

**PHARMATHER HOLDINGS LTD.**  
**MANAGEMENT'S DISCUSSION AND ANALYSIS**

**Year Ended May 31, 2023**

**(Expressed in Canadian Dollars)**

**Dated: September 28, 2023**

## **INTRODUCTION**

PharmaTher Inc. ("PharmaTher") was incorporated under the Business Corporations Act (Ontario) on April 1, 2020. The registered head office of the Company is 82 Richmond Street East, Toronto, Ontario M5C 1P1.

PharmaTher Holdings Ltd. (formerly Newscope Capital Corporation) ("Newscope" or the "Company") was incorporated under the Business Corporations Act (British Columbia) on March 20, 2019. The registered head office of the Company is 1055 West Georgia Street, 1500 Royal Centre, P.O. Box 11117, Vancouver B.C. V6E 4N7, Canada.

On June 10, 2020, Newscope issued 47,240,000 common shares as consideration for acquisition of all the issued and outstanding common shares in the capital of PharmaTher (the "Acquisition"). In addition, Newscope issued an aggregate of 115,000 warrants in exchange for the issued and outstanding warrants of PharmaTher. Each warrant entitles the holder thereof to acquire one common share in the capital of Newscope at an exercise price of \$0.10 for a period of 24 months from the original date of issuance. The Acquisition was accounted for as a reverse takeover ("RTO") whereby PharmaTher was identified as the acquirer for accounting purpose and the resulting consolidated financial statements are presented as a continuance of PharmaTher and the comparative figures presented in the consolidated financial statements after the RTO are those of PharmaTher. After the RTO, the combined entity of Newscope and PharmaTher is referred to as the "Company" in this MD&A (defined below).

PharmaTher is a specialty pharmaceutical company focused on developing and commercializing KETARX™ (racemic ketamine) delivered by intravenous and intramuscular injection, microneedle patch, and on-body pump for mental health, neurological and pain disorders.

The Canadian Dollar is the Company's functional and reporting currency. Unless otherwise noted, all dollar amounts are expressed in Canadian Dollars.

The following management's discussion and analysis ("MD&A") of the financial condition and results of the operations of PharmaTher constitutes management's review of the factors that affected the Company's financial and operating performance for the year ended May 31, 2023. This MD&A was written to comply with the requirements of National Instrument 51-102 – Continuous Disclosure Obligations. This discussion should be read in conjunction with the audited annual financial statements of the Company for the fiscal year ended May 31, 2023 and 2022, together with the notes thereto. Results are reported in Canadian dollars, unless otherwise noted. The Company's financial statements and the financial information contained in this MD&A are prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB") and interpretations of the IFRS Interpretations Committee ("IFRIC"). In the opinion of management, all adjustments (which consist only of normal recurring adjustments) considered necessary for a fair presentation have been included. Information contained herein is presented as at September 28, 2023, unless otherwise indicated.

For the purposes of preparing this MD&A, management, in conjunction with the Board of Directors, considers the materiality of information. Information is considered material if: (i) such information results in, or would reasonably be expected to result in, a significant change in the market price or value of the Company's common shares; (ii) there is a substantial likelihood that a reasonable investor would consider it important in making an investment decision; or (iii) it would significantly alter the total mix of information available to investors. Management, in conjunction with the Board of Directors, evaluates materiality with reference to all relevant circumstances, including potential market sensitivity.

Further information about the Company and its operations can be obtained from the offices of the Company.

**CAUTIONARY NOTE REGARDING FORWARD LOOKING INFORMATION**

*This MD&A contains forward-looking information and statements (“forward-looking statements”) which may include, but are not limited to, statements with respect to the future financial or operating performance of the Company. Forward-looking statements reflect the current expectations of management regarding the Company’s future growth, results of operations, performance and business prospects and opportunities. Wherever possible, words such as “may”, “would”, “could”, “will”, “anticipate”, “believe”, “plan”, “expect”, “intend”, “estimate” and similar expressions have been used to identify these forward-looking statements. These statements reflect management’s current beliefs with respect to future events and are based on information currently available to management. Forward-looking statements involve significant risks, uncertainties and assumptions. Many factors could cause the actual results, performance or events to be materially different from any future results, performance or events that may be expressed or implied by such forward-looking statements, including, without limitation, those listed in the “Risk Factors” section of this MD&A. Although the Company has attempted to identify important factors that could cause actual results, performance or events to differ materially from those described in the forward-looking statements, there could be other factors unknown to management or which management believes are immaterial that could cause actual results, performance or events to differ from those anticipated, estimated or intended. Should one or more of these risks or uncertainties materialize, or should assumptions underlying the forward-looking statements prove incorrect, actual results, performance or events may vary materially from those expressed or implied by the forward-looking statements contained in this MD&A. These factors should be considered carefully, and readers should not place undue reliance on the forward-looking statements. Forward-looking statements contained herein are made as of the date of this MD&A and the Company assumes no responsibility to update forward looking statements, whether because of new information or otherwise, other than as may be required by applicable securities laws.*

<b>Forward-Looking Statements</b>	<b>Assumptions</b>	<b>Risk Factors</b>
The Company’s (i) development of product candidates, (ii) demonstration of such product candidates’ safety and efficacy in clinical trials, and (iii) obtaining regulatory approval to commercialize these product candidates.	Financing will be available for development of new product candidates and conducting clinical studies; the actual results of the clinical trials will be favourable; development costs will not exceed the Company’s expectations; the Company will be able to retain and attract skilled staff; the Company will be able to recruit suitable patients for clinical trials; all requisite regulatory and governmental approvals to commercialize the product candidates will be received on a timely basis upon terms acceptable to the Company; applicable economic conditions are favourable to the Company.	Availability of financing in the amount and time frame needed for the development and clinical trials may not be favourable; increases in costs; the Company’s ability to retain and attract skilled staff; the Company’s ability to recruit suitable patients for clinical trials; timely and favourable regulatory and governmental compliance, acceptances, and approvals; interest rate and exchange rate fluctuations; changes in economic conditions.
The Company’s ability to obtain the substantial capital it requires to fund research and operations.	Financing will be available for the Company’s research and operations and the results thereof will be favourable; debt and equity markets, exchange and interest rates and other applicable economic conditions are favourable to the Company.	Changes in debt and equity markets; timing and availability of external financing on acceptable terms; increases in cost of research and operations; interest rate and exchange rate fluctuations; adverse changes in economic conditions.
Factors affecting pre-clinical research, clinical trials and regulatory approval process of the Company’s product candidates.	Actual costs of pre-clinical research, clinical and regulatory processes will be consistent with the Company’s current expectations; the Company will be able to retain and attract skilled staff; the Company will be able to recruit suitable	The Company’s product candidates may require time-consuming and costly pre-clinical and clinical studies and testing and regulatory approvals before commercialization; the Company’s ability to retain and

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Forward-Looking Statements	Assumptions	Risk Factors
	patients for clinical trials; the Company will be able to complete pre-clinical research and clinical studies on a timely basis with favourable results; all applicable regulatory and governmental approvals for product candidates will be received on a timely basis with terms acceptable to the Company; debt and equity markets, exchange and interest rates, and other applicable economic and political conditions are favourable to the Company; there will be a ready market for the product candidates.	attract skilled staff; the Company's ability to recruit suitable patients for clinical trials; adverse changes in regulatory and governmental processes; interest rate and exchange rate fluctuations; changes in economic and political conditions; the Company will not be adversely affected by market competition.
The Company's ability to commercialize on its own or find and enter into agreements with potential partners to bring viable product candidates to commercialization.	The Company will be able to commercialize on its own or to find a suitable partner and enter into agreements to bring product candidates to market within a reasonable time frame and on favourable terms; the costs of commercializing on its own or entering into a partnership will be consistent with the Company's expectations; partners will provide necessary financing and expertise to bring product candidates to market successfully and profitably.	The Company will not be able to commercialize on its own or find a partner and/or enter into agreements within a reasonable time frame; if the Company enters into agreements, these agreements may not be on favourable terms to the Company; costs of entering into agreements may be excessive; potential partners will not have the necessary financing or expertise to bring product candidates to market successfully or profitably.
The Company's ability to obtain and protect the Company's intellectual property rights and not infringe on the intellectual property rights of others.	Patents and other intellectual property rights will be obtained for viable product candidates; patents and other intellectual property rights obtained will not infringe on others.	The Company will not be able to obtain appropriate patents and other intellectual property rights for viable product candidates; patents and other intellectual property rights obtained will be contested by third parties; no proof that acquiring a patent will make the product more competitive.
The Company's ability to source markets which have demand for its products and successfully supply those markets in order to generate sales.	The anticipated markets for the Company's potential products and technologies will continue to exist and expand; the Company's products will be commercially viable, and it will successfully compete with other research teams who are also examining potential products.	The anticipated market for the Company's potential products and technologies will not continue to exist and expand for a variety of reasons, including competition from other products and the degree of commercial viability of the potential product.
Future actions with respect to and potential impacts of pending claims.	The Company will be able to settle or otherwise obtain disposition of claims against it on favourable terms.	The Company may will not be able to settle pending claims on favourable terms; claims may be adjudicated in a manner that is not favourable to the Company.

