



# ABOUT CIPHER

Cipher (TSX:CPH) is a specialty pharmaceutical company with a robust and 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 markets those products either directly in Canada or indirectly through partners in Canada, the U.S., and South America. Cipher is focused on a three-pronged growth strategy—including acquisitions, in-licensing, and selective investments in drug development—to assemble a broad portfolio of prescription products that serve unmet medical needs. For more information, visit www.cipherpharma.com.

(All figures in U.S. dollars, unless otherwise noted)

Dear Fellow Shareholders,

2019 was a transformational year for Cipher. We successfully reduced the cost structure of our organization, initiated a strategic review of the Canadian commercial assets, and terminated assets that didn't meet our internal profitability requirements.

One of Cipher's key priorities in 2019, was the renewed focus on cost optimization to ensure a self-funding business model. We are pleased to announce that our fourth quarter results showed strong progress on that front. Total operating expenses decreased 62% in Q4, which translated into a 282% improvement in Adjusted EBITDA and \$2.6 million (\$3.4 in Canadian Dollars<sup>1</sup>) of net income during the fourth quarter.

Total operating expenses were \$15.9 million for the year compared to \$19.4 million for the year ended December 31, 2018. The decrease in operating expenses was due to the significant reduction in selling, general and administrative costs, offset by one-time impairment and restructuring charges. The financial benefit of the cost reduction plan took effect in Q3 and Q4 of 2019, thus the entire impact was not reflected in full-year results.

The Company now has a leaner cost structure and a renewed focus on the key assets that will drive future cash flow.

We are pleased that Epuris is showing strong growth, with annual revenue up 26% to \$7.3 million in 2019. Epuris finished the year with 38% market share in the Canadian market up from 33% last year.

Subsequent to year end, Sun Pharmaceutical Industries, Cipher's marketing partner for Absorica, launched ABSORICA LD capsules in the U.S. for the management of severe recalcitrant nodular acne in patients 12 years of age and older. In addition to the benefits that ABSORICA LD will bring to the patient population, we are thrilled that the launch will trigger an extension of our agreement with Sun Pharmaceuticals, providing us with two additional years of royalties on Sun's isotretinoin product portfolio.

Epuris finished the year with 38% market share in the Canadian market up from 33% last year. On December 9th, the Company's licensing partner for MOB-015, Moberg Pharmaceuticals, announced that MOB-015 met the primary endpoint as well as secondary endpoints in the North American phase 3 Study. MOB-015 is an internally developed topical formula for the treatment of onychomycosis, a common nail fungus. According to IQVIA, in Canada the total prescription market for Onychomycosis was \$97.0M (Canadian) in 2019. Topical drugs account for 84% of the market, growing with a 5-year CAGR of 24% for the period 2014-2019; second Phase III trial results from Europe are expected in the second quarter of 2020.

In October, Cipher received Health Canada approval for Trulance. As part of the Strategic review of the Canadian commercial assets, we were in the process of selecting the best method of distribution for Trulance. Subsequent to year end, Cipher announced it had received a Notice of Termination from Bausch Health in connection with the License, Development and Commercialization Agreement of Trulance. Cipher believes the Notice is without merit and is currently working with Bausch to resolve the matters contained within.

Cipher has assembled an attractive portfolio of assets beyond the currently marketed products, and we are committed to moving our current pipeline products through the regulatory approval process. In addition, Cipher will continue to work with our technology partner, Galephar, to develop new exciting products to market with a focus on U.S. and International markets.

These are exciting times for Cipher, we look forward to reporting our progress through the balance of 2020 and thank you, our shareholder, for your continued support, trust and confidence.

Sincerely,

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Craig Mull Interim Chief Executive Officer

March 31, 2020

# MANAGEMENT'S DISCUSSION AND ANALYSIS

December 31, 2019

The following is a discussion and analysis of the operating results and financial position of Cipher Pharmaceuticals Inc. and its subsidiaries ("Cipher" or "the Company") for the year ended December 31, 2019. This document should be read in conjunction with the audited annual consolidated financial statements and the accompanying notes, which have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board. Additional information about the Company, including the audited annual consolidated financial statements and Annual Information Form for the year ended December 31, 2019, is available on SEDAR at <a href="http://www.sedar.com">www.sedar.com</a>.

The discussion and analysis within this Management's Discussion and Analysis ("MD&A") are as at March 25, 2020. All dollar figures are stated in U.S. dollars unless otherwise indicated.

# **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 and statements relating to the Special Committee's review of the strategic direction of the Company and its strategic priorities including the anticipated benefits thereof. The words "may", "will", "could", "should", "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 including any impact on our contract manufacturers and other third party service providers, our ability to enter into 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; no assurance that we will receive regulatory approvals in the U.S., Canada or any other jurisdictions and current uncertainty surrounding health care regulation in the U.S.; certain of our products are subject to regulation as controlled substances; limitations on reimbursement in the healthcare industry; limited reimbursement for products by government authorities and third-party payor policies; products may not be included on list of drugs approved for use in hospitals; hospital customers may make late payments or not make any payments; various laws pertaining to health care fraud and abuse: reliance on the success of strategic investments and partnerships; the publication of negative results of clinical trials; unpredictable development goals and projected time frames; 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; legacy risks from operations conducted in the U.S.; inability to meet covenants under our long term debt arrangement; compliance with privacy and security regulation; our policies regarding returns, allowances and chargebacks may reduce revenues; certain current and future regulations could restrict our activities; additional regulatory burden and controls over financial reporting; reliance on third parties to perform certain services; 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; litigation in the pharmaceutical industry concerning the manufacture and supply of novel and generic versions of existing drugs; inability to protect our trademarks from infringement; shareholders may be further diluted if we issue securities to raise capital; volatility of our share price; the 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 of the Company 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 MD&A and the Annual Information Form for the year ended December 31, 2019, and elsewhere in our filings with Canadian securities regulators. Except as required by Canadian securities law, 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.

# Market Industry Data

The market and industry data contained in this MD&A is based upon information from independent industry and other publications and our knowledge of, and experience in, the industry in which the Company operates. Market and industry data is subject to variations and cannot be verified with complete certainty due to limits on the availability and reliability of raw data at any particular point in time, the voluntary nature of the data gathering process or other limitations and uncertainties inherent in any statistical survey. Accordingly, the accuracy and completeness of this data are not guaranteed. Cipher has not independently verified any of the data from third party sources referred to in this MD&A or ascertained the underlying assumptions relied upon by such sources.

# Overview

Cipher (TSX:CPH) 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 directly in Canada or indirectly through partners in the U.S., Canada and Latin America.

# **Corporate Strategy**

Cipher's corporate strategy is to build a portfolio of prescription products across a broad range of therapeutic areas that meet an unmet medical need. The focus of the Company's strategy is to:

- 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;
- conserve capital, maximize cashflow and eliminate debt; and
- distribute products through established sales organizations using a royalty based model.

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

# **Significant Transactions**

<u>2019</u>

# CREDIT FACILITY AMENDMENT

On March 31, 2019, the Company entered into a second amendment to its credit agreement with its Canadian lender. The amendment adjusts certain financial covenants for the remainder of the credit facility term.

On September 30, 2019, the Company entered into a third amendment to its credit agreement with its Canadian lender. The amendment adjusts certain financial covenants for the remainder of the credit facility term. In consideration for the amendment, the Company prepaid \$2.0 million against the outstanding balance of the credit facility. There were no penalties associated with this prepayment.

# **TRULANCE®**

On October 10, 2019, Cipher received a Notice of Compliance from Health Canada approving the sale of Trulance. The Company made a \$0.8 million milestone payment relating to this regulatory achievement, subsequent to year end.

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. The Company is working with Bausch to resolve the matters contained within.

## <u>2018</u>

## **TRULANCE® ACQUISITION**

On February 27, 2018, the Company acquired the exclusive Canadian rights to develop, market, distribute and sell Trulance (plecanatide) from Synergy Pharmaceuticals Inc. ("Synergy"), subsequently acquired by Bausch Health. Trulance is a oncedaily tablet approved by the U.S. Food and Drug Administration ("FDA") for the treatment of adults with chronic idiopathic constipation ("CIC") and irritable bowel syndrome with constipation ("IBS-C"). The Company filed a New Drug Submission ("NDS") with Health Canada in the fourth quarter of 2018, which was accepted by Health Canada for review. Under the terms of the licensing agreement, the Company made an upfront payment of \$5.0 million. The transaction also includes a regulatory milestone payment of \$0.8 million and royalties on net product sales in Canada.

The total Canadian laxative and antispasmodic market size (prescription and over-the-counter) is estimated at over CDN\$200.0 million in 2018, of which the prescription market size is estimated at CDN\$19.0 million, according to IQVIA ("IQVIA") formerly IMS Health/IMS Quintiles.

# A-101 ACQUISITION

On April 5, 2018, the Company acquired the exclusive Canadian rights to distribute and commercialize A-101 from Aclaris Therapeutics, Inc. ("Aclaris"). A-101 is an FDA-approved topical product indicated for the treatment of raised seborrheic keratoses ("SK"), which are commonly occurring non-cancerous skin growths that affect more than nine million Canadian adults and can be an aesthetic skin concern. A-101 was approved by the FDA in December 2017 and is marketed by Aclaris in the U.S. under the tradename Eskata™. A-101 is a proprietary, high-concentration hydrogen peroxide-based topical solution designed for in-office application by a healthcare provider and is a targeted treatment applied directly to the raised SK using a pen-like applicator. The most common treatment for SK are surgical procedures such as cryosurgery, which can cause discomfort, cosmetic imperfections, and require wound management. Under the terms of the licensing agreement, the Company made an upfront payment of \$1.0 million, is required to make payments of up to \$2.8 million upon the achievement of certain regulatory and commercial milestones and make royalty payments based on net product sales in Canada. The Company filed an NDS with Health Canada in the fourth quarter of 2018, which was accepted by Health Canada for review. The Company made a \$0.5 million milestone payment upon Health Canada acceptance for review.

On September 1, 2019, Cipher and Aclaris mutually agreed to terminate this agreement as a result of Aclaris voluntarily ceasing commercialization of Eskata in the U.S. market. There were no costs associated with the termination, other than an asset impairment charge of \$0.5 million.

# CARDIOME TRANSACTION AND CREDIT FACILITY AMENDMENT

On May 15, 2018, the Company completed its acquisition of the Canadian business portfolio of Cardiome Pharma Corp. ("Cardiome"), for cash consideration of CDN\$25.5 million. The total transaction costs incurred for the acquisition were CDN\$0.8 million. The Company financed this acquisition with a combination of cash and an amendment to its current credit facility to draw an additional \$5.0 million. Other than an increase in the Company's quarterly principal repayment amounts over the remainder of the term from \$1.7 million to \$2.0 million, there were no material changes to the terms of the credit facility.

The Canadian business portfolio acquired by Cipher included commercial and pipeline hospital products administered in the acute care setting, including:

• Brinavess® (vernakalant IV), for the rapid conversion of recent onset atrial fibrillation to sinus rhythm;

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- Aggrastat<sup>®</sup> (tirofiban hydrochloride), for the reduction of thrombotic cardiovascular events in patients with acute coronary syndrome;
- Xydalba™ (dalbavancin hydrochloride), the first and only 30-minute, one-dose treatment option for the treatment of acute bacterial skin and skin structure infections; and
- Trevyent<sup>®</sup> a drug device combination that delivers treprostinil, the world's leading treatment for pulmonary arterial hypertension.

Brinavess and Aggrastat are currently on the market in Canada. Xydalba, which is approved and marketed by Allergan in the U.S. under the trade name Dalvance, received Health Canada approval in the third quarter of 2018. In light of the Company's strategic review assessment, Management determined that this product was no longer financially viable due to ongoing supply issues and resulting erosion of the period of exclusivity. Additionally, there was no assurance that there would be no further disruption to supply after launch. On September 19, 2019, the Company terminated this agreement at no cost, other than an asset impairment charge of \$0.9 million.

## MOB-015

On September 18, 2018, the Company entered into an exclusive license agreement with Moberg Pharma AB ("Moberg") to commercialize and distribute MOB-015. Moberg is currently running the phase III trial that is required for the regulatory submission to Health Canada. MOB-015 is a patented proprietary formulation of terbinafine for the topical treatment of onychomycosis. Onychomycosis is a fungal nail infection with an estimated prescription market of CDN\$58.0 million according to IQVIA. Under the terms of the agreement, the Company made an upfront payment of \$0.5 million. Additional payments of up to \$14.1 million are required upon successful achievement of certain development and regulatory milestones and upon reaching certain annual net sales in Canada. Moberg will supply finished product to the Company.

# **Significant Partnerships**

# GALEPHAR

In 2002, the Company entered into a master licensing and clinical supply agreement (the "Galephar Agreement") with Galephar, Pharmaceutical Research, Inc. ("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 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.

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 prior to issuance of a patent for a product, only 30% of royalties are payable. If Cipher or its affiliates are directly selling to wholesalers, 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 the product in the country or, if a patent is obtained, when the patents lapse in that country for the product, whichever is later. Galephar also supplies product to Cipher through commercial supply agreements for each product.

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 spheronization 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.

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. As a result, Galephar is considered a related party.

# **Commercial Products**

## EPURIS® (CIP-ISOTRETINOIN)

CIP-ISOTRETINOIN is an innovative formulation of the active ingredient isotretinoin, which is used in the treatment of severe acne. CIP-ISOTRETINOIN, which is based on the oral Lidose<sup>®</sup> technology, has been in-licensed from Galephar. CIP-ISOTRETINOIN provides more consistent absorption under fed and fasted conditions, as compared to existing isotretinoin products. 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.

CIP-ISOTRETINOIN was approved by Health Canada in 2012 under the trade name Epuris and Cipher launched the product in Canada in June 2013. The Company purchases Epuris from Galephar and pays a single-digit royalty to Galephar on net sales of Epuris in Canada. According to IQVIA, the Canadian market for oral isotretinoin was CDN\$31 million for the 12 months ended December 31, 2019 compared to CDN\$27 million for the same period in 2018. In December 2019, Epuris had a prescription market share of over 39% in Canada.

## OZENOXACIN

In 2015, Cipher in-licensed the Canadian rights to Ozanex<sup>™</sup> (ozenoxacin 1%), a topical treatment for adult and paediatric patients with impetigo, from Ferrer International SA ("Ferrer"), a privately-held Spanish pharmaceutical company. Under the terms of the agreement, Ferrer received an upfront payment and is eligible for development milestones and royalties from net product sales in Canada. Ferrer supplies finished product to Cipher.

On May 2, 2017, Cipher received a Notice of Compliance from Health Canada, approving the sale of Ozanex. The Company paid a CDN\$0.2 million milestone to Ferrer upon obtaining regulatory approval in Canada. The term of the agreement is for 12 years, which commenced in January 2018 with an automatic renewal for an additional two year period. Under this agreement, all milestones have been paid. Cipher is not responsible for any future development costs, should any be required.

In January 2018, the Company launched Ozanex in Canada.

## **ACTIKERALL®**

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. Cipher acquired the Canadian rights to Actikerall from Almirall S.A. ("Almirall") in May 2015 and the product was launched in Canada in February 2016. Under the terms of the agreement with Almirall, the Company pays a royalty on net sales that includes the transfer price for finished goods. Almirall supplies finished product to Cipher. The agreement is for a term of ten years, which commenced in April 2015 with automatic annual renewals. As at December 31, 2019, Actikerall captured approximately 12% of the actinic keratosis prescriptions market.

## VANIQA®

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. Cipher acquired the Canadian rights to Vaniqa from Almirall in May 2015. Under the terms of the agreement with Almirall, the Company pays a royalty on net sales that includes the transfer price for finished goods. Almirall supplies finished product to Cipher. The agreement is for a term of ten years, which commenced in March 2015 with automatic annual renewals. The Company launched Vaniqa in the Canadian market in June 2015. According to IQVIA, Vaniqa prescriptions have been stable year over year.

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# BETEFLAM<sup>®</sup> PATCH

In 2012, Cipher obtained the exclusive license and distribution rights in Canada to market the Beteflam Patch (previously named the Betesil Patch), a novel, patent-protected, self-adhesive medicated plaster for the treatment of inflammatory skin conditions such as plaque psoriasis, from Institut Biochemique SA ("IBSA").

On March 1, 2019, the Company and IBSA mutually agreed to terminate this agreement at no cost. The Company had the right to sell its remaining inventory of products that were supplied by IBSA, which ceased in January 2020.

## **BRINAVESS®**

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, which the Company will now satisfy. 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.

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. Correvio supplies 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 ("NSTE-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. Correvio supplies finished product to the Company.

