

WPD Pharmaceuticals Inc.

Management's Discussion & Analysis

For the years ended December 31, 2022 and 2021 (Expressed in Canadian Dollars)

# **WPD Pharmaceuticals Inc.** Management's Discussion & Analysis For the Years Ended December 31, 2022 and 2021

This Management's Discussion and Analysis ("MD&A") provides relevant information on the operations and financial results of WPD Pharmaceuticals Inc. ("WPD" or the "Company") for the years ended December 31, 2022 and 2021.

Except for historical information, this MD&A includes forward-looking statements which are subject to risks and uncertainties. See – "*Cautionary Note Regarding Forward-Looking Information*". Actual results may differ materially from those in such forward-looking statements. The Company assumes no obligation to update its forward-looking statements to reflect results, changes in assumptions or changes in other factors affecting such statements.

The following discussion is Management's assessment and analysis of the results of operations and financial conditions of the Company and should be read in conjunction with the Company's audited consolidated financial statements and related notes thereto for the years ended December 31, 2022 and 2021, which have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB") and can be found on SEDAR at <u>www.sedarplus.ca</u>.

This MD&A is based on information available up to January 25, 2024, the date on which it was prepared and approved by the Board of Directors. All dollar figures stated herein are expressed in Canadian dollars except unless otherwise specified.

# Narrative Description of the Business

WPD is a biotechnology research and development company with a focus on oncology, namely research and development of medicinal products involving biological compounds and small molecules. It operates its business primarily through WPD Pharmaceuticals Sp. z o.o. ("WPD Poland"), the operating branch of the Company and a subsidiary till November 25, 2022. After district court for the city of Warsaw, Poland on November 25, 2022, registered an increase in the share capital at WPD Poland, Houston Pharmaceuticals Inc. ("HPI") and the Company owned 80.95% and 19.05% of WPD Poland's share capital respectively. The Company was determined to have lost control of the previously consolidated subsidiary WPD Poland on November 25, 2022 and has been deconsolidated accordingly effective that date.

WPD has 8 novel drug candidates with 4 that are in clinical development stage. These drug candidates were researched at institutions including Mayo Clinic and Emory University ("Emory"). WPD currently has ongoing collaborations with Wake Forest University and leading hospitals, scientific institutes and academic centers in Poland. WPD has entered into license agreements with Wake Forest University Health Sciences and sublicense agreements with Moleculin Biotech Inc. ("Moleculin") and CNS Pharmaceuticals, Inc. ("CNS Pharmaceuticals"), respectively, each of which grant WPD an exclusive, royalty-bearing sublicense in certain territories to certain technologies of or licensed to the licensor. The sublicense agreement with Moleculin was terminated in March 2023. Such agreements provide WPD with certain research, development, manufacturing and sales rights, among other things. The sublicense territory from CNS Pharmaceuticals includes 30 and 29 countries, respectively, in Europe, Asia, including Russia.

#### About Moleculin

Moleculin is a clinical stage pharmaceutical company focused on the development of a broad portfolio of oncology drug candidates for the treatment of highly resistant tumors and viruses. The Company's clinical stage drugs are: Annamycin, a Next Generation Anthracycline, designed to avoid multidrug resistance mechanisms with little to no cardiotoxicity being studied for the treatment of relapsed or refractory acute myeloid leukemia, more commonly referred to as AML, WP1066, an Immune/Transcription Modulator capable of inhibiting p-STAT3 and other oncogenic transcription factors while also stimulating a natural immune response, targeting brain tumors, pancreatic cancer and hematologic malignancies, and WP1220, an analog to WP1066, for the topical treatment of cutaneous T- cell lymphoma. Moleculin is also engaged in preclinical development of additional drug candidates, including other Immune/Transcription Modulators, as well as WP1122 and related compounds capable of Metabolism/Glycosylation Inhibition.

# About CNS Pharmaceuticals

CNS Pharmaceuticals is developing novel treatments for primary and metastatic cancers of the brain and central nervous system. Its lead drug candidate, Berubicin, is proposed for the treatment of glioblastoma multiforme (GBM), an aggressive and incurable form of brain cancer. CNS Pharmaceuticals holds a worldwide exclusive license to the Berubicin chemical compound and has acquired all data and know-how from Reata Pharmaceuticals, Inc. related to a completed Phase 1 clinical trial with Berubicin in malignant brain tumors, which Reata conducted in 2006. CNS commended Patient Enrollment in Potentially Pivotal Study of Berubicin during 2021. In December 2022 first patient enrolled in the Phase 1B/2 WPD clinical trial of intravenously infused Berubicin in the treatment of adult patients with recurrent glioblastoma multiforme (WHO grade IV) after failure of standard first line therapy, has received the first dosing of Berubicin.

The Company's business objective is the pursuit of regulatory approvals to sell medicines to the public. To accomplish this objective, the Company intends to:

- (a) continue drug trials and research;
- (b) scale up its manufacturing process to be ready for Good Manufacture Practice ("GMP") manufacturing; and
- (c) partner with an established pharmaceutical company to develop or license out and distribute our products.

The above objective may change at any time depending on market conditions. There is no certainty that the Company's business objective will be achieved on the terms anticipated or at all. See "*Risk Factors*".

To accomplish the foregoing business objectives, the Company will target the following milestones:

- (a) in vitro and animal trials; and
- (b) clinical and human trials.

The above milestones may change at any time depending on market conditions and are subject to various risks associated with conducting clinical trials, receiving regulatory approval and acquiring additional funding, as applicable, on terms acceptable to the Company. See – "Risk Factors".

#### **Principal Products or Services**

# WPD101

WPD101 is a biologic compound developed by WPD under the Wake Forest License Agreement. It is composed of recombinant proteins conjugated with bacterial toxins preferentially targeting GBM-specific receptors. After internalization of the protein-receptor complex, cancer cells are eliminated due to the bacteria-toxins-induced cytotoxic effects, thereby limiting tumor growth. WPD101 is currently in clinical development in animals and its consistent anticancer properties are demonstrated and validated in dogs. Overall, results of these studies indicate the significant potential of WPD101 demonstrating the same effective treatment of GBM in humans. Start of Phase 1 clinical trials is dependent on identifying a suitable Good Manufacture Practice GMP vendor.

# WPD101 Program

The WPD101 research and development program under agreement with the Polish National Center for Research and Development ("NCRD") is planned to continue until 2023. On May 1, 2023 The Company divided the WPD101 program into WPD101a and WPD101b products. WPD101a is ready for GMP manufacturing for clinical studies, but due to limited financial resources and failure to meet the deadlines set out in the project agreement, management decided to withdraw from the implementation of the WPD101 project. WPD informed a grant provider, National Center for Research and Development, of management's decision and terminated the contract for these projects at an early stage of development. WPD will seek partners and investors, who could help in further development of WPD101a and other products that may be developed under the license agreement with Wake Forest University and plans to submit applications for new grants for further development of this line of product.

The grant funds, currently committed together with the portion of expenditures required by the grants to be contributed by WPD from other sources, will enable the completion of the research program, including production of the biologically active compound in a GMP facility with all the necessary quality standards and pre-clinical development using animal models.

# Berubicin (WPD104)

Berubicin is a new anthracycline proposed for the treatment of glioblastoma multiforme (GBM), an aggressive and incurable form of brain cancer. CNS holds a worldwide exclusive license to the Berubicin chemical compound and has acquired all data and know-how from Reata Pharmaceuticals, Inc. related to a completed Phase 1 clinical trial with Berubicin in malignant brain tumors, which Reata conducted in 2006. In this trial, 44% of patients experienced a statistically significant improvement in clinical benefit. This 44% disease control rate was based on 11 patients (out of 25 evaluable patients) with stable disease, plus responders. One patient experienced a durable complete response and remains cancer-free as of February 20, 2020. These Phase 1 results represent a limited patient sample size and, while promising, are not a guarantee that similar results will be achieved in subsequent trials Phase 1/2 of the clinical trial is expected to begin in 2021. WPD also plans to continue development of Berubicin in the pediatric population (first-in-children Phase 1 clinical trial).

A clinical trial for adults and a Phase 1 clinical trial for children is planned for Berubicin. In December 2022 first patient enrolled in the Phase 1B/2 clinical trial of intravenously infused Berubicin in the treatment of adult patients with recurrent glioblastoma multiforme (WHO grade IV) after failure of standard first line therapy, has received the first dosing of Berubicin. In Phase 2 trials, WPD plans to evaluate the candidate drug's effectiveness in about 50 adult patients with GBM, and examine the possible short- term side effects (adverse events) and risks associated with the drug. WPD will verify whether the drug acts in accordance with the expected molecular mechanism, and whether the drug improves the GBM condition. Researchers will analyze optimal dose strength and schedules for using the drug. If the results of the Phase 2 trial are positive, the drug will move on to Phase 3 trials. All Phase 2 clinical trials must be reviewed and approved by an independent ethics committee and either the European Medicines Agency ("EMA") or the local country's authorized medical agency. Successful completion of Phase 2 allows for commencement of Phase 3. At the Phase 3 stage, there may be additional interest from third parties to sub- license some of the technology developed.

