

## HLS THERAPEUTICS INC.

ANNUAL INFORMATION FORM

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#### MEANING OF CERTAIN REFERENCES

HLS Therapeutics Inc. ("HLS" or the "Company") presents its consolidated financial statements in United States dollars. In this Annual Information Form, all references to "US\$" are to United States dollars and all references to "C\$" are to Canadian dollars. The information contained in this Annual Information Form is provided as at December 31, 2022 unless otherwise indicated. Certain terms used in this Annual Information Form are defined under "Glossary".

#### FORWARD-LOOKING STATEMENTS

This Annual Information Form contains forward-looking information within the meaning of applicable securities laws. In some cases, forward-looking statements may be identified by words such as "expect", "anticipate", "continue", "estimate", "objective", "ongoing", "may", "will", "project", "should", "believe", "plans", "intends", "potential" and similar expressions. Forward-looking statements provide information about management's current expectations and plans and allow investors and others to get a better understanding of the anticipated financial position, results of operations and operating environment of HLS. Readers are cautioned that such information may not be appropriate for other purposes. Forward-looking information is based on the reasonable assumptions, estimates, analyses, beliefs and opinions of management made in light of its experience and perception of trends, current conditions and expected developments, as well as other factors that management believes to be relevant and reasonable at the date that such statements are made. More particularly and without limitation, this Annual Information Form contains forward-looking statements concerning: industry trends, overall market growth rates and the Company's growth rates; expectations regarding revenue, expenses and operations; measures of the Company's operating performance and financial condition; the Company's business plans and strategies, including acquisition opportunities; intentions with respect to, and the ability to execute, the Company's growth strategies; future sales of the Company's products; future regulatory approval and sales of drugs and devices; securing additional licenses from third parties; assessments of suppliers' manufacturing capacity and downstream supply of raw materials; relationships with pharmaceutical and device licensors; relationships with employees; the Company's competitive position in the industry; anticipated trends and challenges in the Company's business and the markets in which it operates; protection of the Company's intellectual property rights; dividends; the effects of any non-compliance with government regulations; the exercise of certain shareholder rights; statements with respect to future prospects for Company products, including Vascepa®, Clozaril®, PERSERIS®, and the MyCare Products (as defined below); the future prospects for the products underlying the Royalty Portfolio (as defined below); HLS's pursuit of additional product and pipeline opportunities in certain therapeutic markets; future milestone payments; the timing and impact of the Company's re-submission of its Trinomia application to Health Canada to resolve the NOD (defined below); the purchase of Common Shares (as defined below) pursuant to the Company's normal course issuer bid; the impact of COVID-19 (as defined below) on the Company's results of operations and financial condition; the launch of PERSERIS; the promotion of Vascepa pursuant to the Pfizer Agreement: the commercialization of Xenpozyme and HLS's belief in its launch success; the expected approval of the MyCare Insite point of care therapeutic drug monitoring system for use with other common antipsychotic drugs; and HLS's anticipated cash needs and its need for additional financing; the pending amendments to the Patented Medicines Regulations (Canada); and other statements that are not historical facts.

By its very nature, forward-looking information requires management to make assumptions and is subject to inherent risks and uncertainties, which give rise to the possibility that management's assumptions, estimates, analyses, beliefs and opinions may not be correct and that HLS's expectations and plans will not be achieved. The forward-looking information contained in this Annual Information Form reflects assumptions regarding, but not limited to: revenue growth and operating efficiencies; customer demand for HLS's products; the sufficiency of budgeted capital expenditures in carrying out planned activities; the availability and cost of labour and services; there being no significant changes in regulatory, tax and healthcare laws and regulations; the absence of a material change in competition; and there being generally stable economic and financial conditions in Canada, the United States and globally. Although HLS believes that the forward-looking information in this Annual Information Form is based on information, assumptions and beliefs that are current, reasonable and complete, this information is necessarily subject to a number of factors that could cause actual results to differ materially from management's expectations and plans as set forth in such forward-looking information. Some of the factors, many of which are beyond HLS's control and the effects of which can be difficult to predict, but may cause actual results to differ from the results expressed by forward-looking information, include: HLS's dependence on revenue from sales of a limited number of products; HLS's reliance on third parties for the manufacture and supply of products; HLS's dependence on Boston Scientific, Takeda, Pfizer and Sanofi Genzyme (each as defined below) for the development, manufacturing, supply, distribution and commercialization of the products underlying the Royalty Portfolio; natural disasters and other crises; risks associated with the COVID-19 pandemic; risks associated with attracting and retaining key managerial personnel; risks and uncertainties related to HLS's acquisition growth strategy; risks and uncertainties related to HLS's ability to obtain or maintain regulatory approvals; risks related to changes in regulatory, tax and healthcare laws and regulations; and risks related to foreign exchange and market rate fluctuations.

This is not an exhaustive list of the factors that may affect the forward-looking information in this Annual Information Form. Investors and others should carefully consider these and other risk factors and not place undue reliance on the forward-looking information and statements. Further information regarding these and other factors are discussed in this Annual Information Form under the heading "Risk Factors" and also in HLS's materials filed with the Canadian securities regulatory authorities from time to time, including, without limitation, HLS's Management's Discussion and Analysis ("MD&A") for the year ended December 31, 2022.

The forward-looking statements and information contained in this Annual Information Form are made as of the date hereof and HLS undertakes no obligation to update publicly or revise any forward-looking statements or information, whether as a result of new information, future events or otherwise, except as required by applicable securities laws.

#### THE COMPANY

## **Incorporation and Office Address**

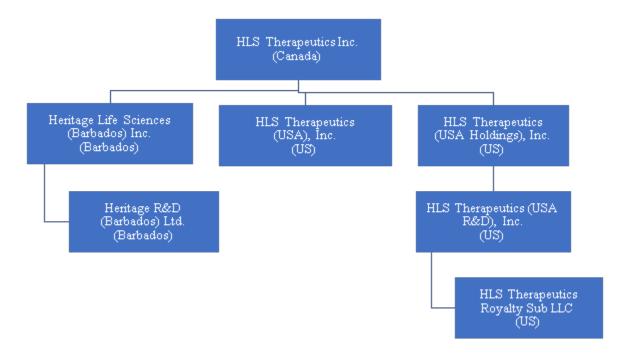
The Company was formed on March 12, 2018 by the amalgamation of HLS Therapeutics Inc. ("Former HLS") and Automodular Corporation ("AMD") by way of a plan of arrangement (the "Arrangement") pursuant to Section 183 of the *Business Corporations Act* (Ontario) (the "OBCA"). The Arrangement constituted a reverse take-over of AMD by Former HLS under the policies of the TSX Venture Exchange (the "TSXV"). Former HLS was incorporated pursuant to the provisions of the *Business Corporations Act* (British Columbia) (the "BCBCA") on June 5, 2014 under the name "Heritage Life Sciences Inc." and changed its name to "HLS Therapeutics Inc." on December 18, 2014. On March 8, 2018, prior to the consummation of the Arrangement, Former HLS continued from the BCBCA to the OBCA.

In this Annual Information Form, the terms "Company" and "HLS" each refer to HLS Therapeutics Inc. and/or to Former HLS, as the context requires.

The head and registered office of the Company is located at 10 Carlson Court, Suite 701, Etobicoke, Ontario M9W 6L2.

## **Intercorporate Relationships**

The following diagram illustrates the Company's intercorporate relationships, including the Company's subsidiaries that account, individually, for more than 10% of HLS's consolidated assets or revenues, or together, for more than 20% of HLS's consolidated assets or revenues. All subsidiaries are wholly-owned, directly or indirectly, by HLS:



## **BUSINESS OF THE COMPANY**

## **General Development of the Business**

## Initial Capital Raise and Going-Public Transaction

In 2015, HLS completed a US\$200 million private placement financing of equity and a US\$185 million debt financing to various investors in North America and overseas for total gross proceeds of US\$385 million. HLS used a portion of the net proceeds of these financings to acquire the United States and Canadian rights to manufacture, market and sell Clozaril (the "Clozaril Acquisition") from Novartis for an aggregate cash purchase price of US\$305 million. For a description of Clozaril, see "- Narrative Description of HLS's Business - Products and Programs".

On December 21, 2017, HLS and AMD entered into an arrangement agreement in respect of the Arrangement pursuant to which, among other things, HLS and AMD agreed to amalgamate and to continue as a company to be known as "HLS Therapeutics Inc."

The Arrangement, which constituted a reverse take-over of AMD by HLS under the policies of the TSXV, was consummated on March 12, 2018. On March 14, 2018, the Common Shares commenced trading on the TSXV under the symbol "HLS" and the AMD Shares were delisted from the TSXV.

Pursuant to the Arrangement, each outstanding Pre-Amalgamation Common Share was exchanged for one Common Share and each outstanding AMD Share was exchanged for 0.165834 Common Shares and one Preferred Share (the "Preferred Shares"). Upon completion of the Arrangement, Former HLS Shareholders held approximately 92% of the outstanding Common Shares, and former AMD Shareholders held approximately 8% of the outstanding Common Shares and 100% of the outstanding Preferred Shares. HLS has redeemed 100% of the Preferred Shares pursuant to their terms. See "—Year Ended December 31, 2021"

On February 7, 2019, HLS completed its graduation to the TSX and the Common Shares began trading on the TSX under the symbol "HLS". In connection with HLS's graduation to the TSX, the Common Shares were voluntarily delisted from the TSXV.

## Year Ended December 31, 2020

## Vascepa Data Protection and Launch

Following Health Canada's approval of Vascepa on December 30, 2019, HLS announced that on January 6, 2020, Vascepa was added to Health Canada's Register of Innovative Drugs. As a result of this development, Vascepa will benefit from data protection until December 30, 2027.

On February 7, 2020, HLS formally launched Vascepa in Canada. In connection with the launch, HLS hired 30 new employees, including 22 new sales representatives and eight other field-based roles, who are responsible for promoting the product to cardiologists, endocrinologists and selected general practitioners. See "—*Narrative Description of HLS's Business*—*Products and Programs—Vascepa (icosapent ethyl capsules)*".

## Acceptance of Filing and Approval of PERSERIS

On January 23, 2020, HLS announced that its new drug submission for PERSERIS was accepted for review by Health Canada. On November 17, 2020, HLS announced that Health Canada approved the use of PERSERIS for the treatment of schizophrenia in adults. See " - Narrative Description of HLS's Business - Products and Programs - PERSERIS (risperidone)".

## Acceptance of Filing and Notice of Deficiency of Trinomia

On March 19, 2020, HLS announced that its new drug submission for Trinomia, a polypill combination of an anticoagulant (aspirin), a statin (atorvastatin) and an angiotensin-converting enzyme inhibitor (ramipril) that is used in certain adult patients for the secondary prevention of cardiovascular events, was accepted for review by Health Canada. On December 16, 2020, HLS announced that Health Canada issued a Notice of Deficiency ("NOD") in respect of Trinomia, indicating that additional scientific data may be required for approval. HLS withdrew its application from Health Canada so that it could be

re-submitted following availability of the requested data. See "- Narrative Description of HLS's Business - Products and Programs - Trinomia (acetyl salicylic acid/atorvastatin/ramipril fixed dose combination capsules)".

## HLS Becomes Exclusive Distributor of MyCare Products and Announces Health Canada Approval

On May 29, 2020, HLS entered into an exclusive supply and distribution licensing agreement (the "Saladax Agreement") with Saladax Biomedical, Inc. ("Saladax"), pursuant to which HLS became the Canadian distributor of certain of Saladax's MyCare<sup>TM</sup> Psychiatry line of products and the MyCare Insite Point-of-Care Device and Antipsychotic Reagents (the "MyCare Products"). On December 16, 2020, HLS announced that Health Canada had approved the MyCare Psychiatric Lab Assays for use in measuring blood levels in patients taking any of the six most common antipsychotic drugs. On July 21, 2021, Health Canada approved the MyCare Insite point of care therapeutic drug monitoring system for use with clozapine patients. In October 2021, HLS and Saladax entered into the Amended and Restated Saladax Agreement, pursuant to which HLS became an exclusive Canadian distributor of certain MyCare Products. See " – Year Ended December 31, 2021" and " – Narrative Description of HLS's Business – Products and Programs – MyCare Products".

## CADTH Recommendation and PMPRB Determination

On July 20, 2020, HLS announced that the Canadian Agency for Drugs and Technologies in Health ("CADTH") had recommended that Vascepa be reimbursed by participating public drug plans for statin-treated patients with established cardiovascular diseases and elevated triglycerides. At the same time, HLS also announced that it had received notification by the Patented Medicine Prices Review Board (the "PMPRB") that, further to its review, Vascepa's price did not trigger the investigation criteria for excessive pricing. See " – Narrative Description of HLS's Business – Products and Programs – Vascepa (icosapent ethyl capsules)"

## Acquisition of Royalty Portfolio

On September 30, 2020, HLS entered into the Royalty Agreement, pursuant to which HLS acquired the rights to a diversified portfolio of royalty interests on global sales of four different healthcare products. The four products included in the Royalty Portfolio are (i) the EMBLEM S-ICD System, which is a subcutaneous implantable defibrillator for the treatment of life-threatening ventricular tachyarrhythmias currently marketed by Boston Scientific Corporation ("Boston Scientific"); (ii) Obizur, which is a porcine recombinant Factor VIII for Acquired Hemophilia A currently marketed by Takeda Pharmaceutical Company Limited ("Takeda"); (iii) Eraxis, which is a IV echinocandin for the treatment of Candidemia and other forms of Candida infections currently marketed by Pfizer Inc. ("Pfizer"); and (iv) olipudase alfa, now marketed by Sanofi Genzyme ("Sanofi Genzyme") as Xenpozyme, which is a novel enzyme replacement therapy for acid sphingomyelinase deficiency, an orphan disease with high unmet medical need then in late-stage development. See "-Narrative Description of HLS's Business - Products and Programs - Royalty Portfolio".

## Exercise of Put Right in Absorica Transaction

Effective July 1, 2016, HLS entered into a transaction (the "Absorica Transaction") with Galephar Pharmaceutical Research Inc. ("Galephar") for the acquisition of the United States marketing rights to Absorica (a commercial stage dermatology product in the United States market promoted by a third party) which, in effect, provided HLS with income based on U.S. sales of Absorica. On December 31, 2020, HLS exercised its put right and Galephar repurchased the United States marketing rights to Absorica. During the term of the agreement with Galephar in respect of the Absorica Transaction, HLS paid Galephar an initial payment of US\$17.55 million and additional payments consisting primarily of fixed quarterly payments and milestone payments tied to market conditions or continued supply of product.

## Year Ended December 31, 2021

## Final Redemption of Preferred Shares

On January 11, 2021, HLS redeemed the remaining 3,655,036 outstanding Preferred Shares at a price of C\$0.70 per Preferred Share, for a total redemption payment of approximately C\$2.6 million.

<u>Inclusion of Vascepa in the 2021 Canadian Cardiovascular Society Guidelines for the Management of Dyslipidemia for the Prevention of Cardiovascular Disease in Adults</u>

On March 29, 2021, HLS announced that the Canadian Cardiovascular Society ("CCS") had included Vascepa in its 2021 Canadian Cardiovascular Society Guidelines for the Management of Dyslipidemia for the Prevention of Cardiovascular Disease in the Adult, published in the Canadian Journal of Cardiology.

## Agreement with Pfizer for Vascepa in Canada

On August 13, 2021, HLS entered into a promotional services agreement (the "**Pfizer Agreement**") with Pfizer Inc. ("**Pfizer**") for the promotion of Vascepa in Canada. Under terms of the Pfizer Agreement, Pfizer will deploy a team across Canada to support education about Vascepa with primary care physician groups. HLS's existing sales force and support staff remain primarily focused on the specialist physician audience, and HLS retains responsibility over Vascepa's commercialization and records all revenue related to Vascepa sales in Canada.

#### HLS Becomes Exclusive Distributor of Saladax Lab Products

On October 12, 2021, HLS and Saladax entered into an amended and restated supply and distribution agreement (the "Amended and Restated Saladax Agreement"), pursuant to which HLS became the exclusive Canadian distributor of certain MyCare Products, namely the MyCare<sup>TM</sup> (lab based test) drug level assays. See "- Narrative Description of HLS's Business - Products and Programs - MyCare Products".

#### Year Ended December 31, 2022

## **Impact of COVID-19**

In early 2020, the coronavirus ("COVID-19") was confirmed in multiple countries throughout the world and the World Health Organization declared a global pandemic on March 11, 2020. Between 2020 and 2022, the Company and its employees observed social distancing practices and working from home where possible, consistent with local public health requirements and official closures. As conditions improved throughout 2022, the Company permitted employees to return to offices on a limited, rotational basis and to resume in-person interactions with customers where permitted by local public health authorities and when appropriate protective measures have been in effect. Late in 2022, the Company began a phased return to office. While the Company believes that the conditions related to the COVID-19 pandemic were temporary, the situation was dynamic and the long-term impact of COVID-19 on its results of operations and financial condition are not known.

Despite the various public health restrictions resulting from the COVID-19 pandemic, and particularly in Canada, all of which had an impact on the Company's business, the Company's product sales grew in fiscal year 2022, led by the Company's Clozaril franchises in Canada and the United States, a growing number of sites using the CSAN Pronto system, as well as the continued expansion of Vascepa in Canada.

## LOI with pCPA for Vascepa and PLAs with various Public Payors

On April 26, 2022, the Company announced that it had entered into a Letter of Intent ("LOI") with the pan-Canadian Pharmaceutical Alliance ("pCPA") for the terms and conditions under which Vascepa would qualify for public market reimbursement across the provinces and territories in Canada. The LOI set out the terms for reimbursement of Vascepa for statin-treated patients with established cardiovascular diseases and elevated triglycerides, which follows on the patient-population recommendation issued previously by CADTH.

Following the execution of the LOI, the Company began working with all participating jurisdictions to execute Product Listing Agreements ("PLAs") for Vascepa to be added to their respective plans. As of March 15, 2023, the Company has secured PLAs for the listing of Vascepa with Ontario, Quebec, New Brunswick, Saskatchewan, Northwest Territories and the Non-Insured Health Benefits ("NIHB") program for First Nations and Inuit peoples.

## Entry into Amended and Restated Credit Agreement

The Company and its existing syndicate of bank lenders, administered by JPMorgan Chase Bank, N.A., entered into an amended and restated credit agreement dated September 29, 2022 (as so amended and restated, the "HLS Credit Agreement") to, among other things, extend to maturity of the senior secured term loan by one year, to August 15, 2024. Total

borrowing and unused borrowing capacity remained unchanged, and interest rates remained substantially at the same level as before, while the required annual amortization of loan value was reduced to 5%. As at March 15, 2023, the HLS Credit Agreement also provides for a \$34.5 million revolver facility, of which \$8.5 million is drawn, and an expansion facility providing for up to an additional \$70 million to support growth opportunities.