# **Licensed Products**

## **CIP-ISOTRETINOIN**

## United States - Absorica®

In 2012, Cipher's U.S. distribution partner Sun Pharmaceutical Industries, Inc. ("Sun") (previously Ranbaxy Laboratories Inc.) launched CIP-ISOTRETINOIN under the trade name Absorica.

Absorica is currently protected by five issued patents which are Orange Book listed and expire in September 2021. Galephar was issued a product patent (Patent Number 7,435,427) from the U.S. Patent and Trademark Office in 2008 with a second patent (Patent Number 8,367,102) issued in 2013. A third patent (Patent Number 8,952,064) was issued in February 2015 and the fourth and fifth patents (Patent Numbers 9,078,925 and 9,089,534, respectively) were issued in July 2015. The five patents are formulation-related patents describing the product ingredients.

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 may begin selling its generic version of Absorica in the

U.S. on December 27, 2020 (approximately nine months prior to the expiration of the five Absorica patents in September 2021) or earlier under certain circumstances.

Under the terms of the agreement with Sun, the Company receives a royalty percentage in the mid-teens on net sales. Cipher's agreement with Sun is for a period of 10 years from the first commercial sale expiring in November 2022 and Sun has the right to extend the term for an additional two year period.

In July 2018, the Company amended its distribution and supply agreement (the "Sun Amendment") with Sun for Absorica. The Sun Amendment provides Sun with the ability to launch new isotretinoin products prior to the expiration of the agreement in November 2022. The Company will receive a royalty until December 2024 based on U.S. net sales from Sun's isotretinoin product portfolio. In addition, the Absorica New Drug Application ("NDA") will be returned to the Company on expiry of the agreement in November 2022. On February 3, 2020, Sun launched their new isotretinoin products under the brand name of Absorica LD.

On December 19, 2018, the Company received a Paragraph IV Certification Notice of Filing advising Sun, Sun Pharmaceuticals Industries Ltd. and Galephar that Upsher Smith Laboratories, LLC ("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. The Company is awaiting a response from that meeting.

## Rest of World

In 2014, the Company entered into a definitive distribution and supply agreement with Ranbaxy Laboratories Ltd. ("Ranbaxy India"), a Sun Pharma Company, under which Cipher granted Ranbaxy India the exclusive right to market, sell and distribute isotretinoin capsules in Brazil. Ranbaxy India plans to promote the product through a brand dermatology division in Brazil. Under the terms of this agreement, Cipher received an upfront payment and may be eligible for additional pre-commercial milestone payments. Cipher will supply the product and product manufacturing will be fulfilled by Galephar. Ranbaxy India will be responsible for all regulatory-related activities associated with gaining and maintaining regulatory approval of the product in Brazil.

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. Under the terms of the agreement with Italmex, Cipher is eligible for regulatory and commercial milestone payments. Cipher will supply the product to Italmex, and product manufacturing will be fulfilled by Cipher's partner, Galephar. 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. The dossier has been previously reviewed by a third party which could shorten the response time from COFEPRIS. Italmex expects a response from COFEPRIS by the second quarter of 2020. The product is not currently approved in Mexico.

# LIPOFEN® (CIP-FENOFIBRATE)

Lipofen is a novel 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". Cipher's U.S. marketing and distribution partner for Lipofen is Kowa Pharmaceuticals America, Inc. ("Kowa").

Lipofen was launched in the U.S. market in 2007. In 2014, Cipher and Kowa agreed to pre-emptively launch an authorized generic version of Lipofen in advance of the expiration of the product patent in January 2015. Since the beginning of 2015, Kowa has reduced their commercial efforts significantly on the promotion of Lipofen. Prescriptions for Lipofen and the authorized generic were down approximately 19% in 2019 compared to 2018, according to IQVIA.

# CONZIP® / DURELA® (CIP-TRAMADOL ER)

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. CIP-TRAMADOL ER uses oral controlled-release beads, a drug delivery technology licensed from Galephar. Patents that expire in 2022 have been issued both in the U.S. and Canada for the product.

## United States

The product received FDA approval in 2010. In June 2011, Cipher entered into a distribution and supply agreement with Vertical Pharmaceuticals Inc. ("Vertical"), a U.S. based specialty pharmaceutical company and the product was launched in the U.S. in September 2011 under the trade name ConZip. Under the terms of the agreement with Vertical, the Company receives a mid-teen royalty on net sales. The Company is responsible for product supply and manufacturing, which is fulfilled by Galephar.

According to IQVIA, the U.S. market in 2019 for extended release formulations of tramadol exceeded \$31.0 million, which represents approximately 38% of the total tramadol immediate release and extended release prescription market compared to \$36.0 million in 2018, which represented approximately 40% of the total tramadol immediate release and extended release prescription market.

An authorized generic version of the product was launched by Vertical in the U.S. market in July 2015.

In 2016, the FDA required a new black box warning for tramadol products on the risks of addiction, abuse, misuse, lifethreatening 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. The Company is planning to request a Type C meeting with FDA in 2020 to discuss the feasibility of this study design and to propose alternate solutions for meeting the pediatric requirement.

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 address the safe and effective use of ConZip in pediatric patients ages 12 to less than 17 years. The Company is planning to request a Type C meeting with FDA in 2020 to further discuss the feasibility of the requested study.

In August 2017, the Company received a warning letter issued by the Office of Prescription Drug Promotion of the FDA relating to the professional detail aids for ConZip. The warning letter was addressed to the Company as the NDA holder. The Company's licensing partner, Vertical holds the exclusive U.S. license to market, sell and distribute ConZip. As the exclusive commercial distributor of ConZip in the U.S., Vertical is responsible for preparing and approving all marketing and promotional materials. Vertical has informed Cipher that it took immediate corrective actions and has commenced a corrective action communication to healthcare professionals. The parties are committed to resolving this matter and additional corrective actions will be taken as considered necessary or advisable. The FDA has informed Cipher that all issues raised in the warning letter have been addressed.

## Canada

In August 2011, Cipher received Health Canada approval for CIP-TRAMADOL ER and in September 2011, Cipher entered into a distribution and supply agreement with Medical Futures Inc. ("Medical Futures"), a Canadian-based pharmaceutical company, under which Cipher granted Medical Futures the exclusive right to market, sell and distribute CIP-TRAMADOL ER in Canada under the trade name Durela. Medical Futures was subsequently acquired by Tribute Pharmaceuticals Canada Inc. ("Tribute") and during the same month, POZEN Inc. announced the completion of the acquisition of Tribute. Effective, February 5, 2016, the new combined company was named Aralez Pharmaceuticals Inc., which was subsequently acquired by Nuvo Pharmaceuticals Inc. The Company receives a royalty on net sales of Durela in Canada. Cipher will supply the product and product manufacturing will be fulfilled by Galephar.

According to IQVIA, the Canadian market for extended-release tramadol was approximately CDN\$20.0 million in 2019 compared to CDN\$19.0 million in 2018.

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 is unknown at this time, however the Company is addressing changes that will be required in the tramadol supply chain when the scheduling is official.

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. However, an additional post marketing study is not a requirement as the characterization of use of tramadol in the real world through Canadian data sources that can identify problematic opioid use indicators. The revised t-RMP for Durela is expected to be submitted to Health Canada in the first quarter of 2020.

## 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. 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 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 concerns raised in the rejection notice.

# **Product Pipeline**

# **TRULANCE<sup>®</sup>**

On February 27, 2018, the Company entered into a licensing agreement (the "Bausch Licensing Agreement") to acquire the exclusive Canadian rights to develop, market, distribute and sell Trulance (plecanatide) from Synergy, subsequently acquired by Bausch Health ("Bausch"). Trulance is a once-daily tablet approved by the FDA for the treatment of adults with CIC and IBS-C. Under the terms of the licensing agreement, the Company paid an upfront payment of \$5.0 million. The transaction also includes a regulatory milestone payment of \$0.8 million and royalties on net product sales in Canada. The payment was made subsequent to year end.

On October 10, 2019, Cipher received a Notice of Compliance from Health Canada approving the sale of Trulance. Subsequent to year end, the Company made a \$0.8 million milestone payment relating to this regulatory achievement.

# **TREVYENT®**

Trevyent is a development stage drug/device combination product that combines SteadyMed Ltd's ("SteadyMed") PatchPump technology with treprostinil, a vasodilatory prostacyclin analogue to treat pulmonary arterial hypertension ("PAH"). PatchPump is a proprietary, disposable, parenteral drug administration platform that is prefilled and preprogrammed at the site of manufacture. PAH is a type of high blood pressure that occurs in the right side of the heart and in the arteries that supply blood to the lungs. PAH worsens over time and is life-threatening because the pressure in a patient's pulmonary arteries rises to dangerously high levels, putting a strain on the heart. There is no cure for PAH, but several medications are available to treat symptoms, such as Remodulin (treprostinil sodium), the market-leading prostacyclin PAH therapy.

In April 2017, SteadyMed completed a successful clinical study of Trevyent. The study enrolled 60 healthy adult volunteers in an in-clinic setting designed to examine the performance of the PatchPump used by Trevyent. The goals of the study were to evaluate the safety and performance functions of the PatchPump delivery system as well as the tolerability of the on-body application of the six products. According to SteadyMed, the results indicated that the PatchPump devices performed as intended in all categories of evaluation, including dose accuracy and precision. In July 2017, SteadyMed submitted an NDA to the FDA for Trevyent in the United States. On August 31, 2017, SteadyMed announced that it received a Refusal to File ("RTF") letter from the FDA relating to the NDA. On September 28, 2017, SteadyMed announced that it had submitted a Type A Meeting Request and Briefing Document to the FDA in response to the RTF. On December 8, 2017, SteadyMed announced that it had received final minutes from the FDA on the work necessary to resubmit its NDA. SteadyMed was subsequently acquired by United Therapeutics Corporation ("United") in April 2018. United resubmitted the NDA in June 2019.

Cipher acquired a licence for Canadian marketing rights to Trevyent through the acquisition of the Canadian business portfolio of Cardiome. The license is for a term of 10 years from commercial launch. The license includes a royalty on net sales and milestones. Correvio will supply finished product to Cipher.

## MOB-015

On September 18, 2018, Cipher acquired the exclusive Canadian rights to commercialize, promote, sell and distribute MOB-015 from Moberg Pharma ("Moberg). 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.

In Canada, according to IQVIA, the total prescription market for Onychomycosis was CDN\$97.0M in 2019, 84% of which were topical drugs, growing with a five-year CAGR of 24% for the period 2014-2019.

MOB-015 is an internally developed topical formulation of terbinafine based on Moberg's experience from its leading OTC product Kerasal Nail<sup>®</sup>/Emtrix<sup>®</sup>. 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.

MOB-015 is currently being evaluated over 52 weeks in two randomized, multicenter, controlled Phase 3 studies. The primary endpoint in both studies is the proportion of patients achieving complete cure of their target nail. In total, approximately 750-800 patients are expected to be enrolled in the two studies in North America and Europe.

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% of the patients treated with MOB-015 (p<0.0001).

Results from the second Phase III trial in Europe are expected in the second quarter of 2020.

#### CF101

In March 2015, Cipher entered into an agreement to license the Canadian distribution rights to CF101, 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 results from the prior phase II trial in psoriasis were both positive, showing that CF101 effectively improved disease symptoms. In addition, at the end of 2013, CF101 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 and one for psoriasis. Can-Fite continues to enrol patients into the phase III RA program, which has close to 50% enrolment and has more than 50% patient enrolment for the psoriasis phase III program. Cipher is not responsible for any of these development costs.

Approximately one million people in Canada have psoriasis, according to Canadian Dermatology Association in 2018. 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 the successful completion of the remaining clinical trial program.

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

# DTR-001

In May 2016, the Company licensed the worldwide rights to develop, market and sell an investigational tattoo removal cream from Dalhousie University. 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.

Under the terms of the agreement, an upfront payment of CDN\$75,000 was made by Cipher upon execution of the agreement and the agreement contains milestone payments of up to CDN\$3.6 million based on future regulatory and commercial sales milestones, as well as royalties on commercial sales.

# ASF-1096

In February 2015, Cipher acquired the worldwide rights to ASF-1096 from Astion Pharma. ASF-1096 is a product candidate for the treatment of dermatomyositis. The active agent of ASF-1096 is the R-enantiomer of salbutamol that is thought to exert an anti-inflammatory activity. ASF-1096 contains purified R-salbutamol formulated into a cream.

Cipher has an orphan drug indication in the European Union ("EU") for ASF-1096, a product candidate that the Company believes has promise as a treatment for discoid lupus erythematosus, a highly disfiguring and rare disease with no current cure as well as other potential rare conditions in the European market. In the U.S., this indication does not meet the requirements for orphan drug status. Cipher is reviewing the drug development program and potential indications to support the approval of ASF-1096 in the North American and European markets. In June 2016, Cipher entered into a definitive licensing agreement with Edesa Biotech Inc. ("Edesa"), under which Cipher granted Edesa the exclusive worldwide rights to develop, market and sell ASF-1096 for the treatment of anorectal indications.

During the year, the Company re-considered its efforts to out license ASF1096, and returned the asset to Astion Pharma in consideration of \$0.2 million. The net book value of \$1.1 million was recorded as an impairment.

# Litigation

From time to time, during the ordinary course of business, the Company may be threatened with, or may be named as, a defendant in various legal proceedings, including lawsuits based upon product liability, wrongful dismissal, personal injury, breach of contract and lost profits or other consequential damage claims.

# **Selected Annual Information**

The consolidated statements of income and comprehensive income and consolidated statements of cash flows for the previously reported U.S. segment are presented as discontinued operations, separate from the Company's continuing operations which is comprised of the Canadian segment. This MD&A reflects only the results of continuing operations, unless otherwise noted.

The income from discontinued operations included in the consolidated statement of income and comprehensive income was \$0.6 million for the year ended December 31, 2019 compared to a loss from discontinued operations of \$0.7 million for the year ended December 31, 2018.

The following information has been prepared in accordance with IFRS in U.S. dollars.

(IN MILLIONS OF U.S. DOLLARS EXCEPT FOR PER SHARE AND SHARE AMOUNTS)	2019	2018	2017
	\$	\$	\$
			Restated <sup>(1)</sup>
Net revenue	22.5	22.7	40.1
Total operating expenses	15.9	19.4	15.6
Total other expenses	0.9	0.2	10.4
Income for the year from continuing operations	2.6	1.2	10.6
Income (loss) for the year from discontinued operations	0.6	(0.7)	(6.3)
Income from continuing operations per share:			
Basic and diluted income Income (loss) from discontinued operations per share:	0.10	0.04	0.40
Basic and diluted income (loss)	0.02	(0.02)	(0.24)
Total assets	46.5	55.7	63.0
Total non-current liabilities	1.8	9.7	12.7

<sup>(1)</sup>Restated upon full retrospective adoption of IFRS 15, *Revenue from Contracts with Customers* 

The fluctuations in reported results during 2019 resulted primarily from the following factors:

- Net revenue decreased by 1% due to a decrease in licensing revenue offset by an increase in product revenue;
- Operating expenses decreased by \$3.6 million primarily due to a significant reduction in selling, general and administrative costs offset by impairment and restructuring charges of \$3.5 million and \$1.5 million, respectively;
- Other expenses increased because of the gain on revaluation of the derivative financial instrument in the prior year.

For a detailed review of the operating results, see "Review of Operating Results".

# **Review of Operating Results**

#### REVENUE

(IN THOUSANDS OF U.S. DOLLARS)	2019	2018
	\$	\$
Licensing revenue	14,212	15,869
Product revenue	8,239	6,880
Net revenues	22,451	22,749

Total net revenue decreased by \$0.3 million or 1% to \$22.5 million for year ended December 31, 2019 compared to \$22.7 million for the year ended December 31, 2018.

#### Licensing Revenue

Licensing revenue decreased by \$1.7 million or 10% to \$14.2 million for the year ended December 31, 2019 compared to \$15.9 million for the year ended December 31, 2018.

Licensing revenue from Absorica in the U.S. was \$11.3 million for the year ended December 31, 2019, a decrease of \$1.8 million or 13% compared to \$13.1 million for ended December 31, 2018. Absorica's market share for the year ended December 31, 2019 was approximately 7% compared to approximately 10% for the year ended December 31, 2018.

Licensing revenue from Lipofen and the authorized generic version of Lipofen was \$2.3 million for the year ended December 31, 2019, which remained relatively unchanged from the year ended December 31, 2018.

Licensing revenue from the extended-release tramadol product (ConZip in the U.S. and Durela in Canada) was \$0.6 million for the year ended December 31, 2019, an increase of \$0.1 million compared to revenue of \$0.5 million for the year ended December 31, 2018. The increase related to a one time gross to net adjustment in the prior period.

