

# **TRYP THERAPEUTICS INC.**

**FORM 2A**

**LISTING STATEMENT**

**December 17, 2020**

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**Appendix A:**  
**Final Long Form Prospectus of Tryp Therapeutics Inc.**  
**(see attached)**

*No securities regulatory authority has expressed an opinion about these securities and it is an offence to claim otherwise. This prospectus constitutes an offering of these securities only in those jurisdictions where they may be lawfully offered for sale and therein only by persons permitted to sell such securities. These securities have not been and will not be registered under the United States Securities Act of 1933, as amended (the “U.S. Securities Act”), or any state securities laws, and may not be offered or sold to, or for the account or benefit of, persons in the United States of America, its territories and possessions, any state of the United States or the District of Columbia (collectively, the “United States”) or U.S. persons (as such term is defined in Regulation S under the U.S. Securities Act (“U.S. Persons”)), unless exemptions from the registration requirements of the U.S. Securities Act and applicable state securities laws are available. This Prospectus does not constitute an offer to sell or a solicitation of an offer to buy any of the securities within the United States or to, or for the account or benefit of, U.S. Persons. See “Plan of Distribution”.*

## PROSPECTUS

Initial Public Offering

December 8, 2020



**TRYP THERAPEUTICS INC.**

**\$4,350,000 / 17,400,000 Units**

**Price: \$0.25 Per Unit**

This prospectus (the “**Prospectus**”) qualifies the distribution of 17,400,000 units (the “**Units**”) of Tryp Therapeutics Inc. (the “**Company**”, “**Tryp**”, “**us**” or “**we**”) for total gross proceeds of \$4,350,000 (the “**Offering**”) to be issued and sold at a price of \$0.25 per Unit (the “**Offering Price**”). Each Unit consists of one common share of the Company (a “**Unit Share**”) and one-half of one common share purchase warrant of the Company (each whole warrant, a “**Unit Warrant**”). Each Unit Warrant will entitle the holder, subject to the terms and conditions of the Warrant Indenture (as defined herein) to acquire one additional common share of the Company (a “**Warrant Share**”) at a price of \$0.50 per Warrant Share for a period of 12 months following the Closing Date (as defined herein). If, at any time, following the date that is 60 days from the Listing Date (as defined herein), the daily volume weighted average trading price of the common shares in the capital of the Company (the “**Common Shares**”) on the Canadian Securities Exchange (the “**CSE**”), or such other stock exchange on which the Common Shares are listed, if the Common Shares are listed on any stock exchange, is greater than \$0.75 for the preceding 10 consecutive trading days, the Company may, upon providing written notice to the holders of Unit Warrants, accelerate the expiry date of the Unit Warrants to the date that is 30 days following the delivery of such written notice. The Unit Warrants will be transferable but will not be listed or quoted on any stock exchange or market. This prospectus qualifies the distribution of the Unit Shares and Unit Warrants underlying the Units.

Pursuant to an agency agreement dated December 8, 2020 (the “**Agency Agreement**”) between the Company and Canaccord Genuity Corp. (the “**Agent**”), the Units are being offered on a “commercially reasonable efforts” basis in the provinces of British Columbia, Alberta and Ontario.

	Price to the Public <sup>(1)</sup>	Agent's Commission <sup>(2)(5)</sup>	Net Proceeds to Company <sup>(3)</sup>
Per Unit	\$0.25	\$0.02	\$0.23
Total Offering <sup>(4)</sup>	\$4,350,000	\$348,000	\$4,002,000

**Notes:**

(1) The Offering Price has been determined by negotiation between the Company and the Agent. See *"Plan of Distribution"*.

(2) Pursuant to the terms and conditions of the Agency Agreement, the Agent will receive a fee (the **"Commission"**) equal to the sum of (i) 8.0% of the gross proceeds of the Offering (including any gross proceeds raised on exercise of the Agent's Option (as defined below)), other than the gross proceeds raised from sales to "president's list" purchasers (such sales, the **"President's List Sales"**), and (ii) 4.0% of the gross proceeds raised from the President's List Sales. The Commission will be payable in cash and will be paid from the proceeds of the Offering. The above table assumes that no proceeds are raised from President's List Sales. The Agent will also receive, as additional compensation, compensation options (the **"Compensation Options"**) to purchase that number of Units as is equal to 8.0% of the Units sold pursuant to the Offering (including any Agent's Option Units (as defined herein) sold pursuant to the exercise of the Agent's Option), but excluding the Units sold pursuant to President's List Sales. In connection with the President's List Sales, the Agent will receive Compensation Options to purchase that number of Units that is equal to 4.0% of the Units sold pursuant to the President's List Sales. Each Compensation Option is exercisable to purchase one Unit (a **"Compensation Unit"**) at the Offering Price for a period of 12 months from the Listing Date. Each Compensation Unit consists of one Common Share (a **"Compensation Unit Share"**) and one-half of one Common Share purchase warrant of the Company (each whole warrant, a **"Compensation Unit Warrant"**). Each Compensation Unit Warrant will entitle the holder to acquire one additional Common Share (a **"Compensation Unit Warrant Share"**) at a price of \$0.50 per Compensation Unit Warrant Share for a period of 12 months following the Closing, subject to the same acceleration clause as is applicable to the Unit Warrants. The Company has also agreed to pay the Agent a corporate finance fee, which shall be satisfied by issuing to the Agent such number of Units (the **"Corporate Finance Fee Units"**) equal to 5.0% of the number of Units issued pursuant to the Offering (including any Agent's Option Units (as defined herein) sold pursuant to the exercise of the Agent's Option). Each Corporate Finance Fee Unit will consist of one Common Share (a **"Corporate Finance Fee Unit Share"**) and one-half of one Common Share purchase warrant of the Company (each whole warrant, a **"Corporate Finance Fee Unit Warrant"**). Each Corporate Finance Fee Unit Warrant will entitle the holder to acquire one additional Common Share (a **"Corporate Finance Fee Warrant Share"**) at a price of \$0.50 per Corporate Finance Fee Warrant Share for a period of 12 months following the Closing, subject to the same acceleration clause as is applicable to the Unit Warrants. In addition, the Company has agreed to reimburse the Agent for certain expenses, including legal fees, incurred pursuant to the Offering, toward which a \$50,000 deposit has been paid. This Prospectus also qualifies the distribution of the Compensation Options and the Corporate Finance Fee Units. See *"Plan of Distribution"*.

(3) After deducting the Commission but before deducting the expenses of the Offering. The expenses of the Offering are estimated to be approximately \$350,000 and will be paid by the Company out of the proceeds of the Offering. See *"Plan of Distribution"*.

(4) The Agent has been granted an over-allotment option (the **"Agent's Option"**), exercisable, in whole or in part, at the sole discretion of the Agent, for a period of 30 days from the Closing Date, to increase the size of the Offering by up to 2,610,000 Units (the **"Agent's Option Units"**) at the Offering Price to cover the Agent's over-allocation position, if any, and for market stabilization purposes. If the Offering is fully subscribed and the Agent's Option is exercised in full, the total "Price to the Public", "Agent's Commission" and "Net Proceeds to the Company" will be \$5,002,500, \$400,200 and \$4,602,300, respectively (assuming no proceeds are raised from President's List Sales). This Prospectus qualifies the distribution of the Agent's Option and the Agent's Option Units. A purchaser who acquires Units forming part of the Agent's over-allotment position acquires those Units under this Prospectus, regardless of whether the over-allotment position is ultimately filled through the exercise of the Agent's Option or secondary market purchases. See *"Plan of Distribution"*.

