

# MANAGEMENT'S DISCUSSION AND ANALYSIS

December 31, 2016

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, 2016. This document should be read in conjunction with the audited 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 Annual Financial Statements and Annual Information Form for the year ended December 31, 2016, is available on SEDAR at [www.sedar.com](http://www.sedar.com).

The discussion and analysis within this MD&A are as March 1, 2017. 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 certain securities laws, including the "safe harbour" provisions of the Securities Act (Ontario) and other provincial securities law in Canada and U.S. securities laws. These forward-looking statements include, among others, statements with respect to our objectives, goals and strategies to achieve those objectives and goals, as well as statements with respect to our beliefs, plans, objectives, expectations, anticipations, estimates and intentions. The words "may", "will", "could", "should", "would", "suspect", "outlook", "believe", "plan", "anticipate", "estimate", "expect", "intend", "forecast", "objective", "hope" and "continue" (or the negative thereof), and words and expressions of similar import, are intended to identify forward-looking statements.*

*By their very nature, forward-looking statements involve inherent risks and uncertainties, both general and specific, which give rise to the possibility that predictions, forecasts, projections and other forward-looking statements will not be achieved. Certain material factors or assumptions are applied in making forward-looking statements and actual results may differ materially from those expressed or implied in such statements. We caution readers not to place undue reliance on these statements as a number of important factors, many of which are beyond our control, could cause our actual results to differ materially from the beliefs, plans, objectives, expectations, anticipations, estimates and intentions expressed in such forward-looking statements. These factors include, but are not limited to, there is no certainty that the consideration of strategic alternatives will result in any transaction or alternative being undertaken or pursued; our ability to enter into in-licensing, development, manufacturing and marketing and distribution agreements with other pharmaceutical companies and keep such agreements in effect; our dependency on a limited number of products; 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; reliance on third parties to manufacture our products; we may be subject to 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; 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; 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; 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 it operates; 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; operations 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 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; our delisting from the NASDAQ Global Market (the "NASDAQ") and deregistration of our Common Shares under the U.S. Securities Exchange Act of 1934, as amended (the "U.S. Exchange Act"); 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; certain adverse tax rules applicable to U.S. holders of our Common Shares if we are a passive foreign investment company for U.S. federal income tax purposes; 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; volatility of our share price; a significant shareholder; we do not currently intend to pay dividends; our operating results may fluctuate significantly; and our debt obligations will have priority over the Common Shares in the event of a liquidation, dissolution or winding up.*

*We caution that the foregoing list of important factors that may affect future results is not exhaustive. When reviewing our forward-looking statements, investors and others should carefully consider the foregoing factors and other uncertainties and potential events. Additional information about factors that may cause actual results to differ materially from expectations, and about material factors or assumptions applied in making forward-looking statements, may be found in the "Risk Factors" section hereof and elsewhere in the following Management's Discussion and Analysis of Operating Results and Financial Position for the year ended December 31, 2016, and elsewhere in our filings with Canadian securities regulators. Except as required by Canadian, 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.*

## 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 high unmet medical needs, manages the required clinical development and regulatory approval process, and markets those products either directly in Canada and the U.S. or indirectly through partners in Canada, the U.S., and South America.

## Growth Strategy

With a mandate to leverage Cipher's existing core capabilities, infrastructure and existing product portfolio (led by a novel version of the acne medication isotretinoin, which is marketed as Absorica® in the U.S. and Epuris® in Canada), in fiscal 2014 the Company implemented a three-pronged growth strategy, enabling its transformation from a royalty revenue company into a specialty pharmaceutical company and significantly improving its long-term growth opportunities. The three components of the growth strategy are:

- Building a larger dermatology franchise in Canada through a combination of in-licensing and acquisitions;
- Acquiring and developing potentially transformative technology that can be commercialized efficiently in North America; and
- Establishing a commercial operation in the U.S. through M&A and build a leading dermatology franchise in that country.

The Company is building its business in Canada through multiple product launches in 2016 and over the next few years. In 2016, the Company launched Actikerall and Beteflam. The Company is currently working on its plan to launch Dexiderm which will be the Company's first over-the-counter ("OTC") brand. Ozenoxacin, a topical treatment for adult and paediatric patients with impetigo is pending regulatory approval in Canada, and if approved, the Company expects to launch the product in late 2017. Sitavig, was submitted to Health Canada for review in February 2016. In December 2016, the Company received a Notice of Non-Compliance from Health Canada that required additional information for the application. The Company is working on its response and plans to resubmit to Health Canada in the first quarter of 2017. If the response is accepted and Sitavig receives regulatory approval, the expected launch may be in early 2018.

To support the growth strategy, the Company acquired a number of products, the majority of which are either commercial or late-stage pre-commercial, significantly expanding its product portfolio. The following is a summary of the transactions completed in 2015 and 2016:

- acquired seven pre-clinical compounds for the treatment of melanoma and other cancers from Melanovus Oncology, Inc. ("Melanovus"), including the related intellectual property from The Penn State Research Foundation;
- licensed the Canadian commercial rights for the novel antibacterial compound Ozenoxacin for the treatment of impetigo that is currently pending regulatory approval in Canada;
- licensed the Canadian distribution rights to CF101, a novel chemical entity being developed by Can-Fite Biopharma ("Can-Fite") for moderate to severe plaque psoriasis and rheumatoid arthritis;
- acquired the worldwide rights to three products from Astion Pharma, a Denmark-based specialty pharmaceutical Company. The three products, Dermadexin™, Pruridexin™, and ASF-1096, strengthened Cipher's dermatology product pipeline;
- acquired the Canadian distribution rights to Vaniqa® and Actikerall® from Almirall S.A. Both products had already been approved by Health Canada. Cipher began marketing Vaniqa in Canada in May 2015 and Actikerall was launched in February 2016;
- in April 2015, the Company acquired Innocutis Holdings, LLC ("Innocutis") to establish U.S. commercial sales and marketing capabilities. Innocutis has nine branded dermatology products, led by Sitavig, a treatment for cold sores; and
- in May 2016, Cipher licensed the worldwide rights to develop, market and sell an investigational tattoo removal cream from Dalhousie University. The product candidate is currently at the pre-clinical stage of development.

The Company has an ongoing strategic review process in place to assess options for its U.S. business. The goal of this process is to reduce the cash burn in the U.S. operations.

Looking ahead, the Company plans to continue our focus on investing in the short-term to maximise the potential of our existing products, while at the same time, identifying opportunities to acquire additional late-stage products to further strengthen our existing product portfolio.

## Significant Transactions

### ACQUISITION OF INNOCUTIS

On April 13, 2015, Cipher announced the acquisition of Innocutis. Consideration for the acquisition was US\$45.5 million in cash, paid on closing. The agreement also includes additional Innocutis management incentive payments of up to US\$3.0 million in cash over a three-year period based on the achievement of certain financial performance targets. The first component of the incentive program, related to achievement of an EBITDA target in 2015, was not achieved and, as a result, the maximum that could be paid out in the future, as of the date hereof, is US\$2.0 million.

The acquisition of Innocutis established commercial sales and marketing capabilities for the Company in the U.S. Innocutis had nine branded dermatology products, with the core assets being Sitavig, Nuvail and Bionect. For a discussion of these products, see Commercial Products – United States.

### ATHYRIUM DEBT FACILITY

In connection with the acquisition of Innocutis, the Company closed a private offering of \$100 million in aggregate principal amount of Senior Secured Notes due in 2020 (the "Notes"), provided by investment funds managed by Athyrium Capital Management (together "Athyrium"). The Company received an initial draw down of \$40 million which was used to fund the majority of the purchase price for Innocutis. The balance of the Notes (\$60 million) were not drawn as of June 30, 2016 and expired on that date. The Notes bear interest at a fixed rate of 10.25% per annum, payable quarterly in arrears on the last day of each quarter, and will mature in five years, unless repaid earlier. Upon repayment of the principal in part or in full, a 5% borrowing fee is assessed and payable.

The Notes are secured by all present and future assets of the Company and have certain restrictive covenants, including quarterly consolidated net revenue, minimum cash balance and consolidated leverage ratio. The minimum cash balance that must be maintained is \$6 million. The Company is in compliance with these covenants at December 31, 2016. Under the terms of an amendment to the loan agreement in December 2016, the minimum sales covenant for the fourth quarter was decreased to \$8 million from \$10 million and the Company agreed to prepay its debt obligations using any proceeds received from dispositions of assets. The Company has the option to repay the Notes in part or in full prior to the maturity date subject to a prepayment premium that declines with time. If the Company prepays the Notes from the proceeds received from the disposition of assets, a prepayment premium would be applied.

