

PsyBio Therapeutics Corp. (formerly Leo Acquisitions Corp.)

Management's Discussion and Analysis of Financial Condition and Operating Performance

For the six months ended June 30, 2023 and 2022

Date: August 31, 2023

PsyBio Therapeutics Corp. (formerly Leo Acquisitions Corp.)

Management's Discussion and Analysis

This Management's Discussion and Analysis ("MD&A") has been prepared by management of PsyBio Therapeutics Corp. (formerly Leo Acquisitions Corp.) ("PsyBio" or the "Company") and should be read in conjunction with PsyBio's condensed consolidated interim financial statements and notes as at and for the six months ended June 30, 2023 and 2022 (the "Financial Statements"). The Financial Statements have been prepared using International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB"). All amounts are in United States dollars unless otherwise specified. The Financial Statements may be viewed on the SEDAR profile of PsyBio Therapeutics Corp. (formerly Leo Acquisitions Corp.) at www.sedar.com.

This MD&A contains disclosure related to PsyBio occurring up to and including August 31, 2023.

Forward-Looking Statements

Certain statements contained in this MD&A constitute "forward-looking information" and "forward-looking statements". All statements other than statements of historical fact contained in this MD&A that address activities, events, or developments that the Company expects or anticipates will or may occur in the future are forward-looking statements and information. Such statements can, in some cases, be identified by the use of forward-looking terminology such as "expect", "likely", "may", "will", "should", "intend", or "anticipate", "potential", "proposed", "estimate" and other similar words, including negative and grammatical variations thereof, or statements that certain events or conditions "may" or "will" happen, or by discussions of strategy. The forward-looking statements included in this MD&A are made only as of the date of this MD&A and the Company assumes no obligation to update or revise them to reflect subsequent information, events or circumstances or otherwise, except as required by applicable securities laws.

Forward-looking statements in this MD&A are not guarantees of future performance and involve assumptions, risks and uncertainties that are difficult to predict. Therefore, actual results may differ materially from what is expressed, implied or forecasted in such forward-looking statements. Management provides forward-looking statements because it believes they provide useful information to readers when considering their investment objectives and cautions readers that the information may not be appropriate for other purposes.

Some of the risks which could affect future results and could cause results to differ materially from those expressed in the forward-looking statements contained herein include:

Risks related to our financial position

- limited operating history
- significant losses incurred
- additional funding required for commercialization

Business and industry risks

- COVID-19
- early stage of product development
- termination of the Sponsored Research Agreements (as defined below)
- no assurance that future studies will yield favourable results
- reliance on production and distribution of psychedelics and related products
- limited marketing and sales capabilities
- no assurance of commercial success

- reliance on third parties for pre-clinical and clinical development activities
- risks related to third party relationships
- limited manufacturing experience
- commercial scale product manufacturing
- clinical testing and commercializing product candidates
- future clinical trials may not be successful
- product development costs may increase
- regulatory risks and uncertainties
- reliance on third-party clinical investigators and academic collaborators
- limited number of specialist third-party service providers
- difficulty enrolling patients to participate in clinical trials
- no assurance that clinical trials will be successful
- failure of later stage clinical trials
- safety and efficacy of products
- lack of commercialization experience
- ongoing regulatory review and obligations
- failure to achieve publicly announced milestones
- market access and acceptance
- reliance on third-party therapy sites
- reliance on third party suppliers and manufacturers
- changes in methods of manufacturing
- receiving regulatory designations may not be productive
- failure to enter into or maintain profitable relationships
- unfavourable publicity or consumer perception
- social media
- biotechnology and pharmaceutical market competition
- reliance on key executives and scientists
- employee misconduct
- business expansion and growth
- product side effects
- product liability
- enforcing contracts
- product recalls
- distribution and supply chain interruption
- costs of operating as public company
- foreign regulatory requirements
- conflicts of interest
- cybersecurity and privacy risk
- U.S. operations
- forward-looking statements may prove to be inaccurate
- failure to achieve research and development milestones

Risks related to regulatory compliance

- Drug Enforcement Agency (“DEA”) regulations relating to manufacturing, storage, distribution and physician prescription procedures
- change in substance laws or breach in compliance
- shareholders may be afforded less protection due to foreign private issuer exemptions
- loss of foreign private issuer status
- compliance with U.S. federal laws and regulations
- prosecution, investment or proceeds under forfeiture statutes
- U.S. tax classification of the Company
- enacted and future healthcare legislation

- healthcare fraud laws, false claims, and health information privacy and security laws
- extensive record-keeping, storage and security requirements
- compliance with data protection laws
- deficiencies in regulatory agencies
- availability of government healthcare reimbursements
- compliance with environmental, health and safety laws
- litigation

Risks related to development, clinical testing and commercialization of any future therapeutic candidates

- early stage of the industry
- psilocybin is a controlled substance in many jurisdictions
- potential reclassification of psilocybin and psilocin in the U.S.

Risks related to intellectual property

- trade secrets
- trade names
- patent litigation
- invalid patents
- intellectual property litigation costs
- protection of intellectual property
- third-party licenses
- failure to comply with intellectual property or license agreements
- failure to extend term of patents
- intellectual property rights may fail to protect competitive advantage
- employee patent claim liability
- patent law reforms
- difficulties securing jurisdictional intellectual property rights

Financial and accounting risks

- negative cash flow from operating activities
- additional capital requirements
- lack of product revenue
- estimates or judgments relating to critical accounting policies
- exchange rate fluctuations

Risks related to our securities

- volatile market price for the Company's subordinate voting shares (the "Subordinate Voting Shares")
- an active, liquid, and orderly market for our securities may not develop
- shareholders may suffer dilution
- restriction on the ability to convert the Company's multiple voting shares (the "Multiple Voting Shares")
- active trading market for the Subordinate Voting Shares may not be sustained
- significant sales of Subordinate Voting Shares
- tax issues
- discretion over the use of proceeds
- no dividends

Although the forward-looking statements contained in this MD&A are based upon what management currently believes to be reasonable assumptions, the Company cannot provide any assurance that actual results, performance or achievements will be consistent with these forward-looking statements. In particular, management of the Company have made assumptions regarding, among other things:

- substantial fluctuation of losses from quarter to quarter and year to year due to numerous external risk factors, and anticipation that the Company will continue to incur significant losses in the future;
- uncertainty as to the Company's ability to raise additional funding to support operations;
- the Company's ability to access additional funding;
- the fluctuation of foreign exchange rates;
- the duration of COVID-19 and the extent of its economic and social impact;
- the risks associated with the development of the Company's product candidates which are at early stages of development;
- the risks associated with drug development, which involves long lead times, is very expensive and involves many variables of uncertainty;
- reliance upon industry publications as primary sources for third-party industry data and forecasts;
- risks related to the timely and successful completion of certain preclinical studies;
- reliance on third parties to plan, conduct and monitor preclinical studies and clinical trials;
- reliance on third party contract manufacturers to deliver quality clinical and preclinical materials;
- reliance on third party vendors to complete a range of additional preclinical programs before the final selection of drug candidates for entry into human trials;
- product candidates may fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or may not otherwise produce positive results;
- risks related to filing investigational new drug ("IND") applications to commence clinical trials and to continue clinical trials if approved;
- the risks of delays and inability to complete clinical trials due to difficulties enrolling patients;
- competition from other biotechnology and pharmaceutical companies;
- the Company's reliance on the capabilities and experience of the Company's key executives and scientists and the resulting loss of any of these individuals;
- the Company's ability to adequately protect intellectual property and trade secrets;
- the risk of patent-related or other litigation; and
- the risk of unforeseen changes to the laws or regulations in the United States and Canada and other jurisdictions in which the Company operates.

Drug development involves long lead times, is very expensive and involves many variables of uncertainty. Anticipated timelines regarding drug development are based on reasonable assumptions informed by current knowledge and information available to PsyBio. Every patient treated on future studies can change those assumptions either positively (to indicate a faster timeline to new drug applications and other approvals) or negatively (to indicate a slower timeline to new drug applications and other approvals). This MD&A contains certain forward-looking statements regarding anticipated or possible drug development timelines. Such statements are informed by, among other things, regulatory guidelines for developing a drug with safety studies, proof of concept studies, and pivotal studies for new drug application submission and approval and assumes the success of implementation and results of such studies on timelines indicated as possible by such guidelines, other industry examples, and PsyBio's development efforts to date.

The above risks, uncertainties, assumptions and other factors could cause PsyBio's actual results, performance, achievements and experience to differ materially from PsyBio's expectations, future results, performances or achievements expressed or implied by the forward-looking statements.

In addition to the factors set out above and those identified in this MD&A, other factors not currently viewed as material could cause actual results to differ materially from those described in the forward-looking statements. Although PsyBio has attempted to identify important risks and factors that could cause actual actions, events or results to differ materially from those described in forward-looking statements, there may be other factors and risks that cause actions, events or results not to be anticipated, estimated or intended. Accordingly, readers should not place any undue reliance on forward-looking statements. See "Risk Factors".

COVID-19

The outbreak of the coronavirus, specifically identified as "COVID-19," has resulted in governments worldwide enacting emergency measures to combat the spread of the virus. These measures, which have included the implementation of travel bans, self-imposed quarantine periods and social distancing, have caused material disruption to businesses globally resulting in an economic slowdown and significant market volatility. Governments and central banks have reacted with significant monetary and fiscal interventions designed to stabilize economic conditions.

The impact of the COVID-19 outbreak is unknown at this time, as is the efficacy of the government and central bank interventions. Certain COVID-19 related risks could delay or slow the implementation of the planned objectives resulting in additional costs for the Company to achieve its business objectives. The COVID-19 pandemic may negatively impact the Company's business, which would influence the amount and timing of planned expenditure. The extent to which COVID-19 may impact the Company's business activities will depend on future developments, such as the continued geographic spread of the virus, the duration of the outbreak, travel restrictions, business disruptions, and the effectiveness of actions taken in Canada, the United States, and other countries to contain and treat the virus.

It is not possible to reliably estimate the length and severity of these developments and the impact on the financial results and condition of PsyBio and its operating subsidiaries in future periods. However, depending on the length and severity of the pandemic, COVID-19 could impact PsyBio's operations, could cause delays relating to approval from Health Canada, the FDA and equivalent organizations in other countries, could postpone research activities, and could impair PsyBio's ability to raise funds depending on COVID-19's effect on capital markets. Prolonged disruptions in the supply of goods and services relied on by the Company to research, test, and develop its products or restrictions resulting from government regulations that impact the Company's ability to conduct its studies and clinical trials, may adversely impact the Company's business.

The development of the COVID-19 pandemic and the measures being taken by governments and private parties to respond to it are extremely fluid. While PsyBio has continuously sought to assess the potential impact of the pandemic on its operations, any assessment is subject to extreme uncertainty as to probability, severity and duration. PsyBio has attempted to assess the impact of the pandemic by identifying risks in the following principle areas:

- Mandatory Closure. In response to the pandemic, many provinces, states and localities have previously implemented mandatory shut-downs of business from time to time to prevent the spread of COVID-19. In the locations where PsyBio operates or conducts research activity, these activities have been deemed an "essential service" and thus is not subject to the mandatory closures applicable to nonessential businesses. PsyBio's ability to generate revenue and meet its milestones could be materially impacted by any shut down of operations or services.

- Research and Development Disruptions. PsyBio relies on third parties for its research and development activities. If these third parties are unable to continue operating due to mandatory closures or other effects of the pandemic, it may negatively impact PsyBio's ability to meet its milestones and may significantly delay development. At this time, PsyBio has not experienced any significant disruptions.
- Staffing Disruption. PsyBio is, for the time being, implementing among its staff where feasible “social distancing” measures are recommended by local authorities. PsyBio has implemented remote meetings where possible, and permitted all staff who can work remotely to do so. For those whose duties require them to work on-site, measures have been implemented to reduce infection risk, such as reducing contact with patients, mandating additional cleaning and hand disinfection and providing masks and gloves to certain personnel. Nevertheless, despite such measures, PsyBio may find it difficult to ensure that its operations remain staffed due to employees falling ill with COVID-19, becoming subject to quarantine, or deciding not to come to work on their own volition to avoid infection.

PsyBio continues to actively address the risk to business continuity represented by each of the above factors through the implementation of a broad range of measures throughout its structure and is re-assessing its response to the COVID-19 pandemic on an ongoing basis. The above risks individually or collectively may have a material impact on PsyBio's ability to generate revenue.

PsyBio does not have sufficient cash on hand to fund its operations for the next 12-months and meet its working capital requirements. The Company is looking for opportunities to raise the capital necessary to fund its operations. It is anticipated that the long-term goals of PsyBio will require additional capital contributions via debt or equity financings. In the event that the impact of COVID-19 worsens and negatively affects capital markets generally, there is a risk that PsyBio may not be able to secure funding for these long-term objectives.

PsyBio relies on third parties to conduct and monitor its pre-clinical studies and pre-clinical trials. However, to the knowledge of PsyBio's management, the ability of these third parties to conduct and monitor pre-clinical studies and pre-clinical trials has not been and is not anticipated to be impacted by COVID-19. PsyBio is not currently aware of any changes in laws, regulations or guidelines, including tax and accounting requirements, arising from COVID-19 which would be reasonably anticipated to materially affect PsyBio's business.

Background

PsyBio Therapeutics Corp. (formerly Leo Acquisitions Corp.) was incorporated under the *Business Corporations Act* (Ontario) (the “OBCA”) on October 28, 2009. On February 2, 2011, the Company completed its initial public offering of 3,444,230 common shares at a price of C\$0.1667 per share for total gross proceeds of C\$574,050 and filed for listing as a CPC, as defined in Policy 2.4 of the TSX Venture Exchange (the “TSXV”). The common shares commenced trading on the TSXV on February 8, 2011 under the trading symbol “LEQ”. The Company was unable to complete a Qualifying Transaction (as defined in TSXV Policy 2.4) within the time limits prescribed by the TSXV. As a result, on May 16, 2013, the common shares were transferred to the NEX board of the TSXV and were listed under the symbol “LEQ.H”.

The Transaction

On December 2, 2020, the Company entered into a business combination agreement dated December 2, 2020 (as amended on February 18, 2021) (the “Definitive Agreement”) with PsyBio Therapeutics, Inc. (“PsyBio US”), PsyBio Therapeutics Financing Inc. (“Finco”), 1276949 B.C. Ltd. (“Leo B.C. Sub”) and Eluss, Inc. (“Leo Delaware Sub”), which outlined the terms and conditions pursuant to which the Company agreed to complete a reverse takeover of the Company by the shareholders of

PsyBio US, which constituted its Qualifying Transaction pursuant to the policies of the TSXV (the “Transaction”). The Definitive Agreement was negotiated at arm’s length. The Transaction was completed on February 19, 2021.

Immediately prior to closing of the Transaction, the Company continued out of the jurisdiction of the OBCA into the jurisdiction of the Business Corporations Act (British Columbia) (“BCBCA”) and amended its articles to: (i) reclassify its common shares as Subordinate Voting Shares and amend the terms of such shares, (ii) create a new class of Multiple Voting Shares; (iii) change its name to “PsyBio Therapeutics Corp.”, and (iv) effect the consolidation of the Subordinate Voting Shares on the basis of 1.6667 old Subordinate Voting Shares into one new Subordinate Voting Share.

Pursuant to the Definitive Agreement, immediately prior to closing of the Transaction, PsyBio US filed a certificate of amendment under the laws of the State of Delaware to effect a stock split on the basis of approximately 1.1529 old shares of PsyBio US common stock (“PsyBio US Shares”) for every one new PsyBio US Share, subject to adjustment in accordance with the terms of the Definitive Agreement (the “PsyBio Stock Split”).

Pursuant to the Definitive Agreement, on closing of the Transaction:

- (i) the Company, Leo B.C. Sub and Finco completed a three-cornered amalgamation under the BCBCA, pursuant to which all Finco shareholders exchanged all shares of Finco (“Finco Shares”) for Subordinate Voting Shares on a one-for-one basis and Finco and Leo B.C. Sub amalgamated with the resulting entity (“Amalco”) to continue as a wholly-owned subsidiary of the Company;
- (ii) the Company, Leo Delaware Sub and PsyBio US completed a three-cornered merger under the laws of the State of Delaware, pursuant to which PsyBio and Leo Delaware Sub merged with PsyBio US to continue as the surviving corporation and a wholly-owned subsidiary of the Company; and
- (iii) Amalco was wound-up and dissolved, and all of the assets of Amalco were distributed to the Company.

As a result of the Transaction, each PsyBio US Share was exchanged for 1/1000th of one Multiple Voting Share (on the basis of one PsyBio US Share for every one underlying Subordinate Voting Share) of the Company and any convertible or exchangeable security or other right to purchase or acquire PsyBio US Shares, to the extent not exercised or converted at the time of closing of the Transaction that was outstanding immediately before close of the Transaction, whether vested or unvested, automatically and without any required action on the part of any holder or beneficiary thereof, became convertible securities of the Company exercisable or convertible into an option, warrant, convertible or exchangeable security or other right, as applicable, to purchase or acquire a number of Subordinate Voting Shares or Multiple Voting Shares, as applicable.

The Financing

On December 4, 2020, in connection with the Transaction, PsyBio and Finco completed a brokered private placement (the “Financing”) for aggregate gross proceeds of \$11,456,622 (C\$14,493,394), through the issuance of 41,409,698 subscription receipts of Finco (“Subscription Receipts”) at a price of \$0.28 (C\$0.35) per Subscription Receipt (the “Issue Price”). The Financing was led by Eight Capital, as lead agent, and Canaccord Genuity Corp. (together, the “Agents”).

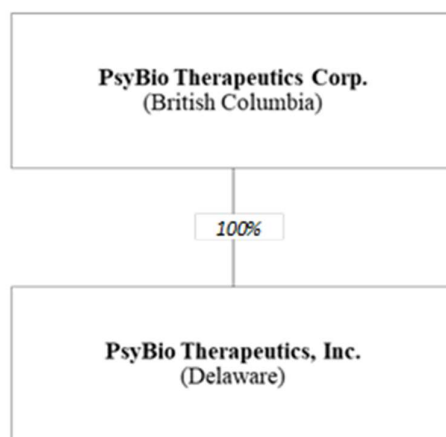
The Financing was completed pursuant to the terms of an agency agreement dated December 4, 2020 (the “Agency Agreement”) among the Company, PsyBio US, Finco, and the Agents. In connection with the Financing, the Agents were issued a total of 1,506,368 compensation warrants (the “Compensation Warrants”) and 1,069,000 advisor warrants (the “Advisor Warrants”), each warrant exercisable to purchase one Finco Share at \$0.28 (CAD\$0.35) for 24 months from the date of closing

of the Transaction. On closing of the Transaction, each compensation warrant and each advisor warrant became exercisable to acquire one Subordinate Voting Share. The fair value of the compensation and advisor warrants was determined to be \$512,653 (CAD\$648,452). Immediately prior to closing the Transaction, each Subscription Receipt was automatically exchanged for one Finco Share pursuant to the terms and conditions of the Subscription Receipts and the subscription receipt agreement governing the Subscription Receipts, including that all conditions precedent to the Transaction were satisfied or waived.

Each Compensation Warrant and each Advisor Warrant was exercisable to acquire one Finco Share at the Issue Price for a period of 24 months from closing of the Transaction. Following closing of the Transaction, the Compensation Warrants and Advisor Warrants became exercisable to acquire Subordinate Voting Shares of the Company in accordance with the same terms.

The Subordinate Voting Shares commenced trading on the TSXV on February 25, 2021 under the symbol “PSYB”. Following completion of the Transaction, the Company carries on the business of PsyBio US. The Company is a US-based biotechnology company developing a new class of drugs intended for the treatment of mental health challenges and other disorders.

The following chart sets out the Company’s material subsidiary as at the date hereof, its jurisdiction of incorporation and the Company’s voting interest in such subsidiary:



The Company’s registered office is located at 25th Floor, 700 W Georgia Street, Vancouver, BC, V7Y 1B3 and its head office is located at 1624 Washington Street, Denver, Colorado 80203, United States. The Company’s Subordinate Voting Shares are listed for trading on the TSXV and Frankfurt Stock Exchange under the symbol “PSYB”.

The Transaction is considered a purchase of the Company’s net assets by the shareholders of PsyBio US. The Transaction is accounted for in accordance with guidance provided in IFRS 2 Share-Based Payment (“IFRS 2”) and IFRS 3 Business Combinations (“IFRS 3”).

As the Company did not qualify as a business according to the definition in IFRS 3, the Transaction does not constitute a business combination; rather, it is treated as an issuance of PsyBio US Shares for the net assets of the Company and the Company’s listing status with PsyBio US as the continuing entity. The resulting Financial Statements are presented as a continuation of PsyBio US and comparative figures presented in the Financial Statements are those of PsyBio US.

In connection with the Transaction, a finder’s fee was paid through the issuance of 1,748,100 Subordinate Voting Shares for an aggregate fair value of \$483,719 (CAD\$611,835). In accordance with IFRS 2, the fair value of the share issuance was determined to be \$0.28 (CAD\$0.35) per share, based on the estimated fair value at the acquisition date. The fair value of the 122,115 options

assumed was determined to be \$0.20 (CAD\$0.25) per share, using the Black-Scholes option pricing model with the following assumptions: estimated volatility of 152%, risk free interest rate of 0.22%, expected life of 2 years, exercise price of \$0.43 (CAD\$0.55) and share price of \$0.28 (CAD\$0.35).

A breakdown of the listing expense is as follows:

	\$
Consideration	
Fair value of shares retained by former Leo Acquisitions Corp. shareholders	732,552
Fair value of shares issued to finders (1,748,100 shares at \$0.28)	483,719
Fair value of options assumed	24,446
Total consideration	1,240,717
Fair value of net assets assumed	
Cash	175,761
Receivables	13,817
Prepaid expenses	1,116
Accounts payable and accrued liabilities	(135,671)
Total net assets	55,023
Excess attributed to the cost of listing	1,185,694
Transaction costs related to the Transaction	51,252
Listing expense	1,236,946

Description of Business

PsyBio US was incorporated under the laws of the State of Delaware on January 21, 2020. PsyBio US was formed for the purpose of conducting a business relating to and promoting the purposes of psychedelically inspired compounds from different fungi and plants with unique psychoactive properties, under the provisions and subject to the requirements of the laws of the State of Delaware. The Company's operations are considered to be a continuance of the business and operations of PsyBio US.

The Company is a US-based biotechnology company developing a new potential class of drugs intended for the treatment of mental health challenges and other disorders. PsyBio is in the process of developing its portfolio of product candidates for sale in the pharmaceutical industry and is using traditional drug development protocols that are published at [fda.gov](https://www.fda.gov).

In collaboration with Miami University, a public university established and existing under the laws of the State of Ohio (the "University" or "Miami University"), PsyBio has: (i) developed a proprietary technology platform that enables the rapid generation of its formulation for its lead compound psilocybin, biosynthetic psilocybin, and other targeted tryptamines through a biosynthetic process using genetically modified bacteria (the "Proprietary Platform"); and (ii) retained the global exclusive rights to a proprietary platform technology that biologically synthesizes psilocybin and other targeted next generation psychoactive compounds that are produced naturally in fungi and plants. The Company is currently undergoing process development and manufacturing at commercial laboratories that have been approved by the DEA. By utilizing contract manufacturers, the Company is developing the chemistry, manufacturing and control ("CMC") section of its IND application and expects to submit such application in the fourth quarter of 2022 to initiate clinical studies.¹

¹ Subject to receipt of all necessary approvals, including as applicable, governmental authorities and the academic and scientific organizations with which PsyBio is working. There are multiple risk factors regarding the ability to successfully scale a chemically synthesized process to obtain tryptamine and other analogues. The material factors and assumptions underlying this forward-looking statement are that drug development involves long lead times, is very expensive and involves many variables of uncertainty. PsyBio has held one pre-IND meeting with the FDA in preparation

Management of PsyBio is motivated by a desire to find better ways to assist and empower people suffering with mental health challenges who are not helped by existing therapies. PsyBio is working towards pioneering the development of a new model of psycholytic therapy in which psychedelics are administered in conjunction with psychological support. The initial focus of the Company's research is on the potential treatment of cancer patients with depression, a subset of broader depressive disorder, comprising patients who are inadequately served by the current treatment paradigm. Early data from academic studies using formulations of psychedelics not developed by PsyBio, have shown that psycholytic therapy can improve outcomes for patients suffering with depression, anxiety and PTSD, and substance abuse with rapid reductions in symptoms and effects lasting up to months after administration of a single dose.² Psilocybin is a controlled substance in many jurisdictions, including in Canada under Schedule III of the Controlled Drugs and Substances Act (Canada) (the "CDSA") and in the United States under the Controlled Substances Act (the "CSA"). In the United States, psilocybin and its active metabolite, psilocin, are listed by the DEA as controlled substances or scheduled substances, under the CSA (specifically as a Schedule I substance).

Sponsored Research Agreements

On May 14, 2020, PsyBio US entered into a license agreement (the "License Agreement") and Master Sponsored Research Agreement (the "Master Sponsored Research Agreement" and, together with the License Agreement, collectively, as amended, the "Sponsored Research Agreements") with Miami University. The Sponsored Research Agreements contemplate research and development services for enhanced psilocybin production via metabolic engineering. On April 26, 2021, the Sponsored Research Agreements were amended to extend and expand the research efforts of the laboratory to include additional research efforts of the Department of Psychology and to provide an additional \$1,500,000 in funding until May 2023 to Miami University to support all such research.

Pursuant to the Sponsored Research Agreements, in collaboration with the University, PsyBio has: (i) developed a proprietary technology platform that enables the rapid generation of its formulation for its lead compound psilocybin, biosynthetic psilocybin, and other targeted tryptamines through a biosynthetic process using genetically modified bacteria; and (ii) retained the global exclusive rights to the Proprietary Platform. The Company is currently undergoing process development and manufacturing at commercial laboratories that have been approved by the DEA. By utilizing contract manufacturers, the Company is developing the CMC section of its IND application and expects to submit such application in the fourth quarter of 2023.³

The Company is currently undergoing process development and manufacturing at commercial laboratories that have been approved by the DEA. By utilizing contract manufacturers, the Company

for the filing of an IND application. Based upon this initial discussion, PsyBio intends to submit compound specific pre-IND meeting requests to define manufacturing and clinical trial parameters. PsyBio has assumed that the FDA will grant such pre-IND meetings and that it will be able to complete the IND approval process; however, there is no guarantee that any such IND application will be accepted or granted by the FDA.

² Griffiths, Roland R et al. "Psilocybin produces substantial and sustained decreases in depression and anxiety in patients with life-threatening cancer: A randomized double-blind trial." *Journal of psychopharmacology (Oxford, England)* vol. 30,12 (2016): 1181-1197; Davis, Alan K et al. "Effects of Psilocybin-Assisted Therapy on Major Depressive Disorder: A Randomized Clinical Trial." *JAMA psychiatry*, (2020).

³ Subject to receipt of all necessary approvals, including as applicable, governmental authorities and the academic and scientific organizations with which PsyBio is working. There are multiple risk factors regarding the ability to successfully scale a chemically synthesized process to obtain tryptamine and other analogues. The material factors and assumptions underlying this forward-looking statement are that drug development involves long lead times, is very expensive and involves many variables of uncertainty. PsyBio has held one pre-IND meeting with the FDA in preparation for the filing of an IND application. Based upon this initial discussion, PsyBio intends to submit compound specific pre-IND meeting requests to define manufacturing and clinical trial parameters. PsyBio has assumed that the FDA will grant such pre-IND meetings and that it will be able to complete the IND approval process; however, there is no guarantee that any such IND application will be accepted or granted by the FDA.

is developing the CMC section of its IND application and expects to submit such application in 2023 to initiate clinical studies.⁴

The Company is conducting all of its research in drug discovery in the laboratory of Dr. J. Andrew Jones in the Department of Chemical, Paper, and Biomedical Engineering (the “Jones Lab”) and the laboratory of Dr. Matthew McMurray in the Department of Psychology (the “McMurray Lab”) at the University under the Sponsored Research Agreements.

The following purports to be a summary of the Sponsored Research Agreements and is qualified in its entirety by reference to the full text thereof.

Master Sponsored Research Agreement

The current sponsored project involves the development of elite psilocybin or derivative tryptophan producing bacterial strains and fermentation processes that are industrially competitive with current chemical synthesis strategies and new commercial research objectives (the “Sponsored Project”).

All rights to the intellectual property developed by the University during the Sponsored Project and all joint intellectual property developed by the University and the employees of PsyBio during the Sponsored Project shall belong to the University. All intellectual property rights conceived of or made solely by the employees of PsyBio shall belong to PsyBio.

The term of the Master Sponsored Research Agreement commenced on May 14, 2020 (the “Effective Date”) and expires on the second anniversary of the Effective Date. Notwithstanding the foregoing, either party may terminate the Master Sponsored Research Agreement in the event the other party commits a material breach of its obligations under the Sponsored Project and fails to cure that breach within 30 days after receiving written notice thereof, effective immediately.

The Company is responsible for paying the costs of the Sponsored Project. Pursuant to the Master Sponsored Research Agreement, the Company is required to pay the University \$1 million, with an initial payment \$250,000 due within 30 days of the Effective Date (the “Initial Payment”). The remaining \$750,000 is payable during the term of the Sponsored Project in equal payments of \$250,000 (each, an “Instalment Payment”) with the first Instalment Payment due upon the six-month anniversary of the Initial Payment, and each subsequent Instalment Payment made in six month increments thereafter. In addition to the Initial Payment and the Instalment Payments, and contingent on the sponsor’s ability to successfully raise \$5 million in three years after the Effective Date, the parties have agreed to work cooperatively to come to an agreement to fund additional work related to the Sponsored Project. All costs and payments pursuant to the Master Sponsored Research Agreement are in addition to the amounts payable under the License Agreement.

As of December 31, 2021, the Company has paid the University an aggregate of \$1,000,000 under the Master Sponsored Research Agreement, representing the entirety of the Initial Payment.

⁴ Subject to receipt of all necessary approvals, including as applicable, governmental authorities and the academic and scientific organizations with which PsyBio is working. There are multiple risk factors regarding the ability to successfully commercially scale a chemically synthesized process to obtain tryptamine and other analogues. The material factors and assumptions underlying this forward-looking statement are that drug development involves long lead times, is very expensive and involves many variables of uncertainty. PsyBio has held one pre-IND meeting with the FDA in preparation for the filing of an IND application. Based upon this initial discussion, PsyBio intends to submit compound specific pre-IND meeting requests to define manufacturing and clinical trial parameters. PsyBio has assumed that the FDA will grant such pre-IND meetings and that it will be able to complete the IND approval process; however, there is no guarantee that any such IND application will be accepted or granted by the FDA.

Amendment to Master Sponsored Research Agreement

On April 26, 2021, the Master Sponsored Research Agreement was amended to extend and expand the research efforts of the laboratory to include additional research efforts of the Department of Psychology and to provide an additional \$1,500,000 in funding until May 2023 to Miami University to support all such research. As of August 2023, PsyBio is negotiating a payment plan related to the final \$450,000 due to the University.

License Agreement

The License Agreement addresses rights related to intellectual property derived from the research and development services of the University pursuant to the Master Sponsored Research Agreement.

Pursuant to the License Agreement, the University, as licensor, granted to PsyBio, as licensee, a license to all technical information (“Licensed Technology”) in tangible form, including, all technical data, know-how, trade information, and trade secrets relating to two provisional patent applications of the University and any patents deriving such patents (collectively, the “Licensed Patents”). The University also licensed PsyBio a license under the License Patents to develop, make, lease, sell, have developed, have made, use or otherwise dispose of products throughout the world using or incorporating the Licensed Technology or whose use, sale, offer for sale or importation without the authorization of the University would infringe any claim of any of the Licensed Patents.

The licenses granted under the License Agreement is exclusive except the University retains limited rights, consistent with the University’s status as a non-profit, to use the intellectual property for non-commercial research purposes. The Company has the right to grant non-exclusive royalty-bearing sublicenses to third parties, only with the prior written consent of the University, which shall not be unreasonably withheld, on terms not inconsistent with the terms of the License Agreement and only until the License Agreement is in effect and exclusive. Notwithstanding the foregoing, the Company shall be responsible for the performance of its sublicensees under any sublicenses, including the payment of any royalties or other payments due under such sublicenses or as a consequence of any such sublicenses.