WPD decided to end the WPD-201 clinical trial for Berubicin in the treatment of recurrent glioblastoma multiforme (GBM). This strategic decision comes in light of progress made by their licensor, CNS Pharmaceuticals (CNS), in the potentially pivotal CNS-201 trial. CNS has successfully enrolled more than 230 patients in the CNS-201 trial, and the Data and Safety Monitoring Board (DSMB) has provided a recommendation following the interim futility analysis to continue the trial without any modification. This milestone underscores that Berubicin has achieved the specified relative level of efficacy and safety in the trial versus the control arm of Lomustine.

Given these developments, WPD Poland has carefully evaluated the landscape and determined that the continuation of the WPD-201 trial, which is currently in its early stages, would not bring any additional material value to the overall Berubicin registration package. WPD Pharmaceuticals recognizes the importance of consolidating efforts with CNS to expedite the development and potential approval of Berubicin for the treatment of recurrent GBM. WPD expects to reallocate resources towards its pipeline of products coming from its license agreement with Wake Forest University.

After Phase 3 clinical trials prove successful, the company can apply to the EMA for marketing authorization, which means the company can sell the product to the medical industry. However, it is most common and likely that the company will partner with an established pharmaceutical company to carry out the sale and distribution of the product.

WPD plans to apply, if possible, with an established pharmaceutical company to the EMA to dispense with the requirements of Phase 3 clinical trials and apply directly to market to the medical industry after Phase 2 clinical trials because of the large unmet medical needs of certain oncology patients, especially glioblastoma.

#### Berubicin Program (WPD104 Program)

The grant funds, currently committed together with the portion of expenditures required by the grants to be contributed by WPD from other sources, will enable the completion of the Berubicin research program, including production of the biologically active compound in a GMP facility. The Berubicin research program will include the following breakdown of anticipated costs:

- (i) direct costs, including all necessary salaries to employees, necessary reagents, chemicals, analytes, many disposable and reusable materials, research and analytical equipment;
- (ii) costs of rental of specialist research equipment and infrastructure for conducting pre-clinical research (in vitro studies); and
- (iii) external service, including active compound manufacturing according to GMP and contract research services.

The Berubicin development program is focused on clinical studies performance. It will include the following breakdown of anticipated costs:

- (i) direct costs including all necessary salaries to employees and costs of contracts with clinical sites and materials and equipment necessary for clinical trial performance; and
- (ii) vendors, including investigational product manufacturing in dedicated GMP facility and cost of drug release for clinical trial, according to standards and regulations, Contract Research Organization ("CRO") service with clinical trial monitoring, pharmacovigilance and biostatistics and analysis of pharmacokinetics.

The Berubicin research program includes pre-clinical tests to determine the prospective use of this molecule with other anticancer compounds. Research includes *in vitro* and *in vivo* studies.

#### Annamycin

Annamycin is a next generation anthracycline that is licensed to WPD from Moleculin and is being developed with an initial focus on acute myeloid leukemia ("AML"). A common problem with leading AML induction therapy drugs is their cardiotoxicity and multidrug resistance induction. On March 20, 2023, the Company signed a sublicence termination agreement with Moleculin Biotech, Inc. ("Moleculin"). Under the termination agreement Moleculin will pay WPD (or its designees) US\$700,000, which has been paid, and will issue to WPD (or its designees) such number of shares of Moleculin's common stock equal to US\$800,000 divided by the five-day average closing price per share of Moleculin prior to the date of the termination agreement.

The term cardiotoxic refers to drugs that can cause severe, permanent and sometimes fatal damage to the heart. Multidrug Resistance ("MDR") refers to mechanisms by which many cancers develop resistance to chemotherapy drugs and is a major factor in the failure of many forms of chemotherapy. MDR mechanisms affect a variety of blood cancers and solid tumors, including breast, ovarian, lung, and lower gastrointestinal tract cancers. Tumors usually consist of mixed populations of malignant cells, some of which are drug-sensitive while others are drug-resistant. Chemotherapy eliminates drug-sensitive cells but leaves behind a higher proportion of drug-resistant cells. As the tumor begins to grow again, chemotherapy may fail because the remaining tumor cells are now able to recognize the chemotherapy and actively expel drugs out of the cells, thus rendering the tumor resistant to the therapy. As MDR begins to counteract chemotherapy drugs, it can require higher doses to eliminate tumor cells, yet the unwanted side effects of the drugs, like cardiotoxicity, ultimately prevent increases in dosing.

Annamycin has little to no cardiotoxicity, avoids multidrug resistance, and has been shown to be more potent in AML cell lines. Moreover, Annamycin has shown activity in patients who failed standard of care. Its unique design prevents it from being recognized by the MDR mechanisms that typically defeat the currently approved anthracyclines, allowing it a better opportunity to accumulate to therapeutic levels without dangerous increases in dosing.

The first line treatment of cancerous AML cells is called "7+3 induction therapy," a 50+ year old treatment that we estimate is effective for only about 20% of the AML population patients. In order to achieve remission and become eligible for a curative bone marrow transplant, the patient must post very positive results from the first-line (induction phase) therapy, which requires destruction of 95% of the leukemia cells. On average, around 80% of all AML patients will fail to respond to or will relapse from this induction therapy. Annamycin is seeking approval as a second line treatment for these 80% of patients.

In a proof-of-concept Phase I/II clinical trial, Annamycin was given to patients who had failed an average of five previous induction therapy attempts and 37% of those patients cleared enough of their leukemic cells to qualify for a bone marrow transplant. WPD's goal is to repeat this performance in a larger clinical trial, which management believes could warrant new drug approval.

# Development

WPD's licensor, Moleculin, is conducting Phase I/II clinical trials, both in the U.S. and EU. In addition, first patient was enrolled in the Phase 1B/2 clinical trial of Annamycin in the treatment of soft tissue sarcoma (STS) lung metastases, has received the first dose of Annamycin. The start of clinical trial is a consequence of the project granted by Agencja Badań Medycznych (The Medical Research Agency), that was communicated by WPD in a news release dated February 9, 2021. The Phase I study (MB-104) of the U.S. trial for Annamycin in Subjects With Acute Myeloid Leukemia (AML) has been completed. Management believes a repeat of prior results should afford Annamycin an accelerated approval pathway as a second line induction therapy for relapsed or refractory AML (R/RAML).

# WPD1066

WP1066, licensed to WPD from Moleculin, represents a new class of drugs, which are called "Immune/Transcription Modulators." It is currently being developed to treat glioblastoma and melanoma brain metastases.

WP1066 has a dual mechanism of action as a first-in-class drug to both directly inhibit tumor signaling (p-STAT3, HIF-1 $\alpha$ , c-Myc) while also stimulating patient immune response (Tregs). In other words, WP1066 has demonstrated the ability to directly induce apoptosis (tumor cell death) but also the ability to stimulate an immune response to tumors allowing T-cells to attack tumor cells. Another important characteristic of WP1066 is its ability to cross the bloodbrain barrier, which could make it a good candidate for potentially treating brain tumors and other malignancies of the central nervous system (CNS), including CNS metastasis.

WP1066 affects tumors both directly and indirectly by modulating transcription factors resulting in direct tumor cytotoxicity while also stimulating a natural immune response by reducing Regulatory T-cells (Tregs).

Unique dual action (direct cytotoxic effect on tumor cells and separately boosting the natural immune system to attack tumors) make WP1066 and its analogs well suited candidates to treat effectively a wide range of tumors and to serve as a critical element in creating effective drug combination therapies, for example with products based on Wake Forest license, for targeting some of the most unresponsive cancers.

#### Development

WP1066 is currently being studied via an investigator-initiated IND at The University of Texas MD Anderson Cancer Center in a dose-escalation Phase I clinical trial in patients with brain tumor or melanoma metastasis to the brain. We recently announced pharmacokinetic data from that trial that demonstrated bioavailability of our drug via oral administration, actually showing the presence of WP1066 in blood plasma.

That continued success is now helping to accelerate plans for another investigator-initiated trial, this time in pediatric brain tumors, at Emory. At the 2018 annual meeting of the Society for Neuro Oncology (SNO), Emory researchers reported encouraging activity in their pediatric brain tumor models using WP1066.

Apart from brain tumors, acute myeloid leukemia, or AML, is often associated with a high upregulation of p-STAT3. Because WP1066 is a potent inhibitor of p-STAT3 and the Phase I clinical trial is now suggesting that we can get WP1066 into patients' bloodstreams, we could now have a new way to combat AML, in addition to our Next Generation Anthracycline, Annamycin.

#### **Operations**

WPD occupies approximately 100 square meters of laboratory and office space in Warsaw, Poland and Wrocław, Poland, and also has access to shared labs at both the University of Warsaw Biological and Chemical Research Centre and Wroclaw Technology Park. WPD has 16 employees, 8 of whom are involved in research and 8 of whom are involved in other aspect of operations, including quality, project management, medical and scientific documentation, grant writing and administration.