#### Product Revenue

Product revenue increased by \$1.4 million or 20% to \$8.2 million for the year ended December 31, 2019 compared to \$6.9 million for the year ended December 31, 2018.

Product revenue from Epuris increased to \$7.3 million for the year ended December 31, 2019 compared to \$5.8 million for the year ended December 31, 2018. Epuris had a prescription market share of over 38% in Canada for the year ended December 31, 2019 compared to 33% for the year ended December 31, 2018, according to IQVIA.

Product revenue for Ozanex, Beteflam, Actikerall, Vaniqa and Brinavess, Aggrastat was \$0.9 million, in the aggregate for the year ended December 31, 2019 compared to \$1.1 million for the year ended December 31, 2018.

## OPERATING EXPENSES

(IN THOUSANDS OF U.S. DOLLARS)	2019	2018
	\$	\$
Cost of products sold	2,906	2,312
Research and development	396	561
Selling, general and administrative	7,647	14,741
Restructuring costs	1,454	_
Impairment of intangible assets	3,454	1,832
Total operating expenses	15,857	19,446

Total operating expenses decreased by \$3.6 million or 18% to \$15.9 million for the year ended December 31, 2019 compared to \$19.4 million for the year ended December 31, 2018. The decrease in operating expenses for the year ended December 31, 2019 was a result of a significant reduction in selling, general and administrative costs offset by impairment and restructuring charges.

#### Cost of Products Sold

Cost of products sold for the year ended December 31, 2019 increased by \$0.6 million to \$2.9 million compared to \$2.3 million for the year ended December 31, 2018. Gross margin decreased to 65% in 2019 from 66% in 2018. In the current year the Company had an increase to its inventory obsolescence provision.

#### **Research and Development**

Research and development ("R&D") expenses represent the costs directly associated with developing and advancing our pipeline products and the cost of regulatory submissions in Canada. R&D expense was \$0.4 million for the year ended December 31, 2019 compared to \$0.6 million for year ended December 31, 2018.

## Selling, General and Administrative

Selling, general and administrative ("SG&A") expense was \$7.6 million for the year ended December 31, 2019, a decrease of \$7.1 million or 48% compared to \$14.7 million for the year ended December 31, 2018. The decrease in SG&A costs for the year was driven by a reduction in human resources related costs.

Also included in SG&A is amortization of intangible assets of \$0.8 million for the year ended December 31, 2019 compared to \$0.6 million for the year ended December 31, 2018.

#### **Restructuring Costs**

Restructuring costs were \$1.5 million for the year ended December 31, 2019. These costs are primarily comprised of termination pay, severance benefits and professional fees.

#### Impairment of Intangible Assets

In Q1 2018, the Company re-assessed its efforts to out license its Astion assets acquired in 2015 and decided not to continue to actively pursue partners for Dermadexin and Pruridexin products in this portfolio. The Company recorded an impairment charge of \$1.8 million representing the carrying value of those assets.

During the year, the Company re-considered its efforts to out license ASF1096, the remaining asset in the Astion portfolio. The Company wrote off the net book value of \$1.1 million, net of \$0.2 million received by Astion Pharma in exchange for returning the asset. Additionally, as part of the Company's strategic review of the business, the licensing agreements for A-101 and Xydalba were terminated. The Company recorded an impairment charge of \$2.4 million, representing the carrying value of those assets.

## OTHER EXPENSES

(IN THOUSANDS OF U.S. DOLLARS)	2019	2018
	\$	\$
Interest expense	965	907
Change in fair value of derivative financial instrument	(11)	(530)
Interest income	(179)	(195)
Foreign exchange loss (gain)	109	(2)
Total other expenses	884	180
•		

Total other expenses increased by \$0.7 million to \$0.9 million for the year ended December 31, 2019 compared to \$0.2 million for year ended December 31, 2018. Other expenses in the current year was mainly related to net interest expense. In the comparative period, interest expense was offset with a gain on revaluation of the derivative financial instrument.

#### **Interest Expense**

Interest expense increased by \$0.1 million to \$1.0 million for year ended December 31, 2019 compared to \$0.9 million for the year ended December 31, 2018. During 2019, interest expense was comprised of interest payable and interest accretion on the credit facility and lease obligations. In the prior year comparative period it was only the credit facility. The average interest rate applicable to the credit facility in 2019 was 4.71% compared to 3.99% in 2018. Due to quarterly principle payments, the interest rate is applied to a declining balance.

#### **Change in Fair Value of Derivative Financial Instrument**

The change in fair value of the derivative financial instrument was a negligible gain for the year ended December 31, 2019 compared to a gain of \$0.5 million for the year ended December 31, 2018. Fluctuations in the fair value of the derivative financial instrument is primarily due to changes in the Company's share price.

#### Interest Income

Interest income for the year ended December 31, 2019 remained relatively unchanged from the year ended December 31, 2018.

#### **Foreign Exchange**

The Company experienced a foreign exchange loss of \$0.1 million for the year ended December 31, 2019 compared to a negligible gain for the year ended December 31, 2018. The Company is exposed to currency risk through certain recurring transactions denominated in Canadian dollars and translation of net assets.

## **INCOME TAXES**

Income tax expense is recognized based on domestic and international statutory income tax rates in the jurisdictions in which the Company operates. These rates are then adjusted to effective tax rates based on management's estimate of the weighted average annual income tax rate expected for the full year in each jurisdiction taking into account taxable income or loss in each jurisdiction and available utilization of deferred tax assets. Deferred tax assets are recognized to the extent that it is probable that the asset can be recovered.

Income tax expense was \$3.1 million for the year ended December 31, 2019 compared to income tax expense of \$1.9 million for the year ended December 31, 2018. The increase in the income tax expense is due to a recent Canada Revenue Agency (the "CRA") assessment claiming the value of certain intangible assets set up upon migrating the Company to Canada was overstated. The Company believes its basis for the valuation is reasonable and intends to rigorously challenge the CRA's proposed valuation. The Company is still in ongoing discussions with the CRA with respect to this matter.

At each reporting date, the Company assesses whether the realization of future tax benefits is sufficiently probable to recognize a deferred tax asset. This assessment requires the exercise of judgement, which includes a review of projected taxable income.

As at December 31, 2019, the Company has recognized a deferred tax asset in the consolidated statement of financial position of \$0.9 million. The Company believes that it is probable that future taxable income will be available against which tax losses can be utilized.

## INCOME (LOSS) AND INCOME (LOSS) PER SHARE

(IN THOUSANDS OF U.S. DOLLARS)	2019	2018
	\$	\$
Income for the year from continuing operations	2,639	1,201
Basic and diluted income per share from continuing operations	0.10	0.04
Income (loss) for the year from discontinued operations	603	(658)
Basic and diluted income (loss) per share from discontinued operations	0.02	(0.02)
Income and comprehensive income for the year	3,242	543

Basic income per common share is calculated using the weighted average number of common shares outstanding during the period. Diluted income per common share is calculated taking into account dilutive instruments that are outstanding. For year ended December 31, 2019, the computation of diluted income per share approximates the basic earnings per share due to the negligible impact of dilutive instruments.

Income from continuing operations per share on both a basic and diluted basis for the year ended December 31, 2019 was \$0.10 compared to income per share on both a basic and diluted basis of \$0.04 for the year ended December 31, 2018.

The weighted average number of Common Shares outstanding for the year ended December 31, 2019 was 26,849,983 (for the year ended December 31, 2018 – 26,773,224).

The dilutive weighted average number of Common Shares outstanding for the year ended December 31, 2019 was 26,955,750 (for the year ended December 31, 2018 – 26,997,196).

# ADJUSTED EBITDA

EBITDA is a non-IFRS financial measure. The term EBITDA (earnings before interest, taxes, depreciation and amortization) does not have any standardized meaning under IFRS and therefore may not be comparable to similar measures presented by other companies. Rather, these measures are provided as additional information to complement IFRS measures by providing a further understanding of operations from management's perspective. The Company defines Adjusted EBITDA as earnings before interest expense, income taxes, depreciation of property and equipment, amortization of intangible assets, non-cash share-based compensation, changes in fair value of derivative financial instruments, impairment of intangible assets and goodwill and foreign exchange gains and losses from the translation of Canadian cash balances.

The Company considers Adjusted EBITDA as a key metric in assessing business and management performance and considers Adjusted EBITDA to be an important measure of operating performance and cash flow, providing useful information to investors and analysts.

Adjusted EBITDA for the year ended December 31, 2019 was \$12.6 million, an increase of \$5.7 million or 84% compared to \$6.9 million for the year ended December 31, 2018.

The following is a summary of how EBITDA and Adjusted EBITDA are calculated:

(IN THOUSANDS OF U.S. DOLLARS)	2019	2018
	\$	\$
Income from continuing operations	2,639	1,201
Add back:		
Depreciation and amortization	1,187	828
Interest expense, net	786	712
Income taxes	3,071	1,922
EBITDA	7,683	4,663
Change in fair value of derivative financial instrument	(11)	(530)
Restructuring costs	1,454	_
Loss from the translation of Canadian cash and lease balances	77	87
Impairment of intangible assets	3,454	1,832
Share-based compensation	(60)	802
Adjusted EBITDA	12,597	6,854
Adjusted EBITDA per share – basic	0.47	0.26
Adjusted EBITDA per share – dilutive	0.47	0.25

# Liquidity and Capital Resources

(IN THOUSANDS OF U.S. DOLLARS)	2019	2018
	\$	\$
Income from continuing operations	2,639	1,201
Cash provided by operating activities	8,860	11,284
Cash used in investing activities	(1,464)	(24,483)
Cash used in financing activities	(10,527)	(1,407)
Cash used in discontinued operations	(929)	(3,191)
Net change in cash	(4,060)	(17,797)
Impact of foreign exchange on cash	49	(87)
Cash, beginning of year	10,357	28,241
Cash, end of year	6,346	10,357

## Cash

As at December 31, 2019, the Company had cash of \$6.3 million compared to \$10.4 million as at December 31, 2018.

## **Operating Activities**

Cash provided by operating activities was \$8.9 million for the year ended December 31, 2019 compared to \$11.3 million for the year ended December 31, 2018. Cash provided by operations, excluding working capital was \$9.5 million for the year ended December 31, 2019 compared to \$6.4 million for the year ended December 31, 2018. The change in cash provided by operating activities reflects an investment in working capital of \$0.6 million in the current year compared to a recovery of \$4.9 million in working capital in the comparative prior year.

#### **Investing Activities**

Cash used in investing activities for the year ended December 31, 2019 was \$1.5 million compared to \$24.5 million for the year ended December 31, 2019. Cash used in investing activities for the year ended December 31, 2018 is related to the acquisition of the Trulance license, A-101 license and Cardiome acquisition (see "Significant Transactions" – 2018).

#### **Financing Activities**

Cash used in financing activities was \$10.5 million for the year ended December 31, 2019 compared to \$1.4 million for the year ended December 31, 2018. During the year, the Company made principal payments towards the credit facility totalling \$10.0 million. In the prior year comparative period, total principal payments of \$5.7 million was offset by a draw-down of the credit facility for \$5.0 million to fund a portion of the Cardiome acquisition.

Future cash requirements will depend on a number of factors, including expenditures on R&D for product candidates, costs associated with maintaining regulatory approvals, the timing of 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 for new products or technologies, the status of competitive products and the success of the Company in developing and maintaining markets for its products.

On July 19, 2018, the Company entered into an office lease agreement for its corporate operations. The new office is located in Oakville, Ontario and is the Company's new registered address. The term of the lease is 10 years and three months, commencing on January 1, 2019. The total undiscounted commitment for the lease term is CDN\$4.3 million.

The following table outlines the Company's undiscounted contractual obligations as at December 31, 2019.

Description	Less than one year	Years two and three	Beyond three years	Total
	\$	\$	\$	\$
Accounts payable and accrued liabilities	8,594	—	_	8,594
Finance lease obligations	287	584	1,981	2,852
Credit facility	7,668	—	—	7,668
Total	16,549	584	1,981	19,114

# **Financial Instruments**

As at December 31, 2019, the Company's financial instruments consisted of cash, accounts receivable, accounts payable and accrued liabilities, the credit facility and a derivative financial instrument. The derivative financial instrument is measured at fair value with any changes recognized through the consolidated statements of income and comprehensive income and is classified as Level 2. Cash, accounts receivable, accounts payable and accrued liabilities are measured at amortized cost and their fair values approximate carrying values.

As at December 31, 2019, the carrying value of the credit facility of \$7.6 million, which approximates the fair value. The fair value is based on cash flows discounted using a rate based on the borrowing rate.

The Company's financial instruments are exposed to certain financial risks, including credit risk, liquidity risk, currency risk, interest rate risk and capital management risk.

# **Risk Management**

In the normal course of business, the Company is exposed to a number of financial risks that can affect its operating performance. These risks are credit risk, liquidity risk, market risk, interest rate risk and capital management risk. The Company's overall risk management program and business practices seek to minimize any potential adverse effects on the Company's financial performance.

## **Credit Risk**

Credit risk is the risk of a financial loss to the Company if a customer or counterparty to a financial instrument fails to meet its contractual obligation. Financial instruments that potentially expose the Company to significant concentration of credit risk consist of cash and accounts receivable. The Company's investment policies are designed to mitigate the possibility of a deterioration of principal and enhance the Company's ability to meet its liquidity needs and provide reasonable returns within

those parameters. Cash is on deposit with Canadian chartered banks. Management monitors the collectability of accounts receivable and estimates an allowance for doubtful accounts.

The Company has concentration risk, as approximately 90% of total revenue came from four customers and approximately 84% of total accounts receivable is due from two customers.

#### Liquidity Risk

Liquidity risk is the risk that the Company will encounter difficulties in meeting its financial liability obligations as they become due. The Company has a planning and budgeting process in place to help determine the funds required to support the Company's normal operating requirements on an ongoing basis.

The Company has financed its cash requirements primarily through operations and its credit facility. The Company controls liquidity risk through management of working capital, cash flows and the availability and sourcing of financing.

The Company has financial covenants in its credit facility that are based on predefined trailing adjusted earnings before interest, taxes, depreciation and amortization ("EBITDA") formula. The Company's adjusted EBITDA is sensitive to significant fluctuations based on revenue from its licensing business. A significant decline in licensing revenue could cause the Company to breach on one or more covenants and/or impact the Company's ability to repay the remaining balance of its credit facility, unless refinanced.

The Company anticipates that its current cash, together with the cash flow that is generated from operations will be sufficient to execute its current business plan for 2020 and meet its debt obligations.

#### **Currency Risk**

The Company is exposed to currency risk related to the fluctuation of foreign exchange rates. The Company is exposed to currency risk through its net assets and certain recurring transactions that are denominated in Canadian dollars. A change of 10 basis points in the U.S./CDN exchange rate on December 31, 2019 would have had a \$0.4 million impact on income and comprehensive income for the year. The following is a summary of the financial assets and financial liabilities denominated in Canadian dollars as of December 31, 2019:

	CDN\$
Cash	721
Accounts receivable	1,421
Accounts payable and accrued liabilities	(3,290)
Finance lease obligations	(2,530)
Net financial liabilities	(3,678)

#### Interest Rate Risk

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. The credit facility bears interest that is pegged to LIBOR and as such is subject to interest rate cash flow risk resulting from market fluctuations in interest rates. A change of 100 basis points in the LIBOR would increase the interest expense by \$228.

## **Capital Risk Management**

The Company's managed capital is comprised of cash, the credit facility and shareholders' equity. The Company's objective when managing its capital structure is to safeguard its ability to continue as a going concern in order to provide returns for shareholders and finance strategic growth plans and financial obligations as they become due. In order to maintain or adjust its capital structure, the Company may issue new Common Shares from time to time. The Company relies on cash on hand, cash flows from operations and debt financing to finance growth initiatives.

# **Outstanding Share Data**

The Company is authorized to issue an unlimited number of preference shares, issuable in series, and an unlimited number of voting Common Shares. As at December 31, 2019, the Company had 26,991,404 common shares issued and outstanding compared to 26,820,483 as at December 31, 2018. Subsequent to year-end, 17,028 common shares were issued under the employee and director share purchase plan, bringing the total number of common shares issued and outstanding to 27,008,432 as of the date of this MD&A.

A total of 425,183 stock options were granted during the year with a weighted average exercise price of CDN\$1.47. As at December 31, 2019, there were 617,485 options outstanding of which 386,156 have vested.

# **Off-Balance Sheet Arrangements**

The Company has no off-balance sheet arrangements.

# **Selected Quarterly Information**

The following amounts are derived from unaudited financial information prepared in accordance with IFRS.

