# BIOCURE TECHNOLOGY INC. (formerly Gravis Energy Corp)

# Management's Discussion & Analysis As at September 30, 2019

## **INTRODUCTION**

The following management's discussion and analysis ("MD&A") is a review of operations, current financial position and outlook for the Company and is performed by management using the information available as at November 29, 2019. We have prepared this MD&A with reference to National Instrument 51-102F1 of the Canadian Securities Administrators. This MD&A should be read in conjunction with the Company's unaudited condensed consolidated interim financial statements for the nine months ended September 30, 2019 and the audited financial statements for the year ended December 31, 2018 and the related notes thereto ("Annual Financial Statements"). The Company's Annual Financial Statements are prepared in accordance with International Financial Reporting Standards ("IFRS"). All amounts are expressed in Canadian dollars unless otherwise indicated. The information contained herein is not a substitute for detailed investigation or analysis on any particular issue. The information provided in this document is not intended to be a comprehensive review of all matters and developments concerning the Company.

As used in this MD&A and unless otherwise indicated, the terms "we", "us", "our", "Company", and "CURE" refer to Biocure Technology Inc. Unless otherwise specified, all dollar amounts are expressed in Canadian dollars. This MD&A contains certain information forward-looking statements. Forward-looking statements may also be made in the Company's other reports filed with or furnished to the Canadian securities commissions. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from such statements. The words "aim," "anticipate," "believe," "continue," "could," "expect," "intend," "likely", "may," "optimistic," "plan," "potential", "predict", "should," "would," and other similar expressions are intended to identify forward-looking statements. These statements are not guarantees of future performance, and therefore you should not put undue reliance upon them. The material assumptions supporting these forward-looking statements include, among other things the Company's ability to:

- obtain any necessary financing on acceptable terms;
- keep pace with rapid changes in consumer demands;
- rely on third party manufacturers;
- manage expansion effectively;
- enforce its intellectual property rights;
- launch additional product lines;
- retain its skilled personnel;
- manage current tax and regulatory regimes;
- manage the fluctuation in foreign currency exchange rates and interest rates; and
- follow general economic and financial market conditions.

Some of the factors that may cause actual results to differ materially from those indicated in these statements are found in the section "Risk Factors" in this MD&A.

The forward-looking statements contained in this MD&A reflect our views and assumptions only as of the date of this MD&A. The Company undertakes no obligation to update or revise any forward-looking statements after the date on which the statement is made, except as required by applicable laws, including the securities laws of Canada.

#### **OUR BUSINESS**

Biocure Technology Inc., formerly known as Gravis Energy Corp., (the "Company") was incorporated under the Business Corporation Act (British Columbia) on August 24, 2007. The Company is engaged in a mineral exploration property project through a limited partnership. The Company is also engaged in developing and commercializing several biopharmaceutical technologies relating to uses of recombinant and ranibizumab. The Company's head office is located at Suite 300, 1055 West Hastings Street, Vancouver, BC, Canada.

On November 24, 2017, the Company acquired 100% of the issued and outstanding common and preferred shares of BiocurePharm Corporation ("BP Korea"), in exchange for the common shares of the Company (the "Transaction"). BiocurePharm Corporation (the "Company" or "Biocure"), a private corporation, was incorporated on August 29, 2005 under the laws of the Republic of Korea. The Company was established to develop and commercialize several Biosimilars and biopharmaceutical technologies for production of biopharmaceuticals in Korea and oversea countries. The Company's registered and head office is located at S-202, Pai Chai University Daedeok Campus, 11-3 Techno 1-ro, Yuseong-gu, Daejeon, Republic of Korea.

Established in 2005, Biocure is a biopharmaceutical company focused on developing biosimilars based on Recombinant Protein Technology, Cell Culture Technology, Protein Purification Technology, and Bio-processing Technology. Biosimilar is defined in Wikipedia as follows: "A biosimilar (also known as follow-on biologic or subsequent entry biologic) is a biologic medical product which is almost an identical copy of an original product that is manufactured by a different company. Biosimilars are officially approved versions of original "innovator" products and can be manufactured when the original patent expires."

Biocure has developed technology to produce three biosimilars such as Interferon-β, Ranibizumab and Filgrastim. Biocure is fully ready to proceed with preclinical and clinical tests for those three products whenever funds are available.

Even after the clinical test is done and products are approved, one of the biggest difficulties and risks to a biopharmaceutical company is gaining a commercial manufacturing facility. Currently, the Company has access to a third-party Good Manufacturing Practice facility ("GMP facility") in Korea to minimize upfront capital requirements as well as investment risks for the commercialization of its products.

Korean government believes the biopharmaceutical industry will drive the nation's growth for the next generation. As a part of its initiatives, Korean government and Daejeon municipality government have invested 25 billion South Korean Wons ("KRW") in total, 12 billion for the Fermentation & Purification process and 13 billion for the Fill & Finish process, to build a GMP facility in 2011 to support venturous biopharmaceutical companies, who lack finances to materialize commercial productions. The GMP facility is equipped with complete lines of the Fermentation & Purification process and the Fill & Finish Packaging process.

The GMP facility has sufficient capacity to commercially manufacture and package biopharmaceuticals based on recombinant bacteria, Interferon- $\beta$ , Ranibizumab, Filgrastim, and Recombinant growth factor. For example, Biocure could produce Interferon- $\beta$  at this facility by 4.8 million vials per year. The world consumption of Interferon- $\beta$  is estimated about 20 million vials a year, so the production from this facility could cover about 24% of world consumption.

Biocure has a right to use this GMP facility at any time on a long-term lease or on a fee basis. Since the GMP facility is a state-run non-profit organization, the terms and conditions are very favourable to Biocure.

The risks to produce and market biosimilars are time and cost until preclinical test, clinical test, product approval and registration process are complete. In order to mitigate these risks, Biocure is in discussion with parties in the countries, who are in serious need for biosimilars that Biocure has technology to produce. Those countries have many patients suffering from diseases that could be treated by Biocure's products, but original products from multinational pharmaceutical firms are too expensive for those patients to access due to the high pricing policy with a patent. Biosimilars could solve such problems and be available at much more affordable prices.

Biocure is offering one-stop solution to those countries, i.e. Collaboration on the implementation of preclinical and clinical test, technology transfer to produce biosimilar, GMP facility design & manufacturing equipment selection, entire quality control process for the final products and so on. By this scheme, Biocure could mitigate risks significantly to enter into new markets with its biosimilar technology. Working with local partners in those countries could significantly reduce financial and marketing risks. In addition, Biocure should be able to get a technology transfer fee as well as a license fee or royalty from the partners upon commercial production

Biocure does not have a positive cash flow and focus on the clinical trial for CAR T Cell Therapy in Korea to expedite the first commercialization of its products.

#### PRODUCT PORTFOLIO

## 1. Interferons- $\beta$

Interferons ("IFNs") are a group of signaling proteins made and released by host cells in response to the presence of several pathogens, such as viruses, bacteria, parasites, and also tumor cells. In a typical scenario, a virus-infected cell will release interferons causing nearby cells to heighten their anti-viral defenses. IFNs belong to the large class of proteins known as cytokines, molecules used for communication between cells to trigger the protective defenses of the immune system that help eradicate pathogens. Interferons are named for their ability to "interfere" with viral replication by protecting cells from virus infections. IFNs also have various other functions: activate immune cells, such as natural killer cells and macrophages; increase host defenses by up-regulating antigen presentation by virtue of increasing the expression of major histocompatibility complex (MHC) antigens. Certain symptoms of infections, such as fever, muscle pain and "flu-like symptoms", are also caused by the production of IFNs and other cytokines. More than twenty distinct IFN genes and proteins have been identified in animals, including humans. They are typically divided among three classes: Type I IFN, Type II IFN, and Type III IFN. IFNs belonging to all three classes are important for fighting viral infections and for the regulation of the immune system.