WPD is conducting research and development using its own resources including researchers, laboratory technicians, pre-clinical and clinical trials managers. It also subcontracts out research and development. This part includes such activities as pre-clinical trials performance on animal models that needs special infrastructure, CRO services, in laboratory pharmacokinetics analysis that meets the standards of Good Laboratory Practice ("GLP"), manufacturing of active pharmaceutical ingredients ("API") and investigational products dedicated for clinical trials, that need to be produced according to GMP standards and quality control defined by national and European regulations.

Development of WPD101 includes production of the active compound in laboratory/small scale and development of methods for quality control. Subcontracting includes manufacturing of the API and IP for the purpose of clinical trials by the specified manufacturer, that meets the standards of GMP.

Development of Berubicin includes testing of the active compound by WPD in laboratory/small scale. Subcontracting includes manufacturing of the API and IP for the purpose of clinical trial by specified manufacturers that meets the standards of GMP.

WPD's operations in Poland are conducted in Polish, but much of WPD's business is done with or in other countries, in which case English becomes the primary language used. Transactions in Poland use the Polish Zloty, but WPD uses the Euro or the United States dollar for most of its most important transactions, including licenses, collaborations, sublicenses, research grant applications, marketing and most other functions. WPD's licensors include Moleculin and CNS Pharma, which are both NASDAQ-listed US companies, and WFUHS, a major U.S. university. Such licensors work with WPD and conduct precise scientific research to ensure that drug candidates are developed to a standard that would be acceptable to the US Food and Drug Administration and the European EMA. WPD's clinical trial standards are comparable to those of large, global drug production companies.

# Summary

The final products that may come from WPD's research and development are years away from commercialization. It is likely that WPD will partner with large pharmaceutical companies to develop and sell its products worldwide should these products prove to be successful. In the meantime, WPD is raising awareness of compounds and its brand in both the oncology and pharmaceutical industries and is working on possible partnerships with established pharmaceutical companies.

WPD is developing products for the global market but, it is worth considering that according to EU Commission data for Poland, where WPD's research base is located, Poland is one of the top five countries in Europe in terms of highest incidence and mortality rates of brain and CNS cancer (source: https://ecis.jrc.ec.europa.eu). Poland is also one of main hubs for clinical research in the Central European region and Europe and regulations for clinical trials are harmonized on the EU level.

# **Operational Update**

In January 2021, the Company engaged an important critical imaging services during the Berubicin phase 2 clinical trials which are scheduled to start in February 2021.

Image Analysis Group ("IAG") has deep expertise in partnering with global biotech companies to provide centralized reading and analysis of patient responses in real time. IAG's scientific and clinical imaging expertise in the field of glioblastoma multiforme ("GBM"), coupled with IAG's proprietary Artificial Intelligence (AI) powered platform DYNAMIKA will allow WPD and its partners to review efficacy assessments, objective responses, and to thoroughly explore Berubicin's effect in patients with GBM.

Advanced cancer therapies often lead to pseudo-progression, a local tissue reaction resulting from immune cell infiltration, causing inflammation, tumor necrosis and oedema which are often misinterpreted as tumor growth on traditional MRIs. Under the arrangement, IAG will utilize its advanced AI-driven methodologies that provide reliable early efficacy readouts. Pseudo-progression is difficult to distinguish from disease progression using routine clinical M RI assessments, and having IAG's advanced technology will be crucial for early detection and progression.

In January 2021, the Company signed a contract with Clinigen Clinical Supplies Management ("Clinigen"), a leading clinical supply management business, to provide critical services during the Berubicin phase 2 adult and phase 1 pediatric clinical trials which are scheduled to start in February 2021 and May 2021, respectively.

For nearly half a century, Clinigen has built a reputation as one of the most trusted specialty logistics companies in the world through its unsurpassed knowledge, global reach and flawless supply chain execution. Clinigen's global supply chain facility and depot network combines market-leading clinical trial services such as comparator sourcing, packaging and labelling with biological sample management. Clinigen delivers tailored solutions for clients globally to ensure clinical trials are a success, regardless of size or scope, from Phase I to Phase IV Trials.

For WPD's trials, Clinigen will cover Qualified Person (QP) services for ensuring and confirming that the Berubicin clinical product has been manufactured in accordance to the European Union Good Manufacturing Practice (EU GMP) standards.

Clinigen will also be responsible for packaging and labeling of the Investigational Medicinal Product ("IMP"), storage in accordance with the product specification and release of the IMP to clinical sites in accordance to Good Distribution Practice (GDP). QP certification of the IMP is crucial to obtain approval of the Regulatory Authority and to initiate the clinical trials. WPD aims to conduct the clinical trials with the highest quality and in compliance with the applicable EU regulations and all applicable requirements including GMP. The services provided by Clinigen are expected to last up to 3 years.

During February 1 - 5, 2021, the Company participated in the LSX World Congress . For 6 years, the LSX World Congress has been bringing together the executives that matter to the future of healthcare and life science strategy, investment, partnering and deal making. LSX World Congress gathers the founders and CEOs of innovative start-ups through to publicly listed life sciences giants, and everyone in between. It represents the breadth and depth of the cutting-edge research and technology driving the advances in the industry right now and in the near future. This year, the event was a virtual experience incorporating all the same features of the usual physical meeting, but spread across a full week.

In February 2021, the Company disclosed that Moleculin, which announced that a preclinical study in animals demonstrated a potentially significant therapeutic benefit of Annamycin against metastatic osteosarcoma. The Moleculin press release of February 2, 2021 states, "This appears to be the result of the high cytotoxic potential of Annamycin previously demonstrated in vitro against sarcoma cells in combination with its high uptake by the lungs where the tumors in this study are localized. Computerized tomography (CT) scans demonstrated that animals treated with Annamycin exhibited significant suppression of tumor growth and not a single death was observed in the treated animals, whereas significant tumor burden contributed to the rapid death of 90% of untreated animals. While the study continues, as of day 130, the survival rate for animals treated with Annamycin was 100%, compared with only 10% for untreated animals.

WPD has not conducted its own independent confirmation testing of Annamycin and is relying solely on the information contained in Moleculin's news releases dated February 2, 2021 in providing this information to WPD's shareholders.

In February 2021, Agencja Badań Medycznych ("The Medical Research Agency"), a Polish state agency responsible for development of scientific research in the field of medical and health sciences, awarded a grant equivalent to US\$1.5 million to the Maria Sklodowska-Curie National Research Institute to fund a Phase 1B/2 clinical trial of Annamycin for the treatment of soft tissue sarcoma (STS) lung metastases.

The grant-funded clinical trial will be led by Prof. Piotr Rutkowski, MD, PhD, Head of Department of Soft Tissue/Bone Sarcoma and Melanoma at the Maria Sklodowska-Curie National Research Institute of Oncology in Warsaw, Poland. In collaboration with WPD, Prof. Piotr Rutkowski will provide support in preparation for and conduct of the clinical trial, which is expected to begin this year.

Treatment options are further limited because of the inherent cardiotoxicity of currently approved anthracyclines, including doxorubicin, which limits the amount of anthracycline that can be given to patients.

Annamycin is a "next generation" anthracycline that has recently been shown in animal models to accumulate in the lungs at up to 34 times the level of doxorubicin. Importantly, Annamycin has also demonstrated a lack of cardiotoxicity in recently conducted human clinical trials for the treatment of acute myeloid leukemia, so the use of Annamycin may not face the same dose limitations imposed on doxorubicin.

In February 2021, the Company signed another services agreement with world-renowned CRO, Worldwide Clinical Trials ("Worldwide") to continue support of Phase 1 and 2 clinical trials on its Berubicin drug candidate.

Part of the program budget will be refunded by a grant already awarded to WPD by The National Center for Research and Development based in Poland under the European Union Smart Growth Operational Program 2014-2020.

In this stage, Worldwide will further support Phase 2 of the clinical trials. This includes expertise on engaging with investigators and site selection for the purpose of clinical trials in adult and pediatric population with Glioblastoma, according to international standards of Good Clinical Practice (ICH GCP) and other applicable regulatory requirements. Requirements include safety management and pharmaco-vigilance and data management. Worldwide will also support services associated with orphan drug designation.

Worldwide is a midsized, global CRO providing full-service Phase 1-4 drug development services to the pharmaceutical and biotechnology industries. The company offers expertise in neuroscience, cardiovascular, metabolic disease, rare disease, oncology and other therapeutic areas. They manage clinical trials across nearly 60 countries in North America, Latin America, Europe, Asia Pacific and Middle East.

In February 2021, the Company received a positive opinion of the Lower Silesian Medical Chamber Ethics Committee in Wrocław, Poland for its planned upcoming Berubicin clinical trial in adults with Glioblastoma Multiforme (GBM) under the WPD-201 Clinical Trial Protocol. CNS Pharmaceuticals has received study level Central (Institutional Review Board ("IRB") approval from the Central IRB for the CNS- 201 Clinical Trial Protocol.