(IN MILLIONS OF U.S. DOLLARS EXCEPT FOR PER SHARE AMOUNTS)	Dec 31, 2019	Sept 30, 2019	June 30, 2019	Mar 31, 2019
	\$	\$	\$	\$
Net revenue	5.9	5.8	5.6	5.1
Income (loss) and comprehensive income (loss) for the period	2.6	(2.1)	1.4	0.8
Basic income (loss) per Common Share	0.10	(0.08)	0.05	0.03
Diluted income (loss) per Common Share	0.10	(0.08)	0.05	0.03
	-		-	
(IN MILLIONS OF U.S. DOLLARS EXCEPT FOR PER SHARE AMOUNTS)	Dec 31, 2018	Sept 30, 2018	June 30, 2018	Mar 31, 2018
	Dec 31, 2018	Sept 30, 2018 \$	June 30, 2018 \$	Mar 31, 2018 \$
	,	• •	,	,
ÂMOUNTS)	\$	\$	\$	\$
AMOUNTS) Net revenue Income (loss) and comprehensive income (loss)	\$ 6.4	\$	\$ 7.0	\$

# **Fourth Quarter Results**

(IN THOUSANDS OF U.S. DOLLARS)	Three months ended December 31, 2019	Three months ended December 31, 2018
	\$	\$
Licensing revenue	3,751	4,612
Product revenue	2,157	1,780
Net revenue	5,908	6,392
Cost of products sold	812	689
Research and development	46	147
Selling, general and administrative	1,344	4,963
Total operating expenses	2,202	5,799
Interest expense	181	270
Change in fair value of derivative financial instrument	3	(110)
Interest income	(28)	(43)
Foreign exchange loss	2	16
Total other expenses	158	133
Income before income taxes from continuing operations	3,548	460
Income taxes	902	961
Income (loss) and comprehensive income (loss) from continuing operations	2,646	(501)
Income (loss) and comprehensive income (loss) from discontinued operations	464	(584)
Income (loss) and comprehensive income (loss) for the period	3,110	(1,085)

#### Revenue

Net revenue decreased to \$5.9 million for the three months ended December 31, 2019, a decrease of \$0.5 million or 8% compared to \$6.4 million for the three months ended December 31, 2018.

Licensing revenue decreased by \$0.9 million or 19% to \$3.8 million for the three months ended December 31, 2019 compared to \$4.6 million for the three months ended December 31, 2018.

Licensing revenue from Absorica in the U.S. was \$3.1 million for the three months ended December 31, 2019, a decrease of \$0.6 million or 16% compared to \$3.7 million for the three months ended December 31, 2018.

Licensing revenue from Lipofen and the authorized generic version of Lipofen was \$0.6 million for the three months ended December 31, 2019, a decrease of \$0.2 million compared to revenue of \$0.8 million for the three months ended December 31, 2018.

Licensing revenue from the extended-release tramadol product (ConZip in the U.S. and Durela in Canada) for the three months ended December 31, 2019 was \$0.1 million, which remained relatively unchanged from the three months ended December 31, 2018.

Product revenue increased by \$0.4 million or 21% to \$2.2 million for the three months ended December 31, 2019 compared to \$1.8 million for the three months ended December 31, 2018.

Product revenue from Epuris increased to \$2.0 million for the three months ended December 31, 2019 compared to \$1.5 million for the three months ended December 31, 2018. According to IQVIA, Epuris had a prescription market share of over 39% in Canada for the three months ended December 31, 2019 compared to 35% for the three months ended December 31, 2018.

Product revenue for Ozanex, Beteflam, Actikerall, Brinavess, Aggrastat and Vaniqa was \$0.2 million, in the aggregate, for the three months ended December 31, 2019 compared to \$0.3 million for the three months ended December 31, 2018.

#### **Operating Expenses**

Total operating expenses for the three months ended December 31, 2019 were \$2.2 million, a decrease of \$3.6 million compared to \$5.8 million for the three months ended December 31, 2018. The decrease for the three months ended was primarily driven by an overall reduction in human resource related costs and a reduction in sales and marketing spend.

# Accounting standards issued but not yet adopted

A number of amendments to standards have been issued but are not yet effective for the financial year ending December 31, 2019, and accordingly, have not been applied in preparing these consolidated financial statements. The Company reviewed these amendments and concluded that there would be no impact on adoption given their nature and applicability.

International Financial Reporting Interpretations Committee (IFRIC), Uncertainty over Income Tax Treatments (IFRIC 23): In June 2017, the IASB issued IFRIC 23, Uncertainty over Income Tax Treatments, with a mandatory effective date of January 1, 2019. The interpretations provide guidance on how to value uncertain income tax positions based on the probability of whether the relevant tax authorities will accept the Company's tax treatments. A company is to assume that a taxation authority with the right to examine any amounts reported to it will examine those amounts and will have full knowledge of all relevant information when doing so. IFRIC 23 is to be applied by recognizing the cumulative effect of initially applying these guidelines in opening retained earnings without adjusting comparative information. The Company assessed there was no financial statement impact upon adoption on January 1, 2019.

Other accounting standards or amendments to existing accounting standards that have been issued, but have future effective dates, are either not applicable or are not expected to have a significant impact on the Company's consolidated financial statements.

# **CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS**

The Company makes estimates and judgments concerning the future that will, by definition, seldom equal actual results. Management reviews its estimates on an ongoing basis to ensure that the estimated values appropriately reflect changes in the Company's business and new information as it becomes available. Revisions to accounting estimates are recognized in the period in which the estimate is revised.

The following are the critical estimates and judgments applied by management that most significantly affect the Company's consolidated financial statements. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of assets or liabilities affected in future periods.

- i) Returns: The provision for returns is a complex estimate used in the recognition of revenue. The Company has a returns policy that allows wholesalers to return product within a specified period prior to and subsequent to the expiration date. Provisions for returns are recognized in the period in which the underlying sales are recognized, as a reduction of product sales revenue. The Company estimates provisions for returns based upon historical experience, representing management's best estimate. While such experience has allowed for reasonable estimations in the past, history may not always be an accurate indicator of future returns. The Company continually monitors provisions for returns and makes adjustments when it believes that actual product returns may differ from established reserves.
- ii) Deferred income taxes: Management uses estimates when determining deferred income assets. These estimates are used to determine the recoverability of non capital tax loss carry forward amounts, research and development expenditures and investment tax credits. Significant judgment is required to determine the probable future cash flows in order to recognize the deferred tax asset. Changes in market conditions, changes in tax legislation, patent challenges and other factors, including the approval or launch of generic versions of any of the Company's products, could adversely affect the ongoing value of deferred tax assets. The carrying amount of deferred income tax assets is reassessed at each reporting period and reduced to the extent that it is no longer probable that sufficient taxable income will be available to utilize all or part of the deferred income tax assets. Unrecognized deferred income tax assets are reassessed at each reporting period and are recognized to the extent that it is probable that there will be sufficient taxable income for the asset to be recovered.

- iii) Share-based compensation: The option pricing model used to determine the fair value of share-based payments requires various estimates relating to volatility, interest rates, dividend yields and expected life of the options granted. Fair value inputs are subject to market factors as well as internal estimates. The Company considers historic trends together with any new information to determine the best estimate of fair value at the date of grant. Separate from the fair value calculation, the Company is required to estimate the expected forfeiture rate of equity-settled share-based payments.
- iv) Impairment of non-financial assets: The Company reviews indefinite-lived, not ready for use and amortized non-financial assets for impairment either annually or whenever events or changes in circumstances indicate that the carrying amount of the assets may be impaired. If the recoverable amount of the respective non-financial asset is less than its carrying amount, it is considered to be impaired. In the process of measuring the recoverable amount, management makes assumptions about future events and circumstances. The actual results may vary and may cause significant adjustments.
- v) Accounting for business combinations: The Company assesses whether an acquisition should be accounted for as an asset acquisition or a business combination under IFRS 3. This assessment requires management to make judgements on whether the assets acquired, and liabilities assumed constitute a business as defined in IFRS 3 and if the integrated set of activities, including inputs, processes acquired, is capable of being conducted and managed as a business and the Company obtains control of the business. The Company's acquisition of Cardiome was accounted for as a business combination (Note 7) and all other acquisitions (Note 11) were accounted for as asset acquisitions.
- vi) Functional currency: Management uses judgment when determining its functional currency. This determination includes an assessment of the indicators as prescribed in IAS 21, *The Effects of Changes on Foreign Exchange Rates* ("IAS 21"). However, applying the factors in IAS 21 does not always result in a clear indication of functional currency. Where IAS 21 factors indicate differing functional currencies, management uses judgment in the ultimate determination of the functional currency.

# **Disclosure Controls and Procedures**

The Company's management is responsible for establishing and maintaining internal controls over financial reporting ("ICFR"), as defined in NI 52-109 and have designed such ICFR to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with IFRS. The control framework the Company's management used to design the Company's ICFR is set forth in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO").

The Company's management evaluated the effectiveness of the Company's ICFR and concluded, as at December 31, 2019, that such ICFR were effective.

There have been no changes in the Company's ICFR during the year ended December 31, 2019 that have materially affected, or are reasonably likely to materially affect, the Company's ICFR.

# **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 document. Before making an investment decision, investors should carefully consider these risk factors. 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.

# 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, such as Absorica. 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 this patent expiration depends, among other things, upon the nature of the market and the position of these products in the market from time to time, the growth of the market, the complexities and economics of manufacture of a competitive product and regulatory approval requirements of generic drug laws. In the event that competition develops from generic products, this competition could have a material adverse effect on 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.

#### 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, reduced customer traffic, and increased 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 it 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 develop 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 complies 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 manufacturers' 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 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 modify 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 products or products or product candidates and 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.

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, 2019, the Company had cash of \$6.3 million and debt of \$7.7 million. The Company also generates commercial revenue which provides a source of cash flow. In 2019, the Company reported total revenue of \$22.5 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, then President Barack Obama signed into law the Patient Protection and Affordable Care Act and the Health Care and Education Affordability Reconciliation Act of 2010 (together the "Affordable Care Act"), a legislation 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. 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 requires pharmaceutical companies to monitor and report payments, gifts, the provision of samples and other remuneration made to physicians and teaching hospitals.

The Affordable Care Act also authorizes the Medicare program to engage in demonstration programs, including programs designed to lower the costs of drugs reimbursed under fee-for-service Medicare, such as drugs reimbursed under Medicare Part B. Proposals under this authority have already been issued, but have not yet been finalized. It is clear, however, that the continued implementation of the Affordable Care Act will continue to put pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. More recently, in August 2011, then President Obama signed into law the Budget Control Act of 2011, which, among other things, creates the Joint Select Committee on Deficit Reduction (the "Joint Select Committee") to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of an amount greater than \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs.

This includes aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, which started in 2013 and continues currently through 2025.

These new laws may result in additional reductions in healthcare funding, which could have a material adverse effect on our customers, which may affect our financial operations. Legislative and regulatory proposals may expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. In addition, in January 2017, newlyelected President Donald Trump signed an executive order intended to "eas[e] the burden of the Affordable Care Act," the full impact of which is unclear and which the Company believes signals President Trump's support for a repeal of the Affordable Care Act by the Republican-controlled U.S. Congress. In December 2017, the U.S. Congress successfully passed a repeal of the Affordable Care Act's individual mandate, a federal requirement under that legislation which stated that most Americans must carry a minimum level of health coverage, which took effect in 2019. Given the individual mandate served as a mechanism to balance insurer risk and costs, as it is perceived that in the absence of such mandate only those individuals who currently need access to the health care system would opt for coverage, the U.S. Congress may attempt to resolve this imbalance by either amending or repealing the Affordable Care Act. However, Cipher cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our products or our other product candidates may be. In response to the repeal of the Affordable Care Act's individual mandate at the federal level, certain U.S. states including Massachusetts, New Jersey and the District of Columbia have passed legislation to penalize individuals for not having health insurance commencing in 2019 and certain other states are considering introducing similar legislation.

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 payor 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 antikickback, 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 antifraud 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 antibribery 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, 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. In the event of the publication of negative results of studies or clinical trials related to 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 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 set 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 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.

## Cipher may not be able to continue to meet certain covenants under its existing long term debt arrangement and inability to meet these covenants could result in acceleration of the Company's long term liabilities.

Cipher's existing long term debt arrangement, specifically the credit facility pursuant to the Credit Agreement require the Company to maintain specified coverage ratios and satisfy financial covenants. There can be no assurance that Cipher will be able to continue to meet the covenants under such existing credit facility. A failure to meet such covenants could result in our lenders seeking to enforce their security under such credit facility. This could have a material adverse effect on Cipher's business, financial condition and results of operations. The credit facility also contains restrictive covenants.

The restrictions in our credit facility governing our other indebtedness may prevent Cipher from taking actions that Cipher believes would be in the best interest of our business and may make it difficult for us to execute our business strategy successfully or effectively compete with companies that are not similarly restricted. The Company may also incur future debt obligations that might subject the Company to additional restrictive covenants that could affect our financial and operational flexibility. We may be unable to refinance our indebtedness, at maturity or otherwise, on terms acceptable to us, or at all.

Our ability to comply with the covenants and restrictions contained in our credit facility may be affected by economic, financial and industry conditions, beyond our control including credit or capital market disruptions. The breach of any of these covenants or restrictions could result in a default that would permit the lenders to declare all amounts outstanding to be due and payable, together with accrued and unpaid interest. If Cipher is unable to repay the indebtedness, the lenders could proceed against the collateral securing the indebtedness. This could have serious consequences to our financial position and results of operations and could cause us to become bankrupt or insolvent.

There is no assurance that Cipher will be able to secure future additional financing to repay its current credit facility should cash flows from operations be insufficient to repay these liabilities.

#### 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 control over financial reporting. The Company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with International Financial Reporting Standards. Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives due to its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is therefore subject to error, 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 control 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.

## 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, 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 are 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 license 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. 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., Canadian 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 an 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 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 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.

A director of the Company, Dr. John D. Mull, owns 9,923,927 Common Shares, representing 36.7% of the total outstanding Common Shares as of March 25, 2020. If Dr. 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, Dr. 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 our 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 periodto-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. In 2018, the Company wrote off the net book value of \$1.1 million, net of \$0.2 million received by Astion Pharma in exchange for returning ASF-1096. Additionally, as part of the Company's strategic review of the business, the licensing agreements for A-101 and Xydalba were terminated. The Company recorded an impairment charge of \$2.4 million, representing the carrying value of those assets. As at December 31, 2019, the Company's intangible assets have a net book value of \$10.4 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.



## **Consolidated financial statements**

December 31, 2019

#### Independent Auditor's Report

#### To the Shareholders of Cipher Pharmaceuticals Inc.

#### Opinion

We have audited the accompanying consolidated financial statements of Cipher Pharmaceuticals Inc. and its subsidiaries (the "Company"), which comprise the consolidated statement of financial position as at December 31, 2019, the consolidated statement of changes in shareholders' equity, consolidated statement of income and comprehensive income, and consolidated statement of cash flows for the year then ended, and the notes to the consolidated financial statements, including a summary of significant accounting policies.

In our opinion, the accompanying consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as at December 31, 2019, and its consolidated financial performance and its consolidated cash flows for the year then ended in accordance with International Financial Reporting Standards ("IFRS").

#### **Basis for Opinion**

We conducted our audit in accordance with Canadian generally accepted auditing standards. Our responsibilities under those standards are further described in the *Auditor's Responsibilities for the Audit of the Consolidated Financial Statements* section of our report. We are independent of the Company in accordance with the ethical requirements that are relevant to our audit of the consolidated financial statements in Canada, and we have fulfilled our ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### **Other Matter**

The consolidated financial statements of the Company for the year ended December 31, 2018 were audited by another auditor who expressed an unmodified opinion on those statements on March 18, 2019.

#### **Other Information**

Management is responsible for the other information. The other information comprises Management's Discussion and Analysis.

Our opinion on the consolidated financial statements does not cover the other information and we do not express any form of assurance conclusion thereon. In connection with our audit of the consolidated financial statements, our responsibility is to read the other information, and in doing so, consider whether the other information is materially inconsistent with the consolidated financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated.

We obtained Management's Discussion and Analysis prior to the date of this auditor's report. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

## Responsibilities of Management and Those Charged with Governance for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of the consolidated financial statements in accordance with IFRS, and for such internal control as management determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, management is responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless management either intends to liquidate the Company or to cease operations, or has no realistic alternative but to do so.

Those charged with governance are responsible for overseeing the Company's financial reporting process.

