ANNUAL INFORMATION FORM

October 29, 2026

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FORWARD-LOOKING STATEMENTS

This annual information form contains "forward-looking statements" and "forward-looking information" within the meaning of applicable Canadian securities laws (collectively, "forward-looking information"). Forward-looking information means disclosure regarding possible events, conditions or financial performance that is based on assumptions about future economic conditions and courses of action and includes financial projections and estimates; statements regarding plans, goals, objectives, intentions and expectations with respect to the Company's future business, operations, research and development, including the focus of the Company's primary drug product candidate, L-DOS47, development of its pre-IND candidates, LEUMUNA™ and GEMCEDA™, and other information relating to future periods. Forward-looking information includes, without limitation, statements concerning: (i) the Company's ability to continue to operate on a going concern basis being dependent mainly on obtaining additional financing; (ii) the Company's growth and future prospects being dependent mainly on the success of L-DOS47, LEUMUNA and GEMCEDA; (iii) the Company's priority continuing to be L-DOS47; (iv) the Company's development programs, including but not limited to, extension of the current drug candidates to other indications, the identification and development of further tumor-targeting antibodies for L-DOS47, and the discovery and design of novel antibody-drug conjugates; (v) the nature, design, anticipated timing and execution of the Company's planned clinical development programs, including the proposed Phase Ib/randomized Phase II study of L-DOS47 in combination with pembrolizumab as first-line treatment for non-small cell lung cancer (NSCLC); (vi) the Company seeking strategic partner support and therapeutic market opportunities; (vii) future expenditures, insufficiency of the Company's current cash resources and the need for financing and the Company's possible response for such matters; (viii) future financing requirements, the seeking of additional funding and anticipated future operating losses; (ix) further evaluation and changes to the Company's disclosure controls and procedures related to internal controls over financial reporting and informing the public of such changes, including the timeline for achieving such changes; (x) changes in the application of accounting standards and interpretations; (xi) industry performance, competition (including potential developments relating to immunotherapies and the Company's possible response to such developments), prospects, and general prevailing business and economic conditions; (xii) the Company's technology and research and development objectives, including development milestones, estimated costs, schedules for completion and probability of success; (xiii) the Company's expectation that it can, in a timely manner, or at all, produce the appropriate preclinical, and if necessary, clinical data required; (xiv) the Company's plans to develop L-DOS47 and the estimated incremental costs (including the status, cost and timing of achieving the development milestones disclosed herein); (xv) the Company's intentions with respect to initiating marketing activities following receipt of the applicable regulatory approvals; (xvi) the Company's seeking of licensing opportunities to expand its intellectual property portfolio; (xvii) the Company's ability to retain key executive officers, attract qualified senior management personnel, and ensure continuity of executive leadership; (xviii) the Company's expectation that it will be able to finance its continuing operations by accessing public markets for its securities; (xix) the Company's intended use of proceeds of any offering of its securities; and (xx) the Company's intention with respect to not paying any cash dividends on its common shares in the capital of the Company ("Common Shares") in the foreseeable future. Forward-looking information can further be identified by the use of forward-looking terminology such as "expects", "plans", "designed to", "potential", "believe", "intended", "continues", "opportunities", "anticipated", "2026", "2027", "2028", "2029", "2030", "next", "ongoing", "seek", "objective", "estimate", "future", or the negative thereof or any other variations thereon or comparable terminology referring to future events or results, or that events or conditions "will", "may", "could", "would", or "should" occur or be achieved, or comparable terminology referring to future events or results.

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

- the Company's lack of operating income and need for additional capital which may not be available in a timely manner or at all;
- the Company's history of losses and expectations regarding incurring additional losses for the foreseeable future;
- rapid technological change and competition from pharmaceutical companies, biotechnology companies and universities, which may make the Company's technology or products obsolete or uncompetitive;
- the Company's dependence on its priority drug product candidate, L-DOS47, uncertainty as to the size and existence of a market opportunity for, and market acceptance of the Company's drug product candidate including as a result of possible changes in the market for the Company's drug candidates resulting from development in immunotherapies or other future cancer treatments;
- the possibility that the market may never accept L-DOS47 or any other drug product candidate the Company successfully develops;
- uncertainty as to product development milestones and, in particular, whether the Company's drug product candidates, especially L-DOS47, will be successfully developed and marketed;
- intellectual property risks, including the possibility that patent applications may not result in issued patents, that issued patents may be circumvented or challenged and ultimately struck down, that any expiry of an issued patent, may negatively impact the further development or commercialization of the underlying technology, and that the Company may not be able to protect its confidential proprietary information;
- risks relating to patent litigation;

- risks relating to security breaches and other disruptions which may compromise the Company's information and expose the Company to liability and cause the Company's business and reputation to suffer;
- risks related to the potential infringement by the Company of the intellectual property rights of third parties, and the possibility that such parties may commence legal proceedings to protect or enforce such rights, the outcome of which would be uncertain and could harm the Company's business;
- risks associated with claims, or potential claims, of infringement of third-party intellectual property and other proprietary rights;
- risks relating to lawsuits or other proceedings commenced by the Company to protect or enforce the Company's patents or other intellectual property, and their potential effect on the Company;
- risks relating to potential claims of third parties that the Company's employees, collaborators, consultants, or independent contractors have wrongfully used or disclosed the confidential information of third parties, or that the Company's employees have wrongfully used or disclosed alleged trade secrets of their former employers;
- research and development risks, including without limitation, the fact that the Company's drug product candidates are complex compounds and the Company faces difficult challenges in connection with the manufacture of clinical batches, and the risk of obtaining negative findings or factors that may become apparent during the course of research or development, any of which may result in the delay or discontinuation of the research or development projects;
- regulatory risks, including the lengthy, unpredictable, and costly FDA regulatory approval process and the potential impact on the Company if such approvals are not ultimately obtained;
- the risk of unknown side effects arising from the development, manufacture, or use of the Company's products;
- risk relating to the difficulty in enrolling patients in clinical trials which may result in delays or cancellation of clinical trials;
- the Company's dependence on third parties, including without limitation, contract research organizations, contract manufacturing organizations, clinical trial consultants, collaborative research consultants, regulatory affairs advisors, and others, whose performance and interdependence can critically affect the Company's performance and the achievement of its milestones;
- the Company's significant dependence on licensed intellectual property and the risk of losing or breaching such licenses;
- the Company's dependence on assurances from third parties regarding licensing of proprietary technology owned by others;
- risks relating to the marketability of the Company's products arising from regulatory delays or inability to obtain regulatory approval, and ongoing regulatory review and requirements;
- uncertainty as to the availability of raw materials that the Company utilizes to manufacture its products, and in particular, Good Manufacturing Practice ("GMP") grade materials, on acceptable terms or at all, and that the Company may not be able to timely obtain alternative suppliers upon commercially viable terms or at all, which could have a material adverse effect on the further development and commercialization of any or all of the Company's drug product candidate(s);
- manufacturing risks, the need to manufacture to regulatory standards, uncertainty whether the manufacturing process for the Company's drug candidates can be further scaled-up successfully or at all and the risk that clinical batches of the Company's drug candidate may not be able to be produced in a timely manner or at all, which would have a negative effect on the timing and/or occurrence of planned clinical trials and the potential commercialization of the drug candidates;
- risks relating to the Company's potential failure to find third party collaborators to assist or share in the costs of product development and the potential impact on the Company's business, financial condition, and results of operations;
- the need for future preclinical and clinical trials, and the reliance by the Company on third parties to conduct such trials, the occurrence and success of which cannot be assured, and the fact that results seen in earlier clinical trials may not be repeated in later trials;
- product liability and insurance risks;
- the risk of lawsuits and other legal proceedings against the Company;
- uncertainty as to the Company's ability to maintain product liability insurance required by third parties and the risk of the corresponding agreement being terminated;
- the need to attract and retain key personnel and reliance on key personnel;
- the risk of misconduct on the part of employees and consultants, including non-compliance with regulatory standards and requirements;
- the risk that indemnification obligations to directors and officers may adversely affect the Company's finances;
- the impact on the Company's finances resulting from shifts in foreign exchange rates, credit risk and interest rate risk;
- risks related to adverse decisions by tax authorities and changes in law;
- risks relating to the potential financial strain on the Company's resources due to the requirements of being a public company;
- the impact of the ongoing volatility in the economic environment;
- risks relating to compliance with environmental laws;
- risk relating to a failure to maintain an effective system of internal controls;
- risks related to epidemics, pandemics, or other health crises, including the coronavirus ("COVID-19") pandemic, and their potential effect on the Company's business, operations and financial condition;
- risks associated with the Company's ability to meet its debt obligations, including principal and interest payments on its outstanding convertible debentures at maturity;

- volatility in the trading price and volume of the Common Shares and potential challenges in maintaining listing requirements;
- the possibility of dilution to current shareholders from future equity or convertible debt financings or through the exercise of stock options ("Options"), warrants ("Warrants") or other securities convertible or exchangeable into Common Shares;
- liquidity of the Common Shares;
- the risk that inaccurate or unfavorable research about the Company's business, or the lack of research about its business, may affect the share price and trading volume of the Common Shares;

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

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

Data relevant to estimated market sizes in connection with Company's lead products under development are presented in this 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 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 under the Canada Business Corporations Act with Helix Product Developments Inc., 6933912 Canada Ltd., Sensium Technologies Inc. and 6965954 Canada Inc.

As of July 31, 2026, the Company's principal place of business is located at 789 West Pender Street, Suite 480, Vancouver, British Columbia, Canada V6C 1H2. The Company's registered office is located at 789 West Pender Street, Suite 480, Vancouver, British Columbia, Canada V6C 1H2. The Company's website is www.helixbiopharma.com.

The Company's articles was amended on August 16, 2024 in order to consolidate all of the issued and outstanding Common Shares of the Company on the basis of one (1) post-consolidation Common Share for five (5) pre-consolidation Common Shares; and in the event of any fractional common shares arising from the consolidation of the Common Shares, such Common Shares will be deemed to have been tendered by its registered owner to the Company for cancellation for no consideration. All shares and per share references in this AIF have been retroactively restated accordingly unless noted otherwise.

