



**ANNUAL INFORMATION FORM**

**FOR THE YEAR ENDED DECEMBER 31, 2022**

**March 22, 2023**

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## EXPLANATORY NOTES

Unless otherwise stated, the information in this Annual Information Form (“AIF”) is stated as of December 31, 2022, and all references to the Company’s fiscal year are to the year ended December 31, 2022. In this AIF, references to the “Company”, “Cipher”, “we”, “us” and “our” refer to Cipher Pharmaceuticals Inc. and its subsidiaries, unless the context requires otherwise.

Information contained on, or otherwise accessed through, the website of the Company, [www.cipherpharma.com](http://www.cipherpharma.com), shall not be deemed to be a part of this AIF and such information is not incorporated by reference herein and should not be relied upon by readers for the purpose of determining whether to invest in the Common Shares of the Company (the “Common Shares”) or any other securities of the Company.

Unless otherwise indicated, all charts, tables and figures are prepared by the Company’s management.

### Trademarks

This AIF includes trademarks which are protected under applicable intellectual property laws and are the property of the Company or its affiliates. Solely for convenience, the trademarks of the Company referred to in this AIF may appear with or without the ® or ™ symbol, but such references or the absence thereof are not intended to indicate, in any way, that the Company or its affiliates will not assert, to the fullest extent under applicable law, their respective rights or the right of the applicable licensor to these trademarks. Any other trademarks used in this AIF are the property of their respective owners.

### Currency

All references to “\$” in this AIF refer to Canadian dollars and all references to “US\$” are to United States dollars, unless otherwise indicated.

### Market Data

This AIF contains statistical data, market research and industry forecasts that were obtained, unless otherwise indicated, from independent industry and government publications and reports or based on estimates derived from such publications and reports and management’s knowledge of, and experience in, the markets in which the Company operates. Industry and government publications and reports generally indicate that they have obtained their information from sources believed to be reliable, but do not guarantee the accuracy and completeness of their information. While the Company believes this data to be reliable, market and industry data is subject to variation and cannot be verified due to limits on the availability and reliability of raw data, the voluntary nature of the data gathering process and other limitations and uncertainties inherent in any statistical survey. The Company has not independently verified the accuracy or completeness of such information contained herein. Accordingly, we do not guarantee the accuracy or completeness of this data. References in this AIF to research reports or to articles and publications should not be construed as depicting the complete findings of the entire referenced report, article or publication. The information in each research report, article or publication is expressly not incorporated by reference into this AIF. In addition, projections, assumptions and estimates of the Company’s future performance and the future performance of the industry in which the Company operates are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described under the heading “Risk Factors” in this AIF.

## CAUTION REGARDING FORWARD-LOOKING STATEMENTS

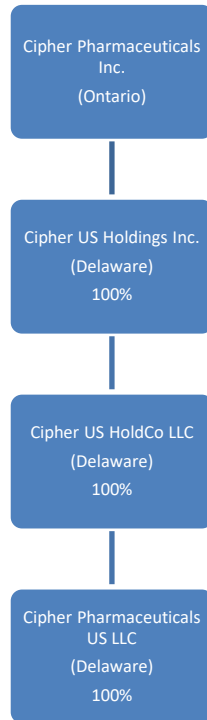
*This document includes forward-looking statements within the meaning of applicable securities laws. These forward-looking statements include, among others, statements with respect to our objectives and goals and strategies to achieve those objectives and goals, as well as statements with respect to our beliefs, plans, expectations, anticipations, estimates and intentions. The words “may”, “will”, “could”, “should”, “would”, “suspect”, “outlook”, “believe”, “plan”, “anticipate”, “estimate”, “expect”, “intend”, “forecast”, “objective”, “hope” and “continue” (or the negative thereof), and words and expressions of similar import, are intended to identify forward-looking statements.*

*By their very nature, forward-looking statements involve inherent risks and uncertainties, both general and specific, which give rise to the possibility that predictions, forecasts, projections and other forward-looking statements will not be achieved. Certain material factors or assumptions are applied in making forward-looking statements and actual results may differ materially from those expressed or implied in such statements. We caution readers not to place undue reliance on these statements as a number of important factors, many of which are beyond our control, could cause our actual results to differ materially from the beliefs, plans, objectives, expectations, anticipations, estimates and intentions expressed in such forward-looking statements. These factors include, but are not limited to, the extent and impact of the coronavirus (COVID-19) outbreak on our business, our ability to enter into in-licensing, development, manufacturing and marketing and distribution agreements with other pharmaceutical companies and keep such agreements in effect; our dependency on a limited number of products; our dependency on protection from patents that will expire; integration difficulties and other risks if we acquire or in-license technologies or product candidates; reliance on third parties for the marketing of certain products; the product approval process is highly unpredictable; the timing of completion of clinical trials, regulatory submissions and regulatory approvals; reliance on third parties to manufacture our products and events outside of our control that could adversely impact the ability of our manufacturing partners to supply products to meet our demands; we may be subject to future product liability claims; unexpected product safety or efficacy concerns may arise; we generate license revenue from a limited number of distribution and supply agreements; the pharmaceutical industry is highly competitive; requirements for additional capital to fund future operations; products in Canada may be subject to pricing regulation; dependence on key managerial personnel and external collaborators; certain of our products are subject to regulation as controlled substances; limitations on reimbursement in the healthcare industry; the publication of negative results of clinical trials; rising insurance costs; ability to enforce covenants not to compete; risks associated with the industry in which we operate; we may be unsuccessful in evaluating material risks involved in completed and future acquisitions; we may be unable to identify, acquire or integrate acquisition targets successfully; compliance with privacy and security regulation; our policies regarding returns, allowances and chargebacks may reduce revenues; additional regulatory burden and controls over financial reporting; general commercial litigation, class actions, other litigation claims and regulatory actions; the difficulty for shareholders to realize in the United States upon judgments of U.S. courts predicated upon civil liability of the Company and its directors and officers who are not residents of the United States; the potential violation of intellectual property rights of third parties; our efforts to obtain, protect or enforce our patents and other intellectual property rights related to our products; changes in U.S., Canadian or foreign patent laws; inability to protect our trademarks from infringement; shareholders may be further diluted if we issue securities to raise capital; volatility of our share price; fact that we have a significant shareholder; we do not currently intend to pay dividends; our operating results may fluctuate significantly; and our debt obligations will have priority over the Common Shares in the event of a liquidation, dissolution or winding up.*

*We caution that the foregoing list of important factors that may affect future results is not exhaustive. When reviewing our forward-looking statements, investors and others should carefully consider the foregoing factors and other uncertainties and potential events. Additional information about factors that may cause actual results to differ materially from expectations, and about material factors or assumptions applied in making forward-looking statements, may be found in the “Risk Factors” section of this AIF and in our Management’s Discussion and Analysis for the year ended December 31, 2022, and elsewhere in our filings with Canadian securities regulators. Except as required by Canadian securities laws, we do not undertake to update any forward-looking statements, whether written or oral, that may be made from time to time by us or on our behalf; such statements speak only as of the date made. The forward-looking statements included herein are expressly qualified in their entirety by this cautionary language.*

## CORPORATE STRUCTURE

Cipher Pharmaceuticals Inc. was formed by articles of incorporation under the *Business Corporations Act* (Ontario) (the “OBCA”) on January 9, 2004. The Company’s head office is located at 5750 Explorer Drive, Suite 404, Mississauga, ON L4W 0A9 and its registered office is located at 209 Oak Park Boulevard, Suite 501, Oakville, Ontario, L5H 0M2. The following chart illustrates Cipher’s relationship to its subsidiaries as at December 31, 2022.



## GENERAL DEVELOPMENT OF THE BUSINESS

### History of the Company

This section describes the important developments for the Company in general and for its products over the last three completed financial years. Additional details related to the Company’s products are included in the “Commercial Products” section of this document.

### Developments in 2020

On January 13, 2020, the Company received a notice of termination from Bausch Health for alleged breach of contract in respect of its licensing agreement for Trulance® (plecanatide), a Guanylate cyclase-C (GCC) agonist in the form of a once-daily tablet for the treatment of adults with irritable bowel syndrome with constipation.

On February 6, 2020 the Company announced that Sun Pharmaceutical Industries, Inc. (previously Ranbaxy Laboratories Inc.) (“Sun”), the Company’s U.S. marketing partner for Absorica, launched ABSORICA LD (isotretinoin) capsules in the U.S. for the management of severe recalcitrant nodular acne in patients 12 years of age and older.

On April 20, 2020 the Company announced that it had been successful in its binding arbitration with Upsher Smith Laboratories, LLC (“Upsher Smith”). For additional details refer to "*Commercial Products - CIP-ISOTRETINOIN (Absorica®/Epuris®)*".

On August 12, 2020, the Company announced that it had filed and the Toronto Stock Exchange had accepted a notice of intention to make a normal course issuer bid. Pursuant to the notice, Cipher was permitted, during the 12-month period commencing August 17, 2020 and ending on August 16, 2021, to purchase for cancellation under the normal course issuer bid (the "NCIB") up to 1,613,592 of its Common Shares, representing 10% of its public float of

16,135,923 Common Shares as of August 5, 2020 (a total of 27,046,396 Common Shares were issued and outstanding as of such date).

On October 8, 2020, the Company announced that shareholders of the Company had elected Cathy Steiner to the Company's board of directors (the "Board" or "Board of Directors") at the annual meeting of shareholders. Ms. Steiner has over 20 years' experience as an investment banker and strategic advisor working with healthcare companies.

On October 31, 2020, the Company paid the last installment of \$1.666 million towards the balance of its credit facility. That concluded the Company's obligation of the credit facility towards its Canadian lender.

### **Developments in 2021**

In January 2021, CIPHER received the results of an arbitration hearing, in which CIPHER was found to be in breach of the agreement with Bausch Health and therefore the licensing agreement for Trulance was terminated. As a result, the Company recorded an impairment charge of \$5.275 million as of December 31, 2020.

On February 10, 2021 CIPHER announced that it had entered into an exclusive co-promotion agreement with Verity Pharmaceuticals Inc. ("Verity") for the marketing, sales and co-promotion of Brinavess, Aggrastat and Trevyent. Under the terms of the agreement, Verity is responsible for the co-promotion of all hospital products inclusive of all costs and expenses associated with those products. Verity is compensated by receiving a tiered percentage of the net margin of the products.

On March 25, 2021 CIPHER announced that it had received approval from the Toronto Stock Exchange to amend its NCIB in order to enter into an automatic repurchase plan with its designated broker to allow CIPHER to provide standard instructions and the purchase Common Shares on the open market during self-imposed blackout periods. Outside of these periods Common Shares can be repurchased in accordance with management's discretion and in compliance with applicable law.

On September 8, 2021, the Company announced the Toronto Stock Exchange had accepted a notice of intention to make a NCIB. Pursuant to the notice, CIPHER was permitted, during the 12-month period commencing September 10, 2021, to purchase for cancellation under the NCIB up to 1,541,445 of its Common Shares, representing 10% of its public float of 15,414,450 Common Shares as of August 27, 2021 (a total of 26,485,401 Common Shares were issued and outstanding as of such date).

### **Developments in 2022**

On March 10, 2022, CIPHER announced that it had entered into an amended and restated distribution and supply agreement (the "Absorica Amended and Restated Agreement") with Sun. Under the terms of the Absorica Amended and Restated Agreement, CIPHER and Sun agreed to extend Sun's exclusive right to market, sell and distribute the isotretinoin product portfolio, Absorica and Absorica AG in the United States through December 31, 2026 and Absorica LD through December 31, 2024. Under the terms of the Absorica Amended and Restated Agreement, CIPHER will continue to earn a royalty on United States net sales from the Sun isotretinoin product portfolio, and will continue to be responsible for manufacturing the supplied product. The Absorica Amended and Restated Agreement extended the relationship with Sun from November 30, 2022 until December 31, 2026.

On March 22, 2022, CIPHER announced that its partner, Moberg Pharma AB ("Moberg") had submitted a regulatory filing for the next clinical Phase 3 study for MOB-015 (nail fungus treatment for which CIPHER holds the exclusive Canadian rights) to the U.S. Food and Drug Administration (the "FDA").

On June 22, 2022, CIPHER held its annual and special meeting of shareholders at which Dr. John Mull decided not to stand for re-election. The Board was comprised of Craig Mull, Chairman and directors (i) Harold Wolkin, (ii) Christian Godin, (iii) Arthur Deboeck and (iv) Cathy Steiner.

On August 11, 2022, CIPHER announced the appointment of Bryan Jacobs as Chief Financial Officer effective August 15, 2022.

On September 19, 2022, Cipher announced that it had filed and the Toronto Stock Exchange had accepted a notice of intention to make a NCIB. Pursuant to the notice, Cipher was permitted, during the 12-month period commencing September 22, 2022, to purchase for cancellation under the NCIB up to 1,403,293 of its Common Shares, representing 10% of its public float of 14,032,934 Common Shares as of September 8, 2022 (a total of 25,115,660 Common Shares were issued and outstanding as of such date).

### **Developments in 2023 to Date**

On March 1, 2023, Cipher announced the closing of a new US\$35 million credit facility with Royal Bank of Canada (the "Credit Facility"). The Credit Facility is structured as a US\$15 million Senior Secured Revolving Term Loan (the "Term Loan") with an additional accordion option to be increased by US\$10 million. Additionally, the Credit Facility has a US\$10 million Senior Secured Revolving Credit Facility (the "Revolving Loan") for general corporate purposes and working capital requirements. The initial term of the Term Loan is 3 years and the Revolving Loan is payable on demand. The Credit Facility bears interest at market prevailing rates once drawn upon.

## **THE BUSINESS**

### **General**

Cipher is a specialty pharmaceutical company with a diversified portfolio of commercial and early to late-stage products. Cipher acquires products that fulfill unmet medical needs, manages the required clinical development and regulatory approval process, and currently markets these products either directly in Canada or indirectly through partners in Canada, the U.S. and Latin America.

### **Strategy**

Cipher's corporate strategy includes the following components:

- strategically market and distribute its Canadian commercial assets indirectly, by way of partnerships;
- out-license products in markets where Cipher does not have a commercial presence;
- selectively invest in drug development programs where we see a favourable risk/return profile;
- conservatively manage capital and maximize cashflow; and
- distribute products through established sales organizations using a royalty based model.

Cipher is actively managing the advancement of our product pipeline development programs including:

- The MOB-015 product for the treatment of nail fungus with our partner Moberg Pharma AB ("Moberg"), presently in phase 3 clinical trials in the U.S.
- Completion of pre-clinical studies for our DTR-001 topical product treatment for the removal of tattoos.
- The Piclidenoson CF-101 program with our partner Canfite, which recently announced positive top-line results from its Phase III COMFORT study of Piclidenoson in the treatment of moderate to severe psoriasis.

The Company is actively assessing and sourcing opportunities that would build on the strengths of the organization, including strategic commercial deployment in Canada. The execution of any transaction is contingent on the Company being able to negotiate acceptable terms and securing the necessary financing.

### **Significant Partnerships**

#### ***Galephar***

In 2002, the Company entered into a Master Licensing and Clinical Supply Agreement (such agreement as amended from time to time being referred to herein as the "Galephar Agreement") with Galephar, a Puerto Rico based pharmaceutical research and manufacturing company. Under the Galephar Agreement, the Company acquired the rights to package, test, obtain regulatory approvals and market CIP-FENOFIBRATE, CIP-ISOTRETINOIN and CIP-



TRAMADOL ER (collectively, the “CIP Products”) in various territories. In particular, the Company has the rights to sell, market and distribute, on a perpetual basis, as follows:

- exclusive rights throughout the world for Galephar’s capsule formulation of Tramadol;
- exclusive rights in North, South and Central America, the Caribbean and Bermuda for Galephar’s capsule formulation of Isotretinoin and non-exclusive rights in certain other countries; and
- exclusive rights in North, South and Central America, the Caribbean and Bermuda for Galephar’s capsule formulation of Fenofibrate and non-exclusive rights in certain other countries.

The Galephar Agreement gives the Company the right to conduct all studies and tests required by the FDA and other regulatory authorities in the geographic area where the pharmaceutical product is being packaged, tested, approved and/or marketed, as well as the right to prepare, file and prosecute any regulatory submissions for approval in such geographic area. Milestone payments for these products have been paid in full.

On sales by Cipher or its affiliates of those products set out in the Galephar Agreement, Cipher is obliged to pay Galephar fifty percent (50%) of any (i) distribution fees it receives, (ii) net sales revenue less manufacturing costs and (iii) royalties received, except that if a patent has not yet been issued for such product, only 30% of royalties are payable. If Cipher or its affiliates are directly selling to wholesalers, an amount equal to 12% of net sales received by Cipher is payable to Galephar, or 7% prior to issuance of a patent. No payments are required with respect to a sale of a product occurring 20 years after the first sale of that product in the country or, if a patent is obtained, when the patent lapses in that country for the product, whichever is later. Galephar also supplies product to Cipher through commercial supply agreements for each product.

On May 11, 2017, the founder, vice president and a shareholder of Galephar was elected to the Company’s Board of Directors as a non-independent member.

Certain of the Company’s marketed products utilize drug delivery technologies licensed from Galephar:

*Oral Lidose® Technology.* Galephar’s oral semi-liquid capsule drug delivery technology is a patent-protected drug delivery system. Active ingredients are incorporated in semi-solid or liquid compositions contained in capsules. This delivery system facilitates low manufacturing costs, while delivering super-bioavailability for relatively water-insoluble compounds. CIP-FENOFIBRATE and CIP-ISOTRETINOIN are based on the Lidose drug delivery system.

*Oral Controlled-Released Bead Technology.* Galephar’s multiple particle-controlled release capsule technology (“MPCRC”), is based on unique extrusion and spherization methods, and produces beads containing up to 80% active ingredient. Each coated bead is a controlled release system in itself, and the multi-particulate system provides smooth consistent plasma levels over an extended period of time. The system is virtually pH-independent enabling the product to be taken with or without food. MPCRC enables CIP-TRAMADOL ER.

## Commercial Products

The following is a description of the Company’s currently marketed products:

### ***CIP-ISOTRETINOIN (Absorica®/Epuris®)***

CIP-ISOTRETINOIN is an innovative formulation of the active ingredient isotretinoin, which is used in the treatment of severe acne. CIP-ISOTRETINOIN has been in-licensed from Galephar and is based on the Lidose drug delivery system. The Company’s marketing rights to CIP-ISOTRETINOIN include North and South America, and a majority of the Pacific Rim. CIP-ISOTRETINOIN provides more consistent absorption under fed and fasted conditions. Due to its high lipophilicity, oral absorption of isotretinoin is enhanced when given with a high fat meal. CIP-ISOTRETINOIN is bioequivalent to Accutane (isotretinoin) capsules when both drugs are taken with a high-fat meal. However, when both drugs are taken under fasted conditions, CIP-ISOTRETINOIN provides 83% greater absorption than Accutane® (isotretinoin) capsules.