#### Auditor's Responsibilities for the Audit of the Consolidated Financial Statements

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with Canadian generally accepted auditing standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

As part of an audit in accordance with Canadian generally accepted auditing standards, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are
  appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of
  the Company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- Conclude on the appropriateness of management's use of the going concern basis of accounting and, based
  on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that
  may cast significant doubt on the Company's ability to continue as a going concern. If we conclude that a
  material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures
  in the consolidated financial statements or, if such disclosures are inadequate, to modify our opinion. Our
  conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future
  events or conditions may cause the Company to cease to continue as a going concern.
- Evaluate the overall presentation, structure, and content of the consolidated financial statements, including the disclosures, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Company to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the audit. We remain solely responsible for our audit opinion.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide those charged with governance with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

The engagement partner on the audit resulting in this independent auditor's report is Martin Lundie.

Crost + young LLP

Chartered Professional Accountants Licensed Public Accountants

Toronto, Canada March 25, 2020

### Consolidated statements of financial position

[in thousands of United States dollars]

As at December 31

2019	2018
\$	\$
6,346	10,357
	10,470
	772
963	1,336
17,230	22,935
	690
	14,130
	15,706
943	2,225
46,455	55,686
8,594	12,055
	1,072
	81
	8,069
	21,277
_	9,500
8	19
1.821	131
18,444	30,927
18,677	18,324
•	5,324
	(9,514)
	10,625
	24,759
46,455	55,686
	\$ 6,346 8,878 1,043 963 17,230 2,198 10,378 15,706 943 46,455 8,594 274 127 7,620 16,615 

Commitments and contingencies [note 20]

The accompanying notes are an integral part of these consolidated financial statements

Approved on behalf of the Board:

(Signed) "Craig Mull" Craig Mull Chair of the Board (Signed) "Harold Wolkin" Harold Wolkin Director

# Consolidated statements of income and comprehensive income

[in thousands of United States dollars]

For the years ended December 31

	2019	2018
	\$	\$
Revenue		
Licensing revenue [note 15]	14,212	15,869
Product revenue	8,239	6,880
Net revenue	22,451	22,749
Operating expenses		
Cost of products sold [note 8]	2,906	2,312
Research and development	396	561
Selling, general and administrative [notes 13, 16 and 17]	7,647	14,741
Restructuring costs	1,454	—
Impairment of intangible assets [note 11]	3,454	1,832
Total operating expenses	15,857	19,446
Other expenses (income)		
Interest expense <i>[notes</i> 7 & 13]	965	907
Change in fair value of derivative financial instrument [note 7]	(11)	(530)
Interest income	(179)	(195)
Foreign exchange loss (gain)	<b>`109</b> ´	(2)
Total other expenses	884	180
Income before income taxes from continuing operations	5,710	3,123
Current income tax expense [note 18]	1,789	659
Deferred income tax expense [note 18]	1,282	1,263
Total income tax expense	3,071	1,922
Income and comprehensive income from continuing operations	2,639	1,201
Income (loss) and comprehensive income (loss) from discontinued operations	603	(658)
Net income and comprehensive income for the year	3,242	543
Income from continuing operations per common share [note 19]		
Basic	0.10	0.04
Diluted	0.10	0.04
Income (loss) from discontinued operations per common share [note 19]		
Basic	0.02	(0.02)
Diluted	0.02	(0.02)

The accompanying notes are an integral part of these consolidated financial statements

### Consolidated statements of changes in shareholders' equity

[in thousands of United States dollars]

	Share ca	pital	Contributed surplus	Accumulated other comprehensive loss	Retained earnings	Total shareholders' equity
	[000s]	\$	\$	\$	\$	\$
Balance, January 1, 2019	26,821	18,324	5,324	(9,514)	10,625	24,759
Net income for the year	-	_	-	-	3,242	3,242
Shares issued under the share purchase plan [note 14]	76	83	-	-	-	83
Shares issued under the Restricted Share Unit plan	94	270	(270)	_	_	-
Share-based compensation expense [note 14]	-	-	(73)	-	-	(73)
Balance, December 31, 2019	26,991	18,677	4,981	(9,514)	13,867	28,011
Balance, January 1, 2018	26,721	18,020	4,715	(9,514)	10,082	23,303
Net income for the year	_	_	_	_	543	543
Exercise of stock options [note 14]	1	2	(1)	_	_	1
Shares issued under the share purchase plan [note 14]	58	129	_	_	_	129
Shares issued under the Restricted Share Unit plan	41	173	(173)	_	_	_
Share-based compensation expense [note 14]	_		783	_	_	783
Balance, December 31, 2018	26,821	18,324	5,324	(9,514)	10,625	24,759

The accompanying notes are an integral part of these consolidated financial statements

## Consolidated statements of cash flows

[in thousands of United States dollars]

For the years ended December 31

S       S         Operating activities       Income for the year from continuing operations       2,639       1,201         Add (deduct) items not affecting cash:       333       182         Depreciation of property and equipment       333       182         Amortization of intangible assets       884       646         Impairment of intangible assets <i>incle 11</i> ]       3,454       1,832         Share-based compensation       (60)       802         Foreign exchange loss on cash and lease obligation       37       87         Change in fair value of derivative       (11)       (530)         Interest on long term liabilities [note 7 & 13]       950       907         Deferred income taxes       1,282       1,263         Changes in working capital balances related to operating operations:       Accounts receivable       1,592       11,436         Inventory       (271)       (276)       129       1246       124         Charge in payable and accrued liabilities       (2,061)       69          Cash provided by operating activities       (2,061)       6515)       6,500         Pruchase of property and equipment       (796)       (128)       Acquisition of intangible assets <i>inote 10</i> ]       (515)       6,560)		2019	2018
Income for the year from continuing operations2,6391,201Add (deduct) items not affecting cash:333182Depreciation of property and equipment333182Amortization of intangible assets [note 11]3,4541,832Share-based compensation(60)802Foreign exchange loss on cash and lease obligation3787Change in fair value of derivative(11)(530)Interest on long term liabilities [note 7 & 13]950907Deferred income taxes1,2821,263Changes in working capital balances related to operating operations:4,26316Accounts receivable1,59211,436Inventory(271)(276)Prepaid expenses and other assets5315Accounts payable and accrued liabilities(2,061)(6,281)Contract liability69		\$	\$
Income for the year from continuing operations2,6391,201Add (deduct) items not affecting cash:333182Amortization of property and equipment333182Amortization of intangible assets854646Impairment of intangible assets854646Impairment of intangible assets854646Impairment of intangible assets854646Share-based compensation(60)802Foreign exchange loss on cash and lease obligation3787Change in fair value of derivative(11)(530)Interest on long term liabilities [note 7 & 13]950907Deferred income taxes1,2821,263Changes in working capital balances related to operating operations:1,59211,436Accounts receivable1,59211,436Inventory(271)(276)Prepaid expenses and other assets5315Accounts payable and accrued liabilities(2,061)(6,281)Contract liability69Cash provided by operating activities(2,061)(6,281)Investing activities(128)Acquisition of intangible assets (note 10)(515)(6,500)Proceeds on disposal of intangible assets and property and equipment2211,700Acquisition of intangible assets (note 21)(1444)(24,483)Cash used in investing activities(10,000)(5,666)Proceeds from credit facility, net-4,892(4,064)Proceeds from shares issued under the share	Operating activities		
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Depreciation of property and equipment         333         182           Amortization of intangible assets [note 11]         34.54         1.832           Share-based compensation         (60)         802           Foreign exchange loss on cash and lease obligation         37         87           Change in fair value of derivative         (11)         (530)           Interest on long term liabilities [note 7 & 13]         950         907           Deferred income taxes         1,282         1,263           Changes in working capital balances related to operating operations:         Accounts receivable         1,592         11,436           Inventory         (271)         (276)         (276)         (6281)           Prepaid expenses and other assets         53         15         Accounts payable and accrued liabilities         (2,061)         (6,281)           Contract liability         69              Cash provided by operating activities         8.660         11,284            Investing activities         (796)         (128)            Purchase of property and equipment         (796)         (128)		,	, -
Amortization of intangible assets854646Impairment of intangible assets $[n06 \ 11]$ 3,4541,832Share-based compensation(60)802Foreign exchange loss on cash and lease obligation3787Change in fair value of derivative(11)(530)Interest on long term liabilities [note 7 & 13]950907Deferred income taxes1,2821,263Changes in working capital balances related to operating operations:Accounts receivable1,59211,436Inventory(271)(276)(727)(276)Prepaid expenses and other assets53155Accounts receivable(6,281)69Cash provided by operating activities(2,061)(6,281)69Purchase of property and equipment(796)(128)Acquisition of intangible assets [note 10](515)(6,500)Proceeds on disposal of intangible assets and property and equipment2211,700Acquisition of Cardiome Pharma Corp. [note 21](374)(19,555)Cash used in investing activities(10,000)(5,666)Proceeds from credit facility, net-4,892Proceeds from screise of stock options-1Cash used in discontinued operations(10,527)(1,407)Cash used in discontinued operations(929)(3,191)Net decrease in cash during the year(4,060)(17,797)Impact of foreign exchage on cash(49(67)Cash used in discontinued operation		333	182
Impairment of intangible assets [note 11] $3,454$ $1,832$ Share-based compensation(60)802Foreign exchange loss on cash and lease obligation $37$ $87$ Change in fair value of derivative(11)(530)Interest on long term liabilities [note 7 & 13] $950$ $907$ Deferred income taxes $1,282$ $1,263$ Changes in working capital balances related to operating operations: $Accounts receivable$ $1,592$ $11,436$ Inventory(271)(276)(276)Prepaid expenses and other assets $53$ $15$ Accounts payable and accrued liabilities $(2,061)$ $(6,281)$ Contract liability $69$ $-$ Cash provided by operating activities $8,860$ $11,284$ Investing activities $(796)$ $(128)$ Acquisition of intangible assets [note 10] $(515)$ $(6,500)$ Proceeds on disposal of intangible assets and property and equipment $(21,464)$ $(24,483)$ Acquisition of Cardiome Pharma Corp. [note 21] $(374)$ $(19,555)$ Cash used in investing activities $(14,64)$ $(24,483)$ Financing activities $(10,000)$ $(5,666)$ Proceeds from shares issued under the share purchase plan $70$ $110$ Proceeds from shares issued under the share purchase plan $70$ $110$ Proceeds from shares issued under the share purchase plan $70$ $110$ Proceeds from shares issued under the share purchase plan $70$ $110$ Proceeds from shares issued under the		854	
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Impact of foreign exchange on cash49(87)Cash, beginning of year10,35728,241	Net decrease in cash during the year	(4.060)	(17.797)
Cash, beginning of year         10,357         28,241			
	Cash, end of year	6,346	10,357

The accompanying notes are an integral part of these consolidated financial statements

[in thousands of United States dollars, except per share amounts]

#### 1. Nature of operations

Cipher Pharmaceuticals Inc. ["Cipher"] and its subsidiaries [together, the "Company"] are a specialty pharmaceutical company with a diversified portfolio of commercial and early to late stage products. The Company acquires products that fulfil unmet medical needs, manages the required clinical development and regulatory approval process, and markets those products either directly in Canada or indirectly through partners in the U.S., Canada and Latin America. Cipher was incorporated under the *Business Corporations Act* of Ontario on January 9, 2004 and is located at 209 Oak Park Blvd., Suite 501, Oakville, Ontario.

#### 2. Basis of preparation

The Company prepares its consolidated financial statements in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board ["IFRS"]. The Board of Directors approved these consolidated financial statements on March 25, 2020.

The significant accounting policies used in the preparation of these consolidated financial statements are described below.

The consolidated financial statements have been prepared on a going concern basis under the historical cost convention, except for certain financial instruments, which are measured at fair value as described below. Management assesses the Company's ability to continue as a going concern at each reporting date, using quantitative and qualitative information available.

The consolidated financial statements include the accounts of the Company and its wholly owned legal subsidiaries: Cipher US Holdings Inc., Cipher US Holdco LLC, Cipher Pharmaceuticals US LLC and Cardiome Pharma Corp. ["Cardiome"]. All significant intercompany balances and transactions have been eliminated upon consolidation.

#### 3. Summary of significant accounting policies

#### Licensing revenue

Licensing revenue is comprised of upfront payments, pre-commercialization milestones, post-commercialization milestones, royalties and product sales. Upfront payments and pre-commercialization milestones, not representing a financing component are recognized to coincide with the timing of when control is transferred, which may either be point in time or over time. Post-commercialization milestones, such as sales targets are recognized as revenue when the underlying condition is achieved and is unconditional on any further performance.

Royalty revenue is recognized in the period in which the Company earns the royalty. Licensing partners report royalty revenue monthly and remit payment within 30 days after each quarter end. Royalty revenue is earned on the net sales reported by the Company's licensing partners. Net sales result after a number of deductions that are generally estimates and are recorded in the same period that the revenues are recognized. The deductions are primarily comprised of rebates, discounts, promotional incentives and product returns that are applied to gross sales to arrive at net sales. These deductions represent best estimates by the Company's licensing partners of the related obligations. Amounts recorded for sales deductions can result from a complex series of judgments about future events and uncertainties and can rely on estimates and assumptions.

Licensing product sales are recognized when the finished products are shipped from Galephar to the Company's licensing partners, at which time control is transferred.

The Company's licensing agreements also contain upfront payments, pre-and post-commercialization milestones of which the Company recognizes 50% as revenue and remits the other 50% to Galephar or other third parties as may be assigned from time to time.

[in thousands of United States dollars, except per share amounts]

#### Deferred revenue

Prior to the adoption of IFRS 15, deferred revenue represented amounts paid by the Company's licensing partners upon achievement of certain milestones and were amortized over a relevant period. These were determined to be point in time recognition to coincide with the timing of when control was transferred.

#### Accounting for costs to fulfil a contract

The Company may incur costs that are directly related to fulfilling a contract. While there were no such costs incurred in the current and comparative period, such amounts will be capitalized to prepaids and other assets in the consolidated statements of financial position.

#### Financing component

Agreements entered into with licensing partners often include an upfront fee upon execution of the agreement. If they are considered significant in the context of the arrangement, these upfront fees are accounted for as a financing component. There were no such amounts recognized in the current year or comparative period.

#### **Product revenue**

Performance obligations for product sales are primarily satisfied upon delivery of product to the Company's customers, however in a few instances it may be upon shipment. The transaction price is based on list prices that are published annually. Revenue is recorded on a net basis, representing the amounts receivable from customers after the deduction for discounts, returns and early payment discounts. The methodology and assumptions used to estimate discounts, returns and early payments discounts are monitored and adjusted in light of contractual and historical information. Invoices are generated at the time of product shipment and are payable in 30 days.

The provision for returns is a critical estimate used in the recognition of revenue. The Company has a returns policy that allows customers to return product within a specified period prior to and subsequent to the expiration date. Provisions for returns are recognized in the period in which the underlying sales are recognized, as a reduction of product sales revenue and recorded as a contract liability on the statement of consolidated financial position. The Company estimates provisions for returns based upon historical experience if applicable, representing management's best estimate. While such experience has allowed for reasonable estimations in the past, history may not always be an accurate indicator of future returns. The Company continually monitors provisions for returns and adjusts when it believes that actual product returns may differ from established reserves.

#### Translation of foreign currencies

The consolidated financial statements are presented in United States dollars ["U.S. dollars"], which is the Company's functional currency. Revenues and expenses denominated in foreign currencies are translated into U.S. dollars using the exchange rate in effect at the transaction date.

Monetary assets and liabilities are translated using the rate in effect at the balance sheet date and non-monetary items are translated at historical exchange rates. Related exchange gains and losses are included in other expenses (income) in the consolidated statement of income and comprehensive income.

#### **Business combinations**

The acquisition of Cardiome in May 2018 has been accounted for as a business combination using the acquisition method. The consideration transferred in a business combination is measured at fair value at the date of acquisition. Acquisition-related transaction costs are recognized in the consolidated statements of income and comprehensive income as incurred. At the acquisition date, the identifiable assets acquired, and the liabilities assumed are initially recognized at their fair value. Goodwill is measured as the excess of the sum of the consideration transferred and the fair value of the acquirer's previously held equity interest in the acquiree [if any]

[in thousands of United States dollars, except per share amounts]

over the net of the acquisition-date amounts of the identifiable assets acquired and liabilities assumed. When the consideration transferred by the Company in a business combination includes assets or liabilities resulting from a contingent consideration arrangement, the contingent consideration is measured at its acquisition-date fair value and included as part of the consideration transferred in a business combination. Measurement period adjustments are adjustments that arise from additional information obtained during the 'measurement period' [which cannot exceed one year from the acquisition date] about facts and circumstances that existed at the acquisition date. Other than measurement period adjustments, contingent consideration that is classified as a financial asset or a financial liability is remeasured at subsequent reporting dates, with the corresponding gain or loss being recognized in the consolidated statements of income and comprehensive income.