Inherent in forward-looking statements are risks, uncertainties, and other factors beyond the Company's ability to predict or control. Please also make reference to those risk factors referenced in the "Risk Factors" section below. Readers are cautioned that the above chart does not contain an exhaustive list of the factors or assumptions that

may affect the forward-looking statements, and that the assumptions underlying such statements may prove to be incorrect. Actual results and developments are likely to differ, and may differ materially, from those expressed or implied by the forward-looking statements contained in this MD&A.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results, performance or achievements to be materially different from any of its future results, performance or achievements expressed or implied by forward-looking statements. All forward-looking statements herein are qualified by this cautionary statement. Accordingly, readers should not place undue reliance on forward-looking statements. The Company undertakes no obligation to update publicly or otherwise revise any forward-looking statements whether as a result of new information or future events or otherwise, except as may be required by law. If the Company does update one or more forward-looking statements, no inference should be drawn that it will make additional updates with respect to those or other forward-looking statements, unless required by law.

## **BUSINESS OVERVIEW**

PharmaTher is a specialty pharmaceutical company focused on developing and commercializing KETARX™ (racemic ketamine) delivered by intravenous and intramuscular injection, microneedle patch, and on-body pump for mental health, neurological and pain disorders. PharmaTher is advancing the clinical development of KETARX™ for anesthesia/sedation, pain, mental health conditions, Parkinson's disease and Amyotrophic Lateral Sclerosis. The Company aims to leverage the U.S. Food and Drug Administration ("FDA") regulatory incentives for expedited approvals, such as the FDA 505(b)(2) regulatory pathway, orphan drug, and fast track designations. PharmaTher's patent portfolio includes granted and provisional patents on method of uses of KETARX™ and drug delivery systems. In addition, the Company actively seeks licensing, acquisition or partnership opportunities from industry and academia.

## **CORPORATE HIGHLIGHTS**

On June 7, 2022, the Company announced positive results from an investigator-led observational study (the "Study") evaluating the impact of KETABET™, a patented drug combination of FDA-approved ketamine and betaine anhydrous, on the unwanted ketamine side effects seen post ketamine treatment for subjects with depression.

On June 29, 2022, the Company announced that it has successfully completed its research study evaluating the Company's patented hydrogel-forming microneedle patch, PHARMAPATCH™, to deliver ketamine and KETABET™ (ketamine and betaine anhydrous), which aims to prevent the potential side effects of repeated ketamine treatment for depression and other indications, including suicidal ideation, substance abuse, post-traumatic stress disorder, neurological disorders, and chronic pain.

On July 13, 2022, the Company announced that the United States Patent and Trademark Office ("USPTO") has provided a Notice of Allowance for patent application No. 15/574,346, titled "Compositions and Methods for Treating Motor Disorders", which includes claims intended to cover ketamine in the potential treatment of Parkinson's Disease and motor disorders that cause involuntary or uncontrollable movement or actions of the body.

On September 7, 2022, the Company announced that it has completed an IND-enabling pharmacokinetic and tolerability study of KETARX™ Ketamine Patch in minipigs.

On September 16, 2022, the Company announced Late-Breaking Abstract Presentation of Positive Efficacy and Safety Data from Phase 1/2 Clinical Study of Ketamine in the Treatment of Levodopa-Induced Dyskinesia in Parkinson's Disease at the MDS International Congress of Parkinson's Disease and Movement Disorders.

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On October 5, 2022, the Company announced that the United States Patent and Trademark Office (“USPTO”) granted US Patent No: 11,426,366, titled “Compositions and Methods for Treating Motor Disorders,” which includes claims intended to cover ketamine in the potential treatment of Parkinson’s Disease and motor disorders that cause involuntary or uncontrollable movement or actions of the body.

On November 14, 2022, the Company announced that a poster presentation of the Phase 1/2 clinical study of ketamine in the treatment of levodopa-induced dyskinesia in Parkinson’s disease was presented at Neuroscience 2022 by the Society for Neuroscience being held November 12-16, 2022, at the San Diego Convention Center in San Diego, California. In addition, the Company has engaged the FDA to establish the next steps for a planned Phase 3 clinical study to allow for the Company’s proprietary ketamine intravenous product, KETARX™, approval for Parkinson’s disease under the 505(b)(2) regulatory pathway.

On December 15, 2022, the Company announced that FDA has granted orphan drug designation for ketamine in the prevention of ischemia-reperfusion injury from organ transplantation.

On January 18, 2023, the Company announced that it has applied with the FDA to receive Orphan Drug Designation (“ODD”) for ketamine to treat Rett Syndrome, a rare genetic neurological disorder. Ketamine has been subject to a Phase 2 clinical trial (NCT03633058) for Rett syndrome.

On February 1, 2023, the Company announced that the FDA has granted orphan drug designation to KETARX™ (racemic ketamine) for the treatment of Rett Syndrome.

On February 7, 2023, the Company submitted its Type B meeting package with the FDA to discuss the remaining requirements for the KETARX™ On-Body Pump System (subcutaneous racemic ketamine) and submission of a New Drug Application (“NDA”) under the 505(b)(2) pathway.

On March 29, 2023, the Company announced an update on the Type C meeting with the FDA for advancing KETARX™ (ketamine) towards Phase 3 clinical development as a treatment for levodopa-induced dyskinesia in Parkinson’s disease (“LID-PD”).

On May 2, 2023, the Company announced the submission of a Fast Track Application to the FDA for KETARX™ (ketamine) for the treatment for levodopa-induced dyskinesia in Parkinson’s disease (“LID- PD”).

On June 12, 2023, the Company provided a corporate update outlining the development and commercialization plans and upcoming milestones for its KETARX™ (racemic ketamine) products and PharmaPatch™ (microneedle patch) delivery system.

On June 20, 2023, the Company announced it has entered into a collaboration agreement with Vitruvius Therapeutics, Inc. (“Vitruvius”), a leading U.S. based specialty generic pharmaceutical company, for the commercialization of the Company’s KETARX™ (racemic ketamine) products in the U.S.

On June 27, 2023, the Company announced that it has filed a Pre-Submission Facility Correspondence in advance of its Abbreviated New Drug Application (“ANDA”) for KETARX™ (racemic ketamine) to the FDA to support expedited review of its priority ANDA.

During the year ended May 31, 2023, the Company signed a settlement agreement with Relevium Technologies Inc. (“Relevium”) relating to a lawsuit commenced by the Company against Relevium for breach

of contract regarding a take-over transaction. Per the agreement, Relevium is to issue shares to the Company for a value of \$225,000 once Relevium's Cease Trade Order with TSX Venture Exchange is lifted.

On July 18, 2023, the Company announced that it has successfully completed a research study evaluating PharmaPatch™, a proprietary microneedle patch, in delivering N,N-dimethyltryptamine ("DMT"). The research study was conducted with Terasaki Institute for Biomedical Innovation ("Terasaki").