CNS Pharmaceuticals has received approval to proceed with their previously submitted Investigational New Drug (IND), from the U.S. Food and Drug Administration (FDA) for Berubicin in the treatment of GBM. The Company plans to initiate its Phase 2 trial evaluating the efficacy and safety of Berubicin in the treatment of adults with GBM who have failed first-line therapy in the first quarter of 2021. The Company has also received Central IRB study level approval for the U.S. portion of the adult GBM study.

In February 2021, WPD Poland signed an agreement with CNS Pharmaceuticals to obtain IMP for use in the planned clinical trials of Berubicin. WPD will purchase half of the batch previously manufactured for CNS Pharmaceuticals by BSP Pharmaceuticals for the WPD-201 and WPD-201P studies which are planned to begin in the first half of 2021. This IMP will be QP certified by Clinigen Clinical Supplies Management on behalf of WPD under European current Good Manufacture Practice ("cGMP") requirements.

In March 2021, the Company engaged Pediatric Oncology expert, Prof. David Walker to support and develop preclinical and clinical programs for WPD101 in glioblastoma.

Prof. Walker will be advising WPD with strategic decisions related to the development of WPD101 in glioblastoma. He will provide expertise and advise on preclinical studies necessary to move product to the clinical stage and to develop First in Human (FIM) protocols in adults and in children.

WPD also announces that it has engaged Arrowhead Business and Investment Decisions, LLC., ("Arrowhead") to provide investor relations support and brand awareness within the investment community. The Company has agreed to pay Arrowhead US\$20,000 for a three month term, with the option to extend for another three month term at the same fixed cost. Arrowhead will not receive any securities of the Company as compensation for their services.

For the Years Ended December 31, 2022 and 2021

In March 2021, WPD Poland entered into an amended and restated sublicense agreement with Moleculin. The amendment of its February 2019 sublicense from Moleculin of certain intellectual property rights, including the rights to Moleculin's Annamycin, WP1066 and WP1122 portfolios to research, develop, manufacture, use, import, offer and sell products derived from these portfolios in the field of human therapeutics ("Products") in 29 countries, including some countries in Europe (the "Territories").

In consideration of the sublicense, WPD agreed that it must use commercially reasonable efforts to develop and commercialize Products in the Territories. The term "commercially reasonable efforts" has been amended to mean expenditure by WPD of at least USD\$2,500,000 during the first 4 years of the agreement on the research, development and commercialization of Products and at least USD\$1,000,000 in each of the 4 years thereafter. WPD also will pay to Moleculin a royalty on Products sold.

The amendment extends the period of time which WPD has to expend the research, development and commercialization costs to 8 years from February, 2019 and increases the amounts required to be spent over that longer period. It also provides a process to extend the period time further, if necessary.

In April 2021, the Company received a prepayment of approximately C\$954,248 (3,000,000 PLN) from NCRD for the further development of Berubicin, the Company's drug candidate targeting glioblastoma multiforme ("GBM").

As a part of the Berubicin development strategy, WPD has requested scientific advice on pre-clinical and clinical development from the EMA. On March 24, 2021, WPD attended a Pre-Submission Meeting with EMA experts during which useful information was provided on the preparation of documentation for the upcoming meeting with the Scientific Advice Working Party ("SAWP") of EMA.

EMA allows medicinal drug developers to request scientific advice during initial drug development, before submission of a marketing authorization application. EMA established SWAP for the purpose of providing scientific advice to applicants by providing advice on quality aspects, methodology and pre-clinical and clinical development of drugs being developed, based on documentation provided by the developer.

In April 2021, the Company declared its participation in an upcoming webinar "*The Potential of Advanced Imaging to Show the Early Treatment Effects of Berubicin in Brain Cancer*" with IAG, a leading medical imaging company providing important critical imaging services during the Berubicin phase 2 clinical trial.

Mariusz Olejniczak, CEO of WPD and Diana Dupont-Roettger, Chief Scientific Alliance Officer of IAG will be discussing how the use of modern trial infrastructure, advanced imaging and selected imaging biomarkers can increase the chances of success in brain cancer drug development and how advanced imaging strategies in global multi-center clinical trials can accelerate drug development through efficient central imaging data management and centralized review. They will also be discussing how IAG and WPD will be collaborating together during upcoming Berubicin trials.

In April 2021, the Company confirmed its attendance in the 10<sup>th</sup> Annual Congress of the Polish Society of Pediatric Oncology and Hematology to be held on May 6-8, 2021.

During the Congress, WPD will present the key assumptions of the WPD-201P Clinical Trial Protocol, which is planned to start in the second quarter of 2021, as a part of the research project: "New approach to glioblastoma treatment addressing the critical unmet medical need", granted by National Research and Development Center ("NRDC") and co-financed by the European Union, under the Smart Growth Operational Program 2014-2020.

WPD also announces it has engaged Strikepoint Media LLC. ("Strikepoint"), to provide digital marketing and brand awareness support. The Company has agreed to pay Strikepoint US\$50,000 for a 3-month digital media term commencing on April 26, 2021. Strikepoint will not receive any securities of the Company as compensation for their services.

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On May 5, 2021, the Company received approval from the British Columbia Securities Commission ("BCSC") for a temporary management cease trade order ("MCTO") under National Policy 12-203 – Management Cease Trade Orders ("NP 12-203"), which prohibits trading in securities of the Company by certain insiders of the Company, whether direct or indirect. The Company required the MCTO as it was unable to file its Annual Filings for the year ended December 31, 2020 within the deadline as required under National Instrument 51-102 – Continuous Disclosure Obligations ("NI 51-102"). Subsequently, the Company completed its annual filing on June 3, 2021. The MCTO is not expected to have any effect on trading in the Company's shares by the public.

On May 11, 2021, WPD Poland was conditionally awarded a grant of \$6,730,036 (20,394,049.68 PLN) from NCRD, for the development of Annamycin, the Company's drug candidate used in the treatment of Acute Myeloid Leukemia ("AML").

On June 10, 2021, WPD Poland was invited to be a member of an international consortium of leading industry experts researching the potential of AGuIX® nanoparticles in maximizing radiotherapy efficiency. The consortium will also explore two of WPD's compounds specifically, WP1066 and WP1122, to restore GBM cells' sensitivity to radiotherapy.

The consortium is coordinated by Dr. Muriel Barberi-Heyob from CRAN, University de Lorraine, France, and has been successfully funded by EuroNanoMed III "European Innovative Research & Technological Development Projects in Nanomedicine" project – "RXnanoBRAIN Nanoparticles to optimize the effects of radiotherapy of brain tumors: Multi-scale modeling and experimental validation". Along with WPD Pharmaceuticals' Dr. Beata Pajak, the consortium includes Oslo University Hospital (Norway) represented by Dr. Kristian Berg, NH TherAguix (France) company represented by Dr. Sandrine Dufort, and Jagiellonian University in Krakow (Poland) represented by Dr. Martyna Elas.

Over the three-year project timeline, the consortium aims to plan and adapt the X-ray doses given to the patient to maximize radiotherapy efficiency on these high-grade tumors while preserving the adjacent healthy tissue. This project will base its work on pre-clinical experiments at different biological scales (cells, tissues, and in vivo on rodent models) and algorithms' development. An evaluation will then be carried out of the therapeutic potential of an innovative nanoparticle which results from the discovery of NH TherAGuIX and is currently in clinical development. Researchers will study the complementarity and effectiveness of the energy of radiotherapy and nanoparticles (NPs) within tumor tissue. Gaining an in-depth understanding of the effects on the immune response to control and comprehensively enhance the potential of the effects of this treatment also represents a crucial innovative step for the project.

In July 2021, WPD Poland announced that CNS Pharmaceuticals Inc. ("CNS") (NASDAQ: CNSP), the company that licenses the drug candidate Berubicin to WPD for 29 countries mainly in Europe, announced that the U.S. Food and Drug Administration (FDA), was granted Fast Track Designation for its lead investigational drug, Berubicin, for the treatment of patients with recurrent glioblastoma multiforme (GBM). As previously reported, CNS had also received Orphan Drug Designation from the FDA for Berubicin for the treatment of patients with recurrent GBM. Fast Track Designation enables more frequent interactions with the FDA to expedite the development and review process for drugs intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical need.

Receiving Fast Track Designation from the U.S. FDA is a significant achievement in the advancement of Berubicin for the treatment of glioblastoma, the most aggressive, deadly and treatment-resistant type of cancer that forms in the brain. Many patients have almost no meaningful options and thousands lose the fight against this cancer every year. With this designation, CNS now has an accelerated pathway to approval for Berubicin and a clear opportunity to bring this potentially impactful investigational therapy more expediently.

The Company held its Annual and Special General Meeting of Shareholders (AGSM) on September 29, 2021 in Vancouver, Canada at 10 AM. The AGSM Notice of Meeting and Management Information Circular was filed on SEDAR and mailed to shareholders shortly thereafter. In light of continued COVID restrictions, shareholders were encouraged to vote their shares online and attend the meeting through Zoom.