(5) Applicable securities rules provide that a prospectus may only qualify securities issued or paid as compensation to the Agent for acting as the agent in respect of the Offering in an amount up to 10% of the Offering (on an as-if-converted basis and including the Agent's Option). As described in Notes 2 and 4 above, the Agent's Compensation Options (and the Compensation Unit Shares and the Compensation Unit Warrant Shares issuable upon the exercise of the underlying Compensation Unit Warrants) and the Corporate Finance Fee Units (and the Corporate Finance Fee Unit Shares and the Corporate Finance Fee

Warrant Shares issuable upon the exercise of the underlying Corporate Finance Fee Unit Warrants) in an amount of 5% and 5%, respectively are qualified by this Prospectus. See "*Plan of Distribution*".

If subscriptions representing the Offering are not received within 90 days of the issuance of a receipt for the final Prospectus, or if a receipt has been issued for an amendment to the final Prospectus, within 90 days of the issuance of such receipt and in any event not later than 180 days from the date of the issuance of a receipt for the final Prospectus, the Offering will cease. The Agent, pending closing of the Offering, will hold in trust all subscription funds received pursuant to the provisions of the Agency Agreement. If the Offering has not closed on or before 90 days from the issuance of a receipt for the final Prospectus, the Offering will be discontinued and all subscription monies will be returned to purchasers by the Agent without interest or deduction, unless an amendment to the Prospectus is filed and a receipt has been issued for such amendment. See "*Plan of Distribution*". The Offering is expected to close on or about December 16, 2020 (the "**Closing Date**") or such other date as the Company and the Agent may agree.

**The Offering is not underwritten or guaranteed by any person or agent.** The price of the Units was determined by negotiation between the Company and the Agent. The Agent hereby conditionally offers the Units to the public in each of the provinces of British Columbia, Alberta, and Ontario on a "commercially reasonable efforts" basis, subject to prior sale, if, as and when issued and sold by the Company and accepted by the Agent in accordance with the conditions contained in the Agency Agreement referred to under "*Plan of Distribution*" and subject to the approval of certain legal and tax matters on behalf of the Company by Pushor Mitchell LLP and Ryan Shewchuk Professional Corporation and on behalf of the Agent by Borden Ladner Gervais LLP. See "*Plan of Distribution*".

The following table sets out the maximum number of securities issuable to the Agent:

Agent's Position	Maximum Size or Number of Securities Available <sup>(5)</sup>	Exercise Period or Acquisition Date	Exercise Price or Acquisition Price
Agent's Option <sup>(1)</sup>	2,610,000 Agent's Option Units (2,610,000 Unit Shares and 1,305,000 Unit Warrants)	30 days from the Closing	\$0.25 per Agent's Option Unit
Compensation Options <sup>(2)(3)</sup>	1,600,800 Compensation Options (1,600,800 Compensation Unit Shares and 800,400 Compensation Unit Warrants)	12 months from the Listing Date	\$0.25 per Compensation Option



Corporate Finance Fee Units <sup>(4)</sup>	1,000,500 (1,000,500 Corporate Finance Fee Unit Shares and 500,250 Corporate Finance Fee Unit Warrants)	On Closing	\$0.50 per Corporate Finance Fee Unit Warrant
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**Notes:**

- (1) This Prospectus also qualifies the distribution of the Agent's Option and the Agent's Option Units. See "*Plan of Distribution*".
- (2) This Prospectus also qualifies the distribution of the Compensation Options. See "*Plan of Distribution*".
- (3) Each Compensation Option is exercisable to acquire one Compensation Unit at the Offering Price for a period of 12 months following the Closing. This Prospectus qualifies the distribution of the Compensation Units. See "*Plan of Distribution*".
- (4) This Prospectus also qualifies the distribution of the Corporate Finance Fee Units. See "*Plan of Distribution*".
- (5) Assumes the Agent's Option is exercised in full.

**There is no market through which these securities may be sold and purchasers may not be able to resell securities purchased under this Prospectus. This may affect the pricing of the securities in the secondary market, the transparency and availability of trading prices, the liquidity of the securities, and the extent of issuer regulation. See "*Risk Factors*".**

As at the date of this Prospectus, the Company does not have any of its securities listed or quoted, has not applied to list or quote any of its securities, and does not intend to apply to list or quote any of its securities, on the Toronto Stock Exchange, Aequitas NEO Exchange Inc., a U.S. marketplace, or a marketplace outside Canada and the U.S. (other than the Alternative Investment Market of the London Stock Exchange or the PLUS markets operated by PLUS Markets Group plc).

The Company has applied to list the Unit Shares on the CSE. The CSE provided its conditional approval of the listing on December 7, 2020. Listing is subject to the Company fulfilling all of the requirements of the CSE, including meeting all minimum listing requirements. There is no guarantee that the CSE will provide approval for the listing of the Common Shares. The Company has not applied and does not intend to list the Unit Warrants. See "*Plan of Distribution*".

**An investment in the Units is speculative and involves a high degree of risk and should only be made by persons who can afford the total loss of their investment. Prospective investors should consider certain risk factors in connection with an investment in the Company. See "*Statement Regarding Forward-Looking Information*" and "*Risk Factors*".**

Each of: (i) William Garner, Executive Chairman and a director of the Company, (ii) James Kuo, Chief Executive Officer of the Company, (iii) Peter Molloy, a director of the Company, and (iv) James Gilligan, President and Chief Scientific Officer of the Company reside outside of Canada and have appointed the following agent for service of process:

Name of Agent	Address of Agent
Pushor Mitchell LLP	301 – 1665 Ellis Street, Kelowna British Columbia, Canada, V1Y 2B3

Purchasers are advised that it may not be possible for investors to enforce judgments obtained in Canada against any person or company that is incorporated, continued or otherwise organized under the laws of

a foreign jurisdiction or resides outside of Canada, even if the party has appointed an agent for service of process. See *“Enforcement of Judgments Against Foreign Persons”*.

The Company is not a “related” nor a “connected issuer” of the Agent as defined in National Instrument 33-105 - *Underwriting Conflicts*.

**Prospective investors are advised to consult their own tax advisors regarding the application of Canadian federal income tax laws to their particular circumstances, as well as any other provincial, foreign and other tax consequences of acquiring, holding, or disposing of Units, including the Canadian federal income tax consequences applicable to a foreign controlled Canadian company that acquires Units.**

Except in certain limited circumstances, the Units distributed under this Prospectus will be deposited with CDS Clearing and Depository Services Inc. (“CDS”) in electronic form on the Closing Date through the non-certificated inventory system administered by CDS. A purchaser of Units will receive only a customer confirmation from the Agent or other registered dealer through whom the Units are purchased.