PharmaTher Inc. the wholly-owned subsidiary of PharmaTher Holdings Ltd, entered into a unanimous shareholders agreement pursuant to which PharmaTher Inc. will subscribe for 144,117,647 common shares of PharmaDrug Inc. ("PharmaDrug")'s subsidiary Sairiyo Therapeutics Inc. ("Sairiyo") for \$300,000. PharmaTher Inc. is a 49% shareholder of Sairiyo. In the event that PharmaDrug elects not to participate in any new issuance, PharmaTher Inc. may increase its ownership from 49% to 51% with an investment of \$250,000. Either side may increase its ownership by 10% for additional \$100,000 investments. Neither side may be diluted beyond a 10% carried interest. The Company is diversifying its product portfolio with its stake in Sairiyo Therapeutics Inc., whose sole asset is a patented reformulated version of the drug Cepharranthine as a potential treatment for medical countermeasures and cancer.

On September 27, 2023, the Company announced that the FDA accepted the ANDA for KETARX™ (racemic ketamine). The FDA assigned a Generic Drug User Fee Amendments of 2022 ("GDUFA") goal date for this priority original ANDA of April 29, 2024.

## **RESEARCH AND DEVELOPMENT**

The Company is a specialty pharmaceutical company focused on developing and commercializing KETARX™ (racemic ketamine) delivered by intravenous and intramuscular injection, microneedle patch, and on-body pump for mental health, neurological and pain disorders. PharmaTher is advancing the clinical development of KETARX™ for anesthesia/sedation, pain, mental health conditions, Parkinson's disease and Amyotrophic Lateral Sclerosis.

### KETARX™

KETARX™ is the Company's Ketamine Hydrochloride injection USP product, or racemic ketamine, and is being developed for rare disorders, such as Parkinson's disease, Amyotrophic Lateral Sclerosis, complex regional pain syndrome, as well as larger unmet needs in anesthesia and procedural sedation. Ketamine is a rapid-acting, nonbarbiturate general anesthetic approved by the FDA in 1970 and is clinically used for analgesia, sedation, and anesthetic induction. Ketamine is a generic drug classified by the Drug Enforcement Agency ("DEA") as a Schedule III controlled substance. Published studies have demonstrated ketamine's potential in major depressive disorder, bipolar depression, depression with suicidal ideation, post-traumatic stress disorder, drug addiction, Parkinson's disease, and pain management.

#### *KETARX™ for anesthesia and procedural sedation*

The Company is developing a generic form of Ketamine Hydrochloride Injection USP multi-dose use. In the U.S., Ketamine Hydrochloride is indicated as an anaesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation. The Company expects to form partnerships with research labs, ketamine clinics and pharmaceutical companies that are: seeking a secure supply of cGMP ketamine and ketamine products for current portfolios; exploring alternative dose forms for multiple existing indications; and requiring support to develop and eventually commercialize specific ketamine products for new indications. In addition, the Company will enter the market with KETARX™ targeting ketamine's FDA approved label for anesthesia and procedural sedation. The

Company will seek to file a supplemental Abbreviated New Drug Application with the FDA and seek regulatory approvals for international markets.

*KETARX™ for Parkinson's disease*

Parkinson's disease is a debilitating disorder that affects over 1 million people in the U.S. and more than 7 million people worldwide. There is currently no cure for Parkinson's disease, although some drug combinations are used to treat the disease symptoms. Levodopa is the gold standard for Parkinson's disease treatment but features significant drawbacks, including the major side effect of dyskinesia and a loss of effectiveness over time. Approximately 50% of patients with PD will develop Levodopa-induced dyskinesia ("LID") 4-5 years after the initiation of levodopa therapy, and this number rises to 80% after 10-12 years of levodopa treatment. LID may interfere with motor function, cause or aggravate pain and is known to worsen the quality of life significantly. Individuals with Parkinson's disease may experience a host of non-motor symptoms such as autonomic dysfunction, psychiatric (depression), cognitive and sensory symptoms (pain). Therefore, there is an urgent need for alternative treatments and has been identified by the regulatory authorities, patient advocacy groups such as Michael J. Fox Foundation, and key opinion leaders as a substantial unmet medical need.

PharmaTher has entered into an exclusive license agreement with the University of Arizona for the development and commercialization of ketamine in the treatment of Parkinson's disease. Ketamine is an FDA-approved drug with a known safety profile. Prior clinical reports suggest that low-dose ketamine infusions are well tolerated and can improve pain and depression, both often comorbidities in Parkinson's disease patients. Inventors Dr. Scott Sherman and Dr. Torsten Falk, both associate professors at The University of Arizona College of Medicine – Tucson, are working with Tech Launch Arizona to patent the results from preclinical data and five case studies in Parkinson's disease patients showing that low-dose sub-anesthetic ketamine infusion indicates tolerability, safety, and the potential of long-term therapeutic benefit to reduce Levodopa-induced dyskinesia, improve on time, and reduce depression.<sup>1-5</sup>

The FDA has approved the Company's Investigational New Drug application to proceed with a Phase 2 clinical trial to evaluate the safety, efficacy and pharmacokinetics of ketamine in the treatment of LID-PD. PharmaTher recently announced the presentation of a Phase 1/2 clinical study involving ketamine in the treatment of LID-PD. The data from this study demonstrated ketamine's safety and tolerability with clinically meaningful efficacy that supports further investigation in a proposed Phase 3 clinical study as a potential new treatment for LID-PD and the Company would seek FDA approval via the 505(b)(2) regulatory pathway.

*KETARX™ for Amyotrophic Lateral Sclerosis*

ALS is a progressive neuromuscular disease with a life expectancy of only two to six years after diagnosis. Currently, there is no known cure for ALS. ALS affects approximately 50,000 people in the U.S. and Europe, with over 5,000 new cases diagnosed annually. As ALS advances, upper and lower motor neurons die, causing the brain to lose its ability to control muscle movement. ALS patients experience progressive loss of voluntary muscle action as an effect of the disease, resulting in the inability to speak, eat, move and, eventually, breathe. The FDA approved only three

1. UA Clinical Trial to Repurpose Ketamine for Parkinson's Patients.
2. US20190060254A1— Compositions and methods for treating motor disorders.
3. Bartlett, et al, 2020. Preclinical evidence in support of repurposing sub-anesthetic ketamine as a treatment for L-DOPA-induced dyskinesia. *Experimental Neurology*. Volume 333.
4. Bartlett, M.J., Joseph, R.M., LePoidevin, L.M., Parent, K.L., Laude, N.D., Lazarus, L.B., Heien, M.L., Estevez, M., Sherman, S.J., Falk, T., 2016. Long-term effect of sub-anesthetic ketamine in reducing L-DOPA-induced dyskinesias in a preclinical model.
5. Sherman, S.J., Estevez, M., Magill, A.B., Falk, T., 2016. Case reports showing a long-term effect of subanesthetic ketamine infusion in reducing L-DOPA-induced dyskinesias. *Case Rep. Neurol.* 8, 53–58.



pharmaceuticals for the treatment of ALS: riluzole, edaravone, and Nuedexta (dextromethorphan HBr and quinidine sulfate). These drugs are effective against disease mechanisms of ALS but fail to have measurable effects on attenuating disease progression or improve survival. Therefore, there is an imperative need for new pharmacological therapies that can stop or slow the muscle decline associated with ALS progression and extend the life expectancy of the ALS patient.

PharmaTher entered into an exclusive license agreement with The University of Kansas to develop and commercialize the intellectual property of ketamine to treat ALS. Ketamine has the potential to effectively increase the life expectancy of those with ALS at any stage and slow the progressive loss of muscle associated with poor outcomes of the disease. The University of Kansas Medical Center researchers and inventors of the potential use of ketamine to treat ALS, Dr. Richard J. Barohn, M.D., John A. Stanford, Ph.D., and Dr. Matthew Macaluso, D.O., have made the promising discovery that ketamine can be administered as an effective treatment for ALS. Unpublished and patent-pending preclinical research has shown that the administration of ketamine preserves muscle function in advancing ALS and increases life expectancy when given in the early stages of muscle decline. Ketamine works by blocking the action of the ionotropic glutamate receptor, the NMDA receptor. Unlike other inhibitors of NMDA receptor function, such as riluzole, ketamine dampens NMDA receptor-related glutamate excitotoxicity indirectly. Further, ketamine can lower D-serine concentrations intracellularly and also partially activates dopamine receptors. Collectively, these mechanisms of ketamine contribute in part to the drug's neuroprotective effects, which may extend to the motor neurons targeted in ALS.