#### Goodwill

For the purpose of impairment testing, goodwill acquired in a business combination is allocated to each of the cash-generating units ["CGUs"], or groups of CGUs, that is expected to benefit from the synergies of the combination. Each unit or group of units to which the goodwill is allocated represents the lowest level within the entity at which the goodwill is monitored for internal management purposes. Goodwill is monitored at the operating segment level. Goodwill impairment assessment is undertaken annually or more frequently if events or changes in circumstances indicate a potential impairment. The estimated fair value may be determined utilizing one or more methods as appropriate. In its analysis, the Company utilized, the market-based approach and fair value less costs to sell as a proxy for fair value. The carrying value of the groups of CGUs that contains goodwill is compared to the recoverable amount. Any impairment is recognized immediately as an expense and is not subsequently reversed.

#### **Financial instruments**

Financial assets and liabilities are recognized when the Company becomes a party to the contractual provisions of the instrument. Financial assets are derecognized when the rights to receive cash flows from the assets have expired or have been transferred and the Company has transferred substantially all risks and rewards of ownership. Financial assets and liabilities are offset, and the net amount reported on the consolidated statements of financial position, when there is a legally enforceable right to offset the recognized amounts and there is an intention to settle on a net basis or realize the asset and settle the liability simultaneously.

At initial recognition, the Company classifies its financial instruments in the following categories depending on the purpose for which the instruments were acquired:

#### Financial assets and liabilities at fair value through profit or loss

A financial asset or liability is classified in this category if acquired principally for the purpose of selling or repurchasing in the short term. The Company's derivative financial instrument is classified as a financial liability at fair value though profit and loss. Financial instruments in this category are recognized initially and subsequently at fair value. Transaction costs are expensed in the consolidated statements of income and comprehensive income. Gains and losses arising from changes in fair value are presented in the consolidated statements of income and comprehensive income and comprehensive income in the period in which they arise.

#### Loans and receivables

These are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. The Company's loans and receivables comprise cash and accounts receivable and are included in current assets due to their short-term nature. Loans and receivables are initially recognized at the amount expected to be received less, when material, a discount to reduce the loans and receivables to fair value. Subsequently, loans and receivables are measured at amortized cost using the effective interest method less a provision for impairment, if needed.

[in thousands of United States dollars, except per share amounts]

#### Financial liabilities at amortized cost

This classification includes accounts payable and accrued liabilities, and the credit facility. Financial liabilities at amortized cost are initially recognized at the amount required to be paid less, when material, a discount to reduce the payables to fair value. Subsequently, financial liabilities at amortized cost are measured at amortized cost using the effective interest rate method. Financial liabilities are classified as current liabilities if payment is due within twelve months. Otherwise, they are presented as non-current liabilities.

The Company does not have any financial instruments classified as fair value through other comprehensive income.

#### Fair value of financial instruments

Fair value is defined as the price that would be received from the sale of an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The best evidence of fair value is quoted bid or ask prices in an active market. Quoted prices are not always available for over-the-counter transactions, as well as transactions in inactive or illiquid markets. In these instances, pricing models, normally with observable market-based inputs, are used to estimate fair value. Financial instruments traded in a less active market have been valued using indicative market prices, present value or other valuation techniques. Where financial instruments trade in inactive markets or when using models where observable parameters do not exist, greater management judgment is required for valuation purposes. In addition, the calculation of estimated fair value is based on market conditions at a specific point in time and, therefore, may not be reflective of future fair values.

As at December 31, 2019, the Company's financial instruments consisted of cash, accounts receivable, accounts payable and accrued liabilities, the credit facility and a derivative financial instrument. The derivative financial instrument is measured at fair value with any changes recognized through the consolidated statements of income and comprehensive income as other expenses (income) and is classified as Level 2 [as defined under IFRS]. Cash, accounts receivable, accounts payable and accrued liabilities are measured at amortized cost and their fair values approximate their carrying values.

The credit facility is measured at amortized cost. As at December 31, 2019, the fair value of the credit facility is approximately \$7,620. The fair value is based on cash flows discounted using a rate based on the borrowing rate.

#### Impairment of financial assets

At each reporting date, the Company assesses whether there is objective evidence that a financial asset is impaired. If such evidence exists, the Company recognizes an impairment loss. Impairment losses on financial assets carried at amortized cost are reversed in subsequent periods if the amount of the loss decreases and the decrease can be related objectively to an event occurring after the impairment was recognized.

#### Cash

Cash includes deposits held with banks.

#### Accounts receivable

Accounts receivable consist of amounts due from licensing partners for royalties and product sales in the normal course of business. Trade receivables are carried at amounts due, net of expected lifetime credit losses. The Company has adopted the simplified approach for estimating credit losses as historical credit losses have been insignificant.

[in thousands of United States dollars, except per share amounts]

#### Inventory

Inventory, which is comprised of finished goods, is valued at the lower of cost and net realizable value. Cost is determined using the weighted-average cost method. Net realizable value is the estimated selling price less applicable selling cost. If the carrying value exceeds net realizable amount, a provision is recognized. The provision may be reversed in a subsequent period if the circumstances which caused the write down no longer exists.

#### Prepaid expenses and other assets

Prepaid expenses consist of amounts paid in advance for services that have future value to the Company, such as insurance policy premiums, subscription-based fees, U.S. Food and Drug Administration ["FDA"] fees and deposits.

#### Property and equipment

Property and equipment are recorded at historical cost less accumulated depreciation and accumulated impairment losses. The useful lives of property and equipment are reviewed at least annually, and the depreciation charge is adjusted for prospectively. Depreciation is computed using the straight-line method, over the following estimated useful lives of the assets or lease terms:

Computer equipment	3 years
Vehicles	4 years
Furniture and fixtures	5 years
Leasehold improvements	Over the term of the lease
Office lease	Over the term of the lease

#### Intangible assets

Intangible assets include product rights that consist of marketing and other rights relating to products and licensing rights and these are recorded at cost less accumulated amortization and accumulated impairment losses. Intangible assets have a finite life and are amortized using the straight-line method over their estimated useful lives. The useful lives of the intangible assets are reviewed at least annually. Amortization is recognized straight-line over the contract term or life of the patent, as applicable.

#### Impairment of non-financial assets

Indefinite-lived intangible assets or intangible assets not ready to use are tested at least annually for impairment or when indicators of impairment exist. Intangible assets subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs of disposal and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are largely independent cash inflows [CGU]. Prior impairments of non-financial assets [other than goodwill] are reviewed for possible reversal at each reporting date.

#### Share capital

Common shares are classified as equity. Incremental costs directly attributable to the issuance of shares are recognized as a deduction from equity.

#### Cost of products sold

Cost of products sold includes the cost of finished goods, royalties to license holders, inventory provisions, distribution costs and direct overhead expenses necessary to acquire the finished goods.

[in thousands of United States dollars, except per share amounts]

#### **Research and development**

The Company conducts research and development programs and incurs costs related to these activities, including employee compensation, materials, professional services and services provided by contract research organizations. Research and development costs, net of related tax credits and contractual reimbursements from development partners, are expensed in the periods in which they are incurred.

#### Income taxes

Income tax comprises current and deferred tax. Current tax is the expected tax payable on the taxable income for the year using tax rates enacted or substantively enacted at the end of the reporting period and any adjustment to tax payable in respect of previous years.

Deferred tax is recognized in respect of temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. Deferred income tax is determined on a nondiscounted basis using tax rates and laws that have been enacted or substantively enacted at the consolidated statements of financial position date and are expected to apply when the deferred tax asset or liability is settled.

Deferred tax assets are recognized to the extent that it is probable that the assets can be recovered.

#### Stock-based compensation

The fair value of options granted to employees and directors is estimated on the date of the grants using the Black-Scholes option pricing model. Stock options vest over four years [25% per year] for both employees and directors and expire after seven or ten years and can only be settled in common shares. Each tranche in an award is considered as a separate award with its own vesting period and grant date fair value. Share-based compensation expense is recognized over the tranche's vesting period based on the number of awards expected to vest, by increasing contributed surplus. The number of awards expected to vest is reviewed annually, with any impact being recognized immediately. Stock option forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Share-based compensation expense is included within the respective functional departments in operating expenses in the statements of income and comprehensive income and in contributed surplus in the statements of financial position. The consideration received on the exercise of stock options is credited to share capital at the time of exercise.

Restricted share units ["RSUs"] are notional common shares of the Company to be issued to employees and directors of the Company. RSUs vest three years from the date of grant [one third per year] or four years from the grant date [one quarter per year] for employees and vest over one year for board of directors and can only be settled in common shares. The Company amortizes the fair value of the RSUs over the service period of the individual RSU grant, which generally equals the vesting period. RSU forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

Performance share units ["PSUs"] are notional common shares of the Company issued to senior employees of the Company. The fair value of PSU's granted to employees is estimated on the date of grant using a Monte Carlo simulation. PSUs cliff vest two or three years from the date of grant and can only be settled in common shares. Awards of PSUs are dependent upon the achievement of performance targets set by the Board of Directors for a two- or three-year period. Compensation expense is recognized over the three-year vesting period for the PSUs based on the progress towards achieving the performance targets.

#### **Termination benefits**

The Company recognizes termination benefits when it is demonstrably committed to either terminating the employment of current employees according to a detailed formal plan without possibility of withdrawal or providing benefits as a result of an offer made to encourage voluntary termination. Benefits falling due more than twelve months after the end of the reporting period are discounted to their present value.

[in thousands of United States dollars, except per share amounts]

#### Earnings per share

Basic earnings per share ["EPS"] is calculated using the treasury stock method, by dividing the net income for the year by the weighted average number of common shares outstanding during the year. Diluted EPS is calculated by adjusting the weighted average number of common shares outstanding for dilutive instruments.

#### **Discontinued operations**

The Company reports financial results for discontinued operations separately from continuing operations to distinguish the financial impact of disposal transactions from ongoing operations. Discontinued operations reporting occurs when the disposal of a component or a group of components of the Company represents a strategic shift that will have major impact on the Company's operations and financial results, and where the operations and cash flows can be clearly distinguished, operationally and for financial reporting purposes, from the rest of the Company.

The results of discontinued operations are excluded from both continuing operations and business segment information in the consolidated financial statements and the notes to the consolidated financial statements, unless otherwise noted, and are presented net of tax in the statement of income and comprehensive income for the current and comparative year. Refer to note 6.

#### Changes in accounting policies

IFRS 16, *Leases* ["IFRS 16"] sets out the principles for the recognition, measurement, presentation and disclosure of leases and requires lessees to account for most leases under a single on-balance sheet model. The Company adopted IFRS 16 using the modified retrospective method of adoption with the date of initial application of January 1, 2019. Under this method, the standard is retrospectively applied with the cumulative effect of initially applying the standard recognized at the date of initial application.

The Company elected to use the following practical expedients: [i] the transition application practical expedient allowing the standard to only be applied to contracts that were previously identified as leases applying IAS 17, *Leases*, [ii] the transition application practical expedient to elect to not apply IFRS 16 to leases that expired within 12 months following the adoption date of January 1, 2019; [iii] the recognition exemption to not apply IFRS 16 to lease contracts for which the underlying asset is of low value, and [iv] the recognition exemption to not apply IFRS 16 to lease contracts that, at the commencement date, have a lease term of 12 months or less and do not contain a purchase option.

Before the adoption of IFRS 16, the Company classified each of its leases at the inception date as either a finance lease or an operating lease. A lease was classified as a finance lease if it transferred substantially all of the risks and rewards incidental to ownership of the leased asset to the Company; otherwise it was classified as an operating lease. Finance leases were capitalized at the commencement of the lease at the inception date fair value of the leased property or, if lower, at the present value of the minimum lease payments. Lease payments were apportioned between interest [recognized as finance costs] and reduction of the lease liability. In an operating lease, the leased property was not capitalized and the lease payments were recognized as rent expense in the consolidated statements of income and comprehensive income on a straight-line basis over the lease term.

Upon adoption of IFRS 16, the Company applied a single recognition and measurement approach for all leases that it is the lessee, except for short-term leases and leases of low-value assets. The Company recognized lease liabilities to make lease payments and right-of-use assets representing the right to use the underlying assets. The Company's previous leased office expired on December 31, 2018 and is, therefore, not recorded in the comparative consolidated statement of financial position in accordance with IFRS 16. Instead, the lease payments for the previous leased office is recorded in the comparative consolidated statements of income and comprehensive income within selling, general and administrative expenses.

[in thousands of United States dollars, except per share amounts]

#### Right-of-use assets

The Company recognizes right-of-use assets at the commencement date of the lease [i.e., the date the underlying asset is available for use]. Right-of-use assets are measured at cost, less any accumulated depreciation and impairment losses, and adjusted for any remeasurement of lease liabilities. The cost of right-of-use assets includes the amount of lease liabilities recognized, initial direct costs incurred, and lease payments made at or before the commencement date less any lease incentives received. Unless the Company is reasonably certain to obtain ownership of the leased asset at the end of the lease term, the recognized right-of-use assets are depreciated on a straight-line basis over the shorter of their estimated useful life and the lease term. Right-of-use assets are subject to impairment.

#### Lease obligations

At the commencement date of the lease, the Company recognizes lease liabilities measured at the present value of lease payments to be made over the lease term. In calculating the present value of lease payments, the Company uses the incremental borrowing rate at the lease commencement date if the interest rate implicit in the lease is not readily determinable. After the commencement date, the amount of lease liabilities is increased to reflect the accretion of interest and reduced for the lease payments made. In addition, the carrying amount of lease liabilities is remeasured if there is a modification, a change in the lease term, a change in the in-substance fixed lease payments or a change in the assessment to purchase the underlying asset.

#### Lease receivable

IFRS 16 requires the Company's subleased office space in the U.S. to be recorded as a financial asset equal to the present value of cash flows expected to be received from the sublessor. The current portion of this amount is recorded within prepaid expenses and other assets while the long-term portion is recorded in lease receivable in the Company's consolidated statements of financial position.

The adoption of IFRS 16 had the following impacts as at January 1, 2019:

	December 31, 2018 \$	January 1, 2019 \$
Assets	as presented	
Prepaid expenses and other assets	1,336	1,512
Property and equipment, net	690	2,302
Lease receivable	—	1,017
	2,026	4,831
Liabilities		
Accounts payable and accrued liabilities	12,055	11,924
Current portion of lease obligations	81	461
Long-term portion of lease obligations	131	2,645
	12,267	15,030

[in thousands of United States dollars, except per share amounts]

#### Accounting standards amendments issued but not yet effective

In October 2018, the IASB issued amendments to the definition of a business in IFRS 3 Business Combinations to help entities determine whether an acquired set of activities and assets is a business or not. The amendments take effect for annual periods beginning on or after January 1, 2020.

The amendments clarify the minimum requirements for a business, remove the assessment of whether market participants are capable of replacing any missing elements, add guidance to help entities assess whether an acquired process is substantive, narrow the definitions of a business and of outputs, and introduce an optional fair value concentration test.

Since the amendments apply prospectively to transactions or other events that occur on or after the date of first application, the Company will not be affected by these amendments on the date of transition.

Other amendments to standards have been issued but are not yet effective for the year ended December 31, 2019, and accordingly, have not been applied in preparing these consolidated financial statements. The Company reviewed these amendments and concluded that there is no impact on adoption given their nature and applicability.

#### 4. Critical accounting estimates and judgments

The Company makes estimates and judgments concerning the future that will, by definition, seldom equal actual results. Management reviews its estimates on an ongoing basis to ensure that the estimated values appropriately reflect changes in the Company's business and new information as it becomes available. Revisions to accounting estimates are recognized in the period in which the estimate is revised.

The following are the critical estimates and judgments applied by management that most significantly affect the Company's consolidated financial statements. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of assets or liabilities affected in future periods.

#### i) Returns

The provision for returns is a complex estimate used in the recognition of revenue. The Company has a returns policy that allows wholesalers to return product within a specified period prior to and subsequent to the expiration date. Provisions for returns are recognized in the period in which the underlying sales are recognized, as a reduction of product sales revenue. The Company estimates provisions for returns based upon historical experience, representing management's best estimate. While such experience has allowed for reasonable estimations in the past, history may not always be an accurate indicator of future returns. The Company continually monitors provisions for returns and makes adjustments when it believes that actual product returns may differ from established reserves.

#### ii) Deferred income taxes

Management uses estimates when determining deferred income assets. These estimates are used to determine the recoverability of non-capital tax loss carry forward amounts, research and development expenditures and investment tax credits. Significant judgment is required to determine the probable future cash flows in order to recognize the deferred tax asset. Changes in market conditions, changes in tax legislation, patent challenges and other factors, including the approval or launch of generic versions of any of the Company's products, could adversely affect the ongoing value of deferred tax assets. The carrying amount of deferred income tax assets is reassessed at each reporting period and reduced to the extent that it is no longer probable that sufficient taxable income tax assets are reassessed at each reporting period and are recognized to the extent that it is probable that there will be sufficient taxable income for the asset to be recovered.