#### 2022 Normal Course Issuer Bid

On November 10, 2022, the Company announced that the TSX had approved the renewal of the Company's normal course issuer bid (the "2022 NCIB"), pursuant to which the Company may repurchase up to 1,620,366 (or approximately 5%) of its issued and outstanding Common Shares, through the facilities of the TSX or through other permitted means (including through other published markets). The 2022 NCIB will remain in effect until the earliest of: (i) November 13, 2023, (ii) the date upon which HLS acquires the maximum number of Common Shares permitted under the 2022 NCIB, and (iii) the date upon which HLS provides written notice of termination of the 2022 NCIB to the TSX. Purchases of Common Shares under the 2022 NCIB will be made by Haywood Securities Inc. ("Haywood") based on the parameters prescribed by the TSX, the provisions of the HLS Credit Agreement, applicable Canadian securities laws and the terms of the written agreement entered into between Haywood and HLS at a price per Common Share equal to the market price at the time of acquisition. All Common Shares acquired by the Company under the 2022 NCIB will be cancelled. As of March 15, 2023, the Company has repurchased an aggregate of 46,400 Common Shares under the 2022 NCIB.

Any shareholder may may obtain, without charge, a copy of the notice of intention to make a normal course issuer bid in respect of the 2022 NCIB filed by the Company with the TSX by contacting the Company at ir@hlstherapeutics.com.

## **Narrative Description of HLS's Business**

#### **Overview**

HLS is a Canada-based North America-focused specialty pharmaceutical company focused on commercializing clinically differentiated pharmaceutical products in the specialty CNS and CV markets. HLS's current product portfolio includes Clozaril (a specialty CNS therapeutic) for the Canadian and U.S. markets, and Vascepa (a CV therapeutic), PERSERIS (a CNS therapeutic) and the MyCare Products (a line of Point-of-Care Device and Antipsychotic Reagents) for the Canadian market. HLS also holds a diversified portfolio of royalty interests on global sales of four different healthcare products which, in effect, provides HLS with income based on worldwide sales of such products. Finally, HLS holds the Canadian rights to Trinomia (a CV therapeutic). HLS intends to pursue additional product and pipeline opportunities in the CNS and CV therapeutic markets, and potentially in other therapeutic areas, through targeted business development efforts. HLS's experienced management team has a long and proven track record of successfully sourcing, developing and commercializing drugs in a variety of therapeutic areas at all stages of their life cycle throughout North America and internationally.

In the financial years ended December 31, 2021 and December 31, 2022, HLS generated revenues of US\$60.0 million and US\$61.5 million, respectively.

#### Strategy

HLS's business strategy is to acquire (through acquisitions or in-licensing or similar arrangements) a diversified portfolio of branded pharmaceutical products for commercialization in North American markets. HLS's current strategic focus is on the acquisition and distribution of pharmaceuticals that address unmet medical needs in specialty CNS disorders, such as schizophrenia within psychiatry, epilepsy, Parkinson's disease and movement disorders within neurology, and CV disorders, such as lipid regulation and cardiovascular risk reduction in general. HLS management believes that HLS is well-positioned to focus on these therapeutic areas having regard to HLS management's proven expertise in the management of branded pharmaceuticals in both the CNS and CV areas in North American markets. Although HLS's strategy includes leveraging HLS management's experience in these therapeutic areas, HLS also intends to expand and diversify its portfolio by pursuing strategic acquisitions of rights to pharmaceutical products in other therapeutic areas. These activities may also include securing options to the rights to selective late-stage clinical assets for commercialization, primarily in the North American market.

In pursuing its strategic objectives, HLS management will continue to exercise financial discipline in the management and utilization of cash flows and balance sheet resources to selectively invest in cashflow generating or growth opportunities, both through strategic acquisitions as well as organic growth of existing product lines, in order to expand product portfolios and development pipeline in addition to supporting overall enterprise growth.

In seeking to acquire and grow the sales of branded pharmaceutical products in the specialty CNS and CV markets, HLS believes its strategy has the potential to create significant value while minimizing the costs and risks typically associated with discovery, and early stage research and development. HLS's focus is on bringing pharmaceutical products to the Canadian and/or U.S. markets, especially if they are already being commercialized and/or have been approved outside of such territory. The agreements that HLS has entered into in respect of Vascepa, PERSERIS, Trinomia and MyCare Products are examples of this strategy.

#### **Products and Programs**

Clozaril (clozapine tablets) and CSAN Pronto

Clozaril (clozapine tablets) is currently HLS's lead product. In Canada, Clozaril is an atypical antipsychotic indicated in the management of symptoms of treatment-resistant schizophrenia. In Canada, Clozaril is a promoted product that is supported by a dedicated sales team and related clinical resources. In the United States, Clozaril is indicated for the management of severely ill patients with schizophrenia who fail to respond adequately to standard drug treatment and for patients with schizophrenia or schizoaffective disorder who are judged to be at chronic risk for re-experiencing suicidal behaviour, based on history and recent clinical state. In the United States, Clozaril is a well-established legacy brand, which is off patent and is not promoted with a sales force.

Net sales for Clozaril in Canada and the United States for the year ended December 31, 2021 were US\$28.7 million and US\$16.0 million, respectively. Net sales for Clozaril in Canada and the United States for the year ended December 31, 2022 were US\$27.5 million and US\$14.7 million, respectively.

In Canada, Clozaril is actively promoted by a dedicated sales force and supported with clinical resources and has a leading market share versus generic clozapine offerings. HLS management believes that Clozaril is supported by HLS's best-in-class programs in place to enhance compliance, meet mandatory regulatory measures for patient safety monitoring and maximize treatment outcomes versus competing products. HLS operates a unique healthcare provider/patient portal for Clozaril that exceeds the requirements of Health Canada, which HLS continues to augment and improve.

One such improvement is the in-licensing of HLS's CSAN Pronto device which is designed to streamline blood testing for both patients and healthcare practitioners by enabling patients to have their blood monitoring work done right in their health care provider's office and to receive test results during their visit. CSAN Pronto uses imaging technology and artificial intelligence to quantitatively determine white blood cell and neutrophil counts from a single drop of blood, obtained from a "finger-stick" blood test. Results are communicated in minutes and are securely uploaded to a patient's CSAN profile becoming simultaneously available to the patient's healthcare team. Once test results are recorded in the CSAN registry, and assuming those results are within accessible range, patients can access their medication from their pharmacist. HLS believes that a point-of-care finger-stick blood test has the potential to reduce two important barriers to Clozaril use, which are a patient's non-adherence to blood work and the burden of the blood work regimen on the patient.

In Canada, HLS management expects that it will continue to promote Clozaril by reinforcing the product's therapeutic relevance as an atypical antipsychotic for treatment resistant schizophrenia patients, and will continue to promote a superior patient environment and safety program through CSAN that is supported by a team of clinical coordinators and field-based nurses and corresponding promotional investment for a total of 25 full time employees dedicated to Clozaril. HLS expects to continue to benefit from Health Canada's stipulation that forbids unilateral switching of the branded product for a generic product at the pharmacy level without the formal consent of the treating physician and related mandatory transfer of the patient from CSAN to the generic manufacturer's product-specific registry. This Health Canada stipulation recognizes the fragile nature of the stabilized patient population and the necessity of allowing the treating physician to preserve the support deemed important in the success of the therapy.

Protecting the privacy and security of personal information is essential and is fundamental to HLS' values and the way we do business. To that end, HLS is subject to and compliant with the Personal Information Protection and Electronic Documents Act in respect to its collection, use and disclosure of personal information.

Specific to patients, their participation in CSAN is subject to a consenting process. Once a decision has been made by a physician to prescribe Clozaril to a patient, the physician must first explain to the patient that their personal information will be collected, used by and shared with HLS, laboratories, other clozapine databases, health care providers (as reasonably needed for the safe utilization of this medication) and Health Canada (in order to maintain the registry and to monitor for potential adverse reactions associated with the medication). Next, the physician must obtain the patient's consent by way of a consent

form that explains what personal information is collected, how it is used, and how it is shared in order to administer the program. The Clozaril product monograph also explains to the patient what personal information is collected and how it is used.

Vascepa (icosapent ethyl capsules)

On September 25, 2017, HLS entered into an exclusive agreement with Amarin Pharmaceuticals Ireland Limited and Amarin Pharma, Inc. (collectively "Amarin") for HLS to register, distribute and commercialize Vascepa (icosapent ethyl capsules) in Canada (the "Vascepa Agreement"). Multiple patents for Vascepa have been issued internationally based on the unique clinical profile of Vascepa, including the drug's ability to lower triglyceride levels in relevant patient populations without raising LDL-cholesterol levels. Multiple patents defining methods of use for the Vascepa product compound associated with various aspects of cardiovascular protection have been filed by Amarin in Canada, and have either issued or are currently pending, and additional patents may be filed in the future.

Under the Vascepa Agreement, HLS is responsible for obtaining and maintaining regulatory approvals, developing and commercializing Vascepa in Canada pursuant to a comprehensive regulatory, pre-launch and launch strategy. Amarin is responsible for providing assistance towards local applications and filings, manufacturing and supplying finished product under negotiated supply terms, and maintaining its intellectual property. Amarin was also responsible for completing the final report of its cardiovascular outcomes study, REDUCE-IT, which was done, and is described in more detail below. Financial terms of the Vascepa Agreement include payments to Amarin consisting of a US\$5 million up-front payment and regulatory and commercial milestone payments of up to an aggregate of US\$60.0 million, of which milestone payments totaling US\$8.8 million have been made as of March 15, 2023. HLS is also required to pay Amarin tiered double-digit royalties on net sales of Vascepa in Canada.

On September 24, 2018, Amarin issued topline results from the Vascepa CV outcomes trial, REDUCE-IT (Reduction of Cardiovascular Events with EPA–Intervention Trial), a global study of 8,179 statin-treated adults with elevated CV risk, which commenced in December 2011. Amarin described REDUCE-IT as a multinational, prospective, randomized, double-blind, placebo-controlled study, and the first prospective cardiovascular outcomes study of any drug in a population of patients who, despite stable statin therapy, have elevated triglyceride levels and residual cardiovascular risk factors. REDUCE-IT met its primary endpoint demonstrating an approximately 25% relative risk reduction, to a high degree of statistical significance (p<0.001), in major adverse CV events in the intent-to-treat patient population with use of Vascepa 4 grams/day as compared to placebo. It was also well tolerated with a safety profile consistent with clinical experience associated with omega-3 fatty acids and current FDA-approved labeling. Amarin shared the REDUCE-IT secondary end points data in greater detail at the 2018 Scientific Sessions of the American Heart Association on November 10, 2018 in Chicago, Illinois. Seven secondary endpoints were achieved at statistically significant levels, namely: cardiovascular death or nonfatal heart attack: 25% relative risk reduction; fatal or nonfatal heart attack: 31% relative risk reduction; urgent or emergent revascularization: 35% relative risk reduction; fatal or nonfatal stroke: 28% relative risk reduction; hospitalization for unstable angina: 32% relative risk reduction; fatal or nonfatal stroke: 28% relative risk reduction; and total mortality, nonfatal heart attack or nonfatal stroke: 23% relative risk reduction.

On March 29, 2019, after reviewing the final data from the REDUCE-IT trial, HLS sought, and Health Canada granted, priority review status for HLS's new drug submission for Vascepa. On April 29, 2019, HLS's new drug submission for Vascepa was accepted for review by Health Canada, based on the REDUCE-IT data. On December 30, 2019, Health Canada approved the use of Vascepa to reduce the risk of cardiovascular events (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, coronary revascularization or hospitalization for unstable angina) in statin-treated patients with elevated triglycerides, who are at high risk of cardiovascular events due to established cardiovascular disease, or diabetes, and at least one other cardiovascular risk factor.

On January 6, 2020, Vascepa was added to Health Canada's Register of Innovative Drugs, otherwise known as having been granted "data protection." According to Health Canada's Guidance, "innovative drugs" are those drugs that contain a medicinal ingredient not previously approved, and that is not a variation of a previously approved medicinal ingredient. Data protection is intended to provide the manufacturer of an innovative drug with an internationally competitive, guaranteed minimum period of market exclusivity of eight years. During this period of time, a manufacturer seeking approval of a "generic" version of the innovative drug, on the basis of a direct or indirect comparison to the innovative drug, will be prevented from filing its drug submission for the first six years of the eight-year period. This market exclusivity is further intended to be provided as an incentive for innovators to invest in research, and to develop and market their products in Canada. As a result, Vascepa will benefit from data protection until December 30, 2027, a term of eight years from the date of Health Canada approval. Vascepa is also the subject of multiple issued and pending patents based on its unique clinical profile.

On February 7, 2020, HLS formally launched Vascepa in Canada. In connection with the launch, HLS hired 30 new employees, including 22 new sales representatives who are responsible for promoting the product to cardiologists, endocrinologists and selected general practitioners, and eight other field-based employees.

On July 20, 2020, HLS announced that CADTH had recommended that Vascepa be reimbursed by participating public drug plans for statin-treated patients with established cardiovascular diseases and elevated triglycerides. At the same time, HLS also announced that it had received notification by the PMPRB that, further to its review, Vascepa's price did not trigger the investigation criteria for excessive pricing. As of March 17, 2021, HLS has reached agreements for Vascepa reimbursement with private insurance plans that cover more than 90% of privately insured Canadians. As of March 15, 2023 HLS has secured PLAs for the listing of Vascepa with Ontario, Quebec, New Brunswick, Saskatchewan, Northwest Territories and the NIHB, and continues to negotiate PLAs with additional provinces and territories.

On March 29, 2021, HLS announced that the CCS had included Vascepa in its 2021 Canadian Cardiovascular Society Guidelines for the Management of Dyslipidemia for the Prevention of Cardiovascular Disease in the Adult, published in the Canadian Journal of Cardiology.

On August 13, 2021, HLS entered into the Pfizer Agreement with Pfizer for the promotion of Vascepa in Canada. Under terms of the Pfizer Agreement, Pfizer deployed a team across Canada to support education about Vascepa with primary care physician groups. HLS's existing sales force and support staff remain primarily focused on the specialist physician audience, and HLS retains responsibility over Vascepa's commercialization and records all revenue related to Vascepa sales in Canada.

#### PERSERIS (risperidone)

On May 8, 2019, HLS entered into an exclusive licensing agreement (the "PERSERIS Agreement") with Indivior PLC ("Indivior"), pursuant to which HLS acquired the rights to register, distribute and commercialize PERSERIS (a novel long-acting injectable risperidone product for the treatment of schizophrenia) in Canada.

Risperidone is a well-established treatment for schizophrenia, and PERSERIS uses a sub-cutaneous extended-release delivery system that forms a depot providing sustained therapeutic levels of risperidone over a one-month period from a single injection. HLS believes that PERSERIS will provide Canadian patients and healthcare practitioners with another treatment option. HLS also believes that PERSERIS is complementary to the Company's CNS business, which includes Clozaril and CSAN Pronto.

Under the PERSERIS Agreement, HLS is responsible for supporting the regulatory approval process, developing and commercializing PERSERIS and all associated costs. Indivior is responsible for providing assistance towards local filings, maintaining regulatory approvals, supplying finished product under negotiated supply terms and maintaining intellectual property. HLS agreed to pay Indivior US\$1.0 million upon signing of the PERSERIS Agreement and is required to make additional regulatory and pre-commercial milestone payments of up to US\$4.0 million, of which US\$2.5 million was paid in 2021. Upon commercialization of PERSERIS in Canada, HLS is further obligated to make escalating double-digit royalty payments to Indivior based on annual net sales of PERSERIS.

On January 23, 2020, PERSERIS was accepted for review by Health Canada, and on November 17, 2020, HLS announced that Health Canada approved the use of PERSERIS for the treatment of schizophrenia in adults. In June 2022, the pCPA announced that negotiations had concluded without an agreement with respect to public market reimbursement despite an earlier positive listing recommendation from CADTH. This decision caused a delay in the commercialization of PERSERIS. Commercialization of PERSERIS will depend on the outcome of listing discussions that need to be pursued with individual provinces in the absence of an agreement with the pCPA.

If HLS's pursuit of listings with individual provinces is successful, HLS currently anticipates that its commercial expenses for the first years of commercialization for PERSERIS for the Canadian market will be between US\$1.0 million and US\$2.0 million.

Trinomia (acetyl salicylic acid/atorvastatin/ramipril fixed dose combination capsules)

On November 20, 2017, HLS entered into an exclusive agreement with Ferrer Internacional S.A. ("Ferrer") for HLS to distribute and commercialize Trinomia in Canada (the "Trinomia Agreement"). Trinomia has been approved for use in

over 30 countries for the secondary prevention of cardiovascular events as substitution therapy in adult patients adequately controlled with the monocomponents given concomitantly at equivalent therapeutic doses.

Under the Trinomia Agreement, HLS is responsible for supporting the regulatory approval process, developing and commercializing Trinomia and all associated costs. Ferrer is responsible for providing assistance towards local filings, maintaining regulatory approvals, supplying finished product under negotiated supply terms and maintaining intellectual property. Financial terms of the Trinomia Agreement included a nominal up-front payment and regulatory and commercial-based milestone payments of up to an aggregate of approximately C\$31 million. HLS is also required to pay Ferrer tiered royalties on the net sales of Trinomia in Canada.

HLS presented scientific data on the quality, safety and efficacy of Trinomia to Health Canada in pre-submission interactions in the spring of 2018. Following the pre-submission interactions, it was determined that a bioequivalence study would be performed using the Canadian reference listed drugs as a base of comparison. Following the meeting with Health Canada, Ferrer and HLS completed a pharmacokinetic bioequivalence trial versus the Canadian reference listed drugs and proceeded to file a new drug submission with Health Canada for Trinomia.

On February 19, 2020, Trinomia was accepted for review by Health Canada. On December 16, 2020, HLS announced that Health Canada had issued an NOD in respect of Trinomia, indicating that additional scientific data would be required for approval. In particular, Health Canada noted that there is an ongoing study using Trinomia and that a regulatory decision for Trinomia should await these study results. Accordingly, HLS withdrew its application from Health Canada so that it can be resubmitted following availability of the requested data. The study was completed and the positive results were released in August 2022. The Company is working with its licensor to prepare an updated application, which it expects to submit to Health Canada in the second half of 2023.

If HLS brings Trinomia to the Canadian market, HLS currently anticipates that its remaining pre-commercial expenses related to Trinomia will be between US\$1.0 million and US\$2.0 million.

## Royalty Portfolio

On September 30, 2020, HLS entered into the Royalty Agreement to acquire certain entities that hold the rights to a diversified portfolio of royalty interests on global sales of four different products. The products underlying the Royalty Portfolio are marketed and commercialized by blue-chip global industry leaders Boston Scientific, Takeda, Pfizer and Sanofi Genzyme.

The four products that make up the Royalty Portfolio are: (i) the EMBLEM S-ICD System, currently marketed by Boston Scientific, which is a subcutaneous implantable defibrillator for the treatment of life-threatening ventricular tachyarrhythmias; (ii) Obizur, currently marketed by Takeda, which is a porcine recombinant Factor VIII for Acquired Hemophilia A; (iii) Eraxis, currently marketed by Pfizer, which is a IV echinocandin for the treatment of Candidemia and other forms of Candida infections; and (iv) Xenpozyme, developed by Sanofi Genzyme, which is a novel enzyme replacement therapy for acid sphingomyelinase deficiency, an orphan disease with high unmet medical need and for which a regulatory submission was filed with the European Medicines Agency in 2021. On June 28, 2022, this product received regulatory approval in Europe. Xenpozyme was also approved in Japan in March 2022 and the United States in August 2022 and commercial sales began in the third quarter of fiscal 2022.