The IFN- $\beta$  proteins are produced in recombinant bacteria and animal cell. They have antiviral activity that is involved mainly in innate immune response. Two types of IFN- $\beta$  have been described, IFN- $\beta$ 1 (IFNB1) and IFN- $\beta$ 3 (IFNB3). IFN- $\beta$ 1 is used as a treatment for multiple sclerosis as it reduces the relapse rate. IFN- $\beta$ 1 is not an appropriate treatment for patients with progressive, non-relapsing forms of multiple sclerosis.

The originator of Interferon beta was Schering AG (Berlex in North America), now part of Bayer HealthCare, and the patent expired in 2010. Currently, EMD Serono Canada Inc., Bayer HealthCare, and Biogen are manufacturing Interferon beta.

The total world market size of multiple sclerosis is worth 24.8 billion USD by 2024 (Source:https://www.thepharmaletter.com/article/multiple-sclerosis-therapeutics-market-to-be-worth-24-8-billion-by-2024) and Interferon-β in 2015 was U\$6.3 billion USD (Source: <a href="http://www.researchandmarkets.com/reports/2221752/interferon-market-forecast-to-2015.pdf">http://www.researchandmarkets.com/reports/2221752/interferon-market-forecast-to-2015.pdf</a>).

Dr. Sang Mok Lee, the CEO of Biocure, completed a preclinical test for this product earlier in 2001 before he established Biocure, but he could not complete a clinical test due to a small number of patients in Korea at that time. Biocure completed another preclinical test in 2008, but again could not advance to a clinical test due to lack of funds.

Biocure has completed with a preclinical test again in Korea in 2019, as Interferon-beta shall be the first one to be commercialized out of Biocure's product portfolio. Since Korea does not have a sufficient number of patients for a clinical test, Biocure will submit the application to Korea FDA for the implementation of clinical test in other countries with more patients. Upon the consent from Korea FDA, Biocure plans to carry out a clinical test in Europe or Canada, subject to fund availability. The estimated cost of preclinical and clinical test would be KRW 3 Billion, but it can vary depending on the rules and regulation of authorities in each country. The cost estimation is under progress.

Once clinical test in another country is complete, Biocure shall be able to obtain a product registration from Korea FDA with such clinical test results. An approval from Korea FDA will allow Biocure to start commercial production in Korea and export to other countries. In order to market this product to other countries such as Europe or Canada, a similar product registration procedures should be taken with local authorities. However, it would be much quicker and easier with an approval from Korea FDA. Instead of a full scale of clinical test results, a Bridge Test or a Racial Difference Test could be acceptable to obtain a product registration.

Biocure plans to generate revenue by manufacturing Interferon-beta at the GMP facility in Korea and exporting to overseas where products are registered. The ultimate plan of Biocure is building a local GMP facility in those countries through the Joint Venture with reliable local partners who are willing to finance the construction of GMP Facility. Then, Biocure could secure a stable cash flow from technology transfer fees, royalties and dividends.

# 2. Ranibizumab

Ranibizumab is used for treating macular degeneration. It is also used to treat a type of eye problem known as macular edema. Ranibizumab (trade name Lucentis among others) is a monoclonal antibody fragment (Fab) created from the same parent mouse antibody as bevacizumab. It is an anti-angiogenic that has been approved to treat the "wet" type of age-related macular degeneration (AMD, also ARMD), a common form of age-related vision loss.

Its effectiveness is similar to that of bevacizumab. Its rates of side effects also appear similar. However, ranibizumab typically costs \$2,000 a dose, while the equivalent dose of bevacizumab typically costs \$50.

Ranibizumab was developed by Genentech and is marketed in the United States by Genentech and elsewhere by Novartis, under the brand name Lucentis, and the patent will expire in 2017. The total market size of Lucentis is estimated US\$4.3 billion in 2013.

The number of patients who need Ranibizumab in Korea is on the rise and its annual growth rate is 38%, the world's highest. (Source: Statistic Bureau, MIC; Ministry of Health, Labour and Welfare, United Nations) The average market price is known to be US\$1,200 per vial. (Source: https://www.drugs.com/price-guide/lucentis) Due to its high price, Medical Service Plan or National Health Insurance Program has a limit to cover the cost for the needed patients and very few patients receive benefits for this medicine.

When Biocure manufactures this product at the GMP facility in Korea, the expected selling price could be reduced to less than 50% of the current market price, if required. The price competitiveness of a biosimilar against the original product is generally very high. Since the Korean market for this product is growing fast, its commercial production in Korea could bring the Company good cash flows and a high chance to enter into the Turkey market.

#### 3. Filgrastim

Filgrastim is used to treat neutropenia, a lack of certain white blood cells caused by cancer, bone marrow transplant, chemotherapy, or by other conditions. It is a type of anti-cancer treatment which plays an important role for recovery of immunity for cancer patients.

The original product developer was Amgen, USA and its patent expired in 2013. Therefore, many biosimilar producers exist throughout the world already.

With the completion of product development, Biocure can start preclinical tests at any time. But the Company is evaluating a right timing to start due to its priority against other products of the Company, considering of limited fund availability and financial constraints.

The Company plans to start a preclinical and clinical test in Korea first and collaborate with local parties in other countries, whoever the Company could enter into an agreement with first.

When Biocure discusses about biosimilar technology transfer or GMP facility JV, Filgrastim is included in the target product portfolio for local manufacturing.

#### 4. CAR T Cell Therapy

The Company through its wholly owned subsidiary BiocurePharm Corporation ("Biocure Korea") has entered into a joint R&D agreement with Pharos Vaccine Inc. dated November 30, 2017 for the purpose of carrying out research and development activities relating to the commercialization of anti-CD19 CAR-T (Chimeric Antigen Receptor T Cell) and for the pursuit of pre-clinical and clinical trials.

In August 2017, Novartis Pharmaceuticals Corp. was the first company to obtain FDA approval for gene immune-therapy in the United States with its product "Kymriah", which is for usage in treatment of pediatric and young adult patients with a form of acute lymphoblastic leukemia. Kymriah is a CAR-T cell therapy product. In October 2017, Gilead Sciences Inc. received FDA approval for its lymphoma product "Yescarta" another CAR-T cell therapy product used to treat adult patients with certain types of non-Hodgkin lymphoma.

The market for CAR-T Cell therapies is expected to grow steadily till 2028 by 53.9% of annual growth rate and reach U\$8.3 Billion in value. (Source: Coherent Market Insight, CAR-T Cell Therapy Market, 2017. 2)

Chimeric Antigen Receptor modified T cell immunotherapy, so called, CAR-T Cell Therapy, is one of the most competitive and advanced treatments for Acute Lymphoblastic Leukemia (ALL). Specific antigen receptor of CAR-T cell is made by use of virus vector after extracting T cell from patient bloods, and re-infuse to patient. Within the patient's body, the CAR-T cells have the potential to recognize the cancer cells and other cells expressing a specific antigen and attach to them, which may initiate direct cell death.