[in thousands of United States dollars, except per share amounts]

#### iii) Share-based compensation

The option pricing model used to determine the fair value of share-based payments requires various estimates relating to volatility, interest rates, dividend yields and expected life of the options granted. Fair value inputs are subject to market factors as well as internal estimates. The Company considers historic trends together with any new information to determine the best estimate of fair value at the date of grant. Separate from the fair value calculation, the Company is required to estimate the expected forfeiture rate of equity-settled share-based payments.

#### iv) Impairment of non-financial assets

The Company reviews indefinite-lived and not ready for use non-financial assets for impairment either annually or whenever events or changes in circumstances indicate that the carrying amount of the assets may be impaired. The Company reviews amortized non-financial assets for impairment when impairment indictors exist. If the recoverable amount of the respective non-financial asset is less than its carrying amount, it is considered to be impaired. In the process of measuring the recoverable amount, management makes assumptions about future events and circumstances. The actual results may vary and may cause significant adjustments.

#### v) Accounting for business combinations

The Company assesses whether an acquisition should be accounted for as an asset acquisition or a business combination under *Business Combinations* IFRS 3 ["IFRS 3"]. This assessment requires management to make judgements on whether the assets acquired, and liabilities assumed constitute a business as defined in IFRS 3 and if the integrated set of activities, including inputs, processes acquired, is capable of being conducted and managed as a business and the Company obtains control of the business. The Company's acquisition of Cardiome was accounted for as a business combination [note 7] and all other acquisitions [note 11] were accounted for as asset acquisitions.

#### vi) Functional currency

Management uses judgment when determining its functional currency. This determination includes an assessment of the indicators as prescribed in IAS 21, *The Effects of Changes on Foreign Exchange Rates* ["IAS 21"]. However, applying the factors in IAS 21 does not always result in a clear indication of functional currency. Where IAS 21 factors indicate differing functional currencies, management uses judgment in the ultimate determination of the functional currency.

#### 5. Risk management and uncertainties

In the normal course of business, the Company is exposed to a number of financial risks that can affect its operating performance. These risks are: credit risk, liquidity risk, market risk, interest rate risk and capital management risk. The Company's overall risk management program and business practices seek to minimize any potential adverse effects on the Company's financial performance.

#### i) Credit risk

Credit risk is the risk of a financial loss to the Company if a customer or counterparty to a financial instrument fails to meet its contractual obligation. Financial instruments that potentially expose the Company to significant concentration of credit risk consist of cash and accounts receivable. The Company's investment policies are designed to mitigate the possibility of deterioration of principal, enhance the Company's ability to meet its liquidity needs and provide high returns within those parameters. Cash is on deposit with Canadian and U.S. chartered banks. Management monitors the collectability of accounts receivable and other receivables and estimates an allowance for doubtful accounts.

As at December 31, 2019, the expected lifetime credit losses for receivable aged as current was nil [2018 – nil] and the accounts that were past due was negligible [2018 – nil].

The Company has concentration risk, as approximately 90% [2018 – 92%] of total revenue came from four [2018 – four] customers and approximately 84% [2018 – 88%] of total accounts receivable is due from two [2018 – two] customers.

[in thousands of United States dollars, except per share amounts]

#### ii) Liquidity risk

Liquidity risk is the risk that the Company will encounter difficulties in meeting its financial liability obligations as they become due. The Company has a planning and budgeting process in place to help determine the funds required to support the Company's normal operating requirements on an ongoing basis.

The Company has financed its cash requirements primarily through operations and its credit facility. The Company controls liquidity risk through management of working capital, cash flows and the availability and sourcing of financing.

The Company has financial covenants in its credit facility that are based on predefined trailing adjusted earnings before interest, taxes, depreciation and amortization ["EBITDA"] formula. The Company's adjusted EBITDA is sensitive to significant fluctuations based on revenue from its licensing business. A significant decline in licensing revenue could cause the Company to breach on one or more covenants and/or impact the Company's ability to repay the remaining balance of its credit facility, unless refinanced.

The Company anticipates that its current cash, together with the cash flow that is generated from operations will be sufficient to execute its current business plan for 2020 and meet its debt obligations.

The following table outlines the Company's undiscounted contractual obligations as at December 31, 2019.

Description	Less than one year	Years two and three	Beyond three years	Total
	\$	\$	\$	\$
Accounts payable and accrued liabilities	8,594	-	-	8,594
Lease obligations	287	584	1,981	2,852
Credit facility	7,668	-	-	7,668
Total	16,549	584	1,981	19,114

The current portion of lease obligations are recorded at the net present value of 127 [2018 - 81] in lease obligations. The non-current portion of the lease obligation of 1,821 [2018 - 131] is recorded in long term lease obligations.

#### iii) Market risk

The Company is exposed to currency risk related to the fluctuation of foreign exchange rates. The Company operates primarily in U.S. dollars. The Company is exposed to currency risk through its net assets denominated in Canadian dollars ["CDN\$"]. A change of 10 basis points in the U.S./CDN exchange rate on December 31, 2019 balance would have had a \$368 impact on income and comprehensive income. The following are the financial assets and financial liabilities denominated in Canadian dollars as of December 31, 2019:

ODM

	CDN\$
Cash	721
Accounts receivable	1,421
Accounts payable and accrued liabilities	(3,290)
Lease obligations	(2,530)
Net financial liabilities	(3,678)

[in thousands of United States dollars, except per share amounts]

#### iv) Interest rate risk

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. The credit facility bears interest that is pegged to LIBOR and as such is subject to interest rate cash flow risk resulting from market fluctuations in interest rates. A change of 100 basis points in the LIBOR would increase/decrease the interest expense by \$143 for the year ended December 31, 2019.

#### v) Capital risk management

The Company's managed capital is comprised of cash, the credit facility and shareholders' equity. The Company's objective when managing its capital structure is to safeguard its ability to continue as a going concern in order to provide returns for shareholders, finance strategic growth plans and financial obligations as they become due. In order to maintain or adjust the capital structure, the Company may issue new common shares from time to time. The Company relies on cash on hand, cash flows from operations and debt financing to finance growth initiatives.

#### 6. Discontinued operations

In May 2017, the Company entered into an Asset Purchase Agreement and completed the sale of substantially all of the assets comprising the U.S. segment.

As at December 31, 2019, the liabilities retained by the Company are \$237 [2018 – \$1,223] recorded in accounts payable and accrued liabilities and \$164 [2018 – \$1,031] recorded in contract liability. During the year, there was a reduction in the contract liability of \$291.

#### 7. Credit facility

In November 2017, the Company entered into a credit agreement with a Canadian lender to extinguish its existing senior secured notes and replace with a credit facility. In connection with the credit agreement, the Company used proceeds of \$20,000 to fully extinguish the remaining balance of the senior secured notes. The credit facility has a three-year term expiring on November 3, 2020, carrying an interest rate of LIBOR plus an applicable margin ranging from 1.5% - 2.5% based on the total debt to EBITDA ratio, as defined in the credit agreement. Principal and interest payments are payable quarterly in arrears. The credit facility also carries an accordion feature that allows for an additional US\$10,000 of capacity, subject to customary terms and conditions. The Company is subject to certain financial and non-financial covenants. The credit facility is secured by the assets of the Company. The interest rate applicable in the fourth quarter was approximately 4.60%. The effective interest rate was 5.59%.

In May 2018, concurrent with the acquisition of Cardiome, the Company drew \$5,000 from its existing credit facility. Net of transaction costs of \$108, the amount recorded to the consolidated statement of financial position was \$4,892. As a result, the scheduled quarterly payments increased from \$1,666 to \$2,000. There was no corresponding change in the interest rate terms or term of the credit facility. Subsequent to the drawdown, the accordion was reset to \$10,000.

On March 31, 2019, the Company entered into a second amendment to its credit agreement with its Canadian lender. The amendment adjusts certain financial covenants for the remainder of the credit facility term.

On September 30, 2019, the Company entered into a third amendment to its credit agreement with its Canadian lender. The amendment adjusts certain financial covenants for the remainder of the credit facility term. In consideration for the amendment, the Company prepaid \$2,000 of the outstanding balance on the credit facility. There were no penalties associated with the prepayment.

\$

[in thousands of United States dollars, except per share amounts]

The following is the continuity of the credit facility for the year ended December 31, 2019:

	*
Balance, January 1, 2018	18,120
Proceeds, net	4,892
Interest expense	753
Interest paid	(684)
Imputed interest accretion	154
Repayment	(5,666)
Balance, January 1, 2019	17,569
Interest expense	690
Interest paid	(759)
Imputed interest accretion	120
Repayment	(10,000)
Balance, December 31, 2019	7,620
Current portion	7,620
Long-term portion	—

#### **Derivative financial instrument**

In April 2015, the Company issued 600,000 common share purchase warrants to the lender of the senior secured notes with an option for a cashless exercise in which the settlement price caused the conversion ratio to be variable. Accordingly, the warrants are classified as a financial liability. Gains and losses on re-measurement are presented separately in the consolidated statements of income and comprehensive income. The exercise price of the warrants is \$9.22 [equal to the five-day volume-weighted average price on the Toronto Stock Exchange prior to closing, converted to U.S. dollars] and expire seven years from the date of issuance. Black-Scholes pricing model with observable market-based inputs was used to estimate the fair value of the warrants issued. The estimated fair value of the warrants as at December 31, 2019 and December 31, 2018 was \$8 and \$19, respectively.

The variables used to compute the fair value as at December 31, 2019 and December 31, 2018 are follows:

	2019 201	
	\$	\$
Share price	1.15	1.25
Expected life	2.3 years	3.2 years
Volatility	61.8%	55.3%
8. Inventory		
Inventory consists of the following:		
	2019	2018
	\$	\$
Finished goods	1,141	1,114
Obsolescence provision	(98)	(342)
	1,043	772

Inventory amounts recorded to cost of products sold during the year is \$1,911 [2018 - \$1,638].

[in thousands of United States dollars, except per share amounts]

#### 9. Property and equipment

			Furniture			
	Computer		and	Leasehold	Office	
	equipment	Vehicles	fixtures	improvements	lease	Total
Cost	\$	\$	\$	\$	\$	\$
Balance, January 1, 2018	247	185	144	63	—	639
Additions	74	166	—	377		617
Disposals	—	(23)	—	—	_	(23)
Balance, December 31, 2018	321	328	144	440		1,233
Additions	_	106	124	369	1,500	2,099
Disposals	(193)	(407)	(141)	(63)	_	(804)
Balance, December 31, 2019	128	27	127	746	1,500	2,528
Accumulated depreciation						
Balance, January 1, 2018	192	67	70	44	_	373
Depreciation	36	56	71	19	_	182
Disposals	—	(12)	_	_	_	(12)
Balance, December 31, 2018	228	111	141	63	_	543
Depreciation	52	45	21	69	146	333
Disposals	(192)	(150)	(141)	(63)	_	(546)
Balance, December 31, 2019	88	6	21	69	146	330
Net book value						
As at December 31, 2018	93	217	3	377		690
As at December 31, 2019	40	21	106	677	1,354	2,198

Depreciation expense of \$333 [2018 – \$182] is recorded in selling general & administrative expenses in the consolidated statements of income and comprehensive income. Fully amortized assets no longer in use of \$374 were written off during the year and is included in disposals.

As at December 31, 2019, nil [2018 – \$323] is included in accounts payable and accrued liabilities for the acquisition of property and equipment.

#### 10. Intangible assets

On February 27, 2018, the Company acquired the exclusive Canadian rights to market, distribute and sell Trulance<sup>®</sup>, an FDA approved product. Under the terms of the licensing agreement, the Company paid an upfront payment of \$5,000 upon execution of the agreement. The transaction includes a regulatory milestone payment of \$750 and royalties on net product sales in Canada. As at December 31, 2019, the regulatory milestone of \$750 [2018 – \$500] is included in accounts payable and accrued liabilities. The milestone payment was made subsequent to year end.

On April 5, 2018, the Company acquired the exclusive Canadian rights to distribute and commercialize A-101. A-101 is an FDA approved topical product, marketed under the brand name of Eskata in the U.S. Under the terms of the licensing agreement, the Company paid an upfront payment of \$1,000 and upon achievement of certain milestone events, additional regulatory and commercial milestones of up to \$2,750 are payable, as well as royalties

[in thousands of United States dollars, except per share amounts]

from net product sales in Canada. The Company made a \$0.5 million milestone payment upon Health Canada acceptance for review in the first quarter of 2019. On September 1, 2019, Cipher and Aclaris mutually agreed to terminate this agreement as a result of Aclaris voluntarily ceasing commercialization of Eskata in the U.S. market. There were no costs associated with the termination. Refer to note 11.

On September 18, 2018, the Company acquired the exclusive Canadian rights to distribute and commercialize MOB-015. Under the terms of the licensing agreement, the Company made an upfront payment of \$500 and will pay additional development, regulatory and sales milestones of up to \$14,050 upon achievement of predetermined targets.

Cost	Licensing and intellectual property rights \$
Balance, January 1, 2018	13,381
Additions	7,000
Additions related to business combination [note 21]	4,208
Impairment [ <i>note 11</i> ]	(2,792)
Balance, December 31, 2018	21,797
Additions	756
Impairment [note 11]	(4,561)
Balance, December 31, 2019	17,992

#### Accumulated amortization and impairment

Balance, January 1, 2018	7,981
Additions	646
Impairment [note 11]	(960)
Balance, December 31, 2018	7,667
Additions	854
Impairment [ <i>note 11</i> ]	(907)
Balance, December 31, 2019	7,614

Net book value	
As at December 31, 2018	14,130
As at December 31, 2019	10,378

Amortization expense of \$854 [2018 – \$646] is recorded in selling general & administrative expenses in the consolidated statements of income and comprehensive income. The average remaining amortization period of the intangible assets is 9.1 years.

#### 11. Impairment of intangible assets

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In 2018, the Company reassessed its efforts to out-license its Astion assets acquired in 2015 and decided not to continue to actively pursue partners for Dermadexin and Pruridexin products in this portfolio. Accordingly, the Company wrote off the net book value of these assets in the amount of \$1,832 in operating expenses in the consolidated statements of income and comprehensive income.

In 2019, the Company reconsidered its efforts to out-license ASF1096, the remaining asset in the Astion portfolio. Accordingly, the Company wrote off the net book value in the amount of \$1,090, net of \$200 received by Astion in

[in thousands of United States dollars, except per share amounts]

consideration for returning the asset. Additionally, as part of the Company's strategic review of the business, the licensing agreements for A-101 and Xydalba were terminated. As a result, the Company recorded an impairment charge of \$2,364, representing the net book value of those assets.

#### 12. Contract liabilities

Contract liabilities relate to estimates made for product returns for our Canadian operations and our discontinued U.S. operations. The provision for product returns relates to potential returns due to expiration or other return rights under the terms of distribution and supply agreements with customers, taking into account historical returns. The adequacy of the contract liabilities is evaluated based on product sales activity and estimates of expiring products in the distribution chain.

The following is the continuity of the contract liabilities for the year ended December 31, 2019:

	\$
Balance, January 1, 2018	1,669
Additions	965
Payments	(1,264)
Transferred to accounts payable and accrued liabilities	(298)
Balance, December 31, 2018	1,072
Reductions	(39)
Payments	(759)
Balance, December 31, 2019	274

Amounts transferred to accounts payable and accrued liabilities represents returns that have been approved but not yet paid. As at December 31, 2019, the contract liability relating to the Canadian operations is \$110 [2018 – \$41], and the balance of \$164 [2018 – \$1,031] relates to the U.S. discontinued operations. Payments include \$576 for product returns relating to the U.S. discontinued operations.

#### 13. Lease obligations

In July 2018, the Company entered into an office lease agreement for its corporate operations to replace the previous office lease, which expired on December 31, 2018. The term of the lease is 10 years and three months and commenced on January 1, 2019. Upon adoption of IFRS 16 on January 1, 2019, the Company recorded a lease obligation and corresponding right-of-use asset for \$1,612. During the second quarter, the final rentable square footage was determined, resulting in a reduction of the lease obligation. This was offset by a reimbursement for leasehold improvements from the landlord in the amount of \$416. As at December 31, 2019, the undiscounted commitment for the remaining lease term is approximately CDN\$3,675.

In 2015, the Company entered into a lease for office space in Charleston, South Carolina for its U.S. operations. The lease commenced on February 22, 2016 and ends on January 31, 2023. Upon adoption of IFRS 16, the Company recorded a lease obligation of \$1,282. The Company sub-leased this office space after divesting of the U.S. operations for the remainder of the term, resulting in a lease receivable of \$844 upon adoption of IFRS 16. On December 31, 2019, the lease and the sublease were terminated and both the lease obligation of \$1,068 and lease receivable of \$1,066 were derecognized accordingly.