Inter-corporate relationship

On May 20, 2025, the Company has closed the Laevoroc asset acquisitions as follows:

Laevoroc Immunology AG
The Company entered into an asset purchase agreement with Laevoroc Immunology AG, a privately held, Swiss immune-oncology company. As a result of the transaction, the Company acquired the intellectual property, assigned agreements and rights to LEUMUNA™ (ulodesine hemiglutarate, formerly LR 09), an oral purine nucleoside phosphorylase (PNP) inhibitor and immune checkpoint modulator in preclinical development for patients experiencing leukemia relapse following allogeneic stem cell transplantation (allo-SCT). LEUMUNA received orphan drug designation from the United States Food and Drug Administration in 2022. In an unpublished preclinical study conducted at Fred Hutchinson Cancer Center using a murine B-cell acute leukemia model following allogeneic stem cell transplantation, PNP inhibition was associated with improved overall survival and a statistically significant reduction in leukemia-related mortality, without a statistically significant increase in graft-versus-host disease-related mortality. These findings provide preclinical

support for the potential of PNP inhibition to enhance graft-versus-leukemia immune activity. Further studies are required to establish whether these effects translate into clinical benefit in patients.

Historical clinical studies of ulodesine (BCX4208), the predecessor compound to LEUMUNA (ulodesine hemiglutarate), have evaluated more than 500 participants across Phase I and Phase II trials. In a randomized, placebo-controlled Phase II study in patients with gout, ulodesine was administered in combination with allopurinol, with comparable rates of infectious adverse events across treatment groups and no observed increase in infection-related safety signals. While these findings provide historical human safety data relevant to LEUMUNA's development, they do not establish the safety or efficacy of LEUMUNA in its proposed oncology indication.

Pursuant to the agreement, the Company acquired all the IP assets and certain liabilities of Laevoroc Immunology in consideration for the issuance of 11,555,076 Common Shares on the closing date of the transaction (Note 6).

Laevoroc Chemotherapy AG
The Company entered into an asset purchase agreement with Laevoroc Chemotherapy AG, a privately held Swiss company. Pursuant to the transaction, the Company acquired the intellectual property, assigned agreements and rights to GEMCEDA™, an oral gemcitabine prodrug administered in combination with cedazuridine, currently in preclinical development. Preclinical studies have demonstrated oral bioavailability approaching that of intravenous gemcitabine. GEMCEDA is being developed as a potential oral treatment option for patients with advanced, difficult-to-treat cancers. Through this transaction, the Company acquired substantially all the IP assets of Laevoroc Chemotherapy in consideration for the issuance of 9,454,153 Common Shares on the closing date of the transaction.

At the time of the Laevoroc asset acquisitions, the Company's Chief Executive Officer was also President of the Board and Chief Executive Officer of both Laevoroc entities and metaShape Pharma AG ("metaShape"), the lender under the loan payable assumed in the transaction. As of July 31, 2026, the Company's Chief Executive Officer was no longer Chief Executive Officer of metaShape.

GENERAL DEVELOPMENT OF THE BUSINESS

Helix BioPharma Corp. is a clinical-stage biopharmaceutical company focused on developing therapies for patients with difficult-to-treat cancers. Its lead drug candidate, L-DOS47, is an antibody-enzyme conjugate targeting CEACAM6 and designed to modulate tumor acidity. The Company is planning a Phase Ib/randomized Phase II clinical study evaluating L-DOS47 in combination with pembrolizumab as first-line treatment for non-small cell lung cancer (NSCLC). Helix is also advancing early-stage CEACAM6-targeted antibody-drug conjugate and radioligand research programs, alongside two preclinical drug candidates, LEUMUNA™, an oral immune checkpoint modulator being developed for leukemia relapse following allogeneic stem cell transplantation, and GEMCEDA™, an oral gemcitabine prodrug being developed for advanced, difficult-to-treat cancers. The advancement of these programs is dependent on securing sufficient financing.

Important events which have occurred in the last three fiscal years and the period subsequent to July 31, 2026, up to the date of filing this AIF under the Company's profile on SEDAR+ at https://www.sedarplus.ca and include the following:

August 1, 2026, to the Date of this AIF

- On September 28, 2026, the Board appointed Karen Krumeich as Chair and appointed Dirk Brockstedt, Charmaine Lykins, and Jamieson Bondarenko as directors. Karen Krumeich was also appointed Chair of the Audit Committee.
- On September 17, 2026, Jacek Antas, Jerzy Leszczynski and Malgorzata Laube resigned as directors.
- On August 17, 2026, Thomas Mehrling resigned as Chief Medical Officer and Markus Loeffler was appointed Chief Medical Officer. Thomas Mehrling continues as Chief Executive Officer and had been appointed a director effective August 14, 2026.
- On August 12, 2026, Janusz Grabski resigned as a director.

Fiscal Year ended July 31, 2026

- On June 30, 2026, the Company announced the appointments of Helen Middleton as General Counsel and David Browning as Vice President of Clinical Operations.
- On June 12, 2026, the Company announced the filing of its interim financial statements for the three- and nine-month periods ended April 30, 2026 (the "Financial Statements"), together with the related Management's Discussion and Analysis (MD&A) relating to the Financial Statements, and CEO and Chief Financial Officer (CFO) certifications relating to the Financial Statements (collectively, the "Interim Filings"). The filings were made available on SEDAR+ and the Company's website.
- On May 27, 2026, the Company issued unsecured convertible debentures with aggregate principal of $3.673 million. The debentures bear simple interest at 25% per annum, mature on July 27, 2027 and are convertible at the holder's option on maturity, with principal convertible at $1.42 per Common Share.
- On May 21, 2026, the Company granted 1,297,000 stock options at an exercise price of $1.63 per Common Share, expiring May 21, 2031. The Company also announced the cancellation of 2,200,000 previously granted stock options held by a director, exercisable at $1.10 per common share, resulting in a net reduction of 903,000 outstanding stock options.

- On May 13, 2026, the Company announced the appointment of Zachary T. Stadnyk, former Head of Life Sciences at the TSX and TSXV, to its Board of Directors, and Natalia L. Butterworth, an experienced corporate governance professional, as Corporate Secretary. The Company also announced plans to relocate its registered and records office from Toronto to Vancouver, British Columbia.
- On March 16, 2026, the Company announced the filing of its interim financial statements for the three- and six-month periods ended January 31, 2026 (the "Financial Statements"), together with the related MD&A and CEO and CFO certifications. The filings were made available on SEDAR+ and the Company's website.
- On February 24, 2026, the Company announced the presentation of data from its CEACAM6-directed antibody-drug conjugate (ADC) program at the 16th Annual World ADC London conference. The presentation, delivered by Dr. Jonathan Davis, Director of ADC Discovery, highlighted the therapeutic potential of CEACAM6 across multiple epithelial cancers and preclinical data demonstrating the tumor-selective binding profile of the Company's proprietary anti-CEACAM6 VHH (nanobody).
- On February 5, 2026, the Company announced the extension of its Research and Exclusive Option Agreement with metaShape Pharma AG covering LEUMUNA™ for adipose tissue-related and metabolic diseases through December 31, 2028. Under the agreement, metaShape is developing the compound, designated MS 001, as an oral co-therapy for GLP-1 receptor agonists, with preclinical data demonstrating improved weight loss outcomes and reduced weight regain following GLP-1 withdrawal. The extension preserves the Company's strategic optionality in metabolic indications while allowing it to maintain its primary focus on the oncology applications of the compound.
- On January 30, 2026, the Company announced the voting results of its Annual General and Special Meeting of Shareholders, at which all resolutions were approved with over 99.99% of votes cast in favor, including the re-election of four directors, the appointment of Clearhouse LLP as auditor, and a proposed share consolidation at a ratio of up to five pre-consolidation Common Shares for one post-consolidation common share, with the final ratio to be determined by the Board of Directors. A total of 61,885,815 Common Shares were voted, representing 81.03% of the Company's issued and outstanding shares.
- On December 15, 2025, the Company announced the filing of its interim financial statements for the three-month period ended October 31, 2025, together with the related MD&A and CEO and CFO certifications. The filings were made available on SEDAR+ and the Company's website.
- On December 3, 2025, the Company entered into a subscription agreement for a proposed $33.370 million equity financing. The subscriber subsequently declared bankruptcy, no proceeds were received and the financing did not close.
- On October 29, 2025, the Company announced its financial results for the fiscal year ended July 31, 2025, reporting a net loss of $5,205,000 ($0.09 per share), compared with $9,264,000 ($ 0.21 per share) in fiscal 2024.
- On October 6, 2025, the Company issued a statement in response to recent market activity, confirming that it was not aware of any material undisclosed information that would account for the increase in the market price and trading volume of its Common Sshares.
- On September 9, 2025, the Company announced its participation in the Q3 2025 Investor Summit Virtual on September 16–17, 2025, where CEO Thomas Mehrling, MD, PhD, would present the Company's ongoing preparations for LDOS007.
- On September 5, 2025, the Company announced it will not proceed with the previously announced equity draw-down subscription facility with GEM Global Yield LLC SCS and GEM Yield Bahamas Limited (together, "GEM"), given that the Company determined that the GEM facility no longer aligns with its capital strategy or its commitment to maximizing long-term shareholder value.
- On August 22, 2025, the Company closed a non-brokered private placement of 2,222,333 Common Shares at $0.75 per Common Share for gross proceeds of $1.667 million.
- On August 13, 2025, the Company announced the publication of a peer-reviewed article by *Frontiers in Oncology* reporting results from a previously completed Phase I/II clinical study of L-DOS47 as a single agent in patients with advanced non-small cell lung cancer (NSCLC) and titled "Safety of unconventional antibody-drug conjugate L-DOS47 in a Phase I/II monotherapy study targeting advanced NSCLC".
- On August 8, 2025, the Company received written feedback from the US Food and Drug Administration (FDA) in lieu of a scheduled End-of-Phase I meeting regarding the proposed LDOS007 study. The planned Phase Ib/randomized Phase II study will evaluate L-DOS47 in combination with pembrolizumab as first-line treatment for non-small cell lung cancer (NSCLC). Following the FDA's written feedback, the Company elected not to proceed with the scheduled meeting and instead to advance preparations for the next regulatory submission, subject to sufficient financing.

Fiscal Year ended July 31, 2025

- On June 16, 2025, the Company announced the filing of its interim financial statements for the three- and nine-month periods ended April 30, 2025 (the "Financial Statements"), together with the related Management's Discussion and Analysis (MD&A) relating to the Financial Statements, and CEO and Chief Financial Officer (CFO) certifications relating to the Financial Statements (collectively, the "Interim Filings"). The filings were made available on SEDAR+ and the Company's website.
- On June 2, 2025, the Company announced appointment of Rohit Babbar as CFO of the Company, replacing James B. Murphy.
- On May 20, 2025, the Company closed the Laevoroc asset acquisition transactions, acquiring substantially all of the assets and certain liabilities of Laevoroc Immunology AG and Laevoroc Chemotherapy AG in consideration for the issuance of 11,555,076 Common

Shares at a fair value of $9,880,000 and 9,454,153 Common Shares at a fair value of $8,083,000.