Relapsed and refractory acute lymphoblastic leukemia (ALL) remains to be a significant cause of cancer associated morbidity and mortality for children and adults. CAR-T cell therapy, as one of the most promising targeted immunotherapies, has drawn extensive attention and resulted in multiple applications. Biocure Korea have established pre-clinical and clinical designs of 2nd generation CAR-T cell immunotherapy in 2017: standard protocol for conditioning and infusion, better control of complications, and combination with other therapeutic options and etc. On July 5, 2018, the Company's wholly owned subsidiary, BiocurePharm Corp. (BP Korea), has started conducting a preclinical trial of its CAR-T cell. On October 16, 2018, the Company released successful results of the preclinical trial of its CAR-T cell. Achievements have made by the Company up to date are including, but not limited to, Clinical trial protocol, Construction of master cell bank, Establishment of manufacturing process, Stability test, Establishment of quality control, Specification and Assay. GMP documentation, Validation of manufacturing process, Validation of Quality control and quality assurance, CMC assay for clinical trial samples, documentation for clinical trial applicant and so on.

It is expected to help a lot leukemia patients. According to the NIH, more than 340,000 people in the U.S. suffered from leukemia in 2015. Global CAR-T Cell therapeutics market was \$72 million in 2017. In the next 11 years (from 2017~2028), the annual growth rate will steadily increase to 53.9%. (Coherent Market Insights, CAR-T Cell therapy market (2017.2)) CAR-T Cell therapeutics is expected to generate huge revenue opportunities in commercial.

#### 5. Foot-and-mouth Disease (FMD) Vaccine

Pharos Vaccine Inc. has succeeded in developing an advanced recombinant vaccine using E. coli instead of producing the vaccine through existing cell culture. Pharos Vaccine has the ability to manufacture customized vaccines that match foot-and-mouth disease virus types. It uses Escherichia coli for production and its production cost is much less than that of cell culture, therefore it would be able to produce the large quantities within a shorter period at much more affordable price.

Pharos Vaccine Inc. does not have sufficient resources to manufacture any products at commercial scale despite its own innovative technology. Pharos mainly focuses on research & development and does not have any marketing experience or resources in the international market. Therefore, Biocure and Pharos have agreed to cooperate to enter into overseas markets through Biocure's international business expertise and Biocure's accessibility to a GMP facility for biosimilars.

Pharos Vaccine Inc. has developed Foot-and-Mouth Disease (FMD) vaccine in 2015 and Biocure has a license agreement with Pharos to produce and market FMD vaccine to Korea and overseas, except China for 10- years from the product registration date.

The Korean Foot-and-Mouth Disease (FMD) vaccine market is worth about KRW60 billion a year. Merial, a UK based multinational pharmaceutical company, provides bulk vaccine to six local animal vaccine manufacturers in Korea. The six local manufacturers repack the vaccines under their own brands and ship them to the Korean Public Procurement Services.

The advantage of the Pharos Vaccine is that it can easily manufacture all different vaccines for the known seven virus types by changing epitopes. On the other hand, Merial's vaccines are effective in only three types of viruses, which means Merial's vaccines are not effective in the other four types of viruses. As Merial's products are through animal cell culture process, it would take Merial much longer to produce new vaccines for the other four type of virus.

Biocure will bear all costs and expenses after the transfer of technology. In other words, all the burdens that arise in the self-domain are the principle of the parties.

For overseas markets, Biocure has a manufacturing and marketing right to any countries in the world for 10 years from the product registration date except China where Pharos appointed another Chinese firm as a partner for the Chinese market. Biocure will be responsible for all costs and expenses for business after the transfer of Pharos's technology.

If Pharos completes a preclinical and clinical test in Korea, Biocure does not expect a same level of preclinical and clinical test would be required in other countries. Nevertheless, there is no assurance that other countries' regulatory authorities will waive a preclinical and clinical test with the data of product approval in Korea. The Company anticipates that the process shall be much simpler and shorter to register the product for sales in other countries.

Biocure is researching overseas markets such as Brazil, Colombia and Turkey where a number of livestock vulnerable to FMD such as beef, cattle, and pig are raised. Biocure should be able to export vaccines to those countries from the veterinary GMP plant in Korea upon the product registration in respective countries. Setting up a local plant could be an option, if the regional market is big enough.

# 6. Hair Growth Agent

Biocure has a technology to produce growth factors through Recombinant Protein Process. Growth factors were identified from stem-cell culture technology and have been well-known as a great effect on hair growth, skin revitalization, wrinkle removal, and wound healing. Special functional cosmetics using growth factor have already been popular by many cosmetic companies in the market, but products that are applied as hair growth stimulant have not been introduced yet.

This product is a functional hair growth solution originating from ADSC (adipocyte stem cells) and has been under development since 2012. The major components of this product are five types of growth factors such as IGF (Insulinlike Growth Factor), VeGF (Vascular endothelial Growth Factor), TGF (Transforming Growth Factor), EGF (Endothelial Growth Factor), and FGF (Fibroblast Growth Factor).

IGF is part of a complex system that cells use to communicate with their physiologic environment. VeGF is a signal protein produced by cells that stimulates vasculogenesis and angiogenesis. It is part of the system that restores the oxygen supply to tissues when blood circulation is inadequate such as in hypoxic conditions. TGFs are multifunctional cytokines that regulate cell proliferation, growth, differentiation and motility, as well as synthesis and deposition of the extracellular matrix.

EGF has a profound effect on the differentiation of specific cells in vivo and is a potent mitogenic factor for a variety of cultured cells of both ectodermal and mesodermal origin.

FGF involved in angiogenesis, wound healing, embryonic development and various endocrine signaling pathways. The FGFs are heparin-binding proteins and interactions with cell-surface-associated heparan sulfate proteoglycans have been shown to be essential for FGF signal transduction. FGFs are key players in the processes of proliferation and differentiation of wide variety of cells and tissues.

Five main growth factors have been developed in 2017.

Biocure has applied these Growth Factors to cosmetic products so that no clinical test would be required. Biocure is considering a spin-off of this product line to maximize the efficiency of business and concentrate on CAR T Cell and other Biosimilars.

# **CORPORATE UPDATES**

On March 21, 2017, the Company entered into a merger agreement (the "Merger Agreement") with Gravis Energy Corp. ("Gravis"), to merge with Gravis by way of Reverse Takeover ("RTO"). The merger is subject to approval by the Canadian Securities Exchange ("CSE") in accordance with applicable laws and regulations.

## Under the agreement:

- In May 2017, the Company issued 275,000 common shares of its own equity at a share price of \$9.70 (KRW 8,000) for gross proceeds of up to \$2,667,872 (KRW 2,200,000,000);
- The Company will complete a consolidation of its outstanding common shares on a 6.033479 for 1 basis;
- As consideration for acquiring 100% of the outstanding common shares of the Company, Gravis will issue 24 post-consolidated common shares for each common share to the shareholders of the Company.

On November 27, 2017, the Company completed the RTO.

On November 30, 2017, the Company's wholly owned subsidiary, BiocurePharm Corporation, entered into a joint R&D agreement (the "Agreement") with Pharos Vaccine Inc. ("Pharos") for the purpose of carrying out research and development activities relating to the commercialization of anti-CD19 CAR-T (Chimeric Antigen Receptor T Cell) and for the pursuit of pre-clinical and clinical trials.