### *United States*

In August 2008, the Company entered into a definitive development, distribution and supply agreement with Sun (the “Sun Agreement”), under which Sun was granted the exclusive right to market, sell and distribute CIP-ISOTRETINOIN in the U.S. Under the terms of the Sun Agreement, the Company received an initial upfront payment of US\$1.0 million. The Sun Agreement also provided for additional pre- and post-commercialization milestone payments of up to US\$23.0 million, all of which have been received. The Company receives a royalty percentage on net sales. The Company is responsible for product supply and manufacturing, which is fulfilled by Galephar. The Sun Agreement was for a period of 10 years from the first commercial sale and Sun had the right to extend the term for additional two-year periods.

In May 2012, the Company received FDA approval for CIP-ISOTRETINOIN in the U.S., and in November 2012, Sun launched Absorica in the U.S. market.

In September 2013, Sun received a Paragraph IV Certification Notice of filing from Actavis of an abbreviated new drug application (“ANDA”) to the FDA for a generic version of Absorica (isotretinoin capsules). A Paragraph IV Certification Notice is filed when the sponsor company of the ANDA believes that its generic product is not infringing on a particular patent, and/or that such patent is not valid. A patent infringement lawsuit against Actavis was filed by Sun, Cipher and Galephar in October 2013 and, as a result, the ANDA was subject to a 30-month stay of FDA approval, beginning on the date the notification letter was received. In October 2015, the Company, along with Sun and Galephar, entered into a settlement agreement with Actavis that dismissed the patent litigation suit. As part of the settlement agreement, Cipher, Sun and Galephar entered into a non-exclusive license agreement with Actavis under which Actavis was permitted to begin selling its generic version of Absorica in the U.S. on December 27, 2020 (approximately nine months prior to the expiration of Absorica’s five patents in September 2021) or earlier under certain circumstances. The settlement agreement was subject to review and no further action was requested by the U.S. Federal Trade Commission and the U.S. Department of Justice.

In July 2018, the Company entered into the Absorica Amendment which provided Sun with the right to launch new isotretinoin products prior to the expiration of the Sun Agreement in November 2022. The Company is entitled to receive a royalty until December 2024 based on U.S. net sales from Sun’s isotretinoin product portfolio. On February 3, 2020, Sun launched their new isotretinoin products under the brand name of Absorica LD.

On December 19, 2018, the Company received notice of a Paragraph IV Certification in ANDA No. 212333 advising Sun, Sun Pharmaceutical Industries, Ltd and Galephar that Upsher Smith has filed an ANDA with the FDA seeking approval to manufacture, use, or sell a generic version of Absorica (10 mg, 20 mg, and 30 mg) prior to the expiration of U.S. Patent Nos. 7,435,427; 8,367,102; 8,952,064; 9,078,925; and 9,089,534. On January 30, 2019, Sun, Cipher and Galephar filed a complaint against Upsher Smith asserting infringement of the five patents. On February 12, 2019, Upsher Smith filed its answer to the complaint. On March 9, 2020, an arbitration meeting was held. On April 20, 2020, the Company announced that it had been successful in its binding arbitration with Upsher Smith.

In March 2022, the Company entered into the Absorica Amended and Restated Agreement. Under the terms of the Absorica Amended and Restated Agreement, Cipher and Sun agreed to extend Sun's exclusive right to market, sell and distribute the isotretinoin product portfolio, Absorica and Absorica AG in the United States through December 31, 2026 and Absorica LD through December 31, 2024. Under the terms of the Absorica Amended and Restated Agreement, Cipher will continue to earn a royalty on United States net sales from the Sun isotretinoin product portfolio, and will continue to be responsible for manufacturing the supplied product. The Absorica Amended and Restated Agreement extended the relationship with Sun from November 30, 2022 until December 31, 2026. In addition, the Absorica New Drug Application (“NDA”) will be returned to the Company on expiry of the Absorica Amended and Restated Agreement.

According to Symphony Health, the U.S. isotretinoin prescription market decreased approximately 2.9% for 2022 compared to 2021.

#### *Canada*

In November 2012, the Company received approval from Health Canada for CIP-ISOTRETINOIN under the trade name Epuris. In June 2013, Cipher launched Epuris in the Canadian market with a dedicated sales force. According to IQVIA, the Canadian market for oral isotretinoin was approximately \$38.6 million in 2022 compared to \$38.9 million in 2021. In December 2022, Epuris had a prescription market share of over 43% in Canada. There is no

patent protection for Epuris in Canada. The Company purchases Epuris from Galephar and pays a single-digit royalty to Galephar on net sales of Epuris in Canada.

#### *Rest of World*

In January 2018, the Company entered into a distribution and supply agreement with Italmex Pharma S.A. ("Italmex") granting Italmex the exclusive rights to market, sell and distribute isotretinoin products in Mexico. The Distribution and Supply agreement was assigned by Cipher to Galephar in May 2020 in exchange for a royalty on net sales. Under the terms of the agreement with Italmex, Italmex was required to pay an upfront payment and payments for additional regulatory and commercial milestones being achieved. Galephar will manufacture and supply the product to Italmex. Italmex will be responsible for all regulatory activities associated with gaining and maintaining regulatory approval of the product in Mexico.

In August 2019, Italmex submitted their dossier to Mexican regulatory agency, COFEPRIS, for review. In October 2021, Italmex received approval of Epuris 10mg and 20mg in Mexico by COFEPRIS. Upon achievement of certain regulatory milestones, payments totalling up to \$175,000 were due. During 2020, one regulatory milestone was achieved, and a payment of \$120,000 was made, which was split equally between Cipher and Galephar. During 2021, a second regulatory milestone was achieved and a payment of \$55,000 was made, which was split equally between Cipher and Galephar.

#### ***CIP-FENOFIBRATE (Lipofen®)***

CIP-FENOFIBRATE was in-licensed from Galephar in November 2000. CIP-FENOFIBRATE is a novel patented formulation of the active ingredient fenofibrate, which is used in the treatment of Hyperlipidemia, a cholesterol disorder. Hyperlipidemia is a condition characterized by high levels of low-density lipoprotein ("LDL") cholesterol and/or triglycerides (a type of fat found in the blood). Fenofibrate is known to lower LDL cholesterol and triglycerides and increase high-density lipoproteins ("HDL"), known as "good cholesterol".

The market for existing fenofibrate formulations in the U.S. was approximately US\$490.7 million in 2022 compared to US\$606.5 million in 2021, according to Symphony Health. CIP-FENOFIBRATE is based on the Lidose delivery system. The drug was approved under the label Lipofen in three dosages: 50 mg, 100 mg, and 150 mg. All patents for this product have expired.

#### *United States*

In September 2021, Cipher entered into a distribution and supply agreement (the "ANI Agreement") with ANI Pharmaceuticals, Inc. ("ANI"). Under the ANI Agreement, ANI was granted the exclusive right to market, sell and distribute Lipofen and fenofibrate in the United States (previously this right was held by Know Pharmaceuticals America Inc.). The ANI Agreement is for a period of five years and ANI has the right to extend the term for two additional two-year periods. The Company receives a royalty on a percentage of net profit. After product-related expenses are deducted, approximately 50% of net revenue received by Cipher under the ANI Agreement is paid to Galephar. The Company is responsible for product supply and manufacturing, which is fulfilled by Galephar.

Prescriptions for Lipofen and the authorized generic were down approximately 2.8% in 2022 compared to 2021, according to Symphony Health.

#### ***CIP-TRAMADOL ER (ConZip® / Durela®)***

CIP-TRAMADOL ER was in-licensed from Galephar on an exclusive worldwide basis in January 2001. CIP-TRAMADOL ER is a novel, extended-release formulation of the active ingredient tramadol, which is used for the management of moderate to moderately severe pain. Tramadol is a synthetic opioid molecule, which was developed to have the analgesic efficacy of the opioid family of drugs without the well-known side effects, including addiction. CIP-TRAMADOL ER is enabled by oral controlled-release beads, an extended-release drug delivery technology licensed from Galephar. The novel formulation means that CIP-TRAMADOL ER delivers extended-release drug

delivery properties, with once-daily dosing, supporting ease-of-use for physicians, and a high level of compliance among chronic pain sufferers.

In May 2010, the FDA approved CIP-TRAMADOL ER and in October 2010, the U.S. Patent and Trademark Office (“USPTO”) issued a patent for the product that expired in 2022.

#### *United States*

In June 2011, Cipher entered into a distribution and supply agreement with Vertical Pharmaceuticals Inc. (“Vertical”), a U.S.-based specialty pharmaceutical company, under which Vertical was granted the exclusive right to market, sell and distribute CIP-TRAMADOL ER under the trade name ConZip in the U.S. (the “ConZip Distribution and Supply Agreement”). The Company received an up-front payment of US\$0.5 million and a payment of US\$0.75 million upon launch of the product in 2011. In 2015, a milestone payment of US\$0.75 million was received for the achievement of a sales level. The Company also receives a five percent royalty on net sales. The Company is responsible for product supply and manufacturing, which is fulfilled by Galephar.

According to Symphony Health, the U.S. market in 2022 for extended release formulations of tramadol was US\$77.2 million, which represents approximately 44% of the total tramadol immediate release and extended release prescription market compared to US\$79.1 million in 2021, which represented approximately 43% of the total tramadol immediate release and extended release prescription market.

In 2016, the FDA required a new black box warning for tramadol products on the risks of addiction, abuse, misuse, life-threatening respiratory depression and interactions with CNS depressants including alcohol. In addition, the FDA said that a new Risk Evaluation and Mitigation Strategy (“REMS”) program would be required. In September 2017, the Company received a letter from the FDA requiring Cipher to commit to a post-approval REMS program. In 2018, Cipher joined the industry consortium REMS program for opioid analgesic drugs in the U.S. and continues to be a participating member of this program.

In June 2017, the Company requested a full waiver from a post-marketing pediatric study post-approval commitment to assess the pharmacokinetics, efficacy and safety of tramadol for the management of moderate to moderately severe chronic pain in pediatric patients aged 2 to 17. In August 2017, the Company received a partial waiver from the FDA that amended the age group required for the study. The new requirement is to study the pharmacokinetics, efficacy and safety of ConZip for the management of pain severe enough to require daily around-the-clock, long-term opioid treatment for which alternative treatment options are inadequate in pediatric patients ages 12 to less than 17 years. In 2020, the Company conducted a review of tramadol use in the pediatric population and submitted an updated proposal to the FDA on September, 17, 2020 to address the pediatric post-marketing requirement. On July 14, 2021, the Company received confirmation from the FDA that an additional pediatric study with Conzip is not required and officially released Cipher from this post-marketing requirement.

#### *Canada*

In August 2011, Cipher received Health Canada approval for CIP-TRAMADOL ER. Cipher distributes CIP-TRAMADOL ER in Canada (formerly distribution was through Nuvo Pharmaceuticals Inc).

According to IQVIA, the Canadian market for extended-release tramadol was approximately \$16.9 million in 2022 compared to \$18.4 million in 2021.

The patents issued for CIP-TRAMADOL ER in Canada expired in 2022.

Due to the increased focus on opioid abuse in Canada, Health Canada is strengthening their post market oversight of prescription opioids. As a result, the Minister has imposed terms and conditions on DURELA in a letter sent October 17, 2018, which required the Company to prepare a targeted Risk Management Plan (“t-RMP”) by January 15, 2019. The Company submitted the t-RMP which proposed multiple surveillance tactics that precluded the need for a post-marketing study.

On June 28, 2019, the Company received the review decision from Health Canada stating that the t-RMP is acceptable pending a few revisions. There is no requirement for an additional post-marketing study as the characterization of use of tramadol in the real world can be obtained through Canadian data sources that can identify

problematic opioid use indicators. The revised t-RMP for Durela was submitted to Health Canada in the first quarter of 2020.

In June 2018, Health Canada issued a notice of intent to all tramadol manufacturers indicating it has initiated efforts to add tramadol to Schedule I of the *Controlled Drugs and Substance Act* and the Schedule to the Narcotic Control Regulations. The effective date of this proposed change was April 1, 2022. The Company addressed the changes in the labelling and packaging required in the tramadol supply chain.

#### *Rest of World*

In April 2013, Cipher entered into a distribution and supply agreement with Tecnofarma International Ltd. (“Tecnofarma”) under which Tecnofarma was granted the exclusive right to market, sell and distribute CIP-TRAMADOL ER in Latin America (the “Tecnofarma Agreement”). Tecnofarma, headquartered in Uruguay, operates in 18 Latin American countries and plans to launch the product in certain territories, including Brazil and Mexico. Under the terms of the Tecnofarma Agreement, Cipher received an upfront payment and is eligible for additional milestones based upon regulatory approval in Brazil and Mexico. Cipher will supply product to Tecnofarma and product manufacturing will be fulfilled by Galephar. Tecnofarma launched CIP-TRAMADOL ER in Argentina in May 2016.

In February 2019, the Company was notified by its partner in Brazil that the application for registration with the National Agency of Sanitary Surveillance was completed. The two highest strengths of tramadol (200mg and 300mg) were not approved, however the 100mg strength was approved subject to additional information being provided to the agency on chemistry and manufacturing. The Company and its partner are considering their options to address the issues raised in the rejection notice.

#### **ACTIKERALL<sup>®</sup>**

In May 2015, Cipher acquired the Canadian rights to Actikerall from Almirall (the “Actikerall Agreement”). Actikerall (0.5% fluorouracil and 10% salicylic acid) is indicated for the topical treatment of slightly palpable and/or moderately thick hyperkeratotic actinic keratosis (Grade I/II) of the face, forehead, and balding scalp in immunocompetent adult patients. Actinic keratosis, also known as solar keratosis, is a skin condition caused by exposure to ultraviolet radiation. Actikerall has been shown to be superior to placebo and non-inferior to diclofenac gel in the treatment of actinic keratosis. The product was approved by Health Canada on July 31, 2014. Under the terms of the Actikerall Agreement, Almirall received an upfront payment of \$0.45 million for the rights to Actikerall and is eligible for certain milestones from product sales in Canada. The Company pays a royalty on net sales that includes the transfer price for finished goods. Almirall supplies finished product to Cipher. The Actikerall Agreement is for a term of 10 years, which commenced in April 2015, with automatic annual renewals.

The Company launched Actikerall in the Canadian market on February 22, 2016. For the year ended December 2022, Actikerall captured approximately 10.6% of the actinic keratosis market on a prescription basis, according to IQVIA.

#### **VANIQA<sup>®</sup>**

In May 2015, Cipher acquired the Canadian rights to Vaniqa from Almirall S.A. (the “Vaniqa Agreement”). Vaniqa is a prescription cream clinically proven to reduce the growth of unwanted facial hair in women. Vaniqa cream is an enzyme inhibitor and works by blocking an enzyme necessary for hair to grow. The product was approved by Health Canada in May 2001. The Company pays a royalty on net sales that includes the transfer price for finished goods. Almirall supplies finished product to Cipher. The Vaniqa Agreement is for a term of 10 years, which commenced in March 2015, with automatic annual renewals. The Company launched Vaniqa in the Canadian market on June 2, 2015. Vaniqa prescriptions grew by approximately 2.6% year over year in 2022.

#### **BRINAVESS<sup>®</sup>**

Brinavess was approved by Health Canada in March 2017 for the rapid conversion of recent onset atrial fibrillation (“AF”) to sinus rhythm in adults, for non-surgery patients with AF of seven days or less and for use in post-cardiac surgery patients with AF of three days or less. The approval from Health Canada included a requirement that Cardiome conduct a post-marketing study. The proposed study design is a retrospective observational registry

conducted in patients receiving Brinavess in Canada. The study will characterize prescription practices and the profile of patients receiving Brinavess and will assess the safety of Brinavess in the Canadian real-world setting. Cipher did submit data from the European post-marketing study (SPECTRUM) to Health Canada as part of the post-marketing safety requirement. Data from this real world study did not indicate any new or heightened safety signals. On January 30, 2020, Health Canada agreed to postpone the commitment of a Canadian Registry study due to feasibility concerns associated with current limited market uptake of Brinavess® in Canada and, therefore, restricted ability to enroll patients. However, should market conditions improve, Cipher's commitment to conduct the Canadian Registry study may be reconsidered. Health Canada maintained the requirement for a Drug Utilization Survey. That survey will be addressed once market conditions improve. Five Canadian patents have been issued for Brinavess®, the latest expiring in 2031.

The Company acquired the exclusive Canadian rights to Brinavess as part of the acquisition of the Canadian business portfolio of Cardiome and re-launched Brinavess in October 2018. Advanz Pharma supplies the finished product to the Company.

### ***AGGRASTAT®***

Aggrastat contains tirofiban hydrochloride, which is a reversible GP IIB/IIIa inhibitor (an intravenous anti-platelet drug) for use in patients with Acute Coronary Syndrome. Aggrastat is used to help assist the blood flow to the heart and to prevent chest pain and/or heart attacks (both ST-segment elevation myocardial infarction ("STEMI"), and non-ST-elevation acute myocardial infarction ("NSTEMI-ACS")). It works by preventing platelets, cells found in the blood, from forming into blood clots within the coronary arteries and obstructing blood flow to the heart muscle (myocardium), which can result in a heart attack. The medicine may also be used in patients whose heart vessels are dilated with a balloon (percutaneous coronary intervention "PCI"), a procedure used to open up three blocked or obstructed arteries in the heart in order to improve the blood flow to the heart muscle with or without the placement of a coronary stent. Aggrastat is administered intravenously and has been on the market for many years. In Canada, Aggrastat is approved for the management of adult patients with non-ST elevation acute coronary syndrome, including patients who may subsequently undergo PCI, to decrease the rate of refractory ischemic conditions, new myocardial infarctions and death.

The Company acquired the exclusive Canadian rights to Aggrastat as part of the acquisition of the Canadian business portfolio of Cardiome. Advanz Pharma supplies finished product to the Company.