In addition, the Company, issued 600,000 common share purchase warrants. The warrants are exercisable at \$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 following issuance.

## Significant Partnerships

### GALEPHAR

In 2002, the Company entered into a Master Licensing and Clinical Supply Agreement ("the Galephar 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 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.

In 2016, Galephar entered into an agreement with another party ("Galephar Assignee") to assign certain rights relating to CIP-ISOTRETINOIN in the U.S. market. The Company is a party to this contract, agreeing to remit revenue on the same terms as the Galephar Agreement from licensing and distribution within the U.S. for CIP-ISOTRETINOIN directly to the Galephar Assignee.

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.

## Commercial Products

### Canada

#### 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® 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 Q4 2012 under the trade name Epuris and Cipher launched the product in Canada in June 2013 with its own sales force. According to IMS, the Canadian market for isotretinoin was CDN\$18.3 million in 2016 compared to CDN\$17.5 million in 2015. In December 2016, Epuris had a prescription market share of over 25% in Canada. There is no patent protection for Epuris in Canada. The Company purchases Epuris from Galephar and pays a single-digit royalty to Galephar on net sales of Epuris in Canada.

#### BETEFLAM® PATCH

In 2012, Cipher obtained the exclusive license and distribution rights in Canada to market the Beteflam Patch (previously named the Betsil Patch), a novel, patent-protected, self-adhesive medicated plaster for the treatment of inflammatory skin conditions such as plaque psoriasis, from Institut Biochimique SA ("IBSA"). The Beteflam Patch is expected to provide distinct advantages over existing treatment options, particularly for patients who suffer from plaque psoriasis in hard to treat areas such as knees and elbows, based on feedback from Canadian dermatologists. The efficacy and safety of the product has been established in three successful European phase III trials and one successful phase IV trial conducted by IBSA. The Beteflam patch is currently marketed in several European countries. Beteflam was launched in Canada in April 2016.

The Beteflam Patch is based on IBSA's self-adhesive medicated plaster technology. This technology is based on a unique self-adhesive medicated patch providing twenty four hour delivery of medication to the affected skin area. The self-adhesive plaster is 75cm<sup>2</sup> (7.5 x 10 cm) and is composed of multiple layers, including a transparent plastic film layer, an intermediate tissue layer, an adhesive layer containing the drug and a protective layer (to be removed prior to application). The plaster acts as an occlusive dressing and provides a continuous sustained release of the drug. The plaster can be trimmed to exactly cover the affected area, delivering a uniform concentration of the drug specifically to the affected area, thereby reducing the risk of exposure of the drug outside the treated area. The plaster also acts as a barrier, preventing further damage of the area from trauma or scratching, which may aid in the healing process.

Under the terms of the agreement, IBSA is eligible for certain milestones based on commercial and regulatory targets and they supply the finished product to Cipher. The term of the agreement is for 10 years with an automatic renewal for an additional 5-year period.

#### 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 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 10 years with automatic annual renewals.

#### 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 Vaniqa from Almirall in May 2015. Under the terms of the agreement 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 10 years with automatic annual renewals. The Company launched Vaniqa® in the Canadian market on June 2, 2015. Vaniqa prescriptions have been stable year over year (source: IMS).

### United States

Cipher acquired Innocutis on April 13, 2015. All financial information for the year ended December 31, 2015 includes the results of the U.S. operations starting April 13, 2015.

#### SITAVIG®

Sitavig, which was launched in July 2014, is a unique, timed-release, mucoadhesive buccal tablet containing acyclovir indicated for the treatment of recurrent herpes labialis (cold sores) in immunocompetent adults. Sitavig is based on proprietary Lauriad® technology from Onxeo S.A. ("Onxeo"). Administration of a single Sitavig tablet enables the active ingredient to penetrate the surrounding tissues in significantly higher concentrations than is possible through systemic delivery. The prescription herpes labialis market is largely genericized. The Company licensed Sitavig from Onxeo. Under the terms of the licensing agreement, Onxeo will supply the finished product to the Company. The Company pays a royalty on net sales of Sitavig and Onxeo is eligible for certain milestones based on cumulative product sales. The Company has the rights to Sitavig for North America.

Cipher is pursuing several strategies to capitalize on this market opportunity and increase market penetration of Sitavig. Currently, a majority of Sitavig total prescriptions come from dermatology and the product has only been marketed to dermatologists, however, there is also a large non-dermatology component to the herpes labialis market. Total prescriptions grew 23% in 2016 compared to 2015 based on Symphony data and data from the Assembia Speciality Pharmacy Network ("ASPN"). There are three patents listed in the FDA's Approved Drug Products List (Orange Book) in the U.S. with expiry dates ranging from 2027 to 2030.

#### NUVAIL®

Nuvail is a medical device that is a polymer solution (poly-ureaurethane) indicated for managing the signs and symptoms of nail dystrophy. The product is applied once-daily and dries with a clear matte finish. The prescription nail dystrophy market is relatively small in the U.S. with sales of approximately \$5.8 million in 2016. Onychomycosis ("OM") and nail dystrophy are common comorbidities. It appears that the new OM treatments are competing with products indicated for nail dystrophy by only addressing the issue of fungus and not nail dystrophy. Cipher focuses on nail dystrophy, which is often a pre-cursor to fungus infections. Nail dystrophy is seen in mycotic, psoriatic, and brittle nails. It is estimated that 20% of adults in the U.S. have Brittle Nail Syndrome.

Nuvail was licensed from Chesson Laboratory Associates, Inc. ("Chesson"). Under the terms of the licensing agreement, Chesson will supply the finished product to the Company. The Company pays a royalty on net sales of Nuvail. The Company has the rights to Nuvail for the U.S. and South Korea. The agreement expires in November 2021 and provides for a 5-year automatic renewal.

#### BIONECT®

Bionect is a topical hyaluronic acid ("HA") indicated for the treatment of signs and symptoms of skin irritation and was approved by the FDA as a medical device. The topical HA market was approximately \$5.7 million in 2016. Bionect maintained the majority of the topical HA market throughout fiscal 2016. Bionect is licensed from Fidia Farmaceutici S.p.A ("Fidia") for the U.S. market. Under the terms of the licensing agreement, Fidia will supply the finished product to the Company. The Company pays a royalty on net sales of Bionect. The current term expires on April 30, 2017 and the Company is currently negotiating an extension with Fidia.

## Royalty Products

### CIP-ISOTRETINOIN

#### *United States - Absorica*

In 2012, Cipher's U.S. distribution partner Ranbaxy Laboratories Inc. ("Ranbaxy") a Sun Pharma Company, launched CIP-ISOTRETINOIN under the trade name Absorica. According to IMS, the U.S. isotretinoin market was over \$643 million in 2016 a decrease of 5% compared to \$680 million in 2015 and total isotretinoin prescriptions were 3% higher year-over-year.

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) were issued in July 2015. The five patents are formulation-related patents describing the product ingredients. There is one additional new Absorica patent application pending with the U.S. Patent and Trademark Office.

In September 2013, Ranbaxy 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 when the sponsor company of the ANDA believes that it is not infringing the patent and/or the patent is not valid. A patent infringement lawsuit against Actavis was filed by Ranbaxy, 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 Ranbaxy and Galephar, entered into a settlement agreement with Actavis that dismissed the patent litigation suit. As part of the settlement agreement, Cipher, Ranbaxy 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 patents in September 2021) or earlier under certain circumstances. The settlement agreement was subject to review by the U.S. Federal Trade Commission and the U.S. Department of Justice.

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

#### *Rest of World*

In 2014, the Company entered into a distribution and supply agreement with Laboratorios Andrómaco S.A. ("Andrómaco") under which Cipher granted Andrómaco the exclusive right to market, sell and distribute Cipher's isotretinoin capsules in Chile. With over 70 years of experience, Andrómaco is a leader in the production and marketing of pharmaceutical products in Chile and certain other Latin American countries. The registration process is completed for 10 mg, 20 mg and 30 mg strengths. Andrómaco is owned by Grünenthal GmbH, Germany. Andrómaco, has not launched the product and in January 2017, the Company sent a notice of material breach to Andrómaco that was not remediated in the required period. The Company is looking for a new licensing partner for this market.

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 them 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. Brazil is the largest isotretinoin market in Latin America, with annual sales exceeding \$50 million, and the market has been growing steadily. 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. The product is not currently approved in Brazil.