Pursuant to the Agreement, Biocure Korea will fund all fees and expenditures throughout all stages until product registration and commercial sales license are obtained and is setting up a GMP (Good Manufacturing Practice) Facility to manufacture products and will perform worldwide marketing except in China. Pursuant to the Agreement, Pharos will provide a license for the use of its technology, prepare products for pre-clinical & clinical trial and address all technology-related activities until product registration and conditional commercial sales license are obtained. Additionally, Biocure Korea shall pay to Pharos Technology License Fees in the aggregate amount of 3.8 billion Korean won, of which 500 million Korean won shall be paid in five equal installments over the first year of the Agreement, 300 million Korean won will be paid once the application for phase 1 clinical trials are approved, 1 billion Korean won will be paid once the phase 2 clinical trials are completed and the final 2 billion Korean won will be paid once the phase 2 clinical trials are completed. Biocure Korea will also pay certain sales linked technical fees from sales of the product developed.

Any technical achievements or outcomes completed under the Agreement shall belong to both parties as joint intellectual property and cannot be sold or transferred to the third party without consent of the other party. If there is any profit generated from such intellectual property, it shall be equally shared by both parties, subject to the sales linked technical fees.

Pursuant to the Agreement, Biocure Korea is obligated to set up GMP Facilities in the second half of 2018 to manufacture Pharos' Lentivirus which is a lentivirus vector for manufacturing anti-CD19 CAR-T-cell. It is a non-replicative viral vector of high-efficiency gene that has been independently researched and developed by Pharos. The facility is to be transferred to Pharos at it requires subject to negotiations regarding the value of such facility.

The Agreement has a 15-year term. Each of Biocure Korea and Pharos have been selected by the Ministry of Health and Welfare in Korea as a Project for CIDD (Consulting for Innovative Drug Development) Program by which the companies could receive financial aids and government policy supports from Korean Government in developing innovative drugs such as CAR T Cell.

On June 18, 2018, the Company began trading on OTCQB under the symbol BICTF.

On July 5, 2018, the Company's wholly owned subsidiary, BiocurePharm Corporation (BP Korea), has started conducting a preclinical trial of its CAR-T cell.

Furthermore, the Company has announced that BP Korea has successfully developed a GMP (good manufacturing practice) manufacturing of viral vectors as MCB (master cell bank) in Korea and successfully completed the efficacy and toxicity test.

On July 18, 2018, the Company's wholly owned subsidiary, BiocurePharm Corporation (BP Korea), has implemented the preclinical trial of interferon beta 1b since late 2017 and is pleased to update shareholders on its progress. BP Korea announces that it has completed most of the toxicity testing and has developed MCB (master cell bank) and WCB (working cell bank). Currently, BP Korea is in the middle of an in vivo potency test. The Company has already produced 35,000 vials of interferon beta 1b for its preclinical trial and stability test at the GMP manufacturing facility in Korea. BP Korea expects the preclinical trial shall be completed by the end of Q1 2020 and will advance to clinical trial in Q3 2020.

On October 16, 2018, the Company released successful results of the preclinical trial of safety and toxicity of CAR-T cells-based treatment for Acute Lymphocytic Leukemia. The trial results demonstrated a complete remission of the cancerous cells within 7 and 28 days from the injection of reengineered CAR-T cells into a mouse. The study further showed encouraging results as no toxicity symptoms have risen from the high-volume injection.

In 2018, the Company has successfully completed the safety test of a Biodistribution analysis study and toxicity study for single dose intravenous injection as per the Korea FDA guidelines. This milestone allows BioCure to advance into the actual production of anti-CD19 CAR-T Cell for a clinical trial. The Company has already contracted CdmoGen Co. Ltd. and Master Cell Bank to produce a Lentiviral Vector under GMP standards necessary for advancing to the next stage of CAR-T Cell based clinical trials.

On January 14, 2019, Biocurepharm Corporation ("BPK"), a wholly owned subsidiary of the Company entered into a collaboration agreement with Y Biologics ("YB"), a private R&D company in Korea that specialized in antibody therapeutics in cancer, autoimmune disease and metabolic disease. The purpose of this agreement is to research the effectiveness of combined treatment of Immune Checkpoint Inhibitor PD-1 (Programmed Cell Death Protein-1) developed by YB and anti-CD 19 CAR T-Cell Therapy developed by BPK. BPK and YB believe that the above combined treatment could maximize anticancer effects and eventually develop a next generation anticancer treatment for solid tumors.

BPK and YB agreed to collaborate in the following areas to verify combined therapy of YBL-006 and anti-CD19 CAR T-cell therapy;

- a. Plan and implement pre-clinical trial(animal) for combined therapy;
- b. Conduct a study of action mechanism and bio marker of combined therapy;
- c. Development of anticancer treatment and exchange of information; and
- d. And other essential items to fulfill the intended goal of the agreement.

On February 7, 2019, the Company received Depository Trust Company ("DTC") eligibility.

On May 16, 2019, BPK entered into an agreement with Pharos Vaccine Inc. for the development of overseas market of CAR-T-cell products on an exclusive basis. The two companies will work together in developing anti-CD19 CAR-T-cell therapy products, conducting preclinical and clinical trials, and commercializing anti-CD19 CAR-T-cell therapy products overseas to treat leukemia and lymphoma patients. Some of the highlights of collaborative research and development work scopes in the agreement include:

- 1. Manufacture products for preclinical trial of contract product;
- 2. Preclinical trial of contract product;
- 3. Manufacture three batches of test product for clinical trial application of contract product;
- 4. Application for clinical trial of contract product;
- 5. Manufacture product for clinical trial of contract product;
- 6. Clinical trial of the contract product;
- 7. Establishment of manufacturing technology and SOP of contract product;
- 8. Establishment of quality control test method and SOP of contract product;
- 9. Preparation of safety/efficacy data of contract product;
- 10. Establishment and operation of GMP (good manufacturing practice) facility of contract product;

- 11. Biologics licence application (BLA) of contract product;
- 12. Obtaining the product registration and (conditional) sales permit for contract product.

Pharos and BPK have agreed on the exclusive manufacturing and marketing rights of anti-CD19 CAR-T-cell products for 15 years from the starting date of sales in the markets. The territories BPK shall have exclusive rights under this agreement are all the countries, except China.

On October 17, 2019, BPK has appointed CLIPS (Clinical Professional Services) as the CRO (Contract Research Organization) to proceed with a Clinical Trial for CAR-T products in Korea. After reviewing multiple competent CRO's in Korea and multiple meetings with them, BPK has selected CLIPS who has outstanding experience as well as expertise in gene therapies and cell therapies. In addition, their knowledge on the clinical trials convinced BPK it could achieve a successful clinical trial for CAR-T products within the given timeline.

# **Key Management Change**

On March 1, 2018, Mr. Konstantin Lichtenwald has been appointed as a director and as Chief Financial Officer of the Company, replacing Collin Kim who will remain as a director. Ms. Julie Hajduk has resigned as director.

On September 4, 2018, Mr. Hans Frykman has been appointed as a director of the Company, Mr. Marco Nonni has resigned as a member of the board of directors. He will continue working with the Company on a consulting basis.

Effective March 14, 2019, Dr. Danny Joh has been appointed as a director of the Company.

# **Equity**

During the nine months ended September 30, 2019, the Company's wholly owned subsidiary, BP Korea issued 156,808 shares for proceeds of \$1,758,250.

During the year ended December 31, 2018, the Company issued 3,549,380 common shares related to the exercise of stock options for gross proceeds of \$1,419,752.

#### Loans

# Loans Receivable

The Company entered into loan agreements to lend a total of \$97,744 (KRW 83,000,000) to a director. The loans receivable were unsecured and due between April 16, 2019 (in default) and September 4, 2020. The loans bore interest of 1.20% per annum. During the year ended December 31, 2018, the loans were written off in full.