Under the Royalty Agreement, HLS paid US\$30.8 million upfront on closing, may make potential commercial milestone payments of up to US\$18.5 million payable on achievement of certain sales thresholds by the products underlying the Royalty Portfolio and assumed an existing US\$10.0 regulatory milestone obligation. In July 2022, HLS paid the acquired regulatory approval milestone obligation following the regulatory approval of the fourth product in the portfolio in key markets.

## MyCare Products

On June 1, 2020, HLS announced that it had become a Canadian distributor of the MyCare Products. On October 12, 2021, HLS and Saladax entered into the Amended and Restated Saladax Agreement, pursuant to which HLS became an exclusive Canadian distributor of certain MyCare Products.

MyCare<sup>TM</sup> Psychiatric Lab Assays are a line of tests that can be processed on major analyzers used in large Laboratory systems to measure the blood levels of the most common antipsychotic drugs, including clozapine, risperidone, quetiapine, aripiprazole, olanzapine and paliperidone ("Therapeutic Drug Monitoring", or "TDM"). MyCare Insite is a point-of-care device, similar to a blood glucose test, that requires only a single drop of blood taken by a finger stick to measure patient drug levels, providing

TDM results in just minutes. Saladax filed for, and gained approval of, the MyCare Psychiatric Lab Assays from Health Canada in 2020, and HLS launched MyCare in first in the medical laboratory environment during the second half of 2022, and the benefits are being disseminated to clinicians in parallel. On July 21, 2021, Health Canada approved the MyCare Insite point of care TDM system for use with clozapine patients.

## Competitive Conditions

The pharmaceutical industry is highly competitive and subject to rapid and significant technological change. HLS's competitors in the pharmaceutical market range from large multinational pharmaceutical development corporations to small, single-product companies that may limit their activities to a particular therapeutic area or drug, or region or territory. Many of these competitors have greater financial resources and marketing capabilities than HLS has. HLS's competitors in Canada, the United States and abroad are numerous and include, among others, major pharmaceutical and chemical companies.

Due to HLS's focus on commercial stage assets, one of HLS's main areas of competition is from manufacturers of generic pharmaceutical products. Generic versions are generally significantly less expensive than branded versions, and, where available, may be required in preference to the branded version under third party reimbursement programs, or substituted by pharmacies. If competitors introduce new products, delivery systems or processes with therapeutic or cost advantages, HLS's products can be subject to progressive price reductions or decreased volume of sales, or both. Most products that HLS would acquire under its strategy must compete with other products already on the market or products that are later developed by competitors. Manufacturers of generic pharmaceuticals typically invest far less in research, development and promotion than research-based pharmaceutical companies and therefore can price their products significantly lower than branded products. Accordingly, when a branded product loses its market exclusivity and enters its established brand stage, it normally faces intense price competition from generic forms of the product.

With respect to HLS's acquisition strategy, HLS management expects to compete principally with other pharmaceutical companies that seek to acquire late stage, mature and promotional stage pharmaceutical products as part of their growth strategy.

## Competitive Strengths

HLS management believes that HLS's key business strengths include the following:

Product Acquisition and Operational Expertise of HLS Management

Members of HLS's executive management team and the HLS Board have on average more than 20 years of pharmaceutical product acquisition and operational experience. Before founding HLS, Greg Gubitz and Gilbert Godin were the former Senior Vice President, Corporate Development and General Counsel, and former Executive Vice President and Chief Operating Officer, respectively, of Biovail. Mr. Gubitz and Mr. Godin were key members of the team that formulated and implemented the turnaround of Biovail starting in the spring of 2008 through restructuring and refocusing Biovail's business on CNS drugs, managed a large portfolio of branded pharmaceutical products, including promoted brands and established products, and ultimately merged Biovail with Valeant Pharmaceuticals International, Inc. at the end of 2010. As a result, the HLS management team has a broad network within the industry and a proven track record of success.

Members of HLS's broader management team are also experienced in various aspects of governance, corporate financing, pharmaceutical operations, including product development, clinical research, technology transfer, manufacturing, legal and regulatory affairs, intellectual property, sales and marketing, strategic planning and integration. In addition, members of management maintain a significant ownership interest in HLS in order to align interests with shareholders.

Superior Business Model for Acquisitions

In seeking to in-license or acquire innovative pharmaceutical products primarily for the purpose of generating a stream of stable, long-duration revenues and cash flow, HLS has the flexibility to consider a broad range of acquisition targets from a variety of therapeutic areas in addition to the CNS and CV space. Moreover, HLS management believes that the HLS management team's history of successfully acquiring pre-commercial or commercial stage brands from major pharmaceutical companies, coupled with its long and established track record and proven success in efficiently transitioning and judiciously managing acquired products and programs, will provide HLS with proficiency in choosing acquisition targets and will be viewed favourably by vendors and licensors in selecting their preferred partner for future transactions. Because HLS has

operations in both Canada and the U.S., it has the ability to acquire and commercialize products in either or both of such territories; such flexibility may be advantageous to certain vendors or licensors.

#### Predictable Cost Structure

HLS's management has considerable experience managing commercial-stage pharmaceutical operations in North American markets. HLS's management has established and intends to continue to maintain a predictable cost structure by relying on a small but experienced employee base and outsourcing to leading outsource service providers certain of the operational functions associated with HLS's business, including warehousing, distribution, customer service, invoicing, collections, regulatory affairs, medical and drug information, human resources and informational technology. HLS's management believes the predictability, scalability, flexibility and efficiency gained by contracting with established, experienced service organizations will assist HLS in improving HLS's margins, achieving profitability and facilitating growth.

#### Pricing

The HLS model is not dependent on price increases. HLS management expects that, where and when appropriate, HLS will make competitively sound and typically modest pricing adjustments to maintain product viability and competitiveness.

## Partnership with Leading Service Providers

HLS has a network of leading external advisors. While retaining strategic direction and direct oversight, management of HLS has entered into, and intends to continue to enter into, on a case-by-case basis, outsourcing relationships with select leading providers of pharmaceutical contract services for many of the operational functions associated with HLS's business. These outsourcing relationships minimize the need for significant overhead and provide HLS with scalability, and flexibility to adapt to market conditions in a cost-effective manner.

#### Market

#### Background

Most pharmaceutical products in the North American marketplace follow very similar paths of development from the drug discovery stage through to the established brand stage. The key stages are as follows:

- Drug Discovery. In the drug discovery stage, researchers study the molecular mechanisms of a particular disease and attempt, through a variety of methods, to find or create a molecule that affects the way the disease functions. Typically, when a new molecule is identified that offers the potential to proceed further in development, a patent application is filed claiming the chemical formula that defines the new molecule and/or the process by which the new molecule is formulated and/or used. If issued, the patent permits the patent holder to exclude others from making, using or selling the discovery claimed in the patent for the patent lifespan.
- Pre-clinical and Clinical Development. Following the drug discovery stage, candidate drugs typically undergo between one and three years of extensive pre-clinical laboratory and animal testing to assess safety and demonstrate biological activity against a disease, followed by clinical (human) trials, which can take from two to ten years or more, during which safety and efficacy of the new molecule is determined.
- Regulatory Approval, Product Launch and Growth. Once the drug developer submits all data and information generated during the discovery and development stages to the appropriate regulatory body (i.e., the FDA in the United States and Health Canada in Canada) scientists and advisory committees review it and decide whether the data justifies approval for widespread patient use and marketing. If approved, the new drug is introduced into the marketplace. Sales of a branded drug, often driven by sizeable promotional investment, may rise sharply after introduction as the drug gains popularity and becomes widely prescribed by physicians.
- *Maturity*. After years of growth, sales of a new drug typically slow or reach a plateau, a stage of the product's lifecycle referred to as maturity. The duration of the maturity stage is often dependent on the type of exclusivity the drug enjoys (e.g. patent exclusivity or regulatory exclusivity), or other barriers to competition.

- Loss of Market Exclusivity. When market exclusivity is lost and competing generic versions of the products enter the market, the brand may lose material market share very rapidly. Typically, the brand will lose approximately 84% of its market volume within one year of losing market exclusivity and the introduction of generic competition (Source: Recent trends in brand-name and generic drug competition, Journal of Medical Economics 2013). Competition comes principally from generic drugs, which are drugs that regulatory bodies such as the FDA or Health Canada approve as substitutable products that are bio-equivalent to the brand based on abbreviated clinical development. Generic drugs are typically priced at substantial discounts to branded drugs, and in many states, provinces and territories can be dispensed, and in some cases are required to be dispensed, in place of the brand by a pharmacist, without consent from the prescribing physician.
- Established Brand Stage. Once a drug loses market exclusivity to a substitutable product and market share erodes, the drug enters the final stage of the product lifecycle, the established brand stage. Although market share continues to decline in this late stage, it rarely erodes to zero. This is due to a number of factors, the most common ones being brand recognition, physicians/patients preferring to prescribe/receive branded drugs and top tier drug plans that continue to reimburse branded drugs regardless of the cost difference and availability of generics. Therefore, demand for these drugs, while substantially reduced, often remains predictable year after year. It is often at this stage when brand companies may consider divesting the drug. See "— Industry Trends".

## Size of Market

The global pharmaceutical industry is a highly diverse and complex industry comprised of a variety of sectors, including large branded pharmaceutical companies, small to mid-sized specialty and niche market pharmaceutical manufacturers and marketers, biotechnology firms, research and development organizations and generic drug manufacturers. These participants compete for market share based on advantages including clinical efficacy and safety, technological innovation or novelty, convenience or ease of administration and cost effectiveness. In 2021, the global pharmaceutical market generated estimated gross sales of US\$1.4 trillion, of which US\$619 billion (43%) were in North America (Source: IQVIA World Review Executive<sup>TM</sup> 2022).

The global market for CNS therapeutics, consisting broadly of drugs for the treatment of psychiatric disorders, neurological disorders and pain, was estimated at US\$158 billion in IQVIA gross sales in 2021. The North American market represents the largest market globally, with an estimated 50% market share or estimated US\$84 billion in IQVIA gross sales in 2021 (the U.S. market is estimated at US\$74.5 billion and Canadian market is estimated at US\$4.3 billion) (Source: IQVIA World Review Executive<sup>TM</sup> 2022).

The global market for anti-psychotic therapeutics is estimated at US\$21.8 billion in IQVIA gross sales in 2021. The North American market represents the largest market globally, with an estimated 64.5% market share or US\$14 billion in IQVIA gross sales in 2021. The Canadian market for anti-psychotic therapeutics was estimated at US\$636 million in IQVIA gross sales in 2021 (Source: IQVIA World Review Executive<sup>TM</sup> 2022).

The global market for CV therapeutics, consisting of drugs for the treatment of critical disorders such as hypertension, hyperlipidemia, heart failure, and clotting disorders, was estimated at US\$86.6 billion in IQVIA gross sales in 2021. The North American market represents the largest market globally, with estimated an estimated 28.6% market share or US\$24.7 billion in IQVIA gross sales in 2021. Lipid modifying agents represent 23% of the North American CV therapeutics market or estimated US\$5.6 billion in IQVIA gross sales in 2021. The Canadian market for CV therapeutics was estimated at US\$1.7 billion in 2021 with lipid modifying agents representing 29.4% or US\$500 million in estimated gross sales in 2021 (Source: IQVIA World Review Executive<sup>TM</sup> 2022). Cardiovascular disease is the leading cause of death in the U.S. and globally (Source: AHA Heart Disease and Stroke Statistics 2023 Update; WHO Cardiovascular Disease Fact Sheet, June 2021). It is the second leading cause of death in Canada behind cancer (Source: Public Health Agency of Canada, May 2018).

## **Industry Trends**

HLS's management believes that a number of trends in the pharmaceutical industry create a favourable environment for the acquisition and distribution of well differentiated promotional stage and established brand stage products.

## Demographics

Growth of the population in general and aging of the population in particular will continue to drive demand for pharmaceutical therapies. Favourable perception towards brands will result in sustained opportunities for selected established brand assets and promotional stage products.

## Medicare Coverage

Often, established brand pharmaceutical products subject to Medicare, Medicaid or falling under the Federal Supply Schedule may still be competitive to alternatives due to mandatory rebates and average manufacturer price calculation rules prescribed by U.S. legislation. The Federal Supply Schedule is a list of contractors that have been awarded a contract by the General Services Administration, an independent agency of the U.S. government, and such contractors can be used by all U.S. federal agencies.

Healthcare Reform - The Patient Protection and Affordable Care Act

The United States *Patient Protection and Affordable Care Act* resulted in an increase of access to healthcare services and treatments. This trend may continue but will be attenuated by changes in the legal and political environment, including changes in formulary management practices.

#### **Product Divestitures**

HLS management believes that as large pharmaceutical companies continue to focus on their core therapeutic areas, additional non-core or non-strategic products or development projects will be divested, many of which will likely fall into the pre-filing, established brand or promotional stage categories.

## Sales and Marketing

Management of HLS pursues a number of market access strategies and has established a number of marketing and promotional agreements in Canada and the United States.

In Canada, HLS's Clozaril sales force is comprised of approximately 12 commercial representatives who promote Clozaril to healthcare practitioners, institutions and payors, such as insurance companies and governments. In addition, HLS has entered into agreements with local providers and buying groups, with the goal of growing product knowledge, trial and usage in those regions.

HLS has deployed a dedicated cardiovascular sales force comprised of 22 commercial representatives who promote Vascepa to cardiologists, endocrinologists and selected general practitioners, in addition to eight other field-based roles. HLS has also entered into the Pfizer Agreement, pursuant to which Pfizer will deploy a team across Canada to support education about Vascepa with primary care physician groups, and HLS retains responsibility over Vascepa's commercialization and records all revenue related to Vascepa sales in Canada.

HLS has secured Vascepa listings on private insurance plans covering more than 90% of privately insured Canadians. As of March 15, 2023, HLS has secured PLAs for the listing of Vascepa with Ontario, Quebec, New Brunswick, Saskatchewan, Northwest Territories and the NIHB, and continues to negotiate public reimbursement with additional provinces and territories.

#### **Customers**

HLS has a limited number of customers, and the majority of HLS's sales of its main products, including Clozaril and Vascepa, are to large national wholesalers and institutions.

## Manufacturing, Supply and Distribution

HLS is focused on managing the production and distribution of pharmaceutical products and therefore partners with thirdparty contract manufacturers or its licensors for the manufacture and supply of the pharmaceutical products in its portfolio. Any products that HLS acquires will need to be manufactured in facilities, and by processes, that comply with the requirements of Health Canada and the FDA, as applicable. HLS and its product suppliers are, and will be, subject to extensive governmental regulation in connection with the manufacture of any pharmaceutical products. HLS and its product suppliers must ensure that all of the processes, methods and equipment are compliant with the requirements of Health Canada and the FDA. HLS relies on national third-party logistics providers in Canada and the United States to administer the distribution process – from warehousing to order processing, to shipping, invoicing and collection of sales proceeds. See "–

Risks Relating to the Business – Reliance on Third Parties for the Manufacture and Supply of Products", " –

Risks Relating to the Business - Supply Interruptions May Negatively Impact Maintenance of Inventory Levels" and "-

Risks Relating to the Business - Reliance on Third Parties to Perform Distribution, Logistics, Regulatory and Sales Services".

Pursuant to a transition services agreement entered into on closing of the Clozaril Acquisition, Novartis manufactured and supplied Clozaril for Canada for HLS until mid-2018. In mid-2018, HLS completed the qualification and approval of selected third party manufacturers for the manufacture of Clozaril for Canada.

In the U.S. market, HLS assumed the rights and obligations of Novartis under a U.S. production agreement between Novartis and a third-party contract manufacturer. This agreement has an initial term of five years and is renewable automatically for successive 12-month renewal terms. In addition, HLS has completed the qualification and approval of a second contract manufacturer for the supply of product to its markets.

With respect to Vascepa, PERSERIS and the MyCare Products, Amarin, Indivior and Saladax, respectively, are responsible for supplying HLS with finished product under negotiated supply terms.

## Properties and Equipment

HLS maintains offices in Toronto, Ontario (Etobicoke); Montreal, Quebec (Dorval); Philadelphia, Pennsylvania (Rosemont); and Barbados. HLS's registered and head office is located at 10 Carlson Court, Suite 701, Etobicoke, Ontario, M9W 6L2. Since HLS purchases its products from third-party contract manufacturers or its licensors, HLS has very limited investment in property, plant or equipment for product production.

#### **Employees**

As of December 31, 2022, HLS had 99 employees, and as of March 15, 2023, HLS had 96 employees, none of whom are unionized.

## **Proprietary Protection**

The pharmaceutical industry is highly dependent on protection of intellectual property rights for branded and promoted drug products. Patents are among the most important of such rights and include: (i) patents on drug products; (ii) patents on formulations of drug products; and (iii) patents on the processes for the manufacture and the use (method of treatment) of drug products. Patents have a finite lifespan (20 years from the date of filing on the discovery claimed in the patent) and have more importance to a company during the drug discovery process through the launch and growth of a product and diminishing to no importance once patent exclusivity is lost and the product reaches the established brand stage, as is the case with Clozaril. Thus, patent protection will likely have little if any significance for HLS's acquisition of established brand products. However, adequate patent protection will be important for any future HLS acquisitions of commercial stage products that have not yet lost patent exclusivity, like Vascepa, which will factor into the value of the acquisition.

Other intellectual property rights are also important in protecting a branded drug, such as brand names/trademarks in order to distinguish the drug from other branded drugs and generic versions. Such brand names are important in marketing the drug to physicians and patients and in identifying the drug in formularies. In both Canada and the United States, once a trademark is registered, the trademark owner must file for renewal, together with a statement that the trademark is being used, every 10 years to prevent its cancellation or expiration of the registration. HLS has acquired from Novartis the exclusive license to the Clozaril trademark in the United States and Canada, and to the CSAN trademark in Canada, and works with Novartis to maintain the registrations in force. Similarly, HLS has acquired the exclusive licenses to the Vascepa and PERSERIS trademarks in Canada from Amarin and Indivior, respectively. In addition, HLS has obtained trademark registrations in Canada and the United States for the HLS company name and logo, and is in the process of obtaining a trademark registration for CSAN Pronto in Canada, all of which are used to identify and brand HLS's marketed products and promotional materials.

Pharmaceutical companies register and maintain domain names (websites) for information about the company and the various drugs they market. HLS has acquired and maintains various domain names and related websites relating to Clozaril, Vascepa, PERSERIS and MyCare.

As part of its acquisition of Clozaril, HLS also licensed additional intellectual property rights from Novartis relating to Clozaril manufacturing and know-how, in order to be able to commercialize the product in the United States and Canada. HLS expects that it may enter into such license agreements for future product acquisitions. Such licenses are important for obtaining the technology transfer in order to commercialize acquired assets.

#### Data Protection

In addition to patent protection, drug products in Canada can benefit from data protection. Data protection is intended to provide the manufacturer of an innovative drug with an internationally competitive, guaranteed minimum period of market exclusivity of eight years, with the goal of providing incentives for innovators to invest in research, and to develop and market their products in Canada. During this period of time, a manufacturer seeking approval of a "generic" version of the innovative drug, on the basis of a direct or indirect comparison to the innovative drug, will be prevented from filing its drug submission for the first six years of the eight-year period.