The FDA has accepted an investigator-initiated investigational new drug application to proceed with a Phase 2 clinical trial evaluating ketamine in the treatment of ALS. Assuming the study is positive, the Company will request a meeting with the FDA to discuss its plan and obtain an agreement to move to a Phase 3 clinical study and accelerated marketing approval. The Company will seek regulatory approval under the FDA 505(b)(2) regulatory pathway.

#### *KETARX™ Microneedle Patch*

The Company is developing KETARX™ (racemic ketamine) microneedle patch, for mental health, neurological and pain disorders. KETARX™ microneedle patch aims to empower patients to dose their medication remotely, safely and conveniently rather than being under supervision by a healthcare provider at a certified medical office. KETARX™ microneedle patch has the potential to incorporate anti-tampering and anti-abuse features and the delivery format of the product that would parallel the approach used for the tamper-resistant transdermal fentanyl patch. In a research project with The Queen's University of Belfast, led by Professor Ryan Donnelly, the Company has successfully completed the evaluation of a patented hydrogel-forming microneedle patch to deliver KETARX™. This de-risking milestone supports the Company's expansion in finalizing IND-enabling studies and the clinical manufacturing scale up with LTS Lohmann, a leader in transdermal delivery systems, to support FDA and international regulatory submissions.

#### *KETARX™ On-body Pump*

PharmaTher aims to commercialize KETARX™ On-body Pump (subcutaneous racemic ketamine) for the maintenance of general anesthesia for diagnostic and surgical procedures. The Company believes that subcutaneous infusion of racemic ketamine via the on-body pump device has several advantages for ketamine procedural sedation, including decreased requirement for skilled personnel for its administration, reduction in pain and irritation associated with administration, and a reduced risk of systemic infection and other complications seen with IV administration. The Company has partnered with CC Biotechnology Corporation, a leader in the design and manufacturing of wearable, pen and auto injectors, for the development of the KETARX™ On-body Pump solution for mental health, neurological and pain disorders. The Company believes that in the natural evolution of chronic

disease management, a logical progression from IV and IM to wearable injection systems could increase the convenience, compliance, and dose flexibility for both caregivers and patients.

### PHARMAPATCH™

PHARMAPATCH™ is the Company's microneedle patch technology solution, such as its hydrogel-forming delivery system and its gelatin methacryloyl delivery system, for psychedelics (i.e., ketamine, psilocybin, DMT, LSD and MDMA, etc) and infectious diseases. The Company seeks to develop and partner these programs with life sciences companies.

#### *Hydrogel-Forming Microneedle Delivery*

PharmaTher entered into an exclusive worldwide patent and know-how license agreement with The Queen's University of Belfast ("QUB") to develop and commercialize a patented hydrogel-forming microneedle patch delivery technology developed by Professor Ryan Donnelly to support PharmaTher's product and clinical development initiatives involving ketamine. The patented microneedle patch delivery system consists of hydrogel-forming microneedle arrays and an accompanying reservoir which will overcome any limitations by the quantity of drug that can be loaded into the needles or onto the needle surfaces. The microneedle patch can significantly increase drug permeating through the microneedle array and into the skin.

Most recently, Professor Donnelly's lab successfully completed research and published a paper titled "Hydrogel-forming microneedle arrays as a therapeutic option for transdermal esketamine delivery," validating the delivery of esketamine, the S(+) enantiomer of ketamine, in a novel microneedle patch which may overcome the drawbacks associated with ketamine administration in an intravenous or nasal spray format.

PharmaTher entered into a sponsored research agreement with QUB to further develop the hydrogel-forming microneedle delivery system.

#### *Gelatin Methacryloyl Microneedle Delivery System for Psychedelics*

PharmaTher entered into an exclusive license agreement with BioRAE, Inc., for the development and commercialization of a novel biocompatible and biodegradable gelatin methacryloyl microneedle ("GelMA-MN") delivery technology developed at the University of California, Los Angeles ("UCLA") for use with psychedelic pharmaceuticals, including, but not limited to Psilocybin, Ketamine, LSD, MDMA, DMT, and Cannabinoids.

The GelMA-MN delivery technology was invented and developed by the members of the Khademhosseini Lab at UCLA. Studies have shown that GelMA can be used for the fabrication of MN arrays and the delivery of both water-soluble and insoluble drugs with desirable release profiles. GelMA is derived from the natural polymer gelatin with cross linkable methacrylate group making it an ideal candidate for MN fabrication and various other biomedical applications. The GelMA-MNs are biocompatible and biodegradable, can efficiently penetrate the stratum corneum layer (outer layer of the skin), enable flexible drug load capacity and combinations, and control-release delivery. MNs are considered as a promising way to achieve systemic effects by transdermal delivery of drugs. In addition to applications on the skin, MNs may be applied in other organs and tissues like the eyes and mucosal surfaces. MNs are minimally invasive, painless, and may overcome the potential drawbacks of oral administration, subcutaneous injections and other transdermal delivery systems.

PharmaTher entered into a sponsored research agreement with the Terasaki Institute to further develop the GelMA MN patch for the delivery of psilocybin, DMT, MDMA and LSD.

## TRENDS AND ECONOMIC CONDITIONS

Management regularly monitors economic conditions and estimates their impact on the Company's operations and incorporates these estimates in both short-term operating and longer-term strategic decisions.

Apart from these and the risk factors noted under the heading "Risk Factors" and "Cautionary Note Regarding Forward-Looking Information", management is not aware of any other trends, commitments, events or uncertainties that would have a material effect on the Company's business, financial condition or results of operations.

## SELECTED ANNUAL INFORMATION

	Year ended May 31, 2023 \$	Year ended May 31, 2022 \$	Year ended May 31, 2021 \$
Total assets	6,309,000	12,161,737	5,943,974
Total liabilities	892,478	330,318	361,060
Working capital	5,416,522	11,831,419	5,764,504
Expenses (Income)	4,014,790	4,102,354	3,149,007
Net (loss) income	(6,416,319)	(4,010,636)	2,664,196
Net (loss) earnings per share, basic and diluted	(0.07)	(0.05)	0.04

## SELECTED QUARTERLY INFORMATION

A summary of selected information for each of the quarters presented below is as follows:

For the Period Ended	Net Income (Loss)		Total assets (\$)
	Total (\$)	Basic and diluted loss per share (\$)	
May 31, 2023	(1,594,046)	(0.01)	6,309,711
February 28, 2023	(754,048)	(0.01)	7,574,537
November 30, 2022	(2,279,890)	(0.03)	8,090,961
August 31, 2022	(1,788,335)	(0.02)	10,190,220
May 31, 2022	54,910	0.00	12,163,870

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February 28, 2022	(3,020,322)	(0.03)	11,871,521
November 30, 2021	(137,079)	(0.00)	14,962,863
August 31, 2021	(917,474)	(0.01)	5,199,110

## **FINANCIAL RESULTS**

The Company reported a net loss of \$6,416,319 for the year ended May 31, 2023, which is comprised of unrealized loss on investment of \$2,633,334, research of \$3,018,122, consulting fees of \$477,046, general, and administrative of \$348,859, shareholder information and filing fees of \$54,947 and professional fees of \$115,816. The Company is maintaining its reporting issuer status while moving forward in its research initiatives as outlined under "Research and Development" above.

The Company reported a net loss of \$4,010,636 for the year ended May 31, 2022, which is comprised of unrealized loss on investment of \$133,333, current income tax recovery of \$39,551, deferred income tax recovery of \$185,500, research of \$2,605,142, consulting fees of \$490,260, general, and administrative of \$172,286, stock-based compensation of \$373,409, shareholder information and filing fees of \$140,694 and professional fees of \$320,563.

The Company reported a net loss of \$1,594,046 for the three months ended May 31, 2023, which is comprised of research of \$850,423, consulting fees of \$135,560, general, and administrative of \$118,134, shareholder information and filing fees of \$4,727 and professional fees of \$24,673. The Company is maintaining its reporting issuer status while moving forward in its research initiatives as outlined under "Research and Development" above.