# Loans Payable

The following table summarizes the principal and interest amount in loans payable:

	Sept	ember 30, 2019	Dec	ember 31, 2018
Loans payable, unsecured:				
Non-interest bearing, unsecured and due on demand	\$	47,000	\$	47,000
Interest at 4.6% per annum, unsecured and due on demand (Note 11)		349,133		413,563
Interest at 5% per annum, unsecured and due on demand		235,945		251,226
Interest at 10% per annum, unsecured and due on demand		209,151		215,240
Total	\$	841,229	\$	927,029

During the period ended September 30, 2019, the Company recorded interest expenses of \$37,305 (2018 - \$Nil) related to short-term loans payable.

Long-term Loans Payable

Balance, December 31, 2017	\$ -
Additions	798,135
Effect of foreign exchange	17,049
Balance, December 31, 2018	\$ 815,184
Additions	367,632
Interest	22,611
Effect of foreign exchange	(80,702)
Balance, September 30, 2019	\$ 1,124,725

During the year ended December 31, 2018, the Company assumed a loan payable to the Industrial Bank of Korea ("IBK") to fund the land purchase agreement with KLHC.

The loan terms are as follows:

- Interest rate of 3.3% per year;
- Loan amount shall consist of 5 instalments of \$403,920 (KRW 330,000,000) and the sixth instalment of \$410,040 (KRW 335,000,000) starting on June 12, 2018 where the balance shall be covered by the Company;
- The Company shall pay interest only for the first 3 years and principle plus interest for the following 5 years; and
- If the Company defaults and does not proceed with land purchase, IBK shall be paid by KLHC.

#### LAND DEPOSIT

During the year ended December 31, 2017, the Company entered into an agreement with Korea Land & Housing Corp. ("KLHC") to acquire land for the purpose of constructing a research and development facility. The payment schedule is as follows:

Date	KRW	\$
December 12, 2017 (paid)	281,395,000	344,427
June 12, 2018 (paid)	422,555,000	517,207
December 12, 2018 (paid)	422,000,000	516,528
June 12, 2019 (paid)	422,000,000	516,528
December 12, 2019	422,000,000	516,528
June 12, 2020	427,908,000	523,759
December 12, 2020	429,405,230	525,592
	2,827,263,230	3,460,570

The title of the land transfers to the Company upon completion of the scheduled payments.

For the December 12, 2018 payment, the Company only paid \$407,592 (KRW 333,000,000) of the \$516,528 (KRW 422,000,000). The unpaid amount of \$108,936 (KRW 89,000,000) was paid during the period ended June 30, 2019.

For the June 12, 2019 payment, the Company only paid \$376,623 (KRW 333,000,000) of the \$516,528 (KRW 422,000,000). The unpaid amount of \$139,905 (KRW 89,000,000) was paid during the period ended September 30, 2019.

If the Company defaults and does not proceed with the purchase, the initial payment of \$344,427 (KRW 281,395,000) shall be forfeited.

### **OVERALL PERFORMANCE**

Since its inception in August 2005, Biocure has accumulated a deficit of \$23,171,386 (December 31, 2018 - \$20,007,358). While the Company generated minimal revenue during the years ended December 31, 2017 and 2016, the Company started generating revenue from its commercial platform during the year ended December 31, 2018, but near-term profitability is not expected. Biocure expects its operating losses to continue in the next fiscal year as it builds its commercial platform and invests in its product development, with primary focus for the next two years on Biopharmaceutical Production project and FMD production project.

The Company has funded its operations with proceeds from loans payable, equity financings, and expects to seek additional funding through equity financings to finance its product development, and corporate growth. However, if Biocure's product development and commercial activities do not show positive progress, or if capital market conditions in general or with respect to the life sciences sector or development stage companies such as Biocure are unfavorable, its ability to obtain additional funding will be adversely affected.

# **SELECTED QUARTERLY FINANCIAL INFORMATION**

The following table sets forth selected financial information for the three and nine months ended September 30, 2019 and comparable three and nine months ended September 30, 2018. The selected financial information set out below has been derived from the Interim Financial Statements and accompanying notes, in each case prepared in accordance with IFRS. The selected financial information set out below may not be indicative of the Company's future performance. The following discussion should be read in conjunction with the Interim Financial Statements.

(in Canadian dollars, unless noted otherwise)

				Three Months		For the Nine Months Ended			
				Septe	mber 30,			Septer	nber 30,
	Note		2019		2018		2019		2018
DEVENHE		Ф	1.642	Ф	75 100	Ф	2 102	Ф	77.227
REVENUE		\$	1,643	\$	75,129	\$	3,103	\$	77,337
COSTS OF GOODS SOLD	-		595		26,195		877		27,848
EVDENCEC			1,048		48,934		2,226		49,489
EXPENSES	0.0		24.665		<b>5</b> .6		104 225		62.001
Amortization	8,9		34,665		56		104,325		63,891
Consulting	11		107,381		26,190		230,313		68,291
Director fees	11		15,000		-		45,000		-
Filing fees			4,751		4,085		25,574		85,427
Finance costs	18		3,315		-		3,315		-
General and administrative			44,243		30,934		122,200		77,199
Interest	12,17		28,364		-		92,048		-
Management fees (recovery)	11		-		15,000		1,258		42,500
Motor vehicle expenses			1,268		1,302		3,448		5,411
Payroll	11		88,000		116,849		264,245		343,396
Professional fees			31,471		25,573		112,551		202,937
Rent			31,095		18,057		67,814		51,542
Research and development			160,588		52,889		459,088	1	,068,990
Share-based compensation			98,542		190,558		467,531		,154,279
Supplies			4,640		3,529	,	13,375	_	12,181
Travel and entertainment			76,777		65,970		147,977		233,790
Utilities			(2,223)		1,423		3,988		3,906
o unites	-		(2,223)		(552,415)	(3.1	64,050)	(5.4	413,740)
OTHER INCOME (EXPENSES)	-		121,011)		(332,713)	(3,1	104,050)	(5,	113,710)
Donation					(2,913)				(2,913)
Foreign exchange loss			9		296		(394)		286
Interest income							258		
			(5)		(35)				1,892
Loss on valuation of marketable securities	-		(791)		(2.652)		(2,068)		(50.5)
	-		(787)		(2,652)		(2,204)		(735)
LOSS FOR THE PERIOD		\$ (	(727,616)	\$	(506,133)	\$ (3,	164,028)	\$(5,	364,986)
OTHER COMPREHENSIVE INCOME (LOSS)									
Foreign currency translation			9,083		163,753		76,169		161,668
COMPREHENSIVE LOSS FOR THE PERIOD	-		(718,533)		(342,380)	(2.0	087,859)	(5 '	203,318)
COMIT REMEMSIVE LUSS FOR THE PERIOD			(110,333)	-	(342,380)	(3,0	101,039)	(3,	203,318)
BASIC AND DILUTED LOSS PER SHARE		\$	(0.01)	\$	(0.01)	\$	(0.03)	\$	(0.06)
WEIGHTED AVERAGE SHARE	(	Φ	(0.01)	Ф	(0.01)	Ф	(0.03)	Φ	(0.00)
OUTSTANDING – BASIC AND DILUTED	,	0,6	5,937,001	Q.	6,734,768	96	,937,001	05	,433,068
OUTSTAIDHIO - DASIC AND DILUTED		<b>り</b>	J, J J I , UU I	フ	U, / JT, / UO	70,	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	73	, <del>,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,</del>

### For the nine months ended September 30, 2019

#### Revenue

Revenue during the nine months ended September 30, 2019 and 2018 was \$3,103 and \$77,337, respectively.