Vascepa was granted data protection and was added to Health Canada's Register of Innovative Drugs and will therefore benefit from data protection until December 30, 2027. Whether a drug product is eligible for data protection depends on the unique profile of that particular product and is determined by Health Canada at the time of approval. HLS expects to continue to consider innovative products for future acquisitions or in-licensing opportunities, where possible, and the potential for obtaining data protection status will continue to be an important due diligence matter.

## Regulatory Environment

Government authorities in the United States, in Canada and in other countries extensively regulate, among other things, the research, development, testing, approval, manufacturing, labeling, post-approval monitoring and reporting, packaging, promotion, storage, advertising, distribution, marketing and export and import of pharmaceutical products at the federal, state, provincial and local level. The process of obtaining and maintaining approvals and the subsequent compliance with applicable federal, state, provincial, local and foreign regulatory requirements require the expenditure of substantial time, risk and financial resources. FDA approval must be obtained in the United States and approval of Health Canada must be obtained in Canada prior to marketing or manufacturing new pharmaceutical products for use by humans. Regulation by other agencies, such as the Drug Enforcement Administration, and state and local authorities in the United States, and by comparable agencies in other countries, may also be relevant. In the United States, the *Federal Food, Drug and Cosmetic Act*, as amended, and the regulations promulgated thereunder, and other federal and state statutes and regulations, govern, among other things, the testing, manufacture, safety, effectiveness, labeling, storage, record-keeping, approval, sale, distribution, advertising and promotion of HLS's products. In Canada, the federal *Food and Drugs Act*, as amended, and the regulations promulgated thereunder, and other federal and provincial statutes and regulations, govern, among other things, the testing, manufacture, safety, effectiveness, labeling, packaging, storage, record keeping, approval, import, sale, distribution, advertising, promotion and post-approval monitoring of HLS's products.

In addition to drug product approvals, applicable laws require that most companies involved in pharmaceutical production and sale hold licenses in respect of their activities and establishments. For example, the Canadian *Food and Drugs Act* requires that, subject to limited exceptions, all Canadian establishments must hold an establishment licence to fabricate, package, label, distribute, import, wholesale, and/or test a pharmaceutical product. Further, to the extent that these activities are conducted outside of Canada, foreign sites must be included on an importer's license. Companies involved in the manufacture of pharmaceutical products are required to comply with manufacturing regulations, including current good manufacturing practice requirements enforced by the FDA and Health Canada and similar regulations enforced by regulatory agencies outside the United States and Canada. HLS and its suppliers will be subject to such regulatory requirements, and will also be subject to regular inspections from regulatory authorities. See "Risk Factors —

Risks Relating to the Business – Limitations Imposed by Government Regulation".

HLS may be subject to price control restrictions on its pharmaceutical products in many countries in which it operates, which will limit the amount it can charge for its products. The potential volume of sales of HLS's products may also depend on whether such products are and continue to be listed on public and private formularies. See "Risk Factors –

Risks Relating to the Business – Limitations Imposed by Government Regulation".

In the United States, the Federal Trade Commission, the FDA and state and local authorities regulate the advertising of pharmaceuticals. In Canada, Health Canada, the Competition Bureau and a number of self-regulatory authorities are among those that regulate the advertising of pharmaceuticals. In each case, advertising is strictly regulated and can be very limited.

The FDA can require a boxed warning (sometimes referred to as a "black box" warning) for products that have shown a significant risk of severe or life-threatening adverse events and similar warnings are also required to be displayed on such product in certain other jurisdictions, which can reduce the potential market for a product. See "Risk Factors –

Risks Relating to the Business - Publication of Negative Results of Studies or Clinical Trials" and "Risk Factors -

Risks Relating to the Business – Limitations Imposed by Government Regulation".

HLS is also subject to extensive federal and state health care marketing and fraud and abuse regulations, such as the federal *False Claims Act* in the United States, and federal, provincial and territorial marketing regulation in Canada. The United States federal *False Claims Act* imposes civil and criminal liability on individuals or entities who submit (or cause the submission of) false or fraudulent claims for payment to the government. See "*Risk Factors* –

Risks Relating to the Business – Limitations Imposed by Government Regulation".

If HLS or its operations are found to be in violation of any of these laws, regulations, rules or policies or any other law or governmental regulation, or if interpretations of the foregoing change, HLS may be subject to loss of product approvals or necessary licenses to conduct its business, recalls, stop sales, public warnings, adverse publicity, civil and criminal penalties, damages, fines, exclusion from government programs, such as Medicare and Medicaid programs, and the curtailment or restructuring of its operations. See "*Risk Factors* –

Risks Relating to the Business - Limitations Imposed by Government Regulation".

#### DESCRIPTION OF SHARE CAPITAL

The Company's authorized share capital consists of an unlimited number of Common Shares and 12,976,527 Preferred Shares. As of December 31, 2022, there were 32,355,618 Common Shares outstanding and no Preferred Shares outstanding. The Preferred Shares were issued to former AMD Shareholders in connection with the Arrangement and redeemed in tranches between 2018 and 2021. See "Year Ended December 31, 2021 – Final Redemption of Preferred Shares".

The holders of the Common Shares are entitled:

- (a) to vote at all meetings of shareholders of HLS except meetings at which only holders of a specified class of shares are entitled to vote:
- (b) to receive, subject to the rights of the holders of another class of shares, any dividend declared by HLS (less any tax required to be deducted and withheld by HLS); and
- (c) to receive, subject to the rights of the holders of another class of shares, the remaining property of HLS on the liquidation, dissolution or winding up of HLS, whether voluntary or involuntary.

#### DIVIDENDS AND DIVIDEND POLICY

On August 15, 2018, the Board established a dividend policy providing for the payment of quarterly dividends of C\$0.05 per Common Share. The following table summarizes the cash dividends declared per Common Share for the past three years.

<b>Declaration Date</b>	Dividend Declared Per Common Share
March 15, 2023	C\$0.05
November 9, 2022	C\$0.05
August 10, 2022	C\$0.05

<b>Declaration Date</b>	Dividend Declared Per Common Share
May 4, 2022	C\$0.05
March 16, 2022	C\$0.05
November 3, 2021	C\$0.05
August 4, 2021	C\$0.05
May 5, 2021	C\$0.05
March 17, 2021	C\$0.05
November 4, 2020	C\$0.05
August 5, 2020	C\$0.05
May 6, 2020	C\$0.05
March 18, 2020	C\$0.05

The Company's dividend policy will be reviewed from time to time by the Board in the context of HLS's earnings, financial condition and other relevant factors.

Under the terms of the HLS Credit Agreement, dividends may not be paid by the Company unless (a) both before and immediately after the payment of such dividends no default has occurred or would occur under the HLS Credit Agreement as a result of the payment of such dividends, (b) the Company is in compliance with its financial covenants as of the last completed fiscal quarter, and (c) the Company remains in pro forma compliance with its financial covenants (as if such dividends had been paid) as at the beginning of the fiscal quarter in which such dividends will be paid.

See "Risk Factors – Risks Relating to the Ownership of Common Shares – Dividends on the Common Shares Not Guaranteed".

## PRIOR ISSUANCES OF UNLISTED SECURITIES

Since the beginning of the most recently completed financial year, HLS has not issued any securities that are not listed or quoted on a marketplace.

#### MARKET FOR SECURITIES

The Common Shares are listed on the TSX under the symbol "HLS." The following table sets forth, for the periods indicated, the reported high and low prices and the aggregate volume of trading of the Common Shares on the TSX.

	Price		
Period	High	Low	Trading Volume
January 2022	15.49	14.09	363,053
February 2022	15.55	13.62	234,730
March 2022	16.44	14.20	120,816
April 2022	15.45	13.70	171,876
May 2022	15.59	11.98	203,099
June 2022	15.00	11.60	211,766
July 2022	13.26	11.00	429,489
August 2022	11.21	13.25	412,007

September 2022	11.45	8.55	439,376
October 2022	10.30	8.55	256,609
November 2022	8.30	10.31	1,567,334
December 2022	9.01	11.22	390,078

Source: TSX

## **DIRECTORS AND EXECUTIVE OFFICERS**

The following table sets forth certain information regarding each individual who is currently a Director or executive officer of the Company, including each such individual's province or state and country of residence and principal occupation during the five preceding years. Each Director will hold office until the close of the next annual meeting of shareholders or until their successors are elected or appointed, unless such office is earlier vacated in accordance with the Company's by-laws.

Name and Municipality of Residence	Position(s) with HLS	Age	Principal Occupation(s) for the past five years
Greg Gubitz  Ontario, Canada  Director since 2014	Director	65	Corporate director since October 2020; CEO of HLS from June 2014 to October 2020; CEO of Grosvenor Ventures since 2007
J. Spencer Lanthier  Ontario, Canada  Director since 2015	Director <sup>(1), (2)</sup>	82	Corporate director
Yvon Bastien  Quebec, Canada  Director since 2015	Director <sup>(1), (3)</sup>	75	Corporate director
Rodney Hill  Ontario, Canada  Director since 2018	Director <sup>(1), (2)</sup>	55	Chief Risk Officer of Ontario Municipal Employees Retirement System since November 2015
Don DeGolyer  South Carolina, U.S.A.  Director since 2018	Director <sup>(1), (3)</sup>	61	Senior advisor to healthcare companies and corporate director since 2020; Founder/CEO Vertice Pharama from 2015 – 2020
Laura A. Brege  California, U.S.A.  Director since 2019	Director <sup>(1), (3)</sup>	65	Advisor to biotechnology companies since 2015; Managing Director of Cervantes Life Science Partners, LLC from 2015 to 2017
John Welborn	Director <sup>(1), (2)</sup>	46	Senior Advisor, Stadium Capital Management, LLC

Name and Municipality of Residence	Position(s) with HLS	Age	Principal Occupation(s) for the past five years
Colorado, U.S.A.			
Director since 2021			
Norma Beauchamp			
Ontario, Canada	Director (1), (3)	61	Corporate Director, President and CEO of Cystic Fibrosis Canada from 2014 to 2017
Director since 2021			
Kyle Dempsey			
Massachusetts, U.S.A.	Director (1), (2)	34	Partner at MVM Partners LLP since 2017
Director since 2022			
Gilbert Godin	Chief Executive Officer		
Pennsylvania, U.S.A.	Director	64	CEO of HLS since October 2020; President and COO of HLS from April 2014 to October 2020
Director since 2020			
Tim Hendrickson  Ontario, Canada	Chief Financial Officer	51	Chief Financial Officer of HLS since September 2018; Vice President, Finance & Administration of HLS from August 2015 to September 2018
Sanjiv Sharma  Pennsylvania, U.S.A.	Chief Commercial Officer	67	Chief Commercial Officer of HLS since September 2018; Vice President, Commercial Operations of HLS Therapeutics (USA), Inc. from July 2014 to September 2018
Ryan C. Lennox  Ontario, Canada	Senior Vice President, Legal, HR and Compliance and Corporate Secretary	42	Senior Vice President, Legal, HR and Compliance of HLS from March 25, 2021; General Counsel and Corporate Secretary of HLS from May 2018 to March 25, 2021; Senior Counsel at Amgen Canada Inc. from April 2012 to May 2018
Jason Gross Ontario, Canada	Vice President, Scientific Affairs	58	Vice President, Scientific Affairs of HLS since June 2014
David Spence	Vice President, Corporate	55	Vice President, Corporate Controller since June 2022; Corporate Controller of HLS from January 2018 to June
Ontario, Canada	Controller		2022.
Patricia Perry  Quebec, Canada	Vice President, Human Resources	47	Vice President of HR of HLS since March 25, 2021; Senior Director of HR of HLS from July 2019 to March 25, 2021; President of P2Conseils, providing HR consultancy work since 2015.

Name and Municipality of Residence	Position(s) with HLS	Age	Principal Occupation(s) for the past five years
Dawn Edinboro  Bottom Bay, Barbados	Vice President, General Manager, Heritage Life Sciences (Barbados) Inc.	50	Vice President, General Manager of Heritage Life Sciences (Barbados), Inc. since July 2022; Senior Director, Finance and Administration, Heritage Life Sciences (Barbados), Inc. from July 2017 to June 2022.

#### Notes:

- (1) Independent director.
- (2) Member of the Audit Committee.
- (3) Member of the Compensation and Governance Committee.

As at March 15, 2023, based on publicly available information, the directors and executive officers of the Company, as a group, beneficially owned, or controlled or directed, directly or indirectly, 1,076,965 Common Shares, representing approximately 3.3% of the Company's Common Shares on a basic basis.

## **Corporate Cease Trade Orders**

To the knowledge of the Company, no Director or executive officer of the Company (nor any personal holding company of any of such individuals) is, as of the date of this Annual Information Form, or was within ten years before the date of this Annual Information Form, a director, chief executive officer or chief financial officer of any company (including the Company), that: (i) was subject to a cease trade order (including a management cease trade order), an order similar to a cease trade order or an order that denied the relevant company access to any exemption under securities legislation, in each case that was in effect for a period of more than 30 consecutive days (collectively, an "Order"), that was issued while the individual was acting in the capacity as a director, chief executive officer or chief financial officer; or (ii) was subject to an Order that was issued after the individual ceased to be a director, chief executive officer or chief financial officer and which resulted from an event that occurred while that individual was acting in the capacity as director, chief executive officer or chief financial officer.

#### **Penalties or Sanctions**

To the knowledge of the Company, no Director or executive officer (nor any personal holding company of any of such individuals) and no securityholder holding a sufficient number of securities of HLS to affect materially the control of HLS, has been subject to: (i) any penalties or sanctions imposed by a court relating to securities legislation or by a securities regulatory authority or has entered into a settlement agreement with a securities regulatory authority; or (ii) any other penalties or sanctions imposed by a court or regulatory body that would be likely to be considered important to a reasonable investor in making an investment decision.

## **Bankruptcies**

Except as otherwise disclosed herein, to the knowledge of the Company, no Director or executive officer of the Company (nor any personal holding company of any of such individuals) and no securityholder holding a sufficient number of securities of HLS to affect materially the control of HLS: (i) is, as of the date of this Annual Information Form, or has been within the ten years before the date of this Annual Information Form, a director or executive officer of any company (including the Company) that, while that individual was acting in that capacity, or within a year of that individual ceasing to act in that 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 ten years before the date of this Annual Information Form, 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 its assets. John Welborn was a director of Ascena Retail Group, Inc. in July 2020 when it filed for Chapter 11 bankruptcy protection.

## **Conflicts of Interest**

To the best of HLS's knowledge, there are no known existing or potential conflicts of interest among HLS or any of its subsidiaries and a director or officer of HLS or any of its subsidiaries as at the date hereof.

#### AUDITOR AND AUDIT COMMITTEE INFORMATION

## **Audit Committee Charter**

The Audit Committee operates under the Mandate of the Audit Committee set out at Appendix A hereto. The Audit Committee's main function is to oversee the Company's accounting and financial reporting processes, internal systems of control, independent auditor relationships and the audits of the Company's financial statements. The Audit Committee's responsibilities include:

- reviewing and pre-approving the engagement of the Company's independent auditors to perform audit services and any permissible non-audit services;
- evaluating the performance of the Company's independent auditors and deciding whether to retain their services;
- reviewing the Company's annual and quarterly financial statements and reports and discussing the statements and reports with the Company's independent auditors and management;
- reviewing with the Company's independent auditors and management significant issues that may arise regarding accounting principles and financial statement presentation, as well as matters concerning the scope, adequacy and effectiveness of the Company's financial controls; and
- establishing procedures for the receipt, retention and treatment of complaints received by the Company regarding financial controls, accounting or auditing matters.

## **Composition of the Audit Committee**

HLS's Audit Committee consists of Rodney Hill (Chair), J. Spencer Lanthier, John Welborn and Kyle Dempsey. The Board has determined that each of Rodney Hill, J. Spencer Lanthier, John Welborn and Kyle Dempsey meets the requirements for independence under National Instrument 52-110 – *Audit Committees* ("NI 52-110").

The Board has also determined that each of the members of the Audit Committee meets the requirements for being "financially literate" within the meaning of NI 52-110. For the purposes of NI 52-110, an individual is financially literate if he or she has 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 HLS's financial statements. All members of the Audit Committee have experience reviewing financial statements and dealing with related accounting and auditing issues. Below is a description of the education and experience of each member of HLS's Audit Committee relevant to the performance of his duties as a member of the Company's Audit Committee:

Rodney Hill is an independent Director. Mr. Hill has extensive experience in business management, risk management, finance and accounting. He is currently the Chief Risk Officer of Ontario Municipal Employees Retirement System Administration Corporation ("OMERS") which has approximately C\$120 billion of net assets under management. Mr. Hill joined OMERS in 2011 as Executive Vice President & Chief Auditor and moved to his current position in 2015. Prior to joining OMERS, Mr. Hill spent over 20 years working at PricewaterhouseCoopers and the last 10 years as a Partner specializing in auditing complex public and private companies in a variety of sectors including pharmaceuticals. Mr. Hill holds an Honours degree in Accounting with Computing from University of Kent at Canterbury. He is an Associate of the Institute of Chartered Accountants in England and Wales (ACA-UK) and a Chartered Professional Accountant (CPA, CA) in Canada.

J. Spencer Lanthier is an independent Director and Lead Director. Mr. Lanthier served as the Chair of the board of directors of Ellis-Don Inc. and has also previously served as a director of, among other companies, the following publicly-listed companies: TMX Group Inc., Torstar Corporation, Biovail Corporation and Rona Inc. Mr. Lanthier is a former Chairman and Chief Executive Officer of KPMG Canada and served as the Lead Director of the Bank of

Canada. Mr. Lanthier is also the Founding Chair of the 30% Club Canada. Mr. Lanthier is a Chartered Professional Accountant, Chartered Accountant and holds a honorary Doctor of Laws degree from the University of Toronto. Mr. Lanthier is a Member of the Order of Canada.

John L Welborn, Jr. currently serves as a Senior Advisor to Stadium Capital Management, LLC, an investment advisory firm. Previously, Mr. Welborn was Managing Director and Co-Chief Investment Officer of Stadium. Mr. Welborn joined Stadium in 2000 as an Associate. From 1998 to 2000, Mr. Welborn was a Financial Analyst at The Beacon Group, LLC, a principal investment and advisory firm that is now part of J.P. Morgan Chase & Co. At Beacon, Mr. Welborn was a member of the Mergers & Acquisitions Group, focusing on financial services companies and the Liquid Investments Committee. Mr. Welborn earned a B.S. degree in Commerce, with concentrations in Finance and Accounting, from the McIntire School of Commerce at the University of Virginia in 1998. Mr. Welborn has served on the boards of Intermountain Community Bancorp, Panhandle State Bank, Inc., and Ascena Retail Group, Inc. He has also served as a board observer at West Coast Bancorp.