### 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". Fibrates have proven to be superior in lowering triglycerides and raising HDL levels. Cipher's U.S. marketing and distribution partner for Lipofen is Kowa Pharmaceuticals America, Inc. ("Kowa").

According to IMS, the hyperlipidemia market in the U.S. exceeded US\$11.1 billion in 2016 compared to US\$12.6 billion in 2015 and is made up of three primary groups of drugs: statins, fibrates and the prescription DHA/EPA (omega 3) market. The market for existing fenofibrate formulations in the U.S. exceeded US\$630 million in 2016 compared to approximately US\$840 million during 2015.

Lipofen was launched in the U.S. market in late 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 5% in 2016 compared to 2015.

### 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. The novel formulation delivers rapid absorption, similar absorption under different dietary conditions, and 24-hour coverage, supporting ease-of-use for physicians and a high level of compliance among chronic pain sufferers. 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 IMS, the U.S. market in 2016 for extended release formulations of tramadol exceeded US\$50 million, which represents 43.4% of the total tramadol immediate release and extended release prescription market compared to US\$60 million in 2015, which represented 42.5% of the total tramadol immediate release and extended release prescription market. An authorized generic version of the product was launched by Cipher in the U.S. market in July 2015 through Vertical.

In 2016, the FDA required a new black box warning for tramadol products on the risks of addiction, abuse, misuse, life-threatening respiratory depression and interactions with central nervous system depressants including alcohol. In addition, the FDA said that a new Risk Evaluation and Mitigation Strategy ("REMS") program would be required.

#### *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 under the trade name Durela® in Canada. 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. The Company receives a royalty on net sales of Durela in Canada. The Company is responsible for product supply and manufacturing, which is fulfilled by Galephar.

According to IMS, the Canadian market for extended-release tramadol was approximately CDN\$28 million in 2016 compared to CDN\$27 million in 2015.

Health Canada has required market authorization holders of tramadol products to conduct an abuse potential observational study. Cipher is part of the consortium of Canadian tramadol manufacturers overseeing and funding this study. The current proposal for cost sharing among the approximately 20 members is based on market share. The study is expected to be initiated in 2017 and the total cost estimate is approximately CDN\$2 million which will be shared by the consortium.

#### *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.

## Product Pipeline

The Company continues to pursue the acquisition or in-licensing of new early to late-stage to commercial-stage product candidates.

### OZENOXACIN

In 2015, Cipher in-licensed the Canadian rights to Ozenoxacin, 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 revenues from product sales in Canada. Ferrer will manufacture Ozenoxacin and deliver finished product to Cipher.

In 2013, Ferrer successfully completed a first phase III clinical trial of Ozenoxacin in adult and paediatric patients aged two years and older with impetigo. The study demonstrated the superiority of Ozenoxacin one per cent cream versus a placebo, applied topically twice daily for five days, on both the clinical and bacteriological endpoints by end of therapy visit. In addition, Ozenoxacin demonstrated a superior bacteriological cure compared to placebo by the second visit (day three-four). The trial also demonstrated that Ozenoxacin is safe and very well tolerated in the adult and paediatric populations. Ferrer commenced a second phase III trial of Ozenoxacin which was completed in July 2015. The multicenter, randomized, double-blinded, clinical study comparing Ozenoxacin one per cent cream versus placebo was conducted in approximately 412 patients aged two months and older with a clinical diagnosis of non-bullous or bullous impetigo.

In Q3 2016, Cipher's New Drug Submission for Ozenoxacin was accepted for review by Health Canada. If approved, the Company is targeting a product launch in late 2017. Cipher is not responsible for any future development costs, should any be required.

### DERMADEXIN™, PRURIDEXIN™ AND ASF-1096

In 2015, Cipher acquired the worldwide rights to three products from Astion Pharma ("Astion"), a Denmark-based specialty pharmaceutical company. The three products are focused on inflammatory dermatological diseases: Dermadexin, Pruridexin, and ASF-1096. The terms of the agreement with Astion included an upfront payment of \$6.0 million, which was funded from Cipher's cash resources. The agreement includes approximately \$34.1 million in additional payments contingent upon clinical milestones, regulatory approvals, commercialization and sales milestones in the both the U.S. and other regions. Over time, Cipher expects to out-license the products to partners in certain other regions.

#### *Dermadexin and Pruridexin*

Dermadexin and Pruridexin target common, chronic conditions that are insufficiently addressed today.

- Dermadexin is a patent-protected topical barrier-repair cream containing the pharmacologically active ingredient Pyridine-3-Carboxamide Glycerol Monocaprylate ("P3GCM"), which has dual mechanisms of action. First, P3GCM inhibits fatty acid amide hydrolase ("FAAH"), which is induced in dermal inflammation. FAAH breaks down the anti-pruritic and anti-inflammatory dermal endocannabinoids; thus P3GCM gives rise to enhanced dermal endocannabinoid levels which exert anti-inflammatory and anti-itch effects via cannabinoid receptors on peripheral sensory nerve endings and various inflammatory cells. In addition, P3GCM inhibits Nuclear Factor Kappa B (NF-κB) mediated inflammatory gene expression, giving rise to lower dermal levels of inflammation. The product was approved in the European Union (EU) in 2014 as a Class III medical device for the treatment of seborrheic dermatitis, an inflammatory skin disorder affecting the scalp, face, and torso. Dermadexin SD Cream has been tested in two placebo-controlled, multicenter clinical trials (436 patients) where it displayed a marked and statistically significant effect on the symptoms of facial seborrhoeic dermatitis, with a fast onset of action and an increasing effect over time.
- Pruridexin is a patent-protected topical cream for the treatment of chronic pruritis (itching), which is a significant unmet need. The active agent of Pruridexin is a formulation of P3GCM, which compared to Dermadexin is less viscous and is more appropriate for use on larger areas of the body such as extremities and the back. Pruridexin Cream has been tested in two placebo-controlled, multicenter clinical trials (352 patients) and displayed a marked and statistically significant effect on the pruritus, with a fast onset of action and an increasing effect over time. Pruridexin exerts its therapeutic effects via similar mechanisms of action as Dermadexin.

In Q3 2015, Cipher received an Acceptance Review Notification for its 510(k) submissions for both Dermadexin™ and Pruridexin™ to the FDA. The notification confirmed that the submission contained all of the necessary elements and information needed to proceed with the substantive review. The FDA put the review on hold due to the uncertainty of the functions of the ingredients. The FDA requested that Cipher submit a "Request for Determination" ("RFD") to the Office of Combination Products to determine whether the products are considered drugs or devices. In April 2016, Cipher submitted an informal RFD for Dermadexin and received a non-binding regulatory determination that the product, which contained nicotinamide (a new ingredient not listed in the device database) should be

reviewed under the jurisdiction of the Center for Drug Evaluation and Research (CDER). The Company is currently working with consultants to determine the regulatory pathway for Dermadexin and Pruridexin in the U.S.

In April 2016, Cipher received Health Canada approvals (via Natural and Non-Prescription Health Products Directorate “NNHPD”) for DexiDerm SD Cream and DexiDerm AD Cream (also known as Dermadexin and Pruridexin) and is developing launch plans for the products in Canada. DexiDerm CD was approved by the NNHPD in August 2016 and DexiDerm Scalp was approved on November 3, 2016.

In Europe, Helioclin® Dermatitis SD Cream (also known as Dermadexin) was approved in Europe in 2014 and Helioclin® Pruritus SD Cream (also known as Pruridexin) was approved in April 2016, as a Class III medical device. Cipher is seeking partners in Europe for Pruridexin and Dermadexin.

#### ASF-1096

Cipher has an orphan drug indication in the EU for ASF-1096, a product candidate that has promise as a treatment for a highly disfiguring rare disease, discoid lupus erythematosus, 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. Under the terms of the agreement, Cipher is eligible to receive clinical, regulatory and commercial milestone payments, along with a royalty on net sales.

#### CF101

In 2015, Cipher in-licensed 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.

Can-Fite completed a phase II/III double-blind, placebo-controlled study, which was designed to test the efficacy of CF101 in patients with moderate to severe plaque psoriasis. The study enrolled 326 patients through 17 clinical centers in the U.S., Europe, and Israel. Top-line results from the trial were published by Can-Fite at the end of March 2015. Results from this phase II/III trial and final results from the prior phase II trial in psoriasis were both positive showing that CF101 effectively improved disease symptoms. In addition, at the end of 2013, Can-Fite completed a phase IIb study for CF101 for active rheumatoid arthritis (“RA”), and has now completed the study design for a phase III program. Can-Fite plans to start enrolling patients into the phase III RA program in the first half of 2017 and start the psoriasis phase III program in the second half of 2017. The timeline to regulatory submissions to Health Canada will be determined by the successful completion of these registration clinical trial programs. Cipher is not responsible for any of these development costs.