**PROSPECTIVE INVESTORS SHOULD RELY ONLY ON THE INFORMATION CONTAINED IN THIS PROSPECTUS. NEITHER THE AGENT NOR THE COMPANY HAVE AUTHORIZED ANYONE TO PROVIDE YOU WITH DIFFERENT INFORMATION. READERS SHOULD ASSUME THAT THE INFORMATION APPEARING IN THIS PROSPECTUS IS ACCURATE ONLY AS OF ITS DATE, REGARDLESS OF ITS TIME OF DELIVERY. THE COMPANY’S BUSINESS, FINANCIAL CONDITION, RESULTS OF OPERATIONS AND PROSPECTS MAY HAVE CHANGED SINCE THAT DATE.**

**AGENT**

**CANACCORD GENUITY CORP.  
161 Bay Street, Suite 3000  
Toronto, Ontario  
M5J 2S1  
Telephone: 416-869-7368**

Psilocybin is currently a Schedule III drug under the Controlled Drugs and Substances Act, S.C. 1996, c. 19 (the “CDSA”) and it is a criminal offence to possess substances under the CDSA without a prescription. Health Canada has not approved psilocybin as a drug. While the Company is focused on developing products using psilocybin, the Company does not have any direct or indirect involvement with the illegal selling, production or distribution of any substances. The Company does not currently manufacture, store or otherwise handle psilocybin directly and will only do so through agents within laboratory and clinical trial settings conducted within approved regulatory frameworks. The Company’s products that contain psilocybin or other psychedelic compounds will not be commercialized prior to applicable regulatory approval, which will only be granted if clinical evidence of safety and efficacy for the intended uses is successfully developed.

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## GLOSSARY

In this Prospectus, the following capitalized terms have the following meanings, in addition to other terms defined elsewhere in this Prospectus.

“**Agency Agreement**” means the agency agreement dated December 8, 2020 between the Agent and the Company in respect of the Offering.

“**Agent**” means Canaccord Genuity Corp.

“**Agent’s Commission**” means the cash commission to be paid on the Closing Date by the Company to the Agent pursuant to the Agency Agreement.

“**AMRI**” means Albany Molecular Research Institute.

“**API**” means an active pharmaceutical ingredient.

“**Articles**” means the articles of the Company.

“**Audit Committee**” means the Audit Committee of the Board.

“**BCBCA**” means the *Business Corporations Act* (British Columbia).

“**Board**” or “**Board of Directors**” means the board of directors of the Company.

“**CEO**” means the Chief Executive Officer of the Company.

“**CFO**” means the Chief Financial Officer of the Company.

“**cGMP**” means current good manufacturing practice.

“**Closing**” means the completion of the Offering on the Closing Date.

“**Closing Date**” means the day on which the Offering is closed, which in any event must occur within 90 days of the issuance of the receipt for this Prospectus.

“**Common Shares**” means the common shares in the capital of the Company, as currently constituted.

“**CRO**” means contract research organization.

“**CSA**” means the Comprehensive Drug Abuse Prevention and Control Act (United States).

“**CSE**” or “**Exchange**” means the Canadian Securities Exchange.

“**DEA**” means the U.S. Drug Enforcement Agency.

“**EMA**” means the European Medicines Agency.

“**Escrow Agent**” means Computershare Investor Services Inc.

“**FDA**” means the U.S. Food and Drug Administration.

“**FDCA**” means the U.S. *Federal Food, Drug and Cosmetics Act*, as amended.

“**GCP**” means good clinical practices;

“**GLP**” means good laboratory practices;

“**HIF**” means hypoxia-inducible transcription factors.

“**HPPD**” means Hallucinogen Persisting Perception Disorder.

“**IFRS**” means the International Financial Reporting Standards as issued by the International Accounting Standards Board and the interpretations thereof by the International Financial Reporting Interpretations Committee and the former Standing Interpretations Committee.

“**IND**” means an investigational new drug.

“**Insider**” means a director or senior officer of the Company; a director or senior officer of a company that is an insider or subsidiary of the Company; a person that beneficially owns, directly or indirectly, or controls or has direction over, or a combination of such ownership and control and direction over, voting shares carrying more than 10% of the voting rights attached to all outstanding voting shares of the Company; or the Company itself if it holds any of its own securities.

“**Listing Date**” means the date the Company’s Common Shares are first listed for trading on the Exchange.

“**MD&A**” means management’s discussion and analysis of the Company for the year ended August 31, 2020.

“**NCE**” means a new chemical entity.

“**NDA**” means a new drug application.

“**NEO**” has the meaning ascribed to such term under “Director and Executive Compensation”

“**NI 41-101**” means National Instrument 41-101 – *General Prospectus Requirements*.

“**NI 52-110**” means National Instrument 52-110 – *Audit Committees*.

“**NI 58-101**” means National Instrument 58-101 – *Disclosure of Corporate Governance Practices*.

“**NP 46-201**” means National Policy 46-201 – *Escrow for Initial Public Offerings*.

“**NP 58-201**” means National Policy 58-201 – *Corporate Governance Guidelines*.

“**Offering**” means the offer for sale by the Company of the Units at the Offering Price in accordance with the terms of the Agency Agreement and this Prospectus.

“**Offering Price**” means \$0.25 per Unit.

“**Option**” means an option to purchase a Common Share issued pursuant to the Stock Option Plan.



“**Option Holder**” has the meaning ascribed to such term under “*Options to Purchase Securities – Stock Option Plan*”.

“**Order**” has the meaning ascribed to such term under “*Directors and Executive Officers – Cease Trade Orders, Bankruptcies*”.

“**PCT Application**” means an application under the Patent Cooperation Treaty.

“**PFN™**” means the Company’s psilocybin-for--neuropsychiatric disorders program.

“**Plan**” means the Company’s stock option plan.

“**pO<sub>2</sub>**” means partial pressure of oxygen.

“**Preferred Shares**” means the preferred shares in the capital of the Company, as currently constituted.

“**Prospectus**” means this Prospectus.

“**PWS**” means Prader-Willi Syndrome.

“**RDSP**” means a “registered disability savings plan”, as defined in the Tax Act.

“**Registered Plan**” means a TFSA, RRSP, RRIF, RDSP or RESP.

“**Regulations**” means the regulations promulgated under the Tax Act.

“**RESP**” means a “registered education savings plan” as defined in the Tax Act.

“**RRIF**” means a “registered retirement income fund” as defined in the Tax Act.

“**RRSP**” means a “registered retirement savings plan” as defined in the Tax Act.

“**SAE**” means serious adverse events.

“**SEDAR**” means the System for Electronic Document Analysis and Retrieval.

“**Selling Provinces**” means British Columbia, Alberta and Ontario, in which this Prospectus has been filed and in which the Offering will be made.

“**STS**” means soft tissue sarcoma.

“**Tax Act**” means the *Income Tax Act* (Canada), as amended from time to time.

“**TFSA**” means a “tax-free savings account” as defined in the Tax Act.

“**Transfer Agent**” means Computershare Investor Services Inc.

“**TRP-1001**” means our oral dosage form of razoxane which we are currently evaluating for the treatment of STS.

“**TRP-8802**” means our initial PFN™ program candidate, which is an oral dosage form of psilocybin that we are currently evaluating for the treatment of fibromyalgia.

“**United States**” or “**U.S.**” means the United States of America, its territories and possessions, any State of the United States and the District of Columbia.

“**UPS**” means undifferentiated pleomorphic sarcoma.

“**U.S. Securities Act**” has the meaning ascribed to such term on the cover page of this Prospectus.

“**Warrant Agent**” means Computershare Trust Company of Canada.

“**Warrant Indenture**” means the warrant indenture to be dated as of the Closing Date between the Company and the Warrant Agent.

## NOTE TO INVESTORS

### About this Prospectus

Except as otherwise indicated or the context otherwise requires in this Prospectus, references to the “Company”, “us”, “we”, “our” refer to Tryp Therapeutics Inc., a company incorporated under the laws of British Columbia.

Words importing the singular in this Prospectus include the plural and vice versa, and words importing any gender include all genders.