Kyle Dempsey is a Partner at MVM Partners LLP (MVM), a growth equity firm that has invested in innovative, high growth healthcare businesses since 1997. Mr. Dempsey joined MVM in 2017 as an Investment Principal. Before joining MVM, Mr. Dempsey was a consultant at Bain & Company, working mainly in the healthcare practice to support clients with commercialization and business development projects. He received his M.D. from Harvard Medical School, his M.B.A. from Harvard Business School, and his B.A. in biochemistry from Bowdoin College. Mr. Dempsey currently serves as a board director for Optinose (NASDAQ: OPTN) and GT Medical, and he is also a board observer at MDxHealth (NASDAQ: MDXH).

#### **Audit Committee Oversight**

At no time during the Company's most recently completed financial year was a recommendation of the Audit Committee to nominate or compensate an external auditor (currently, Ernst & Young LLP) not adopted by the Board.

## **Reliance on Certain Exemptions**

At no time since the beginning of the most recently completed financial year has the Company relied on the exemptions set out in section 2.4 (De Minimis Non-Audit Services), subsection 3.2 (Initial Public Offerings), subsection 3.4 (Events Outside Control of Member) or subsection 3.5 (Death, Disability or Resignation of Audit Committee Member) in NI 52-110, or on any exemption granted under Part 8 (Exemptions) of NI 52-110.

## **Pre-Approval Policies and Procedures**

The Audit Committee must pre-approve and disclose, as required, the retention of the external auditor for non-audit services to be provided to the Company that are permitted under applicable law. Annually, the external auditor submits its work plan to the Audit Committee, including the nature and scope of any audit-related advisory services planned for the upcoming year. That plan is then reviewed and pre-approved by the Audit Committee. Any unplanned Audit Committee related advisory services or other advisory services are presented for pre-approval at the regularly scheduled meetings of the Audit Committee. Audit Committee pre-approval of non-audit services is not required if the engagement for the services is entered into pursuant to pre-approval policies and procedures established by the Audit Committee regarding HLS's engagement of the external auditor, provided the policies and procedures are detailed as to the particular service, the Audit Committee is informed of each service provided and the policies and procedures do not include delegation of the Audit Committee's responsibilities under applicable Canadian securities laws to HLS's management. The Audit Committee may delegate to a member of the Audit Committee the authority to grant pre-approvals, provided the pre-approvals are presented to the Audit Committee at its next subsequent meeting.

#### **External Auditor Service Fees**

The aggregate fees billed by the external auditors of HLS in each of the last two fiscal years were as follows:

Financial Year Ended	Audit Fees	Audit-Related Fees <sup>(1)</sup>	Tax Fees <sup>(2)</sup>	All Other Fees <sup>(3)</sup>
December 31, 2021	C\$318,089	C\$41,070	C\$152,467	-
December 31, 2022	C\$517,500	C\$115,115	C\$99,759	

#### Notes:

- (1) Audit-related fees were for assurance and related services reasonably related to the performance of the audit of the consolidated financial statements and are not reported under "Audit Fees" above.
- (2) Tax fees were incurred for services consisting of tax compliance, including the preparation and review of tax returns, assistance regarding tax audits and tax advisory services relating to domestic and international taxation.
- (3) All Other Fees represent fees incurred for services other than audit fees, audit-related fees and tax fees.

#### **RISK FACTORS**

An investment in securities of the Company involves significant risks. Investors should carefully consider the risks described below, the other information described elsewhere in this Annual Information Form and those risks set out in HLS's MD&A for the year ended December 31, 2022 (as updated by subsequent interim MD&A of the Company) before making a decision to buy securities of the Company. If any of the following or other risks occur, the Company's business, prospects, financial condition, financial performance and cash flows could be materially adversely impacted. In that case, the trading price of securities of the Company could decline and investors could lose all or part of their investment in such securities. There is no assurance that risk management steps taken will avoid future loss due to the occurrence of the below described or other unforeseen risks.

#### **Risks Relating to the Business**

The operations of HLS are speculative due to the nature of its business, which is the acquisition and commercialization of clinically differentiated pharmaceutical products in the specialty CNS and CV markets. The risks below are not the only ones facing HLS. Additional risks not currently known to HLS, or that HLS currently deems immaterial, may also impair HLS's operations. If any of the following risks actually occur, HLS's business, financial condition and operating results could be adversely affected.

## **Limited Operating History**

HLS was formed in June 2014 and acquired the U.S. and Canadian rights to manufacture, market and sell Clozaril from Novartis in August 2015 and had no operations prior to acquiring the rights to Clozaril. HLS's limited operating history may make it difficult for investors to evaluate HLS's prospects for success. On March 12, 2018, HLS and AMD amalgamated pursuant to a plan of arrangement under the OBCA to form the Company. There is no assurance that HLS will be successful and the likelihood of success must be considered in light of its relatively early stage of operations.

#### All Revenue from Sales of a Limited Number of Products

HLS currently derives all of its revenue from sales of Clozaril and Vascepa, and from royalties on worldwide sales of the products underlying the Royalty Portfolio, and such sales are expected to continue to account for most of HLS's revenue in the near term. Accordingly, if demand for Clozaril, Vascepa or the products underlying the Royalty Portfolio declines significantly or the revenue therefrom of otherwise declines significantly, the business, financial condition and operating results of HLS would be adversely affected.

#### Reliance on Third Parties for the Manufacture and Supply of Products

HLS does not have the internal capability to manufacture pharmaceutical products and relies on third parties to manufacture its products, including Clozaril. HLS also relies on third parties to manufacture products such as Vascepa, PERSERIS, Trinomia and the products underlying the Royalty Portfolio that are covered under licensing and other agreements. HLS cannot be certain that manufacturing sources it utilizes currently or new manufacturing sources in the future will continue to be available or that it will be able to continue to outsource the manufacturing of its products on reasonable or acceptable terms. In addition, outsourcing manufacturing exposes HLS to a number of risks which are outside of its control, including: (i)

HLS's suppliers may fail to comply with current government mandated good manufacturing practices which would result in mandated production halts or limitations; and (ii) HLS's suppliers may experience manufacturing, quality, control, yield or other issues, including those arising from extreme weather or natural disasters and the availability of raw materials and key components, which would require the supplier to halt or limit production of HLS's products.

If HLS encounters delays or difficulties with sourcing or obtaining raw materials, active pharmaceutical ingredients suppliers, contract manufacturers, packagers or distributors, sales of its products could be delayed. If HLS changes the source or location of supply or modifies the manufacturing process or source of raw materials, regulatory authorities will require it to demonstrate that the product produced by the new source or from the modified process is equivalent to the product used in any clinical trials that were conducted. If HLS is unable to demonstrate this equivalence, it will be unable to manufacture products from the new source or location of supply, or use the modified process. HLS may incur substantial expenses in order to ensure equivalence. This may negatively affect its business, financial condition and operating results.

## Supply Interruptions May Negatively Impact Maintenance of Inventory Levels

Supply interruptions may occur, and HLS's inventory of finished products may not always be adequate to satisfy demand. Numerous factors could cause interruptions in the supply of HLS's finished products, including: (i) failure to have a third-party supply chain validated in a timely manner; (ii) shortages in raw material and packaging components required by HLS's manufacturers; (iii) changes in sources for manufacturing or packaging; (iv) changes in regulatory, legal or compliance requirements for products, suppliers or manufacturers; (v) HLS's failure to timely locate and obtain replacement manufacturers as needed; (vi) conditions affecting the cost and availability of raw materials; and (vii) product recall stemming from quality or regulatory reasons impacting the integrity of the product. There can be no assurances that HLS's supply of products will not be interrupted in the future. An interruption may have an adverse effect on HLS's business, financial results and operations.

## Reliance on Third Parties to Perform Distribution, Logistics, Regulatory and Sales Services

HLS relies on third parties to provide information technology, medical, distribution, logistics, regulatory and sales services including warehousing of finished product, accounts receivable management, billing, collection and record keeping. If the third parties cease to be able to provide HLS with these services, or do not provide these services in a timely or professional manner HLS may not be able to successfully manage the product revenues or integrate new products into its business, which may result in decreases in sales. Additionally, any delay or interruption in the process or in payment could result in a delay delivering product to HLS's customers, which could have a material effect on HLS's business, financial condition and operating results.

## **Dependence on Wholesalers**

HLS sells to wholesalers in the U.S. and to wholesalers and institutions in Canada. Wholesalers act as an intermediary between a manufacturer or its distributor and institutional and retail customers. All of HLS's sales in the U.S. and a portion of HLS's sales in Canada are to wholesale distributors. HLS relies on wholesalers to maintain adequate stock and to provide appropriate customer service and order fulfillment to their customers within the territories in which HLS is authorized to distribute its products. If wholesalers do not perform these duties adequately, then such performance could negatively impact HLS's business and financial results. Wholesale distributors will typically charge fees for services that are a function of volume. If there is a change in HLS's volumes, such fees could increase, or such fees could increase unilaterally independent of changes in HLS's volumes. Any such increase in fees could adversely impact HLS's revenues and results of operations.

## Reliance on Third Parties to Undertake Promotion and Distribution of Products

HLS has entered into promotion and distribution agreements with selected partners, and intends to enter into additional promotion and distribution agreements with selected partners in the future. HLS will rely on these partners to undertake marketing and sales efforts where promotion and distribution rights have been granted. Reliance on these agreements will likely expose HLS to a number of risks, including the following: (i) partners may not devote sufficient resources to HLS's products; (ii) disputes may arise with respect to payments that HLS believes are due under such promotion and distribution agreements; (iii) unwillingness on the part of partners to provide updates regarding the progress of its marketing and sales activities, or to permit public disclosure of these activities; (iv) partners may terminate the relationship; (v) disputes with partners could result in litigation or arbitration; (vi) partners may pursue higher priority programs or change the focus of their programs, which could affect the partner's commitment to their respective territories; (vii) non-renewal of distribution agreements or renewal on less favorable terms; (viii) partners may market or distribute products that compete with HLS's products; and (ix) partners' activities may result in compliance issues. There is no assurance that partners will effectively be able to achieve significant sales of

products in their respective territories and their inability to do so may impact adversely HLS's revenues and results of operations.

# Dependence on Third Parties for the Development, Manufacturing, Supply, Distribution and Commercialization of the Products Underlying the Royalty Portfolio and the Collection of the Royalty Amounts

HLS is not involved in any aspect of the operations relating to the products underlying the Royalty Portfolio. HLS relies on Boston Scientific, Takeda, Pfizer and Sanofi Genzyme for the continued development, manufacturing, supply, distribution and commercialization of the products underlying the Royalty Portfolio. HLS's royalty income from the worldwide sales of the products underlying the Royalty Portfolio is dependent on the ability and continued efforts of Boston Scientific, Takeda, Pfizer and Sanofi Genzyme to profitably carry out their respective development, manufacturing, supply, distribution and commercialization activities. Delays, interruptions, or failures to carry out these activities profitably may reduce HLS's royalty income and impact its revenues, which is outside of HLS's control.

# The COVID-19 Pandemic Could Have a Material Adverse Effect on the Company's Business Strategy and Objectives, the Result of Which Could Adversely Impact the Sales of its Products, its Revenues, Results of Operations and Research and Development Activities

The outbreak of COVID-19, its recent and future variants and any other outbreaks of contagious diseases or other adverse public health developments could have a material adverse effect on the successful implementation of the Company's business strategy and objectives, the results of which could materially adversely impact the sales of its products, revenues, results of operation and research and development activities. The outbreak of COVID-19 has resulted in governmental authorities implementing numerous measures to try to contain the pandemic, such as travel bans and restrictions, quarantines, shelter in place orders, increased border and port controls and closures, and shutdowns. Although most industrialized countries are relaxing some of the restrictive measures, there remains considerable uncertainty regarding the consequences such relaxed measures may have on the pandemic and the population worldwide and regarding the reimplementation of such measures and potential future measures.

Since the onset of the COVID-19 pandemic, the Company's office personnel have been observing social distancing practices and working from home where possible, consistent with local public health requirements and official closures. Throughout various periods in 2020 and 2021, and since March 2022, the Company has permitted employees to return to offices on a limited, rotational basis and to resume in-person interactions with customers where permitted by local public health authorities and when appropriate protective measures have been in effect. However, the Company may require employees to work remotely in the future. At different points throughout the past year, access to hospitals and other health care facilities have been limited in many jurisdictions where the Company operates and such access may be limited in the future. Because the Company's sales and marketing processes are dependent on, among other things, access to health care facilities and providers, this has resulted in HLS's sales force being limited in their ability to meet face-to-face with health care professionals to detail its products and this may continue in the future.

The COVID-19 pandemic has significantly increased economic and demand uncertainty throughout North America. The COVID-19 pandemic has caused disruption and volatility in the global capital markets, which, depending on further developments, could impact the Company's capital resources and liquidity in the future, including the availability of financing on attractive terms, if at all.

The extent to which COVID-19 could impact HLS's operations, financial condition, liquidity, results of operations, and cash flows is still highly uncertain and will depend on future developments, including the efficacy of the vaccines against the coronavirus and its variants, the access to and adoption of those vaccines, the success of mitigation measures effected by the Company to date and those which may be taken by it in the future and the actions that may be taken by various governmental authorities and other third parties in response to the pandemic.

## Natural Disasters and Other Crises

Third parties on which HLS relies, including its manufacturers, suppliers and distributors, have operations around the world and are exposed to a number of global and regional risks outside of our control. These include, but are not limited to, natural disasters, such as earthquakes, tsunamis, power shortages or outages, floods or monsoons, public health crises, such as pandemics and epidemics, political crises, such as terrorism, war, political instability or other conflict, or other events outside of our control. This could materially and adversely affect HLS's business and could have a material adverse effect on HLS and its financial results.

#### Inability to Attract and Retain Key Managerial Personnel

HLS is highly dependent upon a relatively small group of qualified managerial personnel. These individuals have an in-depth understanding of HLS's business objectives and the markets within which HLS intends to operate. The loss of the services of one or more of HLS's directors or officers could have a detrimental effect on HLS, its operations and its ability to execute its strategy successfully, which could materially and adversely affect HLS's business.

In addition, HLS's anticipated growth will require additional expertise and the addition of new qualified personnel. There is intense competition for qualified personnel in the pharmaceutical field. Therefore, HLS may not be able to attract and retain the qualified personnel necessary for the development of its business. The failure to recruit additional key managerial personnel in a timely manner would harm HLS's business development programs, its ability to manage day-to-day operations, attract collaboration partners, attract and retain other employees and generate revenues. HLS may not maintain key person life insurance on any of its employees.

## Acquisition Growth Strategy Subject to Significant Risks

As part of its business strategy, HLS intends to engage in acquisitions to acquire rights to (or other economic benefit from) late stage, post-clinical and commercial stage branded pharmaceutical products for the North American market. This includes acquisition or in-licensing of soon-to-be fileable or promotional stage branded pharmaceutical products in selected therapeutic areas and the acquisition of select established stage pharmaceutical products. Acquisition of target products or businesses may also require that HLS acquire ancillary products or businesses that are outside of its business strategy. If HLS identifies suitable acquisition candidates, it may be unable to successfully negotiate the acquisition at a price or on terms and conditions acceptable to HLS, including as a result of the limitations imposed by HLS's debt obligations.

HLS may also encounter intense competition from other entities having a business objective similar to HLS's to acquire rights to pharmaceutical products, which makes it more difficult to find attractive opportunities on acceptable terms. Many of these entities are well-established and may possess greater technical, human and other resources than HLS and HLS's financial resources will be relatively limited when contrasted with those of many of these competitors. HLS's ability to compete with respect to the acquisition of rights to late stage, post-clinical, promotional stage branded pharmaceutical products and established stage branded pharmaceutical products in selected therapeutic areas will be limited by HLS's available financial resources. If financing is available through the sale of debt, equity or other securities, the terms of such financing may not be favourable to HLS. In addition, the HLS Credit Agreement contains restrictions on the ability of HLS to raise capital through issuing or incurring additional debt. Failure to raise capital when required could materially and adversely affect HLS's business and unsuccessful acquisition attempts could result in direct expenses to HLS and adversely impact HLS's operating results.

HLS's future financial performance depends in part upon its ability to effectively integrate acquired companies and assets. The integration of acquired companies and other assets may require significant management time and resources that would otherwise be available for the ongoing management of HLS's existing operations. Failure to expand operational and financial systems and controls or to integrate appropriate personnel at a pace consistent with HLS's growth could also adversely affect its operating results. Management of HLS cannot forecast the number, timing or size of future acquisitions, or the effect that any such acquisitions may have on HLS's operating or financial results.

Even if HLS is able to acquire rights to pharmaceutical products, it may not generate sales sufficient to create a profit or otherwise avoid a loss. For example, the marketing strategy, distribution channels and levels of competition with respect to acquired products may be different than those of Clozaril or Vascepa, and HLS's ability to compete favourably in those product categories may be limited.

## Failure to Realize Expected Returns on Vascepa, PERSERIS and Trinomia

In-licensing transactions involve risks that could materially and adversely affect HLS's business, including the failure of the commercialization endeavours under the Vascepa Agreement, the PERSERIS Agreement or the Trinomia Agreement to realize the results HLS expects. If the commercialization endeavours under the Vascepa Agreement, the PERSERIS Agreement or the Trinomia Agreement fail to realize the results that HLS expects, such transaction(s) could materially and adversely affect HLS's business and could have a material adverse effect on HLS and its financial results.

## Inability to Obtain or Maintain Regulatory Approvals

The commercialization of pharmaceutical products in Canada and the U.S. and other jurisdictions is highly regulated, which significantly increases the difficulty and costs involved in obtaining and maintaining regulatory approval for marketing new and existing products, and approval is never guaranteed.

HLS previously submitted an application to Health Canada for approval to commercialize Trinomia in Canada and in response received a NOD from Health Canada indicating that additional scientific data may be required for approval. HLS withdrew its application from Health Canada so that it can be re-submitted following availability of the requested data (described in greater detail above, see "Business of the Company – General Development of the Business – Year Ended December 31, 2020 – Acceptance of Filing and Notice of Deficiency of Trinomia" and "Business of the Company – Narrative Description of HLS's Business – Products and Programs – Trinomia (acetyl salicylic acid/atorvastatin/ramipril fixed dose combination capsules)"). Such remedial activities by HLS may not be sufficient to obtain regulatory approval or to obtain any period of market exclusivity as existing clinical and other data for Trinomia (described in greater detail above) may be interpreted differently by Health Canada than by HLS and/or regulatory authorities in other jurisdictions and may not be sufficient to obtain regulatory approval. Despite the approval of Trinomia for use in over 30 countries, there is no assurance that Trinomia will be approved for commercialization in Canada, or if Trinomia is approved, that the approved production indication or specifications will make it commercially feasible to launch Trinomia in Canada.

The regulatory approval process can be long and may involve significant delays despite HLS's best efforts. Even if HLS's product candidates, including Trinomia and any future product candidates, were to successfully obtain approval from regulatory authorities, such approval may not be obtained in a timely manner, and any such approval might significantly limit the approved indications for use, including more limited patient populations, require that precautions, contraindications or warnings be included on the product labeling, including black box warnings, require expensive and time-consuming post-approval clinical studies, risk management plans or Risk Evaluation and Mitigation Strategy (as may be required by the FDA under the *Food and Drug Administration Amendments Act* and/or Health Canada under the *Food and Drugs Act* and related *Food and Drug Regulations*), or surveillance as conditions of approval, or, through the product label, the approval may limit the claims that HLS may make, which may impede the successful commercialization of HLS's product, including substantial reductions in the projected peak revenues and lifetime product potentials for HLS's products. Such limitations in the approved indication could materially and adversely affect HLS's business and could have a material adverse effect on HLS and its financial results.