## **Expenses**

Expenses for the nine months ended September 30, 2019 and 2018 were \$3,164,050 and \$5,413,740 respectively. The decrease of 42% was primarily due to the decrease in share-based compensation, filing fees, management fees, professional fees, travel and entertainment, and research development costs incurred during the current period. Decreases were partially offset by increases in amortization, general and administrative, interest, rent, director fees, and consulting fees. Overall, expenses decreased as a result of the decrease of the Company's share-based compensation and research and development activities during the current period.

#### Other comprehensive income

Other comprehensive income for the nine months ended September 30, 2019 and 2018 was \$76,169 and \$161,668, respectively. The change was due foreign currency translation.

# For the three months ended September 30, 2019

#### Revenue

Revenue during the three months ended September 30, 2019 and 2018 was \$1,643 and \$75,129, respectively.

#### **Expenses**

Expenses for the three months ended September 30, 2019 and 2018 were \$727,877 and \$552,415 respectively. The increase of 32% was primarily due to the increase in research and development, consulting fees, amortization, interest expenses, rent, and general and administrative expenses. Increases were partially offset by decreases in share-based compensation, payroll, and management fees. Overall, expenses increased as a result of the increase of the Company's research and development activities during the current period.

## Other comprehensive income

Other comprehensive income for the three months ended September 30, 2019 and 2018 was \$9,083 and \$163,753 respectively. The change was due foreign currency translation.

#### **QUARTERLY FINANCIAL INFORMATION**

The following table summarizes selected unaudited financial date for each of the last eight fiscal quarters, prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB") and Interpretations of Financial Reporting Interpretations Committee ("IFRIC"):

	Quarter Ended				
	September 30, 2019	June 30, 2019	March 31, 2019	December 31, 2018	
	("Q3 2019")	("Q2 2019")	("Q1 2019")	("Q4 2018")	
	\$	\$	\$	\$	
Revenue	1,643	413	-	10,942	
Operating expenses	727,877	1,869,179	567,339	1,166,383	
Other income (loss)	(787)	(1,417)	-	(93,814)	
Net loss for the period	(727,616)	(1,869,072)	(567,339)	(1,220,852)	
Basic and diluted loss per common					
share	(0.01)	(0.02)	(0.01)	(0.01)	

	Quarter Ended					
	September 30, 2018	June 30, 2018	March 31, 2018	December 31, 2017		
	("Q3 2018")	("Q2 2018")	("Q1 2018")	("Q4 2017")		
	\$	\$	\$	\$		
Revenue	75,129	2,208	-	(8,050)		
Operating expenses	552,415	3,849,244	1,012,081	270,556		
Other income (loss)	(2,652)	(153)	2,070	(2,917,640)		
Net loss for the period	(506,133)	(3,848,842)	(1,010,011)	(3,196,246)		
Basic and diluted loss per common						
share	(0.01)	(0.04)	(0.01)	(0.04)		

# LIQUIDITY AND CAPITAL RESOURCES

The continuing operations of the Company are dependent upon its ability to raise additional capital during the next twelve months and beyond to support current operations and planned development. As at September 30, 2019, the Company has not earned significant revenue and has an accumulated deficit of \$23,171,386 (December 31, 2018 - \$20,007,358). In order to reach sustainable business operations, they will continue to seek additional sources of financing.

The Company's cash balance as of September 30, 2019 was \$100,784 compared to \$108,616 as of December 31, 2018. As of September 30, 2019, the Company had current assets of \$367,214, current liabilities of \$1,470,606, and a working capital deficiency of \$1,103,392 compared to a working capital deficiency of \$1,725,999 as of December 31, 2018. The increase in working capital is primarily due to the Company's wholly owned subsidiary, BP Korea issuing 156,808 shares for proceeds of \$1,758,250 during the current period.

# **Operating Activities**

During the nine months ended September 30, 2019 and 2018, the Company's activities generated a decrease in cash of \$2,069,324 and \$2,164,799, respectively. The decrease in cash flows used in operating activities for the nine months ended September 30, 2019 is mainly attributable to the decrease in loss from operating activities after adjustments for non-cash items offset by the changes in non-cash working capital items. The change arose primarily from the net loss for the period of \$3,164,028, amortization of \$104,325, share-based compensation of \$1,467,531, interest of \$57,844, increase in prepaids and deposits of \$203,371 and a decrease in payables of \$351,830. The decrease in cash flows used in operating activities for the nine months ended September 30, 2018 arose primarily from the net loss for the period of \$5,364,986, amortization of \$63,891, share-based compensation of \$3,154,279, increase in prepaid expenses by \$368,525, and increase in payables of \$360,471.

## **Investing Activities**

During the nine months ended September 30, 2019 and 2018, the Company's investing activities generated a decrease in cash of \$564,642 and \$470,696, respectively. These variations are due to the payment of a land deposit in the current period, and the purchase of equipment and intangible assets and issuance of loan receivable during the previous period.

# **Financing Activities**

During the nine months ended September 30, 2019 and 2018, the Company's financing activities generated an increase in cash of \$2,580,504 and \$1,685,603, respectively. The increase in liquidities generated from financing activities during the nine months ended September 30, 2019, are due to the Company's wholly owned subsidiary, BP Korea issuing 156,808 shares for proceeds of \$1,758,250 during the current period, issuing convertible debentures for proceeds of \$490,160, and proceeds from loans of \$332,094. The increase in liquidities generated from financing activities during the nine months ended September 30, 2018, are due to a deposit from exercise of options proceeds of \$1,362,272, proceeds from loans of \$391,624. These increases are reduced by a repayment of advances from related party of \$68,293.

# **OFF-BALANCE SHEET ARRANGEMENTS**

The Company does not have any off-balance sheet arrangements, financings, or other relationships with unconsolidated entities or other persons, also known as "special purpose entities".

## **RELATED PARTY TRANSACTIONS**

#### **Key management compensation**

Key management personnel include those persons having authority and responsibility for planning, directing and controlling the activities of the Company as a whole. The Company has determined that key management personnel consist of members of the Company's Board of Directors and the Chief Executive Officer ("CEO"). The remuneration of directors and key management personnel were as follows:

	Nine months ended September 3			eptember 30,
		2019		2018
Management and Directors Fees	\$	257,421	\$	175,676
Share-based payments		629,901		824,623
Management fees –Former Director of the Company		=		4,500
Total	\$	887,322	\$	1,004,799

#### Loan payable to related parties

As of September 30, 2019, the Company has a loan of \$47,000 (December 31, 2018 - \$47,000) payable to a significant shareholder which is non-interest bearing, unsecured, and due on demand. As of September 30, 2019, the Company has a loan of \$349,133 (KRW 316,243,977 (December 31, 2018 - \$413,563 (KRW 339,660,102)) payable to the CEO of the Company which bears interest at 4.6% per annum, unsecured, and due on demand.

# PROPOSED TRANSACTIONS

The Company continues to engage in discussions with several financing groups and intends to provide a market update when the Company's management and board make a decision to proceed with any such financing.

#### SIGNIFICANT ACCOUNTING ESTIMATES

## **Significant Estimates and Assumptions**

The preparation of financial statements in accordance with IFRS requires the Company to make estimates and assumptions concerning the future. The Company's management reviews these estimates and underlying assumptions on an ongoing basis, based on experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. Revisions to estimates are adjusted for prospectively in the period in which the estimates are revised.