**An investor should read this entire Prospectus and consult their own professional advisors to assess the income tax matters, legal requirements, risk factors and other aspects of their investment in the Units.**

**An investor should rely only on the information contained in this Prospectus. The Company has not, and the Agent has not, authorized anyone to provide investors with additional or different information. If anyone provides an investor with additional or different or inconsistent information, including statements in media articles about the Company, the investor should not rely on it.**

We are not, and the Agent is not, offering to sell these securities in any jurisdictions where the offering or sale is not permitted. The information contained in this Prospectus is accurate only as of the date of this Prospectus, regardless of the time of delivery of this Prospectus or any sale of the Units. The Company’s business, financial condition, results of operations and prospects may have changed since the date of this Prospectus.

For investors outside Canada, neither the Company nor the Agent have done anything that would permit the Offering or possession or distribution of this Prospectus in any jurisdiction where action for that purpose is required, other than in Canada. Investors are required to inform themselves about, and to observe any restrictions relating to, the Offering and the distribution of this Prospectus.

The information contained on the Company’s website is not intended to be included in or incorporated by reference into this Prospectus and investors should not rely on such information when deciding whether or not to invest in the Units.

Any graphs, tables or other information demonstrating the historical performance or current or historical attributes of the Company or any other entity contained in this Prospectus are intended only to illustrate historical performance or current or historical attributes of the Company or such entities and are not necessarily indicative of future performance of the Company or such entities.

This Prospectus includes a summary description of certain material agreements of the Company, such as the Agency Agreement. See “*Material Contracts*”. The summary description discloses all attributes that the Company believes would be material to a prospective purchaser of Units but is not complete and is qualified in its entirety by reference to the terms of such material agreements, which will be filed with the Canadian securities regulatory authorities and available on SEDAR. Investors are encouraged to read the full text of such material agreements.

Investors are urged to read the information under the headings “*Risk Factors*” and “*Cautionary Note Regarding Forward-Looking Information*” appearing elsewhere in this Prospectus.

## **Presentation of Financial Information and Accounting Principles**

The Company presents its financial statements in Canadian dollars. The financial statements of the Company as at August 31, 2020 and for the period then ended have been prepared in accordance with IFRS. Certain financial information set out in this Prospectus is derived from such financial statements.

In this Prospectus, unless otherwise indicated, all dollar amounts are expressed in Canadian dollars and references to “\$” are to Canadian dollars. References to “USD” are to U.S. dollars.

## **Third Party Information**

Unless otherwise indicated, information contained in this Prospectus concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market share, is based on information from independent industry analysts and third-party sources (including industry publications, surveys and forecasts) and management estimates. Management estimates are derived from publicly available information released by independent industry analysts and third-party sources, as well as data from our internal research, and are based on assumptions made by us based on such data and our knowledge of our industry and markets, which we believe to be reasonable. None of the sources cited in this Prospectus has consented to the inclusion of any data from its reports, nor have we sought their consent. Our internal research has not been verified by any independent source, and we have not independently verified any third-party information. While we believe the market position, market opportunity and market share information included in this Prospectus is generally reliable, such information is inherently imprecise. In addition, projections, assumptions and estimates of our future performance and the future performance of our industry and the markets in which we operate are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described under the “*Cautionary Note Regarding Forward-Looking Information*” and “*Risk Factors*” sections of this Prospectus and elsewhere in this Prospectus. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties or by us.

## **Enforcement of Judgments Against Foreign Persons**

Each of: (i) William Garner, Executive Chairman and a director of the Company, (ii) James Kuo, Chief Executive Officer of the Company, (iii) Peter Molloy, a director of the Company, and (iv) James Gilligan, President and Chief Scientific Officer of the Company reside outside of Canada and have appointed the following agent for service of process:

<b>Name of Agent</b>	<b>Address of Agent</b>
Pushor Mitchell LLP	301 – 1665 Ellis Street, Kelowna British Columbia, Canada, V1Y 2B3

Purchasers are advised that it may not be possible for investors to enforce judgments obtained in Canada against any person or company that is incorporated, continued or otherwise organized under the laws of a foreign jurisdiction or resides outside of Canada, even if the party has appointed an agent for service of process.

## **MARKETING MATERIALS**

Any “template version” of any “marketing materials” (as such terms are defined in NI 41-101) that are utilized by the Agent in connection with the Offering will be incorporated by reference into the Prospectus. However, any such “template version” of “marketing materials” will not form part of the Prospectus to the extent that the contents of the “template version” of “marketing materials” are modified or superseded by a statement contained in the Prospectus.

Any “template version” of “marketing materials” filed under the Company’s profile on SEDAR after the date of the Prospectus and before the termination of the distribution under the Offering (including any amendments to, or an amended version of, any “template version” of any “marketing materials”) will be deemed to be incorporated into the Prospectus.

## **TRADEMARKS, TRADE NAMES AND SERVICE MARKS**

This Prospectus contains certain trademarks, which are protected under applicable intellectual property laws and are the Company’s property. Solely for convenience, the Company’s trademarks and trade names referred to in this Prospectus may appear without the ® or ™ symbol, but such references are not intended to indicate, in any way, that the Company will not assert, to the fullest extent under applicable law, its rights to these trademarks and trade names.

## **CAUTIONARY NOTE REGARDING FORWARD-LOOKING INFORMATION**

This Prospectus contains “forward-looking information” within the meaning of applicable securities laws in Canada. Forward-looking information may relate to our future outlook and anticipated events or results and may include information regarding our financial position, business strategy, growth strategies, budgets, operations, financial results, taxes, dividend policy, plans and objectives. Particularly, information regarding our expectations of future results, performance, achievements, prospects or opportunities or the markets in which we operate is forward-looking information. In some cases, forward-looking information can be identified by the use of forward-looking terminology such as “plans”, “targets”, “expects” or “does not expect”, “outlook”, “prospects”, “strategy”, “intends”, “believes”, or variations of such words and phrases or state that certain actions, events or results “may”, “could”, “would”, “might”, “will”, “occur” or “be achieved”. In addition, any statements that refer to expectations, intentions, projections or other characterizations of future events or circumstances contain forward-looking information. Statements containing forward-looking information are not historical facts but instead represent management’s expectations, estimates and projections regarding future events or circumstances.

Forward-looking information contained in this Prospectus and other forward-looking information are based on our opinions, estimates and assumptions in light of our experience and perception of historical trends, current conditions and expected future developments, as well as other factors that we currently believe are appropriate and reasonable in the circumstances. Despite a careful process to prepare and review the forward-looking information, there can be no assurance that the underlying opinions, estimates and assumptions will prove to be correct.

The forward-looking information in this Prospectus represents our expectations as of the date of this Prospectus. The Company does not have any policies to update or revise any forward-looking information

whether as a result of new information, future events or otherwise, except as required under applicable securities laws in Canada.