- On April 24, 2025, the Company announced appointment of Veronika Kandziora as Chief Operating Officer ("COO").
- On April 21, 2025, the Company issued 125,000 Common Shares for the exercise of 125,000 stock options for cash proceeds of $113,000.
- On April 10, 2025, the Company announced appointment of Thomas Mehrling, MD, PhD as CEO, taking over from Jacek Antas, who continued to be a Director and the Chairman of the Board.
- On March 26, 2025, the Company announced the voting results from the Annual and Special Meeting of its Shareholders ("the Meeting"), which was held on the same day. A total of 40,294,667 Common Shares were voted at the Meeting, representing 76% of the Company's total issued and outstanding Common Shares, with all items of business approved by an overwhelming majority of the Common Shares represented (>99.5%).
- On March 18, 2025, the Company completed filing of the Company's interim financial statements for the three and six months ended January 31, 2025 (the "Financial Statements"), the management's discussion and analysis relating to the Financial Statements, and the CEO and CFO certifications relating to the Financial Statements (collectively, the "Interim Filings").
- On January 8, 2025, the Company closed its private placement financing for gross proceeds of $3,000,000 from the issuance of 4,000,000 Common Shares at a price of $0.75 per common share. In connection with the closing, the Company paid a cash fee of 10% of gross proceeds raised to an eligible finder.
- On November 8, 2024, the Company announced the resignation of its Chief Financial Officer ("CFO") and Corporate Secretary, Praveen Varshney, with immediate effect. On December 11, 2024, the Company appointed James B. Murphy as its Chief Financial Officer ("CFO").
- Effective September 30, 2024, the Company changed its registrar and transfer agent from Computershare Trust Company to Endeavor Trust Corporation.
- On September 10, 2024, the Company commenced trading on the Frankfurt Boerse under the trading symbol "HBP0".
- Effective August 16, 2024, the Common Shares of the Company commenced trading on a 1-for-5 consolidation basis under the new CUSIP number 422910208 and existing stock symbol "HBP".

In the second half of 2024, the Company conducted an extensive review of its assets and forward strategy, that resulted in the following key decisions:

- The Company decided to focus its resources on developing L-DOS47 as a combination therapy with PD-1 inhibitor, pembrolizumab, as first-line therapy for NSCLC. This decision was the result of an extensive expert review of available pre-clinical and clinical data on L-DOS47, the significant unmet medical need in NSCLC despite the emergence of immunotherapy as the standard of care, and an assessment of where a pharmacological tumor alkalization therapy is most likely to deliver meaningful clinical impact in the near term, also keeping in mind the shortest time to FDA approval.
- On August 9, 2024 and August 13, 2024, the research collaborations with University of Tuebingen, Germany, and Peter Mac, Australia, respectively, were terminated. Projects with these institutions were outside the scope of the new focus on NSCLC.
- The Company resolved to close its laboratory in Edmonton Canada, which was closed on 31 October, 2024, with liquidation of laboratory equipment and safekeeping of documents, reagents, and lab samples with a third-party storage provider.
- The Company reviewed its CMC practices and entered discussions with several Contract Drug Manufacturing Organizations to optimize both resource expenditure as well as plan for manufacturing of the next batch of drug in advance.

Fiscal year ended July 31, 2024

- On July 19, 2024, the Company granted 4,280,000 incentive stock options to directors, officers, employees and consultants of the Company, pursuant to its equity compensation plan with an exercise price of $1.10 for a period of five years from the date of grant with a range of vesting periods.
- On July 1, 2024, the Company hired Dr. Thomas Mehrling MD, PhD as Chief Medical Officer. Dr. Mehrling is a medical oncologist with extensive experience in clinical trials, drug development, and commercialization. He has worked with several pharma companies in the past focusing on oncology related assets.
- On May 31, 2024, the Company closed its private placement financing for gross proceeds of $2,350,000 from the issuance of 3,133,333 Common Shares at a price of $0.75 per common share. In connection with the closing, the Company paid a cash fee of 10% of gross proceeds raised to an eligible finder.
- On May 16, 2024, the Company completed filing of the Company's interim financial statements for the six months ended January 31, 2024 (the "Financial Statements"), the management's discussion and analysis relating to the Financial Statements, and the CEO and CFO certifications relating to the Financial Statements (collectively, the "Interim Filings"). The Company's principal regulator, the Ontario Securities Commission, lifted the management cease trade order effective May 15, 2024 following the filing of the Interim Filings.
- On April 1, 2024, Dr. Gary Frank Renshaw resigned as Chief Medical Officer. Dr. Srikanth Sola, who has extensive clinical trial experience, assumed the role of interim CMO.

- On February 8, 2024, Praveen Varshney was appointed as Chief Financial Officer and Corporate Secretary replacing Hatem Kawar and Namrata Malhotra, respectively.
- On January 18, 2024, the Company announced the voting results of the Company's annual & special meeting of shareholders held on January 18, 2024.
- On November 1, 2023, the Company relieved Atul Deshpande PhD from his role as a Consultant for the Company.
- On October 10, 2023, the Company presented new preclinical data on L-DOS47 in combination with PD-1 checkpoint inhibition at the 2023 AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in the Hynes Convention Center, Boston, via in person attendance, October 11-15, 2023.
- On October 1, 2023, the Company hired Dr. Srikanth Sola as Chief Strategic Officer, to provide guidance on Helix's strategic path forward.
- On August 22, 2023, the Company closed its private placement financing for gross proceeds of $2,998,000 from the issuance of 3,331,111 Common Shares at a price of $0.90 per Common Shares. In connection with the closing, the Company paid a cash fee of 10% of gross proceeds raised to an eligible finder.
- On August 21, 2023, Janusz Grabski was appointed to the board of directors who replaced Christopher Maciejewski.

DESCRIPTION OF THE BUSINESS

OVERVIEW

Helix is a clinical-stage biopharmaceutical company focused on developing therapies for underserved patient populations with difficult-to-treat cancers. The Company's oncology pipeline is centered on its proprietary CEACAM6-targeting technology, with L-DOS47 as its lead clinical-stage drug candidate and additional CEACAM6-targeted antibody-drug conjugate and radioligand therapeutic programs in discovery. The Company's pipeline also includes LEUMUNA™ and GEMCEDA™, two preclinical-stage oncology programs acquired in May 2025.

The GEMCEDA and LEUMUNA programs were acquired by the Company under the terms of an asset purchase agreement on November 28, 2024 and amended on December 5, 2024, with Laevoroc Immunology AG and Laevoroc Chemotherapy AG, both privately held, Swiss oncology companies (together, the "Laevoroc asset acquisitions"). The transactions closed on May 20, 2025 and as a result, Helix acquired the intellectual property, assigned agreements and rights to LEUMUNA (LR 09, ulodesine hemiglutarate) and GEMCEDA.

LEUMUNA is an oral purine nucleoside phosphorylase (PNP) inhibitor and immune checkpoint modulator in preclinical development for the treatment of leukemia relapse following allogeneic stem cell transplantation (allo-SCT). The program aims to enhance graft-versus-leukemia (GvL) immune activity through modulation of the purine metabolism pathway. LEUMUNA received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) in 2022. In an unpublished preclinical study conducted at Fred Hutchinson Cancer Center using a murine B-cell acute leukemia model following allogeneic stem cell transplantation, PNP inhibition was associated with improved overall survival and a statistically significant reduction in leukemia-related mortality, without a statistically significant increase in graft-versus-host disease-related mortality. These findings provide preclinical support for the potential of PNP inhibition to enhance graft-versus-leukemia immune activity. Further studies are required to establish whether these effects translate into clinical benefit in patients.

Historical clinical studies of ulodesine (BCX4208), the predecessor compound to LEUMUNA (ulodesine hemiglutarate), have evaluated more than 500 participants across Phase I and Phase II trials. In a randomized, placebo-controlled Phase II study in patients with gout, ulodesine was administered in combination with allopurinol, with comparable rates of infectious adverse events across treatment groups and no observed increase in infection-related safety signals. While these findings provide historical human safety data relevant to LEUMUNA's development, they do not establish the safety or efficacy of LEUMUNA in its proposed oncology indication.

GEMCEDA is an oral gemcitabine prodrug combined with cedazuridine in preclinical development for the treatment of solid tumors. The formulation is designed to improve the oral delivery of gemcitabine, a chemotherapy agent included on the World Health Organization's List of Essential Medicines. Preclinical studies have demonstrated approximately 90% oral bioavailability, supporting the potential development of an oral alternative to intravenous gemcitabine administration. Further development is required to establish GEMCEDA's safety and efficacy in clinical studies..

L-DOS47, the Company's lead clinical-stage drug candidate, is a CEACAM6-targeted antibody-enzyme conjugate designed to counter tumor acidosis by increasing extracellular pH within the tumor microenvironment. Tumor acidosis is associated with immune suppression, treatment resistance, and poor clinical outcomes.
Building on its CEACAM6-targeting technology, the Company is advancing discovery-stage programs exploring multispecific antibody-drug conjugates (ADCs) for gastrointestinal cancers and radioligand therapeutics for pancreatic cancer. These programs are intended to extend the Company's CEACAM6-targeting approach into additional therapeutic modalities and remain at an early stage of research and development.

L-DOS47 has been evaluated in four clinical studies, including three studies in non-small cell lung cancer (NSCLC) and one in

pancreatic cancer. These comprise a Phase I/II monotherapy study in NSCLC (LDOS002), a Phase I combination study with pemetrexed and carboplatin in NSCLC (LDOS001), a Phase II combination study with vinorelbine and cisplatin in NSCLC (LDOS003), and a Phase Ib/II combination study with doxorubicin in advanced pancreatic cancer (LDOS006). All four studies have concluded, with the clinical study report for LDOS006 expected to be issued around September 2026.

The Company is now prioritizing the development of L-DOS47 in combination with pembrolizumab for the first-line treatment of advanced NSCLC through the planned LDOS007 Phase Ib/randomized Phase II study. Further details of the study design, regulatory status, and anticipated development activities are provided under “L-DOS47 Clinical Program” below.

The Company previously conducted preclinical research in collaboration with Moffitt Cancer Center (“Moffitt”) in Tampa, Florida, investigating the potential benefits of combining L-DOS47 with immune checkpoint inhibition. The collaboration has concluded, and the final report has been received. The results of this research, including enhanced antitumor activity observed with L-DOS47 in combination with anti-PD-1 therapy in a preclinical pancreatic cancer model, have been published.