### **Pipeline Products**

#### ***CAN-FITE, CF101, Psoriasis treatment***

On March 23, 2015, Cipher entered into an agreement to license the Canadian distribution rights to CF101 (the "Can-Fite Agreement"), a novel chemical entity being developed by Can-Fite BioPharma Ltd. ("Can-Fite") for moderate to severe plaque psoriasis and rheumatoid arthritis ("RA"). The active agent of CF101 is IB-MECA (methyl 1-[N6-(-3-iodobenzyl)-adenin-9-yl]-beta-D-ribofuronamide), that is active by modulating the key signaling proteins such as NF-kB and PI3K, resulting in inhibition of inflammatory cytokine production. CF101 completed a phase II/III double-blind, placebo-controlled study, which was designed to test the efficacy of CF101 in patients with moderate to severe plaque psoriasis. The study enrolled 326 patients through 17 clinical centers in the U.S., Europe and Israel. Top-line results from the trial were published by Can-Fite at the end of March 2015. Results from this phase II/III trial and final results from the prior phase II trial in psoriasis were both positive, showing that CF101 effectively improved disease symptoms. Can-Fite is conducting a phase III program for psoriasis (COMFORT).

In 2020, Can-Fite discontinued to enrol patients into the phase III RA program, ACROBAT, after an interim analysis by the data monitoring committee of the study recommended not to continue patient enrollment. Although Piclidenoson treatment was superior to placebo, Piclidenoson treatment was not "non inferior" to Methotrexate, the comparator treatment arm of the study. Can-Fite made the decision to stop the ACROBAT study and focus on the psoriasis COMFORT study.

Piclidenoson completed a phase II/III double-blind, placebo-controlled study, which was designed to test the efficacy of CF-101 in patients with moderate to severe plaque psoriasis. The study enrolled 326 patients through 17 clinical centers in the U.S., Europe, and Israel. Results from this phase II/III trial and results from the prior phase II trial in psoriasis were both positive, showing that Piclidenoson effectively improved disease symptoms. In addition,

at the end of 2013, Piclidenoson completed a phase IIb study for active RA, and Can-Fite has completed the study design for a phase III program. Can-Fite is commencing two phase III programs, one for RA (ACROBAT) and one for psoriasis (COMFORT).

During September 2022, Can-Fite reported topline results from its Phase III COMFORT™ study, which met its primary endpoint with statistically significant improvement over the placebo in psoriasis patients and an excellent safety profile for Piclidenoson. Can-Fite indicated that the Phase III COMFORT™ data point towards a better safety profile for Piclidenoson as compared to Otezla, the leading oral therapy for psoriasis on the market.

On January 10, 2023, Can-Fite announced it has submitted a market registration plan to the European Medicines Agency ("EMA") for Piclidenoson and that a submission to the FDA will follow. Registration plans for both the EMA and FDA include final efficacy and safety results from Can-Fite's successful COMFORT™ Phase III study and the protocol for its upcoming Phase III pivotal trial together with a request for registration advice from the regulators. Current chemistry, manufacturing, and controls (CMC), nonclinical data, and human pharmacokinetic data are also included.

Approximately one million people in Canada have psoriasis, according to the Canadian Dermatology Association and data from IQVIA CompuScript in December 2022. The total Canadian market for plaque psoriasis is estimated to be CAD\$600 million where this novel product would participate. In moderate to severe cases, the most common treatment options are systemic biologic drugs, which are delivered by injection or intravenous infusion and have well-known shortcomings, including increased risk of infection. CF101 is an oral small molecule drug formulated in a tablet and has an excellent human safety profile, demonstrated in more than 1,000 patients.

The timeline to regulatory submissions to Health Canada will be determined by Can-Fite's anticipated successful COMFORT™ Phase III study and clinical trial program.

Under the terms of the Can-Fite Agreement, Can-Fite received an upfront payment of US\$1.65 million and is eligible for milestone payments of up to US\$2.0 million and royalties from product sales in Canada. The Can-Fite Agreement provides that Can-Fite will supply product to Cipher.

### ***Moberg, MOB-015, Nail Fungus treatment***

On September 18, 2018, Cipher acquired the exclusive Canadian rights to commercialize, promote, sell and distribute MOB-015 from Moberg Pharma AB. MOB-015 is a topical formulation of terbinafine for treatment of onychomycosis, a common and destructive nail infection caused predominately by dermatophyte fungi. Approximately 10% of the general population suffer from onychomycosis and a majority of those afflicted go untreated.

MOB-015 is a topical formulation of terbinafine based on Moberg's experience from its leading OTC product Kerasal Nail®/Emtrix®. Oral terbinafine is currently the standard of care for treating onychomycosis but is associated with safety issues, including drug interactions and liver damage. For many years, developing a topical terbinafine treatment without the safety issues of oral terbinafine has been highly desirable, but unsuccessful due to insufficient delivery of the active substance through the nail.

In a previous phase 2 study, MOB-015 demonstrated delivery of high microgram levels of terbinafine into the nail and through the nail plate into the nail bed. Mycological cure of 54% and significant clear nail growth was observed in patients who completed the phase 2 study. Plasma levels of terbinafine with MOB-015 were substantially lower than after oral administration, reducing the risk of liver toxicities observed with oral terbinafine.

On December 9, 2019, Moberg Pharma AB announced that MOB-015 met the primary endpoint as well as the key secondary endpoints in the North American Phase 3 study. This clinical trial included 365 patients with mild to moderate toenail onychomycosis (nail fungus) affecting 20-60% of the large toenail. The study was conducted at 32 sites in the U.S. and Canada. Patients received treatment for 48 weeks and had the last follow up assessment at 52 weeks. At week 52, significantly more patients reached complete cure when treated with MOB-015 than when treated with vehicle (p=0.019) following 48 weeks of daily treatment.

The primary endpoint, the proportion of patients achieving complete cure of the target toenail at 52 weeks, was achieved in 4.5 percent of the patients receiving MOB-015 and in none of the patients receiving vehicle ( $p=0.019$ ). Complete cure is a composite endpoint that requires both a completely clear nail and a mycological cure. Mycological cure is defined as both negative KOH test and a negative dermatophyte culture. Mycological cure was achieved in 70 percent of the patients treated with MOB-015 ( $p<0.0001$ ).

On June 25, 2020, Moberg Pharma AB announced that MOB-015 met the primary endpoint in the European Phase 3 study including 452 onychomycosis patients, showing non-inferiority versus topical ciclopirox. Mycological cure was achieved in 84 percent of patients, which is unprecedented for a topical treatment and even higher than reported for oral treatments. The pattern is consistent with the results from the North American Phase 3 study, with low complete cure rates, despite the high mycological cure rates.

This is the second Phase 3 study for MOB-015. The study was conducted at sites in Germany, the U.K. and Poland and included 452 patients with mild to moderate distal subungual onychomycosis (DSO) affecting 20-60 percent of the great toenail. Patients were randomized to daily treatment for 48 weeks, either with MOB-015 or 8 percent ciclopirox, the most widely used topical drug for onychomycosis.

The primary endpoint, the proportion of patients with complete cure of their target toenail at 52 weeks, was achieved in 1.8 percent of patients receiving MOB-015 and in 1.6 percent of patients receiving ciclopirox. Mycological cure was achieved in 84 percent of patients for MOB-015, superior to 42 percent for ciclopirox. Treatment success (mycological cure and almost or completely clear great toenail) was reached for 21.9 percent of the MOB-015 patients versus 18.9 percent in the ciclopirox group. The study confirmed early onset of action with 46 percent of patients mycologically cured already at 12 weeks.

On September 22, 2021, Moberg Pharma AB announced that it has received approval of the pediatric plan for MOB-015 from EMA's paediatric committee. This approval enables Moberg Pharma AB to pursue a full marketing authorization application providing up to ten years of exclusivity in Europe following approval.

This positive decision means that Moberg Pharma will conduct a pediatric study during and after the approval process for MOB-015. The study includes 30 children, 6 to 17 years of age, and will be initiated in the second half of 2022. The pediatric study supplements the already completed clinical program, including the two phase 3 studies with a total of more than 800 patients, where the primary endpoint was achieved in both the North American and European studies.

On November 8, 2021, Moberg Pharma AB announced it had entered into a collaboration with Allderma AB for the launch of MOB-015 in Sweden, Norway and Denmark. In the collaboration, Allderma is responsible for marketing, distribution and sales in Sweden, Denmark and Norway, while Moberg Pharma is responsible for the manufacture and delivery of the product. The agreement also includes co-financing of marketing activities and market-based financial terms. The agreement with Allderma complements the existing licensing agreement for MOB-015 in Europe.

On December 23, 2021, Moberg Pharma AB announced that the Medical Products Agency in Sweden has agreed to be the reference member state for Moberg Pharma AB's registration application for MOB-015.

On March 28, 2022, Moberg submitted a full application, which offers the possibility of data exclusivity in Europe for up to ten years following market approval. The Swedish Medical Products Agency is the reference member state and will lead the review of the application. Moberg's goal is to receive its first market approval and launch MOB-015 in 2023.

On May 10, 2022, Moberg announced that patient enrollment started in an additional North American Phase III study for MOB-015 (nail fungus treatment) with the FDA. The randomized, multicenter, vehicle-controlled Phase III study will include approximately 350 patients in North America. The patients will be evaluated over 52 weeks and the primary endpoint will be the proportion of subjects achieving complete cure of their target nail. The purpose of the new study is to facilitate market approval in the US, as well as strengthen the product's clinical evidence and marketing claims globally.



In Canada, according to data from IQVIA, the total prescription market for Onychomycosis was \$86 million in 2022, 90% of which were topical products, growing with a five-year CAGR of 7% for the period 2017-2022.

### ***Dalhousie, DTR-001, Tattoo Removal treatment***

On May 2, 2016, the Company licensed the worldwide rights to develop, market and sell an investigational tattoo removal cream from Dalhousie University (the “Dalhousie Agreement”). The product candidate, which is applied topically, has shown encouraging results in pre-clinical testing for the removal or reduction of the appearance of tattoos. The product candidate is currently at the pre-clinical stage of development. Cipher has invested in further development of the formulation to facilitate key proof of concept studies.

Under the terms of the Dalhousie Agreement, an upfront payment of \$75,000 was made by Cipher upon execution. The Dalhousie Agreement contains milestone payments of up to \$3.6 million based on future regulatory and commercial sales milestones, as well as royalties on commercial sales. The US patent office issued a Notice of Allowance for the US patent application covering tattoo dermal compositions (topical, transdermal and intradermal). We have received encouraging results from some proof of concept studies and identified a lead candidate compound. Additional in vitro studies were conducted in 2021 to optimize the formulation and demonstrate successful penetration of human skin, further strengthening the proof-of-concept evidence. Further progress was also made in broadening patent protection. In 2021, three patents were granted relating to the Company’s tattoo removal program. A Brazilian patent was issued on January 5, 2021, Hong Kong patent was issued on January 15, 2021 and New Zealand patent was issued on August 31, 2021 for “COMPOSITIONS AND METHODS FOR THE REMOVAL OF TATTOOS”. In addition, on December 29, 2021, a Canadian patent application was allowed. These patents have terms to 2034 and are part of a larger family that includes granted U.S., Australian and European patents and a pending US application.

### **Specialized Skill and Knowledge**

The Company specializes in selling and acquiring pharmaceutical products. Cipher searches for and acquires/in-licenses prescription products that it can sell with its own sales force in Canada. By enlisting the support of experienced clinical trial, regulatory and legal consultants, the Company is able to use expert knowledge to assist in the successful development of its products and the protection of its intellectual property.

### **Competitive Conditions**

The Company competes for both in-licensing and out-licensing opportunities. The pharmaceutical industry is intensely competitive and includes a range of players from large top-tier multinational companies to a smaller group of mid-tier companies and a large number of smaller, regional companies, often owned and operated by researchers. The Company believes that competition in the pharmaceutical industry will continue to increase as disease management and patient compliance become more important in the overall strategy of cost containment in the healthcare sector. In addition, pharmaceutical companies are increasingly taking steps to extend market exclusivity for their products by utilizing new drug delivery technologies and then filing patents on the resulting new formulations. Many of the Company’s major drug development competitors have more experience in developing products and obtaining regulatory approvals and many are better capitalized.

The Company believes that its competitive strengths include management’s expertise evaluating drug candidates and launching commercial products, experience with clinical studies and regulatory matters, and the quality and reputation of its strategic partners and management team.

### **Environmental, Health and Safety Matters**

Currently, the Company does not manufacture any of its products. However, the operations of its subcontractors and suppliers are subject to various laws and regulations relating to environmental, health and safety matters, and their failure to comply with such laws and regulations could have a material adverse effect on the Company’s business and reputation, result in an interruption or delay in the development or manufacture of its product candidates, or increase the costs for the development or manufacture of its product candidates.

### **Manufacturing, Supply and Production**

The Company does not own or operate manufacturing facilities for the production of its products. The Company relies on third-party contract manufacturers for all of its required raw materials, active ingredients and finished products.

Development and commercial quantities of any products that Cipher develops will need to be manufactured in facilities, and by processes, that comply with the requirements of Health Canada and the U.S. FDA and the regulatory agencies of other jurisdictions in which the Company is seeking or has approval. Cipher employs internal resources to manage its manufacturing contractors and plays an active role in working with manufacturers to maintain the quality of the products supplied to its distribution partners. The manufacturers of Cipher's drugs have advised Cipher that they are compliant with both current Good Laboratory Practices ("cGLP") and Good Manufacturing Practices ("cGMP").

Cipher and its contract manufacturers are, and will be, subject to extensive governmental regulation in connection with the manufacture of any pharmaceutical products or medical devices. Cipher and its contract manufacturers must ensure that all of the processes, methods and equipment are compliant with cGMP and cGLP for drugs on an ongoing basis, as mandated by the FDA and foreign regulatory authorities, and conduct extensive audits of vendors, contract laboratories and suppliers. Please see "Risk Factors".

### Employees

As at December 31, 2022, the Company had 6 full-time employees, all located in Canada. The distribution of the Company's full-time employees according to main areas of activities is set forth in the following table:

Area of Activity:	<u>Employees</u>
Executive	1
Finance	3
Regulatory and Quality	1
Sales and Marketing	1
Total	<u>6</u>

The Company also uses senior consultants, hired on a contract basis which are not included in the employees above, and outsources its clinical development programs to various contract research organizations.

### Liquidity and Capital Resources

As of December 31, 2022, the Company had cash of US\$28.8 million compared to US\$20.5 million as at December 31, 2021 and no outstanding debt. The Company expects that its cash on hand and its cash flows from operations and its credit facility will be sufficient to fund product development and operating costs.

Cash provided by operating activities was US\$10.6 million for the year ended December 31, 2022, compared to US\$13.8 million for the year ended December 31, 2021. Cash provided by operations, excluding working capital was US\$13.6 million for the year ended December 31, 2022, compared to US\$9.1 million for the year ended December 31, 2021. The change in cash provided by operating activities reflects a use in working capital of US\$3.0 million in the current year compared to a recovery of US\$4.7 million in working capital in the comparative prior year.

On March 1, 2023, Cipher announced the closing of a new US\$35 million credit facility with Royal Bank of Canada (the "Credit Facility"). The Credit Facility is structured as a US\$15 million Senior Secured Revolving Term Loan (the "Term Loan") with an additional accordion option to be increased by US\$10 million. Additionally, the Credit Facility has a US\$10 million Senior Secured Revolving Credit Facility (the "Revolving Loan") for general corporate purposes and working capital requirements. The initial term of the Term Loan is three years and the Revolving Loan is payable on demand. The Credit Facility bears interest at market prevailing rates once drawn upon.

The development and licensing of pharmaceutical products is a process that can require significant investment. The Company's MOB-015 and CF-101 development products discussed in the pipeline section of this AIF involve research and development which is performed by our development partners, and whereby Cipher can be subject to milestone payments when successful clinical trial metrics have been achieved. Under the terms of the agreement with the Company, Can-Fite received an upfront payment of US\$1.65 million and is eligible for milestone payments of up to US\$2.0 million and royalties from product sales in Canada. The agreement provides that Can-Fite will deliver finished product to Cipher. The Company has potential development and regulatory milestone payments

of up to US\$4.05 million related to its near-term pipeline product, MOB-015 that may become payable upon achievement of certain clinical trial and regulatory approval metrics. If these metrics are reached, MOB-015 may also have net sales milestones payable of US\$10 million upon achievement of certain sales thresholds. The Company expects to incur research and development expenses, related to its DTR-001 preclinical trials. During the year ended December 31, 2022, the Company spent US\$0.1 million on research and development activities (2021 - US\$0.1 million). The Company also expects that its selling, general and administrative expenses may increase in the future as it expands business development activity and incurs costs in connection with being a public company, including directors' and officers' insurance, investor relations programs and professional fees.

The Company's future capital requirements will depend on a number of factors, including the success of its commercial products, the continued progress of its research and development of product candidates, the timing and outcome of clinical trials and regulatory approvals, payments received or made under licensing or other collaborative agreements, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights, defending against patent infringement claims, the acquisition of licenses to new products or technologies, the status of competitive products and the success of the Company in developing and maintaining markets for its products and services.

The Company anticipates that its current cash, its undrawn credit facility, together with the cash flow that is generated from operations will be sufficient to execute its current business plan for 2023.

### **Revenues for the Last Two Financial Years**

The Company reported total revenue, comprised of licensing revenue and product sales, of US\$20.7 million in 2022 compared to US\$21.9 million in 2021, a decrease of US\$1.2 million or 5.5%.

Licensing revenue was US\$8.1 million in 2022 compared to US\$10.4 million in 2021. Absorica revenue in 2022 was US\$5.2 million, a decrease of US\$2.4 million compared to US\$7.6 million in 2021. Licensing revenue from Lipofen and the authorized generic version of Lipofen was US\$2.9 million in 2022 compared to US\$2.6 million in 2021.

Total product sales from the Company's commercial products was US\$12.5 million in 2022, an increase of U.S.\$1.0 million compared to US\$11.5 million in 2021. The majority of the revenue from Canadian commercial products is related to Epuris. Epuris revenue was US\$11.3 million in 2022 compared to US\$10.9 million in 2021. The balance of the revenue is related to sales of Ozanex, Actikerall, Beteflam, Vaniqa, Durela, Brinavess and Aggrastat in the aggregate amount of US\$1.2 million in 2022 compared to US\$0.6 million in 2021.

### **RISK FACTORS**

An investment in the securities of the Company is speculative and involves a high degree of risk including, but not limited to, the risk factors discussed in this AIF. Our actual results may differ from those expected as of the date of this AIF. Before making an investment decision, investors should carefully consider these risk factors as well as the other information contained in this AIF. If any of the factors identified as risks actually occur, there could be a material adverse effect on the Company's business, financial condition and results of operations. However, the risks described below are not the only ones the Company faces. Additional risks not currently known to the Company, or those that it currently believes to be immaterial, may also harm the Company's business. The market price of our Common Shares could decline if one or more of those risks and uncertainties develop into actual events and you may lose all or part of your investment.