Forward-looking information in this Prospectus includes, but is not limited to, information relating to:

- the timing, progress, and results of preclinical and clinical studies for TRP-8802, TRP-1001, and any future drug candidates we may develop, including statements regarding the timing of initiation and completion of studies and related preparatory work, the period during which the results of the studies will become available, and our research and development programs;
- the potential of undesirable side effects or other properties relating to our drug candidates that could delay or prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences following any potential marketing approval;
- the potential for our identified research priorities to advance our drug candidates;
- the potential benefits of and our ability to establish collaborations or strategic relationships or obtain additional funding;
- the potential for substantial delays in our clinical studies or our failure to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities;
- our ability to obtain and maintain regulatory approval of our drug candidates, including TRP-8802, TRP-1001, and any other future drug candidates, and any related restrictions, limitations and/or warnings in the label of an approved product candidate;
- our intellectual property position, including the scope of protection, if any, we are able to establish and maintain for intellectual property rights covering TRP-8802, TRP-1001, and any additional drug candidates we may develop, and our ability not to infringe, misappropriate, or otherwise violate any third-party intellectual property rights;
- our ability and the potential to successfully manufacture our drug candidates for clinical studies and for commercial use, if approved;
- the commercial prospects of our drug candidates in light of the intellectual property rights of others;
- our ability to obtain funding for our operations, including funding necessary to complete further development of our drug candidates;
- our plans to research, develop, and commercialize our drug candidates;
- our ability to attract collaborators with development, regulatory, and commercialization expertise;
- the size and growth potential of the markets for our drug candidates;
- the rate and degree of market acceptance and clinical utility of TRP-8802, TRP-1001 and any future drug candidates we may develop, if approved;

- the pricing and reimbursement of TRP-8802, TRP-1001 and any future drug candidates we may develop, if approved;
- regulatory developments in the United States and other countries;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- the success of competing therapies that are or may become available;
- our ability to retain the continued service of our key professionals and to identify, hire, and retain additional qualified professionals;
- the accuracy of our estimates regarding expenses, future revenue, capital requirements, and needs for additional financing;
- the impact of laws and regulations and potential changes to laws and regulations; and
- our expectations related to the use of proceeds from this Offering.

We have based the forward-looking information largely on the Company's current expectations, estimates, assumptions, and projections about future events and financial and other trends that the Company believes, as of the date of such statements, may affect its business, financial condition and results of operations. Such expectations, estimates, assumptions, and projections, many of which are beyond our control, include, but are not limited to: (i) the Company's ability to obtain positive results of preclinical and clinical studies; (ii) the Company's ability to obtain regulatory approvals; (iii) general business and economic conditions; (iv) the Company's ability to successfully out-license or sell its current drug candidates and in-license and develop new drug candidates; (v) the availability of financing on reasonable terms; (vi) the Company's ability to attract and retain skilled staff; (vii) market competition; (viii) the products and technology offered by the Company's competitors; and (ix) the Company's ability to protect patents and proprietary rights.

In evaluating forward-looking information, current and prospective shareholders should specifically consider various factors, including risks related to:

- Actual results could differ materially from those anticipated in the forward-looking information as a result of the risk factors described herein, including those described in the section entitled "Risk Factors" in this Prospectus.
- We have incurred operating losses since our inception and anticipate that we will incur significant continued losses for the foreseeable future. Even if this Offering is successful, we will need to raise additional funding to advance our drug candidates through preclinical and clinical studies, and such funding may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our drug development efforts or other operations.
- We are heavily dependent on our PFN™ program and the successful development of drug candidates discovered through such program, including TRP-8802, which is in the early stages of development.

We cannot give any assurance that we will continue to create a pipeline of drug candidates or that our drug candidates will receive regulatory approval.

- We intend to concentrate a significant amount of our research and development efforts on the treatment of disorders of the brain and nervous system, a field that has seen limited success in drug development.
- Our drug candidates may cause serious adverse events or other undesirable side effects that could delay their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following market approval, if any.
- Failures or delays in the commencement or completion of, or ambiguous or negative results from, our ongoing or planned clinical studies of our drug candidates could result in increased costs to us and could delay, prevent, or limit our ability to continue our business.
- Many other entities are developing drug candidates that include psilocybin or other psychoactive 5HT<sub>2A</sub> receptor agonists as an API, which may result in competition from off-label use.
- We may depend on collaborations with third parties for the research, development, and commercialization of certain of our drug candidates. If any such collaborations are not successful, we may not be able to realize the market potential of those drug candidates.
- We expect to rely on third parties to conduct any clinical studies for our drug candidates, on third-party suppliers to manufacture our clinical drug supplies for our drug candidates, and on single-source suppliers for some of the components and materials used in our drug candidates. If these third parties do not successfully carry out their contractual or legal duties or meet expected deadlines, we may not receive regulatory approval and our business could be substantially harmed.
- Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection for licensed patents, licensed pending patent applications and potential future patent applications and patents could be reduced or eliminated for non-compliance with these requirements.
- Any claims or lawsuits relating to infringement of intellectual property rights brought by or against us will be costly and time consuming and may adversely affect our business, financial condition, and results of operations.
- Our executive officers, directors, principal shareholders, and their affiliates represent beneficial ownership, in the aggregate, of approximately 36.05% of our outstanding Common Shares (on a post-Offering basis, assuming the Agent's Option is not exercised) and will, acting together, be able to exercise significant control over the Company after the initial public offering, which will limit the ability of our other shareholders to influence corporate matters, could delay or prevent a change in corporate control, and may adversely affect the market price of our Common Shares.

This list of factors should not be construed as exhaustive. All subsequent forward-looking information attributable to our Company herein is expressly qualified in its entirety by the cautionary statements contained in or referred to herein.



## SUMMARY OF PROSPECTUS

*The following is a summary of the principal features of the Offering and is qualified in its entirety by, and should be read together with, the more detailed information, financial statements and MD&A contained elsewhere in this Prospectus. This summary does not contain all of the information a potential investor should consider before investing in the Units.*

### **The Company**

The Company was incorporated under the BCBCA on September 24, 2019 under the name “Artos Pharma Corp.”. On June 30, 2020, the Company changed its name to “Tryp Therapeutics Inc.” The Company’s registered and records and head office is located at #335, 1632 Dickson Avenue, Kelowna, British Columbia V1Y 7T2.

The Company is a pharmaceutical company focused on bringing transformative medicine with known safety profiles to diseases with no effective first-line treatments. We intend to do this through the development of compounds with known activity and/or safety profiles. Our lead program is designed to address neuropsychiatric disorders through the therapeutic dosing of synthetic psilocybin. We are currently evaluating potential lead indications for our psilocybin-for-neuropsychiatric disorders program, which we refer to as our PFN™ program, including fibromyalgia and Prader-Willi Syndrome. In addition to our PFN™ program, we are developing razoxane for the treatment of soft-tissue sarcomas. We continue to evaluate potential additional indications for our existing programs, as well as other drug candidates with known activity and/or safety profiles that may have utility in the treatment of rare diseases or other diseases with high unmet medical needs.

### **The Offering**

**Offering:** The Company is offering 17,400,000 Units at a price of \$0.25 per Unit for gross proceeds of \$4,350,000. The Units are being offered on a “commercially reasonable efforts” basis pursuant to an Agency Agreement dated December 8, 2020 between the Company and the Agent.

This Offering is subject to the completion of a minimum subscription of 17,400,000 Units (\$4,350,000). In the event such subscriptions are not attained within 90 days of the issuance of the final receipt for this Prospectus or, if a receipt is issued for an amendment to this Prospectus, within 90 days of the issuance of such receipt and, in any event, not later and 180 days from the date the receipt for the Prospectus, all subscription monies will be returned to the subscribers without interest or deduction, unless the subscribers have otherwise instructed the Agent.

See “*Plan of Distribution*”.

