. The regulatory agency that oversees the development, manufacture, sale and use of diagnostic and therapeutic medical products in the United States.

GAAP: Generally accepted accounting principles.

GMP: Good Manufacturing Practice.

Health Canada: The department of the federal government of Canada that is responsible for all health related matters in Canada on a national level.

Histological: Of, pertaining to, or characterized by histology, which is the branch of biology dealing with the study of tissues, cells and their structure, especially at the microscopic level.

HPV: Human Papilloma Virus. One of the most common sexually transmitted infections, causing cervical dysplasia and ano-genital warts as well as being linked to a variety of cancers.

Immunoconjugate: A molecular complex consisting of one or more antibodies linked to a second compound.

IND: Investigational New Drug.

Intraepithelial: Occurring in or among cells of the epithelium including the cells of the epithelial layer of the skin.

Lipid: Fats or fat-like substances characterized by being water-insoluble.

Low-grade cervical lesions: For the purposes of this AIF, this term refers to cervical abnormalities combining an LSIL finding on Pap smear and a CIN1 or CIN2 diagnosis on colposcopy.

LSIL: Low-grade Squamous Intraepithelial Lesions.

Neoplasia: A pathological process that results in the abnormal and often uncontrolled growth and proliferation of cells, and is usually associated with cancer.

NRC: National Research Council of Canada.

NSCLC: Non-small cell lung cancer.

Pharmacokinetic: The action of drugs in the body over a period of time, including the processes of absorption, distribution, localization in tissues, biotransformation (metabolism) and excretion.

Phase I clinical trials: Clinical trials used to assess the potential toxicity of a new drug, primarily involving healthy volunteers, under the regulations of the applicable jurisdiction.

Phase II clinical trials: Clinical trials used to assess the effectiveness and most effective dosage of a new drug under the regulations of the applicable jurisdiction.

Phase III clinical trials: Late stage clinical trials used to assess a drug for efficacy and safety at several independent sites in a large number of patients under the regulations of the applicable jurisdiction.

RECIST: Response Evaluation Criteria In Solid Tumors. A set of published rules that define when cancer patients improve, stay the same, or worsen during treatments.

Therapeutic: A medical treatment or curative product for a disease.

Topical Interferon Alpha-2b: A topical preparation under development by the Company that is intended to be self-applied to HPV-infected tissues, in order to deliver interferon-alpha intradermally. It is based on Helix's proprietary BiphasixTM drug delivery technology.

TSX: The Toronto Stock Exchange.

Transdermal: Access to the systemic blood circulation via migratory passage through the multiple layers of skin.

Transmucosal: Access to the systemic blood circulation via migratory passage through the multiple layers of mucosa.

Vaccine: A suspension of living, attenuated or killed microorganisms or genetic material administered for the prevention or treatment of infectious or hereditary diseases.

SCHEDULE A

HELIX BIOPHARMA CORP.

AUDIT COMMITTEE CHARTER

The Audit Committee of the Board of Directors (the "Board") of Helix BioPharma Corp. (the "Corporation") shall have the composition, responsibilities, powers, duties and authority specified in this Charter.

I. Purpose

The Audit Committee's purpose is to:

- a. Assist the Board's oversight of:
 - i. The integrity of the Corporation's financial statements;
 - ii. The Corporation's financial accounting and reporting, the system of internal controls established by management, and the adequacy of internal and independent auditing relative to these activities;
 - iii. The Corporation's compliance with legal and regulatory requirements; and
 - iv. The qualifications, independence and performance of the independent public accounting firm auditing the Corporation's financial statements.
- b. Prepare such reports as may be required from time to time by applicable securities laws and by the rules and regulations of applicable regulatory authorities (including any stock exchange on which the Corporation's securities are listed) (such laws, rules and regulations being hereinafter referred to, collectively, as the "Rules and Regulations").
- **c.** Oversee the work of the Corporation's independent accounting firm, including the resolution of disagreements between management and the independent public accounting firm regarding financial reporting.

II. Composition, Appointment and Procedures.

- a. The Audit Committee shall consist of at least three members of the Board, each of whom shall be, subject to such exceptions as may be permitted by the Rules and Regulations, an "independent director" and "financially literate" within the meaning of the Rules and Regulations.
- b. No member of the Audit Committee may concurrently serve on the audit committee of more than two other public companies unless the Board determines that such simultaneous service would not impair the ability of such director to effectively serve on the Audit Committee.
- c. The members of the Audit Committee shall be appointed by the Board and shall continue to act until their successors are appointed. Members shall be subject to removal at any time by the Board.

- d. The Audit Committee shall meet at least four times each year. At such meetings, the Audit Committee shall discuss such audit matters as the Audit Committee deems appropriate with the Corporation's CFO and independent public accounting firm.
- e. Periodically, the Audit Committee shall meet separately with the independent public accounting firm.