#### **Risks Related to Cipher and its Business Operations**

*Our success depends, in large measure, on our ability to enter into in-licensing, development, manufacturing and marketing and distribution agreements with other pharmaceutical companies and keep such agreements in effect.*

Currently, a significant portion of our marketed product pipeline is in-licensed from Galephar. If Cipher breaches the underlying agreement, Galephar could terminate the agreement in its entirety or with respect to any particular product. Additionally, the Company works with other partners in the specialty pharmaceutical industry.

Factors that may affect the success of our collaborative efforts with partners (including Galephar) include, but are not limited to, the following:

- our partners may be pursuing alternative technologies or developing alternative products, either on their own or in collaboration with others, that may be competitive with the products as to which they are collaborating with us, which could affect their commitment to our product development efforts;
- our partners may not fulfill their contractual obligations and not be able to adequately supply products for us in commercial quantities, which would adversely affect revenues;
- reductions in marketing or sales efforts or a discontinuation of marketing or sales of our products by our commercial partners may reduce future revenues, which will be based on a percentage of net sales by these partners;
- our partners may terminate their collaborations with the Company, which could make it difficult for us to attract new partners or adversely affect how Cipher is perceived in the business and financial communities; and
- our partners are responsible for complying with all government legislation and regulations related to selling the Company's products in their respective territories. If any of the Company's partners do not comply, this could have a material adverse impact on the cash flows of the Company.

While the Company attempts to minimize risk by maintaining strong relationships with its partners, the development, marketing and commercialization of pharmaceutical products are processes that require large investments and can take years to complete. Projects can be abandoned along the way or regulatory authorities can refuse to approve new products.

*Our current revenues are highly dependent on a limited number of products.*

Our current licensing revenue is highly dependent on CIP-Isotretinoin, CIP-Fenofibrate and CIP-Tramadol. Our current product sales revenue is highly dependent on Epuris. Each of these products faces competition and the ability to grow the market and our market share may be limited.

*Our revenue is dependent on protection from patents that will expire.*

Cipher has and may in the future acquire rights to products that have patent protection. This patent protection will eventually expire and, in such situations, in order to continue to obtain commercial benefits from these products, Cipher will rely on product manufacturing trade secrets, know-how and related non-patent intellectual property. The effect of patent expiration depends upon, among other things, 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 Cipher'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 Cipher's business, financial condition and results of operations.

*Disease outbreaks may negatively impact the performance of the Company*

A local, regional, national or international outbreak of a contagious disease, including the COVID-19 coronavirus, Middle East Respiratory Syndrome, Severe Acute Respiratory Syndrome, H1N1 influenza virus, avian flu or any other similar illness, could interrupt supplies and other services from third parties upon which the Company relies (including contract manufacturers, marketing and transportation and logistics providers), decrease demand for our products, decrease the general willingness of the general population to travel, cause staff shortages, reduce customer traffic, and increase government regulation, all of which may materially and negatively impact the business, financial condition and results of operations of the Company. In particular, if the current outbreak of the COVID-19 coronavirus continues or increases in severity, the Company could experience difficulty in executing its strategic plans and the marketing, sales, production, logistics and distribution of its products could be severely disrupted. These events could materially and adversely affect the Company's business and could have a material adverse effect on the Company and its financial results.

*If in the future Cipher acquires or in-licenses technologies or product candidates, it may incur various costs, may have integration difficulties and may experience other risks that could harm the business and results of operations.*

Any product candidate or technologies Cipher in-licenses or acquires will likely require additional development efforts prior to commercial sale, approval by the FDA, Health Canada and/or applicable foreign regulatory authorities. All product candidates are prone to risks of failure inherent in pharmaceutical product development, including the possibility that the product candidate, or product developed based on in-licensed technology, will not be shown to be sufficiently safe and effective, or otherwise meet the necessary requirements for approval by regulatory authorities. If intellectual property related to product candidates or technologies in-licensed is not adequate, Cipher may not be able to commercialize the affected products, even after expending resources on their development. In addition, the Company may not be able to manufacture economically or successfully commercialize any product candidate that is developed based on acquired or in-licensed technology that is granted regulatory approval, and such products may not gain wide acceptance or be competitive in the marketplace. Moreover, integrating any newly acquired or in-licensed product candidates could be expensive and time-consuming. If Cipher cannot effectively manage these aspects of the business strategy, the business may not succeed.

*Cipher relies on third parties for the marketing of certain products.*

Currently, our out-licensed products are marketed by third parties by way of license arrangements. Even if acceptable and timely marketing arrangements are available, the products developed may not be accepted in the marketplace and, even if such products are initially accepted, sales may thereafter decline.

Additionally, our distribution partners may make important marketing and other commercialization decisions with respect to products they develop without our input or may not perform in the manner expected. As a result, many of the variables that may affect the Company's revenues, cash flows and net income may not be exclusively within its control. The termination of any such contracts or services with such third parties could also have a material adverse effect on our business, financial condition and results of operations.

*The product approval process is highly unpredictable and may take longer than expected.*

Cipher does seek product approvals in foreign jurisdictions and in Canada for a number of products as part of its growth strategy. Approvals may be refused or delayed for a number of reasons, including the requirement for additional clinical and non-clinical studies or patent infringement challenges by patent holders. Challenges of this type are not uncommon and may delay regulatory approvals.

*The timing of completion of clinical trials, anticipated regulatory approvals, pricing approvals, obtaining reimbursement codes or the timing of product launch may vary due to factors such as delays or setbacks in the conducting of our clinical trials, regulatory approvals or in the manufacturing and marketing of an approved product.*

We may experience numerous unforeseen events that could delay or prevent our ability to receive regulatory approval, including:

- regulatory requests for additional analyses, reports, data, non-clinical studies, and clinical trials;
- clinical trials or non-clinical studies could produce negative or inconclusive results, statistically non-significant results, or regulatory authorities may disagree with our interpretation of the results or the design or conduct of our studies;
- clinical trials or non-clinical studies may reveal unacceptable adverse events or side effects;
- clinical trials may enroll slower than anticipated, may not be completed on schedule, or at all;
- regulators, institutional review boards or ethics committees may not authorize commencement of a clinical trial the continuation of a clinical trial, or amendment of a clinical trial on a timely basis, or at all;
- the applicable regulatory authorities may not accept foreign clinical trial data;

- the Company may elect to suspend or terminate clinical trials due a potential health risk;
- the supply or quality of product necessary to conduct clinical trials of the product candidates may be insufficient or inadequate;
- our clinical or non-clinical studies may not be conducted in accordance with the applicable regulatory requirements;
- regulatory authorities may determine that our product candidates are combination products, requiring additional studies, or that CIPHER comply with additional regulatory requirements;
- CIPHER may not be able to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks; and
- there may be changes in governmental regulations or guidelines that render our data insufficient for approval.

If CIPHER does not meet its timelines within the projected timeframe, our business, financial condition and results of operations could be materially adversely affected. Also, a delay in the launch of a product could negatively impact overall revenues and profitability relating to a product, particularly because the lifespan of our products is expected to be considerably shorter than the average lifespan of new chemical entities.

*We have no experience manufacturing products and rely, and intend to rely, on third parties to manufacture our products. The development and commercialization of our products could be stopped or delayed if any such third party fails to provide us with sufficient quantities of product or fails to do so at acceptable quality levels or prices or fails to maintain or achieve satisfactory regulatory compliance.*

CIPHER relies on direct contracts with third-party contract manufacturers or our partners who manage their contract manufacturers. The facilities used by our third-party contract manufacturers may undergo pre-approval inspections by the applicable regulatory authorities, including the FDA, after submitting our NDA to the FDA, and must be able to demonstrate readiness for commercial marketing and conformance with FDA cGMP regulations and related requirements of other applicable regulatory authorities.

Third-party manufacturers may not perform as agreed, may be unable to comply with FDA cGMP regulations, applicable guidelines, state and foreign regulatory requirements or may terminate their agreements with us. If any third-party manufacturers cannot successfully manufacture material that conforms to our specifications and the applicable regulatory authorities' strict regulatory requirements, or undergo successful governmental regulatory inspection, our business will be adversely affected. We have no direct day-to-day control over a third-party manufacturer's ability to maintain adequate quality control, quality assurance and qualified personnel. If third-party manufacturers are unable to satisfy the regulatory requirements for the manufacture of our products, or if our suppliers or third-party manufacturers decide they no longer want to manufacture our products, the Company or our licensing partners may need to find alternative manufacturing facilities. The number of third-party manufacturers with the necessary manufacturing and regulatory expertise and facilities is limited, and it could be expensive and take a significant amount of time to arrange for alternative suppliers, which could have a material adverse effect on business, financial condition and results of operations. Changes in the manufacturing site of our product will require prior FDA or Health Canada approval before the products may be marketed in the U.S. or Canada, respectively. We might be unable to identify manufacturers for long-term commercial supply on acceptable terms or at all.

Manufacturers are subject to ongoing periodic announced and unannounced inspections by the FDA and other governmental authorities to ensure compliance with government regulations. If the FDA or other regulatory authority has any concerns following an inspection of these manufacturing facilities, the facility may be ordered to cease operations until such issues are resolved, which could have a material adverse effect on the Company's business, financial condition and operating results. We and our products or product candidates may also be subject to regulatory actions. Manufacturing facilities and companies that import products to the U.S. may further be subject to import detention if inspections identify compliance concerns.

Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced U.S. federal, state, Canadian and foreign regulations. Furthermore, if microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot be assured that any stability or other issues relating to the manufacture of any of our products will not occur in the future. Additionally, contract manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If contract manufacturers, component fabricators or secondary service providers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide any product candidates to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Following product approval or clearance, any delay or interruption in supply could also impact our commercial success.

If the Company changes the source or location of supply or modifies the manufacturing process, regulatory authorities may require CIPHER to provide them with notification of the change, obtain approval for the change, or 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 CIPHER is unable to meet the regulatory authorities' requirements, it will be unable to manufacture products from the new source or location of supply or use the modified process.

More recently, the Company is monitoring the outbreak of the COVID-19 coronavirus. While the precise impacts of the COVID-19 virus on the Company remain unknown, rapid spread of the COVID-19 virus may have a material adverse effect on global economic activity, and can result in volatility and disruption to global supply chains, operations, mobility of people and the financial markets. As a result, current business disruptions could impact our manufacturers. Any adverse developments affecting commercial manufacturing of our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, enforcement actions, import alerts, import detentions, or other interruptions in the supply of our products or product candidates. We may also have to take inventory write-offs and incur other charges and expenses for products or product candidates that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could materially adversely affect our business and delay or impede the development and commercialization of any of our products or product candidates and could have a material adverse effect on the Company's business, financial condition and results of operations.

*We may be subject to product liability claims, which can be expensive, difficult to defend and may result in large judgments or settlements.*

Drug development involves the testing of drugs on human subjects. Such studies create a risk of liability for personal injury or death to participants as a result of an unexpected adverse reaction to the tested drug or as a result of negligence or misconduct. Furthermore, the administration of drugs to humans 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 us. In addition, third party collaborators and licensees may not protect us from product liability claims. Product liability claims may also result in regulatory actions.

We currently maintain product liability insurance in connection with the marketing of our products. The Company may not be able to obtain or maintain adequate protection against potential liabilities arising from product sales. In addition, CIPHER could become subject to potential liabilities as successor owner of an asset, product or business (even if not specifically assumed by us). In such circumstances, the Company's insurance policies may not provide enough coverage for such liabilities. If CIPHER is unable to obtain sufficient levels of insurance at acceptable cost or otherwise protect against potential product liability claims, the Company will be exposed to product liability claims. A successful product liability claim in excess of the Company's insurance coverage could have a material adverse effect on our business, financial condition and results of operations. In addition, any successful claim may prevent the Company from obtaining adequate product liability insurance in the future on commercially desirable terms or at all. Even if a claim is not successful, defending such a claim may be time-consuming and expensive. Product liability claims, whether or not merited, could also result in negative perception of the Company and its

products which could have a material adverse effect on the Company's business, financial condition and results of operations.

*Unexpected product safety or efficacy concerns may arise.*

Unexpected safety or efficacy concerns can arise with respect to our marketed and commercialized products, whether or not scientifically justified, leading to product recalls, withdrawals, post-approval requirements, such as studies or REMS, labeling revisions, withdrawal of regulatory approvals for the affected products, issuance of safety alerts, Dear Healthcare Provider letters, or other safety notices, required labeling changes, or declining sales, as well as product liability, consumer fraud and/or other claims. If product safety issues present a public health risk, products in the field may be subject to seizure or injunctive action preventing their distribution. This could have a material adverse effect on our business, financial condition and results of operations.

*We generate license revenue from a limited number of distribution and supply agreements.*

The Company currently generates license revenues from a limited number of distribution and supply agreements. A significant proportion of our revenue is derived from Absorica. The loss of that source of revenue for any reason could have a material adverse effect on our business, financial condition and results of operations.

*The pharmaceutical industry is highly competitive and may be impacted by rapid technological change.*

The Company competes to obtain licenses for products and competes to secure distribution channels. Moreover, our products compete with other products.

The pharmaceutical industry is subject to rapid and substantial technological change. The patents protecting the active ingredients for the products currently in our product pipeline have expired. In order to obtain commercial benefits from our products, Cipher relies on proprietary drug delivery systems. Our products will face intense competition from conventional forms of drug delivery systems and from delivery systems, which are similar to those in-licensed by the Company. We will compete with companies in North America and abroad, including major pharmaceutical and chemical companies, research and development firms, universities and other research institutions.

Many of the Company's competitors have greater financial resources and market capabilities, have greater experience in drug development and have greater experience in obtaining FDA and other regulatory approvals. The Company's competitors may succeed in developing technologies and products that are more effective or cheaper to use than any products that Cipher may develop or license. These developments could render the Company's technologies and products obsolete or uncompetitive, which could have a material adverse effect on our business, financial condition and results of operations. These competitors could also be viewed as more favourable partners to licensors and/or distributors.

*We may require additional capital to fund future operations.*

We may have a need for capital resources to fund possible future operational needs, scheduled debt payments, product development expenditures and future strategic initiatives. We may expend amounts to fund research and development activities in order to develop new products and, to a lesser degree, to complete existing products under development. These expenditures may cause us to incur operating losses and cash flow deficiencies for the near future and until such time as sales of our products by commercial partners generate sufficient additional revenues. We attempt to mitigate the risk associated with drug development costs through the terms of our in-licensing agreements, where the risk of additional research and development costs is borne by our development partners and Cipher pays milestone amounts only when development milestones are achieved.

As at December 31, 2022, the Company had cash of \$28.8 million and no debt. The Company also generates commercial revenue which provides a source of cash flow. In 2022, the Company reported total revenue of \$20.7 million.

We expect the cash on hand and the cash generated from operations may be sufficient to fund current product development and operating costs. Additional funding may be required for the development of new products in-licensed from technology partners and/or for additional acquisitions. Although Cipher believes that the Company could obtain



additional capital through future equity or debt financing, there can be no assurance that it will be able to do so on terms acceptable to us or at all. If Cipher was unable to obtain sufficient additional capital, the development of our existing principal products and/or additional products could be disrupted, which could have a material adverse effect on our business, financial condition and operating results.

*The Company's products in Canada may be subject to pricing regulation and changes in regulations or pricing adjustments could impact profitability.*

All patented pharmaceutical products introduced in Canada are subject to the post-approval product pricing regulation of the Patented Medicine Prices Review Board ("PMPRB"). Certain patented products may form part of Cipher's portfolio of products from time to time and may be subject to such regulation by the PMPRB. The PMPRB will monitor compliance through a review of the average transaction price of each patented drug product to be reported by Cipher 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 Cipher 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 the Company'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 the Company's ability to profitably commercialize the product to its full market potential or at all. This could materially and adversely affect the Company's business and could have a material adverse effect on the Company and its financial results.

Furthermore, future changes to the regulations and/or guidelines of PMPRB or other relevant regulatory bodies may result in less favourable product pricing directives and requirements. The Company's ability to predict and/or adapt to such directives or requirements may be limited.

*Cipher depends on key managerial personnel and external collaborators for our continued success.*

Product development capacity will depend, to a great extent, on the ability to attract and retain highly qualified staff. The competition in the industry in which the Company operates is intense. Cipher's success will be highly dependent upon our Chief Executive Officer and the Company's small team of senior officers, our scientific personnel as well as our consultants and collaborators. The loss of key employees or collaborators, if any, could compromise the pace and success of our product development.

*Although Cipher obtained regulatory approval in the U.S. and Canada for our commercialized products, there is no assurance that the Company will receive regulatory approvals in the U.S., Canada or any other jurisdictions for the other products in development or for future products.*

The cost of obtaining and complying with government regulation can be substantial. Government authorities in the U.S., Canada and comparable authorities in foreign countries regulate the research and development, manufacture, testing and safety of pharmaceutical products as well as the approval and commercialization of such products. The regulations applicable to our existing and future products may change. There can be long delays in obtaining required clearances from regulatory authorities in any country after applications are filed. Government agencies in the U.S., Canada and other countries in which Cipher intends to carry on business regulate pharmaceutical products intended for human use. Regulations require extensive clinical trials and other testing and government review and final approval before the Company can market our products.

Requirements for approval vary widely from country to country outside of the U.S. and Canada. Whether or not approved in the U.S. or Canada, regulatory authorities in other countries must approve a product prior to the commencement of marketing the product in those countries. The time required to obtain any such approval may be longer or shorter than in the U.S. and Canada. Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may have a negative effect on the regulatory process in others.

Any failure or delay in obtaining regulatory approvals could adversely affect the market for any products Cipher develops and commercialize and therefore our business, financial condition and results of operations.

Even if Cipher obtains regulatory approval of our products in the U.S., Canada, or elsewhere, any such approval might significantly limit the indications for use, to include a more limited patient population, require that

certain precautions, contraindications or warnings be included on the product labeling, including black box warnings, require time-consuming post-approval clinical studies, or require that REMS be followed. For instance, CIP-Isotretinoin, called Absorica in the U.S. is subject to REMS requirements.