**Agent’s Commission:** Pursuant to the terms and conditions of the Agency Agreement, the Company has agreed to pay the Agent the Commission, equal to the sum of (i) 8.0% of the gross proceeds of the Offering (including any gross proceeds raised on exercise of the Agent’s Option), other than the gross proceeds raised from President’s List Sales and (ii) 4.0% of the gross proceeds raised from President’s List Sales, payable in cash from the proceeds of the Offering. The Agent will also receive, as additional compensation, Compensation Options to

purchase that number of Compensation Units that is equal to 8.0% of the Units sold pursuant to the Offering (including any Agent's Option Units sold pursuant to the exercise of the Agent's Option), but excluding the Units sold pursuant to President's List Sales. In connection with President's List Sales, the Agent will receive Compensation Options to purchase that number of Compensation Units that is equal to 4.0% of the Units sold pursuant to the President's List Sales. Each Compensation Option is exercisable to purchase one Compensation Unit at a price of \$0.25 for a period of 12 months from the Listing Date. The Company has also agreed to pay the Agent a corporate finance fee, which shall be satisfied through the issuance to the Agent of such number of Corporate Finance Fee Units as equals 5.0% of the number of Units issued pursuant to the Offering (including any Agent's Option Units sold pursuant to the exercise of the Agent's Option).

This Prospectus also qualifies the grant of the Compensation Options and the Compensation Units issuable upon exercise of the Compensation Options and the Corporate Finance Fee Units. See "*Plan of Distribution*".

**Agent's Option:**

Pursuant to the terms and conditions of the Agency Agreement, the Company granted the Agent an option to increase the size of the Offering by up to 2,610,000 Units. The Agent's Option is exercisable for a period of 30 days from the Closing Date at a price of \$0.25 per Agent's Option Unit. This Prospectus qualifies the grant of the Agent's Option and the distribution of any Agent's Option Units issued pursuant to the exercise of the Agent's Option. See "*Plan of Distribution*".

**Use of Proceeds:**

Assuming the Agent's Option is not exercised, the Company estimates receiving net proceeds of \$4,002,000 after deduction of the Commission (assuming no proceeds are raised from President's List Sales) but before deducting estimated expenses of the Offering of \$350,000.

If the Agent exercises the Agent's Option in full, the net proceeds to the Company from the Offering will be approximately \$4,602,300 after deduction of the Commission (assuming no proceeds are raised from President's List Sales) but before deducting estimated expenses of the Offering of \$350,000.

The working capital of the Company on the last day of the month before filing the Prospectus was \$497,794 (unaudited). The net funds expected to be available to the Company upon completion of the Offering and its intended use of such funds are indicated in the following tables:

Source of Funds	Amount (\$)
Working Capital as at November 30, 2020	\$497,794
Estimated Net Proceeds from the Offering <sup>(1)</sup>	\$4,002,000
Total Available Funds (unaudited)	\$4,499,794

**Note:**

(1) Assuming the Agent's Option is not exercised.

<b>Use of Available Funds</b>	<b>Amount (\$)</b>
Research, Development and IND-Enabling Activities for TRP-8802	\$1,500,000
Research, Development and IND-Enabling Activities for TRP-1001	\$400,000
General and Administrative Expenses <sup>(1)(2)</sup>	\$2,200,000
Unallocated Working Capital <sup>(3)</sup>	\$399,794
Total Available Funds (unaudited)	\$4,499,794

**Notes:**

(1) Includes \$350,000 estimated expenses of the Offering.

(2) Estimated operating expenses for the next 12 months are comprised of: \$660,000 for consulting fees, of which approximately \$464,000 is allocated to executive compensation; \$237,500 for professional services (including accounting and legal services); \$485,000 for investor relations activities; \$245,000 for administrative expenses; \$200,000 related to maintenance and protection of intellectual property; and \$272,500 for other miscellaneous expenses.

(3) Our unallocated working capital is to provide additional contingency for overhead and general and administrative expense overrun.

While the Company intends to spend the net proceeds from the Offering as stated above, there may be circumstances where, for sound business reasons, funds may be re-allocated at the discretion of the Board or management. See "Use of Proceeds".

**Risk Factors:**

An investment in the Company involves a substantial degree of risk and should be regarded as highly speculative due to the nature of the business of the Company. Prospective investors should carefully consider and evaluate all risks and uncertainties involved in an investment in the Company, including risks related to: government or regulatory approvals; permits and government regulation; the Company's limited operating history; laws and regulation; uninsured and underinsured risks; public health crises such as the COVID-19 pandemic; the global economy; the environment; social and environmental activism; dependence on management and key personnel; claims and legal proceedings; conflicts of interest; negative cash flow from operating activities; going concern risk; uncertainty of use of available funds; the Company's status as a reporting issuer; risks associated with acquisitions; force majeure; infrastructure; intellectual property risks; the possible lack of established market for the Common Shares; the speculative nature of an investment in the Company; price of the Common Shares may not represent the Company's performance or intrinsic fair value; securities or industry analysts; price volatility of publicly traded securities; dilution; dividends; the expected listing of the Common Shares on the CSE, and conflicts of interest. Prospective

purchasers should carefully consider the information set out under “*Risk Factors*” and the other information in this Prospectus before purchasing securities of the Company.

### **Selected Financial Information**

The following table sets out certain selected financial information of the Company for the period and as at the dates indicated. This information has been derived from the audited financial statements and related notes thereto included in this Prospectus. The Company prepares its financial statements in accordance with IFRS. Investors should read the following information in conjunction with those financial statements and related notes thereto, along with the MD&A.

	<b>Incorporation (September 24, 2019) to August 31, 2020 (audited)</b>
Total Revenues	Nil
Total Assets	\$2,035,045
Total Liabilities	\$192,708
Expenses	\$422,617
Net Loss	(\$422,617)
Net Loss per Common Share (basic and diluted)	\$0.02
Total Liabilities and Shareholders' Equity	\$2,035,045

### **Financial Statements**

The following financial statements of the Company are included as a schedule to this Prospectus:

Schedule A: Audited financial statements for the period ended August 31, 2020

The financial statements listed above have been prepared in accordance with IFRS.

Certain information included in the Company’s MD&A is forward-looking and based upon assumptions and anticipated results that are subject to uncertainties. Should one or more of these uncertainties materialize or should the underlying assumptions prove incorrect, actual results may vary significantly from those expected. See “*Cautionary Note Regarding Forward-Looking Information*”.

## CORPORATE STRUCTURE

### Name, Address and Incorporation

The Company was incorporated under the BCBCA on September 24, 2019 under the name “Artos Pharma Corp.” On January 9, 2020, the Company split its issued and outstanding common shares on a 1 (old) to 200 (new) basis. On June 23, 2020, the Company consolidated its issued and outstanding common shares on a 1 (old) to 250 (new) basis. On June 23, 2020, the Company replaced its articles. On June 30, 2020, the Company changed its name to “Tryp Therapeutics Inc.”

The Company’s registered and records and head office is located at #335, 1632 Dickson Avenue, Kelowna, British Columbia V1Y 7T2.

### Intercorporate Relationships

The Company has no subsidiaries.

## GENERAL DEVELOPMENT AND BUSINESS OF THE COMPANY

### Overview

We are a pharmaceutical company focused on developing compounds with known activity and/or safety profiles for the treatment of rare or orphan diseases and other diseases with high unmet medical needs. Our lead development program, which we refer to as our psilocybin-for-neuropsychiatry, or PFN™, program, is designed to treat neuropsychiatric disorders through the dosing of formulations of synthetic psilocybin. The initial indication for our PFN™ program is fibromyalgia. We are also evaluating additional indications for our PFN™ program, including hyperphagia in Prader-Willi Syndrome (“PWS”) and other neuropsychiatric-based chronic pain conditions and eating disorders.

In addition to our PFN™ program, we intend to pursue non-psychedelic drug candidates with known activity and/or safety profiles that may have utility in the treatment of rare or orphan diseases or other diseases with high unmet medical needs. As part of that program, we are developing a proprietary formulation of razoxane for the treatment of soft tissue sarcomas. We continue to evaluate additional indications for our existing programs, as well as other drug candidates that meet our criteria for development.