Approximately 500,000 people in Canada receive treatment for psoriasis. 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.

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 million and royalties from product sales in Canada. The agreement provides that Can-Fite will deliver finished product to Cipher.

#### NANOLIPOLEE-007

In 2014, Cipher acquired the assets of Melanovus, a Pennsylvania-based life sciences company. The assets include seven pre-clinical compounds for the treatment of melanoma and other cancers, with world-wide rights. The lead product candidate, Nanolipolee-007, is a liposomal formulation of a plant-derived compound that is a first-in-class cholesterol-transport inhibitor which has demonstrated anti-proliferative activity against certain melanoma cell lines (including B-RAF resistant strains) in-vitro as well as in early in-vivo studies. Cipher is engaged in pre-clinical studies for its oral and IV formulations which may lead to Investigational New Drug status with the FDA, Health Canada and other health authorities. The plan for the development of the remaining six topical and oral skin cancer compounds in the portfolio has not yet been established. The transaction included an upfront payment to Melanovus of US\$500,000, as well as the payment of certain IP expenses related to patent prosecution and maintenance.

#### TATTOO REMOVAL CREAM

In May 2016, Cipher 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 upon execution of the agreement and the agreement contains milestones of up to CDN\$3.6 million based on future regulatory and commercial sales milestones, as well as royalties on commercial sales.

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

### FINANCIAL INFORMATION

(IN MILLIONS OF U.S. DOLLARS EXCEPT FOR PER SHARE AND SHARE AMOUNTS)

	2016	2015
	\$	\$
Total revenue	40.7	34.4
Net income (loss) for the year	(39.1)	1.8
Basic earnings (loss) per share	(1.49)	0.07
Diluted earnings (loss) per share	(1.49)	0.07
Total assets	77.4	109.6
Total non-current liabilities	38.4	36.9

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

- In 2016, revenue reflects a full year of revenue from the U.S. segment as well as modest organic growth;
- In 2016, the Company recognized impairments charges to goodwill and intangible assets of \$29.2 million;
- In 2015, the acquisition of Innocutis on April 13, 2015 resulted in an increase in product revenue as well as a significant increase in operating expenses;
- In 2015, the Company recognized a deferred tax asset that contributed \$6.2 million to net income.

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

## Review of Operating Results

*Cipher acquired Innocutis on April 13, 2015. All financial information for the year ended December 31, 2015 includes the results of the U.S. operations starting April 13, 2015.*

### REVENUE

(IN THOUSANDS OF U.S. DOLLARS)

	2016	2015
	\$	\$
Licensing revenue	25,555	25,963
Product revenue	15,185	8,446
Total revenue	40,740	34,409

Total revenue increased to \$40.7 million for the year ended December 31, 2016 compared to \$34.4 million for the year ended December 31, 2015. The increase in product revenue was primarily the result of the acquisition of Innocutis in April 2015. Product revenue from

the U.S. operations was \$11.1 million in 2016 compared to \$5.6 million for the period following the acquisition in 2015. The balance of the increase related to growth in Canadian product sales of \$1.2 million to \$4.1 million in 2016, partially offset by a \$0.4 million decrease in licencing revenue.

### Licensing Revenue

Licensing revenue decreased by 2% or \$0.4 million to \$25.6 million for the year ended December 31, 2016 compared to \$26.0 million for the year ended December 31, 2015.

Licensing revenue from Lipofen and the authorized generic version of Lipofen were \$4.4 million for the year ended December 31, 2016, a slight decrease of \$0.2 million compared to sales of \$4.6 million for the year ended December 31, 2015.

Licensing revenue from the extended-release tramadol product (ConZip in the U.S. and Durela in Canada) were \$1.9 million for the year ended December 31, 2016, a decrease of \$0.2 million compared to sales of \$2.1 million for the year ended December 31, 2015.

Licensing revenue from Absorica and Isotretinoin in Brazil and Chile were unchanged at \$19.2 million for the year ended December 31, 2016 and the year ended December 31, 2015.

### Product Revenue

Product revenue increased by 80% or \$6.7 million to \$15.2 million for the year ended December 31, 2016 compared to \$8.4 million for the year ended December 31, 2015.

The growth for the year ended December 31, 2016 primarily related to a full year of results from the U.S. operations which was acquired in April 2015. Product revenue in the U.S. segment was \$11.1 million for the year ended December 31, 2016 compared to \$5.6 million in 2015 for the period following the acquisition. In the U.S., revenue from Sitavig in 2016 was \$4.2 million compared to \$1.7 million in 2015; Nuvail was \$3.3 million in 2016 compared to \$1.7 million in 2015 and Bionect was \$3.0 million in 2016 compared to \$1.0 million in 2015.

Product revenue in the Canadian segment increased to \$4.1 million for the year ended December 31, 2016 compared to \$2.9 million for the year ended December 31, 2015. The growth in the Canadian product revenue primarily related to an increase in Epuris sales of \$1.1 million to \$3.7 million in 2016 compared to \$2.6 million in 2015 and the launch of Beteflam and Actikerall in 2016.

## OPERATING EXPENSES

(IN THOUSANDS OF U.S. DOLLARS)

	2016	2015
	\$	\$
Cost of products sold	4,587	2,525
Research and development	561	502
Selling and marketing	14,459	9,254
General and administrative	23,739	20,389
Impairment of intangible assets	23,111	-
Impairment of goodwill	6,112	-
<b>Total operating expenses</b>	<b>72,569</b>	<b>32,670</b>

Total operating expenses increased significantly to \$72.6 million for the year ended December 31, 2016 compared to \$32.7 million for the year ended December 31, 2015. The significant increase related to a \$29.2 million impairment charge against intangible assets and goodwill related to the acquisition of Innocutis in 2015. The increase is also related to higher selling and marketing expenses and general and administrative expenses related to the inclusion of a full year of expenses from the U.S. operation compared to 2015 that only included U.S. expenses for the period starting April 13, 2015 to December 31, 2015.

### Cost of Products Sold

Cost of products sold increased by \$2.1 million or 82% to \$4.6 million for the year ended December 31, 2016 compared to \$2.5 million for the year ended December 31, 2015. The increase is attributed to an increase in product sales and an increase in inventory provisions. The Company took an increase in the provision of \$0.7 million in 2016 compared to \$0.1 million in 2015.

The gross margin on product sales was \$10.6 million or 70% for the year ended December 31, 2016 compared to \$5.9 million or 70% for the year ended December 31, 2015.

## **Research and Development**

Research and development (“R&D”) expenses increased slightly to \$0.6 million for the year ended December 31, 2016 compared to \$0.5 million for the year ended December 31, 2015. R&D expenses represents the cost of the Company’s drug development activities and the cost of regulatory submissions in Canada.

## **Selling and Marketing**

Selling and marketing (“S&M”) expenses were \$14.5 million for the year ended December 31, 2016, an increase of \$5.2 million or 56% compared to \$9.2 million for the year ended December 31, 2015. S&M expenses are focused on the Company’s commercial products in the U.S. and Canada. The increase primarily related to higher S&M expenses in the U.S. as the comparative period only included the operations of Innocutis from April 2015 and an increase in Canadian S&M expenses primarily related to the launch of Actikerall and Beteflam.

## **General and Administrative**

General and administrative (“G&A”) expense for the year ended December 31, 2016 was \$23.7 million, an increase of \$3.3 million or 16% compared to \$20.4 million for the year ended December 31, 2015. The increase in G&A expenses reflects the results of the U.S. operations for the full year ended December 31, 2016 whereas the comparative period includes the U.S. operations of Innocutis from April 2015. In addition, the Company incurred severance costs related to changes in the management team and costs related to its ongoing strategic review process.

Also included in G&A is amortization of intangible assets of \$5.5 million for the year end December 31, 2016 compared to \$4.4 million for the year ended December 31, 2015.

## **Impairment of Intangible Assets**

Impairment of intangible assets for the year ended December 31, 2016 was \$23.1 million. No impairment was taken for the comparative period.

Intangible assets have a finite life and are amortized using the straight-line method over their estimated period of useful life. The useful lives are assessed periodically and accounted for prospectively if facts and circumstances warrant an adjustment to the useful life. Intangible assets are reviewed for impairment when events or other changes in circumstances indicate that the carrying amount of the assets may not be recoverable.