The Company also conducted a preclinical collaboration with the University Hospital of Tübingen to investigate the effects of L-DOS47 on tumor acidity using imaging technologies. This collaboration was terminated in August 2024 following the Company's decision to prioritize clinical development of L-DOS47 in combination with pembrolizumab in NSCLC.

The Company's CEACAM6-targeted discovery programs include the development of multispecific antibody-drug conjugates (ADCs) for gastrointestinal cancers and radioligand therapeutics for pancreatic cancer. The radioligand therapeutic program is undergoing AI-assisted optimization of its CEACAM6-targeting component, with a focus on binding affinity and manufacturability. For the multispecific ADC program, the Company is evaluating potential development partners and service providers to support antibody engineering, construct development, and characterization. Both programs remain at the discovery stage, with further development activities subject to the availability of sufficient funding.

LEUMUNA and GEMCEDA remain in preclinical development. The Company has undertaken pharmacology, active pharmaceutical ingredient (API), and formulation development activities for both programs, with further toxicology and regulatory requirements to be determined in consultation with the U.S. Food and Drug Administration (FDA).

For LEUMUNA, the Company's planned development activities include chemistry, manufacturing, and controls (CMC) development, clinical batch manufacturing, IND-enabling studies, and preparation for a potential Phase I/II clinical study in patients experiencing acute leukemia relapse following allogeneic stem cell transplantation. The timing and execution of these activities remain contingent upon securing sufficient financing, completion of the necessary development work, and applicable regulatory requirements. Further development of GEMCEDA will likewise depend on the availability of financing and completion of the necessary preclinical and regulatory activities.

The Company has an extensive patent portfolio that includes company-owned and licensed patents and pending applications, including, but not limited to, the use of L-DOS47 as immunoconjugate for cancer treatment. Issued patents have coverage in all major pharmaceutical markets including North America, Europe, and Asia and the company has secured composition-of-matter patents on L-DOS47 through at least 2036.

In November 2024, the Company was issued U.S. Patent No. 11931422, entitled ‘Antibody-Urease Conjugates for Therapeutic Purposes’, relating to Helix’s first-in-class antibody-drug conjugate (ADC) platform, L-DOS47, and the optimization of conjugation ratios for a proprietary antibody that precisely binds to tumor cells expressing high levels of CEACAM6, conjugated to urease, an enzyme capable of alkalizing the acidic tumor microenvironment (TME).

The patent applications acquired through the GEMCEDA and LEUMUNA asset acquisitions are currently undergoing national-phase prosecution in various jurisdictions. If granted and maintained, these patents are expected to provide protection through 2043 for GEMCEDA and 2041 for LEUMUNA, subject to applicable patent laws and requirements.

In September 2024, the Company commenced trading on the Frankfurt Boerse under the following:

Trading symbol: HBP0
WKN: A40GN1
ISIN: CA4229102088

RESEARCH AND DEVELOPMENT ACTIVITIES

Background

CEACAM6 Platform Technology

CEACAM6 is a cell-surface protein that is overexpressed in several solid tumor types, including non-small cell lung cancer (NSCLC), pancreatic cancer, and colorectal cancer. Its expression has been associated with tumor progression, invasion, metastasis, and adverse clinical outcomes. CEACAM6 is accessible on the tumor cell surface and has relatively limited expression in certain normal tissues, making

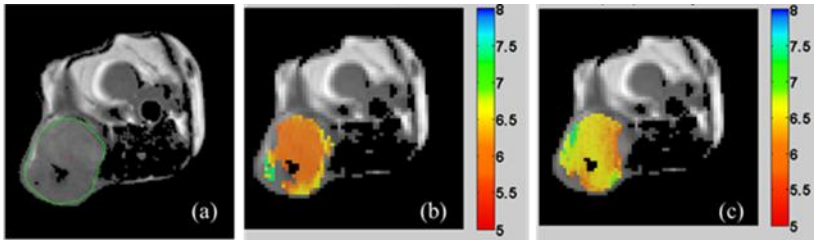
it a potential target for therapeutic development. The Company's CEACAM6-targeting technology forms the basis of its lead clinical-stage candidate, L-DOS47, and its discovery-stage antibody-drug conjugate and radioligand therapeutic programs.

L-DOS47 Background

L-DOS47 is a first-in-class antibody–enzyme conjugate (AEC) designed to neutralize the acidic tumor microenvironment (TME) and thus potentially improve antitumor immune activity. It consists of a jack-bean urease enzyme chemically linked to antibody fragments (nanobodies) that target CEACAM6, a cell-surface protein overexpressed in many NSCLC tumors but sparse in healthy tissue. Upon intravenous administration, the L-DOS47 nanobodies guide the urease to CEACAM6-positive tumor cells, anchoring it in the tumor milieu. The urease then converts endogenous urea into ammonia and carbon dioxide, raising the local pH and neutralizing tumor acidity.

Solid tumors often acidify their surroundings via aerobic and anaerobic metabolism, creating an immunosuppressive "acidic stronghold" that blunts T-cell infiltration/activity and reduces chemotherapy efficacy. Low pH in the TME impairs immune cell function and helps tumors evade immune checkpoints and resist drugs. By buffering tumor acidity, L-DOS47 aims to recondition the TME: higher pH can improve T-cell infiltration, activation, and cytokine release, making tumors more susceptible to immune attack. L-DOS47 is being developed to potentially enhance responses to established anticancer therapies – it does not directly kill tumor cells in the traditional cytotoxic sense but primes the tumor to respond better to today's cancer treatments (chemotherapy, checkpoint inhibitors, etc.).

Key preclinical experiments demonstrated the ability of L-DOS47 to raise the pH of the tumor microenvironment *in vivo* in both lung and pancreatic cancer preclinical models, using multiple imaging methods, including Phosphorus-31 Magnetic Resonance Spectroscopy (PMRS) and Chemical Exchange Saturation Transfer Magnetic Resonance Imaging (CEST MRI, see images below). *In vitro* experiments have shown that L-DOS47 successfully restored CD8+ T cell activity, as observed by increased production of the proinflammatory cytokine, interleukin-2 (IL-2). Treatment with L-DOS47 significantly enhanced the ability of an anti-PD1 antibody to control growth of human CEACAM6-expressing pancreatic tumors in mice. In an orthotopic pancreatic cancer model, combination treatment with L-DOS47 and anti-PD-1 therapy reduced representative endpoint tumor volume by approximately 70% and mean tumor weight by 50% compared with anti-PD-1 treatment alone. A manuscript on this work was recently published in the journal *Biomedicines* (Jardim-Perassi, BV *et al* 2024).



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

LDOS47 Clinical Program

The Company has completed four clinical studies under the L-DOS47 program. Three clinical studies involved the treatment of NSCLC: A Phase I combination study (LDOS001) conducted in the U.S., a Phase I/II monotherapy study concluded in Poland (LDOS002), and a Phase II combination study running in Eastern Europe (LDOS003). A fourth clinical study, a Phase Ib/II study (LDOS006) investigating the treatment of metastatic pancreatic adenocarcinoma, is completed and in the final stage of generating the CSR (Clinical Study Report).

LDOS001 *– A Phase I combination therapy trial in lung cancer*

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

Fourteen (14) patients were enrolled across six dosing cohorts, starting at 0.59 and increasing up to 9.0 µg/kg. The MTD was not achieved as none of the patients experienced any dose-limiting toxicity ("DLT"). Fifty percent (50.0%) of patients experienced at least one treatment emergent adverse event assessed as study drug-related, with 14.3% of patients experiencing at least one grade 3/4 drug-related toxicity. Although the study was not designed specifically to assess efficacy, preliminary results showed that of 12 patients evaluable for efficacy, five patients (41.7%) had a partial response ("PR"), four patients (33.3%) experienced stable disease (SD) and three patients (25.0%) had progressive disease ("PD"). The objective response rate was 41.7%, with a median duration of 187 days, and a clinical benefit rate of 75.0% with a median duration of 141 days. L-DOS47, in combination with pemetrexed and carboplatin, was generally well tolerated and demonstrated preliminary antitumor activity in this Phase I study in patients with non-squamous NSCLC.

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

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

Despite a total of 55 patients being dosed across 16 dose levels ranging from 0.12 up to 1**3.5**5 µg/kg, the MTD was not reached. There was only one single DLT of spinal/bone pain reported at the 5.76 µg/kg dose level. The weekly dosing schedule of L-DOS47 for all doses up to 13.55 µg/kg was otherwise well tolerated. A dose response trend was observed when comparing the percentage of patients who were progression-free at 16 weeks across dose ranges, according to Response Evaluation Criteria in Solid Tumors ("RECIST") version 1.1. In an exploratory analysis of Phase I patients grouped into four dose quartiles, median progression-free survival (PFS) was 4.1 months in the highest-dose quartile (5.76–13.55 µg/kg), with differences observed across dose quartiles (log-rank p = 0.0203). These findings were exploratory and do not establish a causal dose-response relationship. A similar trend was observed when comparing the percentage of patients who had stable disease and had a reduction in target lesions.

Evaluation of initial results from Phase II, Stage 1 did not yield ≥1 partial or complete response at any time point as defined by protocol. Consequently, the study did not proceed to Phase II, Stage 2, and the development of L-DOS47 as monotherapy treatment of non-squamous NSCLC was discontinued. The results are recently published in *Frontiers in Oncology*, https://doi.org/10.3389/fonc.2025.1544967.

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

LDOS003 was a Phase II, open-label, randomized study of L-DOS47 in combination with vinorelbine/cisplatin vs vinorelbine/cisplatin alone in patients with lung adenocarcinoma. The approved protocol called for patients receiving L-DOS47 to be dosed on days 1 and 8 of each 21-day treatment cycle, along with standard vinorelbine/cisplatin chemotherapy for a total of four treatment cycles.

Patient recruitment began in February 2019 and was halted in April 2020 due to COVID-19 restrictions and supply chain disruptions. At that time, the first two dose-escalation cohorts had been completed, while the third cohort remained incomplete. The Company subsequently decided to terminate recruitment and not proceed with Part II of the study. The war in Ukraine further affected the clinical study environment and complicated the completion of study-related activities. The study has been discontinued, and the Company has no plans to resume it.

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

LDOS006 is a phase Ib/II, open label, non-randomized study designed to evaluate the safety, tolerability, and preliminary efficacy of L-DOS47 in combination with doxorubicin in patients aged ≥ 18 years old with metastatic pancreatic cancer who have progressed on at least two prior treatment regimens. The study applied a standard 3 + 3 algorithm for the initial dose escalation (starting at 3 µg/kg) to determine the L-DOS47 maximum tolerated dose to be later used in combination with doxorubicin for the Phase II part of the study to assess preliminary anti-tumor activity. Patients were dosed weekly with four weeks making up one treatment cycle up to a maximum of eight cycles. The trial was initiated in November 2019, with enrollment concluded and final patient follow-up completed in October 2024. The study has concluded, and the Company is completing the remaining data analyses and clinical study reporting activities.