Because conducting large Phase 3 clinical trials and establishing manufacturing and commercialization operations are expensive, time consuming and carry increased levels of risk, our strategy includes:

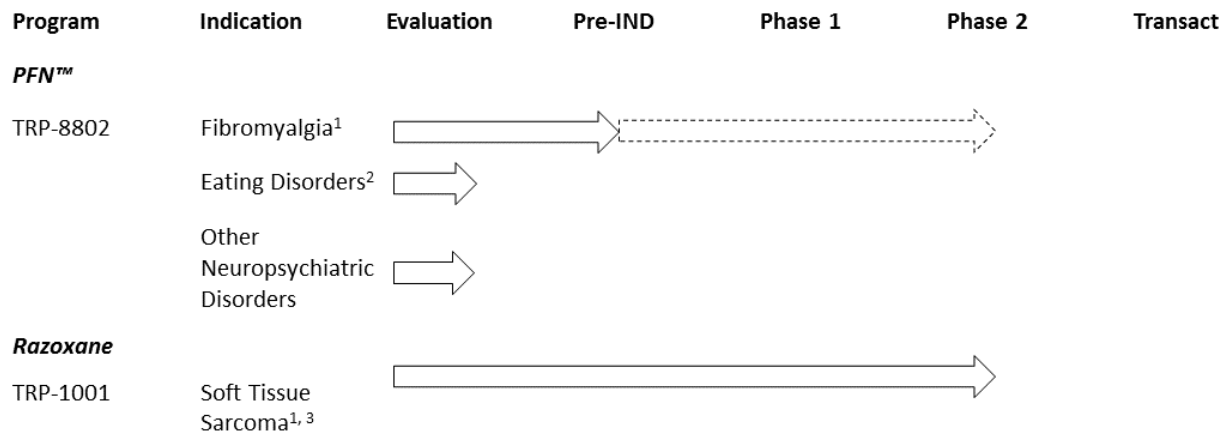
- partnering with other pharmaceutical companies to incorporate our PFN™ program into new and existing drug development programs;
- developing a robust pipeline of promising drug candidates at various stages of the development process to establish optionality, regular value inflection opportunities, and revenues;
- leveraging the existing preclinical and clinical data of our drug candidates and pursuing accelerated clinical development with smaller, shorter clinical trials when appropriate;
- co-developing certain drug candidates with leading academics and academic institutions, which may allow us to decrease our costs and the risks associated with the development of any such drug

candidates while leveraging the expertise and infrastructure of the academics and their related institutions;

- entering into relationships with established developers and manufacturers of API and finished drug products, including AMRI for our PFN™ program, that have the capacity to produce product at both research and development and commercial scale;
- pursuing approval of our drug candidates in the United States through the 505(b)(2) regulatory pathway. The 505(b)(2) pathway allows the filing of a new drug application (“NDA”) where at least some of the information required for approval comes from data in the public domain or the U.S. Food and Drug Administration’s (“FDA”) prior conclusions regarding the safety and effectiveness of approved compounds. The 505(b)(2) regulatory pathway is described further in *Government Regulation - Orange Book Listing*.
- developing drug candidates from the earlier stages of clinical development through Phase 2 clinical trials, with the objectives of rapid, cost effective risk reduction and value creation followed by strategic sales of the candidates to larger pharmaceutical companies or establishment of strategic partnerships for late stage clinical development and subsequent commercialization; and
- entering into early discussions with the FDA regarding our clinical development plans, requirements for approval of our drug candidates, and our ability to proceed directly into Phase 2 clinical trials, when appropriate.

We have carefully selected specific drug candidates and diseases that we believe offer the greatest opportunity for therapeutic efficacy and commercial success. We also seek to treat diseases with unmet needs where we believe competition is limited. In consultation with leading academic institutions, researchers, clinicians, and key opinion leaders (“KOLs”), we intend to design clinical development programs that have clearly defined and achievable endpoints, which we believe will increase our chance of commercial success.

**Our Pipeline**



<sup>1</sup>Tryp intends to seek approval from FDA to proceed directly into a Phase 2 clinical trial based on existing preclinical and clinical data for the active pharmaceutical ingredients in TRP-8802 and TRP-1001.

<sup>2</sup>Eating disorders under evaluation include hyperphagia in the orphan disease Prader-Willi Syndrome.

<sup>3</sup>Multiple Phase 2 clinical trials of razoxane for the treatment of STS have been conducted by clinicians unaffiliated with Tryp.

For information regarding the clinical development plans for our drug candidates see “TRP-8802 For Fibromyalgia – Fibromyalgia – Clinical Development Plan”, “TRP-8802 for Hyperphagia in Prader-Willi Syndrome – PWS – Clinical Development Plan” and “TRP-1001 for Soft Tissue Sarcoma – TRP-1001 – Clinical Development Plan”.

## **History**

### *Fiscal 2019 (Inception to August 2020)*

The Company was incorporated in September 2019 under the BCBCA. The initial directors of the Company were William Garner, MD and James Kuo, MD. Dr. Garner was appointed Executive Chairman and Dr. Kuo was appointed CEO. In consultation with the Company’s advisors, Dr. Garner and Dr. Kuo focused the Company’s core business strategy on discovering and developing compounds with known efficacy and/or safety profiles for the treatment of rare or orphan diseases and other diseases with high unmet medical needs.

In July 2019, the Company began discussions with Gage Jull about joining the Board of Directors. Mr. Jull is a co-founder and Chairman of Bordeaux Capital Inc., a Toronto-based mergers & acquisitions advisory firm focused on emerging companies in the natural resources and other sectors.

In September 2019, Dr. Garner filed a provisional patent application with the United States Patent and Trademark Office for compositions and methods to improve the therapeutic benefit of bis-dioxopiperazines, which includes the drug razoxane (the “**Razoxane Patent Application**”).

In September 2019, the Company began discussions with Mr. Peter Molloy about joining the Board of Directors. Mr. Molloy has 25 years of experience creating, advising and investing in private and public companies, with a particular focus on the healthcare sector.

In September 2019, Mr. Thomas D’Orazio joined the Company as its Chief Operating Officer on a consulting basis. Mr. D’Orazio previously held positions at ImmunoPrecise Antibodies, Superna Life Sciences, QLT, and Merck, among others.

In January 2020, Dr. Garner assigned the Razoxane Patent Application to the Company.

In March 2020, Dr. Peter Guzzo joined the Company as its Vice President, Development on a consulting basis. Dr. Guzzo previously held positions at Consynance Therapeutics, Albany College of Pharmacy and Health Sciences, and Albany Molecular Research, Inc., among others.

In April 2020, Dr. Garner and Dr. Kuo filed a provisional patent application with the United States Patent and Trademark Office for therapeutic methods using psilocybin (the “**Psilocybin Patent Application**”).

In May 2020, the Company initiated discussions with multiple contract research, development and manufacturing organizations about developing and manufacturing a proprietary form of razoxane.

In May 2020, the Company initiated discussions with Dr. Rachel Wevrick, one of the leading research scientists specializing in translational research in PWS, including the development of preclinical animal models of PWS.

In May 2020, Mr. Larry Norder joined the Company as its Vice President, Manufacturing on a consulting basis. Mr. Norder previously held positions at Xenobiotix, IMC Group, and PanXome, among others.

In June 2020, the Company initiated discussions with Dr. Robin Carhart Harris, one of the world's leading academic researchers in the use of psychedelics as therapeutics, about providing advisory services regarding the use of our PFN™ program for the treatment of certain neuropsychiatric disorders.