The University may convert the licenses granted under the License Agreement from exclusive to non-exclusive in the event (i) the University becomes entitled to terminate the License Agreement due to any action or inaction by the Company; or (ii) the Company fails to achieve any milestone associated with the Licensed Patents or Licensed Technology.

Under the License Agreement, PsyBio US issued the University shares of common stock representing 7% of the outstanding common stock of PsyBio US on a fully-diluted, as converted basis. None of those shares have been converted from Multiple Voting Shares to Subordinate Voting Shares in 2021.

Under the Sponsored Research Agreements, the Company must pay Miami University royalties of 4% of the net sale value of all licensed products (“Earned Royalties”). The Company shall also make minimum royalty payments (“Minimum Royalties”) of (i) \$50,000 per year for so long as the cumulative net sales value of all licensed products is zero; and (ii) \$75,000 per quarter starting with the first calendar during which the licensed products are billed out or invoiced by the Company or sublicensee. Earned Royalties paid by the Company in any calendar quarter shall be credited against the Minimum Royalties due for that quarter. No Earned Royalty or Minimum Royalties payments may be carried over as a credit for any subsequent quarter and no amount of Earned Royalties paid for any quarter shall be credited against any Minimum Royalties due for any other quarter.

The term of the License Agreement commenced on the Effective Date of the Master Sponsored Research Agreement and continues until terminated by either party.

The Company may terminate the License Agreement at any time upon three months written notice to the University. Either party shall have the right to terminate the License Agreement by written notice to the other party if: (i) the other party is in material breach or default of any part of the License Agreement and the breach or default is not cured after thirty (30) days' notice given to the party in breach or default; or (ii) the other party shall: (A) apply for or consent to the appointment of a receiver, trustee or liquidator of it or any of its property; (B) admit in writing its inability to pay its debts as they mature; (C) make a general assignment or trust mortgage for the benefit of creditors; (D) file a voluntary petition in bankruptcy, or a petition or an answer seeking reorganization or an arrangement with creditors or to take advantage of any bankruptcy, reorganization, insolvency, readjustment of debt, dissolution or liquidation law or statute, or an answer admitting the material allegations of a petition filed against it in any proceeding under any such law; or (E) take corporate action for the purpose of effecting any of the foregoing; provided that, in the case of the University, such event shall not cause a right to terminate if the Company is able to make the royalty payments or other payments due under the License Agreement, or give adequate assurance of its ability to do so; or (ii) an order, judgment or decree shall be entered against the other party by any court of competent jurisdiction, approving a receiver, trustee or liquidator of such other party or of all or a substantial portion of its assets, and such order, judgment or decree shall not be released, vacated, or appealed within sixty (60) days after its issue or entry; or (iii) any judgment, writ, warrant of attachment or execution or similar process shall be issued or levied against a substantial part of the property of the other party, and such judgment, writ, or similar process shall not be released, vacated, or fully bonded within sixty (60) days after its issue or levy.

The University may terminate the License Agreement by written notice to the Company if: (i) as a result of any action or inaction by the Company, the University is entitled to terminate the Master Sponsored Research Agreement; or (ii) the Master Sponsored Research Agreement or any Sponsored Project agreed to by the parties pursuant to that agreement, is terminated by the Company; or (iii) the Company does not satisfy any milestone by the date specified for such milestone and does not cure such failure by the date set for the next milestone or, if there is no date set for a next milestone, within one hundred and twenty (120) days of the date specified for the unsatisfied milestone.

The Company's obligations to pay any amount payable under the License Agreement and to report to the University and to pay royalties to the University as to any licensed product made, leased, or sold under any license or sublicense granted pursuant to the License Agreement prior to the termination of the License Agreement shall survive such termination.

Upon termination of the License Agreement, the Company shall have no further right to utilize the Licensed Technology or the Licensed Patents.

Any sublicense in effect at the termination of the License Agreement shall remain in effect, but for the benefit of the University, provided the sublicensee shall continue to make all reports and payments required under its sublicense and is not otherwise in breach or default thereunder, such reports and payments then to be made to the University. Upon such termination the Company shall promptly assign each such sublicense to the University without further consideration.

The remaining milestones under the License Agreement consist of (i) the creation of additional milestones as are necessary, including, without limitation, completion of any applicable regulatory filings, the provision of additional cash commitments for any Sponsored Projects, etc. within thirty six (36) months from the Effective Date and for the remainder of the term of the License Agreement; and (ii) the submission of an IND application with United States Food and Drug Administration (or a similar type of application with an equivalent non-US regulatory agency) within forty two (42) months from the Effective Date.

Recent Developments

On July 21, 2023, the Company announced that it has been awarded approval to manufacture biosynthetic tryptamines at scale. The authorization allows Psybio to initiate the manufacturing process leading to the production of a sufficient quantity biosynthetic tryptamine for testing and human clinical trials.

Regulatory Framework and Licensing Regime

A summary of the applicable regulatory framework for PsyBio's business and proposed business activity are set forth below.

Business Segment	Current/Proposed Location of Operation	Summary of Applicable Regulatory Frameworks	Third-party Researchers, Suppliers, and/or Manufacturers	Agreements/Contracts Related to Operations ⁽¹⁾
Research, development and commercialization of psychedelic-inspired regulated medicines	United States	The United States federal governments regulate drugs through the CSA, which place controlled substances in a schedule.⁽²⁾ Under the CSA, psilocybin is currently a Schedule I drug.⁽³⁾ Misuse of Drugs Regulations 2001 and the Misuse of Drugs Regulations 2001	• Dr. Andrew Jones • Dr. Matthew McMurray • Miami University	• Master Sponsored Research Agreement • License Agreement

Notes:

- (1) For more information regarding contracts related to the operations of PsyBio, please see "Description of Business".
- (2) In the United States, the federal government is responsible for regulating, among other things, the approval, import, sale and marketing of drugs, including any psychedelic substances, whether natural or novel. The U.S. FDA have not approved psilocybin as a drug for any indication. It is illegal to possess such substances without a prescription. PsyBio does not directly engage in any activities that would trigger the need to comply with any federal laws related to psychedelic substances. See "Regulatory Framework – United States" below.
- (3) For further information on the United States regulatory framework, see "Regulatory Framework – United States" below.

United States

In order to develop regulated therapies, PsyBio's business must be conducted in strict compliance with the regulations of federal, state, local and regulatory agencies in the United States, and the equivalent regulatory agencies in the other jurisdictions in which it operates. These regulatory authorities regulate, among other things, the research, manufacture, promotion and distribution of drugs in specific jurisdictions under applicable laws and regulations.

The regulatory approval process is generally lengthy and expensive, with no guarantee of a positive result. Failure to comply with applicable regulatory authorities or other requirements may result in civil or criminal penalties, recall or seizure of products, injunctive relief including partial or total suspension of production, or withdrawal of a product from the market.

The U.S. FDA and other federal, state, local and foreign regulatory agencies impose substantial requirements upon the clinical development, approval, labeling, manufacture, marketing and distribution of drug products. These agencies regulate, among other things, research and development activities and the testing, approval, manufacture, quality control, safety, effectiveness, labeling,

storage, record keeping, advertising and promotion of any product candidates or commercial products. The regulatory approval process is generally lengthy and expensive, with no guarantee of a positive result. Moreover, failure to comply with applicable U.S. FDA or other requirements may result in civil or criminal penalties, recall or seizure of products, injunctive relief including partial or total suspension of production, or withdrawal of a product from the market.

PsyBio has held one pre-IND meeting with the FDA in preparation for the filing of an IND application. Based upon this initial discussion, PsyBio intends to submit compound specific pre-IND meeting requests to define manufacturing and clinical trial parameters. PsyBio has assumed that the FDA will grant such pre-IND meetings and that it will be able to complete the IND approval process; however, there is no guarantee that any such IND application will be accepted or granted by the FDA.

Psilocybin, psilocin, dimethyltryptamine, and 5-Methoxy-N-N-dimethyltryptamine are strictly controlled under the federal CSA as Schedule I substances. Schedule I substances by definition have no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and criteria for importation. Anyone wishing to conduct research on substances listed in Schedule I under the CSA must register with the U.S. DEA, and obtain U.S. DEA approval of the research proposal.

Various regulatory authorities regulate, among other things, the research, manufacture, promotion and distribution of drugs in the United States under the United States Federal Food, Drug, and Cosmetic Act and other statutes and implementing regulations. The process required by the U.S. FDA before prescription drug product candidates may be marketed in the United States generally involves the following:

- completion of extensive nonclinical laboratory tests, animal studies and formulation studies, all performed in accordance with the U.S. FDA's Good Laboratory and/or Manufacturing Practice regulations;
- submission to the U.S. FDA of an IND application, which must become effective before human clinical trials may begin;
- approval by an institutional review board or independent ethics committee at each clinical trial site before each trial may be initiated;
- for some products, performance of adequate and well-controlled human clinical trials in accordance with the U.S. FDA's regulations, including Good Clinical Practices, to establish the safety and efficacy of the product candidate for each proposed indication;
- submission to the U.S. FDA of a new drug application ("NDA"); and
- U.S. FDA review and approval of the NDA prior to any commercial marketing, sale or shipment of the drug.

The testing and approval process requires substantial time, effort and financial resources, and PsyBio cannot be certain that any approvals for its product candidates will be granted on a timely basis, if at all.

Nonclinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals and other animal studies. The results of nonclinical tests, together with manufacturing information and analytical data, are submitted as part of an IND to the U.S. FDA. Some nonclinical testing may continue even after an IND is submitted. The IND also includes one or more protocols for the initial clinical trial or trials and an investigator's brochure.

An IND automatically becomes effective 30 days after receipt by the U.S. FDA, unless the U.S. FDA, within the 30-day time period, raises concerns or questions relating to the proposed clinical trials as outlined in the IND and places the clinical trial on a clinical hold. In such cases, the IND sponsor and the U.S. FDA must resolve any outstanding concerns or questions before any clinical trials can begin. Clinical trial holds also may be imposed at any time before or during studies due to safety concerns or non-compliance with regulatory requirements.

An independent institutional review board (“IRB”) at each of the clinical centers proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the consent form signed by the trial participants and must monitor the study until completed. The U.S. FDA, the IRB, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public registries.

The U.S. FDA offers a number of regulatory mechanisms that provide expedited or Accelerated Approval procedures for selected drugs and indications which are designed to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These include programs such as Breakthrough Therapy designations, Fast Track designations, Priority Review and Accelerated Approval, which PsyBio may need to rely upon in order to receive timely approval or to be competitive.

PsyBio may plan to seek orphan drug designation for certain indications qualified for such designation. The U.S., E.U. and other jurisdictions may grant orphan drug designation to drugs intended to treat a “rare disease or condition” which, in the U.S., is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or 200,000 or more individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug available in the United States for this type of disease or condition will be recovered from sales of the product. In the E.U., orphan drug designation can be granted if: the disease is life threatening or chronically debilitating and affects no more than 50 in 100,000 persons in the E.U.; without incentive it is unlikely that the drug would generate sufficient return to justify the necessary investment; and no satisfactory method of treatment for the condition exists or, if it does, the new drug will provide a significant benefit to those affected by the condition. Orphan drug designation must be requested before submitting an NDA. If a product that has an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, meaning that the applicable regulatory authority may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for a period of seven years in the U.S. and 10 years in the E.U. Orphan drug designation does not prevent competitors from developing or marketing different drugs for the same indication or the same drug for different indications. After orphan drug designation is granted, the identity of the therapeutic agent and its potential orphan use are publicly disclosed. Orphan drug designation does not convey an advantage in, or shorten the duration of, the development, review and approval process. However, this designation provides an exemption from marketing and authorization (NDA) fees.

Drugs manufactured or distributed pursuant to U.S. FDA approvals are subject to continuing regulation by the U.S. FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, reporting of adverse experiences with the product, and complying with promotion and advertising requirements. The U.S. FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the U.S. FDA may require post-market testing, including Phase IV clinical trials, and surveillance to further assess and monitor the product’s safety and effectiveness after commercialization. In addition, drug

manufacturers and their subcontractors involved in the manufacture and distribution of approved drugs are required to register their establishments with the U.S. FDA and certain state agencies and are subject to periodic unannounced inspections by the U.S. FDA and certain state agencies for compliance with ongoing regulatory requirements, including current GMP, which impose certain procedural and documentation requirements. Failure to comply with statutory and regulatory requirements may subject a manufacturer to legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, civil penalties or criminal prosecution. There is also a continuing, annual prescription drug product program user fee.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, requirements for post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a risk evaluation and mitigation strategy.

Controlled Substances

Psilocybin is strictly controlled under the federal CSA. Psilocybin is a Schedule I drug under the CSA, which means that it currently has no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse. Anyone wishing to conduct research on substances listed in Schedule I under the CSA must register with the U.S. DEA, and obtain U.S. DEA approval of the research proposal.

The CSA and its implementing regulations establish a “closed system” of regulations for controlled substances. The CSA imposes registration, security, recordkeeping and reporting, storage, manufacturing, distribution, importation and other requirements under the oversight of the U.S. DEA. The U.S. DEA is responsible for regulating controlled substances, and requires those individuals or entities that manufacture, import, export, distribute, research, or dispense controlled substances to comply with the regulatory requirements in order to prevent the diversion of controlled substances to illicit channels of commerce.

Facilities that manufacture, distribute, import or export any controlled substance must register annually with the U.S. DEA. The U.S. DEA registration is specific to the particular location, activity(ies) and controlled substance schedule(s).

The U.S. DEA inspects all manufacturing facilities to review security, recordkeeping, reporting and handling prior to issuing a controlled substance registration. The specific security requirements vary by the type of business activity and the schedule and quantity of controlled substances handled. The most stringent requirements apply to manufacturers of Schedule I and Schedule II substances. Required security measures commonly include background checks on employees and physical control of controlled substances through storage in approved vaults, safes and cages, and through use of alarm systems and surveillance cameras. Once registered, manufacturing facilities must maintain records documenting the manufacture, receipt and distribution of all controlled substances. Manufacturers must submit periodic reports to the U.S. DEA of the distribution of Schedule I and II controlled substances, Schedule III narcotic substances, and other designated substances. Registrants must also report any controlled substance thefts or significant losses, and must obtain authorization to destroy or dispose of controlled substances. Imports of Schedule I and II controlled substances for commercial purposes are generally restricted to substances not already available from a domestic supplier or where there is not adequate competition among domestic suppliers. In addition to an importer or exporter registration, importers and exporters must obtain a permit for every import or export of a Schedule I and II substance or Schedule III, IV and V narcotic, and submit import or export declarations for Schedule III, IV and V non-narcotics.

For drugs manufactured in the United States, the U.S. DEA establishes annually an aggregate quota for the amount of substances within Schedules I and II that may be manufactured or produced in the United States based on the U.S. DEA's estimate of the quantity needed to meet legitimate medical, scientific, research and industrial needs. The quotas apply equally to the manufacturing of the active pharmaceutical ingredient and production of dosage forms. The U.S. DEA may adjust aggregate production quotas a few times per year, and individual manufacturing or procurement quotas from time to time during the year, although the U.S. DEA has substantial discretion in whether or not to make such adjustments for individual companies.

Individual U.S. states also establish and maintain separate controlled substance laws and regulations, including licensing, recordkeeping, security, distribution, and dispensing requirements. State authorities, including boards of pharmacy, regulate use of controlled substances in each state. Failure to maintain compliance with applicable requirements, particularly as manifested in the loss or diversion of controlled substances, can result in enforcement action that could have a material adverse effect on PsyBio's business, operations and financial condition. The U.S. DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution.

Patent Cooperation Treaty

The Patent Cooperation Treaty ("PCT") facilitates filing for patent recognition in multiple jurisdictions simultaneously using a single uniform patent application. 193 countries, including Canada and the United States have ratified the PCT.

Ultimately, patents are still granted in each country individually. As such, the PCT procedure consists of two phases: filing of an international application, and national evaluation under the patent laws in force in each country where a patent is sought.

Within 12 months of filing a provisional patent application at the United States Patent and Trademark Office, PsyBio may elect to file a regular utility patent application in the United States in tandem with filing a PCT application with the World Intellectual Property Office, in each case claiming priority to the provisional patent application. Within 30 months of the provisional filing date, deadlines begin for a PCT application to enter the national phase in desired jurisdictions globally, such as Canada (30 months) and Europe (31 months), in each case claiming priority to the provisional patent application.

While PsyBio is focused on programs using psychedelic-inspired compounds, PsyBio does not have any direct or indirect involvement with the illegal selling, production or distribution of any substances in the jurisdictions in which it operates. PsyBio is exploring drug development within approved laboratory clinical trial settings conducted within approved regulatory frameworks. Though highly speculative, should any prescription drug product be developed by PsyBio (which, if it does occur, would not be for several years), such drug product will not be commercialized prior to receipt of applicable regulatory approval, which will only be granted if clinical evidence of safety and efficacy for the intended use(s) is successfully developed. PsyBio may also employ non-prescription drugs, where appropriate.

Compliance with Applicable Laws

PsyBio oversees and monitors compliance with applicable laws in each jurisdiction in which it operates. In addition to PsyBio's senior executives, advisors, consultants and the employees responsible for overseeing compliance, PsyBio has local counsel engaged in every jurisdiction in which it operates and has received legal opinions or advice in each of these jurisdiction regarding (a) compliance with applicable regulatory frameworks, and (b) potential exposure to, and implications arising from, applicable laws in jurisdictions where PsyBio has operations or intends to operate.

PsyBio works with third parties who require regulatory licensing in order to handle scheduled drugs. PsyBio continuously updates its compliance and channel programs to maintain regulatory standards set for drug development. PsyBio also works with clinical research organizations who maintain batch records and data storage for PsyBio's clinical programs.

Additionally, PsyBio has established a Scientific Advisory Team, a Research, Clinical and Regulatory Team and a Government Relations and Communications Team with cross-functional expertise in business, neuroscience, pharmaceuticals, mental health and psychedelics to advise management.

In collaboration with the University, PsyBio oversees and implements training on PsyBio's protocols. PsyBio will continue to work closely with external counsel and other compliance experts, and is evaluating the engagement of one or more independent third party providers to further develop, enhance and improve its compliance and risk management and mitigation processes and procedures in furtherance of continued compliance with the laws of the jurisdictions in which PsyBio operates.

The programs currently in place include monitoring by executives of PsyBio to ensure that all operations materially conform to and comply with required laws, regulations and operating procedures. PsyBio is currently in compliance with the laws and regulations in all jurisdictions and the related licensing framework applicable to its business activities.

PsyBio and, to its knowledge, each of its third-party researchers, suppliers and manufacturers have not received any non-compliance, citations or notices of violation which may have an impact on the Company's licences, business activities or operations.

PsyBio conducts due diligence on third-party researchers, medical professionals, clinics, cultivators, processors and others as applicable, with whom it engages. Such due diligence includes but is not limited to the review of necessary licenses and the regulatory framework enacted in the jurisdiction of operation. Further, the Company generally obtains, under its contractual arrangements, representations and warranties from such third parties pertaining to compliance with applicable licensing requirements and the regulatory framework enacted in the jurisdiction of operation.

Overall Performance and Outlooks

Pharmaceutical grade psilocybin is being produced for clinical trials and research using a chemical synthesis process. This method uses starting materials such as toxic catalysts, solvents and reagents, creates multiple unstable reaction intermediates and undergoes numerous purification steps. This long reaction scheme takes 5 to 15 days. The published literature on this process also states that the active pharmaceutical ingredient costs approximately \$2,000 per gram and attempting to purchase research grade psilocybin garners prices between \$7,000 and \$20,000 per gram. PsyBio has developed a biosynthetic process using readily available materials, which undergoes a 2 to 4 day, 1 pot autocatalytic process allowing the manufacturer to set and forget. The result is a product with high stability at room temperature and the pre-purified material costs approximately \$10 per gram to produce.

PsyBio relies on a third parties for its research and development activities. If these third parties are unable to continue operating due to mandatory closures or other effects of the pandemic, it may negatively impact PsyBio's ability to meet its milestones and may significantly delay development. At this time, PsyBio has not experienced any significant disruptions.

In response to the pandemic, many provinces, states and localities have implemented mandatory shut-downs of businesses to prevent the spread of COVID-19. In the locations where PsyBio operates or conducts research activity, these activities have been deemed an "essential service", and thus not

subject to the mandatory closures applicable to nonessential businesses. PsyBio's ability to generate revenue and meet its milestones could be materially impacted by any shut down of operations or services.

PsyBio licenses all intellectual property relating to its proprietary platform technology, other than its trade names. In the future, there may not be any patents in the US or in foreign countries that are available to license on acceptable terms. PsyBio's inability to obtain such licenses may hinder or eliminate its ability to manufacture and market its products. Further, if PsyBio obtains third-party licenses but fails to pay annual maintenance fees, development and sales milestones, or it is determined that PsyBio does not use commercially reasonable efforts to commercialize licensed products, PsyBio could lose its licenses which could have a material adverse effect on its business and financial condition.

Quarterly Financial Information

	June 30, 2023	March 31, 2023	December 31, 2022	September 30, 2022
Three months ended,	\$	\$	\$	\$
Total revenue	-	-	-	-
Net loss and comprehensive loss	(956,179)	(812,161)	(941,758)	(921,385)
Basic and diluted net loss per share	(0.01)	(0.01)	(0.01)	(0.01)
	June 30, 2023	March 31, 2023	December 31, 2022	September 30, 2022
Three months ended,	\$	\$	\$	\$
Total revenue	-	-	-	-
Net loss and comprehensive loss	(1,918,410)	(1,585,424)	(2,292,142)	(2,320,841)
Basic and diluted net loss per share	(0.01)	(0.01)	(0.02)	(0.02)

- 1) The Company's net loss decreased in the three months ended June 30, 2023, as compared to the preceding quarter. Share-based compensation increased from \$219,969 to \$220,229 due to the additional expense related to the modification of the exercise price and expiry date of stock options during the current quarter. Professional fees, research and development and insurance were reduced during the current quarter as compared to the prior quarter, which was partially offset by an increase in office expense, investor relations and travel.

Results of operations for the three months ended June 30, 2023

For the three months ended June 30, 2023, PsyBio incurred a net loss and comprehensive loss of \$956,179 (June 30, 2022 – \$812,161).

Revenue

The Company generated no revenue during the three months ended June 30, 2023 and 2022. PsyBio is mainly in a pre-operative stage so therefore is not able to generate any revenues yet.

In collaboration with Miami University, PsyBio has developed the Proprietary Platform which is expected to enable the rapid generation of highly stable compounds cheaper, faster and greener than any other published production methods,⁵ and the Company's initial data has been publicly published in Metabolic Engineering Journal demonstrating its results. See "Forward-Looking Statements".

⁵ The material factors and assumptions underlying this forward-looking statement are that drug development involves long lead times, is very expensive and involves many variables of uncertainty. Pharmaceutical grade psilocybin produced for clinical trials and research may be produced using a chemical synthesis process. This method uses starting materials

PsyBio is currently working in the laboratory at Miami University on over twenty psychedelically inspired compounds from different fungi and plants with unique psychoactive properties. It is also in the process of preparing the initial molecules for clinical batch manufacturing and concurrently preparing an IND application to study the compounds in patients with cancer related depression.

PsyBio intends to use available capital to fund process development, manufacturing, non-Good Laboratory Practice (“GLP”) studies, GLP studies, regulatory, clinical and general corporate expenses. Anticipated costs will be divided between manufacturing, pre-clinical studies, regulatory approvals, new molecule discovery and general corporate overhead. PsyBio will be utilizing laboratory facilities at Miami University for new molecule discovery, outside contract manufacturing organizations for process development and manufacturing and outsourced clinical research organizations for clinical trial management.

In order to reach commercial production, PsyBio will be required to comply with standard FDA drug development protocols, the anticipated cost and timing of which is not yet fully known. In order to achieve its stated business objectives and for products to be in commercial production, PsyBio will be required to receive FDA approval for any of its molecules under development. The Company currently anticipates the following objectives, estimated costs, and target completion times in respect of its upcoming milestones.

Non-Revenue Generating Projects

The Company currently has two significant projects, which have not yet generated revenue:

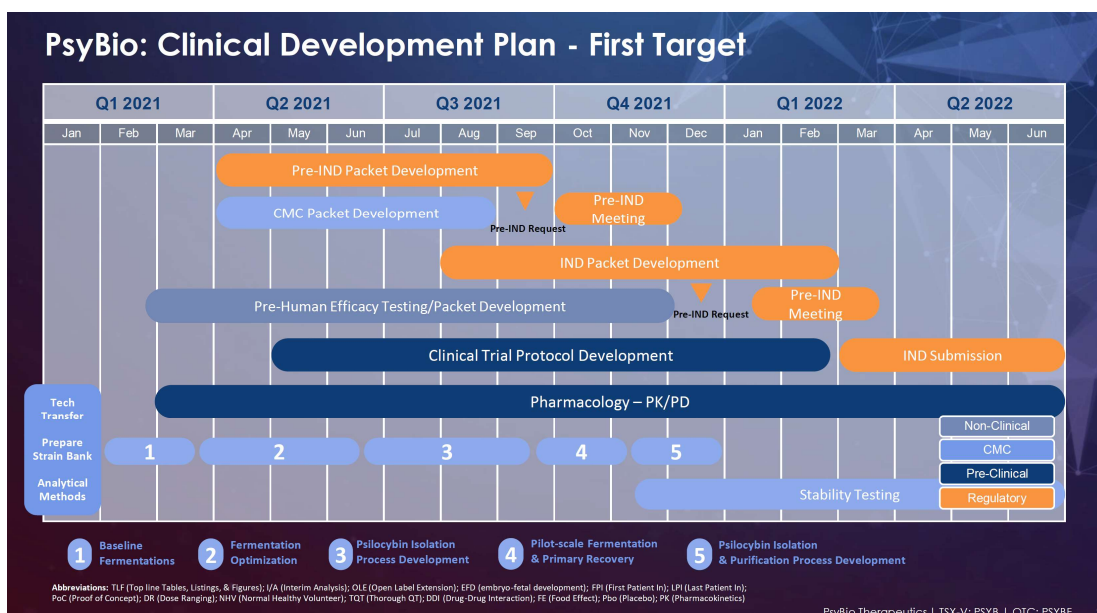
a. Novel Drug Discovery in Psychoactive Compounds

PsyBio is developing an advanced life science platform technology in the emerging psychedelic research industry. The filed intellectual property is based on producing and scaling drug candidates using genetically modified organisms. The PsyBio team has extensive experience in drug discovery and development based on synthetic biology, metabolic engineering, medicinal chemistry and clinical pharmacology, as well as clinical and regulatory expertise progressing drugs through human studies and governmental protocols. The team collectively has experience managing thousands of clinical trials and achieving hundreds of regulatory approvals related to therapeutics, diagnostics and devices. The Company has filed sixteen patent applications to date on its discovery accomplishments.

Building superior products to mono therapy psilocybin by combining psilocybin with its intermediates that are produced naturally in a magic mushroom are critical for the commencement of clinical testing. Using its expertise in metabolic engineering, formulation development and strain optimization, the Company is creating recombinant host cells to produce the target enzymes at its laboratories at Miami University. The Company has successfully produced multiple target tryptamines and run animal model testing for ratio optimization. Genetic optimization will remain an ongoing process. The Company expects to have multiple psychoactive formulations with different properties and characteristics.

such as toxic catalysts, solvents and reagents requiring numerous purification steps. The current standard processing time for chemical synthesis is between five to fifteen days with current costs ranging from approximately \$2,000 to \$20,000 per gram. Using readily available materials, PsyBio has developed a biosynthetic process that takes between approximately two and four days. The result is a product with high stability and room temperature, with current pre-purified material costs of approximately \$10 per gram. PsyBio has held one pre-IND meeting with the FDA in preparation for the filing of an IND application. Based upon this initial discussion, PsyBio intends to submit compound specific pre-IND meeting requests to define manufacturing and clinical trial parameters. PsyBio has assumed that the FDA will grant such pre-IND meetings and that it will be able to complete the IND approval process; however, there is no guarantee that any such IND application will be accepted or granted by the FDA. At this time PsyBio has not entered into commercial supply agreements and has no control over price or conditions. PsyBio’s assumption is that it will be able to enter into such agreements.

The Company is conducting all of its research in drug discovery in the Jones Lab and the McMurray Lab at Miami University under the Sponsored Research Agreements. To date, the Company has spent \$3,137,600 pursuant to the terms of the Sponsored Research Agreements, with funds being directed to Miami University and Dr. Andrew Jones.



There are currently multiple global studies of psilocybin ongoing for different therapeutic benefits. The Company is planning to file an IND application for cancer-related depression by Q4 2023, and is currently building its IND Application and Chemistry, Manufacturing and Controls section. The studies are anticipated to be very similar to currently conducted protocols and the Company is in the process of studying all the published research to optimize its therapeutics outcome. Due to the delay

in government regulations restricting the manufacturing of psilocybin, the Company's IND application has taken longer than anticipated.

The Company has not spent any money to date on these endeavors.

Gross profit

The Company did not realize any gross profit for the three months ended June 30, 2023 and 2022.

Operating expenses

For the three months ended June 30, 2023, the Company's operating expenses decreased to \$156,992 as compared to \$801,475 for the comparative period of the prior year.

For the three months ended June 30, 2023 the Company's office expenses decreased to \$27,902 as compared to \$264,079 for the comparative period of the prior year. Office expenses decreased as the Company reduced its advertising and marketing compared to the comparative period of the prior year.

For the three months ended June 30, 2023, the Company's management fees decreased to \$25,661 as compared to \$250,000 for the comparative period of the prior year.

For the three months ended June 30, 2023, the Company's royalty fees were \$12,500, which is consistent with royalty fees for the comparative period of the prior year. Royalty fees remained consistent as there were no changes to the terms of the royalty fees. The royalty fees were attributable to quarterly fees due to the Miami University pursuant to the Sponsored Research Agreements further discussed under "Other Obligations".

For the three months ended June 30, 2023, the Company's research and development were \$Nil compared to \$Nil for the comparative period of the prior year. Although, the research fees in Miami University are covered under the Sponsored Research Agreements, the Company has expressed its desire for additional research of new molecules which would result in filings for additional intellectual property. On April 26, 2021 the Company amended its Master Sponsored Research Agreement to include additional research efforts of the Jones Lab and of the McMurray Lab. The Company will provide an additional \$1.5 million in funding until May 2023 to Miami University to support all such research. The decrease in research and development is primarily due to the Company reducing its spending in the most recent quarter to conserve its cash resources until additional financing is obtained.

For the three months ended June 30, 2023, the Company's professional fees decreased to \$Nil as compared to \$331,472 for the comparative period in the prior year. Professional fees decreased during the current quarter due to the Company reducing its spending in the most recent quarter to conserve its cash resources until additional financing is obtained.

On May 14, 2020, PsyBio US entered into the Sponsored Research Agreements with Miami University for the development of enhanced psilocybin production strategies via metabolic engineering. Under the terms of the Sponsored Research Agreements, PsyBio US issued 3,626,000 PsyBio US Shares (on a pre-PsyBio Stock Split Basis) with a value of \$362,600 and recorded under licensing expenses, to Miami University in consideration for the initial licensing fees. PsyBio US also agreed to fund specific projects with the initial project funding commitment of \$1,000,000. PsyBio US made initial payments of \$250,000 in each of June and November 2020. The Company paid \$250,000 in May 2021 and \$250,000 in November 2021 clearing the remaining balance.

The Sponsored Research Agreements were amended on April 26, 2021 to extend and expand the research efforts of the laboratory and to provide an additional \$1,500,000 in funding until May 2023. The Company paid \$300,000 up front, \$250,000 in May 2021, \$250,000 in December 2021 and \$250,000 in June 2022 bringing the current balance owing down to \$450,000 and non-current balance owing down to \$Nil. As at June 30, 2023, a total current balance of \$450,000 and non-current balance of \$Nil was payable.

For the three months ended June 30, 2023, the Company's share-based compensation decreased to \$Nil respectively compared to \$148,258 in the comparative period of the prior year. The share-based compensation relates to the modification of the exercise price and expiry date of stock options during the current quarter. Share-based compensation during the comparative period in the prior year was attributable to the vesting of stock options issued upon the completion of the Transaction during February 2021.