LDOS007 *– A Phase Ib/II randomized combination trial in lung cancer*

LDOS007 is a planned Phase Ib/randomized Phase II clinical study evaluating L-DOS47 in combination with pembrolizumab for the first-line treatment of advanced non-small cell lung cancer (NSCLC) in patients with high PD-L1 expression. In August 2025, the Company received positive written feedback from the U.S. Food and Drug Administration (FDA) on the proposed study design, in lieu of an End-of-Phase I meeting.

The study is designed to include an initial dose-escalation safety lead-in evaluating L-DOS47 in combination with pembrolizumab, followed by a randomized Phase II component comparing selected L-DOS47 dose levels in combination with pembrolizumab against pembrolizumab alone. Depending on the results of the Phase Ib component, two or three dose levels may be evaluated in Phase II. The primary objective is to identify an appropriate dose for subsequent clinical development.

The Company is targeting submission of a clinical trial application (CTA) in Q1 2027, subject to securing financing. The timing of study initiation and subsequent development milestones will depend on the availability of sufficient funding, applicable regulatory authorizations, and operational readiness.

Manufacturing

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

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

use in the clinic. The Company has extensively characterized L-DOS47 and maintains a comprehensive analytical program for the drug substance, drug product, and the urease and antibody intermediates.

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

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

The Company's supply of L-DOS47 drug product remained within specification for all clinical trials completed to date. Additional material continues to be subjected to stability assays according to ICH Q1A (R2) guidelines, with the current lot placed on a stability study protocol which can be extended as long as the product continues to meet specifications. The batch has been found to be stable at least through the last testing point (January 2025). If the product becomes Out-of-Specification (OOS) at the real-time storage condition (2-8ºC) for two consecutive pulls before the final time point, further stability testing and clinical use may be discontinued. The current lot of Polysorbate 80, 1% diluent also remains within specification as of August 2025.

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

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

Product focus and strategy

The Company's primary clinical development priority is L-DOS47 in combination with pembrolizumab (Keytruda®) for the first-line treatment of advanced non-small cell lung cancer (NSCLC). The planned LDOS007 Phase Ib/randomized Phase II study is intended to evaluate the safety, tolerability, and preliminary efficacy of the combination and identify an appropriate dose for subsequent clinical development.

In parallel, the Company is advancing discovery-stage CEACAM6-targeted multispecific antibody-drug conjugates (ADCs) for gastrointestinal cancers and radioligand therapeutics for pancreatic cancer.

The Company's additional oncology programs include LEUMUNA, an oral immune checkpoint modulator being developed for leukemia relapse following allogeneic stem cell transplantation, and GEMCEDA, an oral gemcitabine-based therapy under development for solid tumors.

The timing and execution of the Company's development activities remain contingent upon securing sufficient financing, applicable regulatory authorizations, and successful completion of the necessary research and development activities.

Commercialization

The Company's commercialization strategy includes pursuing strategic partnerships with pharmaceutical companies for the further development and potential commercialization of its drug candidates, either individually or across multiple programs. The Company may also evaluate other strategic alternatives, including licensing arrangements, corporate transactions, or a potential sale of the Company.

Key personnel

Thomas Mehrling, MD, PhD, Veronika Kandziora and Rohit Babbar were appointed Chief Executive Officer ("CEO"), Chief Operating Officer ("COO") and Chief Financial Officer ("CFO"), respectively, in April and June 2025, before the start of the year ended July 31, 2026.

On April 10, 2025, the Company announced the appointment of Thomas Mehrling as CEO, succeeding Jacek Antas, who continued as a director and Chair of the Board at that time.

On April 24, 2025, the Company announced the appointment of Veronika Kandziora as COO. On June 2, 2025, the Company announced the appointment of Rohit Babbar as CFO, replacing James B. Murphy.

On May 13, 2026.2026, the Company announced the appointment of Zachary T. Stadnyk as Director of the Company.

During the year ended July 31, 2026, the Company's arrangement for CFO services through Brio Financial Group LLC ended on May 21,

2026.

On May 22, 2026, the Company entered into a consulting agreement for CFO services with Accountin.ai LLC, a company controlled by the Company's current CFO.

Subsequent to July 31, 2026, the Company announced the appointment of Markus Loeffler, MD, as Chief Medical Officer in August 2026. The Company also completed a renewal of its Board of Directors, including the appointment of Karen Krumeich as Chair of the Board and the addition of Thomas Mehrling, MD, PhD, Jamieson Bondarenko, CFA, CMT, Charmaine Lykins, MBA, and Dirk Brockstedt, PhD, as directors. Three directors resigned in September 2026.

RISK FACTORS

RISKS AND UNCERTAINTIES

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

Risks Related to the Company's Business

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

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

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

The Company's primary focus continues to be on its research and development of drug product candidates. The research and development of drug product candidates require the expenditure of significant amounts of cash over a relatively long-time period. The Company expects to continue to incur losses from continuing operations for the foreseeable future. The Company's accumulated deficit as of July 31, 2026 is $219,230,000. There can be no assurance that the Company will record earnings in the future or that the drug product candidates under development by us will be approved for sale in Canada, the United States, or elsewhere. Furthermore, there can be no assurance that if such products are approved, they will be successfully commercialized, and the extent of our future losses and the timing of our profitability are highly uncertain. If we are unable to achieve profitability, we may be unable to continue our operations.

The Company faces risks in connection with competition and technological change

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

The rapid advancement of immunotherapies has significantly changed the treatment of cancer and may continue to affect the potential patient populations and treatment approaches available for investigational therapies such as L-DOS47. In response to developments in the NSCLC treatment landscape, the Company has prioritized the development of L-DOS47 in combination with pembrolizumab as first-line treatment for advanced NSCLC, replacing its previous focus on later-line chemotherapy combinations. Further changes in standards of care, competing therapies, or clinical evidence may require additional modifications to the Company's development strategy, resulting in increased costs, delays, or the discontinuation of development activities. The Company remains substantially dependent on the successful development of L-DOS47, its lead clinical-stage drug candidate.

The Company's discovery-stage CEACAM6-targeted antibody-drug conjugate (ADC) and radioligand therapeutic programs face significant scientific and technical risks. These programs remain at an early stage of research and development, and there can be no

assurance that the selected targets, antibody constructs, or therapeutic approaches will demonstrate the necessary activity, safety, or manufacturability to advance into preclinical or clinical development. Unsuccessful research outcomes, technical challenges, or insufficient financing could delay or prevent their further development.

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

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

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

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

The Company is heavily dependent on the success of its drug product pipeline

The Company's future success depends primarily on its ability to advance its drug product candidates through development, obtain regulatory approvals, and ultimately commercialize approved products. L-DOS47 remains the Company's lead and only clinical-stage drug candidate, while LEUMUNA and GEMCEDA are in preclinical development and its CEACAM6-targeted antibody-drug conjugate and radioligand therapeutic programs remain at the discovery stage. The Company does not have any products that have obtained regulatory approval. The development of these candidates will require substantial additional research, clinical testing, regulatory activities, and financing, and there can be no assurance that any of them will be successfully developed or commercialized. Accordingly, the Company's near-term prospects remain substantially dependent on advancing its pipeline, particularly L-DOS47, and securing sufficient financing to support its development activities.

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

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

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

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

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

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

The Company will require significant additional financing to advance its development programs, and there can be no assurance that sufficient funding will be available

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

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

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

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

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

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

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

Patent applications relating to or affecting the Company's business may have been filed by a number of pharmaceutical and

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

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

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

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

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

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

Further, some of our partners may store personal or confidential information that we share with them. If these third parties fail to implement adequate data-security practices or fail to comply with our terms and policies, sensitive data may be improperly accessed, acquired, or disclosed. And even if these third parties take all these steps, their networks and information technology systems may still suffer a security breach, which could compromise our data.

The Company may infringe the intellectual property rights of others

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

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

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

Third parties may assert patent or other intellectual property infringement claims against the Company or its other licensors arising from the manufacture, use, or sale of the Company's current or future product candidates. An unfavorable outcome could result in loss of patent

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

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

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

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

The Company or its licensors may be subject to claims that former employees, collaborators or other third parties have an interest in the Company's owned or in-licensed patents, trade secrets, or other intellectual property as an inventor or co-inventor. For example, the Company or its licensors may have inventorship disputes arise from conflicting obligations of employees, collaborators, consultants, or others who are involved in developing the Company's product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship of the Company's or its licensors' ownership of the Company's owned or in- licensed patents, trade secrets or other intellectual property. The Company may not have the financial means to defend such claims and in the event the Company or its licensors fail in defending any such claims, in addition to paying monetary damages, the Company may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to the Company's product candidates. Even if the Company is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on the Company's business, financial condition, results of operations and prospects.

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

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

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

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

loss of patent rights in the relevant jurisdiction. In such an event, the Company's competitors might be able to enter the market and this circumstance would have a material adverse effect on the Company's business.

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

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

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

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

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

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

While the Company continues to explore opportunities to expand its drug product pipeline with new DOS47-based therapeutics pending the identification of further 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 regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming, expensive, and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed

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

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

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a New Drug Application, or NDA, or other submission or to obtain regulatory approval in the United States or elsewhere; the FDA or comparable

foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and

- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

In addition, the agreements under which the Company currently licenses intellectual property or technology from third parties are complex,

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

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

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

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

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

We are substantially dependent on third parties for the manufacture of our clinical supplies of our product candidates, and we intend to rely on third parties to produce commercial supplies of any approved product candidate. Therefore, our development of our products could be stopped or delayed, and our commercialization of any future product could be stopped or delayed or made less profitable if third party manufacturers fail to obtain approval of the FDA or comparable regulatory authorities or fail to provide us with drug product in sufficient quantities or at acceptable prices

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

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

We and/or our third-party manufacturers may be adversely affected by developments outside of our control, and these developments may delay or prevent further manufacturing of our products. Adverse developments may include labor disputes, resource constraints, shipment delays, inventory shortages, lot failures, unexpected sources of contamination, lawsuits related to our manufacturing techniques, equipment used during manufacturing, or composition of matter, unstable political environments, acts of terrorism, war, natural disasters, and other natural and man-made disasters. If we or our third-party manufacturers were to encounter any of the above difficulties, or otherwise fail to

comply with contractual obligations, our ability to provide any product for clinical trial or commercial purposes would be jeopardized. This may increase the costs associated with completing our clinical trials and commercial production. Further, production disruptions may cause us to terminate ongoing clinical trials and/or commence new clinical trials at additional expense. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications or pass safety inspections. If production difficulties cannot be solved with acceptable costs, expenses, and timeframes, we may be forced to abandon our clinical development and commercialization plans, which could have a material adverse effect on our business, prospects, financial condition, and the value of our securities.