Estimates and assumptions where there is significant risk of material adjustments to assets and liabilities in future accounting periods include the recoverability of investments in KWULP and KWUC, useful lives of equipment, recoverability of receivables, fair value measurement and the timing of future cash flows of financial instruments, and the measurement of deferred tax assets and liabilities.

#### **Significant Judgements**

The preparation of consolidated financial statements in accordance with IFRS requires the Company to make judgments, apart from those involving estimates, in applying accounting policies. The most significant judgments in applying the Company's accounting policies in these consolidated financial statements were:

• Evaluating whether or not costs incurred by the Company in developing its pharmaceutical products meet the criteria for capitalization to intangible assets. Management determined that as at September 30, 2019, it was not yet able to demonstrate with sufficient certainty that future economic benefits will flow to the Company. Accordingly, all research and development costs incurred to date have been expensed.

Other significant judgments in applying the Company's accounting policies relate to the assessment of the Company's ability to continue as a going concern, the classification of its financial instruments and the classification of leases as either operating or finance type leases.

# NEW ACCOUNTING STANDARDS ADOPTED DURING THE PERIOD

As of January 1, 2019, the Company adopted the new and amended IFRS pronouncements in accordance with transitional provisions outlined in the respective standards. The adoption of these standards did not have a material impact on the consolidated results, financial position or accounting policies of the Company. Significant standards adopted include the following:

### New standard IFRS 16 "Leases"

This new standard replaces IAS 17 "Leases" and the related interpretative guidance. IFRS 16 applies a control model to the identification of leases, distinguishing between a lease and a service contract on the basis of whether the customer controls the asset being leased. For those assets determined to meet the definition of a lease, IFRS 16 introduces significant changes to the accounting by lessees, introducing a single, on-balance sheet accounting model that is similar to current finance lease accounting, with limited exceptions for short-term leases or leases of low value assets. Lessor accounting is not substantially changed. The standard is effective for annual periods beginning on or after January 1, 2019, with early adoption permitted for entities that have adopted IFRS 15.

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 financial statements.

### FINANCIAL INSTRUMENTS AND RISKS

Classification of financial instruments

Financial assets included in the statement of financial position are as follows:

	Septen	ıber 30, 2019	Decemb	er 31, 2018
Fair value through other comprehensive income (loss)				_
Investments	\$	1,967,234	\$	1,969,633
	\$	1,967,234	\$	1,969,633

Financial liabilities included in the statement of financial position are as follows:

	<b>September 30, 2019</b>		<b>December 31, 2018</b>		
Fair value through profit or loss				_	
Non-derivative financial liabilities:					
Accounts payable	\$	454,543	\$	772,757	
Loans payable		1,965,654		1,742,213	
	\$	2,420,497	\$	2,514,970	

#### Fair value

The Company has applied a three-level hierarchy to reflect the significance of the inputs used in making fair value measurements. The three levels of fair value hierarchy are:

- Level 1 Unadjusted quoted prices in active markets for identical assets or liabilities;
- Level 2 Inputs other than quoted prices that are observable for assets or liabilities, neither directly or indirectly; and
- Level 3 Inputs for assets or liabilities that are not based on observable market data.

The Company's financial instruments consist of cash, loan receivable, accounts payable, due to related party, preferred share liabilities and loans payable. The fair value of these financial instruments, other than cash and preferred share liabilities, approximates their carrying values due to the short-term nature of these instruments. Cash is measured at fair value using level 1 inputs.

Financial liabilities measured at fair value consisted of preferred share liabilities, which is measured using level 3 inputs.

The Company is exposed to a variety of financial risks by virtue of its activities including currency, credit, interest rate and liquidity risk.

## a) Credit risk

Credit risk is risk of financial loss to the Company if the counterparty to a financial instrument fails to meet its contractual obligations. The Company's cash is held in large Korean financial institutions and is not exposed to significant credit risk.

## b) Interest rate risk

Interest rate risk is the risk that the fair value of future cash flows of a financial instrument will fluctuate because of changes in market interest rates. The Company is exposed to limited interest rate risk.

# c) Liquidity risk

Liquidity risk is the risk that the Company will not be able to meet its obligations as they come due. The Company's ability to continue as a going concern is dependent on management's ability to raise the required capital through future equity or debt issuances. The Company manages its liquidity risk by forecasting cash flows from operations and anticipating any investing and financing activities. Management and the directors are actively involved in the review, planning, and approval of significant expenditures and commitments.

## d) Foreign currency risk

The Company's functional currency is the South Korean Won and major transactions are in South Korean Wons. As of September 30, 2019, the Company had \$316,685 (December 31, 2018: \$94,822) in financial liabilities denominated in Canadian Dollars. The remaining values in financial assets and financial liabilities are denominated in South Korean Wons. Management believes that the foreign exchange risk related to currency conversion is minimal and therefore does not hedge its foreign exchange risk.

#### e) Capital Management

The Company defines capital that it manages as its shareholders' equity. When managing capital, the Company's objective is to ensure the entity continues as a going concern as well as to maintain optimal returns to shareholders and benefits for other stakeholders. The Board of Directors does not establish quantitative return on capital criteria for management, but rather relies on the expertise of the Company's management to sustain future development of the business.

Management reviews its capital management approach on an ongoing basis and believes that this approach, given the relative size of the Company, is reasonable. There were no changes to the Company's approach to capital management during the period ended September 30, 2019.

## RISKS AND UNCERTAINTIES

Possible Failure to Realize Anticipated Benefits of the Arrangement

Biocure has completed a "going public" transaction by way of a reverse take-over to better position itself in the industrial stage of the biopharmaceutical industry and to create opportunities to realize certain benefits such as commercialization of the biopharmaceutical industry, increased liquidity, greater access to capital markets, and increased ability to pursue acquisition opportunities. Biocure has a long-term objective to expand its business to overseas markets such as South America, Middle East, North Africa, and Asia. The reverse takeover transaction could provide Biocure with a platform to achieve such a goal. There can be no assurance that after the RTO transaction, Biocure will be able to realize the anticipated growth opportunities and synergies required to achieve the anticipated benefits.

### Biopharmaceutics Public Market Risks

Prospects for companies in the biopharmaceutical industry generally may be regarded as uncertain given the nature of the industry and, investments in biopharmaceutical companies should be regarded as speculative. Biopharmaceutical research and development involves a significant degree of risk. However, main products of Biocure are biosimilar, which are known and proven products by multinational pharmaceutical companies. Biocure has been developing a few biosimilar products from the patents of which were expired or about to expire in the near future. Therefore, the risks involved in such biosimilar products are relatively lower than that of so called, new biopharmaceuticals.

Nevertheless, an investor should carefully consider the risks and uncertainties described below. The risks and uncertainties described below are not an exhaustive list. Additional risks and uncertainties not presently known to Biocure or that Biocure believes to be immaterial may also adversely affect Biocure's business. If any one or more of the following risks occur, Biocure's business, financial condition, and results of operations could be seriously harmed.

Further, if Biocure fails to meet the expectations of the public market in any given period, the market price of Biocure shares could decline.

#### Commercialization Uncertainties

To launch biosimilar products of Biocure to the market, additional investment in development, product validation, manufacturing, production scale-up, pre-clinical & clinical testing, and regulatory submissions of such products is required prior to commercialization. There can be no assurance that any such products will be commercialized in the time as planned.