Liquidity

As of June 30, 2023, the Company had working capital deficit of \$1918,410 (December 31, 2022 – \$21,804,294), cash of \$12,373 (December 31, 2022 – \$848) and cash held in trust of \$Nil (December 31, 2022 - \$156,410). In order to carry out its operation plans through June 30, 2024, management believes it will require additional financing as its cash is not sufficient to meet these needs.

Cash used in operating activities during the six months ended June 30, 2023, was (\$15,887) (June 30, 2022 – \$355,487)

Cash generated for investing activities during the six months ended June 30, 2023 was \$622 (June 30, 2022 – \$Nil).

Cash used for financing activities during the six months ended June 30, 2023 was \$849,537 (June 30, 2022 – \$290,829).

As a research and development company, the Company expects to spend substantial funds to continue the research, development and testing of its product candidates and to prepare to commercialize products subject to applicable regulatory approvals. Substantial additional financing may be required if the Company is to be successful in continuing to develop its business and its products. No assurances can be given that the Company will be able to raise the additional capital that it may require for its anticipated future development. Any additional equity financing may be dilutive to investors and debt financing, if available, may involve restrictions on financing and operating activities. There is no assurance that additional financing will be available on terms acceptable to the Company, if at all. If the Company is unable to obtain additional financing as needed, it may be required to reduce the scope of its operations or anticipated expansion.

To date, the Company has not generated product revenue and cannot predict when and if it will generate product revenue. The Company's ability to generate product revenue and ultimately become profitable depends upon its ability, alone or with partners, to successfully develop its product candidates, obtain regulatory approval and commercialize products, including any of its current product candidates or other product candidates that it may develop, in-license or acquire in the future. The Company does not anticipate generating revenue from the sale of products for the foreseeable future.

New laws and additional health reform measures may result in additional reductions in Medicare and other healthcare funding, which may adversely affect customer demand and affordability for PsyBio's therapeutic candidates and any future therapeutic candidates and, accordingly, the results of PsyBio's financial operations and capital available to the Company.

PsyBio may also incur significant costs to comply with these current or future environmental and health and safety laws and regulations. If PsyBio fails to comply with such laws and regulations, PsyBio could be subject to fines or other sanctions.

The degree of future protection afforded by PsyBio's intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect PsyBio's business, or permit PsyBio to maintain PsyBio's competitive advantage. Should the Company lose intellectual property protection, it could have a material adverse effect on PsyBio's business, financial condition, results of operations, and prospects for additional capital required for ongoing business operations.

Also, global equity markets may experience significant volatility and weakness in the future. It is not possible to reliably estimate the length and severity of any possible economic downturn and the impact on the financial results and condition of the Company and its operating subsidiaries in future periods. An extended economic downturn could result in a lack of additional capital available from lenders and investors for additional capital.

All of the above examples could significantly affect the Company's ability to raise additional capital necessary to meet its contractual obligations and ongoing operating expenses.

Contractual obligations and commitments

As of June 30, 2023, the payments due by period are set out in the following table:

	Less than 1 year	1-3 years	4 – 5 years	After 5 years	Total
Debt	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil
Finance Lease Obligations	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil
Operating Leases	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil
Purchase Obligations	\$Nil	\$Nil	\$Nil	\$Nil	\$Nil
Other Obligations	\$1,957,048	\$Nil	\$Nil	\$Nil	\$1,957,048
Total Contractual Obligations	\$1,957,048	\$Nil	\$Nil	\$Nil	\$1,957,048

Capital Resources

The Company constantly monitors and manages its capital resources to assess the liquidity necessary to fund operations and capacity expansion. As of June 30, 2023, the Company had a cash balance of \$12,373 (December 31, 2022 – \$848), cash held in trust of \$Nil (December 31, 2022 - \$156,410), and current liabilities of \$1,970,670 (December 31, 2022 – \$1,981,308).

As of June 30, 2023 the Company's current expenditure obligations include a commitment to pay Miami University \$250,000 in November 2022 and an additional \$200,000 in May 2023 as part of the Sponsored Research Agreements. Pursuant to the Sponsored Research Agreements, the Company must pay Miami University royalties of 4% of the net sale value of all licensed products. For so long as the cumulative net sales value of all licensed products is zero, the Company must pay Miami University a minimum royalty payment of \$50,000 per year. In addition, on a quarterly basis, starting with the first calendar quarter during which any licensed products are sold, the Company shall pay Miami University a minimum quarterly royalty amount of \$75,000.

The Company also has additional obligations to the University and the lead consultant under the Sponsored Research Agreements, as described above including a quarterly licensing fee of \$12,500 to the University and a semi-annual royalty fee of at least \$25,000 for a minimum royalty payment. The lead consultant who is in charge of the research for PsyBio at Miami University has a consulting agreement with the Company that includes a monthly consulting fee and a semi-annual payment of \$25,000.

The expected source of funds to meet these commitments is unknown at this time. The Company's current resources are not sufficient to settle its current commitments and liabilities as at the date of this MD&A and management continues to look for opportunities to raise the capital necessary to become a fully operational enterprise. Management believes the current resources and opportunities available to it will provide for operations and fundraising activities, barring any unforeseen delays or complications. The Company may periodically have to raise funds to continue operations and, although it has been successful in doing so in the past, there is no assurance it will be able to do so in the future. See "Forward-Looking Statements" and "Risk Factors".

Off-balance Sheet Arrangements

As of June 30, 2023 and the date of this MD&A, 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.

Other Obligations

Additional obligations include any and all outstanding accounts payable at the end of June 30, 2023, including payables related to legal and accounting matters.

Pursuant to the Sponsored Research Agreements, the Company must pay Miami University royalties of 4% of the net sale value of all licensed products. For so long as the cumulative net sales value of all licensed products is zero, the Company must pay Miami University a minimum royalty payment of \$50,000 per year. In addition, on a quarterly basis, starting with the first calendar quarter during which any licensed products are sold, the Company shall pay Miami University a minimum quarterly royalty amount of \$75,000.

An additional \$1,000,000 may be payable to Miami University if they are able to reasonably demonstrate a need for the funds. In addition, contingent upon the Company's ability to successfully raise up to \$5,000,000 within three years of the execution of the agreement, both parties shall work cooperatively to come to an agreement to fund additional work. The agreement was amended on April 26, 2021 to extend and expand the research efforts of the laboratory and to provide an additional \$1,500,000 in funding until May 2023.

The Company also has additional obligations to the University and Dr. Andrew Jones under the Sponsored Research Agreements, as described above, including a quarterly licensing fee of \$12,500 to the University and a semi-annual royalty fee of at least \$25,000 for the Minimum Royalties payment. Dr. Andrew Jones who is in charge of the research for PsyBio at Miami University has a consulting agreement with the Company that includes a monthly consulting fee and a semi-annual payment of \$25,000.

On January 19, 2022, the Company agreed to settle all matters relating to actions brought up against the Company, and all claims asserted, or which could have been asserted in those actions. The Company will pay a total of \$150,000 as part of this settlement to be paid as \$25,000 instalments starting five days after the execution of the settlement agreement and every three months thereafter. The Company paid the first instalment of \$25,000 in the month ended January 31, 2022, the second

instalment of \$25,000 in the month ended April 30, 2022, the third instalment of \$25,000 in the month ended July 31, 2022, the fourth instalment of \$25,000 in the month ended October 31, 2022, and the fifth instalment of \$25,000 in the month ended January 31, 2023. As at June 30, 2023, the Company had a current balance of \$Nil (December 31, 2022 – \$50,000) and non-current balance of \$Nil (December 31, 2022 – \$Nil).

Transactions Between Related Parties

Related parties to PsyBio are considered to be key management personnel including persons having the authority and responsibility for planning, directing, and controlling the activities of the Company as a whole, either directly or indirectly. The Company has determined that key management personnel include the Company's executive officers and directors. The remuneration of key management personnel for the three months ended June 30, 2023 is provided in Note 11 of the Financial Statements.

Key management personnel are those persons having authority and responsibility for planning, directing and controlling the activities of the Company, directly or indirectly. Key management personnel include the Company's executive officers and directors. The only key management personnel of the Company are Evan Levine, the Chief Executive Officer, Noah Davis, the Chief Financial Officer, and Dr. Michael Spigarelli, the Chief Medical Officer.

During the three months ended June 30, 2023, the Company's transactions with related parties were as follows:

- (i) The Company incurred management fees of \$Nil (June 30, 2022 – \$60,000) to Evan Levine, the Chief Executive Officer and a director of the Company. On February 19, 2021, the Company granted Evan Levine stock options to purchase 2,970,000 Subordinate Voting Shares that are exercisable at a price of \$0.28 (CAD\$0.35) per share at any time prior to February 19, 2026 and vest in equal 1/3 installments every six months starting on August 19, 2021. On January 10, 2023, the Company approved, subject to approval of the TSXV and disinterested shareholders (in respect of the insiders) at the Company's next shareholders meeting, the repricing and expiry date extension of these 2,970,000 stock options to an exercise price of CAD\$0.05 with an expiry date of January 10, 2028. The Company incurred \$Nil (June 30, 2022 – \$55,837) in share-based compensation to Evan Levine and a company with significant influence by Evan Levine. As of June 30, 2023, \$Nil (December 31, 2022 – \$60,000) was owed to this related party.
- (ii) The Company incurred management fees of \$Nil (June 30, 2022 – \$45,000) to Noah Davis, the Chief Financial Officer and a director of the Company. On February 19, 2021, the Company granted Noah Davis stock options to purchase 1,476,000 Subordinate Voting Shares that are exercisable at a price of \$0.28 (CAD\$0.35) per share at any time prior to February 19, 2026 and vest in equal 1/3 installments every six months starting on August 19, 2021. On January 10, 2023, the Company approved, subject to approval of the TSXV and disinterested shareholders (in respect of the insiders) at the Company's next shareholders meeting, the repricing and expiry date extension of these 1,476,000 stock options to an exercise price of CAD\$0.05 with an expiry date of January 10, 2028. The Company incurred \$Nil (June 30, 2022 – \$27,749) in share-based compensation to Noah Davis and a company controlled by Noah Davis. As of June 30, 2023, \$Nil (December 31, 2022 – \$37,500) was owed to this related party.
- (iii) The Company incurred management fees of \$Nil (June 30, 2022 – \$25,000) to Ross Carmel, a director of the Company. On February 19, 2021, the Company granted Ross

Carmel stock options to purchase 990,000 Subordinate Voting Shares that are exercisable at a price of \$0.28 (CAD\$0.35) per share at any time prior to February 19, 2026 and vest in equal 1/3 installments every six months starting on August 19, 2021. On January 10, 2023, the Company approved, subject to approval of the TSXV and disinterested shareholders (in respect of the insiders) at the Company's next shareholders meeting, the repricing and expiry date extension of these 990,000 stock options to an exercise price of CAD\$0.05 with an expiry date of January 10, 2028. The Company incurred \$Nil (June 30, 2022 – \$18,612) in share-based compensation to Ross Carmel. As of June 30, 2023, \$Nil (December 31, 2022 – \$20,833) was owed to this related party.

- (iv) As of June 30, 2023, \$155,204 (December 31, 2022 – \$155,204) in legal fees were owed to this related party. These amounts are non-interest bearing, unsecured and payable on demand. As of June 30, 2023, \$1,200 (December 31, 2022 – \$1,200) was recognized as prepaid expenses to this related party.
- (v) The Company incurred \$6,000 (June 30, 2022 - \$Nil) in rent expenses from 3122 Pine Island LLC, a company with common officers, Evan Levine and Noah Davis who hold a majority interest in the Company. As of June 30, 2023, \$Nil (December 31, 2022 - \$3,000) was owed to this related party.
- (vi) The Company paid advertising and marketing fees of \$16,000 (June 30, 2022 – \$16,000) to 154 Agency LLC, a company with common officers, Evan Levine and Noah Davis who indirectly hold a majority interest in the company. As of June 30, 2023, \$Nil (December 31, 2022 - \$22,500) was owed to this related party.
- (vii) The Company incurred \$22,500 (June 30, 2022 – \$22,500) in consulting and advisory services, and \$25,000 (June 30, 2022 – \$Nil) in laboratory research fees to Dr. Andrew Jones. On February 19, 2021, the Company granted a Dr. Andrew Jones stock options to purchase 990,000 Subordinate Voting Shares that are exercisable at a price of \$0.28 (CAD\$0.35) per share at any time prior to February 19, 2026 and vest in equal 1/3 installments every six months starting on August 19, 2021. The Company incurred \$Nil (June 30, 2022 – \$Nil) in share-based compensation to Dr. Andrew Jones. As of June 30, 2023, \$66,250 (December 31, 2022 – \$43,750) was owed to this related party.

Legal Proceedings

During November 2021, the Company entered into a consulting agreement (the “**Consulting Agreement**”) with a business advisory services firm (the “**Advisor**”) pursuant to which the Advisor agreed to assist the Company with formulating and implementing marketing strategies along with assisting the Company with its corporate structure and financing strategy needs. As part of the Consulting Agreement, the Advisor made representations that its services would generate significant interest in the Company from prospective investors. The Company is of the view that the terms of the Consulting Agreement were breached by the Advisor as it failed to formulate marketing and financing strategies for the Company, develop corporate presentation materials that were of adequate quality or complete investor meetings in a timely manner. The Advisor has filed a claim in the Province of Alberta, Canada seeking to be paid the fees set out in the Consulting Agreement. While it is the Company's view that the claim is unwarranted and the Company intends to defend its position that no amount should be owed to the Advisor, the Company has recorded a legal provision of \$13,539 based on the probable likelihood the Company will be required to settle the dispute.

Critical Accounting Estimates

The preparation of the Financial Statements in accordance with IFRS requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the

Financial Statements and reported amounts of expenses during the reporting period. Actual outcomes could differ from these estimates. The Financial Statements include estimates which, by their nature, are uncertain. The impacts of such estimates are pervasive throughout the Financial Statements and may require accounting adjustments based on future occurrences. Revisions to accounting estimates are recognized in the period in which the estimate is revised, and the revision affects both the current and future periods.

Significant assumptions about the future and other sources of estimation uncertainty that management has made at the statement of financial position date, that could result in a material adjustment to the carrying amounts of assets and liabilities, in the event that actual results differ from judgments made, relate to, but are not limited to, those set out under “Forward-Looking Statements”.

Going concern

The Company has not generated revenue from operations. During the three months ended June 30, 2023, the Company had a net loss of \$181,922 (June 30, 2022 - \$811,491), negative cash flows from operating activities of \$15,887 (June 30, 2022 - \$355,487) and working capital deficit of \$1,918,410 (December 31, 2022 – \$1,755,623). At June 30, 2023, the Company’s deficit was \$22,873,138. The Company’s continuation as a going concern is contingent on the completion of financings to adequately cover the Company’s working capital deficit and planned operating expenditures. The Company will periodically have to raise funds to continue operations and, although it has been successful in doing so in the past, there is no assurance it will be able to do so in the future. These factors comprise a material uncertainty which cast significant doubt about the Company’s ability to continue as a going concern.

The estimates used by management in reaching this conclusion are based on information available as of the date of these financial statements and were authorized for issuance based on an internally generated cash flow forecast. Accordingly, actual results could differ from these estimates and resulting variances may be material to management’s assessment. See “Forward-Looking Statements” and “Risk Factors”.

Functional currency

The functional currency determination will be based on management’s assessment of the primary economic environment in which the entities operate. The functional currency of the Company is the Canadian dollar while the functional currency of PsyBio US is the US dollar.

Business combinations

At the time of acquisition, the Company considers whether each acquisition represents the acquisition of a business or the acquisition of an asset. The Company accounts for an acquisition as a business combination where an integrated set of activities and assets, is acquired. More specifically, consideration is given to the extent to which significant processes are acquired.

When the acquisition of subsidiaries does not represent a business combination, it is accounted for as an acquisition of a group of assets and liabilities. The cost of the acquisition is allocated to the assets and liabilities acquired based upon their relative fair values, and no goodwill or deferred tax is recognized.

Control

At the time of acquisition, the Company assesses whether it has control over the acquiree. Control exists when the Company has power over an entity, when the Company is exposed, or has rights, to variable returns from the entity and when the Company has the ability to affect those returns through

its power over the entity. Where control exists, the Company consolidates the results of the acquired entity.

In the acquisition of PsyBio US, it was determined that control resides with PsyBio US as the former shareholders of PsyBio US became the majority shareholders of the Company. As a result, the Transaction was accounted for as a reverse takeover.

Fair value of consideration in reverse take-over transaction

The fair value of consideration to acquire the Company in the Transaction comprised of Subordinate Voting Shares and Multiple Voting Shares. Subordinate Voting Shares and Multiple Voting Shares were fair valued on the date of issuance. The Company applied IFRS 2 Share-based Payment in accounting for the Transaction.

Provisions

The amount recognized as a provision is the best estimate of the consideration required to settle the present obligation at the condensed consolidated interim statement of financial position date, taking into account the risks and uncertainties surrounding the obligation. Where a provision is measured using the cash flows estimate to settle the present obligation, its carrying amount is the present value of those cash flows. When some or all of the economic benefits required to settle a provision are expected to be recovered from a third party, the receivable is recognized as an asset if it is virtually certain that reimbursement will be received and the amount receivable can be measured reliably.

Share capital

Common shares are classified as equity. Transaction costs directly attributable to the issue of common shares are recognized as a deduction from equity, net of any tax effects.

The Company has adopted a residual value method with respect to the measurement of shares and warrants issued as private placement units. The residual value method first allocates value to the more easily measurable component based on fair value and then the residual value, if any, to the less easily measurable component. The Company considers the fair value of common shares issued in private placements to be the more easily measurable component of unit offerings and the common shares are valued at their fair value. The balance, if any, is allocated to any attached warrants or other feature. Any fair value attributed to warrants is recorded as reserves.

Warrants

Warrants issued by the Company are recorded at fair value using the Black-Scholes option-pricing model. In assessing the fair value of warrants, estimates have to be made regarding the fair value of the underlying share(s), expected volatility, dividend yield, risk-free rate, and estimated life at the initial grant date.

Share-based payments

Transactions with non-employees that are settled in equity instruments of the Company are measured at the fair value of the services rendered. In situations where the fair value of the goods or services received by the Company as consideration cannot be reliably measured, transactions are measured at fair value of the equity instruments granted. The fair value of the share-based payments is recognized together with a corresponding increase in equity over a period that services are provided, or goods are received.

The fair value of the share-based payments is determined using the Black-Scholes option pricing model. This option pricing model requires the input of subjective assumptions including the expected price volatility, option life, dividend yield, risk-free rate, and estimated forfeitures at the initial grant date.

Leases

The Company assesses, at the inception of entering into a contract, whether it contains a lease. A contract is classified as a lease if the contract conveys the right to control the use of an identified asset for a period of time in exchange for consideration.

The Company recognizes a right-of-use asset and lease liability at the lease commencement date. The right-of-use asset is initially measured at cost, which comprises of the initial amount of the lease liability adjusted for any lease payments made at or before the commencement date, plus any indirect costs incurred.

The right-of-use asset is subsequently depreciated using the straight-line method from the commencement date to the earlier of the end of the useful life of the right-of-use asset or the end of the lease term. The estimated useful lives of right-of-use assets are determined using the same criteria as those for property and equipment. In addition, the right-of-use asset is periodically reduced by impairment losses and adjusted for certain remeasurements of the lease liability, if any.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted using the interest rate implicit in the lease or, if that rate cannot be determined, the Company's incremental borrowing rate. The lease liability is subsequently increased by the interest cost on the lease liability and decreased by lease payments made. It is remeasured when there is a change in future lease payments arising from a change in an index or rate, or changes in assessment of whether a purchase or extension option is reasonably certain to be exercised or a termination option is reasonably certain not to be exercised.

The Company has elected not to recognize right-of-use assets and lease liabilities for short-term leases that have a term of 12 months or less and leases of low-value assets. The Company recognizes the lease payments associated with these leases as an expense on a straight-line basis over the lease term.

Accounting Standards and Amendments

The Company has reviewed new and revised accounting pronouncements that have been issued but are not yet effective. The Company has not early adopted any new standards and determined that there are no standards that are relevant to the Company.

Disclosure Controls and Procedures

Management has established processes to provide them sufficient knowledge to support representations that they have exercised reasonable diligence that (i) the condensed consolidated interim financial statements do not contain any untrue statement of material fact or omit to state a material fact required to be stated or that is necessary to make a statement not misleading in light of the circumstances under which it is made, as of the date of and for the periods presented by the condensed consolidated interim financial statements; and (ii) the condensed consolidated interim financial statements fairly present in all material respects the financial condition, results of operations and cash flows of the Company, as of the date of and for the periods presented. In contrast to non-venture issuers, this MD&A does not include representations relating to the establishment and maintenance of disclosure controls and procedures ("DC&P") and internal control over financial reporting ("ICFR"). In particular, management is not making any representations relating to the

establishment and maintenance of: controls and procedures designed to provide reasonable assurance that information required to be disclosed by the Company in its filings or other reports or submitted under securities legislation is recorded, processed, summarized and reported within the time periods specified in securities legislation; and a process to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS. Investors should be aware that inherent limitations on the ability of management of the Company to design and implement on a cost-effective basis DC&P and ICFR may result in additional risks to the quality, reliability, transparency and timeliness of filings and other reports provided under securities legislation.

Loss Per Share

The Company presents the basic and diluted earnings or loss per share data for its Subordinate Voting Shares and Multiple Voting Shares (converted into Subordinate Voting Shares), calculated by dividing the earnings or loss attributable to common shareholders of the Company by the weighted average number of Subordinate Voting Shares and Multiple Voting Shares (converted into Subordinate Voting Shares) outstanding during the period. Diluted earnings or loss per share is determined by adjusting the earnings or loss attributable to shareholders and the weighted average number of total shares outstanding for the effects of all dilutive potential shares.

For the purpose of the loss per share calculation the Multiple Voting Shares were converted into Subordinate Voting Shares.

The calculation of basic and diluted loss per share of \$0.01 (June 30, 2022 - \$0.01) for the three months ended June 30, 2023 was based on the net loss of \$181,992 (June 30, 2022 – \$811,491) attributable to the total weighted average number of shares outstanding of 128,176,468 (June 30, 2022 – 128,176,468).

Risk Management

The following is a description and analysis of the risks associated with financial instruments that may affect the Company:

Fair value of financial assets and financial liabilities

Unless otherwise noted, it is management's opinion that the Company is not exposed to significant interest rate, currency or credit risks arising from its financial instruments. The fair values of the Company's financial assets and financial liabilities approximate their carrying amounts due to their imminent or short-term maturity.

Interest rate risk

The Company has cash balances and no interest-bearing debt. The Company's current policy is to invest excess cash in investment-grade short-term deposit certificates issued by its banking institutions. The Company periodically monitors the investments it makes and is satisfied with the credit ratings of its banks. As at June 30, 2023 the Company had no interest-bearing loans.

Foreign Exchange Risk

Foreign exchange risk is the risk that the market value of financial instruments and the associated revenues will fluctuate due to changes in exchange rates. The Company's presentation currency is the U.S. dollar and historically, major purchases have been transacted in U.S. dollars, while all financing to date have been completed in Canadian dollars. The majority of the Company's expenditures will continue to be incurred in U.S. dollars. The fluctuation of the Canadian dollar in

relation to the U.S. dollar will consequently have an impact upon the financial results of the Company. The Company has not entered into any derivative contracts to manage foreign exchange risk at this time. A significant portion of the Company's cash balance may be held in U.S. dollars in any given period.

Liquidity risk

Liquidity risk is the risk that results from the Company's potential inability to meet its financial obligations as they come due. The Company manages liquidity risk by reviewing the amount of cash available, on a daily basis, to ensure that it can meet its current obligations.

Credit risk

The Company's credit risk is primarily attributable to cash and cash held in escrow. The Company has no significant concentration of credit risk arising from operations. Cash is held with reputable financial institutions and cash held with a law firm, from which management believes the risk of loss to be remote.

Outstanding Share Data

The authorized capital of the Company consists of an unlimited number of Subordinate Voting Shares and an unlimited number of Multiple Voting Shares. Subject to certain restrictions set out in the Company's articles, each Multiple Voting Share is convertible into 1,000 Subordinate Voting Shares and entitles the holder thereof to 1,000 votes per Multiple Voting Share.

As at June 30, 2023, there were 80,851,793 (December 31, 2022 – 61,391,796) Subordinate Voting Shares, 48,686,966 (December 31, 2022 – 48,686,966) Multiple Voting Shares, 10,829,985 (December 31, 2022 – 10,465,954) stock options and 18,199,747 (December 31, 2022 – 2,575,368) warrants issued and outstanding.

As at the date of this MD&A, there were 83,926,793 Subordinate Voting Shares, 48,686,966 Multiple Voting Shares, 10,829,985 stock options and 21,274,747 warrants issued and outstanding.

Equity transactions during the six months ended June 30, 2023

On January 4, 2023, the Company closed the first tranche of a private placement and issued 7,412,656 units at a price of CAD\$0.05 per unit for gross proceeds of CAD\$370,633. In addition, the Company also issued 5,252,956 units at a price of CAD\$0.05 per unit to settle debt of CAD\$262,648. Each unit consists of one Subordinate Voting Share and one Subordinate Voting Share purchase warrant exercisable at CAD\$0.10 per share for a period of 24 months. The expiry date of the warrants may be accelerated by the Company at any time and upon 30 days' notice, if the closing price of the Subordinate Voting Shares on the TSXV is greater than CAD\$0.20 for any 10 non-consecutive trading dates following the date that is four months and one day after the date of issuance and prior to the expiry date of the warrants.

On January 13, 2023, the Company closed the second tranche of a private placement and issued 4,400,350 units at a price of CAD\$0.05 per unit for gross proceeds of CAD\$220,018. In addition, the Company also issued 1,133,785 units at a price of CAD\$0.05 per unit to settle debt of CAD\$56,689. Each unit consists of one Subordinate Voting Share and one Subordinate Voting Share purchase warrant exercisable at CAD\$0.10 per share for a period of 24 months. The expiry date of the warrants may be accelerated by the Company at any time and upon 30 days' notice, if the closing price of the Subordinate Voting Shares on the TSXV is greater than CAD\$0.20 for any 10 non-consecutive trading dates following the date that is four months and one day after the date of issuance and prior to the expiry date of the warrants.

As part of the two tranches of the private placement, the Company incurred share issuance costs of \$3,175.

During the three months ended March 31, 2023, the Company received \$11,720 of proceeds in relation to the third tranche of a private placement that closed subsequent to March 31, 2023. The \$11,720 of cash was held in trust as at March 31, 2023 and recognized in obligation to issue shares.

Equity transactions during six months ended June 30, 2022

During the month ended December 31, 2021, PsyBio purchased an aggregate of 387,000 Subordinate Voting Shares at an average price of \$0.221 (CAD\$0.281) per share, for \$85,372 (CAD\$108,798) under its normal course issuer bid ("NCIB"). The Company recognized \$80,451 (CAD\$102,536) as of December 31, 2021 and \$4,921 (CAD\$6,262) as of December 31, 2022 out of the total \$85,372 (CAD\$108,798) paid. All of the 387,000 Subordinate Voting Shares purchased under the NCIB during the month of December 2021 were cancelled effective January 27, 2022.

During the three months ended March 31, 2022, an aggregate of 2,190,510 Multiple Voting Shares were converted into an aggregate of 2,190,510 Subordinate Voting Shares in accordance with their terms.

Options

On closing of the Transaction, the Company has adopted a new stock option plan (the "Plan") which provides that the Board of Directors of the Company may grant stock options to directors, officers and employees of, and consultants to, the Company and its subsidiaries.

All options granted pursuant to the Plan are subject to the terms and conditions of the Plan. The aggregate number of Subordinate Voting Shares allocated and made available for issuance pursuant to options granted under the Plan shall not exceed 10% of the issued and outstanding Subordinate Voting Shares as at the date of the grant (on a non-diluted basis, but on an as-converted basis as it relates to the Multiple Voting Shares). Any issuance of Subordinate Voting Shares from treasury pursuant to the exercise of options shall automatically replenish the number of Subordinate Voting Shares available for option grants under the Plan. Subordinate Voting Shares in respect of which options are cancelled or not exercised prior to expiry, for any reason, shall be available for subsequent option grants under the Plan. The maximum number of Subordinate Voting Shares reserved for issuance in any 12-month period to any one optionee other than a consultant may not exceed 5% of the issued and outstanding Subordinate Voting Shares at the date of the grant (assuming conversion of all Multiple Voting Shares to Subordinate Voting Shares). The maximum number of Subordinate Voting Shares reserved for issuance in any 12-month period to any consultant may not exceed 2% of the issued and outstanding Subordinate Voting Shares at the date of the grant (assuming conversion of all Multiple Voting Shares to Subordinate Voting Shares). In the event of termination for cause, all Options held by such terminated optionee will be cancelled immediately.

At closing of the Transaction on February 19, 2021, the Company had an aggregate of 122,115 stock options outstanding pursuant to the Plan. Each option entitles the holder thereof to acquire one Subordinate Voting Share at an exercise price of \$0.43 (CAD\$0.55) per share at any time prior to expiry on March 5, 2023, subject to acceleration in certain circumstances. An aggregate of 89,999 of the stock options held by former directors expired on May 20, 2021, in accordance with the terms of the Plan. The expiry date for the balance of the 32,116 stock options held by a former director and current consultant of the Company was amended to August 25, 2022. The remaining 32,116 stock options expired on August 25, 2022.

On February 19, 2021, the Company granted 8,166,141 stock options to certain directors, officers, and consultants of the Company. Each option entitles the holder thereof to acquire one Subordinate Voting Share at an exercise price of \$0.28 (CAD\$0.35) per share, at any time prior to expiry on February 19, 2026, subject to acceleration in certain circumstances. The options vest in equal 1/3 instalments every six months after the grant date. The expiry date for an aggregate of 100,098 stock options held by a former director and current consultant of the Company was amended to August 25, 2022. The remaining 100,098 stock options expired on August 25, 2022. On January 10, 2023, the Company approved, subject to approval of the TSXV and disinterested shareholders (in respect of the insiders) at the Company's next shareholders meeting, the repricing and expiry date extension of 6,445,800 of these stock options to an exercise price of CAD\$0.05 with an expiry date of January 10, 2028.

On April 4, 2021, the Company granted 2,000,000 stock options to a director of the Company. These options entitle the holder to acquire Subordinate Voting Shares of the Company at \$0.28 (CAD\$0.35) per share, at any time prior to expiry on April 4, 2024, subject to acceleration in certain circumstances, and vest in equal 1/3 instalments every six months after the grant date. On January 10, 2023, the Company approved, subject to approval of the TSXV and disinterested shareholders (in respect of the insiders) at the Company's next shareholders meeting, the repricing and expiry date extension of these 2,000,000 stock options to an exercise price of CAD\$0.05 with an expiry date of January 10, 2028.

On April 20, 2021, the Company granted 500,000 stock options to a director of the Company. These options entitle the holder to acquire Subordinate Voting Shares of the Company at \$0.28 (CAD\$0.35) per share, at any time prior to expiry on April 20, 2024, subject to acceleration in certain circumstances, and vest in equal 1/3 instalments every six months after the grant date. On January 10, 2023, the Company approved, subject to approval of the TSXV and disinterested shareholders (in respect of the insiders) at the Company's next shareholders meeting, the repricing and expiry date extension of these 500,000 stock options to an exercise price of CAD\$0.05 with an expiry date of January 10, 2028.

On January 4, 2023, the Company granted 14,000 compensation options in connection with the private placement. These options entitle the holder to acquire Subordinate Voting Shares of the Company at an exercise price of CAD\$0.05 per share for a period of 24 months. The compensation options vest immediately. The compensation options were valued at \$260 using the Black-Scholes option pricing model using the following weighted average assumptions: estimated volatility of 134%, risk free interest rate of 3.99%, expected life of 2.00 years, exercise price of CAD\$0.05, and a share price of CAD\$0.04. The Company estimates volatility based on historical share prices of the Company.

On January 10, 2023, the Company granted 500,000 stock options to a director of the Company. These options entitle the holder to acquire Subordinate Voting Shares of the Company at CAD\$0.05 per share, at any time prior to expiry on January 10, 2028, subject to acceleration in certain circumstances, and vest in equal 1/8 instalments every three months after the grant date.

On January 10, 2023, the Company granted 250,000 stock options to a senior employee of the Company. These options entitle the holder to acquire Subordinate Voting Shares of the Company at CAD\$0.05 per share, at any time prior to expiry on January 10, 2028, subject to acceleration in certain circumstances, and vest in equal 1/8 instalments every three months after the grant date.