The Company reported a net income of \$64,239 for the three months ended May 31, 2022, which is comprised of unrealized gain on investment of \$1,300,000, research of \$1,262,416, consulting fees of (\$64,246), general and administrative of \$31,090, shareholder information and filing fees of \$13,034, professional fees of \$16,888, stock-based compensation of \$204,630, income tax recovery of \$39,551 and deferred tax recovery of \$185,500.

## **LIQUIDITY AND CAPITAL RESOURCES**

The Company's approach to managing liquidity risk is to ensure that it will have sufficient liquidity to meet liabilities when due. The Company's liquidity and operating results may be adversely affected if the Company's access to the capital market is hindered, whether because of a downturn in stock market conditions generally or because of conditions specific to the Company. The Company regularly evaluates its cash position to ensure preservation and security of capital as well as maintenance of liquidity. As the Company does not presently generate revenue to cover its costs, managing liquidity risk is dependent upon the ability to secure additional financing. The recoverability of the carrying value of the assets and the Company's continued existence is dependent upon the achievement of profitable operations, or the ability of the Company to raise alternative financing, as necessary. While management and the Board have been successful in raising the necessary capital, it cannot provide assurance that it will be able to execute on its business strategy or be successful in future financing activities.

As of May 31, 2023, the Company had a cash balance of \$5,919,808 to settle current liabilities of \$892,478. The Company has deficit of \$7,784,892 as of May 31, 2023.

The table below outlines the comparison of the Company's actual and planned uses of working capital from June 1, 2021, to May 31, 2023:

PharmaTher Holdings Ltd.  
Management's Discussion and Analysis  
May 31, 2023  
Dated – September 28, 2023

Use of Capital	Estimated Cost	Spent to May 31, 2023 (approx.)	Remaining Funds to Spend or (excess)
General and administrative <sup>(1)</sup>	\$750,000	\$680,000	\$70,000
Sales and marketing	\$150,000	\$84,000	\$66,000
Research and development <sup>(2)</sup>	\$2,500,000	\$3,018,000	(\$518,000)
<b>Total</b>	<b>\$3,400,000</b>	<b>\$3,782,000</b>	<b>(\$382,000)</b>

Notes:

- (1) This figure is for a forecasted period from June 1, 2022, to May 31, 2023, and is comprised of consulting fees in the amount of approximately \$400,000, professionals' fees in the amount of approximately \$150,000, transfer agent and regulatory fees in the amount of approximately \$50,000, and insurance and office expenses in the amount of approximately \$150,000.
- (2) This figure is for a forecasted period from June 1, 2022, to May 31, 2023, and is comprised of anticipated costs of \$1,000,000 in connection with the development and production of KETARX™ for regulatory submission and future clinical studies, anticipated costs of \$1,000,000 in connection with the development and production of KETARX™ microneedle patch and on-body pump for future clinical studies and anticipated costs of \$500,000 for general research, development, and clinical studies.

As of May 31, 2023, based on current projections, the Company's working capital of \$5,416,522, which is comprised of current assets less current liabilities, is sufficient to meet its planned development activities for the financial year ending May 31, 2024. The table below outlines the Company's planned uses of working capital:

Use of Capital	Estimated Cost
General and administrative <sup>(1)</sup>	\$750,000
Sales and marketing	\$150,000
Research and development <sup>(2)</sup>	\$2,500,000
<b>Total</b>	<b>\$3,400,000</b>

Notes:

- (1) This figure is for a forecasted period from June 1, 2023 to May 31, 2024 and is comprised of consulting fees in the amount of approximately \$400,000, professionals' fees in the amount of approximately \$150,000, transfer agent and regulatory fees in the amount of approximately \$50,000, and insurance and office expenses in the amount of approximately \$150,000.
- (2) This figure is for a forecasted period from June 1, 2023 to May 31, 2024 and is comprised of anticipated costs of \$1,000,000 in connection with the development and production of KETARX™ for regulatory submission and future clinical studies, anticipated costs of \$1,000,000 in connection with the development and production of PHARMAPATCH™ for future clinical studies and anticipated costs of \$500,000 for general research, development and clinical studies.

Unallocated funds will be deposited in the Company's bank account and added to the working capital of the Company. Based on the Company's cash flow requirements, management will determine the appropriate level of liquidity required for operations and will draw down such funds as necessary.

There may be circumstances, where for business reasons, a reallocation of funds may be necessary for the Company to achieve its stated business objectives.

The Company had negative cash flow from operating activities for the year ended May 31, 2023. The Company cannot guarantee it will have a cash flow positive status from operating activities in future periods. As a result, the Company continues to rely on the issuance of securities or other sources of financing to generate sufficient funds to fund its working capital requirements and for corporate expenditures. The Company may continue to have negative cash flow from operating activities until sufficient levels of sales are achieved. To the extent that the Company has negative cash flow from operating activities in future periods, the Company may need to use a portion of proceeds from any offering to fund such negative cash flow.

## RELATED PARTY TRANSACTIONS

### (a) Related party balances and transactions

Related parties include the directors of the Company, close family members and enterprises which are controlled by these individuals as well as persons performing similar functions.

Names	Year Ended May 31, 2023 \$	Year Ended May 31, 2022 \$
Fabio Chianelli (i)	320,000	250,000
Marrelli Support Services Inc. ("MSSI") (ii)	51,569	44,400
DSA Corporate Services Inc. ("DSA") (iii)	40,306	56,489
Larnic Inc. (iv)	220,000	237,500
Marrelli Trust Company Limited ("Marrelli Trust") (v)	6,875	5,521
<b>Total</b>	<b>638,750</b>	<b>593,910</b>

(i) Fees are related to services of Fabio Chianelli to act as the Chief Executive Officer ("CEO") of the Company. Fabio Chianelli is the owner of Fabiotech Inc. As at May 31, 2023, \$nil (May 31, 2022 - \$nil) was owed to the CEO.

(ii) Fees are related to services of Carmelo Marrelli to act as the Chief Financial Officer ("CFO") of the Company. Carmelo Marrelli is the Managing Director of MSSI. Services were incurred for bookkeeping, accounting and CFO services. As at May 31, 2023, MSSI was owed \$2,522 (May 31, 2022 - \$1,463) and this amount was included in accounts payable and accrued liabilities. This amount is unsecured and non-interest bearing.

(iii) The CFO of the Company is an officer of DSA and the Corporate Secretary of the Company is an employee of DSA. Fees are related to corporate secretarial and filing services provided by DSA. As at May 31, 2023, DSA was owed \$2,260 (May 31, 2022 - \$3,277) and this amount was included in accounts payable and accrued liabilities. This amount is unsecured and non-interest bearing.

(iv) During the year ended May 31, 2023, the Company incurred consulting fees of \$220,000 (2022 - \$237,500) to a company controlled by the spouse of the CEO and the consulting fees have been included in research expenses, which services supported aspects of the product and clinical development, regulatory and market research of the Company's product pipeline. As at May 31, 2023, the company controlled by the spouse of the CEO was owed \$nil (May 31, 2022 - \$nil).

(v) The CFO of the Company is a director of Marrelli Trust. Marrelli Trust provided stock transfer services to the Company. As at February 28, 2023, Marrelli Trust was owed \$1,085 (May 31, 2022 - \$nil) and this amount was included in accounts payable and accrued liabilities. This amount is unsecured and non-interest bearing.

(vi) During the year ended May 31, 2021, one of the officers of the Company paid research and development expenses in the amount of \$2,608 on behalf of the Company. As at May 31, 2023, the Company owed \$2,721 (May 31, 2022 - \$2,540) to the officer.

(b) Remuneration of directors and key management

In accordance with IAS 24, key management personnel are those persons having authority and responsibility for planning, directing and controlling the activities of the Company directly or indirectly, including any directors (executive and non-executive) of the Company. During the year ended May 31, 2023 and 2022, the Company incurred no remuneration of management.

(c) Major shareholders

To the knowledge of the directors and senior officers of the Company, as at May 31, 2023, no person or corporation beneficially owns or exercises control over common shares of the Company carrying more than 10% of the voting rights attached to all common shares of the Company other than Mr. Fabio Chianelli who owns 17.54% of the Company. The holding can change at any time at the discretion of the owners.

None of the Company's major shareholders have different voting rights compared to holders of the Company's common shares.