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

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

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

Our strategy for the development and commercialization of our proprietary product candidates may include the formation of collaborative arrangements with third parties. Existing and future collaborators have significant discretion in determining the efforts and resources they apply and may not perform their obligations as expected. Potential third-party collaborators include biopharmaceutical, pharmaceutical and biotechnology companies, academic institutions, and other entities. Third-party collaborators may assist us in:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Consequently, if the Company is unable to attract and/or loses and is unable to replace key personnel, its business could be negatively affected and, in particular, if the Company loses its current resident Canadian director in the future and is unable to find a resident Canadian director to fill the resulting vacancy, the Board will be prevented from taking any action other than appointing an additional resident

Canadian director until such time as a new resident Canadian director has been appointed such that at least 25% of the Company's directors are resident Canadians.

The Company employs a small number of employees who have many years of technical knowledge of the Company's technology and two senior officers, the CEO and CFO.

The Company has established a policy to diligently monitor developments. Because the situation is fluid, the Company will be updating its staff whenever necessary. The Company has implemented and communicated a policy to all staff in order mitigate any potential risk.

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

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

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

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

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

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

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

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

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

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

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

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

The Company's Common Shares are publicly traded on the TSX. As a public company, the Company is subject to the reporting requirements of Canadian securities regulators, the listing requirements of any stock exchange on which its Common Shares are listed for trading and other applicable securities rules and regulations. Compliance with these rules and regulations may increase the Company's legal and financial compliance costs, may make some activities more difficult, time-consuming, or costly and may increase the demand on the Company's systems and resources. Being a public company requires that the Company file continuous disclosure documents, including,

among other things, annual and quarterly financial statements. Management's attention may be diverted from other business concerns, which could have a material adverse effect on the Company's business, financial condition, and results of operations. The Company may need to hire more employees in the future, which will increase its costs and expenses.

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

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

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

Impact of the war in Ukraine on historical clinical activities

The war in Ukraine contributed to the early termination of the Company's LDOS003 clinical study, which was conducted in Eastern Europe. The study was discontinued, and the Company has no plans to resume it.

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

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

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

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

Public health emergencies may disrupt the Company's operations and development activities.

Future epidemics, pandemics, or other public health emergencies could adversely affect the Company's business, operations, and financial condition. Such events may disrupt clinical trials, patient recruitment, regulatory activities, manufacturing, supply chains, and the availability of employees, consultants, and service providers. Public health emergencies may also contribute to financial market volatility and adversely affect the Company's ability to obtain financing. The extent of any resulting disruption would depend on the nature, severity, and duration of the event and the measures implemented in response.

Risks Related to the Common Shares

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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 Canada Business Corporations Act (the "CBCA") and the policies of the TSX.

CAPITAL STRUCTURE

Fiscal 2026 financing and liquidity

As at July 31, 2026, the Company had cash of $804,000, a working capital deficiency of $4.181 million, shareholders' equity of $14.208 million and an accumulated deficit of $219.230 million. The Company's cash resources are insufficient to meet anticipated working-capital and capital-expenditure requirements for the next twelve months or to complete its current research and development initiatives. The Company's ability to continue as a going concern remains dependent mainly on obtaining additional financing.

Current liabilities at July 31, 2026 included convertible debentures with a carrying amount of $3.797 million that mature July 27, 2027. Unless converted, contractual principal and interest of $4.744 million are payable at maturity.

The Company continues to evaluate financing alternatives to support its ongoing operations and planned development activities. Its current financing strategy contemplates securing bridge financing to support near-term corporate objectives and prepare for a subsequent, larger financing intended to fund the next stages of clinical development, including the planned Phase Ib/randomized Phase II study of L-DOS47 in combination with pembrolizumab in first-line non-small cell lung cancer. The timing, scope, and execution of these activities remain contingent upon the Company securing sufficient financing, as well as applicable regulatory approvals and other development requirements. There can be no assurance that the Company will secure financing on acceptable terms or at all.

Share capitalization.

The Company's articles authorize the issuance of an unlimited number of Common Shares and 10,000,000 preferred shares issuable in series. As of July 31, 2026, the Company had 76,378,098 Common Shares and nil preferred shares issued and outstanding.

Common Shares

The holders of the Common Shares are entitled to receive notice of and to attend all meetings of the shareholders of the 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.

Warrants and Stock Options

Warrants have been issued by the Company in connection with the sale of units of the Company, with each unit consisting of one Common Share and one Warrant. The Warrants of the Company are subject to certain restrictions on transfer as set out in the applicable certificates representing such Warrants. The 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.

As of July 31, 2026, the Company had no common share purchase warrants outstanding.

The Company’s equity compensation plan reserves up to 10% of the Company’s outstanding Common Shares from time to time for granting to directors, officers and employees of the Company or any person or company engaged to provide ongoing management or consulting services. Based on the Company’s issued and outstanding Common Shares as of July 31, 2026, options to purchase up to 7,637,810 Common Shares may be granted under the plan. No stock options were exercised during the year ended July 31, 2026. During the year ended July 31, 2026, 1,297,000 options were granted and 2,220,000 options were cancelled or expired.

As of July 31, 2026, options to purchase a total of 2,283,667 Common Shares were issued and outstanding under the equity compensation plan. Subsequent to year-end, 100,000 options expired unexercised, leaving 2,183,667 options outstanding.

MARKET FOR SECURITIES

Trading Price and Volume

The Common Shares began trading on the TSX on June 3, 1996. The current stock symbol is "HBP". The following table sets forth the price ranges and trading volumes of the Common Shares on the TSX for the respective periods.

Date	High	Low	Volume
August-25	$ 1.47	$ 0.98	216,269
September-25	$ 1.69	$ 1.30	69,680
October-25	$ 5.40	$ 1.87	373,518
November-25	$ 2.60	$ 1.93	37,536
December-25	$ 2.40	$ 2.03	39,043
January-26	$ 2.45	$ 1.75	52,502
February-26	$ 2.00	$ 1.78	12,263
March-26	$ 2.20	$ 1.46	60,140
April-26	$ 2.05	$ 1.46	55,065
May-26	$ 2.12	$ 1.44	45,764
June-26	$ 1.58	$ 1.20	28,504
July-26	$ 1.50	$ 1.10	15,289

The Common Shares are quoted on the Berlin Stock Exchange, under the trading symbol "HBP" though trading is negligible.

DIRECTORS AND OFFICERS

Board and officer changes after July 31, 2026

Janusz Grabski resigned as a director effective August 12, 2026, and Thomas Mehrling, the Company's Chief Executive Officer, was appointed as a director effective August 14, 2026. Thomas Mehrling resigned as Chief Medical Officer effective August 17, 2026, and Markus Loeffler was appointed Chief Medical Officer. Jacek Antas, Jerzy Leszczynski and Malgorzata Laube resigned as directors effective September 17, 2026. On September 28, 2026, Karen Krumeich, Dirk Brockstedt, Charmaine Lykins and Jamieson Bondarenko were appointed directors, and Karen Krumeich was appointed Chair of the Board and Chair of the Audit Committee.

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.

During the period under review, the following changes occurred on the board of directors and officers.

- Mr. Rohit Babbar, CPA appointed as the CFO effective June 2, 2025, replacing James B. Murphy.
- Ms. Veronika Kandziora appointed as the COO effective April 24, 2025.
- Mr. Thomas Mehrling, MD, PhD appointed CEO effective April 10, 2025, succeeding Jacek Antas, who remained a Director and Chairman of the Board.
- Mr. James B. Murphy, CPA appointed CFO effective December 11, 2024, succeeding Mr. Praveen Varshney, FCPA, who resigned as CFO and Corporate Secretary on November 8, 2024.

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

- Karen Krumeich (Independent)
  Director since September 2026
  Residence: Pennsylvania, United States

  Karen Krumeich is an experienced life sciences financial executive with expertise spanning venture and public equity financing, investor relations, strategic planning, corporate governance, business development, and operations. She has served as Chief Financial Officer and Executive Vice President for a number of public and private life-sciences companies, including Kazia Therapeutics, TheraVectys and Soligenix, bringing direct experience supporting companies with oncology programs in development. Ms. Krumeich

has extensive experience working with corporate boards and presenting to Audit Committees, and currently serves as fractional Chief Financial Officer with the Lisa Stone Group and as angel investor and Managing Director of Golden Seeds. She holds a Bachelor of Science in Pharmacy from the University of Toledo College of Pharmacy and successfully completed the CPA examination at postgraduate level.

- Thomas Mehrling MD, PhD
  Director since August 2026, CEO since April 2025
  Residence: Basel, Switzerland

  Dr. Dirk Brockstedt is a biotechnology executive and scientist with more than 25 years of experience in research, translational science, and clinical development. He currently serves as Scientific Advisor to Remedy Plan Therapeutics and as scientific consultant to Mulberry Biotherapeutics. Previously, Dr. Brockstedt served as Chief Scientific Officer of RAPT Therapeutics, where he led research and development activities through the company's acquisition by GSK in 2026 and, before that, as Executive Vice President of Research & Development at Aduro BioTech, having played an instrumental role in taking both companies public in 2019 and 2015, respectively. He brings deep expertise in immunology, oncology and drug development spanning discovery through Phase 2, together with executive management and Board-level experience in R&D oversight, partnering, licensing, due diligence, and institutional investor and financing roadshows. Dr. Brockstedt holds a Ph.D. in Cellular Biology and Immunology from the University of Kiel, with graduate research conducted at Stanford University, is an inventor on nine issued U.S. patents, and has authored over 50 peer-reviewed publications in immunology, oncology and vaccine development, including in Nature Medicine, PNAS, and Clinical Cancer Research.

- Jamieson Bondarenko, CFA, CMT (Independent)
  Director since September 2026
  Residence: Vancouver, British Columbia

  Jamieson Bondarenko is an active investor, capital markets executive and public company director with experience advising early-stage life sciences companies on capital markets and corporate development strategy. He currently serves as Chairman of the Board of BriaCell Therapeutics Corp. and as a capital markets advisor to MustGrow Biologics Corp. Previously, Mr. Bondarenko held senior equity capital markets and investment banking roles at Eight Capital and Dundee Securities, following roles at Wellington West Capital Markets and HSBC Securities (Canada). He is a Chartered Financial Analyst and Chartered Market Technician..