Based on the experience of the Company over the past two years, the Company considers Europe as potentially providing a better venue for a biotech research and development company to raise capital. The Company has clinical trials of potentially life saving drugs technically ready to proceed but currently does not have the capital to commence. Because of this, the Company has been exploring various avenues to better access much needed capital and is asking its shareholders to vote at the AGSM to delist its shares from trading on the CSE. The vote needed to pass with two-thirds (66.67%) majority and the current management and control person's votes would not be counted in the tabulation.

One of those avenues is to conduct financing through the Company's Polish subsidiary. Poland is attracting substantial investor interest from European investors based on an excellent track record of biotech success, but Polish investors do not consider the Company to be a Polish company. Coupled with the small, implied total of its enterprise value based on its CSE stock trading price as compared to expectations of valuation in Europe, which may or may not be realized, this has severely hampered the Company's financing efforts. As a result, management considers that a delisting from trading in Canada would allow the Company to explore alternatives with interested European investors. Management further believes that delisting from its listing in Canada is the Company's best opportunity for success.

The Company annunciated also that has signed an agreement with Newtech Comm and its founder Kamil Majcher, for consulting services in the fields of financial communications and investor relations for the Polish market. The Company is paying a monthly fee of 6000 PLN, at current exchange rates just under \$2,000 CDN per month. Newtech Comm is based in Warsaw and will assist with website design, presentations, introductions to news outlets, news releases and communications advice.

On October 1, 2021, the Company declared the results of its annual general and special meeting held September 29, 2021 in Vancouver, Canada, where it re-elected as directors of the Company Liam Lake Corcoran, Teresa Rzepczyk and Peter Novak. The Company's option plan and appointment of auditors were also approved. Because the Company has been exploring various avenues to better access much needed capital, another motion put forward by management was to vote to delist the Company's shares from trading on the CSE (the "Delisting Resolutions"). The reasoning for the delisting was communicated by management in the Company's news release dated September 2, 2021.

In order to protect shareholders, the directors put measures into place to ensure that minority shareholders were overwhelmingly in favor of this proposed course of action. The Delisting Resolution vote could only pass with two-thirds (66.67%) majority of minority shareholders, with current management and the control person's votes not counted in the tabulation. While over 50% of the minority shareholders did vote in favor of the Delisting Resolution, the numbers in favor did not reach two-thirds (66.67%) majority. Therefore, the Delisting Resolution was defeated, and the Company will not delist its shares from trading on the CSE.

In December 2021, WPD Poland signed an agreement with NCRD for a grant of C\$6.3 million (20,394,049.68 PLN) for the development of Liposomal Annamycin for the treatment of Acute Myeloid Leukemia.

The grant signing resulted from the Company receiving a positive evaluation of its application submitted under the 6/1.1.1/2020 - Fast track competition for a grant (POIR.01.01.01-00-1913/20) from the Polish National Center for Research and Development. The funds will be used for the continued development of Annamycin and is expected to cover about 60% of the research activities planned for grant-funded project leading to further development of Annamycin in leukemia. The project is intended to develop a new combination of drugs and clinical verification of its effectiveness in AML therapy. The project entitled: "Innovative approach to the treatment of acute myeloid leukemia (AML)" will be co- financed by the European Union, from the European Regional Development Fund, under the Smart Growth Operational Program 2014-2020.

On December 23, 2021, CNS confirmed that the Company had successfully used "commercially reasonable development efforts" towards the development of Berubicin, defined as expenditures of at least USD\$2,000,000 on the development, testing, regulatory approval or commercialization of the licensed product during the applicable development period, and as such, the Company, through WPD Poland, is entitled to maintain its sublicense of Berubicin subject to the ongoing obligations under the CNS Agreement. The Company's sub-license of Berubicin allows it geographic exclusivity for development and marketing in a region consisting of select countries in Eastern Europe and Central Asia.

# **WPD Pharmaceuticals Inc.** Management's Discussion & Analysis For the Years Ended December 31, 2022 and 2021

On January 25, 2022, WPD Poland entered into an amended and restated sublicense agreement (the "Sublicense Agreement") with Moleculin Biotech Inc. ("Moleculin"). On December 20, 2021, WPD Poland entered into an amendment of its February 2019 sublicense (as amended previously in 2019 and 2021) from Moleculin of certain intellectual property rights, including certain rights to Moleculin's Annamycin, WP1066 and WP1122 portfolios to research, develop, manufacture, use, import, offer and sell products derived from these portfolios in the field of human therapeutics ("Products") in 29 countries, including some countries in Europe (the "Territories").

In consideration of the Moleculin sublicense, WPD agreed that it must use commercially reasonable efforts to develop and commercialize Products in the Territories. The amended agreement provides that, in respect of "commercially reasonable development efforts" ("CRDE"), WPD must spend at least USD\$2,500,000 during the first 4 years of the agreement on the research, development and commercialization of Products and at least USD\$2,100,000 in each of the 5 years thereafter (previously USD\$1,000,000 in each of the 4 years thereafter). Accordingly, the total minimum required CRDE is now USD\$13,000,000, amended from USD\$6,500,000.

The Company also entered into a consent agreement (the "Consent") on December 19, 2021 with Moleculin, WPD Poland, and LPC Enterprises, LLC ("LPC"), whereby Moleculin consented to the potential assignment ("Assignment") by WPD Poland to LPC of WPD Poland's rights, and the assumption of LPC of the duties and obligations of WPD Poland, under the Sublicense Agreement. The Consent was granted by Moleculin in connection with a convertible promissory note (the "Note") issued by WPD Poland to LPC in the principal amount of US\$1,380,000. Moleculin is not a party to the Note. The Note bears interest at a rate of 10% per year, has a maturity date of November 15, 2022, and will be funded as follows: USD\$600,000 on December 5, 2021; USD\$200,000 on January 5, 2022, USD\$200,000 on February 5, 2022, and USD\$200,000 on April 5, 2022. LPC may convert the principal amount and all interest into shares of WPD Poland based on a conversion formula which includes a valuation cap of WPD Poland at USD\$8,000,000. Upon a qualifying event of default under the Note, the Sublicense Agreement would be assigned by WPD Poland to LPC. Moleculin has the right under the Assignment to acquire the Sublicense Agreement in the event of default.

The Company appointed Mr. Romuald Harwas as a director of the Company, effective February 2, 2022. The appointment of Mr. Harwas filled the vacancy created by the prior resignation of Walter Klemp on October 14, 2021. Mr. Harwas brings several years of experience and expertise in finance to WPD Poland's Board of Directors. Mr. Harwas is a specialist in management, accounting and economic analysis.

In February 2022, the Company's board of directors (the "Board") has approved a plan to restructure (the "Restructuring") the outstanding capitalization of the its wholly owned Polish subsidiary WPD Poland. Due to the occurrence of negative shareholders' equity in WPD Poland, under Polish corporate law, WPD Poland is obligated to convene an extraordinary general meeting of its shareholders to vote on the implementation of a recovery plan or file a bankruptcy proceeding. As the Company is sole shareholder of WPD, the Board has approved a recovery plan of WPD Poland, being the Restructuring. Under the Restructuring, the first step is that the outstanding share capital of WPD Poland will be reduced through a voluntary redemption of 53,384 shares of WPD Poland by the Company for no cash consideration, which will increase the supplementary and reserve capitals of WPD Poland.

Under the second step, the share capital of WPD Poland will be increased due to the conversion of loan receivables due to the Company into new shares of WPD Poland. The Company believes that the Restructuring will enable WPD Poland to operate and pursue its research and development objectives. The Company will provide more updates as the Restructuring plan is implemented.

In March 2022, the Company received the final version of the signed Consortium Agreement related to the EuroNanoMed Project. The consortium will research the potential of AGuIX® nanoparticles in maximizing radiotherapy efficiency and explore two of WPD's compounds specifically to restore GBM cells' sensitivity to radiotherapy. The consortium is coordinated by Dr. Muriel Barberi-Heyob from the Research Center for Automatic Control (CRAN). Along with WPD's Dr. Beata Pajak, the consortium includes Oslo University Hospital (Norway), NH TherAguix (France), and Jagiellonian University in Krakow (Poland).

Over the three-year project timeline, the consortium aims to plan and adapt the X-ray doses given to the patient to maximize radiotherapy efficiency on these high-grade tumors while preserving the adjacent healthy tissue.

On May 6, 2022, the Company received approval from the BCSC for a temporary MCTO under National Policy 12-203 - Management Cease Trade Orders ("NP 12-203"), which prohibits trading in securities of the Company by certain insiders of the Company, whether direct or indirect. The Company required the MCTO as it was unable to file its Annual Filings for the year ended December 31, 2021 within the deadline as required under National Instrument 51-102 - Continuous Disclosure Obligations ("NI 51-102"). The MCTO is not expected to have any effect on trading in the Company's shares by the public.