On January 10, 2023, the Company approved, subject to approval of the TSXV and disinterested shareholders (in respect of the insiders) at the Company's next shareholders meeting, the repricing and expiry date extension of 8,945,800 stock options previously granted to certain employees, directors and consultants of the Company to mirror the pricing and expiry date of the stock options granted to a director on January 10, 2023.

During the three months ended June 30, 2023, the Company recorded share-based compensation of \$Nil (June 30, 2022 - \$422,466).

As at June 30, 2023, the following options were outstanding, entitling the holders thereof the right to purchase one Subordinate Voting Share for each option held as follows:

Number of options	Exercise price (CAD\$)	Expiry date	Number vested
14,000	0.05	January 4, 2025	14,000
1,120,185	0.35	February 19, 2026	1,120,185
9,695,800	0.05	January 10, 2028	8,945,800

As at the date of this MD&A, the following options were outstanding, entitling the holders thereof the right to purchase one Subordinate Voting Share for each option held as follows:

Number of options	Exercise price (CAD\$)	Expiry date	Number vested
14,000	0.05	January 4, 2025	14,000
1,120,185	0.35	February 19, 2026	1,120,185
9,695,800	0.05	January 10, 2028	9,038,550

Warrants

In connection with the Financing, a total of 1,506,368 compensation warrants and 1,069,000 advisor warrants were issued, each warrant exercisable to purchase one Finco Share at \$0.28 (CAD\$0.35) per share for 24 months from the date of closing of the Transaction. On closing of the Transaction, each compensation warrant and each advisor warrant became exercisable to acquire one Subordinate Voting Share. The warrants were valued using the Black-Scholes option pricing model using the following weighted average assumptions: share price: \$0.28 (CAD\$0.35), expected life: 2 years, expected volatility: 152%, dividend yield: 0%, risk-free interest rate: 0.27%. The Company estimates volatility based on historical share price of comparable companies, excluding specific time frames in which volatility was affected by specific transactions that are not considered to be indicative of the entities' expected share price volatility. On closing of the Transaction, each compensation warrant and each advisor warrant became exercisable to acquire one Subordinate Voting Share. The fair value of the compensation and advisor warrants was determined to be \$512,653 (CAD\$648,452).

As at June 30, 2023, the following warrants were outstanding, entitling the holders thereof the right to purchase one Subordinate Voting Share for each warrant held as follows:

Number of warrants	Exercise Price (CAD\$)	Expiry date
12,665,612	0.10	January 4, 2025
5,534,135	0.10	January 13, 2025
18,199,747		

As at the date of this MD&A, the following warrants were outstanding, entitling the holders thereof the right to purchase one Subordinate Voting Share for each warrant held as follows:

Number of warrants	Exercise Price (CAD\$)	Expiry date
12,665,612	0.10	January 4, 2025
5,534,135	0.10	January 13, 2025
3,075,000	0.10	April 20, 2025
21,274,747		

Normal Course Issuer Bid

On June 28, 2021, PsyBio announced that it had received approval from the TSXV for its NCIB, which entitles PsyBio to purchase up to 2,983,951 of its issued and outstanding Subordinate Voting Shares, representing approximately 5% of its issued and outstanding Subordinate Voting Shares as of June 24, 2021.

The NCIB commenced on June 30, 2021, and will expire on June 29, 2022, or such earlier date as PsyBio completes its purchases pursuant to the NCIB. The Company engaged Haywood Securities Inc. as the broker through which the Company will conduct purchases under the NCIB, pursuant to a dealer agreement and automatic share purchase plan outlining the terms upon which the NCIB will be conducted. The actual number of Subordinate Voting Shares that will be purchased under the NCIB, if any, and the timing of such purchases will be determined by the Company from time to time. All purchases made pursuant to the NCIB will be made through the facilities of the TSXV in open market transactions or by such other means as may be permitted under applicable securities laws and the policies of the TSXV. The price that the Company will pay for the Subordinate Voting Shares purchased under the NCIB, if any, will be the prevailing market price of such Subordinate Voting Shares at the time of the applicable purchases. All Subordinate Voting Shares purchased under the NCIB will be cancelled.

During the month ended October 31, 2021, PsyBio purchased an aggregate of 397,500 Subordinate Voting Shares at an average price of \$0.314 per share under its NCIB. All of the 397,500 Subordinate Voting Shares purchased under the NCIB during the month of October were cancelled effective November 1, 2021.

During the month ended December 31, 2021, PsyBio purchased an aggregate of 387,000 Subordinate Voting Shares at an average price of \$0.221 (CAD\$0.281) per share under its NCIB. All of the 387,000 Subordinate Voting Shares purchased under the NCIB during the month of December were cancelled effective January 27, 2022.

During the month ended April 30, 2022, the Company purchased an aggregate of 885,000 Subordinate Voting Shares at an average price of \$0.07 (CAD\$0.09) per share under its NCIB. All Subordinate Voting Shares purchased pursuant to the NCIB during the month of April 2022 were cancelled effective May 2, 2022.

During the month ended May 31, 2022, the Company purchased an aggregate of 350,000 Subordinate Voting Shares at an average price of \$0.06 (CAD\$0.07) per share under its NCIB. All Subordinate Voting Shares purchased pursuant to the NCIB during the month of May 2022 were cancelled effective June 2, 2022.

Additional information

Additional information relating to the Company is contained in the filing statement of the Company dated February 17, 2021 (the “Filing Statement”), which may be viewed under the Company’s SEDAR profile at www.sedar.com.

Approval

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

Risk Factors

The following information sets forth material risks and uncertainties that may affect our business, including our future financing and operating results and could cause our actual results to differ materially from those contained in forward-looking statements we have made in this MD&A. The risks and uncertainties below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we believe to be immaterial may also adversely affect our business. Further, if we fail to meet the future expectations of the public market in any given period now that PsyBio's shares are listed, the market price of our Subordinate Voting Shares could decline. The Company operates in a highly competitive environment that involves significant risks and uncertainties, some of which are outside of our control. There are a number of risk factors that could cause future results to differ materially from those described herein. Additional risks and uncertainties, including those found under "Risk Factors" of the Filing Statement and those that PsyBio does not know about or that it currently deems immaterial, could also adversely affect PsyBio's business and results of operations.

Risks Related to Our Financial Position

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

PsyBio has a limited operating history upon which its business and future prospects may be evaluated. PsyBio will be subject to all of the business risks and uncertainties associated with any new business enterprise, including the risk that it will not achieve its operating goals. In order for PsyBio to meet future operating and debt service requirements, it will need to be successful in its growth, marketing and sales efforts. Additionally, where PsyBio experiences increased production and future sales, its current operational infrastructure may require changes to scale its business efficiently and effectively to keep pace with demand, and achieve long-term profitability. If PsyBio's products and services are not accepted by new customers, PsyBio's operating results may be materially and adversely affected.

Since formation, PsyBio has invested most of its resources in developing a portfolio of psychoactive compounds targeted for the treatment of mental health challenges and other disorders, building its intellectual property portfolio, conducting business planning, raising capital and providing administrative support for these operations. PsyBio has not yet demonstrated an ability to conduct later-stage clinical trials, obtain regulatory approvals, manufacture a commercial-scale product, conduct sales and marketing activities necessary for successful product commercialization.

PsyBio may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving its business objectives. PsyBio will eventually need to transition from a company with a development focus to a company capable of supporting commercial activities. PsyBio may not be successful in such a transition.

We are a pre-clinical-stage biotechnology care company and have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.

We are a pre-clinical-stage biotechnology company and we have not generated any revenue to date. We have incurred significant operating losses since our formation. Our historical losses resulted principally from costs incurred in connection with research and development activities and general

and administrative costs associated with our operations. In the future, we intend to continue to conduct research and development, preclinical testing, clinical trials, regulatory compliance, market access, commercialization and business development activities that, together with anticipated general and administrative expenses, will result in incurring further significant losses for at least the next several years. Our expected losses, among other things, may continue to cause our working capital and shareholders' equity (deficit) to decrease. We anticipate that our expenses will increase substantially if and as we, develop our products and pursue our business strategy.

We will need substantial additional funding to complete the development and commercialization of our investigational psilocybin therapy or any future therapeutic candidates. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate certain or all of our product discovery, therapeutic development, research operations or commercialization efforts.

To date, we funded our operations through private placements of equity. To become and remain profitable, we will need to continue developing and eventually commercialize therapies that generate significant revenue. Until we can generate sufficient revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of equity offerings, debt financings, strategic collaborations and alliances, licensing arrangements or monetization transactions.

Our ability to raise additional funds will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. If adequate funds are not available on commercially acceptable terms when needed, we may be forced to delay, reduce or terminate the development or commercialization of all or part of our research programs or our therapeutic candidates, or we may be unable to take advantage of future business opportunities. Market volatility resulting from the COVID-19 pandemic and the related U.S. and global economic impact or other factors could also adversely impact our ability to access capital as and when needed.

We cannot guarantee that future financing will be available in sufficient amounts, or on commercially reasonable terms, or at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of holders of our Subordinate Voting Shares, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our Subordinate Voting Shares to decline. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to our future therapeutics candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Further, any additional fundraising efforts may divert our management from its day-to-day activities, which may adversely affect our ability to develop and commercialize our investigational psilocybin therapy or any future therapeutic candidates.

In addition, heightened regulatory scrutiny could have a negative impact on our ability to raise capital. Our business activities rely on developing laws and regulations in multiple jurisdictions. It is impossible to determine the extent of the impact of any new laws, regulations or initiatives that may be proposed, or whether any proposals will become law. The regulatory uncertainty surrounding our investigational psilocybin therapy or any future therapeutic candidates may adversely affect our business and operations, including without limitation, our ability to raise additional capital.

Risks Related to Our Business

COVID-19

The outbreak of the coronavirus, specifically identified as “COVID-19” has resulted in governments worldwide enacting emergency measures to combat the spread of the virus. These measures, which have included the implementation of travel bans, self-imposed quarantine periods and social distancing, have caused material disruption to businesses globally resulting in an economic slowdown and significant market volatility. Governments and central banks have reacted with significant monetary and fiscal interventions designed to stabilize economic conditions.

The impact of the COVID-19 outbreak is unknown at this time, as is the efficacy of the government and central bank interventions. Certain COVID-19 related risks could delay or slow the implementation of the planned objectives resulting in additional costs for the Company to achieve its business objectives. The COVID-19 pandemic may negatively impact the Company’s business, which would influence the amount and timing of planned expenditure. The extent to which COVID-19 may impact the Company’s business activities will depend on future developments, such as the continued geographic spread of the virus, the duration of the outbreak, travel restrictions, business disruptions, and the effectiveness of actions taken in Canada, the United States, and other countries to contain and treat the virus.

It is not possible to reliably estimate the length and severity of these developments and the impact on the financial results and condition of PsyBio and its operating subsidiaries in future periods. However, depending on the length and severity of the pandemic, COVID-19 could impact PsyBio’s operations, could cause delays relating to approval from Health Canada, the FDA and equivalent organizations in other countries, could postpone research activities, and could impair PsyBio’s ability to raise funds depending on COVID-19’s effect on capital markets. Prolonged disruptions in the supply of goods and services relied on by the Company to research, test, and develop its products or restrictions resulting from government regulations that impact the Company’s ability to conduct its studies and clinical trials, may adversely impact the Company’s business.

The development of the COVID-19 pandemic and the measures being taken by governments and private parties to respond to it are extremely fluid. While PsyBio has continuously sought to assess the potential impact of the pandemic on its operations, any assessment is subject to extreme uncertainty as to probability, severity and duration. PsyBio has attempted to assess the impact of the pandemic by identifying risks in the following principal areas:

- Mandatory Closure. In response to the pandemic, many provinces, states and localities have previously implemented mandatory shut-downs of business from time to time to prevent the spread of COVID-19. In the locations where PsyBio operates or conducts research activity, these activities have been deemed an “essential service” and thus not subject to the mandatory closures applicable to nonessential businesses. PsyBio's ability to generate revenue and meet its milestones could be materially impacted by any shut down of operations or services.
- Research and Development Disruptions. PsyBio relies on third parties for its research and development activities. If these third parties are unable to continue operating due to mandatory closures or other effects of the pandemic, it may negatively impact PsyBio's ability to meet its milestones and may significantly delay development. At this time, PsyBio has not experienced any significant disruptions.
- Staffing Disruption. PsyBio is, for the time being, implementing among its staff where feasible “social distancing” measures recommended by local authorities. PsyBio has implemented remote meetings where possible, and permitted all staff who can work remotely to do so. For those whose duties require them to work on-site, measures have been implemented to reduce infection risk, such as reducing contact with patients, mandating additional cleaning and hand disinfection and providing masks and gloves to certain

personnel. Nevertheless, despite such measures, PsyBio may find it difficult to ensure that its operations remain staffed due to employees falling ill with COVID-19, becoming subject to quarantine, or deciding not to come to work on their own volition to avoid infection.

PsyBio continues to actively address the risk to business continuity represented by each of the above factors through the implementation of a broad range of measures throughout its structure and is re-assessing its response to the COVID-19 pandemic on an ongoing basis. The above risks individually or collectively may have a material impact on PsyBio's ability to generate revenue.

PsyBio currently has no therapies that are approved for commercial sale and may never be able to develop marketable therapies.

Given the early stage of its product development, PsyBio can make no assurance that its research and development programs will result in regulatory approval or commercially viable products. To achieve profitable operations, PsyBio, alone or with others, must successfully develop, gain regulatory approval for, and market its future products. PsyBio currently has no products that have been approved by Health Canada, the U.S. FDA or any similar regulatory authority. To obtain regulatory approvals for its product candidates being developed and to achieve commercial success, clinical trials must demonstrate that the product candidates are safe for human use and that they demonstrate efficacy.

Many product candidates never reach the stage of clinical testing and even those that do have only a small chance of successfully completing clinical development and gaining regulatory approval. Product candidates can fail for a number of reasons, including, but not limited to, being unsafe for human use or due to the failure to provide therapeutic benefits equal to or better than the standard of treatment at the time of testing. Unsatisfactory results obtained from a particular study relating to a research and development program may cause PsyBio or its collaborators to abandon commitments to that program. Positive results of early preclinical research may not be indicative of the results that will be obtained in later stages of preclinical or clinical research. Similarly, positive results from early-stage clinical trials may not be indicative of favourable outcomes in later-stage clinical trials, and PsyBio can make no assurance that any future studies, if undertaken, will yield favourable results. The results of these studies or trials, when published, may have a significant effect on the market for the biopharmaceutical product that is the subject of the study.

The early stage of PsyBio's product development makes it particularly uncertain whether any of its product development efforts will prove to be successful and meet applicable regulatory requirements, and whether any of its product candidates will receive the requisite regulatory approvals, be capable of being manufactured at a reasonable cost or be successfully marketed. If PsyBio is successful in developing its current and future product candidates into approved products, it will still experience many potential obstacles, which would affect its ability to successfully market and commercialize such approved products, such as the need to develop or obtain manufacturing, marketing and distribution capabilities, price pressures from third-party payors, or proposed changes in health care systems. If PsyBio is unable to successfully market and commercialize any of its products, its financial condition and results of operations may be materially and adversely affected.

The termination of the Company's Sponsored Research Agreements with Miami University would have a material adverse effect on its business.

PsyBio's business strategy is reliant on intellectual property that it has licensed from Miami University under the Sponsored Research Agreements. Its failure to pay Miami University \$1,500,000 by May 2023 or continued breach of the Sponsored Research Agreements could cause Miami University to terminate the Sponsored Research Agreements, which would have a material adverse effect on the Company's business.

PsyBio can make no assurance that any future studies, if undertaken, will yield favorable results.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later-stage clinical trials after achieving positive results in early-stage development, and PsyBio cannot be certain that it will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain Health Canada or U.S. FDA approval. If PsyBio fails to produce positive results in its future clinical trials and other programs, the development timeline and regulatory approval and commercialization prospects for PsyBio's leading product candidates, and, correspondingly, its business and financial prospects, would be materially adversely affected. The publication of negative results of studies or clinical trials or adverse safety events related to PsyBio's product candidates, or the therapeutic areas in which PsyBio's product candidates compete, could adversely affect its share price and PsyBio's ability to finance future development of its product candidates, and its business and financial results could be materially and adversely affected. Some of the obstacles and uncertainties include:

- Preclinical testing and clinical trials for PsyBio's products may not achieve the desired results.
- The results of preclinical testing and clinical trials are uncertain.
- Product approvals are subject to a number of contingencies and may not be obtained in the time expected or at all.
- PsyBio's products may not attract a following among patients, retailers and/or providers.
- PsyBio expects to face an inherent risk of exposure to product liability claims, regulatory action and litigation if the products it plans to distribute are alleged to have caused loss or injury.
- There can be no assurance that PsyBio will be able to obtain or maintain product liability insurance on acceptable terms or with adequate coverage against potential liabilities.
- PsyBio's business relies on its ability to access, develop, and sell psilocybin. Psilocybin is a controlled substance in many jurisdictions, including in Canada under Schedule III of the CDSA and in the United States under the CSA.
- PsyBio may face difficulty accessing psilocybin and the public capital markets in Canada as a result of the response of regulators, stock exchanges, and other market participants to PsyBio's development and sale of a controlled substance.
- PsyBio may have limited access to traditional banking services, as well as limited access to debt financing from traditional institutional lenders.
- The medical efficacy of psilocybin has not been confirmed and requires further study and scientific rigour.

PsyBio will be heavily reliant on the production and distribution of psychedelics, psychoactive substances and related products. If they do not achieve sufficient market acceptance, it will be difficult for PsyBio to achieve profitability.

PsyBio expects that its psychedelic based products will account for substantially all of its revenue for the foreseeable future. If the psychedelic market declines or psychedelics fail to achieve substantially greater market acceptance than it currently enjoys, PsyBio will not be able to grow its revenues sufficiently for it to achieve consistent profitability.

Even if products to be distributed by PsyBio conform to international safety and quality standards, sales could be adversely affected if consumers in target markets lose confidence in the safety, efficacy, and quality of psychedelic based products. Adverse publicity about psychedelic based products that PsyBio sells may discourage consumers from buying products distributed by PsyBio.

PsyBio will, for the immediate future, have limited marketing and sales capabilities, and there can be no assurance that it will be able to develop or acquire these capabilities at the level needed to produce and deliver for sale, through industry partners, its products in sufficient commercial quantities.

Further, there can be no assurance that PsyBio, either on its own or through arrangements with other industry participants, will be able to develop or acquire such capabilities on a cost-effective basis, or at all. Finally, there can be no assurance that PsyBio's industry partners will be able to market or sell PsyBio's products in compliance with requisite regulatory protocols or on a cost-effective basis. PsyBio's dependence upon third parties for the production, and marketing or sale, as applicable, of PsyBio's products could have a material adverse effect on PsyBio's business, financial condition and results of operations.

There can be no assurance that PsyBio or its industry partners will be successful in their respective efforts to develop and implement, or assist PsyBio in developing and implementing, a commercialization strategy for PsyBio's products.

The successful commercialization of PsyBio's products will depend on many factors, including, PsyBio's ability to establish and maintain working partnerships with industry participants in order to market its products, PsyBio's ability to supply a sufficient amount of its products to meet market demand, and the number of competitors within each jurisdiction within which PsyBio may from time to time be engaged. There can be no assurance that PsyBio or its industry partners will be successful in their respective efforts to develop and implement, or assist PsyBio in developing and implementing, a commercialization strategy for PsyBio's products.

PsyBio will rely on third parties to conduct a significant portion of its preclinical and clinical development activities.

For example, clinical development activities include trial design, regulatory submissions, clinical patient recruitment, clinical trial monitoring, clinical data management and analysis, safety monitoring and project management. If there is any dispute or disruption in its relationship with third parties, or if it is unable to provide quality services in a timely manner and at a feasible cost, PsyBio's active development programs will face delays. Further, if any of these third parties fails to perform as PsyBio expects or if their work fails to meet regulatory requirements, PsyBio's testing could be delayed, cancelled or rendered ineffective.

Strategic alliances could present unforeseen integration obstacles or costs, may not enhance PsyBio's business, and may involve risks that could adversely affect PsyBio, including significant amounts of management time that may be diverted from operations in order to pursue and complete such transactions or maintain such strategic alliances.

PsyBio intends to enter into strategic alliances with third parties that PsyBio believes will complement or augment its proposed business or will have a beneficial impact on PsyBio. Strategic alliances could present unforeseen integration obstacles or costs, may not enhance PsyBio's business,

and may involve risks that could adversely affect PsyBio, including significant amounts of management time that may be diverted from operations in order to pursue and complete such transactions or maintain such strategic alliances. Future strategic alliances could result in the incurrence of additional debt, costs and contingent liabilities, and there can be no assurance that future strategic alliances will achieve, or that PsyBio's existing strategic alliances will continue to achieve, the expected benefits to PsyBio's business or that PsyBio will be able to consummate future strategic alliances on satisfactory terms, or at all. Any of the foregoing could have a material adverse effect on PsyBio's business, financial condition and results of operations.

In addition to the foregoing, the success of PsyBio's business will depend, in large part, on PsyBio's ability to enter into, and maintain collaborative arrangements with various participants in the psychedelic industry. There can be no assurance that PsyBio will be able to enter into collaborative arrangements in the future on acceptable terms, if at all. There can be no assurance that such arrangements will be successful, that the parties with which PsyBio has or may establish arrangements will adequately or successfully perform their obligations under such arrangements, that potential partners will not compete with PsyBio by seeking or prioritizing alternate, competitor products. The termination or cancellation of any such collaborative arrangement or the failure of PsyBio and/or the other parties to these arrangements to fulfill their obligations could have a material adverse effect on PsyBio's business, financial condition and results of operations. In addition, disagreements between PsyBio and any of its industry partners could lead to delays or time consuming and expensive legal proceedings, which could have a material adverse effect on PsyBio's business, financial condition and results of operations.

Our management has limited manufacturing experience.

PsyBio has limited manufacturing experience. Once it is ready to manufacture a commercial quality drug supply, it will rely on contract manufacturing organizations ("CMOs") to manufacture its product candidates for preclinical studies and clinical trials. PsyBio will rely on CMOs for manufacturing, filling, packaging, storing and shipping of drug product in compliance with current Good Manufacturing Practices ("cGMP") regulations applicable to its products. Health Canada ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with cGMP regulations. The cGMP regulations for drugs contain minimum requirements for the methods, facilities and controls used in manufacturing, processing and packing of a drug product. There can be no assurances that CMOs will be able to meet PsyBio's timetable and requirements. If PsyBio is unable to arrange for third-party manufacturing sources on commercially reasonable terms or in a timely manner, PsyBio may be delayed in the development of its product candidates. Further, CMOs must operate in compliance with cGMP and failure to do so could result in, among other things, the disruption of product supplies. PsyBio's dependence upon third parties for the manufacture of its products may adversely affect its profit margins and its ability to develop and deliver products on a timely and competitive basis.

Manufacturing commercial quality products may have long lead times, may be very expensive and require significant efforts.

PsyBio's products have been manufactured in small quantities for preclinical studies and clinical trials by third party manufacturers. In order to commercialize its product, PsyBio needs to manufacture commercial quality drug supply for use in registration clinical trials. Most, if not all, of the clinical material used in phase 3/pivotal/registration studies must be derived from the defined commercial process including scale, manufacturing site, process controls and batch size. If PsyBio has not scaled up and validated the commercial production of its product prior to the commencement of pivotal clinical trials, it may have to employ a bridging strategy during the trial to demonstrate equivalency of early stage material to commercial drug product, or potentially delay the initiation or completion of the trial until drug supply is available. The manufacturing of commercial quality product may have long lead times, may be very expensive and requires significant efforts including,

but not limited to, scale-up of production to anticipated commercial scale, process characterization and validation, analytical method validation, identification of critical process parameters and product quality attributes, and multiple process performance and validation runs. If PsyBio does not have commercial drug supply available when needed for pivotal clinical trials, PsyBio's regulatory and commercial progress may be delayed, and it may incur increased product development costs. This may have a material adverse effect on PsyBio's business, financial condition and prospects, and may delay marketing of the product.

Clinical testing is expensive and difficult to design and implement, can take many years to complete and has uncertain outcomes. The outcome of pre-clinical studies and early clinical trials may not predict the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results.

Before obtaining marketing approval from regulatory authorities for the sale of PsyBio's product candidates, PsyBio must conduct preclinical studies in animals and extensive clinical trials in humans to demonstrate the safety and efficacy of the product candidates. Clinical testing is expensive and difficult to design and implement, can take many years to complete and has uncertain outcomes. The outcome of preclinical studies and early clinical trials may not predict the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety profiles, notwithstanding promising results in earlier trials. PsyBio does not know whether the clinical trials it may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market any of its product candidates in any jurisdiction. A product candidate may fail for safety or efficacy reasons at any stage of the testing process. A major risk PsyBio faces is the possibility that none of its product candidates under development will successfully gain market approval from Health Canada, the U.S. FDA or other regulatory authorities, resulting in PsyBio being unable to derive any commercial revenue from them after investing significant amounts of capital in their development.

Failure can occur at any time during the clinical trial process and PsyBio's future clinical trial results may not be successful.

PsyBio cannot predict whether any clinical trials will begin as planned, will need to be restructured, or will be completed on schedule, or at all. PsyBio's product development costs will increase if it experiences delays in clinical testing. Significant clinical trial delays could shorten any periods during which PsyBio may have the exclusive right to commercialize its product candidates or allow its competitors to bring products to market before PsyBio, which would impair PsyBio's ability to successfully commercialize its product candidates and may harm its financial condition, results of operations and prospects.

The commencement and completion of clinical trials for PsyBio's products may be delayed for a number of reasons, including but not limited, to:

- failure by regulatory authorities to grant permission to proceed or placing clinical trials on hold;
- suspension or termination of clinical trials by regulators for many reasons, including concerns about patient safety or failure of PsyBio's CMOs to comply with cGMP requirements;
- any changes to PsyBio's manufacturing process that may be necessary or desired, which results in delays or failure to obtain clinical supply from CMOs of PsyBio's products necessary to conduct clinical trials;

- product candidates demonstrating a lack of safety or efficacy during clinical trials, and reports of clinical testing on similar technologies and products raising safety or efficacy concerns;
- clinical investigators not performing PsyBio's clinical trials on their anticipated schedule, dropping out of a trial, or employing methods not consistent with the clinical trial protocol, regulatory requirements or other third parties not performing data collection and analysis in a timely or accurate manner;
- failure of PsyBio's contract research organizations to satisfy their contractual duties or meet expected deadlines;
- inspections of clinical trial sites by regulatory authorities;
- regulatory authorities or ethics committees finding regulatory violations that require PsyBio to undertake corrective action, resulting in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study;
- delays in or failure to recruit a sufficient number of suitable patients to participate in a trial;
- availability of adequately trained therapists and appropriate third-party clinical trial sites for the conduct of the therapy sessions, including preparation, dosing and integration of the therapeutic experience;
- sufficiency of any supporting digital services that may form part of the preparation, integration or long-term follow-up relating to any therapy we develop;
- failure to have patients complete a trial or return for post-treatment follow-up;
- one or more regulatory authorities or ethics committees rejecting, suspending or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial;
- failure to reach agreement on acceptable terms with prospective clinical trial sites; or
- business interruptions resulting from geo-political actions, including war and terrorism, natural disasters including earthquakes, typhoons, floods and fires, pandemics, or failures or significant downtime of PsyBio's information technology systems resulting from cyber-attacks on such systems or otherwise.

Our product development costs will increase if it experiences delays in testing or approval or if PsyBio needs to perform more or larger clinical trials than planned.

Additionally, changes in regulatory requirements and policies may occur, and PsyBio may need to amend study protocols to reflect these changes. Amendments may require PsyBio to resubmit its study protocols to regulatory authorities or ethics committees for re-examination, which may impact the cost, timing or successful completion of that trial. Delays or increased product development costs may have a material adverse effect on PsyBio's business, financial condition and prospects.

Regulatory approvals are required prior to each clinical trial and PsyBio may fail to obtain the necessary approvals to commence or continue clinical testing.

PsyBio's development and commercialization activities and product candidates are significantly regulated by a number of governmental entities, including Health Canada and the U.S. FDA.

Regulatory approvals are required prior to each clinical trial and PsyBio may fail to obtain the necessary approvals to commence or continue clinical testing. PsyBio must comply with regulations concerning the manufacture, testing, safety, effectiveness, labeling, documentation, advertising, and sale of products and product candidates and ultimately must obtain regulatory approval before it can commercialize a product candidate. The time required to obtain approval by such regulatory authorities is unpredictable but typically takes many years following the commencement of pre-clinical studies and clinical trials. Any analysis of data from clinical activities PsyBio performs is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. Even if PsyBio believes results from its clinical trials are favorable to support the marketing of its product candidates, Health Canada, the U.S. FDA or other regulatory authorities may disagree. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions.

PsyBio has not obtained regulatory approval for any product candidate and it is possible that none of its existing product candidates or any future product candidates will ever obtain regulatory approval. PsyBio could fail to receive regulatory approval for its product candidates for many reasons, including:

- the U.S. FDA, Health Canada, or other comparable regulatory authorities may disagree with, question or request changes in the design or implementation of PsyBio's clinical trials;
- the U.S. FDA, Health Canada, or other comparable regulatory authorities may determine that any future therapeutic candidates are not safe and effective, only moderately effective, or have undesirable or unintended side effects, toxicities, or other characteristics that preclude PsyBio's obtaining marketing approval or prevent or limit commercial use;
- the results of clinical trials may not meet the level of statistical significance required by the U.S. FDA, Health Canada, or other comparable regulatory authorities for approval;
- PsyBio may be unable to demonstrate that PsyBio's therapeutic candidate's clinical and other benefits outweigh its safety risks;
- the U.S. FDA, Health Canada, or other comparable regulatory authorities may disagree with PsyBio's interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of PsyBio's product candidates may not be sufficient to support the submission of an NDA or other submission, or to obtain regulatory approval in the United States or elsewhere;
- the U.S. FDA, Health Canada, or other comparable regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which PsyBio contracts for clinical and commercial supplies;
- the approval policies or regulations of the U.S. FDA, Health Canada, or other comparable regulatory authorities may significantly change in a manner rendering PsyBio's clinical data insufficient for approval; and
- the potential risk of PsyBio's novel therapy and delivery method, including the use of third-party clinical trial sites and therapists.

A regulatory authority may require more information, including additional pre-clinical or clinical data to support approval, which may delay or prevent approval and PsyBio's commercialization plans, or PsyBio may decide to abandon the development program. If PsyBio were to obtain approval,

regulatory authorities may approve any of its product candidates for fewer or more limited indications than PsyBio requests, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Moreover, depending on any safety issues associated with PsyBio's product candidates that garner approval, Health Canada, the U.S. FDA or other regulatory authorities may impose a risk evaluation and mitigation strategy, thereby imposing certain restrictions on the sale and marketability of such products.

In addition, even if PsyBio were to obtain approval, regulatory or pricing authorities may approve any future product candidates for fewer or more limited indications than PsyBio requests, may not approve the price PsyBio intends to charge for PsyBio's therapies, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a therapeutic candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that therapeutic candidate.

We will rely on third-party clinical investigators and academic collaborators. PsyBio's failure, or the failure of PsyBio's third-party contractors and [CROs] [no defined] to comply with regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties.

PsyBio has relied upon and plans to continue to rely upon third parties, including independent clinical investigators, academic collaborators and third-party CROs, to conduct PsyBio's preclinical studies and clinical trials and to monitor and manage data for PsyBio's ongoing preclinical and clinical programs. PsyBio relies on these parties for execution of PsyBio's preclinical studies and clinical trials, and controls only certain aspects of their activities. Nevertheless, PsyBio is responsible for ensuring that each of PsyBio's studies and trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and PsyBio's reliance on these third parties does not relieve PsyBio of regulatory responsibilities. PsyBio and PsyBio's third-party contractors and CROs are required to comply with good clinical practices, or GCP requirements, which are regulations and guidelines enforced by the U.S. FDA, Health Canada and comparable foreign regulatory authorities for all of PsyBio's therapies in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we, PsyBio's investigators, academic collaborators or any of PsyBio's CROs fail to comply with applicable GCPs, the clinical data generated in PsyBio's clinical trials may be deemed unreliable and the U.S. FDA, Health Canada, or other comparable regulatory authorities may require PsyBio to perform additional clinical trials before approving PsyBio's marketing applications. PsyBio cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of PsyBio's clinical trials comply with GCP regulations. In addition, PsyBio's clinical trials must be conducted with product produced under cGMP regulations. PsyBio's failure, or the failure of PsyBio's third-party contractors and CROs, to comply with these regulations may require PsyBio to repeat clinical trials, which would delay the regulatory approval process and could also subject PsyBio to enforcement action up to and including civil and criminal penalties.