Following any approval for commercial sale of HLS's product candidates, certain changes to the product, such as changes in manufacturing processes and additional labeling claims, as well as new safety information, will be subject to additional notification to, or review and approval by, regulatory authorities. Furthermore, regulations of the Therapeutic Products Directorate (the "TPD") of Health Canada are rigorous, time consuming and costly and HLS cannot predict the extent to which it may be affected by changes in regulatory developments and its ability to meet such regulations. There is a risk that HLS's current or future products may be withdrawn from the market and the required approvals suspended because of noncompliance with regulatory requirements. If there is delay or failure to obtain or maintain regulatory approvals for HLS's product candidates in Canada or the U.S. or other jurisdictions, or if any approval contains significant limitations, HLS's ability to market to HLS's full target market will be reduced and HLS's ability to realize the full market potential of HLS's product candidates will be hampered. This could materially and adversely affect HLS's business and could have a material adverse effect on HLS and its financial results.

## Limitations Imposed by Government Regulation

In both domestic and foreign markets, the formulation, manufacturing, packaging, labelling, handling, distribution, importation, exportation, licensing, sale and storage of HLS's products are affected by extensive laws, governmental regulations, administrative determinations, court decisions and similar constraints which are beyond HLS's control. Such laws, regulations and other constraints may exist at all levels of government. There can be no assurance that HLS will be in compliance with all of these laws, regulations and other constraints. Failure to comply with these laws, regulations and other constraints or new laws, regulations or constraints could lead to the imposition of significant penalties or claims and could negatively impact HLS's business. In addition, the adoption of new laws, regulations or other constraints or changes in the interpretations of such requirements may result in significant compliance costs or lead HLS to discontinue product sales and may have an adverse effect on the marketing of HLS's products, resulting in significant loss of sales.

In addition, the marketing, promotional and pricing, discount, rebate or co-pay practices of pharmaceutical companies, as well as the manner in which companies, in-house or third-party sales forces interact with purchasers, prescribers and patients,

are subject to extensive regulation, enforcement of which may result in the imposition of civil and/or criminal penalties, injunctions, and/or limitations on marketing practices for HLS's products. Many companies have been the subject of claims related to these practices asserted by federal authorities. These claims have resulted in fines and other consequences.

Companies may not promote drugs for "off-label" uses – that is, uses that are not described in the product's labeling and that differ from those approved by the FDA, Health Canada or other applicable regulatory agencies. A company that is found to have improperly promoted off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. In addition, HLS management's attention could be diverted from business operations and HLS's reputation could be damaged.

## Changes in Pricing, Access or Reimbursement Policies in Canada and the United States

Certain provincial and territorial regulatory authorities in Canada have the ability to determine whether consumers of a drug sold within such province or territory will be reimbursed by a provincial/territorial governmental health plan for that drug by listing drugs on formularies. The listing or non-listing on provincial formularies may affect the prices of drugs sold within provinces/territories and the volume of drugs sold within provinces. Increasing expenditures for healthcare have been the subject of considerable public attention in Canada and the U.S. Both private and government entities are seeking ways to reduce or contain healthcare costs, and third party payors are increasingly challenging the price and examining the cost effectiveness of pharmaceutical products and services. Changes in provincial/territorial formulary policies regarding reimbursement to consumers, or the provision or restriction of co-pay support, for the cost of Clozaril, Vascepa, PERSERIS and Trinomia, and other pharmaceutical products that may be acquired by HLS in the future, could negatively impact demand for HLS's products and HLS's ability to sell its products at viable prices, which could materially and adversely affect HLS's business.

Additionally, in the United States, Medicaid/Medicare, Veteran's Affairs Federal Supply Service, State Fee-for Service and Managed Medicaid and other U.S. federal-funded programs may change any aspects of the law pertaining to formulary coverage, to the level of mandatory rebates, or to the base on which the rebates are calculated. This could negatively impact HLS revenues from loss of volume, or reduction of earnings from changes in level of rebates.

## Product Pricing Regulations on Certain Patented Drug Products

All patented pharmaceutical products introduced in Canada are subject to the post-approval product pricing regulation of the PMPRB. Certain patented products, including Vascepa, PERSERIS and Trinomia, may form part of HLS's portfolio of products from time to time and may be subject to such regulation by the PMPRB. For new patented products, the price in Canada is limited to either the cost of existing drugs sold in Canada or the median of prices for the same drug sold in other specified industrial countries. For existing patented products, prices cannot increase by more than the Consumer Price Index. The PMPRB will monitor compliance through a review of the average transaction price of each patented drug product to be reported by HLS over a recurring six-month reporting period. The PMPRB does not approve prices for drug products in advance of their introduction to the market, rather, it provides guidelines from which companies like HLS set their prices at the time they launch their products. If the PMPRB's guidelines provide a ceiling price for a patented product that is lower than HLS's expectations, or if the PMPRB deems a patented product to be excessively priced, leading to the reduction of the product's price and the potential imposition of a fine, such restriction and regulation may hamper HLS's ability to profitably commercialize the product to its full market potential or at all. This could materially and adversely affect HLS's business and could have a material adverse effect on HLS and its financial results.

On August 9, 2019, the PMPRB first announced amendments to the Patented Medicines Regulations (Canada) that were intended to lower the prices of patented medicines in Canada. These amendments were expected to come into force on July 1, 2021, but were subsequently delayed a number of times, and were finally expected to be implemented on January 1, 2023. Then, in December2022, the PMPRB announced that the coming-into-force of the amendments would be further deferred, and that the interim guidance issued by the PMPRB on August 18, 2022 would remain in place. Health Canada further asked PMPRB to consider pausing the ongoing consultation process, in order to allow all of the stakeholders in the health system to work collaboratively in fully understanding the short and long-term impacts of the PMPRB's various proposals. These changes, or any other future changes, to, among other things, the methodology or policies of PMPRB or other relevant regulatory bodies may result in less favourable product pricing directives and requirements. HLS's ability to predict and/or adapt to such directives or requirements may be limited.

#### Risk of Being Removed from or Failure to be Included in Public and Private Formularies

Managed care organizations, pharmacy benefit managers, group purchasing organizations and other third-party payors try to negotiate the pricing of medical services and drug products to control their costs. Managed care organizations and pharmacy benefit managers typically develop public and commercial formularies to reduce their cost for medications. Formularies can be based on the prices and therapeutic benefits of the available products. Due to their lower costs, generic products are often favoured. The breadth of the products covered by formularies varies considerably from one managed care organization to another, and many formularies include alternative and competitive products for treatment of particular medical conditions. Increasing expenditures for healthcare have been the subject of considerable public attention in Canada and the U.S. Both private and government entities are seeking ways to reduce or contain healthcare costs, and third-party payors are increasingly challenging the price and examining the cost effectiveness of pharmaceutical products and services. Failure to be included in such formularies or to achieve favourable formulary status may negatively impact the utilization of HLS's products. If HLS's products are not included within an adequate number of formularies or adequate reimbursement levels are not provided, or if those policies increasingly favour generic products, HLS's market share and gross margins could be harmed, as could HLS's business, financial condition, results of operations and cash flows.

## Dependence on Product Development and Supply Chain Operations

HLS may undertake product development and technical transfers to maximize the potential of its product rights by exploring opportunities to develop new packaging, dosages, and formulations and consider alternative suppliers that may improve product offerings, increase supply reliability or reduce costs. Product development and technology transfers are expensive, time consuming and outcomes are inherently uncertain.

Flaws in the product development or technology transfer protocols may not become apparent until the work is well-advanced. HLS may experience numerous unforeseen events that could cause its product development or technical transfers to be delayed, suspended or terminated, or which could delay or prevent HLS's ability to receive regulatory approval for or commercialize any output from its product development or technology transfer projects.

## Clinical Trial Process

Some of HLS's product candidates are or will be at the clinical stage of development. These product candidates must undergo all levels of registration clinical trials. The conduct of registration clinical trials and the submission of a successful Investigational New Drug Application or New Drug Application in the U.S. or Clinical Trial Application or New Drug Submission in Canada is a complicated process. As an organization, HLS has not conducted a registration clinical trial before and has limited experience in preparing, submitting and prosecuting regulatory filings. HLS also has had limited interactions with the TPD and FDA and has not discussed HLS's planned clinical trial designs or implementation with the TPD or FDA. Consequently, even if HLS's initial clinical trials are successful, HLS may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to New Drug Application/New Drug Submission and approval of HLS's products candidates including any other future product candidate HLS may develop. HLS may require more time and incur greater costs than HLS's competitors and may not succeed in obtaining regulatory approvals of products that HLS acquires. Failure to commence or complete, or delays in, HLS's planned clinical trials, would prevent HLS from or delay HLS in commercializing HLS's current products candidates or any other future product candidate HLS acquires.

Furthermore, HLS or its licensors may be required to conduct one or more clinical studies in Canada for Trinomia or products, including future products. For example, in order to be approved in Canada, the studied population must adequately represent the Canadian population, and the data must be applicable to the Canadian population and Canadian medical practice in ways that Health Canada deems clinically meaningful. Generally, the patient population for any clinical studies conducted outside of Canada must be representative of the population for whom HLS intends to label the product in Canada. There can be no assurance Health Canada will fully accept data used for U.S. or other countries' approval purposes. If Health Canada chooses to not fully accept this data, it may result in the need for additional studies or data in Canada, which would be costly and time-consuming and delay or permanently halt HLS's commercialization of future products.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. A failure of one or more clinical trials can occur at any stage of testing for a variety of reasons. The outcome of initial clinical trials may not be predictive of the outcome of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. In some instances, there can be significant variability in safety or efficacy results between different trials of the same product candidate due to numerous factors, including changes in or adherence to trial protocols, differences in size and type of the subject populations and the rates of dropout among clinical trial subjects. HLS or its licensors' future clinical trial results

therefore may not demonstrate safety and efficacy sufficient to obtain regulatory approval for its product candidates. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Any future clinical trials HLS or its licensors may undertake may not be successful.

Flaws in the design of a clinical trial may not become apparent until the clinical trial is well-advanced. HLS has never conducted a clinical trial before and may be unable to design and execute clinical trials to support regulatory approval of its product candidates. In addition, clinical trials often reveal that it is not practical or feasible to continue development efforts for a product candidate.

HLS, or its licensors that are conducting the clinical trial, may experience numerous unforeseen events that could cause the planned clinical trials to be delayed, suspended or terminated, or which could delay or prevent HLS's ability to receive regulatory approval for or commercialize any of its product candidates. HLS, or its licensors that are conducting the clinical trial, may voluntarily suspend or terminate its planned clinical trials if at any time it believes that they present an unacceptable risk to subjects. Furthermore, regulatory agencies, institutional review boards or similar research ethics boards, or data safety monitoring boards may at any time order the temporary or permanent discontinuation of planned clinical trials or request that HLS, or its licensors, cease using certain investigators in the clinical trials if such regulatory agencies or boards believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements or that they present an unacceptable safety risk to subjects. If HLS, or any of its licensors that are conducting the clinical trial, elects or is required to suspend or terminate a clinical trial for any of its product candidates, or its product candidate development is otherwise delayed, HLS's costs may increase, its commercial prospects will be adversely impacted, any periods during which it may have the exclusive right to commercialize its product candidates may be shortened and HLS's ability to generate product revenues may be delayed or eliminated.

If the results of the planned clinical trials for HLS's product candidates do not achieve the primary efficacy endpoints or demonstrate unexpected safety issues, the prospects for approval of HLS's product candidates will be materially adversely affected. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in initial clinical trials have failed to achieve similar results in later clinical trials, including longer-term trials, or have failed to obtain regulatory approval of their product candidates. Many compounds that initially showed promise in clinical trials have later been found to cause undesirable or unexpected adverse effects that have prevented further development of the compound.

Unforeseen adverse effects from any of HLS's product candidates could arise either during clinical development or, if approved, after the approved product has been marketed. Any undesirable adverse effects that may be caused by HLS's product candidates could interrupt, delay or halt clinical trials and could result in more restrictive labeling or the denial of regulatory approval by the TPD or FDA, or other regulatory authorities for any or all targeted indications, and in turn prevent HLS from commercializing its product candidates and generating revenues from their sale. Adverse effects could also impact subject recruitment or the ability or willingness of enrolled subjects to complete the trial, or result in product liability claims. Any of these occurrences may harm HLS's business, financial condition and prospects significantly. Certain types of unexpected adverse events for atypical antipsychotic class drugs may also impact the perception of HLS's product and may result in additional regulatory obligations and/or labeling changes.

In addition, if any of HLS's product candidates receive regulatory approval and HLS or others later identify undesirable adverse effects caused by the product, HLS could face one or more of the following consequences: (i) HLS may be required to suspend marketing of, withdraw or recall the product; (ii) regulatory authorities may require the addition of labeling statements, such as a black box warning or a contraindication, or other labeling changes; (iii) regulatory authorities may withdraw their approval of the product; (iv) regulatory authorities may seize the product or seek an injunction against its manufacture or distribution; (v) the TPD or FDA or other regulatory authorities may issue safety alerts, "Dear Healthcare Provider" letters, press releases or other communications containing warnings about the product; (vi) a regulatory authority may require the establishment or modification of a strategy, that may, for example, require HLS to issue a medication guide outlining the risks of such adverse effects for distribution to patients, or restrict distribution of the product, if and when approved, and impose burdensome implementation requirements on HLS; (vii) HLS may be required to conduct additional trials; (viii) HLS may be required to change the way that the product is administered, conduct additional clinical trials or recall the product; (ix) HLS may be subject to litigation or product liability claims, fines, injunctions or criminal penalties; (x) regulatory authorities may impose additional restrictions on marketing and distribution of the product; and (xi) HLS's reputation may suffer. Any of these events could prevent HLS from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing such product, which in turn could delay or prevent HLS from generating significant revenues from its sale.

#### Inability to Secure Additional Financing to Complete Future Acquisitions

There can be no assurance that HLS will be able to raise the additional funding that it will need to carry out its business objectives and to complete acquisitions. The development of HLS's business depends upon prevailing capital market conditions, HLS's business performance and its ability to obtain financing through debt financing, equity financing or other means. There is no assurance that HLS will be successful in obtaining the financing it requires as and when needed or at all in order to complete future acquisitions or to refinance existing debt. If additional financing is raised by the issuance of Common Shares from treasury, shareholders may suffer additional dilution.

## Highly Competitive Pharmaceutical Industry

HLS's products will face competition from new pharmaceutical and biotech products that treat some of the same diseases and conditions as HLS's products. Many of HLS's competitors have greater financial resources and selling and marketing capabilities. HLS will face further competition from drug development companies that focus their efforts on developing, acquiring and marketing products that are similar in nature to HLS's products, but that in some instances offer improvements over its products, such as less frequent dosing, taste-masking, new dosage formats and other novel approaches to improve existing products. HLS's competitors may succeed in developing technologies and products that are more effective, have better side effect profiles, or are less expensive to use than any that it may license or acquire. These developments could render HLS's products obsolete or uncompetitive, which would have a material adverse effect on HLS's business, financial condition and operating results.

## Significant Competition from Manufacturers of Generic Products

Generic versions of pharmaceutical products are generally significantly less expensive than branded versions, and, where available, may be required in preference to the branded version under third-party reimbursement programs, or substituted by pharmacies. If sales of any of HLS's products that no longer enjoy market exclusivity or are not sufficiently protected by associated intellectual property were to increase substantially, competitors may be more likely to develop generic formulations that compete directly with such products. For example, HLS may face increased competition from manufacturers of generic Clozaril in both Canada and the United States. Increased generic competition would have a material adverse effect on HLS's business and financial results.

#### **Expiration of Core Patent Protection**

HLS has and may in the future also acquire rights to additional products that still enjoy patent protection. This patent protection will eventually expire and, in such situations, in order to continue to obtain commercial benefits from these products, HLS will rely on product manufacturing trade secrets, know-how and related non-patent intellectual property. The effect of this patent expiration depends, among other things, upon the nature of the market and the position of these products in the market from time to time, the growth of the market, the complexities and economics of manufacture of a competitive product and regulatory approval requirements of generic drug laws. In the event that competition develops from generic products, this competition could have a material adverse effect on HLS's business, financial condition and operating results. The entrance into the market of a generic pharmaceutical product may erode the branded product's market share which may have a material adverse effect on HLS's business, financial condition and results of operations.

## Inability to Protect, Maintain and Enforce Intellectual Property and Data Protection

HLS's success will depend in part on its ability or on the ability of licensors of products to HLS to protect, maintain and enforce intellectual property rights, data protection and licensing arrangements for its products. No assurance can be given that the licenses or rights used by, or granted to, HLS, will not be challenged, invalidated, infringed or circumvented, or that the rights granted thereunder will provide competitive advantages to HLS. Any loss of intellectual property or data protection is likely to adversely affect HLS's operating results. HLS's commercial success will also depend in part on it or its licensors not infringing patents or proprietary rights of others and not breaching the licenses granted to it or its licensors, as the case may be. There can be no assurance that HLS or its licensors will be able to obtain a license to any third-party technology that may be required to conduct HLS's business or that such technology can be licensed at a reasonable cost. There is no certainty that HLS will not be challenged by its partners for non-compliance with its existing or future licensing arrangements. Consequently, there may be a risk that licensing arrangements are withdrawn with no compensation or penalties to HLS.

HLS will rely on trade secrets, know-how and other proprietary information as well as requiring employees, suppliers and other third-party service providers to sign confidentiality agreements. However, these confidentiality agreements may be

breached, and HLS may not have adequate remedies for such breaches. Others may independently develop substantially equivalent proprietary information without infringing upon any proprietary technology. Third parties may otherwise gain access to HLS's proprietary information and adopt it in a competitive manner. If a third party obtains HLS's proprietary information and adopts it in a competitive manner, it may have a material effect on HLS's business, financial condition and operating results.

## **Product Liability Claims**

The administration of drugs to humans, whether in clinical trials or after marketing clearance is obtained, can result in product liability claims. Product liability claims can be expensive, difficult to defend and may result in large judgments or settlements against HLS. In addition, third-party collaborators and licensees may not protect HLS from product liability claims.

HLS will maintain product liability insurance in connection with the marketing of its products. HLS may not be able to obtain or maintain adequate protection against potential liabilities arising from product sales. If HLS is unable to obtain sufficient levels of insurance at acceptable cost or otherwise protect against potential product liability claims, it will be exposed to product liability claims. A successful product liability claim in excess of its insurance coverage could harm HLS's financial condition, results of operations and prevent or interfere with its product commercialization efforts. In addition, any successful claim may prevent HLS from obtaining adequate product liability insurance in the future on commercially desirable terms. Even if a claim is not successful, defending such a claim may be time-consuming and expensive and would result in HLS needing to divert resources which could otherwise be used in developing its business.

## Unexpected Product Safety or Efficacy Concerns

Unexpected safety or efficacy concerns can arise with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals or declining sales, as well as product liability, consumer fraud and/or other claims. This could have a material adverse effect on HLS's business, financial results and operating results.