As at December 31, 2016, indicators of impairment existed in the Company’s finite lived intangible assets in its U.S. segment. Certain assets were assessed for impairment as they were not meeting expectations. The Company estimated recoverable amount based on fair value less costs to dispose based primarily on certain non-binding offers recently received. There is no guarantee that the Company will consummate a sales transaction and actual sale proceeds could vary from the Company’s estimate. As a result of this analysis, the Company identified an impairment to certain intangible assets, where the carrying values exceeded their recoverable amount. Accordingly, the Company has recognized a total intangible asset impairment charge of \$23.1 million.

## **Impairment of Goodwill**

Goodwill related to the acquisition of Innocutis was allocated to the U.S. operations, which is comprised of a group of cash generating units (“CGUs”) for the purposes of impairment testing.. The Company performed its annual impairment test as at December 31, 2016 to assess the recoverable amount of the group of CGU that comprise the U.S. operations. Upon concluding that certain intangibles assets attributable to the U.S. were impaired, the difference between the fair value less costs to dispose and the recoverable amount of the individual intangible assets was calculated to be the impairment to goodwill. The Company has recognized a goodwill impairment charge of \$6.1 million. No impairment was taken for the comparative period.

**OTHER EXPENSES**  
(IN THOUSANDS OF U.S. DOLLARS)

	2016	2015
	\$	\$
Interest on senior secured notes	7,777	3,824
Change in fair value of derivative financial instrument	(1,175)	(2,374)
Interest income	(54)	(371)
Foreign exchange (gain) loss	(720)	1,807
<b>Total other expenses</b>	<b>5,828</b>	<b>2,886</b>

Total other expenses were \$5.8 million for the year ended December 31, 2016 compared to \$2.9 million for the year ended December 31, 2015. The majority of the increase related to the interest on senior secured notes and a decrease in the change of the fair value of the derivative financial instrument, partially offset by a foreign exchange gain in 2016 compared to a foreign exchange loss in 2015.

**Interest on Senior Secured Notes**

For the year ended December 31, 2016, interest on senior secured notes increased to \$7.8 million from \$3.8 million for the year ended December 31, 2015. The increase related to a full year of interest expense in 2016 of \$4.2 million as the Notes were issued in April 2015. In addition, there is imputed interest of \$1.8 million and a write off of debt issuances costs of \$1.8 million related to the \$60.0 million of available debt that expired in June 2016. The interest rate on the debt is 10.25%.

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

The gain from the change in the fair value of the warrants was \$1.2 million for the year ended December 31, 2016 compared to \$2.4 million for the year ended December 31, 2015. The gain related to the revaluation to fair value of the warrants that were issued to Athyrium. The gain arises from a combination of a decrease in share price and passage of time.

**Foreign Exchange**

The Company experienced a foreign exchange gain of \$0.7 million for the year ended December 31, 2016 compared to a foreign exchange loss of \$1.8 million for the year ended December 31, 2015. The Company is exposed to currency risk through its net assets and certain recurring transactions denominated in Canadian dollars. The impact of the foreign exchange is primarily due to a decrease in the U.S. dollar against the Canadian dollar from December 31, 2015 to December 31, 2016.

**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. The income tax expense of \$1.5 million for the year ended December 31, 2016 related to a drawdown of the deferred tax asset in connection with the Canadian operations compared to an income tax recovery of \$2.9 million for the year ended December 31, 2015 related to the increase in the deferred tax asset to \$8.4 million.

At each balance sheet 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. At December 31, 2016, the Company has recognized a deferred tax asset on the balance sheet of \$6.9 million and drew down \$1.5 million of the deferred tax asset and recognized this as income tax expense. The Company believes that it is probable that future taxable income will be available against which tax losses can be utilized.

The Company also has approximately \$20.7 million (2015 - \$4.5 million) of unrecognized deferred income tax assets, which have not been recognized in the financial statements related to the U.S. operations. These assets consist of non-capital loss carry forwards, timing difference and capital losses which are available to reduce taxable income in future years in the U.S.

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

(IN THOUSANDS OF U.S. DOLLARS EXCEPT FOR PER SHARE AND SHARE AMOUNTS)

	2016	2015
	\$	\$
Income (loss) for the year	(39,149)	1,769
Basic and diluted income (loss) per share	(1.49)	0.07

Net loss was \$39.1 million for the year ended December 31, 2016 compared to net income of \$1.8 million for the year ended December 31, 2015. An increase in revenue of \$6.3 million was offset by a \$39.9 million increase in operating expenses primarily related to a \$29.2 million impairment charge for intangible assets and goodwill related to the U.S. operation and an increase in S&M expenses and G&A expenses. In addition, other expenses increased by \$2.9 million related to the interest on the senior secured notes.

Basic earnings (loss) per share is calculated using the weighted average number of shares outstanding during the period. Diluted loss per share is calculated taking into account dilutive instruments that are outstanding. For the year ended December 31, 2016, the computation of diluted loss per share is equal to the basic loss per share due to the anti-dilutive effect of the share-based compensation.

Net loss per share on a basic and diluted basis for the year ended December 31, 2016 was \$1.49 compared to net income per share on a basic and diluted basis of \$0.07 for the year ended December 31, 2015.

The weighted average number of shares outstanding for the year ended December 31, 2016 was 26,197,942 (December 31, 2015 - 25,943,650). The dilutive weighted average number of shares outstanding for the year ended December 31, 2016 was 27,061,443 (December 31, 2015 - 26,381,704).

## ADJUSTED EBITDA

(IN THOUSANDS OF U.S. DOLLARS)

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 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, 2016 was \$6.1 million, a decrease of \$3.7 million or 38% compared to \$9.8 million for the year ended December 31, 2015. The decrease is related to including a full year of the U.S. operations in 2016 compared to the period from the acquisition date in 2015.

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

	Year ended December 31, 2016	Year ended December 31, 2015
	\$	\$
Net Income (loss)	(39,149)	1,769
Add back:		
Depreciation and amortization	5,725	4,465
Interest expense	7,723	3,453
Income taxes	1,492	(2,916)
EBITDA	(24,209)	6,771
Change in fair value of derivative financial instrument	(1,175)	(2,374)
(Gain) loss from the translation of Canadian cash balances	(10)	3,273
Impairment of intangible assets	23,111	-
Impairment of goodwill	6,112	-
Share-based compensation	2,249	2,168
Adjusted EBITDA	6,078	9,837

## Liquidity and Capital Resources

(IN THOUSANDS OF U.S. DOLLARS EXCEPT FOR PER SHARE  
AND SHARE AMOUNTS)

	Year ended December 31, 2016	Year ended December 31, 2015
	\$	\$
Net income (loss)	(39,149)	1,769
Cash provided by operating activities	11,469	7,764
Cash used in investing activities	(632)	(52,906)
Cash provided by (used in) financing activities	(3,543)	34,004
Impact of foreign exchange on cash	10	(7,048)
Net change in cash	7,304	(18,186)
Cash, beginning of year	27,182	45,368
Cash, end of year	34,486	27,182

### Cash

As at December 31, 2016, the Company has cash of \$34.5 million, compared to \$27.2 million as at December 31, 2015.

### Operating Activities

Cash provided by operating activities was \$11.5 million for the year ended December 31, 2016 compared to \$7.8 million for the year ended December 31, 2015. The increase in cash provided by operating activities related to a \$5.3 million recovery of working capital compared to a \$2.5 million investment in working capital in the prior year. Cash provided by operations, excluding working capital was \$6.1 million, compared to \$10.2 in the comparative year.

### Investing Activities

Cash used in investing activities was \$0.6 million for the year ended December 31, 2016 compared to \$52.9 million for the year ended December 31, 2015. In the current period, the Company's \$0.6 million investment related to the purchase of property and equipment related to the new office space for the U.S. operations and fleet vehicles for the sales team and the upfront payment related to the acquisition of the rights for the tattoo removal cream. In the comparative period, the \$52.9 million investment related to the acquisition of Innocutis and the acquisition of other product rights.

## Financing Activities

Cash used in financing activities was \$3.5 million for the year ended December 31, 2016 compared cash provided by financing activities of \$34.0 million for the year ended December 31, 2015. In the current period, interest payments on the Notes was partially offset by proceeds from shares issued under the share purchase plan and from the exercise of stock options. In the comparative period, cash provided by financing activities of \$34.0 million related to the \$40.0 million Notes from Athryium used to fund the acquisition of Innocutis, partially offset by interest payments on the Notes and the proceeds from shares issued under the share purchase plan and from the exercise of stock options.