Furthermore, in the U.S., Canada, and elsewhere, the manufacturing, packaging, labeling, handling, distribution, importation, exportation, licensing, sale, marketing, promotion and storage of our products are affected by extensive laws, governmental regulations, administrative determinations, court decisions and similar constraints. There can be no assurance that the Company or the Company's third party distributors and manufacturers are in compliance with all of these laws, regulations and other constraints. Failure to comply with these laws, regulations or other constraints or new laws, regulations or constraints could lead to enforcement actions, the imposition of significant penalties or claims or withdrawal of marketing approvals, as a result of which our business, financial condition and financial results could be materially adversely affected. In addition, the adoption of new laws, regulations or other constraints or changes in the interpretation of such requirements may result in significant compliance costs that could be passed on to the Company by its distributors or manufacturers or lead the Company to discontinue product sales and may have an adverse effect on the marketing of our products, resulting in significant loss of sales. For instance, in the U.S., portions of the *Drug Quality and Security Act*, FDA's law on the tracking and tracing of prescription drug products, went into effect in 2015, which will add to our responsibilities and may increase the cost of doing business.

In the U.S., the FDA prohibits any written, verbal, or implied statement used to promote or sell a product that associates the product with an unapproved use that is not reflected in the product's approved label, referred to as off-label information. If any such evidence is found with respect to our products, the FDA or other regulatory authorities, including the U.S. Department of Justice, Department of Health and Human Services' Office of Inspector General, state attorneys general, and members of Congress may take adverse action against us, ranging from a warning letter necessitating cessation of use of the statement to injunctions against product sale, seizures of products promoted with the statements, inquiries, and civil and criminal prosecution, fines, and penalties. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The government has also requested that companies enter into consent decrees under which specified promotional conduct is changed or curtailed.

In the U.S., engaging in the impermissible promotion of our products, following approval or clearance, for off-label uses can also subject us to false claims litigation under federal and state statutes, which can lead to civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which the Company promotes or distributes drug and device products through, for example, corporate integrity agreements, and debarment, suspension or exclusion from participation in federal and state healthcare programs and contracts. These false claims statutes include the federal civil *False Claims Act*, which allows any individual to bring a lawsuit against a company on behalf of the federal government alleging submission of false or fraudulent claims, or causing others to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. These *False Claims Act* lawsuits have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements regarding certain sales practices promoting off-label uses involving fines that are as much as \$3.0 billion. This growth in litigation has increased the risk that a company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid and other federal and state healthcare programs. If Cipher does not lawfully promote our products, if any, the Company may become subject to such litigation and, if not successfully defended against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations and prospects.

*Certain of our products are subject to regulation as controlled substances, subjecting them, us, our contract manufacturers, our partners, prescribers, and dispensers to significant regulatory requirements.*

CIP-Tramadol ER, called ConZip in the U.S., is regulated as a schedule IV narcotic controlled substance, subjecting it, us, our contract manufacturers, our partners, prescribers, and dispensers to significant regulation by the U.S. Drug Enforcement Administration ("DEA"). DEA's regulations address such areas as registration, security, recordkeeping, reporting, storage, distribution, prescribing, importing, exporting, and other requirements. States also may regulate controlled substances, including ConZip. These requirements could limit the commercialization of our

controlled substance products, and failure to abide by these requirements could result in enforcement action. Moreover, in recent years FDA and other government authorities have devoted significant attention to the issue of opioids and opioid abuse, including guidance on the development of abuse deterrent opioids and labeling requirements, and these regulatory activities are ongoing. The Company's products may be subject to these and/or additional requirements that are in effect or may be developed in the future, which could have an adverse impact on our business.

*We expect the healthcare industry to face increased limitations on reimbursement, rebates and other payments as a result of healthcare reform, which could adversely affect third-party coverage of our products and how much, or under what circumstances, healthcare providers will prescribe or administer our products, if approved.*

In the U.S., Canada and other countries, sales of our products, if approved for marketing, will depend in part upon the availability of reimbursement from third-party payors, which include governmental authorities, managed care organizations and other private health insurers. Third-party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services.

Increasing expenditures for healthcare have been the subject of considerable public attention in the U.S. Both private and government entities are seeking ways to reduce or contain healthcare costs. Numerous proposals that would effect changes in the U.S. healthcare system have been introduced or proposed in Congress and in some state legislatures, including reducing reimbursement for prescription products and reducing the levels at which consumers and healthcare providers are reimbursed for purchases of pharmaceutical products.

Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products, which in turn would affect the price the Company can receive for those products. Any reduction in reimbursement that results from federal legislation or regulation may also result in a similar reduction in payments from private payors, as private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates.

In March 2010, the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 (together the "Affordable Care Act") were enacted. The Affordable Care Act intended, among other things, to broaden access to health insurance and reduce or constrain the growth of healthcare spending. The Affordable Care Act increased the minimum rebate due for innovator drugs from 15.1% of average manufacturer price ("AMP"), to 23.1% of AMP and capped the total rebate amount for innovator drugs at 100.0% of AMP; however, effective January 1, 2024, this cap will be eliminated, which means that a manufacturer could pay a rebate amount on a unit of the drug that is greater than the average price the manufacturer receives for the drug. The Affordable Care Act and subsequent legislation also narrowed the definition of AMP.

Furthermore, the Affordable Care Act imposes a significant annual, non-deductible fee on companies that manufacture or import certain branded prescription drug products. Pharmaceutical manufacturers are required to comply with the Sunshine Act, provisions of the Affordable Care Act, which require pharmaceutical companies to monitor and report payments, gifts, the provision of samples and other remuneration made to physicians, physician assistants, certain types of advance practice nurses and teaching hospitals.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, the Budget Control Act of 2011 was enacted, which resulted in aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, and which will remain in effect through 2031.

In recent years, the United States has enacted or proposed legislative and regulatory actions and executive orders affecting the healthcare system that may impact our ability to profitably sell any product for which we obtain marketing approval. For example, the federal government has implemented reforms to government healthcare programs in the United States, including changes to the methods for, and amounts of, Medicare reimbursement and changes to the Medicaid Drug Rebate Program. For example, on November 20, 2020, the United States Department of Health and Human Services ("HHS") finalized a regulation removing safe harbor protection under the Federal Anti-Kickback Statute for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law or unless it is passed through to the dispensing pharmacy and reflected in the price to the patient. The implementation of the rule has been delayed until January 1, 2032.

On September 9, 2021, the Biden administration published a wide-ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. The HHS plan includes, among other reform measures, proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. These proposals recently culminated in the enactment of the Inflation Reduction Act (“IRA”) in August 2022, which will, among other things, allow HHS to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics) can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price. Beginning in January 2023 for Medicare Part B and October 2022 for Medicare Part D, the IRA will also penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Although Cipher cannot predict the full effect on our business of the implementation of existing legislation or the enactment of additional legislation pursuant to healthcare and other legislative reform, it is believed that legislation or regulations that would reduce reimbursement for, or restrict coverage of, our products could adversely affect how much or under what circumstances healthcare providers will prescribe or administer our products. This could materially and adversely affect our business by reducing our ability to generate revenues, raise capital, obtain additional licensees and market our products. In addition, Cipher believes the increasing emphasis on managed care in the U.S. has and will continue to put pressure on the price and usage of pharmaceutical products, which may adversely impact product sales.

*It will be difficult for us to profitably market and sell our products if reimbursement for products is limited by government authorities and third-party payer policies.*

In addition to any healthcare reform measures that may affect reimbursement, market acceptance and sales of the Company’s products and product candidates, if approved, will depend on the reimbursement policies of government authorities and third-party payors. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels.

In Canada, patented pharmaceutical products are subject to price control by the PMPRB. Third-party payers increasingly challenge the pricing of pharmaceutical products. In addition, the trend toward managed healthcare in the U.S., the growth of organizations such as Health Maintenance Organizations (“HMOs”) and Managed Care Organizations (“MCOs”) and legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of pharmaceutical products, resulting in lower prices and reduction in product demand. Such cost containment measures and healthcare reform could affect our partners’ ability to sell our products and may have a material adverse effect on our business, financial condition and results of operations.

Uncertainty exists about the reimbursement status of newly approved pharmaceutical products. Reimbursement in the U.S., Canada or other foreign countries may not be available for some of the Company’s products. Any reimbursement granted may not be maintained or limits on reimbursement available from third-party payers may reduce demand for, or negatively affect the price of, those products. These issues could have a material adverse effect on the Company’s business, financial condition and results of operations. The Company is unable to

predict if additional legislation or regulation impacting the healthcare industry or third-party coverage and reimbursement may be enacted in the future, or what effect such legislation or regulation would have on the Company's business.

*If Cipher is not able to convince public payors and hospitals to include its products on the approved formulary lists, revenues may not meet expectations and business, results of operations and financial condition may be adversely affected.*

Hospitals establish formularies, which are lists of drugs approved for use in each such hospital. If a drug is not included on a hospital's formulary, the ability of the Company's distribution partners and key account managers to promote and sell drugs may be limited or denied. If Cipher fails to secure and maintain formulary inclusion for its drugs on favourable terms or are significantly delayed in doing so, Cipher may have difficulty achieving market acceptance of our drugs and our business, results of operations and financial condition could be materially adversely affected.

*Hospital customers may be late in their payments and in some cases may not pay monies owed.*

Hospital customers that purchase our products and product candidates, if approved, generally bill public payors to cover all or a portion of the costs and fees associated with these purchases. Revenue and financial condition depend on the extent to which the customers are reimbursed for these costs and fees, and the extent to which such payments are made to us according to the timelines required by our contracts or general terms and conditions. Such payments may be delayed or withheld for many reasons, including, but not limited to, regulatory requirements of local and national governments, reimbursement requirements of public payors, the financial condition or access to capital of our customers and public payors or the deterioration of general or local economic conditions. The non-payment or late payment of amounts due from customers and public payors may increase the allowance for doubtful accounts or delay the timing of receipt of cash, which would negatively impact our financial condition. In addition, any increase to the allowance for doubtful accounts or write-off accounts receivable would also negatively impact our financial position and results of operations.

*The Company or its distributors may be subject to various laws pertaining to health care fraud and abuse, including anti-kickback, self-referral, false claims and fraud laws, and any violations by us of such laws could result in fines or other penalties.*

The U.S. federal anti-kickback statute prohibits the offer, receipt, or payment of remuneration in exchange for or to induce the referral of patients or the use of products or services that would be paid for in whole or part by Medicare or other federal health care programs. Remuneration has been broadly defined to include anything of value, including cash, improper discounts, and free or reduced price items and services. Many states have similar laws that apply to their state health care programs as well as private payors. Violations of the anti-kickback laws can result in exclusion from federal health care programs and substantial civil and criminal penalties.

The U.S. federal *False Claims Act* ("FCA") imposes liability on persons who, among other things, present or cause to be presented false or fraudulent claims for payment by a federal health care program. The FCA has been used to prosecute persons submitting, or causing the submission of, claims for payment that are inaccurate or fraudulent, that are for services not provided as claimed, or for services that are not medically necessary. The FCA includes a whistleblower provision that allows individuals to bring actions on behalf of the federal government and share a portion of the recovery of successful claims. If our marketing or other arrangements were determined to violate anti-kickback or related laws, including the FCA, then our revenues could be adversely affected, which would likely harm our business, financial condition, and results of operations.

State and federal authorities have aggressively targeted medical technology companies for alleged violations of these anti-fraud statutes, based on improper research or consulting contracts with doctors, certain marketing arrangements that rely on volume-based pricing, off-label marketing schemes, and other improper promotional practices. Companies targeted in such prosecutions have paid substantial fines in the hundreds of millions of dollars or more, have been forced to implement extensive corrective action plans, and have often become subject to consent decrees severely restricting the manner in which they conduct their business. If Cipher becomes the target of such an investigation or prosecution based on our contractual relationships with providers or institutions, or our marketing and promotional practices, the Company could face similar sanctions, which would materially harm our business.

Also, the U.S. *Foreign Corrupt Practices Act*, the Canadian *Corruption of Foreign Officials Act* and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to non-U.S. officials for the purpose of obtaining or retaining business. Our internal control policies and procedures may not protect us from reckless or negligent acts committed by our employees, future distributors, licensees or agents. Violations of these laws, or allegations of such violations, could result in fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

*The Company relies on the success of strategic investments and partnerships.*

Economic, governmental, industry and internal company factors outside our control affect each of the companies in which Cipher may invest or partner. If these companies do not succeed, the value of our assets and the market price of the Common Shares could decline. Some of the material risks relating to the companies in which the Company may invest in, or partner with, include:

- the ability of these companies to successfully develop and manufacture the products which serve as the basis of our investment;
- the ability of competitors to develop similar or more effective products, making the drugs developed by the companies in which Cipher invests difficult or impossible to market;
- the ability of these companies to adequately secure patents for their products that do not infringe existing patents and protect their proprietary information;
- the ability of the companies to remain technologically competitive, and the dependence of these companies upon key scientific and managerial personnel; and
- the ability of these companies to remain financially viable.

Cipher will have limited or no control over the resources that any company in which it invests may devote to developing products in collaboration with us. Any company in which Cipher invests may not perform as expected. These companies may breach or terminate their agreements or otherwise fail to conduct product discovery and development activities successfully or in a timely manner. If any of these events occur, it could have a material adverse effect on the business, financial condition and results of operations.

*The publication of negative results of clinical trials may adversely impact our products.*

From time to time, studies or clinical trials on various aspects of pharmaceutical products, including a product's active ingredient, are conducted by academic researchers or others, including government agencies. The results of these studies or trials, when published or posted on government websites such as [clinicaltrials.gov](http://clinicaltrials.gov), may have a significant 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 our products, an active ingredient in our products, or the therapeutic areas in which our products compete could adversely affect our sales, the prescription trends for our products and the reputation of our products. In the event of the publication of negative results of studies or clinical trials related to our products, an active ingredient in our products, or the therapeutic areas in which our products compete, this could have a materially adverse effect on our business, financial condition and results of operations.

*Development goals and projected time frames are unpredictable and may not be achieved.*

The Company sets goals for, and make public statements regarding, timing of the accomplishment of objectives material to our success, such as the commencement and completion of clinical trials, anticipated regulatory approval dates, and the timing of product launches. The actual timing of these events can vary dramatically due to factors such as delays or failures in our clinical trials, the uncertainties inherent in the regulatory approval process, and delays in achieving product development, manufacturing or marketing milestones necessary to commercialize our products. There can be no assurance that our clinical trials will be completed on a timely basis or at all, that Cipher will make regulatory submissions or receive regulatory approvals as planned, or that Cipher will be able to adhere to our current schedule for the scale-up of manufacturing and launch of any of our products. If the Company fails to

achieve one or more of these milestones as planned, it could have a material adverse effect on our business, financial condition and results of operations.

*Rising insurance costs could negatively impact our profitability.*

The cost of insurance, including director and officer, product liability and general liability insurance, has risen significantly in recent years and is expected to continue to increase. In response, Cipher may increase deductibles and/or decrease certain coverage to mitigate these costs. These increases, and our increased risk due to increased deductibles and reduced coverage, could have a material adverse effect on our business, financial condition and results of operations.

*Under applicable employment laws, the Company may not be able to enforce covenants not to compete.*

Cipher generally enters into non-competition agreements as part of employment agreements with employees. These agreements generally prohibit Cipher's employees, if they cease working for the Company, from competing directly with us or working for our competitors or clients for a limited period. We may be unable to enforce these agreements under the laws of the jurisdictions in which employees work and it may be difficult to restrict our competitors from benefitting from the expertise our former employees or consultants developed while working for us.

*The Company is subject to risks associated with the industry in which it operates.*

Currently, the Company primarily operates in the North American healthcare industry. Accordingly, the Company is subject to risks associated with operating in a single industry in a concentrated geographic location. Any event affecting this industry could have a material adverse effect on the Company's business, financial condition and results of operations. Moreover, our projected revenues and operating results are based on assumptions concerning certain levels of product purchases in these markets. Any failure to attain the Company's projected revenues and operating results as a result of adverse economic or market conditions could have a material adverse effect on the Company's business and financial condition.

*Cipher may be unsuccessful in evaluating material risks involved in completed and future acquisitions.*

Cipher regularly reviews acquisition opportunities and as part of the review, conducts business, legal and financial due diligence with the goal of identifying and evaluating material risks involved in any particular acquisition. Despite Cipher's efforts, it may be unsuccessful in identifying and/or evaluating all such risks. As a result, Cipher may not realize the expected benefits and synergies of any given acquisition. If Cipher fails to realize the expected benefits and/or synergies from one or more acquisitions or does not identify all of the risks associated with a particular acquisition, this could have a material adverse effect on Cipher's business, financial condition and results of operations.

In addition, Cipher may fail to discover liabilities of any acquired companies for which it may be responsible as a successor owner or operator in spite of any investigation made prior to the acquisition. Such discoveries may divert significant financial, operational and managerial resources from existing operations, and could have a material adverse effect on Cipher's business, financial condition and results of operations.

*The Company may be unable to successfully identify, acquire or integrate acquisition targets.*

Part of Cipher's business strategy includes identifying, acquiring and integrating businesses, products, pharmaceuticals or other assets that Cipher believes are complementary to its existing businesses, products, pharmaceuticals or other assets, and forming strategic alliances, joint ventures and other business combinations, to help drive future growth.

Acquisitions or similar arrangements may be complex, time consuming and expensive. Cipher may enter into negotiations for an acquisition but determine not to, or be unable to, complete any particular acquisition or other arrangement, which could result in a significant diversion of management and other employee time, as well as substantial out-of-pocket fees and costs.

If an acquisition or other arrangement is completed, the integration into CIPHER's business with the business, product or asset that is so acquired or subject to such other arrangement may also be complex and time-consuming and, if any such business, product and/or asset is not successfully integrated, CIPHER may not achieve the anticipated benefits, cost-savings or growth opportunities and may experience other opportunity costs.

Furthermore, these acquisitions and other arrangements, even if successfully integrated, may not advance or enhance CIPHER's business strategy as anticipated (or to an extent that the cost of such acquisitions and other arrangements would be justified), and they may expose CIPHER to increased competition or challenges with respect to CIPHER's products or geographic markets and expose CIPHER to additional liabilities, including litigation, tax and successor liability risks, associated with any business, product or other asset that is acquired or subject to such other arrangement.

Any one of these challenges or risks could impair CIPHER's ability to realize any benefit from any such acquisition or other arrangement and this could have a material adverse effect on CIPHER's business, financial condition and results of operations.