- Charmaine Lykins, MBA (Independent)
  Director since September 2026
  Residence: Florida, United States

  Charmaine Lykins is a seasoned biopharmaceutical executive and commercial leader with more than 30 years of experience spanning commercial strategy and execution, product launch and lifecycle management, market development, and organizational leadership. She currently serves as Chief Executive Officer of Transneural Therapeutics, a preclinical-stage company developing novel therapies for neuropsychiatric disorders, and as strategic advisor to several predominantly CNS-focused biotechnology and healthcare organizations. Previously, she held senior commercial leadership roles at Karuna Therapeutics, MapLight Therapeutics and Acadia Pharmaceuticals, following earlier roles at Lundbeck, Eli Lilly and Sunovion Pharmaceuticals (now Sumitomo Pharma). Over the course of her career, Ms. Lykins has contributed to the commercialization and early commercial strategy of multiple first- and best-in-class therapies, including COBENFY®, NUPLAZID®, REXULTI®, ABILIFY MAINTENA®, LATUDA®, CYMBALTA®, PROZAC® and ZYPREXA®. She holds an MBA in International Business from the University of South Carolina and a Bachelor of Science in Chemistry and Honors Humanities from Ball State University..

- Dirk Brockstedt, PhD (Independent)
  Director since September 2026
  Residence: California, United States

  Dr. Dirk Brockstedt is a biotechnology executive and scientist with more than 25 years of experience in research, translational science, and clinical development. He currently serves as Scientific Advisor to Remedy Plan Therapeutics and as scientific consultant to Mulberry Biotherapeutics. Previously, Dr. Brockstedt served as Chief Scientific Officer of RAPT Therapeutics, where he led research and development activities through the company's acquisition by GSK in 2026 and, before that, as Executive Vice President of Research & Development at Aduro BioTech, having played an instrumental role in taking both companies public in 2019 and 2015, respectively. He brings deep expertise in immunology, oncology and drug development spanning discovery through Phase 2, together with executive management and Board-level experience in R&D oversight, partnering, licensing, due diligence, and institutional investor and financing roadshows. Dr. Brockstedt holds a Ph.D. in Cellular Biology and Immunology from the University of Kiel, with graduate research conducted at Stanford University, is an inventor on nine issued U.S. patents, and has authored over 50 peer-reviewed publications in immunology, oncology and vaccine development, including in Nature Medicine, PNAS, and Clinical Cancer Research.

- Zachary T. Standyk (Independent)

Director since May 2026
Residence: Vancouver, British Columbia

Mr. Stadnyk brings more than 15 years of experience across biotechnology, capital markets, and public company leadership, including serving as Head of Life Sciences at the TSX and TSXV, where he advised biotech issuers, boards and institutional investors on public listings, capital formation and strategic positioning, with deep experience in public market execution. Over the course of his career, he has led and supported over $100 million in institutional financings, contributed to strategic transactions including the $435 million acquisition of The Supreme Cannabis Company by Canopy Growth, and advised public companies across the biotech, healthcare and AI sectors.

To the best of the Company's knowledge, the number and percentage of issued Common Shares beneficially owned, directly or indirectly, by the Directors and Officers of the Company, as a group and individually, as at the date of this AIF are as set out in the following table. The table excludes any stock options or warrants beneficially owned, directly or indirectly by the Directors and Officers of the Company, as a group and individually.

Name	Number of Common Shares Held	Percentage of Class [(1)]
Dr. Thomas Mehrling[(2)]	21,056,229	27.57%
Charmaine Lykins	Nil	Nil
Dirk Brockstedt	Nil	Nil
Jamieson Bondarenko	Nil	Nil
Karen Krumeich	Nil	Nil
Zachary Stadnyk	Nil	Nil

(1) Based on 76,378,098 Common Shares issued and outstanding as at the date of this AIF.

(2) Dr. Thomas Mehrling directly owns 47,000 Common Shares and beneficially owns, controls or directs 9,454,153 Common Shares through Laevoroc Chemotherapy AG, an entity incorporated under the laws of Switzerland, and 11,555,076 Common Shares through Laevoroc Immunology AG, an entity incorporated under the laws of Switzerland.

Cease Trade Orders, Bankruptcies, Penalties and Sanctions

Except as described below, 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.

As of the date of this AIF, 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

Helix has demanded access to certain batch records for its anti-cancer antibody drug, L-DOS47 from BioVectra Inc. in order to remanufacture it. Despite requests, BioVectra has refused to provide the Company with the batch records. The Company believes that BioVectra's refusal to provide the batch records is a breach of the Quality and Manufacture Agreements for L-DOS47 and may cause substantial damage to the Company.

The Company is in the process of considering its legal options and risks.

INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

During the year ended July 31, 2026, the Company entered into various transactions with related parties. The related parties consist of officers, directors and shareholders or companies controlled directly or indirectly by them. Details of the transactions and balances owing for the year ended July 31, 2026 are as follows:

i. During the year ended July 31, 2026, the Company recorded management fees and salaries to executive officers, excluding the CFO service-provider fees disclosed separately below, of $973 (July 31, 2025: $413). The balance outstanding as at July 31, 2026 was $85 (July 31, 2025: $172).
ii. The Company retained Brio Financial Group LLC ("Brio"), a company with which the Company's current CFO was employed, to provide CFO and related accounting services until May 21, 2026. During the year ended July 31, 2026, the Company incurred fees to Brio of $324 (July 31, 2025: $41). The balance outstanding as at July 31, 2026 was $Nil (July 31, 2025: $20).
iii. On May 22, 2026, the Company entered into a consulting agreement for CFO services with Accountin.ai LLC, a company controlled by the Company's current CFO. During the year ended July 31, 2026, the Company incurred fees of $67 (July 31, 2025: $Nil). The balance outstanding as at July 31, 2026 was $28 (July 31, 2025: $Nil).
iv. The carrying amount of the intellectual property acquired through the Laevoroc asset acquisitions was $18,389 as at July 31, 2026 (July 31, 2025: $18,389). The acquisitions closed on May 20, 2025 and included the assumption of a loan payable to metaShape Pharma AG ("metaShape") of $335 (CHF 200). At closing, the Company's current CEO was also the CEO of both Laevoroc entities and metaShape. As at July 31, 2026, the Company's current CEO was no longer the CEO of metaShape.
v. During the year ended July 31, 2026, the Company accrued interest of $14 on the loan payable to metaShape (July 31, 2025: $Nil). The balance outstanding as at July 31, 2026 was $361 (July 31, 2025: $335). The increase of $26 comprised accrued interest of $14 and a foreign exchange adjustment of $12.
vi. On May 27, 2026, a shareholder holding approximately 11.5% of the Company's outstanding common shares subscribed for unsecured convertible debentures with a principal amount of $1,260, on the same terms as the other subscribers. No convertible debentures were outstanding as at July 31, 2025.

TRANSFER AGENT AND REGISTRAR

The Company's transfer agent and registrar for its Common Shares is:

Endeavor Trust Corporation
Suite 702 – 777 Hornby Street
Vancouver, BC V6Z 1S4

MATERIAL CONTRACTS

The following are the material contracts entered into by the Company outside the ordinary course of business, including historical agreements that have expired or been terminated:

1) Technology License Agreement with the National Research Council of Canada (NRC) dated April 28, 2005 and amendment dated December 2, 2009.

   The Company entered into a worldwide exclusive license with the NRC, through which it obtained the right to combine an antibody that specifically binds to lung adenocarcinoma cells with minimal cross reactivity to other tissues with the Company'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. L- DOS47 is subject to this agreement.

On August 17, 2024, the last patent related to this agreement expired. Consequently, this agreement also expired on August 17, 2024.

2) The Company in-licensed the worldwide rights for anti-CEACAM6 single domain antibody 2A3 from the NRC. Pursuant to a collaboration and licensing agreement dated February 20, 2017 with the NRC, the Company is required to pay a royalty of 3% of net sales, with a minimum royalty of $10,000 per annum generated from the use of a certain antibody to target cancerous tissues of the lung. In addition to the royalty payments, the Company is also required to make certain milestone payments for the first licensed product: $25,000 upon successful completion of Phase I clinical trials; $50,000 upon successful completion of Phase IIb clinical trials; $150,000 upon successful completion of Phase III clinical trials; $200,000 upon receipt of first regulatory approval by a regulatory authority; and $200,000 upon receipt of a second regulatory approval by a regulatory authority. For the development of each subsequent licensed product: $200,000 upon receipt of first regulatory approval by a regulatory authority; and $200,000 upon receipt of a second regulatory approval by a regulatory authority. As it relates to sub- licensing arrangement, the Company is required to pay the NRC 33% of any sub-licensing revenues except for royalties that HBP might receive from a third party received.

   In October 2023, the Company and the NRC mutually agreed to terminate the license agreement. The related NRC patent expired on August 17, 2024.

3) The Company signed a collaboration and licensing agreement on March 16, 2018 with ProMab to develop novel antibody and CAR-T for particular hematological malignancies. Under the collaboration agreement, Helix retains commercial rights for Canada and Europe (except Russia).

   a) The Company will pay the following royalties to ProMab:
      i. 5% of annual aggregate net sales up to USD$250,000
      ii. 6% of annual aggregate net sales above USD$250,000

   b) The Company will pay the following milestone to ProMab:
      i. USD$1,000,000 upon the completion of Phase I clinical study meeting primary objectives of the trial for each drug product; and
      ii. USD$5,000,000 upon first commercial sale of each drug product.

   On December 21, 2020 the Company signed a “Partial Assignment and Novation” agreement with ProMab and HIO S.A. (now 4-Cell Therapeutics), a Poland corporation. In this said agreement, Helix assigned European rights of the patent “BCMA-specific Antibodies and Anti BCMA-CAR-T Cells” to HIO, retaining Canadian rights.

   In November 2023, the Company issued a termination notice to ProMab for this agreement.