## HLS's Significant Debt Liabilities

HLS has significant liabilities, contingent or otherwise, including those incurred in connection with the Royalty Agreement, the Vascepa Agreement, the PERSERIS Agreement, the Trinomia Agreement and the HLS Credit Agreement. HLS's ability to satisfy these liabilities will be contingent upon its success in achieving sufficient revenues from the rights to Clozaril, Vascepa, PERSERIS, Trinomia, MyCare and other products it acquires to be able to make payments when due and payable, including payments of deferred purchase price, milestone payments and payments of loan interest and principal repayment. While HLS was successful in securing financing under the HLS Credit Agreement to repay its liabilities under the 2015 Term Loan, there is no assurance that HLS will be able to secure future additional financing to repay its liabilities under the HLS Credit Agreement or pursuant to the Vascepa Agreement, the PERSERIS Agreement and Trinomia Agreement and as required by the Royalty Agreement should cash flows from operations be insufficient to repay these liabilities. HLS's inability to repay outstanding debt when due would have a material adverse impact on its business.

The obligations of HLS under the HLS Credit Agreement and other related finance documents are secured by substantially all the assets of the Company. In the event of a default in payment on, or of the acceleration of, any of HLS's secured indebtedness, and upon the exercise of the remedies on behalf of the lenders under the HLS Credit Agreement, such enforcement would have a material adverse effect on the business, operations, financial condition and prospects of HLS.

## Failure to Achieve Anticipated Tax Benefits

HLS has a corporate structure which involves operations in lower tax jurisdictions. There can be no assurance that the anticipated tax benefits from HLS's corporate structure or from any particular transaction will be achieved by HLS. In addition, changes in tax laws could negatively impact HLS's business, operations and profitability.

## Publication of Negative Results of Studies or Clinical Trials

From time to time, studies or clinical trials on various aspects of pharmaceutical products are conducted by academics or others, including government agencies. The results of these studies or trials, when published, may have a dramatic effect on the market for the pharmaceutical product that is the subject of the study. The publication of negative results of studies or clinical trials related to HLS's products or the therapeutic areas in which HLS's products compete could adversely affect HLS's sales, the prescription trends for its products and the reputation of its products. In the event of the publication of negative results

of studies or clinical trials related to HLS's products or the therapeutic areas in which HLS's products compete, HLS's business, financial condition, and operating results could be materially adversely affected.

## Estimates, Judgments and Assumptions

The preparation of HLS's consolidated financial statements requires management to make estimates, judgments and assumptions that affect the reported amounts of revenues, expenses, assets and liabilities, and the accompanying disclosures, and the disclosure of contingent liabilities. HLS cannot provide assurance that its estimates, judgments and assumptions with respect to, among other things, revenue recognition, amortization and/or impairment of long-lived assets, income taxes, and fair value of stock-based compensation and/or financial instruments, are accurate or adequate, which could have a material adverse effect on HLS's results of operations, financial condition, and cash flows.

## Risk of Foreign Exchange and Market Rate Fluctuations

HLS may be exposed to fluctuations of the Canadian dollar against certain other currencies because HLS publishes its financial statements in U.S. dollars, while a portion of its assets, liabilities, revenues and costs are or will be denominated in other currencies, such as the Canadian dollar. HLS has borrowed funds under the HLS Credit Agreement in U.S. dollars and has payment obligations under the Royalty Agreement, the Vascepa Agreement and the PERSERIS Agreement in U.S. dollars. Exchange rates for currencies of the countries in which HLS operates may fluctuate in relation to the U.S. dollar, and such fluctuations, especially as between the Canadian dollar and the U.S. dollar, may have a material adverse effect on HLS's earnings or assets when translating foreign currency into U.S. dollars. In order to mitigate the risk, HLS has used forward contracts to reduce its exposure to foreign currency risk and may or may not do so in the future. Dependent on the nature, amount and timing of foreign currency receipts and payments, HLS may from time to time enter into foreign currency contracts. Accordingly, HLS may experience economic loss and a negative impact on earnings solely as a result of foreign exchange rate fluctuations, which include foreign currency devaluations against the U.S. dollar. HLS does not typically carry currency convertibility risk insurance.

## Failure to Successfully Evaluate Material Risks in Completed and Future Investments

HLS will regularly review investment opportunities and as part of the review, conduct business, legal and financial due diligence with the goal of identifying and evaluating material risks involved in any particular transaction. Despite HLS's efforts, it may be unsuccessful in ascertaining or evaluating all such risks. As a result, HLS may not realize the intended advantages of any given investment and may not identify all of the risks relating to the investment. If HLS fails to realize the expected benefits from one or more investments, or does not identify all of the risks associated with a particular investment, HLS's business, results of operations and financial condition could be adversely affected.

## Regulations Restricting Revenue Generating Activities

From time to time, governments, government agencies and industry self-regulatory bodies in Canada, the United States and other countries in which HLS may operate have adopted statutes, regulations and rulings that directly or indirectly affect the activities of HLS and its future products. These regulations could adversely impact on HLS's ability to execute its business strategy and generate revenues as planned.

## Inability to Maintain Effective Internal Controls Over Financial Reporting

HLS's management, with the participation of its Chief Executive Officer and its Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over financial reporting. HLS's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS. Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives due to its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is therefore subject to error, collusion, or improper override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis, and although it is possible to incorporate into the financial reporting process safeguards to reduce this risk, they cannot be guaranteed to entirely eliminate it. If HLS fails to maintain effective internal control over financial reporting, then there is an increased risk of an error in its financial statements that could result in HLS being required to restate previously issued financial statements at a later date.

#### Increases in Interest Rates

Increases in interest rates, both domestically and internationally, could negatively affect HLS's cost of financing its operations and investments. Adverse credit market conditions could limit the Company's ability to refinance its existing credit facility and raise additional debt that may be needed to fund the Company's operations. HLS's ability to maintain its current credit facility and its ability to issue or borrow long-term debt and raise financing are critical to the success of HLS's business. The Company's ability to conduct operations could be materially and adversely impacted should these or other adverse conditions affect the Company's sources of liquidity.

# Compromise of Electronic Data

HLS maintains significant amounts of data electronically in locations around the world. This data relates to all aspects of the Company's business and also contains certain patient or customer data, including potentially sensitive patient personal health information. The Company maintains systems and processes designed to protect this data, but notwithstanding such protective measures, there is a risk of intrusion or tampering that could compromise the integrity and privacy of this data. In addition, HLS provides confidential and proprietary information, or personal health information, to its third party business partners in certain cases where doing so is necessary to conduct the Company's business, and in a manner consistent with the scope of the consent provided. While HLS obtains assurances from those parties that they have systems and processes in place to protect such data, and where applicable, that they will take steps to assure the protections of such data by third parties, nonetheless those partners may also be subject to data intrusion or otherwise compromise the protection of such data. While HLS and its third party business partners maintain systems for preventing and detecting a breach of their respective information technology systems, HLS and those third parties may be unaware that a breach has occurred and may be unable to detect an ongoing breach. HLS has exposure to similar security risks faced by other large companies that have data stored on their information technology systems. To its knowledge, HLS has not experienced any material breach of its cybersecurity systems. If HLS's or any third party service providers' systems fail to operate effectively or are damaged, destroyed, or shut down, or there are problems with transitioning to upgraded or replacement systems, or there are security breaches in these systems, any of the aforementioned could occur as a result of natural disasters, software or equipment failures, telecommunications failures, loss or theft of equipment, acts of terrorism, circumvention of security systems, or other cyber-attacks, HLS could experience delays or decreases in product sales, and reduced efficiency of its operations. Any compromise of the confidential data of HLS's patients, customers or itself, or failure to prevent or mitigate the loss of this data could disrupt HLS's operations, damage its reputation, violate applicable laws and regulations and subject the Company to additional costs and liabilities and have a material and adverse impact on its business, financial condition and performance.

# Inability to Obtain Third Party Reimbursement

The Company's ability to successfully market the Company's products may depend in part on whether appropriate reimbursement levels for the cost of the products and related treatments are obtained from government authorities and private health insurers and other organizations, such as health maintenance organizations and managed care organizations. This reimbursement and the associated governmental healthcare reimbursement systems are under constant review. The Company also could lose the ability to access such reimbursement by government authorities and private health insurers and other organizations as a result of changing laws, policies and practices of such entities.

Third party payors increasingly challenge the pricing of pharmaceutical products. In addition, the trend toward managed health care in the U.S., the growth of organizations such as health maintenance organizations and managed care organizations and legislative proposals to reform health care and government insurance programs in the jurisdictions in which the Company sells its products could significantly influence the purchase of pharmaceutical products, resulting in price changes and/or a reduction in product demand. Such cost containment measures and health care reform could affect the Company's ability to sell its products, which could have a material adverse effect on the Company's business, financial condition and results of operations.

# **Risks Relating to Medical Device Business**

#### Medical Device Regulatory Regime

The commercialization of medical devices in Canada, the U.S. and other jurisdictions are highly regulated, and are regulated in a way that is different from those of pharmaceutical products. These medical device regulations significantly

increase the difficulty and costs involved in obtaining and maintaining regulatory approval for marketing new and existing products, and approval is never guaranteed.

# The Company's Performance Will Depend on Successful Improvements to Existing Products and Services and Commercialization of New Products and Services

This market is characterized by rapid change and technological innovation. The Company's performance depends on the successful commercialization of new products and services that reflect and respond to changes in the marketplace, technology and customer demands and increasingly on our ability to anticipate emerging trends in white blood cell count testing. For various reasons, including the potential inability to comply with complex regulatory regimes, we cannot be sure that we will be able to successfully commercialize new products; and our failure to do so could have a material adverse effect on the Company's business, financial condition and results of operations.

# The Company Competes in Highly Competitive Markets and May Lose Market Share to Companies with Greater Resources or More Effective Technologies

New competitors may enter our markets or existing alternatives may reposition to pursue our market. To compete successfully, we must provide technically superior, proven products that deliver more precise, cost-effective, high quality clinical capabilities, in a complete package of products and services, and do so ahead of our competitors.

# Disruption of HLS's Critical Information Systems or Material Cyberattacks or Security Breaches of HLS's Products May Adversely Affect its Business and Customer Relations

Information technology helps us operate CSAN Pronto efficiently, and to interface with and support our customers and patients. There is an increasing threat of information security attacks for companies such as HLS, and our CSAN Pronto provider. Because the techniques used to obtain unauthorized access, or to sabotage systems, change frequently and generally are not recognized until launched against a target, we may be unable to anticipate these techniques or to implement adequate preventative measures.

We distribute physical medical devices that rely upon cloud-based software systems to operate properly and consumables that are used in conjunction with the medical device to prepare and store the test sample. Both of these products often are connected to and reside within our provider's information technology infrastructures. The measures implemented to protect those may not be effective in securing these products, particularly since techniques used to obtain unauthorized access, or to sabotage systems, change frequently and generally are not recognized until launched against a target.

A security breach, whether of our products, of our customers' network security and systems or of third party hosting services, could disrupt treatments, disrupt access to our customers' stored information, and could lead to the loss of, damage to or public disclosure of our customers' stored information, including patient health information. Such an event could have serious negative consequences, including possible patient injury, regulatory action, fines, penalties and damages, reduced demand for our solutions, an unwillingness of our customers to use our solutions, harm to our reputation and brand, and time consuming and expensive litigation, any of which could have an adverse effect on our financial results.

If we, or our providers, were to experience a significant cyberattack or security breach of our information systems or data, the costs associated with the investigation, remediation and potential notification of the breach to customers and counterparties could be material. Our cybersecurity insurance may be inadequate. In the future, our insurance coverage may become prohibitively expensive and/or not be available on acceptable terms or in sufficient amounts, if at all.

# Tariffs or Cross-Border Trade Restrictions Could Increase the Cost of HLS's Products or their Components/Inputs

Between July 2018 and May 2019, the Trump administration imposed a series of tariffs, ranging from 5% to 25%, on numerous products imported into the United States from China, including certain components used in our CSAN Pronto provider's manufacturing and service activities. These measures, as well as other tariffs or trade restrictions that may be implemented from time to time (including those implemented in response to the war between Russia and Ukraine), could increase the cost of our products, or their components/inputs, and negatively impact our ability to compete effectively.

#### Risks Relating to the Ownership of Common Shares

# Unpredictability and Volatility of Common Share Price

Publicly-traded securities such as the Common Shares do not necessarily trade at values determined by reference to the underlying value of its business. The prices at which the Common Shares trade cannot be predicted. The market price of the Common Shares could be subject to significant fluctuations in response to a variety of factors, including the following: actual or anticipated fluctuations in HLS'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 HLS operates; addition or departure of HLS's executive officers and other key personnel; significant acquisitions or business combinations, strategic partnerships, joint ventures or capital commitments by or involving HLS or its competitors; operating and share price performance of other companies that investors deem comparable to HLS; and news reports relating to trends, concerns, technological or competitive developments, regulatory changes and other related issues in HLS's industry or target markets.

In addition, the securities markets have experienced significant price and volume fluctuations from time to time in recent years that often have been unrelated or disproportionate to the operating performance of particular issuers. These broad fluctuations may adversely affect the market price of the shares of HLS. In addition, in the past, following periods of volatility in the overall market and the market price of a company's securities, securities class action litigation has often been instituted against these companies. This litigation, if instituted against HLS, could result in substantial costs and diversion of management's attention and resources.

#### **Global Financial Conditions**

Global financial conditions have always been subject to volatility. This volatility may impact the ability of HLS to obtain equity or debt financing in the future and, if obtained, on terms favourable to HLS. Increased levels of volatility and market turmoil can adversely impact HLS's operations and the value and the price of Common Shares could be adversely affected.

#### Future Sales of Common Shares by Existing Shareholders

Sales of a substantial number of Common Shares in the public market could occur at any time. These sales, or the market perception that the holders of a large number of Common Shares intend to sell Common Shares, could reduce the market price of the Common Shares.

Holders of Options will generally have an immediate income inclusion for tax purposes when they exercise their Options. As a result, HLS expects that such holders will often wish to sell some or all Common Shares purchased on the exercise of their Options in the same year that they exercise their options of HLS. This may result in a greater number of Common Shares being sold in the public market, and fewer long-term holders of Common Shares by HLS's management and employees.

#### Dividends on the Common Shares Not Guaranteed

Although the Company currently has a policy of paying quarterly cash dividends on the Common Shares (see "Dividends and Dividend Policy"), these cash dividends are not guaranteed and dividends may not be declared. The amount of cash available to the Company to pay dividends, if any, can vary significantly from period to period for a number of reasons, including, among other things: the Company's operational and financial performance; fluctuations in market prices; the amount of cash required or retained for debt service or repayment; amounts required to fund capital expenditures and working capital requirements; access to capital markets; foreign currency exchange rates and interest rates; and the other risk factors set forth in this Annual Information Form.

The decision whether or not to pay dividends and the amount of any such dividends are subject to the discretion of the Board, which evaluates proposed dividend payments and the solvency test requirements of the OBCA. In addition, the level of dividends per Common Share will be affected by the number of outstanding Common Shares and other securities that may be entitled to receive cash dividends or other payments. Dividends may be increased, reduced or suspended depending on the Company's operational success. The market value of Common Shares may deteriorate if HLS is unable to meet dividend expectations in the future, and that deterioration may be material.

# Dilution of Shareholders of HLS

HLS may issue additional equity securities to finance its activities, including in order to finance acquisitions. If HLS were to issue Common Shares, a holder of Common Shares may experience dilution in HLS's cash flow or earnings per share. Moreover, as HLS's intention to issue additional equity securities becomes publicly known, the Common Share price may be materially adversely affected.

#### Concentrated Ownership of Common Shares

HLS's management and directors, together with a small number of institutional shareholders, own a substantial number of the outstanding Common Shares. See "Directors and Executive Officers". As such, HLS's management and directors and these institutional shareholders are in a position to exercise significant influence over matters requiring shareholder approval, including the election of directors and the determination of significant corporate actions. As well, these shareholders could delay or prevent a change in control of HLS that could otherwise be beneficial to HLS shareholders.

#### Publication of Inaccurate or Unfavourable Research and Reports

The trading market for the Common Shares relies in part on the research and reports that securities analysts and other third parties choose to publish about HLS. HLS does not control these analysts or other third parties. The price of the Common Shares could decline if one or more securities analysts downgrade the Common Shares or if one or more securities analysts or other third parties publish inaccurate or unfavourable research about HLS or cease publishing reports about HLS. If one or more analysts cease coverage of HLS or fail to regularly publish reports on HLS, HLS could lose visibility in the financial markets, which in turn could cause the Common Share price or trading volume to decline.

#### Enforcement of Judgements Against Foreign Persons May Not be Possible

Certain officers and directors named in this Annual Information Form, are located outside of Canada and, as a result, it may not be possible for Canadian investors to effect service of process within Canada upon these persons. All or a substantial portion of the assets of these persons are likely to be located outside of Canada and, as a result, it may not be possible to satisfy a judgment against such persons in Canada or to enforce a judgment obtained in Canadian courts against such persons outside of Canada.

# **MATERIAL CONTRACTS**

This Annual Information Form includes a summary description of certain material agreements of the Company. The summary description discloses all attributes material to an investor in securities of the Company but is not complete and is qualified by reference to the terms of the material agreements, which have been filed under the Company's profile on SEDAR at <a href="https://www.sedar.com">www.sedar.com</a>. Investors are encouraged to read the full text of such material agreements.

The only material contract, other than those contracts entered into in the ordinary course of business, that HLS entered into within the most recently completed financial year, or that HLS entered into prior to the most recently completed financial year and that is still in effect, is the Vascepa Agreement.

See "The Company – Narrative Description of HLS's Business – Products and Programs – Vascepa (icosapent ethyl capsules)".

#### INTERESTS OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

There were no material interests, direct or indirect, of the directors or executive officers of HLS, any Common Shareholder that beneficially owns, or controls or directs (directly or indirectly), more than 10% of the outstanding Common Shares, or any associate or affiliate of any of the foregoing persons in any transaction within the three most recently completed financial years or during the current financial year that has materially affected or is reasonably expected to materially affect HLS or any of HLS's subsidiaries.

# **LEGAL PROCEEDINGS**

Management of HLS is not aware of any existing or contemplated legal proceedings material to HLS, or a subsidiary of HLS, to which it is a party or to which its property is the subject.

# TRANSFER AGENT AND REGISTRAR

The transfer agent and registrar for the Common Shares is Computershare Investor Services Inc. at its principal offices in Toronto, Ontario.

#### **EXPERTS**

The Company's auditors are Ernst & Young LLP, located in Toronto, Ontario. Ernst & Young LLP has advised that it is independent of the Company within the meaning of the rules of professional conduct of the Chartered Professional Accountants of Ontario.

# ADDITIONAL INFORMATION

Additional information, including directors' and officers' remuneration, principal holders of the Common Shares and securities authorized for issuance under equity compensation plans, is contained in the Company's management information circular dated May 23, 2022, prepared in connection with the annual meeting of shareholders held on June 17, 2022. Additional financial information is provided in the audited annual consolidated financial statements and MD&A of the Company for the year ended December 31, 2022. Such documentation, as well as additional information relating to the Company, may be found under the Company's profile on SEDAR at <a href="https://www.sedar.com">www.sedar.com</a>.