Further, these investigators, academic collaborators and CROs are not PsyBio's employees and PsyBio will not be able to control, other than by contract, the amount of resources, including time, which they devote to PsyBio's therapeutic candidates or any future therapeutic candidates and clinical trials. If independent investigators, academic collaborators or CROs fail to devote sufficient resources to the development of PsyBio's therapeutic candidates or any future therapeutic candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of PsyBio's therapeutic candidates or any future therapeutic candidates that PsyBio develops. In addition, the use of third-party service providers requires PsyBio to disclose PsyBio's proprietary information to these parties, which could increase the risk that this information will be misappropriated. In addition, investigators, academic collaborators and CROs may have

difficulty staffing, undergo changes in priorities or become financially distressed or form relationships with other entities, some of which may be PsyBio's competitors, any of which may materially adversely affect PsyBio's business.

There is a limited number of third-party service providers that specialize in or have the expertise required to achieve our business objectives.

PsyBio's CROs have the right to terminate their agreements with PsyBio in the event of an uncured material breach. In addition, some of PsyBio's CROs have an ability to terminate their respective agreements with PsyBio if it can be reasonably demonstrated that the safety of the subjects participating in PsyBio's clinical trials warrants such termination, if PsyBio makes a general assignment for the benefit of PsyBio's creditors or if PsyBio is liquidated.

If any of PsyBio's relationships with these third-party CROs or clinical investigators terminate, PsyBio may not be able to enter into arrangements with alternative CROs, academic collaborators or investigators on commercially reasonable terms or at all. If CROs, academic collaborators or clinical investigators do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to PsyBio's clinical protocols, regulatory requirements or for other reasons, PsyBio's clinical trials may be extended, delayed or terminated and PsyBio may not be able to obtain regulatory approval for or successfully commercialize PsyBio's therapeutic candidates or any future therapeutic candidates. As a result, PsyBio's results of operations and the commercial prospects for PsyBio's therapeutic candidates or any future therapeutic candidates would be harmed, PsyBio's costs could increase and PsyBio's ability to generate revenue could be delayed.

Switching or adding additional CROs (or investigators) involves additional cost and requires management time and focus. In addition, delays occur during the natural transition period when a new CRO commences work, which can materially impact PsyBio's ability to meet desired development timelines. Though PsyBio carefully manages PsyBio's relationships with PsyBio's CROs, there can be no assurance that PsyBio will not encounter similar challenges or delays in the future, or that these delays or challenges will not have a material adverse impact on PsyBio's business or financial condition and prospects.

We may be unable to enroll patients to complete clinical trials on a timely basis or at all.

As PsyBio's product candidates advance from pre-clinical testing to clinical testing, and then through progressively larger and more complex clinical trials, PsyBio will need to enroll an increasing number of patients that meet its eligibility criteria. There is significant competition for recruiting patients in clinical trials, and PsyBio may be unable to enroll the patients it needs to complete clinical trials on a timely basis or at all. The factors that affect PsyBio's ability to enroll patients are largely uncontrollable and include:

- the size of the patient population required for analysis of the trial's primary endpoints and the process for identifying patients;
- identifying and enrolling eligible patients, including those willing to discontinue use of their existing medications;
- the design of the clinical protocol and the patient eligibility and exclusion criteria for the trial;
- safety profile, to date, of the therapeutic candidate under study;

- the willingness or availability of patients to participate in PsyBio's trials, including due to the perceived risks and benefits, stigma or other side effects of the use of a controlled substance;
- the willingness or availability of patients to participate in PsyBio's trials, including due to impacts of the COVID-19 pandemic;
- perceived risks and benefits of PsyBio's approach to treatment of indication;
- the proximity of patients to clinical sites;
- PsyBio's ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the availability of competing clinical trials;
- the availability of new drugs approved for the indication the clinical trial is investigating;
- clinicians' and patients' perceptions of the potential advantages of the drug being studied in relation to other available therapies, including any new therapies that may be approved for the indications PsyBio is investigating; and
- PsyBio's ability to obtain and maintain patient informed consents.

Even once enrolled, PsyBio may be unable to retain a sufficient number of patients to complete any of PsyBio's trials.

In addition, any negative results PsyBio may report in clinical trials of any future therapeutic candidates may make it difficult or impossible to recruit and retain patients in other clinical trials of that same therapeutic candidate. Delays in the enrollment for any clinical trial of any future therapeutic candidates will likely increase PsyBio's costs, slow down the approval process and delay or potentially jeopardize PsyBio's ability to commence sales of future products. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of future therapeutic candidates.

Further, timely enrollment in clinical trials is reliant on clinical trial sites which may be adversely affected by global health matters, including, among other things, pandemics. For example, PsyBio's clinical trial sites may be located in regions affected by the COVID-19 pandemic or which may in the future be impacted by this or other pandemics. Some factors from the COVID-19 pandemic that PsyBio believe may adversely affect enrollment in PsyBio's trials include:

- the diversion of healthcare resources away from the conduct of clinical trial matters to focus on pandemic concerns, including the attention of infectious disease physicians serving as PsyBio's clinical trial investigators, hospitals serving as PsyBio's clinical trial sites and hospital staff supporting the conduct of PsyBio's clinical trials;
- the limitation of available participants for PsyBio's trials;
- the inability of patients, therapists or physicians to come to hospitals and universities to participate in PsyBio's trials, leading to delays and increased costs;
- limitations on travel that interrupt key trial activities, such as clinical trial site initiations and monitoring and patient preparation and integration sessions;

- interruption in global shipping affecting the transport of clinical trial materials, such as investigational drug product and comparator drugs used in PsyBio's trials; and
- employee furlough days that delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

These and other factors arising from the COVID-19 pandemic could worsen in countries that are already afflicted with the virus or could continue to spread to additional countries, each of which may further adversely impact PsyBio's clinical trials. The global outbreak of COVID-19 continues to evolve and the conduct of PsyBio's trials may continue to be adversely affected, despite efforts to mitigate this impact.

We cannot be certain that any clinical trials we undertake will be successful.

Clinical trials that PsyBio conducts may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market PsyBio's future product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same therapeutic candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. If the results of PsyBio's future clinical trials are inconclusive, if PsyBio does not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with therapeutic candidates, PsyBio may be delayed in obtaining marketing approval, or may never obtain marketing approval.

Even if PsyBio's clinical trials are successfully completed, pre-clinical and clinical data are often susceptible to varying interpretations and analyses and PsyBio cannot guarantee that the U.S. FDA, Health Canada or comparable foreign regulatory authorities will interpret the results as PsyBio does. Accordingly, more trials could be required before PsyBio can submit a future therapeutic candidate for approval. To the extent that the results of the trials are not satisfactory to the U.S. FDA, Health Canada or comparable foreign regulatory authorities for support of a marketing application, approval of future therapeutic candidates may be significantly delayed, or PsyBio may be required to expend significant resources, which may not be available, to conduct additional trials. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. Due to the inherent risk in the development of therapeutic substances, there is a significant likelihood that any future therapeutic candidates will not successfully complete development and receive approval. Many other companies that believed their therapeutic candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain regulatory approval for the marketing of their therapy. If PsyBio does not receive regulatory approvals for future therapeutic candidates, PsyBio may not be able to continue operating. Even if regulatory approval is secured for any future therapeutic candidate, the terms of such approval may limit the scope and use of a specific therapeutic candidate, which may also limit its commercial potential.

Material adverse changes in our final clinical trial data compared to the interim data could significantly harm our business prospects.

From time to time, PsyBio may publish interim, top-line or preliminary data from PsyBio's clinical trials. PsyBio may decide to conduct an interim analysis of the data after a certain number or percentage of subjects have been enrolled, but before completion of the trial. Similarly, PsyBio may report top-line or preliminary results of primary and key secondary endpoints before the final trial results are completed. Interim, top-line and preliminary data from PsyBio's clinical trials may change as more patient data or analyses become available. Preliminary, top-line or interim data from

PsyBio's clinical trials are not necessarily predictive of final results. Interim, top-line and preliminary data are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues, more patient data become available and PsyBio issues PsyBio's final clinical trial report. Interim, top-line and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data PsyBio previously published. As a result, interim, top-line and preliminary data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to the interim data could significantly harm PsyBio's business prospects.

Further, others, including regulatory agencies, may not accept or agree with PsyBio's assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular therapeutic candidate and PsyBio's company in general, and regulatory agencies may request further data from us. In addition, you or others may not agree with what PsyBio determines is material or otherwise appropriate information to include in PsyBio's disclosure, and any information PsyBio determines not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular therapeutic candidate. If the top-line data that PsyBio reports differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, PsyBio's ability to obtain approval for, and commercialize any future product candidate, PsyBio's business, operating results, prospects or financial condition may be harmed.

There can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of any future therapeutic candidates.

Therapeutic candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. Furthermore, there can be no assurance that any of PsyBio's clinical trials will ultimately be successful or support further clinical development of any future therapeutic candidates. There is a high failure rate for drugs proceeding through clinical trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in clinical development even after achieving promising results in earlier studies.

Research and development of drugs targeting the central nervous system is particularly difficult, which makes it difficult to predict and understand why the drug has a positive effect on some patients but not others.

Discovery and development of new drugs targeting central nervous system, or CNS, disorders are particularly difficult and time-consuming, evidenced by the higher failure rate for new drugs for CNS disorders compared with most other areas of drug discovery. For example, in 2019, both Rapastinel and SAGE-217, two new drugs targeting MDD, failed to meet their primary endpoints in Phase III trials. ALKS 5461, another new drug targeting MDD, was rejected by U.S. FDA in 2019 after its Phase III trials as U.S. FDA required additional clinical data to provide substantial evidence of effectiveness. Any such setbacks in PsyBio's clinical development could have a material adverse effect on PsyBio's business and operating results. In addition, PsyBio's later stage clinical trials may present challenges related to conducting adequate and well-controlled clinical trials, including designing an appropriate comparator arm in trials given the potential difficulties related to maintaining the blinding during the trial or placebo or nocebo effects.

Due to the complexity of the human brain and the central nervous system, it can be difficult to predict and understand why a drug may have a positive effect on some patients but not others and why some individuals may react to the drug differently from others.

We have limited organizational experience in the sale or marketing of therapeutic candidates. If PsyBio does not establish commercial capabilities successfully, either on PsyBio's own or in collaboration with third parties, PsyBio may not be successful in commercializing PsyBio's therapies, which in turn would have a material adverse effect on PsyBio's business, prospects, financial condition and results of operations.

While PsyBio plans to assemble a sales and marketing infrastructure, PsyBio has limited organizational experience in the sale or marketing of therapeutic candidates. To achieve commercial success for any approved therapy, PsyBio must develop or acquire a sales and marketing organization, outsource these functions to third parties or enter into partnerships.

If a PsyBio product is approved for commercial sale, PsyBio will establish its own market access and commercialization capabilities in primary markets in North America. In select geographies, PsyBio might also consider relying on the support of a Contract Sales Organization, or CSO, or enter into commercialization arrangements with companies with relevant commercialization capabilities. There are risks involved in establishing PsyBio's own sales and marketing capabilities, as well as with entering into arrangements with third parties to perform these services. Even if PsyBio establishes sales and marketing capabilities, PsyBio may fail to launch PsyBio's therapies effectively or to market PsyBio's therapies effectively since PsyBio has limited organizational experience in the sales and marketing of therapeutic substances. In addition, recruiting and training a sales force is expensive and time-consuming, and could delay any therapeutic launch. In the event that any such launch is delayed or does not occur for any reason, PsyBio would have prematurely or unnecessarily incurred these commercialization expenses, and PsyBio's investment would be lost if PsyBio cannot retain or reposition PsyBio's sales and marketing personnel. Factors that may inhibit PsyBio's efforts to commercialize PsyBio's therapies on PsyBio's own include:

- PsyBio's inability to train an adequate number of therapists to meet the demand for psilocybin therapy;
- the ability of PsyBio's therapists to perform their roles consistently with PsyBio's training and PsyBio's guidelines for the administration of PsyBio's future therapeutic products;
- PsyBio's inability to recruit, train and retain effective market access and commercial personnel;
- the inability of commercial personnel to obtain access to or educate adequate numbers of physicians on the benefits of prescribing any future therapies;
- PsyBio's inability to identify a sufficient number of treatment centers in third-party therapy sites to meet the demands of PsyBio's therapies;
- the lack of complementary therapies to be offered by PsyBio's commercial personnel, which may put PsyBio at a competitive disadvantage relative to companies with more extensive therapeutic lines;
- unforeseen costs and expenses associated with creating an independent market access and commercial organization; and
- costs of market access and commercialization above those anticipated by PsyBio.

If PsyBio enters into arrangements with third parties to perform market access and commercial services for any approved therapies, the revenue or the profitability of these revenues to PsyBio could be lower than if PsyBio were to commercialize any therapies that PsyBio develops itself. Such collaborative arrangements may place the commercialization of any approved therapies outside of

PsyBio's control and would make PsyBio subject to a number of risks including that PsyBio may not be able to control the amount or timing of resources that PsyBio's collaborative partner devotes to PsyBio's therapies or that PsyBio's collaborator's willingness or ability to complete its obligations, and PsyBio's obligations under PsyBio's arrangements may be adversely affected by business combinations or significant changes in PsyBio's collaborator's business strategy. PsyBio may not be successful in entering into arrangements with third parties to commercialize PsyBio's therapies or may be unable to do so on terms that are favorable to PsyBio. Acceptable third parties may fail to devote the necessary resources and attention to commercialize PsyBio's therapies effectively, to set up sufficient number of treatment centers in third-party therapy sites, or to recruit, train and retain adequate number of therapists to administer PsyBio's therapies. In addition, PsyBio is exploring ways in which PsyBio can use digital technology to improve the patient experience and therapeutic outcomes of PsyBio's therapies. Commercialization partners may lack incentives to promote PsyBio's digital technology and PsyBio may face difficulties in implementing PsyBio's digital technologies in third-party therapy sites through such third parties.

If PsyBio does not establish commercial capabilities successfully, either on PsyBio's own or in collaboration with third parties, PsyBio may not be successful in commercializing PsyBio's therapies, which in turn would have a material adverse effect on PsyBio's business, prospects, financial condition and results of operations.

If the U.S. FDA, Health Canada, or any other comparable regulatory authority approves any PsyBio therapeutic candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the therapy and underlying therapeutic substance will be subject to extensive and ongoing regulatory requirements.

If the U.S. FDA, Health Canada, or any other comparable regulatory authority approves any PsyBio therapeutic candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the therapy and underlying therapeutic substance will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs, and with GCPs, for any clinical trials that PsyBio conducts post-approval, all of which may result in significant expense and limit PsyBio's ability to commercialize such therapies. Later discovery of previously unknown problems with any approved therapeutic candidate, including adverse events of unanticipated severity or frequency, or with PsyBio's third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the labeling, distribution, marketing or manufacturing of any future therapeutic candidates, withdrawal of the product from the market, or product recalls;
- untitled and warning letters, or holds on clinical trials;
- refusal by the U.S. FDA, Health Canada, other foreign regulatory body to approve pending applications or supplements to approved applications PsyBio filed or suspension or revocation of license approvals;
- requirements to conduct post-marketing studies or clinical trials;
- restrictions on coverage by third-party payors;
- fines, restitution or disgorgement of profits or revenue;
- suspension or withdrawal of marketing approvals;

- product seizure or detention, or refusal to permit the import or export of the product; and
- injunctions or the imposition of civil or criminal penalties.

In addition, any regulatory approvals that PsyBio receives for any future therapeutic candidates may also be subject to limitations on the approved indicated uses for which the therapy may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase IV clinical trials, and surveillance to monitor the safety and efficacy of such therapeutic candidates.

If there are changes in the application of legislation, regulations or regulatory policies, or if problems are discovered with PsyBio's future products or PsyBio's manufacture of an underlying therapeutic substance, or if PsyBio or one of PsyBio's distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include imposing fines on us, imposing restrictions on the therapeutic or its manufacture and requiring PsyBio to recall or remove the therapeutic from the market. The regulators could also suspend or withdraw PsyBio's marketing authorizations, requiring PsyBio to conduct additional clinical trials, change PsyBio's therapeutic labeling or submit additional applications for marketing authorization. If any of these events occurs, PsyBio's ability to sell such therapy may be impaired, and PsyBio may incur substantial additional expense to comply with regulatory requirements, which could materially adversely affect PsyBio's business, financial condition and results of operations.

PsyBio may not achieve previously announced milestones within expected timeframes, if at all. Any variation in the timing of previously announced milestones could have a material adverse effect on PsyBio's business plan, financial condition or operating results and the trading price of the Subordinate Voting Shares.

From time to time, PsyBio may announce the timing of certain events it expects to occur, such as the anticipated timing of results from its clinical trials. These statements are forward-looking and are based on the best estimates of management at the time relating to the occurrence of such events. However, the actual timing of such events may differ from what has been publicly disclosed. The timing of events such as initiation or completion of a clinical trial, filing of an application to obtain regulatory approval, or announcement of additional clinical trials for a product candidate may ultimately vary from what is publicly disclosed.

PsyBio undertakes no obligation to update or revise any forward-looking information or statements, whether as a result of new information, future events or otherwise, except as otherwise required by-law. Any variation in the timing of previously announced milestones could have a material adverse effect on PsyBio's business plan, financial condition or operating results and the trading price of the Subordinate Voting Shares.

PsyBio may never have a therapy that is commercially successful.

To date, PsyBio has no therapy authorized for marketing. PsyBio's future therapeutic products requires further clinical investigation, regulatory review, significant market access and marketing efforts and substantial investment before it can produce any revenue. Furthermore, if approved, PsyBio's therapy may not achieve an adequate level of acceptance by payors, health technology assessment bodies, healthcare professionals, patients and the medical community at large, and PsyBio may not become profitable. The level of acceptance PsyBio ultimately achieves may be affected by negative public perceptions and historic media coverage of psychedelic substances, including psilocybin. Because of this history, efforts to educate the medical community and third-party payors and health technologies assessment bodies on the benefits of PsyBio's therapeutic compounds may require significant resources and may never be successful, which would prevent

PsyBio from generating significant revenue or becoming profitable. Market acceptance of PsyBio's future therapies by healthcare professionals, patients, healthcare payors and health technology assessment bodies will depend on a number of factors, many of which are beyond PsyBio's control, including, but not limited to, the following:

- acceptance by healthcare professionals, patients and healthcare payors of each therapy as safe, effective and cost-effective;
- changes in the standard of care for the targeted indications for any therapeutic candidate;
- the strength of sales, marketing and distribution support;
- potential product liability claims;
- the therapeutic candidate's relative convenience, ease of use, ease of administration and other perceived advantages over alternative therapies;
- the prevalence and severity of adverse events or publicity;
- limitations, precautions or warnings listed in the summary of therapeutic characteristics, patient information leaflet, package labeling or instructions for use;
- the cost of treatment with PsyBio's therapy in relation to alternative treatments;
- the steps that prescribers and dispensers must take, as well as the perceived risks based upon its controlled substance status;
- the ability to manufacture PsyBio's product in sufficient quantities and yields;
- the availability and amount of coverage and reimbursement from healthcare payors, and the willingness of patients to pay out of pocket in the absence of healthcare payor coverage or adequate reimbursement;
- the willingness of the target patient population to try, and of healthcare professionals to prescribe, the therapy;
- any potential unfavorable publicity, including negative publicity associated with recreational use or abuse of psilocybin;
- any restrictions on the use, sale or distribution of PsyBio's future therapeutic candidates, including through REMS (as defined below);
- the extent to which therapies are approved for inclusion and reimbursed on formularies of hospitals and managed care organizations; and
- whether PsyBio's therapies are designated under physician treatment guidelines or under reimbursement guidelines as a first-line, second-line, third-line or last-line therapy.

If PsyBio's future therapeutic candidates fail to gain market access and acceptance, this will have a material adverse impact on PsyBio's ability to generate revenue to provide a satisfactory, or any, return on PsyBio's investments. Even if some therapies achieve market access and acceptance, the market may prove not to be large enough to allow PsyBio to generate significant revenue.

Our success will depend upon our ability to identify, qualify, prepare, certify and support third-party therapy sites that offer and administer PsyBio's therapies.

If PsyBio is able to commercialize PsyBio's future therapies, PsyBio's success will be dependent upon PsyBio's ability to identify, qualify, prepare, certify and support third-party therapy sites that offer and administer PsyBio's therapies. PsyBio's commercial model of delivering PsyBio's therapeutic products will also involve third-party therapists before, during and after the psilocybin dosing session, which will be hosted in one of the third-party therapy sites. PsyBio intends to commercialize any future therapeutic candidates by building close relationships with qualified third-party therapy sites where these therapists will administer PsyBio's future therapeutic products. Because PsyBio intends to work only with third party sites and providers who agree to adhere strictly to PsyBio's treatment protocols, PsyBio may face limitations on the number of sites available to administer PsyBio's future therapeutic candidate. Any such limitations could make it impracticable or impossible for some potential patients to access PsyBio's future therapeutic candidate, if approved, which could limit the overall size of PsyBio's potential patient population and harm PsyBio's future results of operations. Although PsyBio plans to develop Centers of Excellence to train and certify such third-party therapy sites, conduct further research on and continuously improve PsyBio's treatment protocol, PsyBio expects this to involve significant costs, time and resources, and PsyBio's efforts may not be successful.

If PsyBio is unable to establish a sufficient network of third-party therapy sites certified under applicable standards, including regional, national, state or other applicable standards as needed to render psilocybin therapeutic services, including the certifications that such third-party therapy sites may require, it would have a material adverse effect on PsyBio's business and ability to grow and would adversely affect PsyBio's results of operations and commercialization efforts. PsyBio expects the therapists to be employed by the third-party therapy sites where the therapists administer PsyBio's therapies. Third-party therapy sites could, for a number of reasons, demand higher payments for PsyBio's therapies or take other actions to increase their income from selling PsyBio's therapies, which could result in higher costs for payors and for PsyBio's patients to get access to PsyBio's therapies. For example, legal regimes may have higher levels of licensure which force PsyBio to contract with third-party therapy sites that demand higher payment rates to provide psilocybin therapeutic services. In addition, third-party therapy sites may have difficulty meeting regulatory or accreditation requirements.

Given the novel nature of PsyBio's treatment, third-party therapy sites may face additional financial and administrative burdens in order to deliver any approved therapy, including adhering to a REMS plan in the United States. The process for a third-party therapy site to obtain a certificate under a REMS plan can be very costly and time-consuming, which could delay a third-party therapy site's ability to provide PsyBio's therapies and materially adversely affect PsyBio's commercialization trajectory. Furthermore, third-party therapy sites will need to ensure that they have the necessary infrastructure and equipment in order to deliver PsyBio's future therapeutic candidate, such as adequate audio-visual equipment, ancillary equipment and sufficient treatment rooms. This may deter third-party therapy sites from providing PsyBio's therapeutic candidate and reduce PsyBio's ability to expand PsyBio's network and generate revenue. PsyBio's ability to develop and maintain satisfactory relationships with third-party therapy sites may otherwise be negatively impacted by other factors not associated with PsyBio's operations and, in some instances, outside of PsyBio's direct or indirect control, such as negative perceptions regarding the therapeutic use of psilocybin, changes in Medicare and/or Medicaid or commercial payors reimbursement levels and other pressures on healthcare providers and consolidation activity among hospitals, physician groups and the providers. Reimbursement levels may be inadequate to cover third-party therapy sites' costs of delivering PsyBio's future therapeutic candidate. The failure to maintain or to secure new cost-effective contracts with third-party therapy sites may result in a loss of or inability to grow PsyBio's network of third-party therapy sites, patient base, higher costs to PsyBio's patients and us, healthcare provider network disruptions and/or difficulty in meeting regulatory or accreditation requirements,

any of which could have a material adverse effect on PsyBio's business, financial condition and results of operations.

We will rely on third-party suppliers and manufacturers. The loss or failure of our third-party manufacturers and suppliers to comply with applicable regulations could result in sanctions being imposed on us.

PsyBio does not currently have, nor does PsyBio plan to acquire, the infrastructure or capability necessary to manufacture therapeutic candidates, including the psilocybin incorporated into such therapeutic candidates. PsyBio rely on, and expect to continue to rely on, contract manufacturing organizations, or CMOs, for the development, manufacture and production of the psilocybin and psilocin used in PsyBio's investigational therapies administered in PsyBio's clinical trials and will continue to rely on such CMOs for the development, manufacture and production of any commercial supply, if PsyBio's investigational therapies are approved. Currently, PsyBio engages with multiple different CMOs for all activities relating to the development, manufacture and production of all components. Reliance on third-party providers, such as CMOs, exposes PsyBio to more risk than if PsyBio were to manufacture therapeutic compounds, or any future therapeutic candidates. PsyBio does not control the manufacturing processes of the CMOs PsyBio contracts with and are dependent on those third parties for the production of any future therapeutic candidates in accordance with relevant regulations (such as the U.S. FDA's good laboratory practices, or GLP, cGMPs or similar regulatory requirements outside the US) for the manufacture of drug substances, which includes, among other things, quality control, quality assurance and the maintenance of records and documentation. PsyBio's failure, or the failure of third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on PsyBio, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of COMP360 or any future therapeutic candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of any future therapeutic candidates and harm PsyBio's business and results of operations.

If PsyBio were to experience an unexpected loss of supply of or if any supplier were unable to meet PsyBio's demand for any future therapeutic candidates, PsyBio could experience delays in PsyBio's research or planned clinical studies or commercialization. In addition, quality issues may arise during scale-up activities. PsyBio could be unable to find alternative suppliers of acceptable quality, in the appropriate volumes and at an acceptable cost. For example, the extent to which the COVID-19 pandemic impacts PsyBio's ability to procure sufficient supplies for the development of PsyBio's therapeutic candidates or any future therapeutic candidates will depend on the severity and duration of the spread of the virus, and the actions undertaken to contain COVID-19 or treat its effects. Moreover, PsyBio's suppliers are often subject to strict manufacturing requirements and rigorous testing requirements, which could limit or delay production. The long transition periods necessary to switch manufacturers and suppliers approved, which would materially adversely affect PsyBio's business, prospects, financial condition and results of operations.

In complying with the manufacturing regulations of the U.S. FDA, the U.S. DEA, Health Canada and other comparable foreign authorities, PsyBio and PsyBio's third-party suppliers must spend significant time, money and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that the therapies meet applicable specifications and other regulatory requirements. The failure to comply with these requirements could result in an enforcement action against PsyBio, including the seizure of therapies and shutting down of production, any of which could materially adversely affect PsyBio's business, prospects, financial condition and results of operations. PsyBio and any of these third-party suppliers may also be subject to audits by the U.S. FDA, the U.S. DEA, Health Canada or other comparable foreign authorities. If any of PsyBio's third-party suppliers fails to comply with cGMP or other applicable manufacturing regulations, PsyBio's ability to develop and commercialize the therapies could suffer significant interruptions. PsyBio face risks inherent in relying on a limited number of CMOs, as any disruption,

such as a fire, natural hazards or vandalism at the CMO could significantly interrupt PsyBio's manufacturing capability. PsyBio currently does not have disaster recovery facilities available. In case of a disruption, PsyBio will have to establish alternative manufacturing sources. This would require substantial capital on PsyBio's part, which PsyBio may not be able to obtain on commercially acceptable terms or at all, and PsyBio would likely experience months of manufacturing delays as PsyBio builds or locates replacement facilities and seeks and obtains necessary regulatory approvals. If this occurs, PsyBio will be unable to satisfy manufacturing needs on a timely basis or at all. In addition, operating any new facilities may be more expensive than operating PsyBio's current facility, and business interruption insurance may not adequately compensate PsyBio for any losses that may occur, in which case PsyBio would have to bear the additional cost of any disruption. For these reasons, a significant disruptive event of the manufacturing facility could have a material adverse effect on PsyBio's business, including placing PsyBio's financial stability at risk.

Any changes in methods of manufacturing may affect results or require additional testing, governmental agency notification or approval.

As therapeutic candidates are developed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, may be altered along the way in an effort to optimize processes and results. Any of these changes could cause PsyBio's future therapeutic candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, U.S. FDA notification or U.S. FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of any future therapeutic candidates and jeopardize PsyBio's ability to commence product sales and generate revenue.

Receiving regulatory designations may not be productive.

For drugs that have been designated as breakthrough therapies, interaction and communication between the U.S. FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the U.S. FDA may also be eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the U.S. FDA. Accordingly, even if PsyBio believes any future therapeutic candidates meets the criteria for designation as a breakthrough therapy, the U.S. FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for product candidates and any future therapeutic candidates may not result in a faster development process, review or approval compared to drugs considered for approval under non-expedited U.S. FDA review procedures and does not assure ultimate approval by the U.S. FDA. In addition, even if PsyBio's therapies are eventually designated as a breakthrough therapy, the U.S. FDA may later decide that it, or any future therapeutic candidates that are designated by the U.S. FDA as breakthrough therapies, no longer meet the conditions for qualification.

PsyBio may seek Fast Track designation for any future therapeutic candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for Fast Track designation. The U.S. FDA has broad discretion whether or not to grant this designation, so even if PsyBio believes a particular therapeutic candidate is eligible for this designation, PsyBio cannot assure you that the U.S. FDA would decide to grant it. Even if PsyBio receives Fast Track designation for any future therapeutic candidates, PsyBio may not experience a faster development process, review or approval compared to non-expedited U.S. FDA review procedures. In addition, the U.S.

FDA may withdraw Fast Track designation for any therapeutic candidate that is granted Fast Track designation if it believes that the designation is no longer supported by data from PsyBio's clinical development program.

We may fail to enter into or maintain profitable relationship to discover, develop or commercialize our therapeutics candidates.

PsyBio may enter into collaborations with pharmaceutical companies or others for the discovery, development and/or commercialization of future therapeutic candidates or research programs. If PsyBio fails to enter into or maintain collaborations on reasonable terms, PsyBio's ability to discover and develop future therapeutic candidates and research programs could be delayed or become more costly. Any future collaborations may subject PsyBio to a number of risks, including the following:

- the inability to control the amount and timing of resources that PsyBio's collaboration partner devotes to PsyBio's future research programs and therapeutic candidates;
- for collaboration agreements where PsyBio may be solely or partially responsible for funding development expenses through a defined milestone event, PsyBio may never recoup the costs of these investments if the therapeutic candidate fails to achieve regulatory approval or commercial success;
- PsyBio may rely on the information and data received from third parties regarding their research programs and therapeutic candidates without independent verification;
- PsyBio may not have control of the process conducted by the third party in gathering and composing data regarding their research programs and therapeutic candidates and PsyBio may not have formal or appropriate guarantees with respect to the quality and the completeness of such data;
- PsyBio may not have sufficient funds to satisfy any milestone, royalty or other payments PsyBio may owe to any third party collaborator;
- PsyBio's collaboration agreements may contain non-competition provisions which place restrictions on PsyBio's business operations and the therapeutic candidates and/or indications PsyBio may pursue;
- a collaborative partner may develop or commercialize a competing therapeutic candidate either by itself or in collaboration with others, including one or more of PsyBio's competitors;
- PsyBio's collaborative partners' willingness or ability to complete their obligations under PsyBio's collaboration arrangements may be adversely affected by business combinations or significant changes in a collaborative partner's strategy;
- PsyBio's collaborative partners may experience delays in, or increases in the costs of, the discovery and development of PsyBio's future therapeutic candidates and research programs, and PsyBio may be required to pay for any cost increases;
- PsyBio may have disagreements with collaborative partners, including disagreements over proprietary rights, selection of lead therapeutic candidates, contract interpretation or the preferred course of development that might cause delays or termination of the research, development or commercialization of therapeutic candidates, might lead to additional responsibilities for PsyBio with respect to therapeutic candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;

- PsyBio's collaborative partners may not properly obtain, maintain, defend or enforce intellectual property rights; and
- PsyBio's collaborative partners may infringe, misappropriate or otherwise violate the intellectual property rights of third parties, which may expose PsyBio to litigation and potential liability.