4) The Company signed an exclusive out-license agreement with Xisle for the Company's late-stage, Biphasix™ technology platform, including the lead product candidate, interferon alpha. Xisle is responsible for the continued clinical development and subsequent commercialization of the product for the treatment of HPV-induced, low- grade, cervical intraepithelial lesions. Under the terms of the agreement dated November 18, 2016, Xisle paid an up-front fee of USD$125,000 and agreed to pay subsequent milestone payments as they advance the technology to registration and market approvals and royalties. As part of the agreement, Helix retains marketing rights for Belarus, Bulgaria, Czech Republic, former Eastern Germany, Hungary, Moldova, Poland, Romania, Russia, Slovakia and Ukraine. In addition, the Company also retains non-exclusive rights for co-promotion in Canada.

   a) Milestones as follows:
      i. USD$3,000,000 upon initiation of the first Phase 3 trial anywhere in Xisle’s territory;
      ii. USD$5,000,000 upon first submission of New Drug Application or similar for approval in the Xisle territory; and
      iii. USD$10,000,000 upon first commercial sale of a product in the Xisle territory.

   b) Royalties as follows until the lapse of 10 years from first commercial sale of a product in Xisle’s territory:
      i. 8% on annual net sales up to USD$50,000,000,
      ii. 10% on the next annual net sales of USD$25,000,000, and
      iii. 12.50% on the annual net sales above USD$75,000,000.

5) The Company signed an asset purchase agreement with Laevoroc Immunology AG, a privately-held Swiss oncology company, on 28 November, 2024, to acquire the intellectual property, inventory, assigned agreements and rights to LEUMUNA™ (formerly LR 09, ulodesine hemiglutarate), an oral purine nucleoside phosphorylase (PNP) inhibitor and immune checkpoint modulator in preclinical development for the treatment of leukemia relapse following allogeneic stem cell transplantation (allo-SCT). LEUMUNA received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) in 2022. Under the terms of the agreement, as amended on December 6, 2024, the parties agreed that Helix will acquire substantially all of the assets and certain liabilities of Laevoroc Immunology in consideration for the issuance of 11,555,076 Common Shares of the Company on the closing date of the transaction

("the L-Immu Transaction"), and that all shares issuable in connection with the L-Immu Transaction will be subject to a hold period of four months and one day from the date of issuance.

On 26 March, 2025, the Shareholders of the Company approved the resolution regarding the asset transaction contemplated by the asset purchase agreement with Laevoroc Immunology AG dated 28 November, 2024, as amended on 5 December, 2024, in accordance with the policies of the TSX, with 99.61% of the votes cast in favor. The L-Immu Transaction was closed on 20 May, 2025, with 11,555,076 shares issued to Laevoroc Immunology at a price of $0.95 per share, which represents the closing price of the Common Shares on December 5, 2024, the day before the Company entered into the amendment agreements.

6) The Company signed an asset purchase agreement with Laevoroc Chemotherapy AG, a privately-held Swiss oncology company, on 30 November, 2024, to acquire the intellectual property, inventory, assigned agreements and rights to GEMCEDA™, an oral gemcitabine prodrug combined with cedazuridine in preclinical development for the treatment of solid tumors. The formulation is designed to improve the oral delivery of gemcitabine, a chemotherapy agent included on the World Health Organization's List of Essential Medicines. Preclinical studies have demonstrated approximately 90% oral bioavailability, supporting the potential development of an oral alternative to intravenous gemcitabine administration. Further development is required to establish GEMCEDA's safety and efficacy in clinical studies. Under the terms of the agreement, as amended on December 6, 2024, the parties agreed that Helix will acquire substantially all of the assets and certain liabilities of Laevoroc Chemotherapy in consideration for the issuance of 9,454,153 Common Shares of the Company on the closing date of the transaction ("the L-Chemo Transaction"), and that all shares issuable in connection with the L-Chemo Transaction will be subject to a hold period of four months and one day from the date of issuance.

   On 26 March, 2025, the Shareholders of the Company approved the resolution regarding the asset transaction contemplated by the asset purchase agreement with Laevoroc Chemotherapy AG dated 30 November, 2024, as amended on 5 December, 2024, in accordance with the policies of the TSX, with 99.61% of the votes cast in favor. The L-Chemo Transaction was closed on 20 May, 2025, with 9,454,153 shares issued to Laevoroc Chemotherapy at a price of $0.95 per share, which represents the closing price of the Common Shares on December 5, 2024, the day before the Company entered into the amendment agreements.

   Electronic copies of the contracts set out above may be accessed under the Company's profile on SEDAR+ at https://www.sedarplus.ca.

INTERESTS OF EXPERTS

The Company's auditors are Clearhouse LLP. 2560 Matheson Boulevard, Suite 527, Mississauga, ON L4W 4Y9. Clearhouse LLP is independent of the Company in accordance with the applicable rules of professional conduct/code of ethics of The Chartered Professional 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: Karen Krumeich (Chair), Zachary T. Stadnyk and Jamieson Bondarenko, all of whom are independent directors. Ms Karen Krumeich was appointed Chair of the Audit Committee on September 28, 2026.

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 Company appointed Clearhouse LLP as auditors for fiscal 2026 and 2025. The total fees billed for professional services are as follows:

Item	**2026**		**2025**	
	Amount	Percentage	Amount	Percentage
Audit-Fees	$[65,000] (est)	88%	$58,500	88%
Tax Fee	$[4,000] (est)	6%	$4,000	6%
All Other Fees	$[31,400] (est)	6%	$4,000	6%
Total	$[99,400] (est)	100%	$66,500	100%

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.

Management's Discussion and Analysis of Results of Operations and Financial Condition of the Company as of July 31, 2026, as filed on the Company's profile on SEDAR+ at https://www.sedarplus.ca is incorporated by reference herein.

Any request for documents referred to above should be made to the Chief Financial Officer, attention: Natalia Butterworth, Suite 480, 789 West Pender Street, Vancouver, BC V6C 1H2.

Additional information relating to the Company can be found under the Company's profile on SEDAR+ at https://www.sedarplus.ca and the Company's website at www.helixbiopharma.com.

GLOSSARY

Adenocarcinoma: A type of cancer that develops in glandular cells, including those found in the lungs and pancreas.

Allogeneic stem cell transplantation (allo-SCT): A procedure in which a patient receives blood-forming stem cells from a donor, typically following treatment intended to eliminate diseased cells.

Antibody-drug conjugate (ADC): A therapeutic construct consisting of an antibody linked to a biologically active drug, designed to deliver the drug to cells expressing a specific target antigen.

Antibody-enzyme conjugate (AEC): A therapeutic construct consisting of an antibody or antibody fragment linked to an enzyme, enabling targeted delivery of enzymatic activity.

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

Board: The Board of Directors of the Company.

Canada Business Corporations Act (CBCA): The federal legislation governing the incorporation and operation of federally incorporated corporations in Canada.

Carcinoembryonic antigen-related cell adhesion molecule 6 (CEACAM6): A cell-surface protein expressed in various normal tissues and overexpressed in certain cancers, including non-small cell lung cancer and pancreatic cancer.

Chemistry, manufacturing and controls (CMC): Activities and regulatory documentation relating to the composition, manufacturing processes, quality and consistency of a pharmaceutical product.

Clinical Study Report (CSR): A comprehensive report documenting the methodology, conduct, results and conclusions of a clinical study.

Clinical Trial Application (CTA): A regulatory submission seeking authorization to conduct a clinical trial in a particular jurisdiction.

Current Good Manufacturing Practices (cGMP): Regulatory requirements governing the manufacturing, processing, packaging and quality control of pharmaceutical products to ensure consistent quality.

Food and Drug Administration (FDA): The United States regulatory agency responsible for overseeing the safety, efficacy and quality of pharmaceutical products, among other regulated products.

Health Canada: The Canadian federal department responsible for national health policy and the regulation of pharmaceutical products in Canada.

Helix Immuno-Oncology S.A. (HIO): Helix Immuno-Oncology S.A.

Human papillomavirus (HPV): A group of viruses, certain types of which are associated with the development of cervical and other cancers.

Immunoconjugate: A molecular construct consisting of an antibody or antibody fragment linked to another molecule, such as a drug, enzyme or radioactive compound.

International Financial Reporting Standards (IFRS): Accounting standards issued by the International Accounting Standards Board (IASB) governing the preparation and presentation of financial statements.

Investigational New Drug (IND): A regulatory submission to the FDA that, subject to applicable requirements, allows an investigational drug to be administered to humans in clinical studies in the United States.

National Research Council of Canada (NRC): A Canadian federal research organization involved in scientific research, technology development and industry collaboration.

Non-small cell lung cancer (NSCLC): A category of lung cancers comprising several histological subtypes, including adenocarcinoma and squamous cell carcinoma.

Orphan Drug Designation (ODD): A regulatory designation granted to drugs under development for qualifying rare diseases or conditions, providing certain development incentives. Designation does not constitute regulatory approval.

Pharmacokinetics (PK): The study of how a drug is absorbed, distributed, metabolized and eliminated by the body over time.

Phase I clinical trials: Early-stage clinical trials designed primarily to evaluate the safety, tolerability and appropriate dosing of an investigational drug. In oncology, these trials typically involve patients with cancer rather than healthy volunteers.

Phase II clinical trials: Clinical trials designed to evaluate the preliminary efficacy of an investigational drug in patients with a particular disease or condition, while continuing to assess its safety and, where applicable, further investigating appropriate dosing.

Phase III clinical trials: Clinical trials designed to confirm the efficacy and safety of an investigational drug in a larger patient population, typically by comparing it with an established treatment or other appropriate control.

Programmed cell death protein 1 (PD-1): An immune checkpoint receptor expressed on T cells and other immune cells that regulates immune responses. PD-1 is the target of pembrolizumab.

Programmed death-ligand 1 (PD-L1): A protein that can bind to PD-1 and suppress T-cell activity. PD-L1 expression is used as a biomarker in certain cancer treatment decisions.

Prodrug: A compound designed to undergo conversion in the body to release an active therapeutic agent.

Purine nucleoside phosphorylase (PNP): An enzyme involved in purine metabolism that plays a role in lymphocyte function and immune regulation.

Radioligand therapeutic (RLT): A therapeutic agent consisting of a targeting molecule linked to a radioactive isotope, designed to deliver radiation to cells expressing a specific molecular target.

Response Evaluation Criteria in Solid Tumors (RECIST): Standardized criteria used to assess changes in tumor burden and classify responses to treatment in clinical studies.

Toronto Stock Exchange (TSX): A Canadian stock exchange on which the Company's Common Shares are listed.

Tumor acidosis: The development of an acidic extracellular environment within a tumor, which may contribute to immune suppression and resistance to cancer therapies.

Tumor microenvironment (TME): The cellular and non-cellular environment surrounding tumor cells, including immune cells, blood vessels, connective tissue and extracellular components that can influence tumor growth and treatment response.

SCHEDULE A
AUDIT COMMITTEE CHARTER

HELIX BIOPHARMA CORP.

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:

i. 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 IFRS 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:

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. At least annually, the Audit Committee shall 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 legal counsel any 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.