Future cash requirements will depend on a number of factors, including investments in product launches, 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.

As at December 31, 2016, the Company has finance lease contractual obligations on its fleet and operating leases for the Company's two office locations. The fleet leases expires between June and August 2020. The lease for the Company's Canadian premises expires at the end of December 2018 and the lease for the Company's U.S. premises expires in January 2023.

The following table outlines the Company's undiscounted contractual obligations as at December 31, 2016.

	Less than one year	Years two and three	Beyond three years	Total
	\$	\$	\$	\$
Accounts payable and accrued liabilities	15,961	-	-	15,961
Long term liabilities	-	902	-	902
Finance lease obligations	47	94	13	154
Senior secured notes	-	-	42,000	42,000
<b>Total</b>	<b>16,008</b>	<b>996</b>	<b>42,013</b>	<b>59,017</b>

## Selected Quarterly Information

(IN MILLIONS OF U.S. DOLLARS EXCEPT FOR PER SHARE AND SHARE AMOUNTS)

	March 31, 2016	June 30, 2016	September 30, 2016	<b>December 31, 2016</b>
	\$	\$	\$	\$
Total revenue	9.1	11.7	9.2	<b>10.7</b>
Net loss for the period	(2.7)	(3.4)	(21.8)	<b>(11.3)</b>
Basic loss per share	(0.10)	(0.13)	(0.81)	<b>(0.45)</b>
Diluted loss per share	(0.10)	(0.13)	(0.81)	<b>(0.45)</b>

	March 31, 2015	June 30, 2015	September 30, 2015	December 31, 2015
	\$	\$	\$	\$
Total revenue	7.4	8.8	8.5	9.7
Net income (loss) for the period	2.5	(0.6)	(2.2)	2.0
Basic earnings (loss) per share	0.10	(0.02)	(0.09)	0.08
Diluted earnings (loss) per share	0.09	(0.02)	(0.09)	0.08

## Fourth Quarter Results

(IN THOUSANDS OF U.S. DOLLARS)

	Three months ended December 31, 2016	Three months ended December 31, 2015
	\$	\$
Licensing revenue	5,352	6,637
Product revenue	5,330	3,077
<b>Total revenue</b>	<b>10,682</b>	<b>9,714</b>
Cost of products sold	1,749	557
Research and development	116	252
Selling and marketing	3,302	3,477
General and administrative	5,158	6,351
Impairment of intangibles	5,826	-
Impairment of goodwill	3,835	-
<b>Total operating expenses</b>	<b>19,986</b>	<b>10,637</b>
Interest on senior secured notes	1,443	1,313
Change in fair value of derivative financial instrument	(179)	134
Interest income	(2)	(58)
Foreign exchange loss	187	689
<b>Total other expenses</b>	<b>1,449</b>	<b>2,078</b>
<b>Net loss before income taxes</b>	<b>(10,753)</b>	<b>(3,001)</b>
Income taxes (recovery)	543	(5,041)
<b>Net income (loss) and total comprehensive income (loss)</b>	<b>(11,296)</b>	<b>2,040</b>

### Revenue

Total revenue increased to \$10.7 million for the three months ending December 31, 2016 compared to \$9.7 million for three months ending December 31, 2015. An increase in product revenue of \$2.3 million was partially offset by a decrease of \$1.3 million in licensing revenue.

Product revenue increased to \$5.3 million for the three months ended December 31, 2016 compared to \$3.1 million for the three months ended December 31, 2015. Product revenue from the U.S. operations was \$4.3 million for the three months ended December 31, 2016 compared to \$2.2 million for the three months ended December 31, 2015. The increase of \$2.1 million related to an increase in net revenue from Bionect of \$0.9 million, Sitavig of \$0.7 million and Nuvail of \$0.3 million and \$0.1 million from the legacy products including Umecta and Innova. Product revenue from Canadian products for the three months ended December 31, 2016 increased to \$1.1 million compared to \$0.8 million for the three months ended December 31, 2015. Canadian product revenue performance was driven primarily by Epuris, which had net sales of \$0.9 million during the three months ended December 31, 2016. Vaniqa, Actikerall and Beteflam made up the balance of product revenue. Actikerall and Beteflam were both launched in 2016 in the Canadian market.

Licensing revenue decreased by 19% to \$5.4 million for the three months ending December 31, 2016 compared to \$6.6 million for three months ending December 31, 2015. Licensing revenue from tramadol products (Conzip and Durela) decreased to \$0.4 million for the three months ending December 31, 2016 compared to \$1.0 million for the three months ending December 31, 2015. Absorica licensing revenue decreased to \$3.8 million for the three months ended December 31, 2016 compared to \$4.3 million for the three months ended December 31, 2015 and Lipofen and the authorized generic version of Lipofen decreased to \$1.2 million for the three months ended December 31, 2016 compared to \$1.3 million for the three months ended December 31, 2015.

## Operating Expenses

Total operating expenses for the three months ended December 31, 2016 were \$20.0 million, an increase of \$9.4million compared to \$10.6 million for the three months ended December 31, 2015. The significant increase related to a \$9.7 impairment charge for intangible assets and goodwill related to the U.S. operation and a \$1.2 million increase in cost of products sold related to higher product sales in the current period. Partially offsetting these increase was a decrease in G&A expenses of \$1.2 million related primarily to a reduction in amortization of intangible assets due to the impairment of \$17.3 million in Q3 2016.

## Financial Instruments

At December 31, 2016, the Company's financial instruments consisted of cash, accounts receivable, accounts payable and accrued liabilities, other long term liabilities, the Notes, and the derivative financial instrument. The derivative financial instrument is measured at fair value with any changes recognized through the statements of income (loss) and comprehensive loss and is classified as Level 2 in the fair value hierarchy. Cash, accounts receivable, accounts payable and accrued liabilities and other long term liabilities are measured at amortized cost and their fair values approximate carrying values due to their relatively short periods of maturity.

The senior secured note is measured at amortized cost. At December 31, 2016, the fair value of the senior secured notes is \$39,374. The fair value was 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 and interest rate 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 and market 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 and U.S. chartered banks. Management monitors the collectability of accounts receivable and estimates an allowance for doubtful accounts.

The Company has concentration risk, as approximately 58.5% of total sales came from two customers (wholesalers and licensing partners) and 72.5% of total accounts receivable came from two customers (wholesalers and licensing partners).

### 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.

### Currency 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 and certain recurring transactions that are denominated in Canadian dollars.

### 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 senior secured notes bears interest at fixed rates and as such are not subject to interest rate cash flow risk resulting from market fluctuations in interest rates.

## 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. At December 31, 2016, the Company had 26,313,030 common shares issued and outstanding compared to

26,058,246 at December 31, 2015. Subsequent to year-end, 6,807 common shares were issued under the employee and director share purchase plan, bringing the total number of common shares issued and outstanding to 26,319,837 as of the date of this MD&A.

A total of 687,740 stock options were granted during the year with a weighted average exercise price of \$4.94. As at December 31, 2015, there were 1,557,030 options outstanding of which 858,994 have vested.

## Off-Balance Sheet Arrangements

The Company does not have any off-balance sheet arrangements.

## Accounting Standards Issued but not yet Adopted

*IFRS 15, Revenue from Contracts with Customers:* This standard replaces International Accounting Standards ("IAS") 11 *Construction Contracts*, IAS 18, *Revenue* and IFRIC 13, *Customer Loyalty Programmes* and was issued in May 2014. This standard outlines a single comprehensive model for entities to account for revenue arising from contracts with customers. The latest date of mandatory implementation of IFRS 15 is for annual reporting periods beginning on or after January 1, 2018. The Company is in the process of evaluating the impact on the consolidated financial statements.

*IFRS 9, Financial Instruments:* The final version of IFRS 9, *Financial Instruments*, was issued by the IASB in July 2014 and will replace IAS 39, *Financial Instruments: Recognition and Measurement*. IFRS 9 introduces a model for classification and measurement, a single, forward-looking 'expected loss' impairment model and a substantially reformed approach to hedge accounting. The new single, principle based approach for determining the classification of financial assets is driven by cash flow characteristics and the business model in which an asset is held. The new model also results in a single impairment model being applied to all financial instruments, which will require more timely recognition of expected credit losses. It also includes changes in respect of own credit risk in measuring liabilities elected to be measured at fair value, so that gains caused by the deterioration of an entity's own credit risk on such liabilities are no longer recognized in profit or loss. IFRS 9 is effective for annual reporting periods beginning on or after January 1, 2018, however is available for early adoption. The Company has not yet assessed the impact of IFRS 9 and has not yet determined when it will adopt the new standard.