PsyBio may face significant competition in seeking appropriate collaborative partners. PsyBio's ability to reach a definitive agreement for a collaborative partnership depends, among other things, upon PsyBio's assessment of a potential collaborator's resources and expertise, the terms and conditions of the proposed partnership and the potential collaborator's evaluation of a number of factors. Proposing, negotiating, and implementing collaborations, licensing arrangements, joint ventures, strategic alliances, or partnerships may be a lengthy and complex process. PsyBio has limited institutional knowledge and experience with respect to such activities and PsyBio may also not realize the anticipated benefits of any such transaction or arrangement.

Should any of the foregoing risks materialize, any collaborations PsyBio enters into could fail to result in the development of commercially viable therapeutic candidates or the generation of future revenue, which could have a material adverse effect on PsyBio's business.

Negative public perception about our industry or products could be deemed unfavorably by consumers.

There can be no assurance that future scientific research, findings, regulatory proceedings, litigation, media attention or other research findings or publicity will be favorable to the psychedelic industry or any particular product, or consistent with earlier publicity. PsyBio believes the psychedelic industry is highly dependent upon consumer perception regarding the safety, efficacy and quality of psychedelic products. Consumer perception of PsyBio's psychedelic products can be significantly influenced by scientific research or findings, regulatory investigations, litigation, media attention and other publicity regarding the consumption of psychedelics. There can be no assurance that future scientific research, findings, regulatory proceedings, litigation, media attention or other research findings or publicity will be favourable to the psychedelic industry or any particular product, or consistent with earlier publicity. Future research reports, findings, regulatory proceedings, litigation, media attention or other publicity that are perceived as less favourable than, or that question, earlier research reports, findings or publicity could have a material adverse effect on the demand for PsyBio's psychedelic products and the business, results of operations, financial condition and cash flows of PsyBio. PsyBio's dependence upon consumer perceptions means that adverse scientific research reports, findings, regulatory proceedings, litigation, media attention or other publicity, whether or not accurate or with merit, could have a material adverse effect on PsyBio, the demand for PsyBio's psychedelic products, and the business, results of operations, financial condition and cash flows of PsyBio. Further, adverse publicity reports or other media attention regarding the safety, efficacy and quality of psychedelic products in general, or PsyBio's psychedelic products and services specifically, or associating the consumption of truffles with illness or other negative effects or events, could have such a material adverse effect. Such adverse publicity reports or other media attention could arise even if the adverse effects associated with such products resulted from consumers' failure to consume such products legally, appropriately or as directed.

The potential psilocybin industry, if regulatory approval is received, is highly dependent upon consumer perception regarding the medical benefits, safety, efficacy and quality of the psilocybin distributed for medical purposes to such consumers. There can be no assurance that future scientific research or findings on the medical benefits, viability, safety, efficacy and dosing of psilocybin or isolated constituents, regulatory proceedings, litigation, media attention or other research findings or

publicity will be favourable to the industry or PsyBio or any particular product, or consistent with earlier publicity.

Adverse or inaccurate information about us, our industry or products on social media may harm our business, financial condition and results of operations.

There has been a recent marked increase in the use of social media platforms and similar channels that provide individuals with access to a broad audience of consumers and other interested persons. The availability and impact of information on social media platforms is virtually immediate and many social media platforms publish user-generated content without filters or independent verification as to the accuracy of the content posted. Information posted about PsyBio may be adverse to PsyBio's interests or may be inaccurate, each of which may harm PsyBio's business, financial condition and results of operations.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change.

PsyBio's competitors include large, well-established pharmaceutical companies, biotechnology companies, and academic and research institutions developing therapeutics for the same indications PsyBio is targeting and competitors with existing marketed therapies. Many other companies are developing or commercializing therapies to treat the same diseases or indications for which PsyBio's product candidates may be useful. Although there are no approved therapies that specifically target opioid addiction, some competitors use therapeutic approaches that may compete directly with PsyBio's product candidates.

Many of PsyBio's competitors have substantially greater financial, technical and human resources than PsyBio does and have significantly greater experience than PsyBio in conducting preclinical testing and human clinical trials of product candidates, scaling up manufacturing operations and obtaining regulatory approvals of products. Accordingly, PsyBio's competitors may succeed in obtaining regulatory approval for products more rapidly than PsyBio does. PsyBio's ability to compete successfully will largely depend on:

- the efficacy and safety profile of its product candidates relative to marketed products and other product candidates in development;
- PsyBio's ability to develop and maintain a competitive position in the product categories and technologies on which it focuses;
- the time it takes for PsyBio's product candidates to complete clinical development and receive marketing approval;
- PsyBio's ability to obtain required regulatory approvals;
- PsyBio's ability to commercialize any of its product candidates that receive regulatory approval;
- PsyBio's ability to establish, maintain and protect intellectual property rights related to its product candidates; and
- acceptance of any of PsyBio's product candidates that receive regulatory approval by physicians and other healthcare providers and payers.

Competitors have developed and may develop technologies that could be the basis for products that challenge the discovery research capabilities of products PsyBio is developing. Some of those

products may have an entirely different approach or means of accomplishing the desired therapeutic effect than PsyBio's product candidates and may be more effective or less costly than its product candidates. The success of PsyBio's competitors and their products and technologies relative to PsyBio's technological capabilities and competitiveness could have a material adverse effect on the future preclinical studies and clinical trials of PsyBio's product candidates, including its ability to obtain the necessary regulatory approvals for the conduct of such clinical trials. This may further negatively impact PsyBio's ability to generate future product development programs using psychedelic inspired compounds.

If PsyBio is not able to compete effectively against its current and future competitors, PsyBio's business will not grow, and its financial condition and operations will substantially suffer.

Further, there can be no assurance that potential competitors of PsyBio, which may have greater financial, cultivation, production, sales and marketing experience, and personnel and resources than PsyBio, are not currently developing, or will not in the future develop, products and strategies that are equally or more effective and/or economical as any products or strategies developed by PsyBio or which would otherwise render PsyBio's business, products and strategies, as applicable, ineffective, or obsolete. Increased competition by larger and better financed competitors could materially and adversely affect the business, financial condition and results of operations of PsyBio.

The loss of key members of our management team could adversely affect us.

The loss of key members of PsyBio's management team, including key executives and scientist, could harm PsyBio. PsyBio does not have employment agreements with all members of its staff, although such employment agreements do not guarantee their retention. The Company may not be able to attract the required type and number of employees.

In addition, PsyBio believes that its future success will depend in large part upon its ability to attract and retain highly skilled scientific, managerial, medical, manufacturing, clinical and regulatory personnel, particularly as PsyBio expands its activities and seeks regulatory approvals for clinical trials. PsyBio enters into agreements with its scientific and clinical collaborators and advisors, key opinion leaders and academic partners in the ordinary course of its business. PsyBio also enters into agreements with physicians and institutions who will recruit patients into PsyBio's clinical trials on its behalf in the ordinary course of its business. Notwithstanding these arrangements, PsyBio faces significant competition for these types of personnel from other companies, research and academic institutions, government entities and other organizations. PsyBio cannot predict its success in hiring or retaining the personnel it requires for continued growth. The loss of the services of any of PsyBio's executive officers or other key personnel could potentially harm its business, operating results or financial condition.

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Notwithstanding these arrangements, PsyBio faces significant competition for these types of personnel from other companies, research and academic institutions, government entities and other organizations. PsyBio cannot predict its success in hiring or retaining the personnel it requires for

continued growth. The loss of the services of any of PsyBio's executive officers or other key personnel could potentially harm its business, operating results or financial condition.

We are exposed to the risk of employee fraud or other misconduct.

Misconduct by employees could include failures to comply with Health Canada and the U.S. FDA regulations, provide accurate information to Health Canada and the U.S. FDA, comply with manufacturing standards PsyBio has established, comply with federal and provincial healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to PsyBio. Failure to comply with health and safety laws and regulations may result in additional costs for corrective measures, penalties or in restrictions on PsyBio's manufacturing operations. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements.

PsyBio is exposed to the risk that its employees, independent contractors, consultants, service providers and licensors may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional undertakings of unauthorized activities, or reckless or negligent undertakings of authorized activities, in each case on PsyBio's behalf or in its service that violate (i) various laws and regulations, including healthcare laws and regulations, (ii) laws that require the true, complete and accurate reporting of financial information or data, or (iii) the terms of PsyBio's agreements with third parties. Such misconduct could expose PsyBio to, among other things, class actions and other litigation, increased regulatory inspections and related sanctions, and lost sales and revenue or reputational damage.

The precautions taken by PsyBio to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting PsyBio from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Such misconduct may result in legal action, significant fines or other sanctions and could result in loss of any regulatory licenses held by PsyBio at such time. PsyBio may be subject to security breaches at its facilities or in respect of electronic document or data storage, which could lead to breaches of applicable privacy laws and associated sanctions or civil or criminal penalties; events, including those beyond the control of PsyBio. In addition, these events may negatively affect customers' demand for PsyBio's products.

Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to PsyBio's reputation. If any such actions are instituted against PsyBio, and PsyBio is not successful in defending itself or asserting its rights, those actions could have a substantial impact on PsyBio's business and results of operations, including the imposition of substantial fines or other sanctions.

We may not be able to grow our business timely or sufficiently.

PsyBio intends to grow rapidly and significantly expand its operations within the next twelve (12) to twenty four (24) months. This growth will place a significant strain on PsyBio's management systems and resources. PsyBio will not be able to implement its business strategy in a rapidly evolving market, without an effective planning and management process. In particular, PsyBio may be required to manage multiple relationships with various strategic industry participants and other third parties, which relationships could be strained in the event of rapid growth. Similarly, a large increase in the number of third party relationships PsyBio has, may lead to management of PsyBio being unable to manage growth effectively. The occurrence of such events may result in PsyBio being unable to successfully identify, manage and exploit existing and potential market opportunities.

PsyBio may in the future seek to expand its pipeline and capabilities by acquiring one or more companies or businesses, entering into collaborations, or in-licensing one or more product candidates. Acquisitions, collaborations and in-licenses involve numerous risks, including, but not limited to substantial cash expenditures, technology development risks, potentially dilutive issuances of equity securities, incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition, difficulties in assimilating the operations of the acquired companies, entering markets in which PsyBio has limited or no direct experience, and potential loss of PsyBio's key employees or key employees of the acquired companies or businesses.

PsyBio cannot provide assurance that any acquisition, collaboration or in-license will result in short-term or long-term benefits to it. PsyBio may incorrectly judge the value or worth of an acquired company or business or in-licensed product candidate. In addition, PsyBio's future success would depend in part on its ability to manage the rapid growth associated with some of these acquisitions, collaborations and in-licenses. PsyBio cannot provide assurance that it would be able to successfully combine its business with that of acquired businesses, manage a collaboration or integrate in-licensed product candidates. Furthermore, the development or expansion of PsyBio's business may require a substantial capital investment by PsyBio.

In the event serious side effects caused by our therapeutic candidates occur, our clinical trials could be suspended or terminated and the U.S. FDA, Health Canada, or other comparable regulatory authorities could order us to cease further development of or deny approval of any future therapeutic candidates for any or all targeted indications.

Although existing published data by other sources supports the safety and low toxicity of psilocybin, undesirable side effects that may be caused by any future therapeutic candidates could cause PsyBio or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label, a requirement that PsyBio implements a REMS plan to ensure that the benefits of the therapy outweigh its risks, or the delay or denial of regulatory approval by the U.S. FDA, Health Canada or other comparable foreign authorities. A Risk Evaluation and Mitigation Strategy ("REMS") is a drug safety program that the U.S. FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. PsyBio or regulatory authorities may also learn of and take similar actions based on side effects related any future therapeutic candidates in studies not conducted by PsyBio, including in investigator-initiated studies or studies conducted by other sponsors, from spontaneous reports of use of psilocybin outside of the clinical trial setting or from safety reports in literature.

The results of future clinical studies may show that PsyBio's therapeutic candidates could cause undesirable or unacceptable side effects or even death. There can be no assurance that deaths or serious side effects will not occur, even in a clinical setting. In the event serious side effects occur, PsyBio's trials could be suspended or terminated and the U.S. FDA, Health Canada, or other comparable regulatory authorities could order PsyBio to cease further development of or deny approval of any future therapeutic candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Further, because of the high variability in how different individuals react to psilocybin, certain patients may have negative experiences with the treatment that could subject PsyBio to liability or, if publicized, reputational harm. Any of these occurrences may harm PsyBio's business, financial condition and prospects significantly.

Clinical trials are conducted in representative samples of the potential patient population which may have significant variability. Even if PsyBio receives regulatory approval for any future therapeutic candidates, PsyBio will have tested them in only a limited number of patients during PsyBio's clinical trials. Clinical trials are by design based on a limited number of subjects and of limited duration for exposure to the therapy used to determine whether, on a potentially statistically significant basis, the

planned safety and efficacy of any such therapeutic candidate can be achieved. As with the results of any statistical sampling, PsyBio cannot be sure that all side effects of any future therapeutic candidates may be uncovered, and it may be the case that only with a significantly larger number of patients exposed to such therapeutic candidate for a longer duration, may a more complete safety profile be identified. Further, even larger clinical trials may not identify rare serious adverse effects or the duration of such studies may not be sufficient to identify when those events may occur.

There have been other products and therapies that have been approved by the regulatory authorities but for which safety concerns have been uncovered following approval. Such safety concerns have led to labelling changes or withdrawal of therapies from the market, and PsyBio's therapeutic candidates may be subject to similar risks. PsyBio might have to withdraw or recall future therapeutic candidates from the marketplace. PsyBio may also experience a significant drop in the potential future sales of PsyBio's future therapeutic candidates if and when regulatory approvals for such therapy are obtained, experience harm to PsyBio's reputation in the marketplace or become subject to lawsuits, including class actions. Any of these results could decrease or prevent any sales of PsyBio's approved therapeutic candidates, if any, or substantially increase the costs and expenses of commercializing and marketing future PsyBio therapeutic candidates.

Additionally, if any future PsyBio therapeutic candidates receive marketing approval and PsyBio or others later identify undesirable or unacceptable side effects caused by such therapeutic candidates, a number of potentially significant negative consequences could result, including the following:

- regulatory authorities may withdraw approvals of such therapies and require PsyBio to take PsyBio's approved therapeutic candidates, if any, off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that PsyBio implements a REMS plan to ensure that the benefits of the therapeutic candidate outweigh its risks;
- PsyBio may be required to change the way the therapy is administered, conduct additional clinical trials or change the labeling of the therapeutic candidate;
- PsyBio may be subject to limitations on how PsyBio may promote the therapeutic candidate;
- sales of the therapy may decrease significantly;
- PsyBio may be subject to litigation or product liability claims; and
- PsyBio's reputation may suffer.

Any of these events could prevent PsyBio or PsyBio's potential future collaborators from achieving or maintaining market acceptance of the affected therapeutic candidate or could substantially increase commercialization costs and expenses, which in turn could delay or prevent PsyBio from generating significant revenue from the sale of future PsyBio therapeutic candidates.

We do not have any product liability coverage and a successful liability claim or series of claims brought against us could have a material adverse effect on its business, financial condition and results of operations.

PsyBio currently does not carry any product liability insurance coverage. Even though PsyBio is not aware of any product liability claims at this time, its business exposes itself to potential product

liability, recalls and other liability risks that are inherent in the sale of food products. PsyBio can provide no assurance that such potential claims will not be asserted against it. A successful liability claim or series of claims brought against PsyBio could have a material adverse effect on its business, financial condition and results of operations.

Regardless of the merits or eventual outcome, liability claims may cause, among other things, the following:

- decreased demand for PsyBio's therapies due to negative public perception;
- injury to PsyBio's reputation;
- withdrawal of clinical trial participants or difficulties in recruiting new trial participants;
- initiation of investigations by regulators;
- costs to defend or settle the related litigation;
- a diversion of management's time and PsyBio's resources;
- substantial monetary awards to trial participants or patients;
- recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue from therapeutic sales; and
- the inability to commercialize PsyBio's therapeutic candidates or any future therapeutic candidates, if approved.

Although PsyBio intends to obtain adequate product liability insurance, it cannot provide any assurances that it will be able to obtain or maintain adequate product liability insurance on acceptable terms, if at all, or that such insurance will provide adequate coverage against potential liabilities. Claims or losses in excess of any product liability covered that may be obtained by PsyBio could have a material adverse effect on its business, financial condition and results of operations. If a successful product liability claim or series of claims is brought against PsyBio for uninsured liabilities or in excess of insured liabilities, PsyBio's assets may not be sufficient to cover such claims and PsyBio's business, financial condition and results of operations could be materially adversely affected.

Some of PsyBio's agreements with third parties might require it to maintain product liability insurance. If PsyBio cannot obtain acceptable amounts of coverage on commercially reasonable terms in accordance with the terms set forth in these agreements, the corresponding agreements would be subject to termination, which could have a material adverse impact on its operations.

We may have difficulty enforcing contracts due to the nature of our business.

Due to the nature of the business of PsyBio and the fact that certain of its contracts involve psilocybin, the use of which is not legal under Canadian or U.S. federal law and in certain other jurisdictions, PsyBio may face difficulties in enforcing its contracts in Canadian or U.S. federal and state courts. The inability to enforce any of its contracts could have a material adverse effect on its business, operating results, financial condition or prospects.

In order to manage its contracts with contractors, PsyBio will ensure that such contractors are appropriately licensed. Were such contractors to operate outside the terms of these licenses, PsyBio may experience an adverse effect on its business, including the pace of development of its product.

Our products could be recalled.

Manufacturers, producers and distributors of products are sometimes subject to the recall or return of their products for a variety of reasons, including product defects, such as contamination, unintended harmful side effects or interactions with other substances, packaging safety and inadequate or inaccurate labelling disclosure. If any of PsyBio's products are recalled due to an alleged product defect or for any other reason, PsyBio could be required to incur the unexpected expense of the recall and any legal proceedings that might arise in connection with the recall. PsyBio may lose a significant amount of sales and may not be able to replace those sales at an acceptable margin or at all. In addition, a product recall may require significant management attention.

If PsyBio's psychoactive products are not perceived to have the effects intended by the end user, PsyBio's business may suffer. In general, psychedelic products have minimal long-term data with respect to efficacy, unknown side effects and/or interaction with individual human biochemistry or other supplements or medications. As a result, PsyBio's psychedelic products could have certain side effects if not used as directed or if taken by an end user that has certain known or unknown medical conditions.

There can be no assurance that any quality, potency or contamination problems will be detected in time to avoid unforeseen product recalls, regulatory action or lawsuits. Additionally, if PsyBio is subject to recall, the image of PsyBio could be harmed. A recall for any of the foregoing reasons could lead to decreased demand for PsyBio's products and could have a material adverse effect on the results of operations and financial condition of PsyBio. Additionally, product recalls may lead to increased scrutiny of PsyBio's operations by regulatory agencies, requiring further management attention, potential loss of applicable licenses and potential legal fees and other expenses.

Distribution and supply chain interruptions could seriously impact our ability to sell our products.

PsyBio is susceptible to risks relating to distributor and supply chain interruptions. Distribution in Canada is largely accomplished through independent contractors, therefore, an interruption (e.g., a labour strike) for any length of time affecting such independent contractors may have a significant impact on PsyBio's ability to sell its products. Supply chain interruptions, including a production or inventory disruption, could impact product quality and availability. Inherent to producing products is a potential for shortages or surpluses in future years if demand and supply are materially different from long-term forecasts.

We will incur costs associated with operating a publicly traded company and our management will need to devote time in complying with reporting requirements.

As a public company, PsyBio is subject to various securities rules and regulations, which impose various requirements on PsyBio, including the requirement to establish and maintain effective disclosure and financial controls and corporate governance practices. PsyBio's management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase PsyBio's legal and financial compliance costs and make some activities more time-consuming and costly.

We will incur additional costs to comply with additional rules and regulations if we decide to market and sell any products outside of Canada and the United States.

In order to market any products outside of the United States and Canada, PsyBio must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and effectiveness. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval processes vary among countries and can involve additional product testing and validation and additional or different administrative review periods from those in the United States and Canada, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a therapeutic candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that PsyBio intends to charge for PsyBio's products is also subject to approval.

Seeking foreign regulatory approval could result in difficulties and costs and require additional nonclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of therapeutic candidates in those countries. The foreign regulatory approval process may include all of the risks associated with obtaining U.S. FDA or Health Canada approval. PsyBio does not have any therapeutic candidates approved for sale in any jurisdiction, including international markets, and PsyBio does not have experience in obtaining regulatory approval in international markets. If PsyBio fails to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, PsyBio's target market will be reduced and PsyBio's ability to realize the full market potential of PsyBio's therapeutic candidates will be harmed.

We may face conflicts of interests with our executive officers and directors.

PsyBio may be subject to various potential conflicts of interest because of the fact that some of its officers and directors may be engaged in a range of business activities. PsyBio's executive officers and directors may devote time to their outside business interests, so long as such activities do not materially or adversely interfere with their duties to PsyBio. In some cases, PsyBio's executive officers and directors may have fiduciary obligations associated with these business interests that interfere with their ability to devote time to PsyBio's business and affairs and that could adversely affect PsyBio's operations. These outside business interests could require significant time and attention of PsyBio's executive officers and directors.

In addition, PsyBio may also become involved in other transactions which conflict with the interests of its directors and the officers who may from time to time deal with persons, firms, institutions or companies with which PsyBio may be dealing, or which may be seeking investments similar to those desired by it. The interests of these persons could conflict with those of PsyBio, and from time to time, these persons may be competing with PsyBio for available investment opportunities.

Conflicts of interest, if any, will be subject to the procedures and remedies provided under applicable laws. In particular, in the event that such a conflict of interest arises at a meeting of PsyBio's directors, a director who has such a conflict will abstain from voting for or against the approval of such participation or such terms. In accordance with applicable laws, the directors of PsyBio are required to act honestly, in good faith and in the best interests of PsyBio.

We will face cybersecurity and risks. The failure of our information systems or a component of information systems could, adversely impact our reputation and results of operations.

PsyBio's information systems and any third-party service providers and vendors are vulnerable to an increasing threat of continually evolving cybersecurity risks. These risks may take the form of malware, computer viruses, cyber threats, extortion, employee error, malfeasance, system errors or other types of risks, and may occur from inside or outside of the respective organizations.

Cybersecurity risk is increasingly difficult to identify and quantify and cannot be fully mitigated because of the rapid evolving nature of the threats, targets and consequences. Additionally, unauthorized parties may attempt to gain access to these systems through fraud or other means of deceiving third-party service providers, employees or vendors. PsyBio's operations depend, in part, on how well networks, equipment, IT systems and software are protected against damage from a number of threats. These operations also depend on the timely maintenance, upgrade and replacement of networks, equipment, IT systems and software, as well as pre-emptive expenses to mitigate the risks of failures. However, if PsyBio is unable or delayed in maintaining, upgrading or replacing IT systems and software, the risk of a cybersecurity incident could materially increase. Any of these and other events could result in information system failures, delays and/or increases in capital expenses. The failure of information systems or a component of information systems could, depending on the nature of any such failure, adversely impact PsyBio's reputation and results of operations.

PsyBio may collect and store certain personal information about customers and is responsible for protecting such information from privacy breaches. A privacy breach may occur through procedural or process failure, information technology malfunction, or deliberate unauthorized intrusions. In addition, theft of data is an ongoing risk whether perpetrated via employee collusion or negligence or through deliberate cyber-attack. Any such privacy breach or theft could have a material adverse effect on PsyBio's business, financial condition and results of operations.

In addition, there are a number of laws protecting the confidentiality of certain patient health information, including patient records, and restricting the use and disclosure of that protected information. In particular, the privacy rules under Canada's Personal Information Protection and Electronic Documents Act (PIPEDA) and where applicable, provincial legislation governing personal health information, protect medical records and other personal health information by limiting their use and disclosure of health information to the minimum level reasonably necessary to accomplish the intended purpose. If PsyBio were found to be in violation of the privacy or security rules under PIPEDA or other laws protecting the confidentiality of medical patients health information, PsyBio could be subject to sanctions and civil or criminal penalties, which could increase its liabilities, harm its reputation and have a material adverse effect on PsyBio's business, financial condition and results of operations.

PsyBio is subject to political, economic and other risks arising out of its U.S. operations.

PsyBio carries on operations primarily in the United States. As a result, PsyBio is subject to political, economic and other uncertainties, including, but not limited to, cancellation or modification of contract rights, foreign exchange restrictions, currency fluctuations, export quotas, royalty and tax increases and other risks arising out of foreign governmental sovereignty over the areas in which PsyBio's operations are conducted.

PsyBio's international operations may also be adversely affected by laws and policies of Canada affecting foreign trade, taxation and investment. In the event of a dispute arising in connection with its foreign operations, PsyBio may be subject to the exclusive jurisdiction of foreign courts or may not be successful in subjecting foreign persons to the jurisdiction of courts in Canada or enforcing Canadian judgments in foreign jurisdictions.

PsyBio makes no medical or treatment claims about psilocybin or any of PsyBio's proposed products. Statements regarding psilocybin have not been evaluated by the U.S. FDA or other similar regulatory authorities, nor has the efficacy of psilocybin been confirmed by FDA-approved research. There is no assurance that psilocybin can be used to diagnose, treat, cure or prevent any disease or condition. Robust scientific research is needed. In addition, PsyBio has not conducted clinical trials for the use of its proposed products. Any references to quality, consistency, efficacy and safety of potential products are not intended to imply that such claims have been verified in clinical trials or that PsyBio will be able to complete such trials. If PsyBio is not able to obtain the approvals or research necessary

to commercialize its business, it may have a material adverse effect on PsyBio's performance and operations.

Forward-looking statements may prove to be inaccurate.

Investors should not place undue reliance on forward-looking statements. By their nature, forward-looking statements involve numerous assumptions, known and unknown risks and uncertainties, of both general and specific nature, that could cause actual results to differ materially from those suggested by the forward-looking statements or contribute to the possibility that predictions, forecasts or projections will prove to be materially inaccurate. Additional information on the risks, assumptions and uncertainties can be found in this MD&A under the heading "*Forward-Looking Statements*".

There is no assurance that PsyBio will be able to achieve its anticipated research and development milestones.

PsyBio expects to use a significant portion of its available funds for research and development purposes. There is no assurance that PsyBio's anticipated milestones will be achieved within the time periods specified, or at all. The failure to achieve these milestones could negatively impact PsyBio's ability to raise additional funds required for operations and research and development activities, and could, in turn, impact the financial viability of PsyBio. There is also no assurance that PsyBio's research and development activities will continue to result in commercially viable products.

Risks Related to Regulatory Compliance

Therapeutic candidates containing controlled substances are subject to DEA regulations relating to manufacturing, storage, distribution and physician prescription procedures. As a result, PsyBio will be subject to DEA registration and inspection of its facilities.

Facilities conducting research, manufacturing, distributing, importing or exporting, or dispensing controlled substances must be registered (licensed) to perform these activities and have the security, control, recordkeeping, reporting and inventory mechanisms required by the DEA to prevent drug loss and diversion. All these facilities must renew their registrations annually, except dispensing facilities, which must renew every three years. The DEA conducts periodic inspections of certain registered establishments that handle controlled substances. Obtaining and maintaining the necessary registrations may result in delay of the importation, manufacturing or distribution of PsyBio's future therapeutic compounds. Furthermore, failure to maintain compliance with the CSA, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on PsyBio's business, financial condition and results of operations. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

- **State - controlled substances laws.** Every U.S. state has laws prohibiting possession and use of "controlled substances," or drugs whose use or prescription is prohibited or regulated by the government. These laws are usually based on the classifications of drugs in the federal Controlled Substances Act. To the extent that the Company's products are reclassified as Schedule II pharmaceutical drugs by the DEA under the CSA but remain classified as Schedule I by an individual state, it would prohibit doctors from prescribing any products that the Company develops in that state. PsyBio is not aware of any states which would not mirror the CSA.
- **Clinical trials.** Prior to approval, each of PsyBio's research sites must submit a research protocol to the DEA and obtain and maintain a DEA researcher registration that will allow

those sites to handle and dispense any future psilocybin-based product and to obtain the product from PsyBio's importer. If the DEA delays or denies the grant of a researcher registration to one or more research sites, the clinical trial could be significantly delayed, and PsyBio could lose clinical trial sites. The importer for the clinical trials must also obtain a Schedule I importer registration and an import permit for each import.

- **Importation.** If a future PsyBio therapeutic compound is approved and classified as a Schedule II, III or IV substance, an importer can import it for commercial purposes if it obtains an importer registration and files an application for an import permit for each import. The DEA provides annual assessments/estimates to the International Narcotics Control Board, which guides the DEA in the amounts of controlled substances that the DEA authorizes to be imported. The failure to identify an importer or obtain the necessary import authority, including specific quantities, could affect the availability of PsyBio's future products and have a material adverse effect on PsyBio's business, results of operations and financial condition. In addition, an application for a Schedule II importer registration must be published in the Federal Register, and there is a waiting period for third-party comments to be submitted. It is always possible that adverse comments may delay the grant of an importer registration. If a PsyBio therapeutic compound is approved and classified as a Schedule II controlled substance, federal law may prohibit the import of the substance for commercial purposes. If a PsyBio therapeutic compound is listed as a Schedule II substance, PsyBio will not be allowed to import the drug for commercial purposes unless the DEA determines that domestic supplies are inadequate or there is inadequate domestic competition among domestic manufacturers for the substance as defined by the DEA. Moreover, Schedule I controlled substances, including psilocybin and psilocin, have never been registered with the DEA for importation for commercial purposes, only for scientific and research needs. Therefore, if PsyBio's future therapeutic compounds could not be imported, PsyBio's products would have to be wholly manufactured in the United States, and PsyBio would need to secure a manufacturer that would be required to obtain and maintain a separate DEA registration for that activity.
- **Manufacture in the United States.** If, because of a Schedule II classification or voluntarily, PsyBio were to conduct manufacturing or repackaging/relabeling in the United States, PsyBio's contract manufacturers would be subject to the DEA's annual manufacturing and procurement quota requirements. Additionally, regardless of the scheduling of any future therapeutic compound, the active ingredient in the final dosage form is currently a Schedule I controlled substance and would be subject to such quotas as this substance could remain listed on Schedule I. The annual quota allocated to PsyBio or PsyBio's contract manufacturers for the active ingredient in a therapeutic compound may not be sufficient to complete clinical trials or meet commercial demand. Consequently, any delay or refusal by the DEA in establishing our, or PsyBio's contract manufacturers', procurement and/or production quota for controlled substances could delay or stop PsyBio's clinical trials or product launches, which could have a material adverse effect on PsyBio's business, financial position and results of operations.
- **Distribution in the United States.** If a future PsyBio therapeutic compound is scheduled as Schedule II, III or IV, PsyBio would also need to identify wholesale distributors with the appropriate DEA registrations and authority to distribute any future therapeutic candidates. These distributors would need to obtain Schedule II, III or IV distribution registrations. This limitation in the ability to distribute more broadly may limit commercial uptake and could negatively impact PsyBio's prospects. The failure to obtain, or delay in obtaining, or the loss of any of those registrations could result in increased costs to PsyBio. If future PsyBio therapeutic compounds are labelled Schedule II drugs, participants in PsyBio's supply chain may have to maintain enhanced security with alarms and monitoring systems and they may

be required to adhere to recordkeeping and inventory requirements. This may discourage some pharmacies from carrying the product.

Changes in substance laws or breach in compliance of substance laws could have a material adverse effect on PsyBio's operations and financial performance.

Psilocybin and psilocin are categorized as Schedule I controlled substances under the CSA and are similarly categorized by most states and foreign governments. Even assuming that any future therapeutic candidates containing psilocybin or psilocin are approved and scheduled by regulatory authorities to allow their commercial marketing, the ingredients in such therapeutic candidates would likely continue to be Schedule I, or the state or foreign equivalent. Violations of any federal, state or foreign laws and regulations could result in significant fines, penalties, administrative sanctions, convictions or settlements arising from civil proceedings conducted by either the federal government or private citizens, or criminal charges and penalties, including, but not limited to, disgorgement of profits, cessation of business activities, divestiture, or prison time. This could have a material adverse effect on PsyBio, including on PsyBio's reputation and ability to conduct business, PsyBio's financial position, operating results and profitability. In addition, it is difficult for PsyBio to estimate the time or resources that would be needed for the investigation or defense of any such matters or PsyBio's final resolution because, in part, the time and resources that may be needed are dependent on the nature and extent of any information requested by the applicable authorities involved, and such time or resources could be substantial. It is also illegal to aid or abet such activities or to conspire or attempt to engage in such activities. An investor's contribution to and involvement in such activities may result in federal civil and/or criminal prosecution, including, but not limited to, forfeiture of his, her or its entire investment, fines and/or imprisonment.