On May 16, 2022 Company signed Annex No. 2 into its License Agreement with Wake Forest University Health Sciences ("WFUHS"). On April 22, 2022 WPD Pharmaceuticals Sp. z o.o. ("WPD Poland"), the Polish subsidiary of the Company, signed Annex No 2. into the License Agreement. Previous to Annex No. 2, WPD signed Annex No. 1 to the License Agreement on June 30, 2019. The original License Agreement with WFUHS has been in place since November 28, 2017, and both WPD and WFUHS have worked collaboratively since then.

WPD and WFUHS have confirmed that the Licensed Know-How scope of Annex No.2 is larger than the previous agreement, and concerns information received from WFUHS related to, directly or indirectly, the subject matter of the patent rights or necessary or useful for the development, use or manufacture of the Licensed Products of which a copy is submitted to WPD by WFUHS under the License Agreement. WPD and WFUHS also confirm that the patent rights also cover US 11,136,367 patent (Appl. No.: 16/704,645) as well as any patent applications or patents claiming priority to this patent, any of its foreign equivalents, any patent issued from that patent, as well as any re- examinations, reissues, substitutes, renewals, extensions thereto, or supplementary protection certificates based thereon.

On July 22, 2022, the Company received an order from the BCSC for a temporary cease trade order ("CTO"), which prohibits trading in securities of the Company, whether direct or indirect, due to the Company's failure to file audited and interim financial statements, management's discussion and analysis on the financial statements, and related certifications (together, the "Continuous Disclosure Documents") for the year ended December 31, 2022 within the deadline as required under National Instrument 51-102 – Continuous Disclosure Obligations ("NI 51-102"). Subsequently, on May 1, 2023, the BCSC issued an order partially revoking the CTO permitting the Company to complete a convertible debenture offering.

On November 18, 2022, WPD Poland authorized the subscription for 34,000 shares of WPD Poland at PLN 50 per share by HPI for gross proceeds of PLN 1,700,000. According to the provisions of Polish corporate law, the raise of share capital in WPD Poland and the issuance of the new shares became effective on November 25, 2022, the date of the registration in the national court registry by the registry court. Upon completion, HPI owns 80.95% of WPD Poland's share capital. The next step of the management board of WPD Poland to be undertaken, in line with the recovery program, is to search for domestic Polish and eligible foreign investors also from European Union and USA, who are interested in capital participation in financing the next stages of the development of WPD Poland.

On November 25, 2022 the Company enrolled the first patient in the Phase 1B/2 clinical trial of Annamycin in the treatment of soft tissue sarcoma (STS) lung metastases, has received the first dose of Annamycin. The start of clinical trial is a consequence of the project granted by Agencja Badań Medycznych (The Medical Research Agency).

The grant-funded clinical trial will be led by Prof. Piotr Rutkowski, MD, PhD, Head of Department of Soft Tissue/Bone Sarcoma and Melanoma at the Maria Sklodowska-Curie National Research Institute of Oncology in Warsaw, Poland. WPD is responsible for providing support in preparation and conduct of this clinical trial.

Agencja Badań Medycznych (The Medical Research Agency) is a Polish state agency responsible for development of scientific research in the field of medical and health sciences, awarded a grant equivalent to US\$1.5 million to the Maria Sklodowska-Curie National Research Institute to fund a Phase 1B/2 clinical trial of Annamycin for the treatment of soft tissue sarcoma (STS) lung metastases.

On May 1, 2023, BCSC issued an order partially revoking the CTO, which was issued against the Company on July 22, 2022 due to the Company's failure to file the Continuous Disclosure Documents. The partial revocation order permitted the Company to complete convertible debenture offering.

# WPD Pharmaceuticals Inc.

Management's Discussion & Analysis For the Years Ended December 31, 2022 and 2021

On June 2, 2023, the Company closed a convertible debenture offering through private placement of unsecured convertible debentures (the "Debentures") pursuant to which the Company raised an aggregate principal amount of \$300,000. Each Debenture is convertible into units of the Company (each, a "Unit") at a conversion price of \$0.05 per Unit. Each Unit will consist of one common share and one share purchase warrant exercisable to purchase one additional common share at a price of \$0.05 for three years from the date of issuance of the Unit. The Debentures bear interest at the rate of 18% per annum compounded monthly until maturity and after default. The Debentures will mature on June 2, 2026. The proceeds of this offering will be used to complete and file the outstanding Continuous Disclosure Documents, to pay legal fees, filing fees and certain accounts payable, and for general working capital. The Company may pay finder's fees in cash in connection with this private placement.

# Summary of Annual Information

	December 31, 2022	December 31, 2021	December 31, 2020
	\$	\$	\$
Total revenue	Nil	Nil	Nil
Comprehensive income/(loss)	3,535,474	(5,325,161)	(7,517,771)
Total assets	75,850	1,863,535	2,684,575

# **Summary of Quarterly Information**

Below is selected financial information from continuing operations for the most recent eight quarters. The quarterly results presented in the table below were prepared in accordance with IFRS.

Quarter ended	<b>Comprehensive income (loss)</b>	Income (loss) per share	
	\$	\$	
December 31, 2022	5,547,603	0.05	
September 30, 2022	(778,584)	(0.01)	
June 30, 2022	(650,136)	(0.01)	
March 31, 2022	(583,409)	(0.01)	
December 31, 2021	(2,077,425)	(0.02)	
September 30, 2021	(945,056)	(0.01)	
June 30, 2021	(1,152,276)	(0.01)	
March 31, 2021	(1,150,404)	(0.01)	

# **Results of Operations**

#### Three months ended December 31, 2022 and 2021

For the three months ended December 31, 2022, the Company reported a comprehensive income of \$5,547,603 compared to a comprehensive loss of \$2,077,425 for the same period in 2021, a decrease in loss of \$7,625,028 which was primarily attributable to the following factors:

- (i) The costs incurred by the only operating entity WPD Poland are only till November 25<sup>th</sup> in 2022, as compared to the costs incurred for the full quarter in 2021 due to de-consolidation of WPD Poland.
- (ii) The gain on deconsolidation of WPD Poland of \$4,522,434, as the Company was deemed to have lost control of its only subsidiary WPD Poland, when it raised capital directly from HPI to avoid bankruptcy, was a oneoff transaction in 2022 only relative to the corresponding quarter in 2021.
- (iii) The decrease of expenses in the quarter relating to consultants and research and development costs was \$1,335,609 due to lower research and development activity in the current quarter in 2022 compared the corresponding quarter in 2021. This decrease in 2021 includes \$1,697,740 that were reclassified from research and development to consultants in 2021 based on the nature of expenses incurred.

(iv) Increase in other income recognized in the fourth quarter of 2022 as compared to the corresponding quarter of 2021 by \$2,281,394 is primarily due to the amount and timing of grant income recognized by the Company. In 2022, the Company recognized grant income of \$1,757,763 received from and/or approved by NRDC, which was all recognized only in the last quarter of 2022, after the uncertainty regarding the continuity of WPD Poland ceased to exist when it received the subscription amount for the share capital of WPD Poland. Further, the amount of grant income deferred in the last quarter of 2021 exceeded the income recognized due to timing difference of the approval of application for grant money submitted in 2021.

# Years ended December 31, 2022 and 2021

For the year ended December 31, 2022, the Company reported a comprehensive income of \$3,535,474 compared to a comprehensive loss of \$5,325,161 for the same period in 2021, a decrease in loss of \$8,860,635, which was primarily attributable to (a) period covered in 2022 for WPD Poland that was deconsolidated as of November 25, 2022, compared to full 12 months in 2021; (b) and decrease in average exchange rate between Canadian dollar and Polish zloty in 2022; and (c) gain from loss of control in subsidiary, lower expenses such as amortization and depreciation, consultants, impairment of intangible assets, salaries and higher other income offset by absence of gain on debt forgiveness in 2022.

For the year ended December 31, 2022, the Company incurred amortization and depreciation expenses of \$24,436 compared to \$290,218 in 2021. The decreased expense in 2022 was mainly due to lower amortization of intangible assets. The Company impaired its intangible assets related to patent costs at the end of year after the amortization charge for the full year in 2021.

For the year ended December 31, 2022, the Company incurred consultant expenses of \$1,131,160 compared to \$3,755,478 in 2021. The costs in 2021 was higher significantly mainly due to costs incurred on the progress made under project WPD104 and \$864,855 relating to payments made to CNS for sublicense of Berubicin to assist in the Company's research and development activities related to clinical trials.

For the year ended December 31, 2022, the Company incurred an impairment charge on its intangible assets of \$30,102 compared to \$440,881 in 2021. The lower charge in 2022 was mainly because the lower expense on intangible assets during the year, as compared to the impairment charge for 2021 which represented the full the carrying value of those intangible assets in the books at the time of impairment.

For the year ended December 31, 2022, the Company incurred salaries expense of \$798,862 compared to \$1,044,852 in 2021. The decrease in 2022 was mainly due to fewer staff in WPD Poland as a result of lesser research and development activities relative to 2021.

For the year ended December 31, 2022, the Company's other income was \$1,873,367 compared to \$1,201,710 in 2021. The increase in 2022 is primarily due to the timing difference of the approval of the grants by NCRD that were claimed by the Company for WPD104 and WPD 101.