*IFRS 16, Leases:* On January 13, 2016, the IASB published a new standard, IFRS 16. The new standard will eliminate the distinction between operating and finance leases and will bring most leases on the balance sheet for lessees. This standard is effective for annual reporting periods beginning on or after January 1, 2019. The Company has determined that all its leases will be recorded on the consolidated statements of position.

*IFRS 2, Share-based Payment:* In June 2016, the IASB issued final amendments to IFRS 2, clarifying how to account for certain types of share-based payment transactions. The amendments, which were developed through the IFRS Interpretations Committee, provide requirements on the accounting for: (i) the effect of vesting and non-vesting conditions on the measurement of cash-settled share-based payments; (ii) share-based payment transactions with a net settlement feature for withholding tax obligations; and (iii) a modification to the terms and conditions of a share-based payment that changes the classifications of the transaction from cash-settled to equity-settled. The amendments are effective for annual reporting periods beginning on or after January 1, 2018. The Company has not yet evaluated the impact on the consolidated financial statements.

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

The Company makes estimates and judgments concerning the future that will, by definition, seldom equal actual results. The following are the critical estimates and judgments applied by management that most significantly affect the Company's financial statements. The critical estimates and judgments that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are addressed below.

i) Revenue recognition:

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.

Rebates - The provision for rebates is a complex estimate used in the recognition of revenue. Rebates are granted under contractual and other arrangements with certain customers. Products sold in the U.S. are covered by various programs under which products are sold at a discount. All rebates are recognized in the period in which the underlying sales are recognized as a reduction of revenue. The Company estimates its provision for rebates based on current contractual terms and conditions as well as historical experience and changes to business practices. While such experience has allowed for reasonable estimations in the past, history may not always be an accurate indicator of future rebate provisions. The Company continually monitors the provision for rebates and makes adjustments when it believes that actual rebates may differ from established provisions.

- ii) **Deferred income taxes:** Management uses estimates when determining deferred income taxes. These estimates are used to determine the recoverability of tax loss carry forward amounts, research and development expenditures and investment tax credits depending on the jurisdiction to which they relate. 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) **Estimated useful lives of intangible assets:** Management estimates the useful lives of intangible assets based on the period during which the assets are expected to be available for use and also estimates their recoverability to assess if there has been an impairment. The amounts and timing of recorded expenses for amortization and impairments of intangible assets for any period are affected by these estimates. The estimates are reviewed at least annually and are updated if expectations change as a result of technical or commercial obsolescence, generic threats and legal or other limits to use. It is possible that changes in these factors may cause significant changes in the estimated useful lives of the Company's intangible assets in the future.
- iv) **Impairment of non-financial assets:** The Company reviews amortized non-financial assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may be impaired. It also reviews goodwill annually for impairment. 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) **Inventory obsolescence:** The Company's obsolescence provision is determined at each reporting period and the changes recorded in the consolidated statements of income (loss) and comprehensive loss. This calculation requires the use of estimates and forecasts of future sales. A change in any of the significant assumptions or estimates used could result in a material change to the provision.
- vi) **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, *Business Combinations* (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 Innocutis was accounted for as a business combination and all other acquisitions were accounted for as asset acquisitions.

## Disclosure Controls and Procedures

Cipher's management is responsible for establishing and maintaining disclosure controls and procedures to ensure that information required to be disclosed to satisfy the Company's continuous disclosure obligations is recorded, processed, summarized and reported as required by applicable Canadian securities legislation. Management has carried out an evaluation of the effectiveness as of December 31, 2016 of the design and operation of the disclosure controls and procedures, as defined in *National Instrument 52-109, Certification of Disclosure in Issuers' Annual and Interim Filings*, under the supervision and with the participation of the Interim Chief Executive Officer and the Chief Financial Officer, both positions presently being held by the same individual (the "CEO/CFO"). Based on this evaluation, the CEO/CFO concluded that the disclosure controls and procedures are effective in recording, processing, summarizing and reporting, on a timely basis, information required to be disclosed by the Company to satisfy its continuous disclosure obligations and are effective in ensuring that information required to be disclosed in the reports that the Company files is accumulated

and communicated to management as appropriate to allow timely decisions regarding required disclosure. The Board of Directors has reviewed and approved the Company's policy regarding corporate Disclosure Controls and Procedures.

Based on that evaluation, the Company's CEO/CFO has concluded that the Company's disclosure controls and procedures have been designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with IFRS as at December 31, 2016.

Cipher's management is responsible for designing and implementing internal controls over financial reporting to provide reasonable assurance regarding the reliability of the Company's reporting and the preparation of consolidated financial statements for external purposes in accordance with IFRS. As required under National Instrument 52-109, the Company, under the supervision and with the participation of the CEO/CFO, has carried out a review of its internal controls over financial reporting.

Based on this evaluation, the Company's CEO/CFO concluded that the Company has designed and implemented such internal controls over financial reporting so as to provide reasonable assurance regarding the reliability of the Company's reporting and the preparation of financial statements for external purposes during the year ended December 31, 2016 that have materially affected, or are reasonably likely to materially affect, its internal control over financial reporting. This assessment is performed in accordance with the criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO").

### **Changes in Internal Controls over Financial Reporting**

There have been no changes in the Company's internal control over financial reporting during the year ended December 31, 2016 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

The design of any system of controls and procedures is based in part upon certain assumptions about the likelihood of certain events. There can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

## **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 consideration of strategic alternatives may not result in any transaction.*

In November 2016, pursuant to a review of the Company's business plan by the Board, the Company announced it was working with a strategic advisor to consider various strategic alternatives available to enhance shareholder value, with a focus on the Company's U.S. operation. There is no certainty that the consideration of strategic alternatives will result in any transaction or alternative being undertaken or pursued.

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

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

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

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

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

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

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

Cipher is seeking product approvals in foreign jurisdictions and in Canada for a number of products. 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 505(b)(2) NDA or ANDA approvals by up to 30 months or more.

*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 our 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 lacks the resources and the capability to manufacture our products. Instead, the Company relies on our third-party 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.

Our 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 of our 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 our third-party manufacturers' ability to maintain adequate quality control, quality assurance and qualified personnel. If our 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 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 approval before the products may be marketed in the U.S. We might be unable to identify manufacturers for long-term commercial supply on acceptable terms or at all.

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

Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced U.S. federal, state, Canadian and foreign regulations. Furthermore, if microbial, viral or other contaminations are discovered in our products or in the manufacturing facilities in which our products are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot be assured that any stability or other issues relating to the manufacture of any of our products will not occur in the future. Additionally, our contract manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our 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.

Any adverse developments affecting commercial manufacturing of our products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, enforcement actions, import alerts, import detentions, or other interruptions in the supply of our products or product candidates. We may also have to take inventory write-offs and incur other charges and expenses for products or product candidates that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could materially adversely affect our business and delay or impede the development and commercialization of any of our products or product candidates and could have a material adverse effect on the Company's business, financial condition and results of operations.

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

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

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

*Unexpected product safety or efficacy concerns may arise.*

Unexpected safety or efficacy concerns can arise with respect to our marketed and commercialized products, whether or not scientifically justified, leading to product recalls, withdrawals, post-approval requirements, such as studies or Risk Evaluation and Mitigation Strategies ("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 the area of 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, 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, 2016, the Company had cash of US\$34.5 million and debt of US\$40.0 million. The Company also generates commercial revenue which provides a source of cash flow. In 2016, the Company reported total revenue of US\$40.7 million.

We expect the cash on hand and the cash generated from operations may be sufficient to fund current product development and operating costs. Additional funding may be required for the development of new products in-licensed from technology partners and/or for additional acquisitions. Although Cipher believes that the Company could obtain additional capital through future equity or debt financing, there can be no assurance that it will be able to do so on terms acceptable to us or at all. If Cipher was unable to obtain sufficient additional capital, the development of our existing principal products and/or additional products could be disrupted, which could have a material adverse effect on our business, financial condition and operating results.

*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 a 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 US\$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"), 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 to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of an amount greater than US\$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, newly-elected President Donald Trump signed an executive order intended to "eas[e] the burden of the Affordable Care Act," the 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. Thus, 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.

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.

Our ability to successfully market our products and product candidates, once regulatory approval is obtained, depends, in part, on whether appropriate reimbursement levels for the cost of the products and related treatments are obtained from government authorities and private health insurers and other organizations, such as Health Maintenance Organizations ("HMOs") and Managed Care Organizations ("MCOs").