#### **GLOSSARY**

Certain terms used in this Annual Information Form have the following meanings:

- "2022 NCIB" has the meaning given in "Business of the Company General Development of the Business Year Ended December 31, 2021 Error! Reference source not found.";
- "Absorica Transaction" has the meaning given in "Business of the Company General Development of the Business Year Ended December 31, 2020 Exercise of Put Right in Absorica Transaction";
- "affiliate" means, when describing a relationship between two Persons, that either one of them is under the direct or indirect control of the other, or each of them is directly or indirectly controlled by the same Person;
- "Amarin" has the meaning given in "Business of the Company Narrative Description of HLS's Business Products and Programs Vascepa (icosapent ethyl capsules)";
- "AMD" means Automodular Corporation, a predecessor to HLS;
- "AMD Shareholders" means the registered holders and/or beneficial owners of the AMD Shares, as the context requires;
- "AMD Shares" means the common shares in the capital of AMD;
- "Arrangement" has the meaning given in "The Company Incorporation and Office Address";
- "BCBCA" means Business Corporations Act (British Columbia);
- "Biovail" means Biovail Corporation;
- "Board" means the board of directors of the Company;
- "Boston Scientific" has the meaning given in "Business of the Company General Development of the Business Year Ended December 31, 2020 Acquisition of Royalty Portfolio";
- "business day" means any day, other than a Saturday, a Sunday or a statutory holiday in the Province of British Columbia or the Province of Ontario:
- "CADTH" has the meaning given in "Business of the Company General Development of the Business Year Ended December 31, 2020 CADTH Recommendation and PMPRB Determination";
- "Clozaril Acquisition" has the meaning given in "Business of the Company General Development of the Business Initial Capital Raise";
- "CNS" means central nervous system;
- "Common Shares" means the common shares in the capital of HLS;
- "CrownWheel" means CrownWheel Partners LLC, a wholly-owned portfolio company of Longitude Capital;
- "CSAN" means the Clozaril Support and Assistance Program;
- "CV" means cardiovascular;
- "Directors" means directors of the Company, and "Director" means any one of them;
- "FDA" means the United States Food and Drug Administration;
- "Ferrer" means Ferrer Internacional S.A.;
- "Former HLS" has the meaning given in "The Company-Incorporation and Office Address";

"Former HLS Shareholders" means the registered holders and/or beneficial owners of the Pre-Amalgamation Common Shares, as the context requires;

"Galephar" has the meaning given in "Business of the Company – General Development of the Business – Year Ended December 31, 2020 – Exercise of Put Right in Absorica Transaction";

"HLS Credit Agreement" means the credit agreement dated as of September 29, 2022 among the Company and a syndicate of bank lenders co-led by JPMorgan Chase Bank, N.A. and Silicon Valley Bank pursuant to which the lenders provided the Company with a senior secured term loan with a principal amount of US\$100.0 million and a US\$35.0 million revolving facility of which \$10.0 million was drawn as of the date hereof;

"IFRS" means International Financial Reporting Standards;

"Indivior" has the meaning given in "Narrative Description of HLS's Business – Products and Programs –PERSERIS (risperidone)";

"MyCare Products" has the meaning given in "Business of the Company – General Development of the Business – Year Ended December 31, 2020 – HLS Becomes Exclusive Distributor of MyCare Products and Announces Health Canada Approval";

"NI 52-110" has the meaning given in "Auditor and Audit Committee Information – Composition of the Audit Committee";

"Novartis" means Novartis International AG and/or its affiliates, as the context may require;

"**OBCA**" means *Business Corporations Act* (Ontario);

"Options" means the options to purchase Common Shares awarded under the Stock Option Plan;

"PERSERIS Agreement" has the meaning given in "Narrative Description of HLS's Business – Products and Programs – PERSERIS (risperidone)";

"Person" includes an individual, firm, trust, partnership, association, corporation, joint venture, trustee, executor, administrator, legal representative or government;

"Pfizer" has the meaning given in "Business of the Company – General Development of the Business – Year Ended December 31, 2020 – Acquisition of Royalty Portfolio";

"PMPRB" has the meaning given in "Business of the Company – General Development of the Business – Year Ended December 31, 2020 – CADTH Recommendation and PMPRB Determination";

"Pre-Amalgamation Common Shares" means the common shares in the capital of Former HLS;

"Preferred Shares" means the Class A preferred shares in the capital of HLS;

"Royalty Agreement" means the Membership Interest Purchase Agreement dated September 30, 2020 between HLS and certain entities related to CrownWheel;

"Royalty Portfolio" means the rights to royalty interests based on global sales of (i) the EMBLEM S-ICD System, which is a subcutaneous implantable defibrillator for the treatment of life-threatening ventricular tachyarrhythmias currently marketed by Boston Scientific Corporation; (ii) Obizur, which is a porcine recombinant Factor VIII for Acquired Hemophilia A currently marketed by Takeda Pharmaceutical Company Limited; (iii) Eraxis, which is a IV echinocandin for the treatment of Candidemia and other forms of Candida infections currently marketed by Pfizer; and (iv) Xenpozyme, which is a enzyme replacement therapy for acid sphingomyelinase deficiency, an orphan disease with high unmet medical need, currently marketed by Sanofi Genzyme;

"Saladax" has the meaning given in "Business of the Company – General Development of the Business – Year Ended December 31, 2020 – HLS Becomes Exclusive Distributor of MyCare Products and Announces Health Canada Approval";

"Saladax Agreement" has the meaning given in "Business of the Company – General Development of the Business – Year Ended December 31, 2020 – HLS Becomes Exclusive Distributor of MyCare Products and Announces Health Canada Approval";

"Sanofi Genzyme" has the meaning given in "Business of the Company – General Development of the Business – Year Ended December 31, 2020 – Acquisition of Royalty Portfolio";

"Stock Option Plan" means the Amended and Restated Stock Option Plan of the Company, which was approved by the HLS Board on May 5, 2021 and by holders of Common Shares on June 18, 2021;

"Takeda" has the meaning given in "Business of the Company – General Development of the Business – Year Ended December 31, 2020 – Acquisition of Royalty Portfolio";

"TPD" has the meaning given in "Risk Factors-

Risks Relating to the Business - Inability to Obtain or Maintain Regulatory Approvals";

"Trinomia Agreement" has the meaning given in "Business of the Company – Narrative Description of HLS's Business – Products and Programs – Trinomia (acetyl salicylic acid/atorvastatin/ramipril fixed dose combination capsules)";

"TSX" means the Toronto Stock Exchange;

"TSXV" means the TSX Venture Exchange;

"U.S.", or "U.S.A." means the United States of America; and

"Vascepa Agreement" has the meaning given in "Business of the Company – Narrative Description of HLS's Business – Products and Programs – Vascepa (icosapent ethyl capsules)".

#### APPENDIX A



# HLS THERAPEUTICS INC. <u>AUDIT COMMITTEE MANDATE</u> (this "Mandate")

#### 1. Introduction

The Audit Committee (the "Committee" or the "Audit Committee") of HLS Therapeutics Inc. (the "Company") is a committee of the Board of Directors (the "Board"). The Committee shall oversee the accounting and financial reporting practices of the Company and the audits of the Company's financial statements and exercise the responsibilities and duties set out in this Mandate.

# 2. Membership

#### Number of Members

The Committee shall be composed of three or more members of the Board.

# **Independence of Members**

Each member of the Committee must be independent. "Independent" shall have the meaning, as the context requires, given to it in National Instrument 52-110 *Audit Committees*, as may be amended from time to time.

# Chair

At the time of the annual appointment of the members of the Audit Committee, the Board shall appoint a Chair of the Audit Committee (the "Chair"). The Chair shall be a member of the Audit Committee, preside over all Audit Committee meetings, coordinate the Audit Committee's compliance with this Mandate, work with management to develop the Audit Committee's annual work-plan and provide reports of the Audit Committee to the Board.

#### Financial Literacy of Members

At the time of his or her appointment to the Committee, each member of the Committee shall have, or shall acquire within a reasonable time following appointment to the Committee, 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.

# Term of Members

The members of the Committee shall be appointed annually by the Board. Each member of the Committee shall serve at the pleasure of the Board until the member resigns, is removed, or ceases to be a member of the Board. Unless a Chair is elected by the Board, the members of the Committee may designate a Chair by majority vote of the full Committee membership.

#### 3. Meetings

#### Number of Meetings

The Committee may meet as many times per year as necessary to carry out its responsibilities.

#### Quorum

No business may be transacted by the Committee at a meeting unless a quorum of the Committee is present. A majority of members of the Committee shall constitute a quorum.

#### Calling of Meetings

The Chair, any member of the Audit Committee, the external auditors, the Chairman of the Board, or the Chief Executive Officer or the VP Finance & Administration may call a meeting of the Audit Committee by notifying the Company's Corporate Secretary who will notify the members of the Audit Committee. The Chair shall chair all Audit Committee meetings that he or she attends, and in the absence of the Chair, the members of the Audit Committee present may appoint a chair from their number for a meeting.

#### Minutes; Reporting to the Board

The Committee shall maintain minutes or other records of meetings and activities of the Committee in sufficient detail to convey the substance of all discussions held. Upon approval of the minutes by the Committee, the minutes shall be circulated to the members of the Board. However, the Chair may report orally to the Board on any matter in his or her view requiring the immediate attention of the Board.

#### Attendance of Non-Members

The external auditors are entitled to, at the expense of the Company, attend and be heard at each Audit Committee meeting. In addition, the Committee may invite to a meeting any officers or employees of the Company, legal counsel, advisors and other persons whose attendance it considers necessary or desirable in order to carry out its responsibilities.

# Meetings without Management

The Committee shall hold unscheduled or regularly scheduled meetings, or portions of meetings, at which management is not present.

#### **Procedure**

The procedures for calling, holding, conducting and adjourning meetings of the Committee shall be the same as those applicable to meetings of the Board by default, but the Committee shall have the power to otherwise regulate its procedure.

#### Access to Management

The Committee shall have unrestricted access to the Company's management and employees and the books and records of the Company.

# 4. Duties and Responsibilities

The Committee shall have the functions and responsibilities set out below as well as any other functions that are specifically delegated to the Committee by the Board and that the Board is authorized to delegate by applicable laws and regulations. In addition to these functions and responsibilities, the Committee shall perform the duties required of an audit committee by any exchange upon which securities of the Company are traded, or any governmental or regulatory body exercising authority over the Company, as are in effect from time to time (collectively, the "Applicable Requirements").

#### Financial Reports

#### (a) General

The Audit Committee is responsible for overseeing the Company's financial statements and financial disclosures. Management is responsible for the preparation, presentation and integrity of the Company's financial statements and financial disclosures and for the appropriateness of the accounting principles and the reporting policies used by the Company. The auditors are responsible for auditing the Company's annual consolidated financial statements and for reviewing the Company's unaudited interim financial statements.

# (b) Review of Annual Financial Reports

The Audit Committee shall review the annual consolidated audited financial statements of the Company, the auditors' report thereon and the related management's discussion and analysis of the Company's financial condition and results of operation ("MD&A"). After completing its review, if advisable, the Audit Committee shall approve and recommend for Board approval the annual financial statements and the related MD&A.

# (c) Review of Interim Financial Reports

The Audit Committee shall review the interim consolidated financial statements of the Company, the auditors' review report thereon and the related MD&A. After completing its review, if advisable, the Audit Committee shall approve and recommend for Board approval the interim financial statements and the related MD&A.

#### 5. Review Considerations

In conducting its review of the annual financial statements or the interim financial statements, the Audit Committee shall:

- (i) meet with management and the auditors to discuss the financial statements and MD&A;
- (ii) review the disclosures in the financial statements:
- (iii) review the audit report or review report prepared by the auditors;
- (iv) discuss with management, the auditors and internal legal counsel (if any) as requested, any litigation claim or other contingency that could have a material effect on the financial statements;
- (v) review the accounting policies followed and critical accounting and other significant estimates and judgements underlying the financial statements as presented by management;
- (vi) review any material effects of regulatory accounting initiatives or off-balance sheet structures on the financial statements as presented by management, including requirements relating to complex or unusual transactions, significant changes to accounting principles and alternative treatments under Canadian GAAP;
- (vii) review any material changes in accounting policies and any significant changes in accounting practices and their impact on the financial statements as presented by management;
- (viii) review management's report on the effectiveness of internal controls over financial reporting;
- (ix) review the factors identified by management as factors that may affect future financial results;
- (x) oversee the administration of and review the results of the Company's complaints reporting and whistleblower hotline program; and

(xi) review any other matters, related to the financial statements, that are brought forward by the auditors, management or which are required to be communicated to the Audit Committee under accounting policies, auditing standards or Applicable Requirements.

# (b) Approval of Other Financial Disclosures

The Audit Committee shall review and, if advisable, approve and recommend for Board approval financial disclosure in a prospectus or other securities offering document of the Company, press releases disclosing, or based upon, financial results of the Company and any other material financial disclosure, including financial guidance provided to analysts, rating agencies or otherwise publicly disseminated.

#### Auditors

#### (a) General

The Audit Committee shall be responsible for oversight of the work of the auditors, including the auditors' work in preparing or issuing an audit report, performing other audit, review or attest services or any other related work.

# (b) Nomination and Compensation

The Audit Committee shall review and, if advisable, select and recommend for Board approval the external auditors to be nominated and the compensation of such external auditor. The Audit Committee shall have ultimate authority to approve all audit engagement terms and fees, including the auditors' audit plan.

#### (c) Resolution of Disagreements

The Audit Committee shall resolve any disagreements between management and the auditors as to financial reporting matters brought to its attention.

#### (d) Discussions with Auditors

At least annually, the Audit Committee shall discuss with the auditors such matters as are required by applicable auditing standards to be discussed by the auditors with the Audit Committee. The Audit Committee shall also review on an ongoing basis with the auditors and management significant issues that may arise regarding accounting principles and financial statement presentation, as well as matters concerning the scope, adequacy and effectiveness of the Company's financial controls.

# (e) Audit Plan

At least annually, the Audit Committee shall review a summary of the auditors' annual audit plan. The Audit Committee shall consider and review with the auditors any material changes to the scope of the plan.

# (f) Quarterly Review Report

The Audit Committee shall review a report prepared by the auditors in respect of each of the interim financial statements of the Company.

# (g) Independence of Auditors

At least annually, and before the auditors issue their report on the annual financial statements, the Audit Committee shall obtain from the auditors a formal written statement describing all relationships between the auditors and the Company; discuss with the auditors any disclosed relationships or services that may affect the objectivity and independence of the auditors; and obtain written confirmation from the auditors that they are objective and independent within the meaning of the applicable Rules of Professional Conduct/Code of Ethics adopted by the provincial institute or order of chartered accountants to which the auditors

belong and other Applicable Requirements. The Audit Committee shall take appropriate action to oversee the independence of the auditors.

#### (h) Evaluation and Rotation of Lead Partner

As appropriate, the Audit Committee shall review the qualifications and performance of the lead partner(s) of the auditors and determine whether it is appropriate to adopt or continue a policy of rotating lead partners of the external auditors.

# (i) Requirement for Pre-Approval of Non-Audit Services

The Audit Committee shall approve in advance any retainer of the auditors to perform any non-audit service to the Company that it deems advisable in accordance with Applicable Requirements and Board approved policies and procedures. The Audit Committee may delegate pre-approval authority to a member of the Audit Committee. The decisions of any member of the Audit Committee to whom this authority has been delegated must be presented to the full Audit Committee at its next scheduled Audit Committee meeting.

# (j) Approval of Hiring Policies

The Audit Committee shall review and approve the Company's hiring policies regarding partners, employees and former partners and employees of the present and former external auditors of the Company.

#### (k) Financial Executives

The Committee shall review and discuss with management and the Board the appointment of key financial executives.

#### Internal Controls

#### (1) General

The Audit Committee shall review the Company's system of internal controls.

# (m) Establishment, Review and Approval

The Audit Committee shall require management to implement and maintain appropriate systems of internal controls in accordance with Applicable Requirements, including internal controls over financial reporting and disclosure and to review, evaluate and approve these procedures. At least annually, the Audit Committee shall consider and review with management and the auditors:

- (i) the effectiveness of, or weaknesses or deficiencies in: the design or operation of the Company's internal controls (including computerized information system controls and security); the overall control environment for managing business risks; and accounting, financial and disclosure controls (including, without limitation, controls over financial reporting), non-financial controls, and legal and regulatory controls and the impact of any identified weaknesses in internal controls on management's conclusions;
- (ii) any significant changes in internal controls over financial reporting that are disclosed, or considered for disclosure, including those in the Company's periodic regulatory filings;
- (iii) any material issues raised by any inquiry or investigation by the Company's regulators;
- (iv) the Company's fraud prevention and detection program, including deficiencies in internal controls that may impact the integrity of financial information, or may expose the Company to other significant internal or external fraud losses and the extent of those losses and any disciplinary action in respect of fraud taken against management or other employees who have a significant role in financial reporting; and

(v) any related significant issues and recommendations of the auditors together with management's responses thereto, including the timetable for implementation of recommendations to correct weaknesses in internal controls over financial reporting and disclosure controls.

# Compliance with Legal and Regulatory Requirements

The Audit Committee shall review reports from the Company's Corporate Secretary and other management members on: legal or compliance matters that may have a material impact on the Company; the effectiveness of the Company's compliance policies; and any material communications received from regulators. The Audit Committee shall review management's evaluation of and representations relating to compliance with specific applicable law and guidance, and management's plans to remediate any deficiencies identified.

#### Audit Committee Hotline Whistleblower Procedures

The Audit Committee shall establish a complaints reporting procedure and whistleblower hotline for (a) the receipt, retention, and treatment of complaints received by the Company, including regarding accounting, internal accounting controls, or auditing matters; and (b) the confidential, anonymous submission by employees of the Company of concerns regarding the Company's affairs, including questionable accounting or auditing matters. Any such complaints or concerns that are received shall be reviewed by members of the Audit Committee and, if the Audit Committee determines that the matter requires further investigation, it will direct the Chair of the Audit Committee to engage outside advisors, as necessary or appropriate, to investigate the matter and will work with management and the general counsel (if any) to reach a satisfactory conclusion, in each case in accordance with the Complaints Reporting and Whistleblowing Policy of the Company.

#### Audit Committee Disclosure

The Audit Committee shall prepare, review and approve any audit committee disclosures required by Applicable Requirements in the Company's disclosure documents.

# Delegation

The Audit Committee may, to the extent permissible by Applicable Requirements, designate a sub-committee to review any matter within this mandate as the Audit Committee deems appropriate.

# 6. No Rights Created

This Mandate is a statement of broad policies and is intended as a component of the flexible governance framework within which the Audit Committee, functions. While it should be interpreted in the context of all applicable laws, regulations and listing requirements, as well as in the context of the Company's Articles and by-laws, it is not intended to establish any legally binding obligations.

#### 7. Mandate Review

The Committee shall review and update this Mandate as deemed advisable from time to time and present it to the Board for approval.

REVIEW AND APPROVAL			
Approved By:	Board of Directors	Adopted:	March 12, 2018
		Updated:	October 26, 2018