For the year ended December 31, 2022, the Company recorded a gain from loss in control of subsidiary of \$4,522,434 resulting from capital restructuring and issuance of new capital directly by WPD Poland that resulted in the Company's ownership coming down from 100% to 19.05% and the consequent deconsolidation of WPD Poland. This was a one-off transaction in 2022 only. The main components of the gain are net liabilities of \$3,635,766 that are no longer consolidated and hence released and the reclassification to income statement of balance in foreign exchange translation adjustment under accumulated other comprehensive income primary upon deconsolidation.

For the year ended December 31, 2022, there was no gain on forgiveness of debt, which was a one-off item in 2021 resulting from the COVID loan subsidy from the Polish government of \$72,035 that confirmed in 2021 and \$162,522 debt from lenders who had foregone the loan amounts payable to them in 2021.

# Liquidity and Capital Resources

The Company has financed its operations to date through the issuance of common shares and debt. The Company continues to seek capital through various means including the issuance of equity and/or debt.

As at December 31, 2022, the Company had a working capital deficit of 478,792 (December 31, 2021 – 4,123,700) inclusive of cash of 23,794 (December 31, 2021 – cash and restricted cash of 1,708,675).

Although the Company has previously been successful in raising the funds required for its operations, there can be no assurance that the Company will have sufficient financing to meet its future capital requirements or that additional financing will be available on terms acceptable to the Company in the future.

#### Summary of Outstanding Share Data

As at December 31, 2022 and the date of this report, the Company had 113,438,244 common shares and nil warrants issued and outstanding.

The Company had 4,585,000 stock options as at December 31, 2022 and 3,390,000 stock options as at the date of this report that were issued and outstanding with an exercise price of \$0.86. **Off-Balance Sheet Arrangements** 

The Company has not entered into any off-balance sheet arrangements.

#### **Related Party Transactions**

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 Board and corporate officers, including the Company's Chief Executive Officer and Chief Financial Officer.

Key management compensation for the years ended December 31, 2022 and 2021 was as follows:

	December 31,		December 31,	
		2022		2021
Consultants	\$	45,630	\$	864,855
Salaries		31,991		39,122
Management and consulting fees		51,500		213,600
Share-based payments		-		42,110
Director fees		7,500		18,000
	\$	136,621	\$	1,177,687

As at December 31, 2022, current liabilities include \$214,432 (December 31, 2021 – \$831,654) payable to key management personnel and other related parties. Amounts due to related parties included in accounts payable and accrued liabilities and in due to related parties are unsecured, non-interest-bearing and are without fixed terms of repayment.

Management's Discussion & Analysis For the Years Ended December 31, 2022 and 2021

During the years ended December 31, 2022 and 2021, the Company also had the following transactions with related parties:

a) CNS Agreements

On August 30, 2018, WPD Poland entered into a sublicense agreement (the "CNS Sublicense Agreement") with CNS Pharmaceuticals, Inc. ("CNS Pharma"). In connection, WPD Poland is committed to spend at least US \$2 million on the development, testing, regulatory approval, or commercialization of the products governed under the CNS License Agreement by August 30, 2021. On December 23, 2021, CNS confirmed that WPD Poland spent the committed amount, and as such, WPD Poland is entitled to maintain its sublicense in perpetuity of Berubicin subject to the ongoing obligations under the CNS Agreement. The Company's sub-license of Berubicin allows it geographic exclusivity for development and marketing in a region consisting of select countries in Eastern Europe and Central Asia. WPD Poland has no further spending commitments under this agreement.

CNS Pharma is a related party due to its founder and controlling shareholder being a significant shareholder of the Company.

#### b) Moleculin Sublicense Agreement

On February 19, 2019, WPD Poland entered into a sublicense agreement (the "Moleculin Sublicense Agreement") with Moleculin Biotech, Inc. ("Moleculin"), under which Moleculin sublicensed certain intellectual property rights to WPD, including rights to certain products. In consideration for sublicensing rights provided, the Company, through WPD Poland, agreed to make expenditure of at least: (i) USD \$2,500,000 during the first two years of the agreement on the research, development and commercialization of products in the licensed territories, and (ii) USD \$1,000,000 annually for the two years thereafter on the research and development of products in the licensed territories.

On March 22, 2021, these durations of these terms were extended to first 4 years and annually in each of the 4 years thereafter respectively, along with a process to extend the period of time further, if necessary.

On December 19, 2021, WPD Poland entered into a consent agreement (the "Consent") with Moleculin and LPC Enterprises, LLC ("LPC"), whereby Moleculin consented to the potential assignment ("Assignment") by WPD Poland to LPC of WPD Poland's rights, and the assumption of LPC of the duties and obligations of WPD Poland, under the Sublicense Agreement. The Consent was granted by Moleculin in connection with a convertible promissory note (the "Note") issued by WPD Poland to LPC in the principal amount of USD \$1,380,000 (see Note 8 above). Moleculin, however, is not a party to the Note.

On December 20, 2021, WPD Poland entered into an amendment of its February 2019 sublicense (as amended previously in 2019 and 2021) from Moleculin of certain intellectual property rights, including certain rights to Moleculin's Annamycin, WP1066 and WP1122 portfolios to research, develop, manufacture, use, import, offer and sell products derived from these portfolios in the field of human therapeutics ("Products") in 29 countries, including some countries in Europe (the "Territories").

In consideration of the Moleculin sublicense, WPD Poland agreed to use commercially reasonable efforts to develop and commercialize Products in the Territories. The amended agreement provides that, in respect of "commercially reasonable development efforts" ("CRDE"), WPD Poland must spend certain minimum amounts during the first 4 years and the 5 years thereafter on the research, development and commercialization of Products. Accordingly, the total minimum required CRDE is now USD \$13,000,000, amended from USD \$6,500,000.

On March 20, 2023, the Company signed a sublicense termination agreement with Moleculin, under which Moleculin will pay WPD Poland (or its designees) US\$700,000 and will also issue to WPD Poland (or its designees) certain number of shares of Moleculin's common stock equal to US\$800,000. These final settlement considerations upon termination were not paid to WPD Poland, instead were paid directly to LPC in full and final settlement of their loan to WPD Poland (see Note 8(A)). WPD Poland has no further spending commitments under this agreement following the termination in March 2023.

Moleculin is a related party due to its founder being a significant shareholder of the Company.

#### Proposed Transactions

As of December 31, 2022, the Company did not have any proposed transactions.

#### **Critical Accounting Estimates and Judgments**

The preparation of this MD&A is based on critical accounting estimates and judgments consistent with those used in the preparation of the audited annual consolidated financial statements for the years ended December 31, 2022 and 2021. For further information, see Note 2 of the Company's audited annual consolidated financial statements for the years ended December 31, 2022 and 2021.

# Accounting Policies

The preparation of this MD&A is based on accounting principles and practices consistent with those used in the preparation of the audited annual consolidated financial statements for the years ended December 31, 2022 and 2021. For further information, see Note 3 of the Company's audited annual consolidated financial statements for the years ended December 31, 2022 and 2021.

# **Financial Instruments and Other Instruments**

# Fair Value of Financial Instruments

The Company's financial instruments consist of cash, receivables and accounts payables. The carrying values of cash, receivables and accounts payable approximate their fair values because of their short-term nature and/or the existence of market related interest rates on the instruments. These estimates are subjective and involve uncertainties and matters of significant judgment and therefore cannot be determined with precision. Changes in assumptions could significantly affect the estimates.

Financial instruments measured at fair value are classified into one of the three levels in the fair value hierarchy according to the relative reliability of the inputs used to estimate the fair values. The three levels of hierarchy are:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Other techniques for which all inputs which have a significant effect on the recorded fair value are observable, either directly or indirectly.

Level 3: Techniques which use inputs that have a significant effect on the recorded fair value that are not based on observable market data.

#### **Financial Instruments Risk**

The Company is exposed in varying degrees to a variety of financial instrument-related risks. The Board approves and monitors the risk management processes:

#### (i) Credit Risk

Credit risk is the risk of loss associated with a counterparty's inability to fulfill its payment obligations. The Company limits its exposure to credit loss for cash by placing its cash with high quality financial institutions. The credit risk for cash is considered negligible since the counterparties are reputable banks with high quality external credit ratings.

#### (ii) Liquidity Risk

Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they become due. The Company's objective in managing liquidity risk is to maintain sufficient readily available reserves in order to meet its liquidity requirements at any point in time. The Company achieves this by maintaining sufficient cash on hand to meet its financial obligations.

# (iii) Interest Rate Risk

Interest rate risk is the risk that future cash flows will fluctuate as a result of changes in market interest rates. Interest on the Company's loans payable and debentures is based on a fixed rate, and as such, the Company is not exposed to significant interest rate risk.

# (iv) Tax Risk

The Company is subject to various taxes including, but not limited to the following: income tax; goods and services tax; sales tax; land transfer tax; and payroll tax. The Company's tax filings will be subject to audit by various taxation authorities. While the Company intends to base its tax filings and compliance on the advice of its tax advisors, there can be no assurance that its tax filing positions will never be challenged by a relevant taxation authority resulting in a greater than anticipated tax liability.