*CIPHER may be unsuccessful in applying its tax loss carry forwards*

Deferred income tax assets and liabilities are determined using enacted or substantially enacted tax rates for the effects of net operating losses and temporary differences between the book and tax bases of assets and liabilities. We recognize deferred tax assets to the extent it is probable that taxable profit will be available against which the asset can be utilized. In making this determination, certain judgements are made relating to the level of expected future taxable income and to available tax-planning strategies and their impact on the use of existing loss carryforwards and other income tax deductions. Judgement is required in the application of income tax legislation. We are subject to assessments by various taxation authorities who may interpret tax legislation differently. These differences may affect the final amount or timing of the payment of taxes. We also consider historical profitability and volatility to assess whether we believe it is probable that the existing loss carry forwards and other income tax deductions will be used to offset future taxable income otherwise calculated. If judgements or estimates in the determination of our current and deferred tax provision prove to be inaccurate, or if certain tax rates or laws change, or new interpretations or guidance emerge on the application of tax legislation, our results from operations and financial position could be materially impacted.

*CIPHER historically conducted certain of its operations through U.S. subsidiaries.*

CIPHER historically conducted certain of its operations through U.S. subsidiaries. CIPHER may thus be subject to a number of associated legacy risks which are beyond its control. While these factors cannot be accurately predicted, CIPHER believes the relative risk of its historic operations in the United States is low on a world-wide scale.

*Compliance with privacy and security regulation.*

The Company may also be subject to various privacy and security regulations, including, but not limited to, the U.S. federal *Health Insurance Portability and Accountability Act* of 1996 ("HIPAA"), as amended by the U.S. federal *Health Information Technology for Economic and Clinical Health Act* of 2009. HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common health care transactions (e.g. health care claims information and plan eligibility, referral certification and authorization, claims status, plan enrolment, coordination of benefits and related information), as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition to many other jurisdictions, several U.S. states have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA. Failure to comply with any of these laws could result in the imposition of significant civil and criminal penalties. The costs of compliance with these laws or similar laws in other countries and the potential liability associated with any failure to comply with these laws could have a material adverse effect on the Company's business, financial condition and results of operations.



*Our policies regarding returns, allowances and chargebacks may reduce revenues in future fiscal periods.*

We cannot ensure that our estimated reserves are adequate or that actual product returns, allowances and chargebacks will not exceed the estimates, which could have a material adverse effect on our results of operations, financial condition, and cash flows.

*The Company may be subject to certain regulations that could restrict its activities and abilities to generate revenues as planned.*

From time-to-time, governments, government agencies and industry self-regulatory bodies in Canada, the U.S. and other countries in which Cipher will operate have adopted statutes, regulations and rulings that directly or indirectly affect the activities of Cipher and our future clients. These regulations could adversely impact on our ability to execute our business strategy and generate revenues as planned.

*The Company is subject to risks related to additional regulatory burden and controls over financial reporting.*

The Company is subject to the continuous and timely disclosure requirements of Canadian laws and the rules, regulations and policies of the TSX. These rules, regulations and policies relate to, among other things, corporate governance, corporate controls, internal controls, disclosure controls and procedures and financial reporting and accounting systems. The Company has made, and will continue to make, changes in these and other areas, including the Company's internal controls over financial reporting. However, there is no assurance that these and other measures that it may take will be sufficient to allow the Company to satisfy its obligations as a public company on a timely basis. In addition, compliance with reporting and other requirements applicable to public companies create additional costs for the Company and require the time and attention of management of the Company. The Company cannot predict the amount of the additional costs that the Company may incur, the timing of such costs or the impact that management's attention to these matters will have on the Company's business.

In addition, the Company's inability to maintain effective internal controls over financial reporting could increase the risk of an error in its financial statements. Cipher's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, is responsible for establishing and maintaining adequate internal controls over financial reporting. The Company's internal controls 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 International Financial Reporting Standards. Internal controls over financial reporting cannot provide absolute assurance of achieving financial reporting objectives due to its inherent limitations. Internal controls over financial reporting is a process that involves human diligence and compliance and is therefore subject to error, improper override or improper application of the internal controls. 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 the Company fails to maintain effective internal controls over financial reporting, then there is an increased risk of an error in the Company's financial statements that could result in the Company being required to restate previously issued financial statements at a later date.

*The Company relies on third parties to perform distribution, logistics, invoicing, regulatory and sales services for its products.*

The Company relies on third parties to provide distribution, logistics, invoicing, regulatory and sales services including warehousing of finished products, accounts receivable management, billing, collection, record keeping and processing of invoices (including with insurance companies). If the third parties cease to be able to provide the Company with these services or do not provide these services in a timely or professional manner, or in accordance with the applicable regulatory requirements, or if contracts with such third parties are terminated for any reason, the Company may not be able to successfully manage the logistics associated with distributing and selling its products which could result in a delay or interruption in delivering products to its customers and could impact product sales and revenues or the Company's ability to integrate new products into its business, any of which could have a material adverse effect on the Company's business, financial condition and results of operations. Such third parties' failure to comply with the applicable regulatory requirements could also subject us to regulatory action.

In addition, the supply of the Company's products to its customers (or, in some cases, supply from the Company's contract manufacturers to the Company) is subject to and dependent upon the use of transportation services and third party distribution facilities. Such supply chain logistics result in the Company not being in control of its products at all times, while maintaining liability for such products. Moreover, transportation services or third party distribution facilities may be disrupted (including as a result of weather conditions or due to technical, labour or other difficulties or conditions), any of which could have a material adverse effect on the Company's business, financial condition and results of operations.

*The Company is subject to risks related to general commercial litigation, class actions, employment claims and other litigation claims, as well as potential administrative and regulatory actions, as part of its operations.*

In the course of its business, the Company receives general commercial claims related to the conduct of its business and the performance of its products and services, employment claims and other litigation claims, and the Company also could become subject to class actions. Litigation resulting from these claims could be costly and time-consuming and could divert the attention of management and other key personnel from the Company's business and operations. The complexity of any such claims and the inherent uncertainty of commercial, class action, employment and other litigation increases these risks. In recognition of these considerations, the Company could suffer significant litigation expenses in defending any of these claims and may enter into settlement agreements. If the Company is unsuccessful in its defense of material litigation claims or is unable to settle the claims, the Company may be faced with significant monetary damage awards or other remedies against it including injunctive relief that could have a material adverse effect on the Company's business, financial condition and results of operations. Administrative or regulatory actions against the Company or its employees could also have a material adverse effect on the Company's business, financial condition and results of operations.

*It may be difficult for shareholders to realize in the United States upon judgments of U.S. courts predicated upon civil liability of the Company and its directors and officers.*

The Company is a corporation existing under the laws of the Province of Ontario, Canada. Many of the Company's assets are located outside of the United States, and certain of its officers and directors are residents of countries other than the United States. As a result, it may be difficult for shareholders to effect service of process within the United States upon the Company and its directors and officers, or to realize in the United States upon judgments of courts of the United States predicated upon civil liability of the Company and its directors and officers under United States federal securities laws.

### **Risks Related to Our Intellectual Property**

*If the Company infringes or is alleged to infringe or otherwise violate intellectual property rights of third parties, our business could be harmed.*

Our research, development and commercialization activities may infringe, or otherwise violate or be claimed to infringe or otherwise violate, patents or patent applications owned or controlled by other parties. Competitors in the field of therapies that are similar to Cipher, have developed large portfolios of patents and patent applications relating to our business. There may be granted patents that could be asserted against us in relation to such product candidates.

There may also be granted patents held by third parties that may be infringed or otherwise violated by our other product candidates and activities, and Cipher does not know whether or to what extent the Company is infringing or otherwise violating third party patents. There may also be third party patent applications that, if approved and granted as patents, may be asserted against us in relation to our products or any of our product candidates or activities. These third parties could bring claims against Cipher that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages and legal fees. Further, if a patent infringement suit were brought against us, we could be temporarily or permanently enjoined or otherwise forced to stop or delay research, development, manufacturing, marketing or sales of the product candidate or method that is the subject of the suit.

As a result of patent infringement claims, or to avoid potential claims, Cipher may choose or be required to seek licenses from third parties. These licenses may not be available on acceptable terms, or at all. Even if Cipher is able to obtain a license, the license would likely obligate the Company to pay license fees or royalties or both, and the rights granted to the Company might be nonexclusive, which could result in competitors gaining access to the same intellectual property, or such rights might be restrictive and limit our present and future activities. Ultimately, Cipher or a licensee could be prevented from commercializing a product or be forced to cease some aspect of business operations if, as a result of actual or threatened patent infringement claims, the Company is unable to enter into or maintain licenses on acceptable terms.

*If efforts to obtain, protect or enforce our patents and other intellectual property rights related to our products or any of our product candidates are not adequate, Cipher may not be able to compete effectively and otherwise may be harmed.*

Our commercial success depends in part on our ability to obtain and maintain patent protection and utilize trade secret protection for our intellectual property and proprietary technologies, our products and their uses, as well as our ability to operate without infringing upon the proprietary rights of others. We rely upon a combination of patents, trade secret protection and confidentiality agreements, assignment of invention agreements and other contractual arrangements to protect the intellectual property related to our products and our other development programs. There can be no assurance as to the breadth or degree of protection that existing or future patents or patent applications may afford us or that any patent applications will result in issued patents or that our patents will be upheld if challenged. Limitations on the scope of our intellectual property rights may limit our ability to prevent third parties from designing around such rights and competing against us. For example, some of our patents typically do not claim a new compound, in which case the active pharmaceutical ingredients of our products are existing compounds and our granted patents and pending patent applications are directed to, among other things, novel formulations and/or uses of these existing compounds. Accordingly, other parties may compete with us, for example, by independently developing or obtaining competing formulations that design around our patent claims, but which may contain the same active ingredients, or by seeking to invalidate our patents. Moreover, any disclosure to or misappropriation by third parties of our confidential proprietary information, unless the Company has sufficient patent and/or trade secret protection and is able to enforce such rights successfully, could enable competitors to quickly duplicate or surpass our technological achievements, eroding our competitive position in our market.

However, the patents and patent applications that Cipher owns or licenses may fail to result in granted patents in the U.S. or foreign jurisdictions or, if granted, may fail to prevent a potential infringer from marketing its product or be deemed invalid and unenforceable by a court. Our ability to obtain and maintain valid and enforceable patents depends on various factors, including interpretation of our technology and the prior art and whether the differences between them allow our technology to be patentable. Patent applications and patents granted from them are complex, lengthy and highly technical documents that are often prepared under very limited time constraints and may not be free from errors that make their interpretation uncertain. The existence of errors in a patent may have a materially adverse effect on the patent, its scope and its enforceability. Our pending patent applications may not issue, and the scope of the claims of patent applications that do issue, may be too narrow to adequately protect our competitive advantage. Also, our granted patents and applications may be subject to challenges, including ownership challenges, or may be narrowly construed and may not provide adequate protection.

Even if these patents do successfully issue, third parties may challenge the validity, enforceability or scope of such granted patents or any other granted patents Cipher owns or licenses, which may result in such patents being narrowed, invalidated or held unenforceable. For example, patents granted by the European Patent Office may be opposed by any person within 9 months from the publication of their grant. Also, patents granted by the USPTO may be subject to re-examination and other challenges. In addition, recent changes to the patent laws of the U.S. provide

additional procedures for third parties to challenge the validity of patents issuing from patent applications filed after March 15, 2013. Furthermore, efforts to enforce our patents could give rise to challenges to their validity or unenforceability in court proceedings. If the patents and patent applications Cipher holds or pursues with respect to our products or any of our other product candidates are challenged, it could threaten our competitive advantage for our products or any of our other product candidates. Furthermore, even if they are not challenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. To meet such challenges, which are part of the risks and uncertainties of developing and marketing product candidates, the Company may need to evaluate third party intellectual property rights and, if appropriate, to seek licenses for such third party intellectual property or to challenge such third party intellectual property, which may be costly and may or may not be successful, which could also have a material adverse effect on the commercial potential for products and any other product candidates.

Furthermore, for applications filed before March 16, 2013, or patents issuing from such applications, an interference proceeding can be invoked by a third party, or instituted by USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications and patents. As of March 16, 2013, the U.S. transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO under the new first-to-file system before us could therefore be awarded a patent covering an invention of ours even if Cipher had made the invention before it was made by the third party.

The change to “first-to-file” from “first-to-invent” is one of the changes to the patent laws of the U.S. resulting from the *Leahy-Smith America Invents Act* signed into law on September 16, 2011. Among some of the other changes to the patent laws are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. Because of a lower evidentiary standard in certain USPTO proceedings compared to the evidentiary standard in U.S. federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

Even where patent, trade secret and other intellectual property laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights and the outcome of such litigation would be uncertain. Moreover, any actions Cipher may bring to enforce our intellectual property against our competitors could provoke them to bring counterclaims against us, and our competitors have intellectual property portfolios of their own, some of which are substantial. An unfavorable outcome could have a material adverse effect on our business and could result in the challenged patent being interpreted narrowly or invalidated, or one or more of our patent applications may be not be granted.

We also rely on trade secret protection and confidentiality agreements to protect our know-how, data and information prior to filing patent applications and during the period before they are published. We further rely on trade secret protection and confidentiality agreements to protect proprietary know-how that may not be patentable, processes for which patents may be difficult to obtain or enforce and other elements of our product development processes that involve proprietary know-how, information or technology that is not covered by patents.

In an effort to protect our trade secrets and other confidential information, Cipher incorporates confidentiality provisions in all our employees’ agreements and require our consultants, contractors and licensees to which the Company discloses such information to execute confidentiality agreements upon the commencement of their relationships with us. These agreements require that confidential information, as defined in the agreement and disclosed to the individual by us during the course of the individual’s relationship with us, be kept confidential and not disclosed to third parties for an agreed term. These agreements, however, may not provide Cipher with adequate protection against improper use or disclosure of confidential information, and these agreements may be breached. Adequate remedies may not exist in the event of unauthorized use or disclosure of the Company’s confidential information. A breach of confidentiality could significantly affect our competitive position and Cipher could lose our trade secrets or they could become otherwise known or be independently discovered by our competitors. Also, to the extent that our employees, consultants or contractors use any intellectual property owned by others in their work for us, disputes may arise as to the rights in any related or resulting know-how and inventions. Additionally, others may

independently develop the same or substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets and other confidential information. Any of the foregoing could deteriorate our competitive advantages, undermine the trade secret and contractual protections afforded to our confidential information and have material adverse effects on our business.

*Changes in U.S., Canadian or foreign patent law could diminish the value of patents in general, thereby impairing our ability to protect our products.*

The strength of patents in the pharmaceutical field involves complex legal and scientific questions and, in the U.S., Canada and many foreign jurisdictions, patent policy also continues to evolve, and the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. This uncertainty includes changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law in ways affecting the scope or validity of granted patents, or both. Particularly in recent years in the U.S., there have been several major legislative developments and court decisions that have affected patent laws in significant ways and there may be more developments in the future that may weaken or undermine our ability to obtain new patents or to enforce existing and future patents owned or licensed.

*There has been substantial litigation in the pharmaceutical industry concerning the manufacture and supply of novel versions of existing drugs as well as generic versions of existing drugs. Regardless of FDA or Health Canada approval, should anyone commence a lawsuit with respect to any alleged patent infringement by the Company, the uncertainties inherent in patent litigation make the outcome of such litigation difficult to predict and the cost involved in defending every lawsuit can be substantial.*

When a drug developer files a 505(b)(2) NDA or ANDA, it is required to certify to the FDA that no patent information on the drug product and drug substance that claims the reference listed drug, in the case of an ANDA, or on which investigations that were relied on by the developer for approval of its application were conducted, in the case of a 505(b)(2) application, as well as claiming methods of use for such drug, has been submitted to FDA. Alternatively, applicants may certify that such patents have expired, the date any such patent will expire, or that any such patent is invalid or will not be infringed by the manufacture, sale or use of the new drug for which the 505(b)(2) NDA or ANDA is submitted. Approval of a NDA is not effective until each listed patent expires, unless the applicant certifies that the patents are not infringed or invalid, or indicates, in the case of method of use patents, that the applicant is not seeking approval for the patented method of use. If the applicant certifies that the patents are not infringed or are invalid, the applicant must notify the patent holder and the holder of the branded product NDA within set timeframes. A patent holder or NDA holder may then bring a patent infringement lawsuit within 45 days of receiving notice. In such a case, the FDA is precluded by statute from making an approval effective until the earlier of 30 months after the receipt of the certification notice by the patent or NDA holder, a final court decision of non-infringement or patent invalidity, settlement, or a shorter or longer period as determined by the court. Challenges of this type are not uncommon. Similar procedures exist in Canada under the Patented Medicines (Notice of Compliance) Regulations.

Third parties own patents relating to product formulations. Claims by these companies that Cipher infringes their proprietary technology may result in liability for damages or may delay the development and commercialization of Cipher's products. In the pharmaceutical industry, it is not uncommon for competitors to advance such claims for strategic purposes. There can be no assurance that additional patents or other litigation will not arise in connection with any of our current or future products or product candidates. Patent litigation, with or without merit, is time-consuming and costly and may significantly impact our financial condition and results of operations, even if the Company prevails. If Cipher does infringe the intellectual property rights of others, the Company could lose the right to develop, manufacture or sell products or could be required to pay monetary damages or royalties to license proprietary rights from third parties. The outcomes of infringement actions are uncertain and infringement actions are costly and divert technical and management personnel from their normal responsibilities.

To the extent our products are patented and the patents are suitable for listing in the FDA's Approved Drug Products List (the "Orange Book"), and are listed in the Orange Book, as required, the patents can be challenged, generic products can be approved under an ANDA, or changes to our drug products can be approved under a 505(b)(2) application. In the United States, under the "Hatch-Waxman Act", the FDA can approve an ANDA, for a generic version of a branded drug. In place of clinical studies, an ANDA applicant usually needs only to submit data demonstrating that its product has the same active ingredient(s), dosage form, strength, route of administration, labeling, performance characteristics and intended use as our product. An ANDA applicant must also demonstrate that

the proposed generic product is bioequivalent to the reference listed drug. This is referred to as the ANDA process. The “Hatch-Waxman Act” requires an applicant for a drug that relies, at least in part, on the patent of a branded drug, to go through the patent certification process described above.

Any litigation could have a material adverse effect on our business, financial condition and operating results.

*If Cipher is unable to protect our trademarks from infringement, our business prospects may be harmed.*

Cipher owns and has licensed trademarks that identify our products and these trademarks have been registered in the U.S. and Canada. Although steps are taken to monitor the possible infringement or misuse of our trademarks, it is possible that third parties may infringe, dilute or otherwise violate our trademark rights. Any unauthorized use of our trademarks could harm our reputation or commercial interests. In addition, our enforcement against third-party infringers or violators may be unduly expensive and time-consuming and the outcome may be an inadequate remedy.