The Company is not aware of any arrangements the operation of which may at a subsequent date result in a change in control of the Company. To the knowledge of the Company, it is not directly or indirectly owned or controlled by another corporation, by any government or by any natural or legal person severally or jointly.

## **SHARE CAPITAL STRUCTURE**

As at the date of this document, the Company had 88,169,065 issued and outstanding common shares and 16,875,000 warrants and broker warrants and 5,699,000 stock options.

## **COMMITMENT**

The Company has entered into a licensing arrangement with the Arizona Board of Regents on behalf of the University of Arizona, whereby certain milestone payments and royalties are payable upon the achievement of certain events. The Company will record these amounts as the events occur.

## **OFF-BALANCE SHEET ARRANGEMENTS**

As of the date of this filing, the Company does not have any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on the results of operations or financial condition of the Company including, without limitation, such considerations as liquidity and capital resources that have not previously been discussed.

## **CAPITAL MANAGEMENT**

The Company considers its capital to be its shareholders' equity. As at May 31, 2023, the Company had shareholders' equity of \$5,417,233. The Company's objective when managing its capital is to seek continuous improvement in the return to its shareholders while maintaining a moderate to high tolerance for risk. The objective is achieved by prudently managing the capital generated through internal growth and profitability, through the use of lower cost capital, including raising share capital or debt when required to fund opportunities as they arise. The Company may also return capital to shareholders through the repurchase of shares, pay dividends or reduce debt where it determines any of these to be an effective method of achieving the above objective. The Company does not use ratios in the management of its capital. There have been no changes to management's approach to managing its capital during the year ended May 31, 2023.

## **RISK FACTORS**

Due to the nature of the Company's business, the legal and economic climate in which PharmaTher operates and the present stage of development of its business, the Company may be subject to significant risks. An investment in the Company's shares should be considered highly speculative. The Company's future development and actual operating results may be very different from those expected as at the date of this MD&A. There can be no certainty that the Company will be able to implement successfully its strategies. No representation is or can be made as to the future performance of the Company and there can be no assurance that the Company will achieve its objectives. An investor should carefully consider each of, and the cumulative effect of, the following factors.

### **History of Operating Losses**

To date, PharmaTher has a history of operating losses and may not achieve or sustain profitability. Since incorporation, PharmaTher has accumulated net losses and expects such losses to continue as it commences product, clinical, and commercial development for its products and its technologies. Management expects to continue to incur substantial operating losses unless and until such time as sales generate sufficient revenues to fund continuing operations and may not be able to sustain or increase profitability and failure to do so could adversely affect the Company's business, including its ability to raise additional funds.

### **Going-Concern Risk**

The Company's financial statements have been prepared on a going concern basis under which the Company is considered to be able to realize its assets and satisfy its liabilities in the ordinary course of business. PharmaTher's future operations are dependent upon the identification and successful completion of equity or debt financing and the achievement of profitable operations at an indeterminate time in the future. There can be no assurances that the Company will be successful in completing additional equity or debt financing or in achieving profitability. The financial statements do not give effect to any adjustments relating to the carrying values and classification of assets and liabilities that would be necessary should we be unable to continue as a going concern.



### **Early Stage Development**

PharmaTher has not begun to market any product or to generate revenues. The Company expects to spend a significant amount of capital to fund research and development and on further laboratory, animal studies and clinical trials. As a result, the Company expects that its operating expenses will increase significantly and, consequently, it will need to generate significant revenues to become profitable. Even if the Company does become profitable, it may not be able to sustain or increase profitability on a quarterly or annual basis. The Company cannot predict when, if ever, it will be profitable. There can be no assurances that the intellectual property of PharmaTher, or other products or technologies it may acquire, will meet applicable regulatory standards, obtain required regulatory approvals, be capable of being produced in commercial quantities at reasonable costs, or be successfully marketed. The Company will be undertaking additional laboratory, animal studies, and clinical studies with respect to the intellectual property of PharmaTher, and there can be no assurance that the results from such studies or trials will result in a commercially viable product or will not identify unwanted side effects.

### **Ability to Manage Growth**

Recent rapid growth in all areas of PharmaTher's business has placed, and is expected to continue to place, a significant strain on its managerial, operational and technical resources. The Company expects operating expenses and staffing levels to increase in the future. To manage such growth, the Company must expand its operation and technical capabilities and manage its employee base while effectively administering multiple relationships with various third parties. There can be no assurance that the Company will be able to manage its expanding operations effectively. Any failure to implement cohesive management and operating systems, to add resources on a cost-effective basis or to properly manage the Company's expansion could have a material adverse effect on its business and results of operations.

### **Unproven Market**

The Company believes that the anticipated market for its potential products and technologies will continue to exist and expand. These assumptions may prove to be incorrect for a variety of reasons, including competition from other products and the degree of commercial viability of the potential product.

### **Manufacturing, Pharmaceutical Development and Marketing Capability**

The Company has no, and does not expect to have any, in-house manufacturing, product development, or marketing capability. To be successful, a product must be manufactured and packaged in commercial quantities in compliance with regulatory requirements and in reasonable time frames and at accepted costs. The Company intends to contract with third parties to develop its products. No assurance can be given that the Company or its suppliers will be able to meet the supply requirements of the Company in respect of the product development or commercial sales. Production of therapeutic products may require raw materials for which the sources and amount of supply are limited, or may be hindered by quality or scheduling issues in respect of the third party suppliers over which the Company has limited control. An inability to obtain adequate supplies of raw materials could significantly delay the development, regulatory approval and marketing of a product. The Company has limited in-house personnel to internally manage all aspects of product development, including the management of multi-center clinical trials. The Company is significantly reliant on third party consultants and contractors to provide the requisite advice and management. There can be no assurance that the clinical trials and product development will not encounter delays which could adversely affect prospects for the Company's success.

To be successful, an approved product must also be successfully marketed. The market for the Company's product being developed by the Company may be large and will require substantial sales and marketing capability. At the present time, PharmaTher does not have any internal capability to market products or technologies. The Company intends to enter into one or more strategic partnerships or collaborative arrangements with pharmaceutical companies or other companies with marketing and distribution expertise to address this need. If necessary, the Company will establish arrangements with various partners for geographical areas. There can be no assurance that the Company can market, or can enter into a satisfactory arrangement with a third party to market a product in a manner that would assure its acceptance in the market place. However, if a satisfactory arrangement with a third party to market and/or distribute a product is obtained, then the Company will be dependent on the corporate collaborator(s) who may not devote sufficient time, resources, and attention to the Company's programs, which may hinder efforts to market the products. Should the Company not establish marketing and distribution strategic partnerships and collaborative arrangements on acceptable terms, and undertake some or all of those functions, the Company will require significant additional human and financial resources and expertise to undertake these activities, the availability of which is not guaranteed.

The Company will rely on third parties for the timely supply of raw materials, equipment, contract manufacturing, and formulation or packaging services. Although the Company intends to manage these third party relationships to ensure continuity and quality, some events beyond the Company's control could result in complete or partial failure of these goods and services. Any such failure could have a material adverse effect on the financial conditions and result of operation of the Company.

#### **Raw Material and Product Supply**

Raw materials and supplies are generally available in quantities to meet the needs of the Company's business. The Company will be dependent on third-party manufacturers for the products and technologies that it markets. An inability to obtain raw materials or product supply could have a material adverse impact on the Company's business, financial condition, and results of operations.

#### **Need for Additional Capital and Access to Capital Markets**

The Company will need additional capital to complete its current research, development, and commercial programs. It is anticipated that future research, additional pre-clinical and toxicology studies, manufacturing, and marketing initiatives, including that to prepare for market approval and successful product market launch, will require additional funds. Further financing may dilute the current holdings of shareholders and may thereby result in a loss for shareholders. There can be no assurance that the Company will be able to obtain adequate financing, or financing on terms that are reasonable or acceptable for these or other purposes, or to fulfill the Company's obligations under the various license agreements. Failure to obtain such additional financing could result in delay or indefinite postponement of further research and development of the Company's products and technologies with the possible loss of license rights to these products and technologies.