# Additional Financing Requirements and Access to Capital

Biocure will require substantial additional funds for further research and development, planned clinical testing, regulatory approvals, establishment of manufacturing capabilities and, if necessary, and the marketing and sale of its products. Biocure may attempt to raise additional funds for these purposes through public or private equity, debt financing, collaborations with other biopharmaceutical companies, and/or from other sources. There can be no assurance that additional funding or partnership will be available on terms acceptable to Biocure and which would foster successful commercialization of Biocure products.

# Government Regulations

Biopharmaceutical companies operate in a high-risk regulatory environment. Biopharmaceutical products are governed by numerous statutes and regulations in Korea and other countries where Biocure intends to market its products. The subject matter of such legislation includes approval of manufacturing facilities, controlled research and testing procedures, review and approval of manufacturing, preclinical and clinical data prior to marketing approval, as well as regulation of marketing activities. The process of completing clinical testing and obtaining required approvals for biosimilar products is likely to take about a year and require the expenditure of moderate resources. There can be no assurance that the regulators will not require modification to any submissions that may result in delays to obtain regulatory approvals. Any delay to obtain regulatory approvals could adversely affect the ability of Biocure to utilize its technology, thereby adversely affecting operations. There is no assurance that Biocure will be able to timely and profitably produce its products while complying with all the applicable regulatory requirements.

#### Patents and Proprietary Technology

The biosimilar products that Biocure is currently pursuing do not have patent and proprietary issues in general due to the fact that Biosimilar implies they are free from existing patents already. At the same time, Biosimilar technology is not protected by patents or proprietary rights.

Original patent holders could extend the period of the patent in specific countries that Biocure is planning to enter into. There is no assurance that Biocure products do not face any conflicts in patent and proprietary rights.

# Dependence on Collaborative Partners and Others

Biocure activities will require it to enter into various arrangements with corporations, academic collaborators and others for research, development, clinical testing, manufacturing, marketing, and commercialization of its products. Biocure intends to attract corporate partners and enter into additional research collaborations. There can be no assurance, however, that Biocure will be able to establish such additional collaborations on favorable terms, if at all, or that its current or future collaborations will be successful. Failure to attract commercial partners for its products may result in Biocure incurring substantial clinical testing, manufacturing, and commercialization costs prior to realizing any revenue from product sales or result in delays or program discontinuance if funds are not available in sufficient quantities.

If any collaborative partner in oversea countries where Biocure plans to implement pre-clinical and clinical testing program for biosimilar fails to meet its timeline, or local regulations and procedures, Biocure's business may be adversely affected. Failure of a collaborative partner to participate in preclinical and clinical testing program could delay the commercialization of products related to such programs.

In addition, there can be no assurance that the collaborative partners will not pursue other alternative products either alone or in collaboration with others, including Biocure's competitors.

## Rapid Technological Change

The biopharmaceutical industries are characterized by rapid and substantial technological change. There can be no assurance that developments by others will not render Biocure's proposed products or technologies non-competitive, or that Biocure will keep pace with technological developments. Competitors have developed or are developing technologies that could be the basis for competitive products. Some of these products have an entirely different approach, compared with products to be developed by Biocure and could be more effective and less costly than the products to be developed by Biocure. In addition, alternative forms of medical treatment may compete with Biocure's products.

# Competition

Technological competition from biopharmaceutical companies is intense and is expected to increase. Potential competitors of Biocure may have more product development, financial, scientific, marketing, and human resources capabilities exceeding those of Biocure. Competitors may develop products before Biocure obtain regulatory approval for such products more rapidly than Biocure, or develop products which are more effective than those that Biocure intends to develop. Research and development by others may render Biocure's proposed technology or products obsolete or non-competitive.

# Potential Product Liability

Pharmaceutical products involve an inherent risk of product liability claims and associated adverse publicity. Product liability insurance is costly, availability is limited, and may not be available on terms that would be acceptable to Biocure, if at all. A product liability claim brought against Biocure could have a material adverse effect upon Biocure and its financial condition.

Reliance on Key Personnel

Biocure is dependent on certain members of its management and scientific staff, as well as consultants and contractors, the loss of services of one or more of whom could adversely affect Biocure. In addition, Biocure's ability to manage growth effectively will require it to continue to implement and improve its management systems and to recruit and train new employees. There can be no assurance that Biocure will be able to successfully attract and retain skilled and experienced personnel.

# Minimal Product Revenues and History of Losses

To date, Biocure has recorded minimal revenues from the sale of biopharmaceutical products. Biocure expects to incur additional losses during the periods of research and development, clinical testing, and application for regulatory approval of its products. Biocure expects to incur losses until payments from corporate collaborations, product sales and/or royalty payments generate sufficient revenues to fund its continuing operations.

Volatility of Share Price, Absence of Dividends and Fluctuation of Operating Results

Market prices for the securities of biopharmaceutical companies, including Biocure, have historically been highly volatile. Factors such as fluctuation of Biocure's operating results, announcements of technological innovations, patents or new commercial products by Biocure or competitors, results of clinical testing, regulatory actions, or public concern over the safety of biopharmaceutical products, and other factors could have a significant effect on the share price or trading volumes for the common shares. Biocure shares, if traded publically, may be subject to significant price and volume fluctuations and may continue to be subject to significant price and volume fluctuations in the future. Biocure has not paid dividends to date and does not expect to pay dividends in the foreseeable future.

## Conflict of Interest

Certain directors and senior officers of Biocure may, from time to time, be employed by or affiliated with organizations that have entered into agreements with Biocure. As disputes may arise between these organizations and Biocure, or certain organizations may undertake or have undertaken research with competitors of Biocure, there exists the possibility for such persons to be in a position of conflict. Any decision or recommendation made by these persons involving Biocure will be made in accordance with his or her duties and obligations to deal fairly and in good faith with Biocure and such other organizations. In addition, as applicable, such directors and officers will refrain from voting on any matter in which they have a conflict of interest.

No Key Man Insurance

The Company does not currently have key man insurance in place in respect of any of its senior officers or personnel.

#### **OUTSTANDING SHARE DATA**

The Company has authorized an unlimited number of common shares without par value.

As of September 30, 2019, and the date of this MD&A, there were 96,937,001 common shares issued and outstanding.

The Company is authorized to issue an unlimited number of the preferred shares with par value of \$0.02 (KRW 20.83) per share. The preferred shares entitle each holder a voting right and the preference on the dividends and the distribution of assets over the holder of common shares. The preferred shares are cumulative, redeemable, and convertible. As of September 30, 2019, and the date of this MD&A, the Company had Nil preferred shares issued and outstanding.

As of September 30, 2019, and the date of this MD&A, there are Nil warrants issued and outstanding.

As of September 30, 2019, and the date of this MD&A, there are 6,300,000 stock options issued and outstanding.

# **CONTRACTUAL OBLIGATIONS AND COMMITMENTS**

During the year ended December 31, 2016, the Company agreed to participate in a joint research project until August 9, 2019, where it is to pay an annual participation fee of \$18,589 (KRW 17,080,000).

Year	Commitment
2019	\$ -

# **CLAIMS AND LAWSUITS**

None.

# **CONTINGENT LIABILITY**

None.

# **ADDITIONAL INFORMATION**

The Company files annual and other reports and other information with Canadian securities regulatory authorities. The documents are available to the public at <a href="http://www.sedar.com">http://www.sedar.com</a>.

# **APPROVAL**

The Board of Directors of the Company has approved the disclosure contained in this MD&A.