Various federal, state, provincial and local laws govern PsyBio's business in the jurisdictions in which PsyBio operates or currently plans to operate, and to which PsyBio exports or currently plans to export PsyBio's products, including laws relating to health and safety, the conduct of PsyBio's operations, and the production, storage, sale and distribution of PsyBio's products. Complying with these laws requires that PsyBio complies concurrently with complex federal, state, provincial and/or local laws. These laws change frequently and may be difficult to interpret and apply. To ensure PsyBio's compliance with these laws, PsyBio will need to invest significant financial and managerial resources. It is impossible for PsyBio to predict the cost of such laws or the effect they may have on PsyBio's future operations. A failure to comply with these laws could negatively affect PsyBio's business and harm PsyBio's reputation. Changes to these laws could negatively affect PsyBio's competitive position and the markets in which PsyBio operates, and there is no assurance that various levels of government in the jurisdictions in which PsyBio operates will not pass legislation or regulation that adversely impacts PsyBio's business.

In addition, even if PsyBio or third parties were to conduct activities in compliance with U.S. state or local laws or the laws of other countries and regions in which PsyBio conducts activities, potential enforcement proceedings could involve significant restrictions being imposed upon PsyBio or third parties, while diverting the attention of key executives. Such proceedings could have a material adverse effect on PsyBio's business, revenue, operating results and financial condition as well as on PsyBio's reputation and prospects, even if such proceedings conclude successfully in PsyBio's favor. In the extreme case, such proceedings could ultimately involve the criminal prosecution of PsyBio's key executives, the seizure of corporate assets, and consequently, PsyBio's inability to continue business operations. Strict compliance with state and local laws with respect to psilocybin and psilocin does not absolve PsyBio of potential liability under U.S. federal law or Canadian law, nor provide a defense to any proceeding which may be brought against PsyBio. Any such proceedings brought against PsyBio may adversely affect PsyBio's operations and financial performance.

PsyBio is permitted to rely on foreign private issuer exemptions from certain stock exchange corporate governance standards, and as a result, shareholders may be afforded less protection.

As a foreign private issuer, the Company has the option to follow certain home country corporate governance practices, provided that it discloses the requirements that it is not following and describe the home country practices that it is following. Currently, PsyBio intends to follow certain home country corporate governance practices instead of those otherwise required under the stock exchange rules for U.S. issuers.

Any foreign private issuer exemptions that the Company avails itself of in the future may reduce the scope of information and protection to which shareholders are otherwise entitled to. As a result, shareholders may not have the same protections afforded to shareholders of companies that are subject to all other corporate governance requirements of other U.S. stock exchanges.

Violations of any U.S. federal laws and regulations could result in significant fines, penalties, administrative sanctions, convictions or settlements.

Violations of any U.S. federal laws and regulations could result in significant fines, penalties, administrative sanctions, convictions or settlements arising from civil proceedings conducted by either the federal government or private citizens, or criminal charges, including, but not limited to, seizure of assets, disgorgement of profits, cessation of business activities or divestiture. As an entity that conducts business involving psilocybin and psilocin, PsyBio is potentially subject to federal and state forfeiture laws (criminal and civil) that permit the government to seize the proceeds of criminal activity. Civil forfeiture laws could provide an alternative for the federal government or any state (or local police force) that wants to discourage residents from conducting transactions with psilocybin- and psilocin-related businesses but believes criminal liability is too difficult to prove beyond a reasonable doubt. Also, an individual can be required to forfeit property considered to be the proceeds of a crime even if the individual is not convicted of the crime, and the standard of proof in a civil forfeiture matter is lower than the standard in a criminal matter. Depending on the applicable law, whether federal or state, rather than having to establish liability beyond a reasonable doubt, the federal government or the state, as applicable, may be required to prove that the money or property at issue is proceeds of a crime only by either clear and convincing evidence or a mere preponderance of the evidence.

Investors located in jurisdictions where psilocybin and psilocin remains illegal may be at risk of prosecution, investment or proceeds under forfeiture statutes.

Investors located in jurisdictions where psilocybin and psilocin remains illegal may be at risk of prosecution under conspiracy, aiding and abetting, and money laundering statutes, and be at further risk of losing their investments or proceeds under forfeiture statutes. Many jurisdictions remain fully able to take action to prevent the proceeds of psilocybin and psilocin businesses from entering their state. PsyBio's investors and prospective investors should be aware of these potentially relevant laws in considering whether to invest in PsyBio.

Tax reforms could harm our business.

PsyBio conducts business globally and files income tax returns in multiple jurisdictions. PsyBio's consolidated effective income tax rate could be materially adversely affected by several factors, including: changing tax laws, regulations and treaties, or the interpretation thereof; tax policy initiatives and reforms under consideration (such as those related to the Organization for Economic Co-Operation and Development's, or OECD, Base Erosion and Profit Shifting, or BEPS, Project, the European Commission's state aid investigations and other initiatives); the practices of tax authorities in jurisdictions in which PsyBio operates; the resolution of issues arising from tax audits or examinations and any related interest or penalties. Such changes may include (but are not limited to) the taxation of operating income, investment income, dividends received or (in the specific context of withholding tax) dividends paid.

PsyBio is unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on PsyBio's business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices in jurisdictions in which PsyBio operates, could increase the estimated tax liability that PsyBio has expensed to date and paid or accrued on PsyBio's balance sheets, and otherwise affect PsyBio's financial position, future results of operations, cash flows in a particular period and overall or effective tax rates in the future in countries where PsyBio has operations, reduce post-tax returns to PsyBio's shareholders and increase the complexity, burden and cost of tax compliance.

Risks related to United States tax classification

The Company, which is and will continue to be a Canadian corporation as of the date of this MD&A, generally would be classified as a non-United States corporation under general rules of United States federal income taxation. Section 7874 of the U.S. Tax Code, however, contains rules that can cause a non-United States corporation to be taxed as a United States corporation for United States federal income tax purposes. Under section 7874 of the U.S. Tax Code, a corporation created or organized outside the United States (i.e., a non-United States corporation) will nevertheless be treated as a United States corporation for United States federal income tax purposes if each of the following three conditions are met (i) the non-United States corporation acquires, directly or indirectly, or is treated as acquiring under applicable United States Treasury Regulations, substantially all of the assets held, directly or indirectly, by a United States corporation, (ii) after the acquisition, the former stockholders of the acquired United States corporation hold at least 80% (by vote or value) of the shares of the non-United States corporation by reason of holding shares of the United States acquired corporation, and (iii) after the acquisition, the non-United States corporation's expanded affiliated group does not have substantial business activities in the non-United States corporation's country of organization or incorporation when compared to the expanded affiliated group's total business activities.

For this purpose, "expanded affiliated group" means a group of corporations where (i) the non-United States corporation owns stock representing more than 50% of the vote and value of at least one member of the expanded affiliated group, and (ii) stock representing more than 50% of the vote and value of each member is owned by other members of the group. The definition of an "expanded affiliated group" includes partnerships where one or more members of the expanded affiliated group own more than 50% (by vote and value) of the interests of the partnership.

The Company intends to be treated as a United States corporation for United States federal income tax purposes under section 7874 of the U.S. Tax Code and is expected to be subject to United States federal income tax on its worldwide income. However, for Canadian tax purposes, PsyBio is expected, regardless of any application of section 7874 of the U.S. Tax Code, to be treated as a Canadian resident corporation for Canadian income tax purposes. As a result, PsyBio will be subject to taxation both in Canada and the United States which could have a material adverse effect on its financial condition and results of operations.

It is unlikely that PsyBio will pay any dividends on the Subordinate Voting Shares in the foreseeable future. However, dividends received by shareholders who are residents of Canada for purposes of the Income Tax Act (Canada) will be subject to U.S. and Canadian withholding tax. Any such dividends may not qualify for a reduced rate of withholding tax under the Canada-United States tax treaty. In addition, a foreign tax credit or a deduction in respect of foreign taxes may not be available.

Dividends received by U.S. shareholders will not be subject to U.S. withholding tax but will be subject to Canadian withholding tax. Dividends paid by PsyBio will be characterized as U.S. source income for purposes of the foreign tax credit rules under the U.S. Tax Code. Accordingly, U.S. shareholders generally will not be able to claim a credit for any Canadian tax withheld unless, depending on the circumstances, they have an excess foreign tax credit limitation due to other foreign source income that is subject to a low or zero rate of foreign tax.

Dividends received by shareholders that are neither Canadian nor U.S. shareholders will be subject to U.S. withholding tax and will also be subject to Canadian withholding tax. These dividends may not qualify for a reduced rate of U.S. withholding tax under any income tax treaty otherwise applicable to a shareholder of PsyBio, subject to examination of the relevant treaty.

Because the Subordinate Voting Shares will be treated as shares of a U.S. domestic corporation, the U.S. gift, estate and generation-skipping transfer tax rules generally apply to a non-U.S. shareholder of Subordinate Voting Shares.

Enacted and future healthcare legislation could affect PsyBio's future results of operations

In the United States and other foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect PsyBio's future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. biopharmaceutical industry.

Among the provisions of the ACA of importance to PsyBio's potential therapeutic candidates are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications;
- expansion of eligibility criteria for Medicaid programs, a Federal and state program which extends healthcare to low income individuals and other groups, by, among other things, allowing states to offer Medicaid coverage to certain individuals and adding new eligibility categories for certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of manufacturers' rebate liability under the Medicaid Drug Rebate Program, which requires that drug manufacturers provide rebates to states in exchange for state Medicaid coverage for most of the manufacturers' drugs by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price" or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and extending rebate liability to prescriptions for individuals enrolled in Medicare Advantage plans (i.e., a type of Medicare healthcare plan offered by private companies);
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;
- expansion of the types of entities eligible for the 340B drug discount program, which requires drug manufacturers to provide outpatient drugs to eligible healthcare organizations and covered entities at significantly reduced prices;
- establishment of the Medicare Part D coverage gap discount program, which requires manufacturers to provide a 50% point-of-sale-discount (increased to 70% pursuant to the Bipartisan Budget Act of 2018, or BBA, effective as of January 1, 2019) off the negotiated

price of applicable products to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient products to be covered under Medicare Part D;

- creation of a new non-profit, nongovernmental institute, called the Patient-Centered Outcomes Research Institute, to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of the Center for Medicare and Medicaid Innovation within Centers for Medicare & Medicaid, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription product spending.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and PsyBio expects there will be additional challenges and amendments to the ACA in the future. Various portions of the ACA are currently undergoing legal and constitutional challenges in the U.S. Supreme Court; the previous Trump Administration issued various Executive Orders which eliminated cost sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices; and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. PsyBio cannot predict what affect further changes to the ACA would have on PsyBio's business.

Other legislative changes have been proposed and adopted since the ACA was enacted. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on PsyBio's customers and accordingly, PsyBio's financial operations. For example, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. The Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, and, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken. However, these Medicare sequester reductions have been suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In addition, the BBA amended the ACA, effective January 1, 2019, by increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole".

New laws and additional health reform measures may result in additional reductions in Medicare and other healthcare funding, which may adversely affect customer demand and affordability for PsyBio's future therapeutic candidate and any future therapeutic candidates and, accordingly, the results of PsyBio's financial operations.

PsyBio's business operations and current and future relationships with investigators, health care professionals, consultants, third-party payors and customers may be subject, directly or indirectly, to U.S. federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, other healthcare laws and regulations and other foreign privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Although PsyBio does not currently have any therapies on the market, PsyBio's current and future operations may be directly, or indirectly through PsyBio's relationships with investigators, health

care professionals, customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute or the federal Anti-Kickback Statute. Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any therapies for which PsyBio obtains marketing approval. These laws impact, among other things, PsyBio's research activities and proposed sales, marketing and education programs and constrain PsyBio's business and financial arrangements and relationships with third-party payors, healthcare professionals who participate in PsyBio's clinical research program, healthcare professionals and others who recommend, purchase, or provide PsyBio's approved therapies, and other parties through which PsyBio markets, sells and distributes PsyBio's therapies for which PsyBio obtains marketing approval. In addition, PsyBio may be subject to patient data privacy and security regulation by both the U.S. federal government and the states in which PsyBio conducts PsyBio's business, along with foreign regulators (including European data protection authorities). Finally, PsyBio's current and future operations are subject to additional healthcare-related statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which PsyBio conducts PsyBio's business. These laws include, but are not limited to, the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to significant civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act, or the FCA. The definition of the "remuneration" under the federal Anti-Kickback Statute has been interpreted to include anything of value. Further, courts have found that if "one purpose" of remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution; but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection;
- the federal civil and criminal false claims laws, such as the FCA, which prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the U.S. federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- the federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer or remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (i.e., public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements, in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, and as amended again by the Final HIPAA Omnibus Rule, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and certain healthcare providers, as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. federal legislation commonly referred to as Physician Payments Sunshine Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made during the previous year to certain non-physician providers such as physician assistants and nurse practitioners;
- analogous state laws and regulations, including the following: state anti-kickback and false claims laws, which may be broader in scope than their federal equivalents, and which may apply to PsyBio's business practices, including research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict

payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; state and local laws that require the registration of pharmaceutical sales representatives and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts; and

- the Canadian and other foreign law equivalents of each of these laws, including reporting requirements detailing interactions with and payments to healthcare providers, and privacy-related requirements in Canada and other jurisdictions.

The distribution of pharmaceutical products is subject to extensive record-keeping, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Even if precautions are taken, it is possible that governmental authorities will conclude that PsyBio's business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If PsyBio's operations are found to be in violation of any of these laws or any other governmental regulations that may apply to PsyBio, PsyBio may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if PsyBio becomes subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm and the curtailment or restructuring of PsyBio's operations. If any of the physicians or other healthcare providers or entities with whom PsyBio expects to do business is found not to be in compliance with applicable laws, that person or entity may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

Efforts to ensure that PsyBio's business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against PsyBio for violation of these laws, even if PsyBio successfully defends against it, could cause PsyBio to incur significant legal expenses and divert PsyBio's management's attention from the operation of PsyBio's business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Failure to comply with health and data protection laws and regulations could lead to U.S. federal and state government enforcement actions, including civil or criminal penalties, private litigation, and adverse publicity and could negatively affect PsyBio's operating results and business.

PsyBio and any potential collaborators may be subject to U.S. federal and state data protection laws and regulations, such as laws and regulations that address privacy and data security. In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of health-related and other personal information. In

addition, PsyBio may obtain health information from third parties, including research institutions from which PsyBio obtains clinical trial data, which are subject to privacy and security requirements under HIPAA, as amended by HITECH. To the extent that PsyBio acts as a business associate to a healthcare provider engaging in electronic transactions, PsyBio may also be subject to the privacy and security provisions of HIPAA, as amended by HITECH, which restricts the use and disclosure of patient-identifiable health information, mandates the adoption of standards relating to the privacy and security of patient-identifiable health information, and requires the reporting of certain security breaches to healthcare provider customers with respect to such information. Additionally, many states have enacted similar laws that may impose more stringent requirements on entities like ours. Depending on the facts and circumstances, PsyBio could be subject to significant civil, criminal, and administrative penalties if PsyBio obtains, uses, or discloses individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Additionally, in June 2018, the State of California enacted the California Consumer Privacy Act of 2018, or CCPA, which came into effect on January 1, 2020 and provides new data privacy rights for consumers (as that term is broadly defined) and new operational requirements for companies, which may increase PsyBio's compliance costs and potential liability. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact certain of PsyBio's business activities. The CCPA could mark the beginning of a trend toward more stringent state privacy legislation in the United States, which could increase PsyBio's potential liability and adversely affect PsyBio's business.

Compliance with U.S. and foreign privacy and data protection laws and regulations could require PsyBio to take on more onerous obligations in PsyBio's contracts, restrict PsyBio's ability to collect, use and disclose data, or in some cases, impact PsyBio's ability to operate in certain jurisdictions. Failure to comply with these laws and regulations could result in government enforcement actions (which could include civil, criminal and administrative penalties), private litigation, and/or adverse publicity and could negatively affect PsyBio's operating results and business. Moreover, clinical trial subjects, employees and other individuals about whom PsyBio or PsyBio's potential collaborators obtain personal information, as well as the providers who share this information with PsyBio, may limit PsyBio's ability to collect, use and disclose the information. Claims that PsyBio has violated individuals' privacy rights, failed to comply with data protection laws, or breached PsyBio's contractual obligations, even if PsyBio is not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm PsyBio's business.

Inadequate funding for the U.S. FDA and other government agencies could prevent new therapies from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the U.S. FDA to review and approve new therapies can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which PsyBio's operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the U.S. FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect

PsyBio's business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the U.S. FDA and the SEC, have had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, on March 10, 2020 the U.S. FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products through April 2020. On March 18, 2020, the U.S. FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials. As of June 23, 2020, the U.S. FDA announced that it was conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with U.S. FDA quality standards. On July 10, 2020, the U.S. FDA announced its goal to restart domestic on-site inspections during the week of July 20, 2020, but such activities will depend on data about the virus' trajectory in a given state and locality and the rules and guidelines that are put in place by state and local governments. The U.S. FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. Additionally, as of June 23, 2020, the U.S. FDA noted it was continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic; however, the U.S. FDA may not be able to continue its current pace and review timelines could be extended. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the U.S. FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the U.S. FDA to timely review and process PsyBio's regulatory submissions, which could have a material adverse effect on PsyBio's business. Further, upon completion of this offering and in PsyBio's operations as a public company listed in the United States and Canada, future government shutdowns could impact PsyBio's ability to access the public markets and obtain necessary capital in order to properly capitalize and continue PsyBio's operations.

Our ability to achieve acceptable levels of coverage and reimbursement by governmental healthcare programs, private health insurers and other third-party payors for therapies will have an effect on our ability to successfully commercialize, and attract additional collaboration partners to invest in the development of PsyBio's therapeutic candidates or any future therapeutic candidates.

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford therapies such as PsyBio's therapeutic candidates or any future therapeutic candidates, if approved. As Schedule I substances under the CSA, psilocybin and psilocin are deemed to have no accepted medical use and therapies that use psilocybin or psilocin are precluded from reimbursement in the United States. PsyBio's products must be scheduled as a Schedule II or lower controlled substance (i.e., Schedule III, IV or V) before they can be commercially marketed. PsyBio's ability to achieve acceptable levels of coverage and reimbursement for therapies by governmental authorities, private health insurers and other organizations will have an effect on PsyBio's ability to successfully commercialize, and attract additional collaboration partners to invest in the development of PsyBio's therapeutic candidates or any future therapeutic candidates. Even if PsyBio obtains coverage for a given therapy by third-party payors, the resulting reimbursement payment rates may not be adequate or may require patient out-of-pocket costs that patients may find unacceptably high. PsyBio cannot be sure that coverage and reimbursement in the United States, Canada or elsewhere will be available for any therapy that PsyBio may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

PsyBio intends to seek approval to market PsyBio's therapeutic candidates or future therapeutic candidates in both the United States and in selected foreign jurisdictions. If PsyBio obtains approval in one or more foreign jurisdictions, PsyBio will be subject to rules and regulations in those jurisdictions.

In some foreign countries, the pricing of drugs is subject to governmental control and other market regulations which could put pressure on the pricing and usage of PsyBio's therapeutic candidates or PsyBio's future therapeutic candidates. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a therapeutic candidate. In addition, market acceptance and sales of PsyBio's therapeutic candidates or future therapeutic candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for PsyBio's therapeutic candidates or future therapeutic candidates and may be affected by existing and future healthcare reform measures.

Third-party payors are increasingly challenging prices charged for therapeutic substances and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider PsyBio's therapeutic candidates or any future therapeutic candidates as substitutable and only offer to reimburse patients for the less expensive therapy. Even if PsyBio shows improved efficacy or improved convenience of administration with PsyBio's therapeutic candidates or any future therapeutic candidates, pricing of existing drugs may limit the amount PsyBio will be able to charge. These payors may deny or revoke the reimbursement status of a given drug product or establish prices for new or existing marketed therapies at levels that are too low to enable PsyBio to realize an appropriate return on PsyBio's investment in product development. If reimbursement is not available or is available only at limited levels, PsyBio may not be able to successfully commercialize PsyBio's therapeutic candidates or any future therapeutic candidates, and may not be able to obtain a satisfactory financial return on therapeutic candidates that PsyBio may develop.

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved therapies. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse health care providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for PsyBio's therapeutic candidates or any future therapeutic candidates.

Obtaining and maintaining reimbursement status is time-consuming and costly. No uniform policy for coverage and reimbursement for drug therapies exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug therapies can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly

process that will require PsyBio to provide scientific and clinical support for the use of PsyBio's therapies to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and PsyBio believes that changes in these rules and regulations are likely.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the previous Trump administration's budget for fiscal year 2021 included a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out-of-pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out-of-pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services, or HHS, solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019.

On the state level, local governments have been very aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm PsyBio's business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for PsyBio's therapies or put pressure on PsyBio's therapeutic pricing, which could negatively affect PsyBio's business, results of operations, financial condition and prospects. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations. In many countries, the prices of medical therapies are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical therapies, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that PsyBio is able to charge for PsyBio's therapeutic candidates or any future therapeutic candidates. Accordingly, in markets outside the United States, the reimbursement for PsyBio's therapies may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

PsyBio's operations, including PsyBio's research, development, testing and manufacturing activities, are subject to numerous foreign, federal, state and local environmental, health and safety laws and regulations.

These laws and regulations govern, among other things, the controlled use, manufacture, handling, release and disposal of and the maintenance of a registry for, hazardous materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens.

PsyBio may incur significant costs to comply with these current or future environmental and health and safety laws and regulations. Furthermore, if PsyBio fails to comply with such laws and regulations, PsyBio could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, PsyBio faces a risk of environmental liability inherent in PsyBio's current and historical activities, including liability relating to releases of or exposure to hazardous materials and, as a result, may incur material liability as a result of such release or exposure. Environmental, health and safety laws and regulations are becoming more stringent. PsyBio may incur substantial expenses in connection with any current or future environmental compliance or remediation activities, in which case, PsyBio's production and development efforts may be interrupted or delayed and PsyBio's financial condition and results of operations may be materially adversely affected. In the event of an accident involving such hazardous materials, an injured party may seek to hold PsyBio liable for damages that result.

Litigation

The Company may become party to litigation from time to time in the ordinary course of business which could adversely affect its business. Should any litigation in which PsyBio becomes involved be determined against PsyBio such a decision could adversely affect PsyBio's ability to continue operating and the market price for the Subordinate Voting Shares and could use significant resources. Even if PsyBio is involved in litigation and wins, litigation can redirect significant resources of PsyBio.

On June 5, 2020, PsyBio filed an application for injunctive relief in the United States District Court, Northern District of Illinois against a former director and officer of PsyBio, as well as claims for, inter alia, tortious interference, breach of fiduciary duty and privacy violations. In this matter, the defendant filed a counterclaim seeking to be reinstated as an officer and director of PsyBio and for indemnification. On January 19, 2021, the defendant filed a motion to amend his Answer and Counterclaims seeking to add additional claims for appraisal rights, unfair dealing, conversion, and declaratory judgment regarding share ownership. On January 19, 2021, the defendant also filed a motion for a temporary restraining order and preliminary injunction seeking to enjoin the Transaction. On January 26, 2021, the Court heard oral arguments regarding the temporary restraining order. On January 27, 2021, the Court denied the defendant's request for the temporary restraining order stating that the defendant was not entitled to emergency relief and was unlikely succeed on the merits, on the basis that the defendant failed to meet his burden to show the Court that he was the victim of unfair dealing, conversion, or improper conduct on the part of the directors of PsyBio. There is no hearing scheduled for the preliminary injunction, but based on the foregoing, even if the hearing were to take place, the injunction would likely be denied. PsyBio denies the allegations and intends to vigorously prosecute and defend this matter. On July 27, 2020, the defendant in the aforementioned matter, through an entity as a shareholder of PsyBio, filed a separate derivative action in the same Court alleging, inter alia, breach of fiduciary by PsyBio directors and majority shareholders. On January 13, 2021, the Court granted a motion to dismiss filed by the PsyBio directors and shareholders, and as a result, the derivative claim was dismissed.

Risks Related to Development, Clinical Testing and Commercialization of Any Future Therapeutic Candidates

The psychedelic drug industry is a fairly new industry and we cannot predict the impact of the ever-evolving compliance regime in respect of this industry.

PsyBio cannot predict the time required to secure all appropriate regulatory approvals for future products, or the extent of testing and documentation that may, from time to time, be required by governmental authorities. The impact of compliance regimes, any delays in obtaining, or failure to obtain regulatory approvals may significantly delay or impact the development of markets, its business and products, and sales initiatives and could have a material adverse effect on the business, financial condition and operating results of PsyBio.

The success of PsyBio's business is dependent on the reform of controlled substances laws pertaining to psilocybin. If controlled substances laws are not favorably reformed in Canada, the United States, and other global jurisdictions, the commercial opportunity that PsyBio is pursuing may be highly limited.

Psilocybin is a controlled substance in many jurisdictions, including in Canada under Schedule III of the CDSA and in the United States under the CSA.

In Canada, medical and recreational use of certain psychedelic drugs is illegal under Canadian federal laws. While PsyBio is focused on programs using psychedelic inspired compounds, PsyBio does not have any direct or indirect involvement with the illegal selling, production or distribution of any substances in the jurisdictions in which it operates and does not intend to have any such involvement. However, a violation of any Canadian federal laws and regulations could result in significant fines, penalties, administrative sanctions, convictions or settlements arising from civil proceedings initiated by either government entities in the jurisdictions in which PsyBio operates, or private citizens or criminal charges.

In the United States, psilocybin and its active metabolite, psilocin, are listed by the DEA as controlled substances or scheduled substances, under the CSA specifically as a Schedule I substance. The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances. Schedule I substances by definition have a high potential for abuse, have not currently "accepted medical use" in the United States, lack accepted safety for use under medical supervision, and may not be prescribed, marketed or sold in the United States. Pharmaceutical products approved for use in the United States may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest potential for abuse or dependence and Schedule V substances the lowest relative risk of abuse among such substances. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and criteria for importation. In addition, dispensing of Schedule II drugs is further restricted. For example, they may not be refilled without a new prescription and may have a black box warning. Further, most, if not all, state laws in the United States classify psilocybin and psilocin as Schedule I controlled substances. For any product containing psilocybin to be available for commercial marketing in the United States, psilocybin and psilocin must be rescheduled, or the product itself must be scheduled, by the DEA to Schedule II, III, IV or V. Commercial marketing in the United States will also require scheduling-related legislative or administrative action.

Scheduling determinations by the DEA are dependent on U.S. FDA approval of a substance or a specific formulation of a substance. Therefore, while psilocybin and psilocin are Schedule I controlled substances, products approved by the U.S. FDA for medical use in the United States that contain psilocybin or psilocin should be placed in Schedules II-V, since approval by the U.S. FDA satisfies the "accepted medical use" requirement. In addition, the scheduling process may take significantly longer than the 90-day deadline set forth in the CSA, thereby delaying the launch of PsyBio's future psilocybin based therapies in the United States. Furthermore, the U.S. FDA, DEA, or any foreign regulatory authority could require PsyBio to generate more clinical or other data than PsyBio currently anticipates establishing whether or to what extent the substance has an abuse potential, which could increase the cost and/or delay the launch of PsyBio's future therapeutic candidates containing controlled substances.

There is no guarantee that any of PsyBio's investigational therapeutic compounds will be approved for use by Health Canada or the U.S. FDA. The failure to obtain necessary licenses and permits for Schedule I drugs could have an adverse effect on PsyBio's operations.

If any of PsyBio's therapeutic investigational compounds are approved by the U.S. FDA, they will be subject to further DEA regulations relating to manufacturing, storage, distribution and physician prescription procedures.

The potential reclassification of psilocybin and psilocin in the United States could create additional regulatory burdens on our operations and negatively affect our results of operations.

If psilocybin and/or psilocin, other than the U.S. FDA-approved formulation, is rescheduled under the CSA as a Schedule II or lower controlled substance (i.e., Schedule III, IV or V), the ability to conduct research on psilocybin and psilocin would most likely be improved. However, rescheduling psilocybin and psilocin may materially alter enforcement policies across many federal agencies, primarily the U.S. FDA and DEA. The U.S. FDA is responsible for ensuring public health and safety through regulation of food, drugs, supplements, and cosmetics, among other products, through its enforcement authority pursuant to the Federal Food, Drug, and Cosmetic Act, or the FDCA. The U.S. FDA's responsibilities include regulating the ingredients as well as the marketing and labeling of drugs sold in interstate commerce. Because it is currently illegal under federal law to produce and sell psilocybin and psilocin, and because there are no federally recognized medical uses, the U.S. FDA has historically deferred enforcement related to psilocybin and psilocin to the DEA. If psilocybin and psilocin were to be rescheduled to a federally controlled, yet legal, substance, the U.S. FDA would likely play a more active regulatory role. The DEA would continue to be active in regulating manufacturing, distribution and dispensing of such substances. The potential for multi-agency enforcement post-rescheduling could threaten or have a materially adverse effect on our business.

Risks Related to Intellectual Property

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and protect other proprietary information.

PsyBio relies on third parties to develop its products and as a result, must share trade secrets with them. PsyBio seeks to protect its proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with its collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information, to the extent it is able to in accordance with the rights it has for its licensed intellectual property. These agreements typically restrict the ability of PsyBio's collaborators, advisors, employees and consultants to publish data potentially relating to its trade secrets. Its academic and clinical collaborators typically have rights to publish data, provided that PsyBio is notified in advance and may delay publication for a specified time in order to secure any intellectual property rights arising from the collaboration. In other cases, publication rights are controlled exclusively by PsyBio, although in some cases PsyBio may share these rights with other parties. PsyBio may also conduct joint research and development programs which may require it to share trade secrets under the terms of research and development collaboration or similar agreements. Despite PsyBio's efforts to protect its trade secrets, PsyBio's competitors may discover its trade secrets, either through breach of these agreements, independent development or publication of information. A competitor's discovery of PsyBio's trade secrets may impair its competitive position and could have a material adverse effect on its business and financial condition.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

PsyBio's registered or unregistered trademarks and trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. PsyBio may not be able to protect PsyBio's rights to these trademarks and trade names, which PsyBio needs to build name recognition by potential partners or customers in PsyBio's markets of interest. If PsyBio is unable to establish name recognition based on PsyBio's trademarks and trade names, then PsyBio may not be able to compete effectively and PsyBio's business may be adversely affected.

PsyBio may become involved in patent litigation, which could require substantial financial or other resources necessary to enforce or defend.

Patent litigation is becoming widespread in the pharmaceutical industry and PsyBio cannot predict how this will affect its efforts to form strategic alliances, conduct clinical testing, or manufacture and market any of its product candidates that it may successfully develop. If PsyBio becomes involved in any litigation, interference, impeachment or other administrative proceedings relating to its trade names or licensed patents, it will likely incur substantial expenses and the efforts of its technical and management personnel will be significantly diverted. PsyBio cannot make any assurances that it will have the financial or other resources necessary to enforce or defend a patent infringement or proprietary rights violation action. Moreover, if PsyBio's products infringe patents, trademarks or proprietary rights of others, it could, in certain circumstances, become liable for substantial damages, which also could have a material adverse effect on the business of PsyBio, its financial condition and results of operation. Patent litigation is less likely during development as many jurisdictions contain exemptions from patent infringement for the purpose of obtaining regulatory approval of a product. Where there is any sharing of patent rights either through co-ownership or different licensed "fields of use", one owner's actions could lead to the invalidity of the entire patent. If PsyBio is unable to avoid infringing the patent rights of others, PsyBio may be required to seek a license, defend an infringement action or challenge the validity of the patents in court. Such results could have a material adverse effect on PsyBio. Regardless of the outcome, patent litigation is costly and time consuming. In some cases, PsyBio may not have sufficient resources to bring these actions to a successful conclusion, and, even if PsyBio is successful in these proceedings, it may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on PsyBio.