#### **Competition**

The market for PharmaTher's products and technologies is highly competitive. The Company will compete with academic and commercial industries who are also examining potential repurposing psychedelic-derived drugs with artificial intelligence. Many of its competitors have greater financial and operational resources and more experience in research, development, and commercialization than the Company will. These and other companies may have developed or could in the future develop new products and technologies that compete with the Company's products and technologies or even render its products and technologies obsolete.

## **Intellectual Property**

PharmaTher's success depends to a significant degree upon its ability to develop, maintain and protect proprietary products and technologies. PharmaTher has filed provisional patents for PanaceAI and certain neurological disorders. However, patents provide only limited protection of PharmaTher's intellectual property. The assertion of patent protection involves complex legal and factual determinations and is therefore uncertain and expensive. PharmaTher cannot provide assurances that patents will be granted with respect to any of its pending patent applications, that the scope of any of its patents will be sufficiently broad to offer meaningful protection, or that it will develop additional proprietary technologies that are patentable. PharmaTher's current patents could be successfully challenged, invalidated, or circumvented. This could result in PharmaTher's patent rights failing to create an effective competitive barrier. Losing a significant patent or failing to get a patent to issue from a pending patent application that PharmaTher considers significant could have a material adverse effect on PharmaTher's business. The laws governing the scope of patent coverage in various countries continue to evolve. The laws of some foreign countries may not protect PharmaTher's intellectual property rights to the same extent as the laws of Canada and the United States. If PharmaTher is successful in obtaining one or more patents, it will only hold them in selected countries. Therefore, third parties may be able to replicate PharmaTher's products and technologies covered by PharmaTher's patents in countries in which it does not have patent protection.

## **Litigation to Protect the Company's Intellectual Property**

The Company's future success and competitive position depends in part upon its ability to maintain its intellectual property portfolio. There can be no assurance that any patents will be issued on any existing or future patent applications. Even if such patents are issued, there can be no assurance that any patents issued or licensed to the Company will not be challenged. The Company's ability to establish and maintain a competitive position may be achieved in part by prosecuting claims against others who it believes to be infringing its rights. In addition, enforcement of the Company's patents in foreign jurisdictions will depend on the legal procedures in those jurisdictions. Even if such claims are found to be invalid, the Company's involvement in intellectual property litigation could have a material adverse effect on its ability to distribute any products that are the subject of such litigation. In addition, the Company's involvement in intellectual property litigation could result in significant expense, which could materially adversely affect the use responsibilities, whether or not such litigation is resolved in the Company's favour.

## **Risks Related to Potential Inability to Protect Intellectual Property**

PharmaTher's success is heavily dependent upon the Company's intangible property and technologies. The Company licenses certain of its product and technology from third parties and there can be no assurance that the Company will be able to continue licensing these rights on a continuous basis. The Company relies upon copyrights, trade secrets, unpatented proprietary know-how, and continuing technology innovation to protect the product and technology that the Company considers important to the development of its business. The Company relies on various methods to protect its proprietary rights, including confidentiality agreements with its consultants, service providers, and management that contain terms and conditions prohibiting unauthorized use and disclosure of the Company's confidential information. However, despite the Company's efforts to protect our intangible property rights, unauthorized parties may attempt to copy or replicate the Company's product or technology. There can be no assurances that the steps taken by the Company to protect its product and technology will be adequate to prevent misappropriation or independent third-party development of its product and technology. It is likely that other companies can duplicate a production process similar to the Company's. To the extent that any of the above could occur, the Company's revenue could be negatively affected, and in the future, the Company may have to litigate to enforce its intangible property rights, which could result in substantial costs and divert the Company management's attention and our resources.

### **Legal Proceedings**

In the course of the Company's business, the Company may from time to time have access to confidential or proprietary information of third parties, and these parties could bring a claim against the Company asserting that it has misappropriated their technologies and had improperly incorporated such technologies into the Company's products. Due to these factors, there remains a constant risk of intellectual property litigation affecting the Company's business. Additionally, PharmaTher faces litigation risks arising from its use of independent contractors and research collaborations to advance research and development of its product pipeline candidates. The Company may be made a party to litigation involving intellectual property, commercial disputes, and other matters, and such actions, if determined adversely, could have a material adverse effect on PharmaTher.

### **Lack of Supporting Clinical Data**

The clinical effectiveness and safety of any of PharmaTher's current or future products is not yet supported by clinical data and the medical community has not yet developed a large body of peer reviewed literature that supports the safety and efficacy of the PharmaTher's products. If future studies call into question the safety or efficacy of the PharmaTher's products, the Company's business, financial condition or results of operations could be adversely affected.

### **Research and Development Risk**

A principal component of the PharmaTher's business strategy is to expand its product offering to fully exploit the core technologies. As such, PharmaTher's organic growth and long-term success is primarily dependent on its ability to successfully develop new and current products and it will likely incur significant research and development expenditures. PharmaTher cannot be certain that any investment in research and development will yield technically feasible or commercially viable products. Furthermore, its ability to discover and develop products will depend on its ability to:

- retain key scientists as employees or partners,
- identify high quality therapeutic targets,
- identify potential drug candidates,
- develop products internally,
- successfully complete laboratory testing and clinical trials on humans,
- obtain and maintain necessary intellectual property rights to the PharmaTher's products,
- obtain and maintain necessary United States and other regulatory approvals for conducting clinical trials,
- obtain and maintain necessary United States and other regulatory approvals for its products,
- collaborate with third parties to assist in the development of its products, and
- enter into arrangements with third parties to co-develop, license, and commercialize its products.

PharmaTher may not be successful in discovering and developing its products and technologies. Failure to do so could materially and adversely affect the PharmaTher's operations and financial condition.

### **Success of Quality Control Systems**

The quality and safety of the Company's products are critical to the success of the Company's business and operations. As such, it is imperative that the Company and its service providers' quality control systems operate effectively and successfully. Quality control systems can be negatively impacted by the design of the quality control systems, the quality training program, and adherence by employees to quality control guidelines.

Although the Company strive to ensure that all of our service providers have implemented and adhere to high-caliber quality control systems, any significant failure or deterioration of such quality control systems could have a material adverse effect on the Company's business and operating results.

### **Product Liability**

The Company's products will be produced for sale both directly and indirectly to end consumers, and therefore the Company faces an inherent risk of exposure to product liability claims, regulatory action, and litigation if its products are alleged to have caused significant loss or injury. In addition, the manufacture and sale of the Company's products involves the risk of injury to consumers due to tampering by unauthorized third parties or product contamination. Previously unknown adverse reactions resulting from human consumption of the Company's products alone or in combination with other medications or substances could occur. The Company may be subject to various product liability claims, including, among others, that the Company's products caused injury or illness, include inadequate instructions for use or include inadequate warnings concerning possible side effects or interactions with other substances. A product liability claim or regulatory action against the Company could result in increased costs, could adversely affect the Company's reputation, and could have a material adverse effect on the Company's business and operational results.

### **Effectiveness and Efficiency of Advertising and Promotional Expenditures**

PharmaTher's future growth and profitability will depend on the effectiveness and efficiency of advertising and promotional expenditures, including the Company's ability to (i) create greater awareness of its products; (ii) determine the appropriate creative message and media mix for future advertising expenditures; and (iii) effectively manage advertising and promotional costs in order to maintain acceptable operating margins. There can be no assurance that advertising and promotional expenditures will result in revenues in the future or will generate awareness of the Company's technologies or products. In addition, no assurance can be given that we will be able to manage the Company's advertising and promotional expenditures on a cost-effective basis.

### **Maintaining and Promoting the Company's Brands**

PharmaTher believes that maintaining and promoting the Company's brands is critical to expanding the Company's customer base. Maintaining and promoting the Company's brands will depend largely on its ability to continue to provide quality, reliable, and innovative products, which the Company's may not do successfully. PharmaTher may introduce new products and technologies that the Company's customers do not like, which may negatively affect the Company's brand and reputation. Maintaining and enhancing the Company's brands may require substantial investments, and these investments may not achieve the desired goals. If the Company fails to successfully promote and maintain its brands or if the Company incurs excessive expenses in this effort, the Company's business and financial results from operations could be materially adversely affected.