In Canada, patented pharmaceutical products are subject to price control by the Patented Medicine Prices Review Board. 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 HMOs and 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.

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

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

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

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

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

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

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

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

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

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

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

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

The Company 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 identify, acquire or integrate acquisition targets successfully.*

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 currently conducts certain of its operations through U.S. subsidiaries and certain of its assets are held in such entities.*

Cipher currently conducts certain of its operations through U.S. subsidiaries and certain of its assets are held in such entities. Cipher may thus be subject to a number of associated risks which are beyond its control. These risks include, but are not limited to: changes of laws affecting foreign ownership, fluctuations in exchange rates, as well as government participation, taxation, royalties, duties, inflation, exchange control and repatriation of earnings. While these factors cannot be accurately predicted, Cipher believes the relative risk of operations in the United States is low on a world-wide scale. In particular, the ability of Cipher's U.S. subsidiaries to make payments to the parent corporation may be constrained by certain factors, including the level of taxation, particularly corporate profits and withholding taxes, in the United States. Any limitation on the transfer of cash or other assets between the parent corporation and such entities, or among such entities, could restrict Cipher's ability to fund its operations. Any such limitations, or the perception that such limitations may exist now or in the future, could have a material adverse effect on Cipher's business, financial condition and results of operations.

*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 Notes, 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 facilities. A failure to meet such covenants could result in our lenders seeking to enforce their security under such credit facilities. 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 facilities 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 facilities 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 our current credit facilities 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 securities 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 IFRS. Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives due to its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is therefore subject to error, 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, financial condition and results of operations.

*The Company recently voluntarily delisted its Common Shares from NASDAQ and voluntarily de-registered its Common Shares under the U.S. Exchange Act, which will limit the information publicly available to the Company's U.S. shareholders.*

The Company recently voluntarily delisted its Common Shares from NASDAQ and voluntarily de-registered its Common Shares under the U.S. Exchange Act, thereby terminating its obligations to comply with the NASDAQ's continued listing rules and the SEC's reporting requirements applicable to foreign private issuers. As a result, the Company now does not file any reports with the SEC. Therefore, the Company's shareholders will no longer be able to information regarding the Company on the SEC's EDGAR system. Furthermore, filings made by the Company with Canadian regulators on SEDAR comply with Canadian disclosure and reporting requirements, and therefore, may be different than the information and disclosures typically prepared by U.S. reporting companies.

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.

*If we are a passive foreign investment company, or PFIC, for United States federal income tax purposes in any year, certain adverse tax rules could apply to U.S. Holders of our Common Shares.*

Based on estimates of the composition of our income and the value of our assets, we believe that we may be a PFIC for United States federal income tax purposes for our current taxable year.

We will be classified as a PFIC for any taxable year for United States federal income tax purposes if either (i) 75% or more of our gross income in that taxable year is passive income or (ii) the average percentage of our assets by value in that taxable year which produce or are held for the production of passive income (which includes cash) is at least 50%.

PFIC status is determined annually and depends upon the composition of a company's income and assets from time to time. Therefore, there can be no assurance as to our PFIC status for future taxable years. The value of our assets will be based, in part, on the then market value of our Common Shares, which is subject to change.

If we are a PFIC for any taxable year during which a U.S. Holder (as defined below) holds Common Shares, such U.S. Holders could be subject to adverse United States federal income tax consequences (whether or not we continue to be a PFIC). For example, U.S. Holders may become subject to increased tax liabilities under United States federal income tax laws and regulations, and will become subject to burdensome reporting requirements. If we are a PFIC during which a U.S. Holder holds Common Shares, such U.S.

Holder may be able to make a “mark-to-market” election or a “qualified electing fund” election that could mitigate the adverse United States federal income tax consequences that would otherwise apply to such U.S. Holder. [We will provide the information necessary for a U.S. Holder to make the qualified election; however, no assurance can be given that such information will be available for any lower-tier PFIC that we do not control.]<sup>1</sup>

The term “U.S. Holder” means a holder of a common share of the Company that is for United States federal income tax purposes:

- an individual citizen or resident of the United States;
- a corporation (or other entity treated as a corporation for United States federal income tax purposes) created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate the income of which is subject to United States federal income taxation regardless of its source; or
- a trust if it (1) is subject to the primary supervision of a court within the United States and one or more United States persons have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable United States Treasury regulations to be treated as a United States person.

U.S. Holders are urged to consult their own tax advisers as to whether we may be treated as a PFIC and the tax consequences thereof.

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

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

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

Our commercial success depends in part on our ability to obtain and maintain patent protection and utilize trade secret protection for our intellectual property and proprietary technologies, our products and their uses, as well as our ability to operate without infringing upon the proprietary rights of others. We rely upon a combination of patents, trade secret protection and confidentiality agreements, assignment of invention agreements and other contractual arrangements to protect the intellectual property related to our products and our other development programs. There can be no assurance as to the breadth or degree of protection that existing or future patents or patent applications may afford us or that any patent applications will result in issued patents or that our patents will be upheld if

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<sup>1</sup> NTD: Will Cipher undertake to provide this information? If not, remove this sentence.

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, our patents typically do not claim a new compound. Rather, 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 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 U.S. Patent and Trademark Office (the "USPTO") may be subject to re-examination and other challenges. In addition, recent changes to the patent laws of the U.S. provide additional procedures for third parties to challenge the validity of patents issuing from patent applications filed after March 15, 2013. Furthermore, efforts to enforce our patents could give rise to challenges to their validity or unenforceability in court proceedings. If the patents and patent applications Cipher holds or pursues with respect to our products or any of our other product candidates are challenged, it could threaten our competitive advantage for our products or any of our other product candidates. Furthermore, even if they are not challenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. To meet such challenges, which are part of the risks and uncertainties of developing and marketing product candidates, the Company may need to evaluate third party intellectual property rights and, if appropriate, to seek licenses for such third party intellectual property or to challenge such third party intellectual property, which may be costly and may or may not be successful, which could also have a material adverse effect on the commercial potential for products and any other product candidates.

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

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

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

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

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

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

The strength of patents in the pharmaceutical field involves complex legal and scientific questions and, in the U.S., 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 patented method of use. If the applicant certifies that the patents are not infringed or are invalid, the applicant must so notify the patent holder and the holder of the branded product NDA within set timeframes. A patent holder or NDA holder may then bring a patent infringement lawsuit within 45 days of receiving notice. In such a case, the FDA is precluded by statute from making an approval effective until the earlier of 30 months after the receipt of the certification notice by the patent or NDA holder, a final court decision of non-infringement or patent invalidity, settlement, or a shorter or longer period as determined by the court. Challenges of this type are not uncommon. Similar procedures exist in Canada under the Patented Medicines (Notice of Compliance) Regulations.

Third parties own patents relating to product formulations. Claims by these companies that Cipher infringes their proprietary technology may result in liability for damages or may delay the development and commercialization of Cipher's products. In the pharmaceutical industry, it is not uncommon for competitors to advance such claims for strategic purposes. There can be no assurance that additional patent 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 trademarks that identify our products and have registered these trademarks 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.*

The Company has financed its operations to date through the sale of securities, specifically, Common Shares. 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 continued scientific progress in our product discovery and development programs, progress in its pre-clinical and clinical evaluation of products and product candidates, time and expense associated with filing, prosecuting and enforcing its 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) 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 9,749,765 Common Shares, representing 37.1% of the total outstanding Common Shares as of March 1, 2017. 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. 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.

*We do not currently intend to pay dividends on our Common Shares.*

We have never declared or paid any cash dividend on our Common Shares and do not currently intend to do so for the foreseeable future. We currently anticipate that Ciper will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Therefore, the success of an investment in our Common Shares will depend upon any future appreciation in their value. There is no guarantee that our Common Shares will appreciate in value or even maintain the price at which our shareholders have purchased their shares. See “Dividends”.

*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 Ciper may make or receive under these arrangements;
- any intellectual property infringement or other lawsuits in which Ciper 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;
- the timing of wholesaler and distributor purchases; and
- general economic and industry conditions, including potential fluctuations in interest rates.

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

Goodwill and intangible assets represent a significant portion of the Company’s total assets and potential impairment of goodwill and other intangible assets may significantly impact the Company’s profitability. 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. Goodwill and 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. As a result of the significance of goodwill and intangible assets should such an impairment of goodwill or intangible assets occur, it could

have a material adverse effect on the Company's business, financial condition and results of operations. In 2016, the Company recorded an impairment charge of \$29.2 million related to goodwill and intangible assets from the acquisition of Innocutis.

*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