[in thousands of United States dollars, except per share amounts]

The carrying amounts of the Company's lease obligations and movements during the period were as follows:

	\$
Balance, December 31, 2018	212
IFRS 16 adjustment	2,894
Balance, January 1, 2019	3,106
Additions	519
Disposals	(261)
Adjustments	(65)
Interest expense	274
Payments	(644)
Derecognition of lease obligation, net	(1,068)
Foreign exchange	87
Balance, December 31, 2019	1,948
Current portion	127
Long-term portion	1,821

The total expense related to low value leases was \$10 for the year ended December 31, 2019, and is recorded in selling, general and administrative expenses in the consolidated statements of income and comprehensive income. During 2019, the interest expense on the lease obligations related to continuing operations was \$155.

#### 14. Share capital

#### Authorized share capital

Authorized share capital consists of an unlimited number of preference shares, issuable in series, and an unlimited number of voting common shares, with no par value.

The Company has three stock-based compensation plans: The Stock Option Plan ["SOP"], the Employee and Director Share Purchase Plan ["ESPP"] and the Restricted Share Units and Performance Share Units ["PR Plan"].

On May 10, 2018, shareholders of Cipher approved resolutions which provide that the maximum number of common shares issuable in aggregate pursuant to outstanding awards or grants under the SOP and the PR Plan at any time shall be 10% of the number of common shares then issued and outstanding.

#### Share purchase plan

The Company's ESPP allows employees and directors to share in the growth of the Company through share ownership. Through the ESPP, employees and directors may contribute amounts to purchase shares of the Company at a 15% discount from the prevailing trading price. Plan members must hold their shares for a period of at least six months before they can be sold. During the year ended December 31, 2019, 76,514 common shares were issued under the ESPP [2018 – 58,490] at a weighted average trading price of \$1.45 [2018 – \$2.86]. Included in share-based compensation expense is \$13 [2018 – \$19], which is the discount on the common shares issued during the year.

[in thousands of United States dollars, except per share amounts]

#### Stock option plan

The following is a summary of the changes in the stock options outstanding from January 1, 2018 to December 31, 2019:

	Number of options [000s]	Weighted average exercise price [CDN\$]
Balance, January 1, 2018	603	5.80
Granted during the year	585	3.34
Exercised during the year	(1)	2.32
Forfeited/expired during the year	(101)	8.01
Balance, December 31, 2018	1,086	4.27
Granted during the year	425	1.47
Forfeited/expired during year	(893)	3.33
Balance, December 31, 2019	618	3.70

As at December 31, 2019, 386,156 stock options were fully vested and exercisable [2018 - 196,262].

During 2019, the Company granted 425,183 stock options under the SOP. The options granted to employees' vest over a four-year period from the grant date, at a rate of 25% per year and expire seven years from the day of grant. Stock options granted to directors' vest over a one-year period. The expected volatility is based on the Company's historical volatility over a comparable period based on expected life. There is no expected dividend. The exercise price and Black-Scholes weighted average assumptions are as follows:

Grant date	Number granted	Exercise price [CDN\$]	Black-Scholes value [CDN\$]	Risk-free interest rate	Expected life [years]	Expected volatility
March 21, 2019	405,183	1.48	0.69	1.79%	4.9	53.2%
August 8, 2019	20,000	1.18	0.60	1.49%	4.9	54.6%

The following information relates to stock options that were outstanding as at December 31, 2019:

Range of exercise prices [CDN\$]	Number of options [000s]	Weighted average remaining contractual life [years]	Weighted average exercise price [CDN\$]
1.16 – 2.99	167	5.9	1.47
3.00 - 4.99	224	5.3	3.41
5.00 – 13.88	227	5.0	5.64
	618	5.4	3.70

The Company's SOP provides that an option holder may elect to receive a number of shares equivalent to the growth value of vested options, which is the difference between the market price and the exercise price of the options. During the year, no stock options were exercised [2018 – 375 stock options exchanged for 375 common shares]. The total cash consideration received by the Company for stock option exercised in 2019 was nil [2018 – \$1]. The total recovery for stock options for the year ended December 31, 2019 was \$50 [2018 – \$450 expense].

[in thousands of United States dollars, except per share amounts]

#### Restricted share unit and performance share unit plans

On May 13, 2015, the Company adopted RSU and PSU plans. RSUs and PSUs are notional share units exchangeable for common shares of the Company. RSUs are granted to all employees and directors of the Company and PSUs are granted to certain executives. RSUs granted to employees vest annually over three or four years and RSUs granted to directors' vest over a one-year period.

In 2017, 63,282 PSUs were granted to key management personnel that vest October 2020 upon the achievement of certain market-based performance goals, however, if not achieved, the performance date extends to October 2021. If certain targets are achieved by October 2020, up to five times the number of PSUs granted will be awarded, the award is reduced by 50% if the performance period extends to October 2021. Each PSU can be exchanged for an equal number of common shares. The determination of the number of common shares that will ultimately vest was based on weighted average probabilities. The PSU's were valued at \$1.69 using a Monte Carlo simulation model.

A summary of the RSUs and PSUs granted and outstanding as at December 31, 2019 is as follows:

	RSUs number of units [000s]	PSUs number of units [000s]
Balance, January 1, 2018	103	65
Granted during the year	152	_
Vested during the year	(35)	(6)
Forfeited/cancelled during the year	(7)	(5)
Balance, December 31, 2018	213	54
Granted during the year	182	_
Vested during the year	(94)	_
Forfeited/cancelled during the year	(236)	(54)
Balance, December 31, 2019	65	

The total recovery for RSU's and PSU's for the year ended December 31, 2019 was \$23 [2018 - \$333 expense].

#### 15. Revenue

The Company earns licensing revenue from both royalties and product sales to its partners. The breakdown is as follows:

	2019	2018
	\$	\$
Licensing revenue		
Royalty revenue	11,802	13,536
Licensing product sales	2,410	2,333
	14,212	15,869

[in thousands of United States dollars, except per share amounts]

#### 16. Expenses by nature

The consolidated statements of income and comprehensive income include the following expenses by nature:

	2019 \$	2018 \$
Salaries, bonuses and benefits Share-based compensation	2,968 (60)	5,057 802
Termination benefits and severance costs	1,405	42
	4,313	5,901

For the years ended December 31, 2019 and 2018, all employee salaries and benefits are recorded in selling, general and administrative expenses. Termination benefits and severance costs are recorded in restructuring costs.

#### 17. Compensation of key management

Key management includes directors and executives of the Company. The compensation paid or payable to key management for services is shown below:

	2019 \$	2018 \$
Salaries, bonuses and benefits	984	1,346
Share-based compensation	(51)	566
Directors fees	237	239
Termination benefits	908	_
	2,078	2,151

During the year the Company incurred a termination benefit expense relating to two senior executives of the Company. The interim Chief Executive Officer of the Company did not receive compensation in that capacity, however directors' fees were paid.

#### 18. Income tax expense

The components of the income tax expense are as follows:

	2019	2018
	\$	\$
Current income tax expense	1,789	659
Deferred income tax expense	1,282	1,263
	3,071	1,922

Income tax expense as reported differs from the amount that would be computed by applying the combined Canadian federal and provincial statutory income tax rates to income before income taxes. Total current income tax expense of 1,119 (2018 - 639) is recorded in accounts payable and accrued liabilities in the consolidated statements of financial position. The sources and tax effects of the differences are as follows:

[in thousands of United States dollars, except per share amounts]

	2019 \$	2018 \$
	Ψ	Ψ
Income before income taxes from continuing operations	5,710	3,123
Tax provision at the statutory income tax rate of 26.5%	1,513	828
Permanent differences	16	320
Tax exposure	1,253	—
Effect of currency translation adjustment	(201)	529
Change in deferred tax assets not recognized and other	490	245
	3,071	1,922

As at December 31, the Company assesses whether the realization of future tax benefits is sufficiently probable to recognize a deferred tax asset. This assessment requires the exercise of judgement, which includes a review of projected taxable income. In 2019, the Company did not recognize a deferred tax asset of \$48 [2018 – not recognized \$32] arising from capital losses incurred during the current year.

During 2019, the Company received a Canada Revenue Agency [the "CRA"] assessment for its 2014 and 2015 tax filing years. The assessment purports that the valuation of certain intangibles assets upon migration of the Company to Canada in 2004 are overstated. The Company believes its basis for the valuation is reasonable and is in the process of contesting the CRA's assessment. Based on the CRA's proposed changes to the valuation of the intangible assets, the Company has recorded an additional income tax expense including interest of approximately CDN\$1,627 [\$1,253], of which CDN\$589 [\$454] is a current income tax expense. This amount has been recorded to accounts payable and accrued liabilities on the consolidated statements of financial position.

Deferred income tax assets of the Company are comprised of the following:

	2019 \$	2018 \$
Non-capital losses	103	384
Tax credits	516	1,266
Temporary differences	324	575
	943	2,225

The movement in the deferred income tax asset is as follows:

	2019 \$	2018 \$
As at January 1	2,225	3,488
Tax provision	(792)	(1,263)
Deferred tax assets not recognized	(490)	—
As at December 31	943	2,225

The significant components of unrecognized deferred tax assets are summarized as follows:

	<b>2019</b> \$	2018 \$
Capital losses	409	361
Temporary differences	442	277
	851	638

[in thousands of United States dollars, except per share amounts]

The Company has \$516 [2018 – \$1,266] of investment tax credits on Scientific Research & Experimental Development expenditures that are available to be applied against Canadian federal and provincial taxes otherwise payable in future years and expire in varying amounts from 2022 to 2031. The Cardiome subsidiary has non-capital losses of \$211,390 [2018 – \$208,536], investment tax credits of \$13,587 [2018 – \$13,587] and SR&ED expenditures of \$54,859 [2018 – \$54,859]. The non-capital losses expire in varying amounts from 2023 to 2032.

#### 19. Income (loss) per common share

Income (loss) per common share is calculated using the weighted average number of common shares outstanding. The weighted average number of shares outstanding for the year ended December 31, 2019 was 26,849,983 [2018 – 26,773,224].

Diluted income (loss) per common share is calculated using the weighted average number of common shares outstanding taking into consideration the weighted average impact of dilutive securities. The dilutive weighted average for the year ended December 31, 2019 was 26,955,758 [2018 – 26,997,196].

#### 20. Commitments and contingencies

Directors and officers are indemnified by the Company for various items including, but not limited to, costs to settle lawsuits or actions due to their association with the Company, subject to certain restrictions. The Company has purchased directors and officer's liability insurance to mitigate the cost of any potential future lawsuits or actions. The term of the indemnification covers the period during which the indemnified party served as a director or officer of the Company.

Executive employment agreements allow for additional payments if a change of control occurs or for termination with or without cause.

In the normal course of business, the Company has entered into agreements that include indemnities in favour of third parties, such as purchase and sale agreements, confidentiality agreements, engagement letters with advisors and consultants, leasing contracts, license agreements, information technology agreements and various product, service, data hosting and network access agreements. These indemnification arrangements may require the applicable entity to compensate counterparties for losses incurred by the counterparties as a result of breaches in representations, covenants and warranties provided by the Company or as a result of litigation or other third party claims or statutory sanctions that may be suffered by the counterparties as a consequence of the relevant transaction. In some instances, the terms of these indemnities are not explicitly defined.

In the normal course of business, the Company may be the subject of litigation or other potential claims. While management assesses the merits of each lawsuit and defends itself accordingly, the Company may be required to incur significant expenses or devote significant resources to defending itself against litigation.

The Company has development and regulatory milestone payments of up to \$4,050 related to its near-term pipeline products, MOB-015 and Trulance that become payable upon achievement. MOB-015 also has net sales milestones payable upon achievement. As at December 31, 2019, \$750 was accrued for [December 31, 2018 – nil], in relation to achieving a regulatory milestone for Trulance.

#### Licensing agreements with Galephar

In 2002, the Company entered into a Master Licensing and Clinical Supply Agreement [the "Agreement"] with Galephar, a Puerto Rico-based pharmaceutical research and manufacturing company. Under the Agreement, the Company acquired the rights to package, test, obtain regulatory approvals and market CIP-FENOFIBRATE, CIP-ISOTRETINOIN and CIP-TRAMADOL ER [the "CIP Products"] in various countries. In accordance with the Agreement, the Company retains 50% of all revenue from licensing and distribution arrangements entered into with respect to the CIP Products, with the other 50% due to Galephar. Galephar retains the right to manufacture

[in thousands of United States dollars, except per share amounts]

and supply the CIP Products. With respect to licensing and distribution arrangements, the Company manages the product supply arrangements with their respective marketing partners and Galephar; product is shipped directly from Galephar to the respective marketing partners. Where the Company has opted to market and sell the CIP Product directly, the Company purchases the finished goods from Galephar directly.

With respect to CIP-ISOTRETINOIN, the Company has entered into licensing and distribution arrangements for the U.S., Mexico and Brazil, while opting to market and sell the product directly in Canada. The Company also has in place various licensing and distribution arrangements with respect to CIP-FENOFIBRATE in the U.S. and CIP-TRAMADOL ER in Canada, the U.S. and Latin America.

During the year ended December 31, 2019, the Company paid royalties of \$3,556 [2018 – \$3,505]. As at December 31, 2019, the amount in accounts payable and accrued liabilities owed to Galephar was \$1,997 [December 31, 2018 – \$1,963]. Amounts payable to Galephar are remitted quarterly, after the Company collects from its licensing partners. Accordingly, the Company's accounts receivable has a corresponding balance representing amounts owed by its licensing partners.

#### 21. Acquisition of Cardiome Pharma Corp.

On May 15, 2018, the Company acquired the Canadian business portfolio of Cardiome by acquiring all of the issued and outstanding common shares of Cardiome [the "Acquisition"] pursuant to the terms and conditions of a definitive arrangement agreement [the "Arrangement Agreement"] entered into among Cipher, Cardiome and Correvio Pharma Corp. on March 19, 2018. Upon completion of the Acquisition, Cardiome became a wholly owned subsidiary of the Company. The Canadian business portfolio acquired by the Company includes commercial and pipeline hospital products administered in the acute care setting. The Company acquired Cardiome as part of its ongoing efforts to diversify its product base. The total purchase price was CDN\$25,500 [\$19,922], of which CDN\$24,500 [\$19,141] was paid in cash on closing and a holdback of CDN\$1,000 [\$781] was payable in four equal installments quarterly from the date of the agreement. Total transaction costs incurred were \$589, which are recorded in selling, general and administrative expenses in the consolidated statements of income and comprehensive income in the comparative period.

Goodwill of \$15,706 represents Cardiome's unrecognized non-capital losses, investment tax credits and scientific research and experimental development expenditures that Cipher intends to use as a result of carrying on the former Cardiome business. The goodwill recognized is expected to be non-deductible for income tax purposes. The purchase price allocation resulted in a deferred tax liability of \$384 in relation to the intangible assets acquired, however a deferred tax asset has been recognized to the same extent.

Intangible assets represent product and licensing rights, where the Company has exclusivity in Canada. An assigned licensing right includes a milestone payment of \$1,000 upon launching the product and revenue milestones upon achieving a specified level of sales in a calendar year. This assigned licensing agreement was terminated on September 19, 2019, prior to launching the product.

#### 22. Segmented information

The Company's operations are categorized into one industry segment, being specialty pharmaceuticals. Prior to the disposal of the U.S. business, the Company managed its operations geographically in Canada and the United States, representing two segments. Following the disposal of the U.S. operations, the Company has one reportable segment.

The Company generated approximately 37% [2018 – 30%] of its net revenue within Canada, with the remainder attributable to the U.S. There are no significant assets located outside of Canada.

## **CORPORATE DIRECTORY**

#### DIRECTORS

Craig Mull Chair

Arthur Deboeck Director

Christian Godin Director

Dr. John Mull Director

Harold Wolkin Director

#### OFFICERS

Craig Mull Interim Chief Executive Officer

Nadine Jutlah Interim Chief Financial Officer

#### SHAREHOLDER INFORMATION

#### **Stock Exchange Listing**

The Company's common shares are listed on the Toronto Stock Exchange under the symbol "CPH".

#### **Shareholder Inquiries**

Inquiries regarding change of address, transfer requirements or lost certificates should be directed to the Company's transfer agent.

#### **Transfer Agent**

Computershare Investor Services Inc. 100 University Ave., 9th floor North Tower Toronto, Ontario M5J 2Y1 T: 1.800.564.6253 www.computershare.com/service

Legal Counsel Stikeman Elliott LLP

Auditors Ernst & Young LLP

#### **INVESTOR RELATIONS**

#### **IN CANADA:**

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