### **Risks Related to Our Common Shares**

*Shareholders of the Company may be further diluted.*

In order to finance our operations, we may need, or choose, to issue additional Common Shares in the future, which would result in dilution to our existing shareholders. Our long-term capital requirements will depend on many factors, including potential acquisitions of entities or products, continued scientific progress in our product discovery and development programs, progress in our pre-clinical and clinical evaluation of products and product candidates, time and expense associated with filing, prosecuting and enforcing patent claims and costs associated with obtaining regulatory approvals. In order to meet such capital requirements, Cipher will consider contract fees, collaborative research and development arrangements, public financing or additional private financing (including the issuance of additional equity securities and/or additional debt) to fund all or part of our particular programs. We may need to continue our reliance on the sale of such securities for future financing, resulting in dilution to our existing shareholders. Our long-term capital requirements will depend on many factors, including potential acquisitions of entities or products, continued scientific progress in our product discovery and development programs, progress in our pre-clinical and clinical evaluation of products and product candidates, time and expense associated with filing, prosecuting and enforcing patent claims and costs associated with obtaining regulatory approvals. In order to meet such capital requirements, Cipher will consider contract fees, collaborative research and development arrangements, public financing or additional private financing (including the issuance of additional equity securities and/or additional debt) to fund all or part of our particular programs.

Our business, financial condition and results of operations may depend on our ability to obtain additional financing, which may not be available under favourable terms, if at all. Our ability to arrange such financing in the future will depend in part upon the prevailing capital market conditions as well as our business performance. If our capital resources are exhausted and adequate funds are not available, Cipher may have to reduce substantially, or eliminate, expenditures for research and development, testing, production and marketing of our proposed products, or obtain funds through arrangements with corporate partners that require us to relinquish rights to certain of our technologies or products.

*Our share price has been volatile, and an investment in our Common Shares could suffer a decline in value.*

Market prices for the securities of pharmaceutical and biotechnology companies have historically been highly volatile and the market has, from time to time, experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. In addition to the risk factors described herein, factors such as fluctuations in our operating results, the aftermath of any public announcements made by us, concern as to the safety of any drugs developed by us, and general market conditions can, and have had an adverse effect on the market price of the Common Shares.

In the past, when the market price of a stock has been volatile, shareholders have often instituted securities class action litigation against that company. If any of our shareholders brought a lawsuit against us, the Company could incur substantial costs defending the lawsuit. The lawsuit could also divert the time and attention of our management.

*We have a significant shareholder.*

The interim Chief Executive Officer and a director of the Company, Craig Mull, owns or controls 10,023,234 Common Shares, representing approximately 39.9% of the total outstanding Common Shares as of March 22, 2023. If Mr. Mull was to sell his interest in the Company into the public market, or even if the market was to perceive that such a sale may occur, such event might lower the market price of the Common Shares. In addition, Mr. Mull's interests as a shareholder may not be aligned at all times with the interests of all of the other shareholders of the Company and in light of his ownership he is able to influence and/or affect the outcome of decisions.

*Our operating results may fluctuate significantly and any failure to meet financial expectations may disappoint securities analysts or investors and result in a decline in the price of our Common Shares.*

Our operating results have fluctuated in the past and are likely to do so in the future. These fluctuations could cause the price of the Common Shares to decline. Some of the factors that could cause operating results to fluctuate include the following:

- the inability to complete product development in a timely manner that results in a failure or delay in receiving the required regulatory approvals or allowances to commercialize product candidates;
- the timing of regulatory submissions and approvals;
- the timing and willingness of any current or future collaborators to invest the resources necessary to commercialize our product candidates, and the timing of payments Cipher may make or receive under these arrangements;
- any intellectual property infringement or other lawsuits in which Cipher may become involved;
- foreign currency fluctuations;
- the timing of achievement and the receipt of milestone payments from current or future third parties;
- failure to enter into new or the expiration or termination of current agreements with third parties;
- failure to introduce the product candidates to the market in a manner that generates anticipated revenues;
- changes in costs and/or reimbursement for the Company's products;
- costs related to business development transactions;
- changes in the amount the Company spends to market its products;
- delays between the Company's expenditures to acquire new products, technologies or businesses and the generation of revenues from those acquired products, technologies or businesses;
- changes in treatment practices of physicians that currently prescribe certain of the Company's products;
- increases in the cost of raw materials used to manufacture the Company's products;
- manufacturing and supply interruptions;
- the Company's responses to price competition;
- inventory has a limited shelf life and may require write-downs;
- the timing of wholesaler and distributor purchases; and

- general economic and industry conditions, including potential fluctuations in interest rates.

As a result, the Company believes that quarter-to-quarter comparisons of results from operations, or any other similar period-to-period comparisons, should not be construed as reliable indicators of the Company's future performance. The above factors may cause the Company's operating results to fluctuate and could have a material adverse effect on the Company's business, financial condition and results of operations. In any period, the Company's results may be below the expectations of market analysts and investors, which could cause the trading price of the Common Shares to decline.

Intangible assets represented a significant portion of the Company's total assets. Finite-lived intangible assets are subject to an impairment analysis whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Indefinite-lived intangible assets are tested for impairment annually, or more frequently if events or changes in circumstances indicate that the asset may be impaired. If an impairment exists, the Company would be required to take an impairment charge with respect to the impaired asset. Events giving rise to impairment are difficult to predict and are an inherent risk in the pharmaceutical industry. Because of the significance of intangible assets, should such an impairment of intangible assets occur, it could have a material adverse effect on the Company's business, financial condition and results of operations. As at December 31, 2022, the Company's intangible assets have a net book value of \$2.8 million.

*All of the Company's debt obligations, and any future indebtedness the Company may incur, will have priority over the Common Shares with respect to payment in the event of a liquidation, dissolution or winding up.*

In any liquidation, dissolution or winding up of the Company, the Common Shares would rank below all debt claims against the Company. In addition, any convertible or exchangeable securities or other equity securities that the Company may issue in the future may have rights, preferences and privileges more favourable than those of the Common Shares. As a result, holders of the Common Shares will not be entitled to receive any payment or other distribution of assets upon the liquidation or dissolution until after the Company's obligations to its debt holders and holders of equity securities that rank senior to the Common Shares have been satisfied.

## **DIVIDENDS AND DISTRIBUTIONS**

The Company has not declared or paid any dividends since incorporation and has no present intention to declare or pay any dividends in the foreseeable future. Any decision to declare or pay dividends will be made by the Board based upon the Company's earnings, financial requirements and other conditions existing at such future time. Furthermore, pursuant to the Credit Agreement, there are restrictions on the declaration and payment of dividends.

## **DESCRIPTION OF CAPITAL STRUCTURE**

The Company's authorized capital consists of an unlimited number of Common Shares and an unlimited number of preference shares of the Company, issuable in series ("Preference Shares").

The following is a summary of the rights, privileges, restrictions and conditions attaching to the Common Shares and Preference Shares.

### **Common Shares**

The Company is authorized to issue an unlimited number of Common Shares. The Common Shares rank junior to the Preference Shares on any distribution of assets of the Company on the liquidation, dissolution or winding-up of the Company. Holders of Common Shares are entitled to receive notice of and to attend all annual and special meetings of the shareholders of the Company, other than separate meetings of holders of any other class or series of shares, and to one vote in respect of each Common Share held at such meetings. Holders of Common Shares are entitled to receive dividends if, as and when declared by the Board and to receive pro-rata the remaining assets of the Company upon its liquidation, dissolution or winding-up, subject to the rights of holders of Preference Shares and any other class or series of shares of the Company having priority over the Common Shares. As at March 22, 2023, there were 25,078,739 Common Shares issued and outstanding.



## Preference Shares

The Preference Shares are issuable in series and have such rights, restrictions, conditions and limitations as the Board may from time to time determine. The Preference Shares rank senior to the Common Shares with respect to the payment of dividends or on any distribution of assets of the Company on the liquidation, dissolution or winding-up of the Company. Holders of Preference Shares are not entitled to receive notice of or to attend or vote at any meeting of the shareholders of the Company, except as required by law. As at March 22, 2023, no Preference Shares were issued and outstanding.

## MARKET FOR SECURITIES

The Common Shares of the Company trade on the TSX under the symbol “CPH”. The following table sets forth the reported high and low prices as of the close of the market (TSX) and the trading volume for the periods indicated:

Month (2022)	Toronto Stock Exchange (CDN\$)		
	High	Low	Volume
January	1.90	1.66	674,565
February	2.25	1.74	367,763
March	2.62	1.68	488,949
April	2.61	2.07	479,268
May	2.50	2.00	622,393
June	2.40	2.16	386,300
July	2.39	2.14	1,578,138
August	2.62	2.18	453,814
September	3.39	2.59	832,752
October	3.28	2.85	329,158
November	3.81	3.13	597,395
December	4.07	3.44	430,245

## PRIOR SALES

The following table sets out all the securities issued by the Company during the fiscal year ended December 31, 2022, which are not listed or quoted on a marketplace:

Type of Security	Date Issued	Number of securities	Issue price / Exercise Price
Stock options	March 17, 2022	236,518	NA / \$2.17
Stock options	August 15, 2022	150,000	NA / \$2.31
Restricted share units	March 17, 2022	300,955	NA

## DIRECTORS AND OFFICERS

The following table sets forth the name, residence, position with the Company and principal occupation of each director and executive officer of the Company as at December 31, 2022. Directors of the Company hold office until the next annual shareholders’ meeting or until successors are duly elected or appointed.

Name and Province/State of Residence	Principal Occupation	Director Since
CRAIG MULL <sup>3</sup> <i>Ontario, Canada</i>	Interim Chief Executive Officer and Board of Directors of Cipher	March 26, 2019

Name and Province/State of Residence	Principal Occupation	Director Since
HAROLD WOLKIN <sup>1</sup> <i>Ontario, Canada</i>	Retired. Former Managing Director of BMO Capital Markets, Ex VP and Head of Investment Banking for Dundee Capital Markets	August 9, 2016
CHRISTIAN GODIN <sup>2</sup> <i>Quebec, Canada</i>	President of Inovestor Asset Management.	August 9, 2016
ARTHUR M. DEBOECK <i>Gurabo, Puerto Rico</i>	Vice-President and General Manager of Galephar Pharmaceutical Research, Inc. President of Ohemo Life Science	May 11, 2017
CATHY STEINER <sup>4</sup> <i>Ontario, Canada</i>	Principal and Healthcare lead, Origin Merchant Partners	October 8, 2020
BRYAN JACOBS <i>Ontario, Canada</i>	Chief Financial Officer and Secretary	N/A

- (1) Mr. Wolkin is Chair of the Audit Committee and a member of the Nominating and Governance Committee and the Compensation Committee and the lead independent director.
- (2) Mr. Godin is Chair of the Compensation Committee and a member of the Nominating and Governance Committee and member of the Audit Committee
- (3) Mr. Craig Mull is Chairman of the board of directors and a member of the Compensation Committee
- (4) Ms. Steiner is Chair of the Nominating and Governance Committee and a member of the Audit Committee

All of the directors and executive officers of the Company have been engaged for more than five years in their present principal occupations or in other capacities with the companies with which they currently hold positions, with the exception of:

- Craig Mull, prior to joining Cipher in March 2019, Mr. Mull was the Chief Operating Officer of Typhon Group Limited since 1991.
- Bryan Jacobs, prior to joining Cipher in August 2022, Mr. Jacobs held senior finance positions at pharmaceutical and healthcare technology organizations and was most recently Chief Financial Officer at XYZ Automation Group of Companies.

As at March 22, 2023, the current directors and executive officers as a group beneficially own or control, directly or indirectly, 10,712,862 of the outstanding Common Shares, representing approximately 42.72% of the issued and outstanding Common Shares as of such date.

The term of office of all directors of the Company will expire at the next annual and special meeting of the shareholders of the Company.

#### Cease Trade Orders, Bankruptcies, Penalties or Sanctions

Except as disclosed below, none of our directors or executive officers is, as at the date hereof, or was within ten years before the date hereof, a director, chief executive officer or chief financial officer of any company (including Cipher), that was:

- (a) subject to a cease trade or similar order or an order that denied the relevant company access to any exemption under securities legislation, that, in each case, was in effect for a period of more than 30 consecutive days, that was issued while the director or executive officer was acting in the capacity as director, chief executive officer or chief financial officer; or
- (b) was subject to a cease trade or similar order or an order that denied the relevant company access to any exemption under securities legislation, that, in each case, was in effect for a period of more than 30 consecutive days, that was issued after the director or executive officer ceased to be a director, chief

executive officer or chief financial officer and which resulted from an event that occurred while that person was acting in the capacity as director, chief executive officer or chief financial officer.

Except as disclosed below, no director or executive officer of Cipher, nor a shareholder holding a sufficient number of securities of Cipher to affect materially the control of Cipher:

- (a) is, as at the date hereof, or has been within the ten years before the date hereof, a director or executive officer of any company (including Cipher) that, while that person was acting in that capacity, or within a year of that person 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
- (b) has, within the ten years before the date hereof, 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 the assets of the director, executive officer or shareholder.

No director or executive officer of Cipher, nor a shareholder holding a sufficient number of securities of Cipher to affect materially the control of Cipher, has been subject to:

- (a) 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
- (b) any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable investor in making an investment decision.

### **Conflicts of Interest**

Arthur M. Deboeck is the Vice-President and General Manager of Galephar, a pharmaceutical research and manufacturing company that is also a significant partner of Cipher. As a manufacturer of and licensor of certain of Cipher's commercial products, Galephar's business interests may not align with that of Cipher's in certain circumstances. Mr. Deboeck has agreed to excuse himself from portions of Board meetings when discussions take place on projects where he may be, or perceived to be, in a potential conflict of interest.

Additionally, circumstances arise where other members of the Board serve as directors or officers of corporations which are in competition to the interests of Cipher or who are suppliers of goods and services to Cipher. However, each director and executive officer must comply with the disclosure requirements of the OBCA regarding any material interest. If a declaration of material interest is made, the declaring director shall not vote on the matter if put to a vote of the Board. In addition, the declaring director and executive officer may be requested to recuse himself or herself from the meeting when such matter is being discussed.

### **TRANSFER AGENT AND REGISTRAR**

The Company's registrar and transfer agent is Computershare Investor Services Inc. at its principal office in Toronto, Ontario.

### **MATERIAL CONTRACTS**

The following are the material contracts, other than contracts in the ordinary course of business, and material contracts in the ordinary course of business required to be listed, that were entered into by the Company in 2022 or in 2023 prior to March 22, 2023 or prior to 2022 and are still in effect:

## Galephar Agreement

***In February 2002, the Company entered into the Galephar Agreement. Pursuant to the Galephar Agreement, Galephar granted the Company a license to package, test, obtain regulatory approval and/or market certain pharmaceutical products in certain geographical areas more particularly described in the agreement. The license gives the Company the right to conduct all studies and tests required by the FDA and other regulatory authorities in the geographic area where the pharmaceutical product is being packaged, tested, approved and/or marketed, as well as the right to prepare, file and prosecute any regulatory submissions for approval in such geographic area. The license granted for each pharmaceutical product is of perpetual duration and is an exclusive license in the relevant geographic area and a non-exclusive license in other geographic areas more particularly specified in the agreement.***

In March 2022, the Company entered into the Absorica Amended and Restated Agreement. Under the terms of the Absorica Amended and Restated Agreement, Cipher and Sun agreed to extend Sun's exclusive right to market, sell and distribute the isotretinoin product portfolio, Absorica and Absorica AG in the United States through December 31, 2026 and Absorica LD through December 31, 2024. Under the terms of the Absorica Amended and Restated Agreement, Cipher will continue to earn a royalty on United States net sales from the Sun isotretinoin product portfolio, and will continue to be responsible for manufacturing the supplied product. The Absorica Amended and Restated Agreement extended the relationship with Sun from November 30, 2022 until December 31, 2026.

## Credit Agreement

In March 2023, the Company entered into a credit agreement with The Royal Bank of Canada in respect of the Credit Facility provided to the Company. For details regarding the Credit Agreement please see "*Liquidity and Capital Resources*".

## AUDIT COMMITTEE INFORMATION

All of the committee members have been determined by the Board to be “independent” directors and “financially literate” as such terms are defined in National Instrument 52-110 Audit Committees (“NI 52-110”).

### Relevant Education and Experience of Audit Committee Members

The following is a summary of the education and experience of each member of the Audit Committee relevant to the performance of his responsibility as a member of the Committee.

<u>Audit Committee Member</u>	<u>Relevant Education and Experience</u>
Harold Wolkin (Chair)	Mr. Wolkin is an accomplished investment banker and financial analyst with over 30 years of experience. Mr. Wolkin joined BMO Nesbitt Burns as a senior research analyst in 1983. He went on to serve as managing director in the Diversified Industries Group of BMO Capital Markets until January 2008. Most recently, Mr. Wolkin served as Executive Vice-President and Head of Investment Banking for Dundee Capital Markets. Mr. Wolkin currently serves on a number of public company boards. He was the past President of the CFA Society of Toronto and has been a member of the Chartered Financial Institute since 1980. He is a member of the Institute of Corporate Directors. Mr. Wolkin received a Bachelor of Arts in Economics from York University and a Master of Arts in Economics and Finance from The University of Toronto.
Christian Godin	Mr. Godin works at Inovestor Asset Management since 2018 where he acts as President and Board member. He is the former Head of Equities at Montrusco Bolton Investments Inc. (“Montrusco”), sat on its board of directors and was a member of the Management Committee. Prior to joining Montrusco in 2001, Mr. Godin worked for Merrill Lynch Canada where he was a director and senior equity research analyst. He also worked for Midland Walwyn Capital and CTI Capital. Christian holds a Bachelor of Business Administration from Université du Québec à Montréal and a Master of Science in Administration specialized in Finance from HEC Montréal.

Cathy Steiner

Ms. Steiner has over 20 years experience as an investment banker and strategic advisor working with healthcare and growth companies. She is Principal and Healthcare Lead for Origin Merchant Partners, a mergers & acquisitions advisory and investment banking firm, since January 2018. Prior to joining Origin, she was CFO for technology companies through capital raising and M&A transactions (2014 – 2016). Previously Ms. Steiner was Managing Director for Nucleus GC (2002 – 2014), a boutique healthcare advisory firm, and led Healthcare Investment Banking for CIBC World Markets and Yorkton Securities. Ms. Steiner holds an MBA (Schulich School of Business at York University), MSc (Immunology) (McMaster University) and CPA, CA designation.