Any infringement or misappropriation of PsyBio's intellectual property could damage its value and limit its ability to compete. In addition, PsyBio's ability to enforce and protect its intellectual property rights may be limited in certain countries outside the U.S., which could make it easier for competitors to capture market position in such countries by utilizing technologies that are similar to those developed or licensed by PsyBio. Competitors may also harm PsyBio's sales by designing products that mirror the capabilities of its products or technology without infringing on its intellectual property rights. If PsyBio does not obtain sufficient protection for its intellectual property, or if it is unable to effectively enforce its intellectual property rights, its competitiveness could be impaired, which would limit its growth and future revenue. PsyBio may also find it necessary to bring infringement or other actions against third parties to seek to protect its intellectual property rights. Litigation of this nature, even if successful, is often expensive and time-consuming to prosecute and there can be no assurance that PsyBio will have the financial or other resources to enforce its rights or be able to enforce its rights or prevent other parties from developing similar technology or designing around its intellectual property.

PsyBio is not aware of any infringement by it of any person's or entity's intellectual property rights. In the event that products sold by PsyBio are deemed to infringe upon the patents or proprietary rights of others, PsyBio could be required to modify its products or obtain a license for the manufacture and/or sale of such products or cease selling such products. In such event, there can be no assurance that PsyBio would be able to do so in a timely manner, upon acceptable terms and conditions, or at all, and the failure to do any of the foregoing could have a material adverse effect

upon PsyBio's business. If PsyBio's products or proposed products are deemed to infringe or likely to infringe upon the patents or proprietary rights of others, PsyBio could be subject to injunctive relief and, under certain circumstances, become liable for damages, which could also have a material adverse effect on PsyBio's business and its financial condition.

Issued patents covering one or more of our investigational therapeutics could be found invalid or unenforceable if challenged in court.

To protect PsyBio's competitive position, PsyBio may from time to time need to resort to litigation in order to enforce or defend any patents or other intellectual property rights owned by or licensed to PsyBio from time to time, or to determine or challenge the scope or validity of patents or other intellectual property rights of third parties. Enforcement of intellectual property rights is difficult, unpredictable and expensive, and many of PsyBio's or PsyBio's licensors' or collaboration partners' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than PsyBio or PsyBio's licensors or collaboration partners can. Accordingly, despite PsyBio's or PsyBio's licensors' or collaboration partners' efforts, PsyBio or PsyBio's licensors or collaboration partners may not prevent third parties from infringing upon, misappropriating or otherwise violating intellectual property rights PsyBio owns or controls, particularly in countries where the laws may not protect those rights as fully as in Canada and the United States. PsyBio may fail in enforcing its rights, in which case PsyBio's competitors and other third parties may be permitted to use PsyBio's therapies without payment to PsyBio.

In addition, litigation involving PsyBio's licensed patents carries the risk that one or more of PsyBio's licensed patents will be narrowed, held invalid (in whole or in part, on a claim-by-claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to commercialize PsyBio's therapies, and then compete directly with PsyBio, without payment to PsyBio.

If PsyBio were to initiate legal proceedings against a third party to enforce a patent covering one of PsyBio's investigational therapies, the defendant could counterclaim that PsyBio's licensed patent is invalid or unenforceable. In patent litigation in the United States or in Canada, defendant counterclaims alleging invalidity or unenforceability are commonplace. A claim for a validity challenge may be based on failure to meet any of several statutory requirements, for example, lack of novelty, obviousness or non-enablement. A claim for unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement, during prosecution. Third parties may also raise challenges to the validity of PsyBio's patent claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (i.e., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, or amendment to PsyBio's licensed patents in such a way that they no longer cover any future therapeutic candidates. The outcome following legal assertions of invalidity and unenforceability during patent litigation or other proceedings is unpredictable. With respect to the validity question, for example, PsyBio cannot be certain that there is no invalidating prior art, of which PsyBio and the patent examiner were unaware during prosecution. If a defendant or third party were to prevail on a legal assertion of invalidity or unenforceability, PsyBio would lose at least part, and perhaps all, of the patent protection on one or more of any future therapeutic candidates. Such a loss of patent protection could have a material adverse impact on PsyBio's business financial condition, results of operations, and prospects. Further, litigation could result in substantial costs and diversion of management resources, regardless of the outcome, and this could harm PsyBio's business and financial results.

Intellectual property litigation could cause us to spend substantial resources, distract our personnel from their normal responsibilities, harming our reputation and our business operations.

Even if resolved in PsyBio's favor, litigation or other legal proceedings relating to intellectual property claims may cause PsyBio to incur significant expenses and could distract PsyBio's technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on PsyBio. Such litigation or proceedings could substantially increase PsyBio's operating losses and reduce PsyBio's resources available for development and commercialization activities. PsyBio may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of PsyBio's competitors may be able to sustain the costs of such litigation or proceedings more effectively than PsyBio can because of their substantially greater financial resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of PsyBio's confidential information could be compromised by disclosure during this type of litigation. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on PsyBio's ability to compete in the marketplace.

Protection of intellectual property will only be possible to the extent PsyBio's proprietary technologies are covered by valid and enforceable intellectual property rights.

PsyBio will be able to protect its licensed intellectual property from unauthorized use by third parties only to the extent that PsyBio's proprietary technologies, key products and any future products are covered by valid and enforceable intellectual property rights of the licensor, including patents, or are effectively maintained as trade secrets by the licensor, and provided PsyBio has the ability and funds to enforce its rights, if necessary.

PsyBio's inability to obtain third-party licenses for intellectual property may hinder or eliminate its ability to manufacture and market its products.

PsyBio licenses all intellectual property relating to its proprietary platform technology, other than its trade names. In the future, there may not be any patents in the US or in foreign countries that are available to license on acceptable terms. PsyBio's inability to obtain such licenses may hinder or eliminate its ability to manufacture and market its products. Further, if PsyBio obtains third-party licenses but fails to pay annual maintenance fees, development and sales milestones, or it is determined that PsyBio does not use commercially reasonable efforts to commercialize licensed products, PsyBio could lose its licenses which could have a material adverse effect on its business and financial condition.

In addition, a substantial number of patents have already been issued to other biotechnology and pharmaceutical companies. To the extent that valid third-party patent rights cover PsyBio's products or services, PsyBio, the licensor of PsyBio's intellectual property rights, or its strategic collaborators would be required to seek licenses from the holders of these patents in order to manufacture, use or sell these products and services and payments under them would reduce PsyBio's profits from these products and services.

Third-party intellectual property right holders, including PsyBio's competitors, may actively bring infringement, misappropriation or violation claims against PsyBio based on existing or future intellectual property rights, regardless of their merit. PsyBio may not be able to successfully settle or otherwise resolve such infringement claims. If PsyBio is unable to successfully settle future claims on terms acceptable to PsyBio, PsyBio may be required to engage or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing PsyBio's therapies.

If PsyBio is unsuccessful in defending any such claim, in addition to being forced to pay damages, PsyBio or PsyBio's licensor or licensees may be temporarily or permanently prohibited from

commercializing any of PsyBio's investigational therapies that were held to be infringing. If possible, PsyBio might be forced to redesign PsyBio's therapeutic candidates or any future therapeutic candidates so that PsyBio no longer infringes the intellectual property rights of third parties, or PsyBio may be required to seek a license to any such technology that PsyBio is found to infringe, which license may not be available on commercially reasonable terms or at all. Even if PsyBio or PsyBio's licensors or collaboration partners obtain a license, it may be non-exclusive, thereby giving PsyBio's competitors access to the same technologies licensed to PsyBio or PsyBio's licensors or collaboration partners and it could require PsyBio to make significant licensing and royalty payments. In addition, PsyBio could be found liable for significant monetary damages, including treble damages and attorneys' fees, if PsyBio is found to have willfully infringed a patent or other intellectual property right. Claims that PsyBio has misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on PsyBio's business, financial condition, results of operations, and prospects. Any of these events, even if PsyBio were ultimately to prevail, could require PsyBio to divert substantial financial and management resources that PsyBio would otherwise be able to devote to PsyBio's business.

In addition, if the breadth or strength of protection provided by PsyBio's or PsyBio's licensors' or collaboration partners' patents and patent applications is threatened, it could dissuade companies from collaborating with PsyBio to license, develop or commercialize current or future investigational therapies. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of PsyBio's confidential information could be compromised by disclosure during this type of litigation.

If we fail to comply with our obligations under the agreements pursuant to which we license intellectual property rights to or from third parties, or otherwise experience disruptions to our business relationships with our licensors, licensees or collaborators, we could lose the rights to intellectual property that are important to our business.

PsyBio is or may become a party to third-party agreements under which PsyBio grants or is granted rights to intellectual property that are potentially important to PsyBio's business and PsyBio expects that it may need to enter into additional license or collaboration agreements in the future. PsyBio's existing third-party agreements impose, and PsyBio expects that future license agreements will impose, various obligations related to, among other things, therapeutic development and payment of royalties and fees based on achieving certain milestones. In addition, under several of PsyBio's collaboration agreements, PsyBio is prohibited from developing and commercializing therapies that would compete with the therapies licensed under such agreements. If PsyBio fails to comply with PsyBio's obligations under these agreements, PsyBio's licensor or collaboration partner may have the right to terminate the agreement, including any licenses included in such agreement.

The termination of any license or collaboration agreements or failure to adequately protect such license agreements or collaboration could prevent PsyBio from commercializing PsyBio's therapeutic candidates or any future therapeutic candidates covered by the agreement or licensed intellectual property. For example, PsyBio may rely on license agreements which grant PsyBio rights to certain intellectual property and proprietary materials that PsyBio uses in connection with the development of PsyBio's therapies. If this agreement were to terminate, PsyBio would be unable to timely license similar intellectual property and proprietary materials from an alternate source, on commercially reasonable terms or at all, and may be required to conduct additional bridging studies on PsyBio's therapeutic candidates or any future therapeutic candidates, which could delay or otherwise have a material adverse effect on the development and commercialization of PsyBio's therapeutic candidates or any future therapeutic candidates.

Several of PsyBio's existing license agreements are sublicenses from third parties which are not the original licensor of the intellectual property at issue. Under these agreements, PsyBio must rely on PsyBio's licensor to comply with its obligations under the primary license agreements under which

such third party obtained rights in the applicable intellectual property, where PsyBio may have no relationship with the original licensor of such rights. If the licensors fail to comply with their obligations under these upstream license agreements, the original third-party licensor may have the right to terminate the original license, which may terminate the sublicense. If this were to occur, PsyBio would no longer have rights to the applicable intellectual property and, in the case of a sublicense, if PsyBio were not able to secure PsyBio's own direct license with the owner of the relevant rights, which it may not be able to do at a reasonable cost or on reasonable terms, it may adversely affect PsyBio's ability to continue to develop and commercialize PsyBio's therapeutic candidates or any future therapeutic candidates incorporating the relevant intellectual property.

Disputes may arise regarding intellectual property subject to a license or collaboration agreement, including the following:

- the scope of rights granted under the agreement and other interpretation-related issues;
- the extent to which PsyBio's technology and processes infringe on intellectual property of the licensor or collaboration partner that is not subject to the agreement;
- the sublicensing of patent and other rights under any current or future collaboration relationships;
- PsyBio's diligence obligations under the agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by PsyBio's licensors and PsyBio and PsyBio's collaboration partners; and
- the priority of invention of patented technology.

In addition, PsyBio's third-party agreements are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what PsyBio believes to be the scope of PsyBio's rights to the relevant intellectual property or technology, or increase what PsyBio believes to be PsyBio's financial or other obligations under the relevant agreement, either of which could have a material adverse effect on PsyBio's business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that PsyBio has licensed prevent or impair PsyBio's ability to maintain PsyBio's current licensing arrangements on commercially acceptable terms, PsyBio may be unable to successfully develop and commercialize the affected therapeutic candidate, which could have a material adverse effect on PsyBio's business, financial conditions, results of operations, and prospects.

Failure to extend the term of patents covering our investigational therapies could materially harm our business.

In the United States, if all maintenance fees are paid on time, the natural expiration of a patent is generally 20 years from its earliest non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering PsyBio's investigational therapies, their manufacture, or use are obtained, once the patent life has expired, PsyBio may be open to competition from competitive therapies. Given the amount of time required for the development, testing and regulatory review of new investigational therapies, patents protecting such candidates and concomitant therapies might expire before or shortly after such candidates and concomitant therapies are commercialized. As a result, PsyBio's licensed patent

portfolio may not provide PsyBio with sufficient rights to exclude others from commercializing therapies similar or identical to PsyBio's.

Depending upon the timing, duration and conditions of U.S. FDA marketing approval of any future therapeutic candidates, one or more of PsyBio's U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, and similar legislation in other jurisdictions. The Hatch-Waxman Act permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term loss during product development and the U.S. FDA regulatory review process. The patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method of manufacturing it may be extended. However, PsyBio may not receive an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the length of the extension could be less than PsyBio requests. If PsyBio is unable to obtain patent term extension or the term of any such extension is less than PsyBio's requests, the period during which PsyBio can enforce PsyBio's patent rights for that product will not be lengthened and third parties, including PsyBio's competitors, may obtain approval to market competing therapies sooner than PsyBio expects. As a result, PsyBio's revenue from applicable therapies could be materially reduced and PsyBio's business, financial condition, results of operations, and prospects could be materially harmed.

Intellectual property rights may fail to protect our competitive advantage.

The degree of future protection afforded by PsyBio's intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect PsyBio's business, or permit PsyBio to maintain PsyBio's competitive advantage. The following examples are illustrative:

- others may be able to make compounds or develop digital assets that are the same as or similar to PsyBio's therapeutic candidates, any future therapeutic candidates and digital assets but that are not covered by the claims of the patents that PsyBio owns or controls;
- the patents of third parties may have an adverse effect on PsyBio's business;
- PsyBio or PsyBio's licensors or any current or future collaboration partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that PsyBio owns or controls;
- PsyBio or PsyBio's licensors or any current or future collaboration partners might not have been the first to file patent applications covering certain of PsyBio's inventions;
- others may independently develop similar or alternative technologies or duplicate any of PsyBio's technologies without infringing misappropriating or otherwise violating PsyBio's intellectual property rights;
- issued patents that PsyBio has exclusively licensed may not provide PsyBio with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by third parties;
- PsyBio's competitors might conduct research and development activities in countries where PsyBio does not have patent rights and then use the information learned from such activities to develop competitive therapies for sale in PsyBio's major commercial markets;

- third parties performing manufacturing or testing for PsyBio using PsyBio's therapies or technologies could use the intellectual property of others without obtaining a proper license;
- PsyBio may not develop additional technologies that are patentable; and
- PsyBio may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property, or otherwise develop similar know-how.

Should any of these events occur, they could have a material adverse effect on PsyBio's business, financial condition, results of operations, and prospects.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Some of PsyBio's present and future consultants, advisors and employees, including PsyBio's senior management, may have previously been employed at other biotechnology or pharmaceutical companies, including PsyBio's competitors and potential competitors. Some of these individuals executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although PsyBio intends that PsyBio's consultants, advisors and employees do not use proprietary information or know-how of their former employers while working for PsyBio, PsyBio may be subject to claims that PsyBio or these individuals have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. Litigation may be necessary to defend against these claims.

If PsyBio fails in prosecuting or defending any such claims, in addition to paying monetary damages, PsyBio may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and PsyBio could be required to obtain a license from such third party to commercialize PsyBio's therapies. Such a license may not be available on commercially reasonable terms or at all. Even if PsyBio successfully prosecutes or defends against such claims, litigation could result in substantial costs and distract PsyBio's management from its day-to-day activities.

In addition, while it is PsyBio's policy to require PsyBio's employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to PsyBio, PsyBio may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that PsyBio regards as PsyBio's own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and PsyBio may be forced to bring claims against third parties, or defend claims that they may bring against PsyBio, to determine the ownership of what PsyBio regards as PsyBio's intellectual property. Such claims could have a material adverse effect on PsyBio's business, financial condition, results of operations, and prospects.

Changes in patent laws or patent jurisprudence could diminish the value of patents in general or prevent us from obtaining patents and thereby impair our ability to protect our investigational therapies.

As is the case with other companies in PsyBio's industry, PsyBio's success is heavily dependent on PsyBio's intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve technological and legal complexity. Therefore, obtaining and enforcing patents for therapeutics is costly, time-consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States or other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the

enforcement or defense of issued patents. For example, the America Invents Act, or the AIA, enacted in the United States in 2012 and 2013, has resulted in significant changes to the U.S. patent system.

Prior to the enactment of the AIA, assuming that other requirements for patentability are met, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 16, 2013, under the AIA, the United States transitioned to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention regardless of whether a third party was the first to invent the claimed invention. On or after that date, a third party that files a patent application in the USPTO before PsyBio could be awarded a patent covering an invention of ours even if PsyBio made the invention before the third party. The AIA will require PsyBio to be cognizant going forward of the time from invention to filing of a patent application, but circumstances could prevent PsyBio from promptly filing patent applications on PsyBio’s inventions.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and provide additional opportunities for third parties to challenge any pending patent application or issued patent in the USPTO. Such opportunities include allowing third - party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review and derivation proceeding. This applies to all of PsyBio’s U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim in PsyBio’s patents invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate PsyBio’s patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of PsyBio’s patent applications and the enforcement or defense of PsyBio’s issued patents.

Additionally, the United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to PsyBio’s ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained.

Depending on decisions by the United States Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken PsyBio’s ability to obtain new patents or to enforce PsyBio’s existing patents and patents that PsyBio might obtain in the future.

We may not be able to protect our intellectual property rights throughout the world and may face difficulties in certain jurisdictions, which may diminish the value of intellectual property rights in those jurisdictions.

Filing, prosecuting and defending patents on therapeutic candidates in all countries and jurisdictions throughout the world would be prohibitively expensive and PsyBio’s intellectual property rights in some countries outside of Canada and the United States, could be less extensive than those in Canada and the United States, assuming that rights are obtained in Canada and the U.S. Consequently, PsyBio may not be able to prevent third parties from practicing PsyBio’s inventions in all countries outside Canada and the United States, or from selling therapies or importing therapeutic substances made using PsyBio’s inventions in and into Canada and the United States, or other jurisdictions. In

addition, PsyBio may decide to abandon national and regional patent applications before grant. Finally, the grant proceeding of each national/regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others. It is also quite common that depending on the country, the scope of patent protection may vary for the same therapeutic candidate or technology.

Competitors may use PsyBio's and PsyBio's licensors' or collaboration partners' technologies in jurisdictions where PsyBio has not obtained patent protection to develop their own therapies and, further, may export otherwise infringing therapies to territories where PsyBio and PsyBio's licensors or collaboration partners have patent protection, but enforcement is not as strong as that in the Canada and the United States. These therapies may compete with future therapeutic candidates, and PsyBio's and PsyBio's licensors' or collaboration partners' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in Canada and the United States, and companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. If PsyBio or PsyBio's licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for PsyBio's business in such jurisdictions, the value of these rights may be diminished and PsyBio may face additional competition from others in those jurisdictions.

Some countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If PsyBio or any of PsyBio's licensors or collaboration partners is forced to grant a license to third parties with respect to any patents relevant to PsyBio's business, PsyBio's competitive position may be impaired and PsyBio's business and results of operations may be adversely affected.

Proceedings to enforce PsyBio's and PsyBio's licensors' or collaboration partners' patent rights in foreign jurisdictions could result in substantial costs and divert PsyBio's and PsyBio's licensors' or collaboration partners' efforts and attention from other aspects of PsyBio's business, regardless of whether PsyBio or PsyBio's licensors or collaboration partners are successful, and could put PsyBio's and PsyBio's licensors' or collaboration partners' patents at risk of being invalidated or interpreted narrowly. In addition, such proceedings could put PsyBio's and PsyBio's licensors' or collaboration partners' patent applications at risk of not issuing and could provoke third parties to assert claims against PsyBio or PsyBio's licensors or collaboration partners. PsyBio or PsyBio's licensors or collaboration partners may not prevail in any lawsuits that PsyBio or PsyBio's licensors or collaboration partners initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Any of the foregoing could have a material adverse effect on PsyBio's business, financial condition, results of operations, and prospects.

Financial and Accounting Risks

Negative cash flow from operating activities have had and will continue to have an adverse effect on, among other things, shareholder equity, total assets and working capital.

PsyBio has had negative cash flow from operating activities since inception. This has resulted principally from costs incurred in connection with research and development activities and general and administrative costs associated with operations. Significant capital investment will be required to achieve PsyBio's existing plans. PsyBio's net losses have had and will continue to have an adverse effect on, among other things, shareholder equity, total assets and working capital. PsyBio expects that losses may fluctuate from quarter to quarter and year to year, and that such fluctuations may be

substantial. PsyBio cannot predict when it will become profitable, if at all. Accordingly, PsyBio may be required to obtain additional financing in order to meet its future cash commitments.

Substantial additional financing may be required if PsyBio is to be successful in continuing to develop its business and its products.

As a research and development company, PsyBio expects to spend substantial funds to continue the research, development and testing of its product candidates and to prepare to commercialize products subject to applicable regulatory approval. Substantial additional financing may be required if PsyBio is to be successful in continuing to develop its business and its products. No assurances can be given that PsyBio will be able to raise the additional capital that it may require for its anticipated future development. Any additional equity financing may be dilutive to investors and debt financing, if available, may involve restrictions on financing and operating activities. There is no assurance that additional financing will be available on terms acceptable to PsyBio, if at all. If PsyBio is unable to obtain additional financing as needed, it may be required to reduce the scope of its operations or anticipated expansion.

PsyBio has not generated product revenue and cannot predict when and if it will generate product revenue.

To date, PsyBio has not generated product revenue and cannot predict when and if it will generate product revenue. PsyBio's ability to generate product revenue and ultimately become profitable depends upon its ability, alone or with partners, to successfully develop its product candidates, obtain regulatory approval and commercialize products, including any of its current product candidates or other product candidates that it may develop, in-license or acquire in the future. PsyBio does not anticipate generating revenue from the sale of products for the foreseeable future. PsyBio expects its research and development expenses to increase in connection with its ongoing activities, particularly as it advances its product candidates through clinical trials.

Estimates or judgments relating to critical accounting policies are based on historical experience and on various other assumptions that management believes to be reasonable under the circumstances. PsyBio's operating results may be adversely affected if the assumptions change or if actual circumstances differ.

The preparation of the consolidated financial statements in conformity with the International Financial Reporting Standards requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. PsyBio bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets, liabilities, equity, revenue and expenses that are not readily apparent from other sources. PsyBio's operating results may be adversely affected if the assumptions change or if actual circumstances differ from those in the assumptions, which could cause its operating results to fall below the expectations of securities analysts and investors, resulting in a decline in the share price of PsyBio. Significant assumptions and estimates will be used in preparing the consolidated financial statements including those related to the credit quality of accounts receivable, income tax credits receivable, share based payments, impairment of non-financial assets, fair value of biological assets, as well as revenue and cost recognition.

Exchange rate fluctuations could affect PsyBio's business and may have a significant impact on PsyBio's results of operations and cash flows from period to period.

Due to the international scope of PsyBio's current and future operations, PsyBio's assets, future earnings and cash flows may be influenced by movements in exchange rates of several currencies, particularly USD and CAD. The reporting currency and the functional currency of the Company is

USD and CAD, respectively. The functional currency of PsyBio US is USD. PsyBio may also regularly acquire services, consumables and materials in USD, CAD and other currencies. Further, future revenue may be derived from abroad. As a result, PsyBio's business and the price of PsyBio's products may be affected by fluctuations in foreign exchange rates between the U.S. dollar and other currencies, which may also have a significant impact on PsyBio's results of operations and cash flows from period to period. Currently, PsyBio does not have any exchange rate hedging arrangements in place.

Risks Related to Our Securities

The market price of Subordinate Voting Shares may be volatile.

The market price of the Subordinate Voting Shares may be volatile. The volatility may affect the ability of holders to sell Subordinate Voting Shares at an advantageous price or at all. Market price fluctuations in Subordinate Voting Shares may be adversely affected by a variety of factors relating to PsyBio's business, including fluctuations in PsyBio's operating and financial results, such results failing to meet the expectations of securities analysts or investors and downward revisions in securities analysis' estimates in connection therewith, sales of additional Subordinate Voting Shares, governmental regulatory action, adverse change in general market conditions or economic trends, acquisitions, dispositions or other material public announcements by PsyBio or its competitors, along with a variety of additional factors, including, without limitation, those set forth under the heading "Forward-Looking Statements". In addition, the market price for securities on stock markets, including the TSXV, is subject to significant price and trading fluctuations. These fluctuations have resulted in volatility in the market prices of securities that often has been unrelated or disproportionate to changes in operating performance, underlying asset values or prospects of such companies. These broad market fluctuations may materially adversely affect the market price of the Subordinate Voting Shares.

Additionally, the value of our Subordinate Voting Shares is subject to market value fluctuations based upon factors that influence PsyBio's operations, such as legislative or regulatory developments, competition, technological change and changes in interest rates or foreign exchange rates. There can be no assurance that the market price of Subordinate Voting Shares will not experience significant fluctuations in the future, including fluctuations that are unrelated to PsyBio's performance.

An active, liquid, and orderly market for our securities may not develop.

Our Subordinate Voting Shares are listed on the TSXV. An active, liquid and orderly trading market for our securities may never develop or be sustained. If an active market for our securities does not continue to develop or is not sustained, it may be difficult for investors to sell shares of their securities without depressing the market price and investors may not be able to sell their securities at all. An inactive market may also impair our ability to raise capital by selling our securities and may impair our ability to acquire other businesses, applications, or technologies using our securities as consideration, which, in turn, could materially adversely affect our business and the market prices of your securities.

Shareholders may suffer dilution if additional Subordinate Voting Shares are issued for financing purposes.

The financial risk of PsyBio's future activities will be borne to a significant degree by its shareholders. If additional Subordinate Voting Shares are issued from treasury for financing purposes, control of PsyBio may change and purchasers may suffer additional dilution.

The issuance by PsyBio of Subordinate Voting Shares or other securities convertible into Subordinate Voting Shares could result in significant dilution in the equity interest of existing shareholders and adversely affect the market price of the Subordinate Voting Shares. In addition, in the future, PsyBio may issue additional Subordinate Voting Shares or securities convertible into Subordinate Voting Shares, which may dilute existing shareholders. PsyBio's Articles permit the issuance of an unlimited number of Subordinate Voting Shares and an unlimited number of Multiple Voting Shares, and shareholders will have no pre-emptive rights in connection with such further issuances. Also, additional Subordinate Voting Shares may be issued by PsyBio upon the exercise of stock options and upon the exercise or conversion of other securities convertible into Subordinate Voting Shares, including the Multiple Voting Shares. The issuance of these additional equity securities may have a similar dilutive effect on then existing holders of Subordinate Voting Shares.

The market price of the Subordinate Voting Shares could decline as a result of future issuances by PsyBio, including issuances of shares in connection with strategic alliances, or sales by its existing holders of Subordinate Voting Shares or Multiple Voting Shares, or the perception that these sales could occur. Sales by shareholders might also make it more difficult for PsyBio to sell equity securities at a time and price that it deems appropriate, which could reduce its ability to raise capital and have an adverse effect on its business.

The rights of holders of Multiple Voting Shares to convert such shares into Subordinate Voting Shares will be subject to the FPI Protective Restriction in order to maintain the status of PsyBio as a "foreign private issuer" under United States securities laws.

The rights of holders of Multiple Voting Shares to convert such shares into Subordinate Voting Shares will be subject to the FPI Protective Restriction in order to maintain the status of PsyBio as a "foreign private issuer" under United States securities laws. As a result, holders of Multiple Voting Shares may not be able to convert such shares into Subordinate Voting Shares. PsyBio could lose its status as a "foreign private issuer" if all or a portion of the Multiple Voting Shares directly or indirectly held of record by U.S. Residents are converted into Subordinate Voting Shares. The FPI Protective Restriction provides that holders of Multiple Voting Shares shall not have the right to convert any portion of the Multiple Voting Shares to the extent that after giving effect to all permitted issuances after such conversions of Multiple Voting Shares, the aggregate number of Subordinate Voting Shares and Multiple Voting Shares held of record, directly or indirectly, by residents of the U.S. Residents would exceed the 40% Threshold. The Multiple Voting Shares will not be listed for trading in any market and, as such, holders of Multiple Voting Shares will not be able to trade their shares without conversion. For more information on the Multiple Voting Shares and a full description of the FPI Protective Restriction, see "Description of the Securities".

There can be no assurance that an active trading market for Subordinate Voting Shares will develop or, if developed, that any market will be sustained.

PsyBio cannot predict the prices at which Subordinate Voting Shares will trade. Fluctuations in the market price of Subordinate Voting Shares could cause an investor to lose all or part of its investment in Subordinate Voting Shares. Factors that could cause fluctuations in the trading price of Subordinate Voting Shares include: (i) announcements of new offerings, products, services or technologies; commercial relationships, acquisitions or other events by PsyBio or its competitors; (ii) price and volume fluctuations in the overall stock market from time to time; (iii) significant volatility in the market price and trading volume of similar companies in its industry; (iv) fluctuations in the trading volume of Subordinate Voting Shares or the size of PsyBio's public float; (v) actual or anticipated changes or fluctuations in PsyBio's results of operations; (vi) whether PsyBio's results of operations meet the expectations of securities analysts or investors; (vii) actual or anticipated changes in the expectations of investors or securities analysts; (viii) litigation involving PsyBio, its industry, or both; (ix) regulatory developments; (x) general economic conditions and trends; (xi) major catastrophic events; (xii) escrow releases, sales of large blocks of Subordinate Voting Shares;

(xiii) departures of key employees or members of management; or (xiv) an adverse impact on PsyBio from any of the other risks cited herein.

Significant sales of Subordinate Voting Shares could adversely affect the market price of Subordinate Voting Shares and may make it more difficult for investors to sell Subordinate Voting Shares on favorable terms.

Certain Subordinate Voting Shares and Multiple Voting Shares held by certain directors, executive officers, control persons and certain other securityholders are subject to contractual lock-up restrictions and may also be subject to escrow restrictions pursuant to the policies of the TSXV. Sales of a substantial number of Subordinate Voting Shares in the public market after the expiry of lock-up or escrow restrictions, or the perception that these sales could occur, could adversely affect the market price of Subordinate Voting Shares and may make it more difficult for investors to sell Subordinate Voting Shares at a favorable time and price.

There may be income tax consequences in relation to Subordinate Voting Shares.

There may be income tax consequences in relation to Subordinate Voting Shares, which will vary according to circumstances of each investor. Prospective investors should seek independent advice from their own tax and legal advisers.

PsyBio will have discretion concerning the use of the net proceeds of any offerings as well as the timing of their expenditures, and may apply the net proceeds of an offering in ways other than as disclosed.

An investor will be relying on the judgment of PsyBio for the application of the net proceeds of any offering of securities. PsyBio may use the net proceeds of any offering of securities in ways that an investor may not consider desirable. The expected use of net proceeds from the Company's financing activities represents the Company's current intentions based upon its present plans and business condition, which could change in the future as its plans and business conditions evolve. The amounts and timing of the actual use of the net proceeds will depend on multiple factors and there may be circumstances where, for sound business reasons, a reallocation of funds may be necessary in order for the Company to achieve its stated business objectives. The Company may also require additional funds in order to fulfill its expenditure requirements to meet existing and any new business objectives, and the Company expects to either issue additional securities or incur debt to do so. The results and the effectiveness of the application of the net proceeds are uncertain. If the net proceeds are not applied effectively, PsyBio's business, prospects, financial position, financial condition or results of operations may suffer.

PsyBio does not anticipate paying cash dividends on Subordinate Voting Shares in the foreseeable future.

PsyBio's current policy is, and will be, to retain earnings to finance the development and enhancement of its products and to otherwise reinvest in PsyBio. Therefore, PsyBio does not anticipate paying cash dividends on Subordinate Voting Shares in the foreseeable future. PsyBio's dividend policy will be reviewed from time to time by the PsyBio Board in the context of its earnings, financial condition and other relevant factors. Until the time that PsyBio does pay dividends, which it might never do, its shareholders will not be able to receive a return on their Subordinate Voting Shares unless they sell them.