### **Lack of Diversity**

Larger companies have the ability to manage their risk through diversification. However, PharmaTher currently lacks diversification, in terms of the nature of its business. As a result, PharmaTher could potentially be more impacted by factors affecting the pharmaceutical industry in general and PharmaTher in particular than would be the case if the business was more diversified. Currently, PharmaTher's product pipeline targets neurological indications, such as traumatic brain injury, migraines and rare pediatric disorders. Accordingly, PharmaTher is dependent on its ability to develop and commercialize its products and technologies and any factor that materially adversely affects its ability to do so may have a material adverse effect on PharmaTher's financial condition and results of operations.

### **Key Personnel Risk**

PharmaTher's success and future growth will depend, to a significant degree, on the continued efforts of the Company's directors and officers to develop the business and manage operations and on their ability to attract and retain key technical, scientific, sales and marketing staff or consultants. The loss of any key person or the inability to attract and retain new key persons could have a material adverse effect on the Company's business. Competition for qualified technical, scientific, sales and marketing staff, as well as officers and directors can be intense and no assurance can be provided that the Company will be able to attract or retain key personnel in the future. The Company's inability to retain and attract the necessary personnel could materially adversely affect the Company's business and financial results from operations.

### **Fluctuations in Foreign Currency Exchange Rates**

PharmaTher is subject to foreign currency risk. The strengthening or weakening of the Canadian or U.S. dollar versus other currencies will impact the translation of the Company's expenses and net revenues generated in these foreign currencies into Canadian and US dollars. The Company imports certain products from foreign countries, and so may become forced to pay higher rates for these products as a result of the weakening of the Canadian or U.S. dollar.

### **Requirement to Generate Cash Flow for Financial Obligations**

PharmaTher currently has negative operating cash flows. The Company's ability to generate sufficient cash flow from operations to make scheduled payments to the Company's contractors, service providers, and merchants will depend on future financial performance, which will be affected by a range of economic, competitive, regulatory, legislative, and business factors, many of which are outside of the Company's control. If the Company does not generate sufficient cash flow from operations to satisfy its contractual obligations, the Company may have to undertake alternative financing plans. The Company's inability to generate sufficient cash flow from operations or undertake alternative financing plans would have an adverse effect on the Company's business, financial condition, and results or operations, as well as its ability to satisfy the Company's contractual obligations. Any failure to meet the Company's financial obligations could result in termination of key contracts, which could harm the Company's ability to provide its products and technologies.

### **Uninsured or Uninsurable Risk**

The Company may become subject to liability for risks which are uninsurable or against which the Company may opt out of insuring due to the high cost of insurance premiums or other factors. The payment of any such liabilities would reduce the funds available for usual business activities. Payment of liabilities for which insurance is not carried may have a material adverse effect on the Company's financial position and operations.

### **Regulatory Approval and Permits**

PharmaTher may be required to obtain and maintain certain permits, licenses, and approvals in the jurisdictions where its products or technologies are being researched, developed, or commercialized. There can be no assurance that the Company will be able to obtain or maintain any necessary licenses, permits, or approvals. Any material delay or inability to receive these items is likely to delay and/or inhibit the Company's ability to conduct its business, and would have an adverse effect on its business, financial condition, and results of operations.

### **Inability to Implement the Business Strategy**

The growth and expansion of PharmaTher's business is heavily dependent upon the successful implementation of PharmaTher's business strategy. There can be no assurance that PharmaTher will be successful in the implementation of its business strategy.

### **Regulatory Risk**

PharmaTher will require acceptances and/or approvals from the FDA and other foreign health regulatory bodies for conducting human clinical studies and will require approval from the FDA and equivalent organizations in other countries before any drugs can be marketed. There is no assurance that such approvals will be forthcoming. Furthermore, the exact nature of the studies these regulatory agencies will require is not known and can be changed at any time by the regulatory agencies, increasing the financing risk and potentially increasing the time to market PharmaTher faces, which could adversely affect PharmaTher's business, financial condition or results of operations.

In both domestic and foreign markets, the development, formulation, manufacturing, packaging, labelling, handling, distribution, import, export, licensing, sale, and storage of pharmaceuticals are affected by a body of laws, governmental regulations, administrative determinations, including those by the Canada Food Inspection Agency and the FDA, court decisions, and similar constraints. Such laws, regulations and other constraints can exist at the federal, provincial or local levels in Canada and at all levels of Government in foreign jurisdictions. There can be no assurance that PharmaTher and PharmaTher's partners are in compliance with all of these laws, regulations and other constraints. PharmaTher and its partners may be required to incur significant costs to comply with such laws and regulations in the future, and such laws and regulations may have an adverse effect on the business. The failure of PharmaTher or its partners to comply with current or future regulatory requirements could lead to the imposition of significant penalties or claims and may have a material adverse effect on the business. In addition, the adoption of new laws, regulations or other constraints or changes in the interpretations of such requirements might result in significant compliance costs or lead PharmaTher and its partners to discontinue product development and could have an adverse effect on the business.

### **International Operations**

PharmaTher's international operations expose it and its representatives, agents, and distributors to risks inherent to operating in foreign jurisdictions which could materially adversely affect its operations and financial position. These risks include (i) country-specific taxation policies, (ii) imposition of additional foreign governmental controls or regulations, (iii) export license requirements, (iv) changes in tariffs and other trade restrictions, and (v) complexity of collecting receivables in a foreign jurisdiction.

Moreover, applicable agreements relating to business in foreign jurisdictions are governed by foreign laws and are subject to dispute resolution in the courts of, or through arbitration proceedings in, the country or region in which the parties are located or another jurisdiction agreed upon by the parties. PharmaTher cannot accurately predict whether such forum will provide an effective and efficient means of resolving disputes that may arise in the future. Even if it obtains a satisfactory decision through arbitration or a court proceeding, PharmaTher could have difficulty in enforcing any award or judgment on a timely basis or at all.

### **Issuance of Debt**

From time to time, the Company may enter into transactions to acquire assets or the shares of other corporations. These transactions may be financed partially or wholly with debt, which may increase the

Company's debt levels above industry standards. The level of the Company's indebtedness from time to time could impair the Company's ability to obtain additional financing in the future on a timely basis to take advantage of business opportunities that may arise.

### **Conflict of Interest**

Certain of the directors of the Company are also directors and officers of other companies, some of which may be in the pharmaceutical sector, and conflicts of interest may arise between their duties as directors of the Company and as officers and directors of such other companies. Such conflicts must be disclosed in accordance with, and are subject to such other procedures and remedies as apply under the applicable corporate statute.

### **Dilution and Future Issuances of Shares**

The Company may issue additional shares in the future, which may dilute a shareholder's holdings in the Company. The Company's articles permit the issuance of an unlimited number of the Company's shares and an unlimited number of preferred shares, issuable in series, and the shareholders of the Company will have no pre-emptive rights in connection with such further issuances. The Board of Directors of the Company has the discretion to determine the provisions attaching to any series of preferred shares and the price and the terms of issue of further issuances of Company's shares.

### **Risk of Third Party Claims for Infringement**

A third party may claim that the Company has infringed such third party's rights or may challenge the right of the Company to its intellectual property. In such event, the Company will undertake a review to determine what, if any, action should be taken with respect to such claim. Any claim, whether or not with merit, could be time consuming to evaluate, result in costly litigation, cause delays in the operations of the Company or the development of its intellectual property or require the Company to enter into licensing arrangements that may require the payment of a licence fee or royalties to the owner of the intellectual property. Such royalty or licensing arrangements, if required, may not be available on terms acceptable to the Company.



**Additional Disclosure for Venture Issuers Without Significant Revenue**

**Office expenses**

	Year Ended May 31, 2023	Year Ended May 31, 2022
	\$	\$
Research	3,018,122	2,605,142
Professional fees	115,816	320,563
Consulting fees	477,046	490,260
General and administrative	348,859	172,286
Stock-based compensation	nil	373,409
Shareholder information and filing fees	54,947	140,694
<b>Total</b>	<b>4,014,790</b>	<b>4,102,354</b>

**Research and development**

	Year Ended May 31, 2023	Year Ended May 31, 2022
	\$	\$
Ketamine	65,687	769,454
Microneedle	848,972	945,653
Other	2,103,464	890,035
<b>Total</b>	<b>3,018,122</b>	<b>2,605,142</b>