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

The Audit Committee has not adopted specific policies and procedures for the engagement of non-audit services by the external auditor. As set out in section 9.1(d) of the Audit Committee charter, the Audit Committee approves any non-audit services provided by the external auditor on a case-by-case basis.

### External Auditor Service Fees

The fees paid or payable by the Company to Ernst & Young LLP in 2022 and 2021, the Company's external auditors, for the periods noted below for all services performed were as follows:

	Fiscal 2022	Fiscal 2021
Audit fees <sup>(1)</sup>	\$239,000	\$214,000
Audit-related fees	-	-
Tax fees <sup>(2)</sup>	-	-
All other fees <sup>(3)</sup>	-	-
<b>TOTAL</b>	<b>\$239,000</b>	<b>\$214,000</b>

- (1) Fees in respect of audit and interim review services performed in order to comply with Canadian generally accepted auditing standards ("GAAS"). In some cases, these may include an appropriate allocation of fees for tax or accounting consultations, to the extent such services were necessary to comply with GAAS.
- (2) Fees in respect of services performed by the auditor's tax professionals, except those services required in order to comply with GAAS which are included under "Audit Fees". Tax services include assistance with tax compliance and tax planning and advice.
- (3) Fees in respect of all services not falling under any of the foregoing three categories.

### INTEREST OF EXPERTS

The financial statements of the Company for the fiscal year ended December 31, 2022 have been audited by Ernst & Young, LLP which is independent with respect to the meaning of the Rules of Professional Conduct as outlined by the Institute of Chartered Accountants of Ontario.

### ADDITIONAL INFORMATION

Additional information relating to the Company may be found on SEDAR at [www.sedar.com](http://www.sedar.com). Additional information, including directors' and executive officers' remuneration and indebtedness, principal holders of the Company's securities and securities authorized for issuance under equity compensation plans is contained in the Company's management information circular dated May 13, 2022. Additional financial information is available in the Company's financial statements and notes and MD&A for its most recently completed financial year.

## SCHEDULE A

### CHARTER OF THE AUDIT COMMITTEE OF CIPHER PHARMACEUTICALS INC.

#### GENERAL

#### 1. PURPOSE AND RESPONSIBILITIES OF THE COMMITTEE

##### 1.1 Purpose

The primary purpose of the Committee is to assist Board oversight of:

- (a) the integrity of the Corporation's financial statements and of the accounting and financial reporting practices and procedures of the Corporation;
- (b) the adequacy of the internal and accounting controls and procedures of the Corporation;
- (c) the External Auditor's qualifications and independence;
- (d) the performance of the Corporation's internal audit function, if any and the External Auditor; and
- (e) the Corporation's compliance with legal and regulatory requirements, to the extent that such requirements are relevant to the foregoing.

#### 2. DEFINITIONS AND INTERPRETATION

##### 2.1 Definitions

In this Charter:

- (a) "**Board**" means the Board of Directors of the Corporation;
- (b) "**Chair**" means the chair of the Committee;
- (c) "**Committee**" means the audit committee of the Board;
- (d) "**Corporation**" means Cipher Pharmaceuticals Inc.;
- (e) "**Directors**" means the directors of the Corporation;
- (f) "**External Auditor**" means the Corporation's independent auditor; and
- (g) "**GAAP**" means Canadian generally accepted accounting principles.

Any words or terms with initial capital letters which are not defined herein shall have the meanings ascribed thereto in the charter of the Directors.

##### 2.2 Interpretation

The provisions of this Charter are subject to any Applicable Laws.

## CONSTITUTION AND FUNCTIONING OF THE COMMITTEE

### 3. ESTABLISHMENT AND COMPOSITION OF THE COMMITTEE

#### 3.1 Establishment of the Audit Committee

The Committee is hereby continued with the constitution, function and responsibilities herein set forth.

#### 3.2 Appointment and Removal of Members of the Committee

- (a) *Board Appoints Members.* The members of the Committee shall be appointed by the Board.
- (b) *Annual Appointments.* The appointment of members of the Committee shall take place annually at the first meeting of the Board after a meeting of the shareholders at which Directors are elected, provided that if the appointment of members of the Committee is not so made, the Directors who are then serving as members of the Committee shall continue as members of the Committee until their successors are appointed.
- (c) *Vacancies.* The Board may appoint a member to fill a vacancy which occurs in the Committee between annual elections of Directors.
- (d) *Removal of Member.* Any member of the Committee may be removed from the Committee by a resolution of the Board.

#### 3.3 Number of Members

The Committee shall consist of three or more Directors.

#### 3.4 Independence of Members

Each member of the Committee shall be independent as defined under Applicable Laws.

#### 3.5 Financial Literacy

- (a) *Financial Literacy Requirement.* Each member of the Committee shall be financially literate or must become financially literate within a reasonable period of time after his or her appointment to the Committee.
- (b) *Definition of Financial Literacy.* “Financially literate” means 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 Corporation’s financial statements.

#### 3.6 Audit Committee Financial Expert

- (a) *Attributes of an Audit Committee Financial Expert.* To the extent possible, the Board shall appoint to the Committee at least one Director who has the following attributes:
  - (i) an understanding of GAAP and financial statements;
  - (ii) ability to assess the general application of such principles in connection with the accounting for estimates, accruals and reserves;
  - (iii) experience preparing, auditing, analyzing or evaluating financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of issues that can reasonably be expected to be raised by the



Corporation's financial statements, or experience actively supervising one or more persons engaged in such activities;

- (iv) an understanding of internal controls and procedures for financial reporting; and
  - (v) an understanding of audit committee functions.
- (b) *Experience of the Audit Committee Financial Expert.* To the extent possible, the Board shall appoint to the Committee at least one Director who acquired the attributes in (a) above through:
- (i) education and experience as a principal financial officer, principal accounting officer, controller, public accountant or auditor or experience in one or more positions that involve the performance of similar functions (or such other qualification as the Board interprets such qualification in its business judgment);
  - (ii) experience actively supervising a principal financial officer, principal accounting officer, controller, public accountant, auditor or person performing similar functions;
  - (iii) experience overseeing or assessing the performance of companies or public accountants with respect to the preparation, auditing or evaluation of financial statements; or
  - (iv) other relevant experience.

#### **4. COMMITTEE CHAIR**

##### **4.1 Board to Appoint Chair**

The Board shall appoint the Chair from the members of the Committee (or, if it fails to do so, the members of the Committee shall appoint the Chair from among its members).

##### **4.2 Chair to be Appointed Annually**

The appointment of the Committee's Chair shall take place annually at the first meeting of the Board after a meeting of the members at which Directors are elected, provided that if the designation of Chair is not so made, the Director who is then serving as Chair shall continue as Chair until his or her successor is appointed.

#### **5. COMMITTEE MEETINGS**

##### **5.1 Quorum**

A quorum of the Committee shall be a majority of its members.

##### **5.2 Secretary**

The Chair shall designate from time to time a person who may, but need not, be a member of the Committee, to be Secretary of the Committee.

##### **5.3 Time and Place of Meetings**

The time and place of the meetings of the Committee, the calling of meetings and the procedure in all things at such meetings shall be determined by the Committee in accordance with the by-laws of the Corporation; provided, however, the Committee shall meet at least quarterly.

5.4 In Camera Meetings

As part of each meeting of the Committee at which the Committee recommends that the Board approve the annual audited financial statements or at which the Committee approves the quarterly financial statements, the Committee shall meet separately with each of:

- (a) management;
- (b) the External Auditor; and
- (c) the internal auditor, if any.

5.5 Right to Vote

Each member of the Committee shall have the right to vote on matters that come before the Committee.

5.6 Invitees

The Committee may invite Directors, officers and employees of the Corporation or any other person to attend meetings of the Committee to assist in the discussion and examination of the matters under consideration by the Committee. The External Auditor shall receive notice of each meeting of the Committee and shall be entitled to attend any such meeting at the Corporation's expense.

5.7 Regular Reporting

The Committee shall report to the Board at the Board's next meeting the proceedings at the meetings of the Committee and all recommendations made by the Committee at such meetings.

**6. AUTHORITY OF COMMITTEE**

6.1 Retaining and Compensating Advisors

The Committee shall have the authority to engage independent counsel and other advisors as the Committee may deem appropriate in its sole discretion and to set and pay the compensation for any advisors employed by the Committee. The Committee shall not be required to obtain the approval of the Board in order to retain or compensate such consultants or advisors.

6.2 Subcommittees

The Committee may form and delegate authority to subcommittees if deemed appropriate by the Committee.

6.3 Recommendations to the Board

The Committee shall have the authority to make recommendations to the Board, but shall have no decision-making authority other than as specifically contemplated in this Charter.

**7. REMUNERATION OF COMMITTEE MEMBERS**

7.1 Remuneration of Committee Members

Members of the Committee and the Chair shall receive such remuneration for their service on the Committee as the Board may determine from time to time.

## 7.2 Directors' Fees

No member of the Committee may earn fees from the Corporation or any of its subsidiaries other than Directors' fees (which fees may include cash and/or securities or options or other in-kind consideration ordinarily available to Directors, as well as all of the regular benefits that other Directors receive). For greater certainty, no member of the Committee shall accept, directly or indirectly, any consulting, advisory or other compensatory fee from the Corporation or any of its subsidiaries.

### **SPECIFIC DUTIES AND RESPONSIBILITIES**

## **8. INTEGRITY OF FINANCIAL STATEMENTS**

### 8.1 Review and Approval of Financial Information

- (a) *Annual Financial Statements.* The Committee shall review and discuss with management and the External Auditor, the Corporation's audited annual financial statements and related MD&A together with the report of the External Auditor thereon and, when appropriate, shall recommend to the Board that the Board approve the audited annual financial statements and related MD&A.
- (b) *Interim Financial Statements.* The Committee shall review and discuss with management and the External Auditor and, when appropriate, shall recommend to the Board that the Board approve the Corporation's interim unaudited financial statements and related MD&A.
- (c) *Material Public Financial Disclosure.* The Committee shall discuss with management and the External Auditor:
  - (i) the types of information to be disclosed and the type of presentation to be made in connection with earnings press releases,
  - (ii) financial information and earnings guidance (if any) to be provided to analysts, investors and rating agencies, and
  - (iii) press releases containing financial information (paying particular attention to any use of "pro forma" or "adjusted" non-GAAP information),
 and, when appropriate, shall recommend to the Board that the Board approve any such material financial disclosure prior to its release to the public.
- (d) *Procedures for Review.* The Committee shall be satisfied that adequate procedures are in place for the review of the Corporation's disclosure of financial information extracted or derived from the Corporation's financial statements (other than financial statements, MD&A and earnings press releases, which are dealt with elsewhere in this Charter) and shall periodically assess the adequacy of those procedures.
- (e) *Accounting Treatment.* The Committee shall review and discuss with management and the External Auditor:
  - (i) major issues regarding accounting principles and financial statement presentations including any significant changes in the Corporation's selection or application of accounting principles and major issues as to the adequacy of the Corporation's internal controls and any special audit steps adopted in light of material control deficiencies;
  - (ii) analyses prepared by management and/or the External Auditor setting forth significant financial reporting issues and judgments made in connection with the preparation of the financial statements, including analyses of the effects of alternative GAAP methods on the financial statements;

- (iii) the effect of regulatory and accounting initiatives, as well as off-balance sheet structures on the Corporation's financial statements;
- (iv) the management certifications of the financial statements as required by applicable securities laws in Canada or otherwise; and
- (v) pension plan financial statements, if any.

## 9. **EXTERNAL AUDITOR**

### 9.1 External Auditor

- (a) *Authority with Respect to External Auditor.* The Committee shall be directly responsible for the nomination, compensation and oversight of the work of the External Auditor engaged for the purpose of preparing or issuing an audit report or performing other audit, review or attest services for the Corporation. In the discharge of this responsibility, the Committee shall:
  - (i) have sole responsibility for recommending to the Board the person to be proposed to the Corporation's shareholders for appointment as External Auditor for the above-described purposes as well as the responsibility for recommending such External Auditor's compensation and determining at any time whether the Board should recommend to the Corporation's shareholders whether the incumbent External Auditor should be removed from office;
  - (ii) review the terms of the External Auditor's engagement, discuss the audit fees with the External Auditor and be solely responsible for approving such audit fees; and
  - (iii) require the External Auditor to confirm in its engagement letter each year that the External Auditor is accountable to, and shall report directly to, the Committee as the representative of shareholders.
- (b) *Independence.* The Committee shall satisfy itself as to the independence of the External Auditor. As part of this process the Committee shall:
  - (i) assure the regular rotation of the lead audit partner as required by law and consider whether, in order to ensure continuing independence of the External Auditor, the Corporation should rotate periodically, the audit firm that serves as External Auditor;
  - (ii) require the External Auditor to submit on a periodic basis to the Committee, a formal written statement delineating all relationships between the External Auditor and the Corporation and its subsidiaries and that the Committee is responsible for actively engaging in a dialogue with the External Auditor with respect to any disclosed relationships or services that may impact the objectivity and independence of the External Auditor and for recommending that the Board take appropriate action in response to the External Auditor's report to satisfy itself of the External Auditor's independence;
  - (iii) address non-audit services provided by the External Auditor as described in clause (d) below; and
  - (iv) review and approve the policy setting out the restrictions on the Corporation and its subsidiaries hiring partners, employees and former partners and employees of the Corporation's current or former External Auditor.

- (c) *Issues Between External Auditor and Management.* The Committee shall:
- (i) review any problems experienced by the External Auditor in conducting the audit, including any restrictions on the scope of the External Auditor's activities or in access to requested information;
  - (ii) review any disagreements with management and, to the extent possible, resolve any disagreements between management and the External Auditor regarding financial reporting; and
  - (iii) review with the External Auditor:
    - (A) any accounting adjustments that were proposed by the External Auditor, but were not made by management;
    - (B) any communications between the audit team and audit firm's national office respecting significant auditing or accounting issues presented by the engagement;
    - (C) the performance of the Corporation's internal audit function and internal auditors.
- (d) *Non-Audit Services.*
- (i) The Committee shall either:
    - (A) approve any non-audit services provided by the External Auditor or the external auditor of any subsidiary of the Corporation to the Corporation (including its subsidiaries); or
    - (B) adopt specific policies and procedures for the engagement of non-audit services, provided that such pre-approval policies and procedures are detailed as to the particular service, the Committee is informed of each non-audit service and the procedures do not include delegation of the Committee's responsibilities to management.
  - (ii) The Committee may delegate to one or more members of the Committee the authority to pre-approve non-audit services in satisfaction of the requirement in the previous section, provided that such member or members must present any non-audit services so approved to the full Committee at its first scheduled meeting following such pre-approval.
  - (iii) The Committee shall instruct management to promptly bring to its attention any services performed by the External Auditor which were not recognized by the Corporation at the time of the engagement as being non-audit services.
- (e) *Evaluation of External Auditor.* The Committee shall evaluate the External Auditor each year, and present its conclusions to the Board. In connection with this evaluation, the Committee shall:
- (i) review and evaluate the performance of the lead partner of the External Auditor;
  - (ii) obtain the opinions of management and of the persons responsible for the Corporation's internal audit function with respect to the performance of the External Auditor; and
  - (iii) obtain and review a report by the External Auditor describing:
    - (A) the External Auditor's internal quality-control procedures;
    - (B) to the extent permitted by Applicable Laws and by the Canadian Public Accountability Board, any material issues raised by the most recent internal

quality-control review, or peer review, of the External Auditor's firm or by any inquiry or investigation by governmental or professional authorities, within the preceding five years, respecting one or more independent audits carried out by the External Auditor's firm, and any steps taken to deal with any such issues; and

- (C) all relationships between the External Auditor and the Corporation (for the purposes of assessing the External Auditor's independence).
- (f) *Review of Management's Evaluation and Response.* The Committee shall:
- (i) review management's evaluation of the External Auditor's audit performance;
  - (ii) review the External Auditor's recommendations, and review management's response to and subsequent follow-up on any identified weaknesses;
  - (iii) review management's response to significant internal control recommendations of the internal audit staff and the External Auditor;
  - (iv) receive regular reports from management and receive comments from the External Auditor, if any, on:
    - (A) the Corporation's principal financial risks;
    - (B) the systems implemented to monitor those risks; and
    - (C) the strategies (including hedging strategies) in place to manage those risks; and
- (g) recommend to the Board whether any new material strategies presented by management should be considered appropriate and approved.

## **10. INTERNAL AUDIT FUNCTION**

### **10.1 Internal Auditor**

In connection with the Corporation's internal audit function, if any the Committee shall:

- (a) review the terms of reference of the internal auditor, if any, and meet with the internal auditor as the Committee may consider appropriate to discuss any concerns or issues;
- (b) in consultation with the External Auditor and the internal audit group, review the adequacy of the Corporation's internal control structure and procedures designed to ensure compliance with laws and regulations and any special audit steps adopted in light of material deficiencies and controls;
- (c) review the internal control report prepared by management, including management's assessment of the effectiveness of the Corporation's internal control structure and procedures for financial reporting; and
- (d) periodically review with the internal auditor, if any, any significant difficulties, disagreements with management or scope restrictions encountered in the course of the work of the internal auditor.

## **11. COMPLIANCE WITH LEGAL AND REGULATORY REQUIREMENTS**

### **11.1 Risk Assessment and Risk Management**

The Committee shall discuss the Corporation's major financial risk exposures and the steps management has taken to monitor and control such exposures and shall report to the Board with respect thereto.

11.2 Related Party Transactions

The Committee shall review and approve all related party transactions in which the Corporation is involved or which the Corporation proposes to enter into.

11.3 Whistleblowing Policy

The Committee shall put in place, subject to approval by the Board, procedures for:

- (a) the receipt, retention and treatment of complaints received by the Corporation or its subsidiaries regarding accounting, internal accounting controls or auditing matters; and
- (b) the confidential, anonymous submission by employees of the Corporation or its subsidiaries of concerns regarding questionable accounting or auditing matters.

**12. ANNUAL PERFORMANCE REVIEW**

On an annual basis, the Committee shall follow the process established by the Board and overseen by the Nominating and Governance Committee for reviewing the performance of the Committee.

**13. CHARTER REVIEW**

The Committee shall review and assess the adequacy of this Charter annually and recommend to the Board any changes it deems appropriate.

December 28, 2005 and amended August 3, 2006 and March 30, 2015 and February 23, 2016.