#### (v) Foreign Exchange Risk

Foreign currency risk is the risk that the fair values of future cash flows of a financial instrument will fluctuate because they are denominated in currencies that differ from the respective functional currency. The Company is not exposed to currency risk.

# Capital Management

The Company's capital structure consists of cash and share capital. The Company manages its capital structure and makes adjustments to it, based on the funds available to the Company. 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. In order to carry out the planned activities and pay for administrative costs, the Company will spend its existing working capital and raise additional amounts as needed. 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 in the Company's approach to capital management since inception. The Company is subject to externally imposed capital requirements.

#### **Additional Information**

Additional information relating to WPD Pharmaceuticals Inc. can be accessed under the Company's public filings found at <u>www.sedarplus.ca.</u>

#### **Risk Factors - General**

#### COVID-19 Risk

Since December 31, 2019, the outbreak of the novel strain of coronavirus, specifically identified as "COVID- 19", has resulted in governments worldwide enacting emergency measures to combat the spread of the virus. These measures, which include the implementation of travel bans, self-imposed quarantine periods and social distancing, have caused material disruption to businesses globally resulting in an economic slowdown. Global equity markets have experienced significant volatility and weakness. Governments and central banks have reacted with significant monetary and fiscal interventions designed to stabilize economic conditions. The duration and impact of the COVID-19 outbreak was unknown at this time, as is the efficacy of the government and central bank interventions. The pandemic has slowed the pace of its research, including study, start and recruitment in WPD-201 clinical study but has not stopped it. Disruption of supply chain and shift to manufacturing vaccines and biological product for Covid treatment greatly increase cost and time necessary for manufacturing other drugs in development. These factors, together with Russian invasion of Ukraine, also diminish possibility to raise money for company located in Poland.

# Limited Operating History

WPD was incorporated in August of 2017 and has yet to generate any material amount of revenue. The Company is therefore subject to many of the risks common to early-stage enterprises, including under-capitalization, cash shortages, limitations with respect to personnel, financial, and other resources and lack of revenues. There is no assurance that the Company will be successful in achieving a return on shareholders' investment and the likelihood of success must be considered in light of the early stage of operations.

# Liquidity and Future Financing Risk

The Company will likely operate at a loss until its business becomes established and it will require additional financing in order to fund future operations and expansion plans. The Company's ability to secure any required financing to sustain operations and expansion plans will depend in part upon prevailing capital market conditions and business success. There can be no assurance that the Company will be successful in its efforts to secure any additional financing. Moreover, future activities may require the Company to alter its capitalization significantly and, if additional financing is raised by issuance of additional shares of the Company from treasury, control may change and shareholders will suffer dilution. The inability of the Company to access sufficient capital for its operations could have a material adverse effect on the Company's financial condition and results of operations.

# **Risk Factors - Related to the Company's Business and Operations**

- We are developing our drugs to treat patients who are extremely or terminally ill, and patient deaths that occur in our clinical trials could negatively impact our business even if such deaths are not shown to be related to our drugs.
- We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.
- We have recently commenced drug development, have a limited operating history and we expect a number of factors to cause our operating results to fluctuate on an annual basis, which may make it difficult to predict our future performance.
- We have never been profitable, we have no products approved for commercial sale, and to date we have not generated any revenue from product sales. As a result, our ability to reduce our losses and reach profitability is unproven, and we may never achieve or sustain profitability.
- There are limited suppliers for active pharmaceutical ingredients ("API") used in in our drug candidates. Problems with the third parties that manufacture the API used in our drug candidates may delay our clinical trials or subject us to liability.
- We cannot be certain that any of our drug candidates will receive regulatory approval, and without regulatory approval we will not be able to market our drugs.
- Delays in the commencement, enrolment and completion of clinical trials could result in increased costs to us and delay or limit our ability to obtain regulatory approval for any of our product candidates.
- Any product candidate we advance through clinical trials may not have favorable results in later clinical trials or receive regulatory approval.
- Our product candidates may have undesirable side effects that may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.
- If regulatory authorities do not find the manufacturing facilities of our future contract manufacturers acceptable for commercial production, we may not be able to commercialize any of our product candidates.

For the Years Ended December 31, 2022 and 2021

- We have no sales, marketing or distribution experience and we will have to invest significant resources to develop those capabilities or enter into acceptable third-party sales and marketing arrangements.
- We may not be successful in establishing and maintaining development and commercialization collaborations, which could adversely affect our ability to develop certain of our product candidates and our financial condition and operating results.
- We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.
- The intellectual property rights we have licensed from other organizations are subject to the rights of others.
- We have research expenditure and other obligations under the license agreements which provide us with the rights to develop and market certain compounds in certain countries, and we may not be able to meet our obligations and therefore may lose our licensed rights.
- We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.
- If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be significantly diminished.
- We will need to expand our operations and increase the size of our company, and we may experience difficulties in managing growth.
- We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants.
- We do not expect that our insurance policies will cover all of our business exposures thus leaving us exposed to significant uninsured liabilities.
- We may incur penalties if we fail to comply with healthcare regulations.
- We may not be able to recover from any catastrophic event affecting our suppliers.
- We may be materially adversely affected in the event of cyber-based attacks, network security breaches, service interruptions, or data corruption.
- Our Quality Control Systems may not prevent products of poor quality from being sold by us, exposing us to liability for harm or damages caused.
- The Company's business is subject to a number of risks and hazards generally, including adverse environmental conditions, accidents, labour disputes and changes in the regulatory environment. Such occurrences could result in damage to assets, personal injury or death, environmental damage, delays in operations, monetary losses and possible legal liability.
- The Company is subject to various taxes including, but not limited to the following: income tax; goods and services tax; sales tax; land transfer tax; and payroll tax. The Company's tax filings will be subject to audit by various taxation authorities. While the Company intends to base its tax filings and compliance on the advice of its tax advisors, there can be no assurance that its tax filing positions will never be challenged.

# **Internal Controls**

Effective internal controls are necessary for the Company to provide reliable financial reports and to help prevent fraud. Although the Company will undertake a number of procedures and will implement a number of safeguards, in each case, in order to help ensure the reliability of its financial reports, including those imposed on the Company under Canadian securities law, the Company cannot be certain that such measures will ensure that the Company will maintain adequate control over financial processes and reporting. Failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm the Company's results of operations or cause it to fail to meet its reporting obligations. If the Company or its auditors discover a material weakness, the disclosure of that fact, even if quickly remedied, could reduce the market's confidence in the Company's consolidated financial statements and materially adversely affect the trading price of the Company Shares. Management of the Company will ensure the accounting cycle, payroll administration, operational activities, and financial reporting control is the lack of segregation of accounting duties due to the limited size of WPD. However, the threat of this deficiency is considered immaterial as management has taken effective measures to mitigate this weakness.

The potential risk that flows from the identified deficiencies and weaknesses is the risk of potential fraud. However, the risk of fraud is considered low as management has taken measures as stated above to mitigate the potential risk of fraud. Management anticipates taking the following measures to mitigate this weakness: (i) all purchase and payment, including payroll, must be authorized by management; (ii) all capital expenditures must be preapproved by the Board; (iii) all source documents in Polish or any other language other than English must be translated and scanned for accounting entries and recordkeeping purposes; (iv) and almost all of the Company's cash outside of grants received from the Polish government will be deposited with a Canadian bank in Vancouver, Canada. Bank statements of WPD will be reviewed by the CFO of the Company regularly.

Management will continue to monitor the operations of WPD, evaluate the internal controls, and develop measures in the future to mitigate any potential risks and weaknesses.

# **Conflicts of Interest**

Certain of the directors and officers of the Company will be engaged in, and will continue to engage in, other business activities on their own behalf and on behalf of other companies (including other pharmaceutical or biotechnological companies) and, as a result of these and other activities, such directors and officers of the Company may become subject to conflicts of interest. The BCBCA provides that in the event that a director or senior officer has a material interest in a contract or proposed contract or agreement that is material to an issuer, the director or senior officer must disclose his interest in such contract or agreement and a director must refrain from voting on any matter in respect of such contract or agreement, subject to and in accordance with the BCBCA. To the extent that conflicts of interest arise, such conflicts will be resolved in accordance with the provisions of the BCBCA.

#### **Forward Looking Statements**

The information provided in this MD&A, including information incorporated by reference, may contain "forward-looking statements" or "forward-looking information" (collectively referred to hereafter as "**forward looking statements**") about the Company.

All statements, other than statements of historical fact, made by the Company that address activities, events or developments that the Company expects or anticipates will or may occur in the future are forward-looking statements, including, but not limited to, the Company's proposed business objectives and plans relating to biotechnology research and development of medicinal products involving biological compounds and small molecules. These statements speak only as of the date they are made and are based on information currently available and on the then current expectations of the Company and assumptions concerning future events, which are subject to a number of known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements to be materially different from that which was expressed or implied by such forward-looking statements. See "*Risk Factors*".