III. Duties and Responsibilities with Respect to Audit, Accounting and Financial Disclosure.

The Audit Committee shall:

- a. Prior to filing with the applicable regulatory authorities or otherwise publicly disclosing the information, review and discuss with the Corporation's management and independent public accounting firm:
 - i. the Corporation's annual audited financial statements, quarterly financial statements, and annual and quarterly financial press release, including the Corporation's disclosures under "Management's Discussion and Analysis"; and,
 - ii. the scope and results of the annual audit, or any interim reporting;
- b. Review and discuss with the Corporation's management and independent public accounting firm:
 - major issues regarding accounting principles and financial statement presentations, including any significant changes in the Corporation's selection or application of accounting principles, and major issues as to the adequacy of the Corporation's internal controls and any special audit steps adopted in light of material control deficiencies;
 - ii. analyses prepared by management and/or the independent public accounting firm setting forth significant financial reporting issues and judgments made in connection with the preparation of the financial statements, including analyses of the effects of alternative GAAP methods on the financial statements;
 - iii. the effect of regulatory and accounting initiatives, as well as off-balance-sheet structures, on the Corporation's financial statements; and
 - iv. the type and presentation of information to be included in quarterly and annual financial press releases;
- c. Review with the Corporation's independent public accounting firm any audit problems or difficulties and management's response, including:
 - i. any restrictions on the scope of the activities of the independent public accounting firm;
 - ii. any restriction on the independent public accounting firm's access to requested materials:

- iii. any significant disagreements with management; and
- iv. any material audit differences that the independent public accounting firm noted or proposed but for which the Corporation's financial statements were not adjusted;
- d. Resolve any disagreements between the independent public accounting firm and Corporation's management regarding financial reporting;
- e. Discuss with the Corporation's management, independent public accounting firm and Chief Financial Officer the adequacy of the Corporation's internal accounting, financial and operating controls;
- f. Be satisfied that adequate procedures are in place for the review of the Corporation's public disclosure of financial information extracted or derived from the Corporation's financial statements, and periodically assess the adequacy of such procedures; and
- g. Report to the Board with respect to the foregoing.

IV. Specific Responsibilities With Respect to the Corporation's Independent Public Accounting Firm

The Corporation's independent public accounting firm is ultimately accountable to the Board and shall report directly to the Audit Committee.

- a. The Audit Committee shall recommend to the Board of Directors:
 - i. The independent public accounting firm to be nominated for the purpose of preparing or issuing an auditor's report or performing other audit, review or attest services for the Corporation; and
 - ii. The compensation of the independent public accounting firm.
- b. The Audit Committee shall annually evaluate the qualifications, performance and independence of the independent public accounting firm and the lead partner.
- c. The Audit Committee shall pre-approve all non-audit services to be provided to the Corporation or its subsidiary entities by the Corporation's independent public accounting firm.
- d. The Audit Committee shall review and approve the compensation and terms of engagement of the Corporation's independent public accounting firm before the firm provides any audit, audit-related, tax or permitted non-audit services.
- e. At least annually, the Audit Committee shall obtain and review a report by the independent public accounting firm describing:
 - i. the firm's internal quality control procedures,
 - ii. any material issues raised by the firm's most recent internal quality control review or peer review; and

- iii. all relationships between the firm and the Corporation.
- f. Obtain from the independent public accounting firm assurance that they are not aware of any illegal act that has or may have occurred.
- g. The Audit Committee shall report to the Board with respect to the foregoing.

V. Additional Powers, Duties and Authority.

The Audit Committee shall have additional powers, duties and authority to:

- a. Monitor, review, and, if necessary or advisable, revise and update the Corporation's procedures for:
 - i. the receipt, retention and treatment of complaints received by the Corporation regarding accounting, internal accounting controls and auditing matters; and
 - ii. the confidential, anonymous submission by the Corporation's employees of concerns regarding accounting or auditing matters;
- b. Discuss with the Corporation's management the Corporation's guidelines and policies with respect to risk assessment and risk management, including the Corporation's major financial risk exposures and the steps management takes to monitor and control such exposures;
- c. Annually review the Audit Committee's performance and Charter, which shall include evaluating each member's qualifications, attendance, understanding of the Audit Committee's responsibilities and contribution to the functioning of the Audit Committee, and recommend any proposed changes to the Board for approval;
- d. Prepare such reports as are required by the Rules and Regulations;
- e. Review with the Corporation's General Counsel legal matters that may have a material impact on the financial statements, the Corporation's Code of Business Conduct and Ethics and any material reports or inquiries received from regulators or governmental agencies;
- f. As the Audit Committee may deem appropriate, retain and terminate any legal, accounting or other consultants, who shall report directly to the Audit Committee, on such terms and conditions, including fees, as the Audit Committee in its sole discretion shall approve;
- g. Request that any of the Corporation's officers, employees, outside counsel or independent public accounting firm attend any meeting of the Audit Committee or meet with any of the Audit Committee's members or consultants;
- h. Review and approve the Corporation's hiring policies regarding partners, employees and former partners and employees of the Corporation's present and former independent public accounting firm; and
- i. Report to the Board with respect to the foregoing.