In June 2020, the Company changed its name to Tryp Therapeutics Inc.

In June 2020, Ms. Terese Gieselman joined the Company as its Corporate Secretary on a consulting basis.

On August 4, 2020, the Company completed a seed round private placement financing for aggregate gross proceeds of approximately \$569,983. The Company issued an aggregate of 11,399,650 Common Shares at an offering price of \$0.05 per Common Share.

On August 4, 2020 the Company issued 500,000 Common Shares at \$0.05 per Common Share with a value of \$25,000 as shares for debt for marketing and corporate development services.

In August 2020, the Company initiated discussions with one of the world's leading academic research institutes in the field of chronic pain and fatigue regarding a potential collaboration for the clinical development of our PFN™ program for the treatment of fibromyalgia.

In August, 2020, Dr. Garner and Dr. Kuo assigned the Psilocybin Patent Application to the Company.

In August 2020, the Company completed a seed round private placement in two tranches for an aggregate of 3,325,405 Common Shares at a price of \$0.15 per Common Share as follows:

- i) August 14, 2020 – 2,825,405 Common Shares for gross proceeds of \$423,811; and
- ii) August 31, 2020 – 500,000 Common Shares for gross proceeds of \$75,000.

On August 14, 2020 the Company issued 166,667 Common Shares at \$0.15 per Common Share with a value of \$25,000 as shares for debt for marketing and corporate development services.

In August 2020, the Company engaged The Bracken Group as one of its clinical and regulatory affairs consultants regarding the use of razoxane for soft tissue sarcoma and other potential indications, with a particular focus on the United States.

In August 2020, the Company engaged Premier Endpoint as one of its clinical and regulatory affairs consultants regarding the use of razoxane for soft tissue sarcoma and other potential indications, with a particular focus on Europe.

In August 2020, the Company initiated discussions with Dr. Derek Ott, one of the leading clinicians specializing in the care and treatment of individuals with PWS and other genetic causes of early-onset excessive weight gain, about the use of our PFN™ program for the treatment of hyperphagia in PWS.

In August 2020, the Company and AMRI entered into an agreement pursuant to which AMRI will provide research, development and cGMP manufacturing services for a proprietary form of synthetic psilocybin that



will form the basis for the Company's PFN™ program. AMRI is a leading global contract research, development and manufacturing organization.

In September 2020, the Company entered into an agreement with Dr. Wevrick, pursuant to which Dr. Wevrick shall provide advisory services regarding the use of our PFN™ program to treat various neuropsychiatric disorders.

In September 2020, the Company converted the provisional Razoxane Patent Application into a PCT Application.

In September 2020, the Company began discussions with one of the world's leading cancer research centers about a potential collaboration for the clinical and regulatory development of razoxane for the treatment of soft tissue sarcoma.

In September 2020, the Company entered into an agreement with Dr. Ott, pursuant to which Dr. Ott shall provide advisory services regarding the use of our PFN™ program to treat various neuropsychiatric disorders.

In September 2020, the shareholders of the Company voted to expand the number of directors from two to four and to elect Mr. Molloy and Mr. Jull to the Board of Directors.

In October 2020, the Company entered into an agreement with Dr. Carhart Harris, pursuant to which Dr. Carhart Harris shall provide advisory services regarding the use of our PFN™ program to treat various neuropsychiatric disorders.

In November 2020, the Board of Directors of the Company appointed James Gilligan as the Company's President and Chief Scientific Officer and Terese Gieselman as the Company's Chief Financial Officer, each on a consulting basis.

## **Our Psilocybin-for-Neuropsychiatry (PFN™) Program**

### ***Psilocybin***

Psilocybin is a naturally occurring compound produced by numerous species of Psilocybe mushrooms, some of which have been used for centuries by various indigenous peoples for spiritual and cultural purposes. Psilocybin and similar drugs, such as lysergic acid diethylamide (LSD) and mescaline, fall into a pharmacological class often referred to as "classic psychedelics". Classic psychedelics are often characterized as having a dose-dependent capacity to potentiate profound altered states of consciousness through experienced alterations in sense perceptions (such as visual illusions, synesthesia, and distorted proprioception), space-time orientation, and emotional processing.

Psilocybin was first isolated from Psilocybe mushrooms in 1958 by Swiss chemist Dr. Albert Hofmann, and the first reported *de novo* synthesis of psilocybin was in 1963. It was marketed worldwide by Sandoz Ltd. in the 1960s as Indocybin for experimental and psychotherapeutic purposes. Through the late 1970s, more than 1,000 papers exploring the behavioral and clinical effects of classic psychedelics were published. However, concerns around widespread, non-medical use throughout the 1960s led to psilocybin being placed in the Schedule I category of controlled substances under the United Nations 1971 Convention on Psychotropic Substances, which effectively removed it from clinical use or scientific study for the next several decades.

Following ingestion of the psilocybin molecule, its phosphate group is enzymatically cleaved to produce psilocin. Psilocin is known to have an effect on 5-hydroxytryptamine (serotonin), or 5-HT, receptors, along with a host of other biogenic amine neurotransmitters.

Psilocybin is categorized as a Schedule I drug in the U.S. due to its abuse potential. A comprehensive review by researchers at The Johns Hopkins University School of Medicine using the structure of the eight factors of the U.S. Controlled Substance Act to assess the abuse potential of medically administered psilocybin was recently conducted. That review contends that in a medical context psilocybin does not have a high abuse potential and that there is no clear evidence of a physical dependence potential, based on animal and human data. Over the last decade, the therapeutic use of psilocybin has been studied in humans in a number of academic-sponsored studies and at least one industry-sponsored study. While the Company does not intend to take physical possession of psilocybin as part of its PFN™ program, its contract research, development and manufacturing partners will be required to acquire and maintain all licenses required for the possession of psilocybin.

### ***Our PFN™ Program***

By capitalizing on the poly-pharmacology of our PFN™ program, we believe we can create orally-delivered therapies that have distinct advantages over other chemical entities currently in the market, or in development, for certain neuropsychiatric disorders. These advantages include:

- increased efficacy;
- oral versus intravenous or subcutaneous dosing;
- compliance-favorable dosing regimens;
- natural blood-brain barrier penetration;
- enhanced safety and toxicity profiles;
- reduced risk of abuse; and
- reduced risk of addiction.

We are currently focused on therapeutic areas in which we believe our PFN™ program will provide the greatest benefit with a significant market opportunity. Our initial PFN™ program candidate is TRP-8802. The initial indication for TRP-8802 is fibromyalgia, a condition characterized by pain that is chronic and widespread. We intend to utilize our program to build out a pipeline of therapeutics for additional high-value disease targets. Hyperphagia in the orphan disease Prader-Willi Syndrome is currently under evaluation as a second indication for TRP-8802. We are also in discussions with and plan to establish research collaborations regarding our PFN™ program with several prominent universities and research labs and to secure licenses from these groups for the technologies resulting from the collaborations. It is anticipated that all clinical trials for our PFN™ program will take place in the United States.

In August 2020, we entered into an agreement with AMRI pursuant to which AMRI will provide research, development and cGMP manufacturing services for the development of a form of synthetic psilocybin that will form the basis of our PFN™ program. AMRI is a leading global contract research, development and manufacturing organization. While we have not contracted for manufacturing of the finished drug product for our PFN program, we are in discussions with several contract manufacturers for such services.

## ***Existing Preclinical and Clinical Safety Data for Psilocybin***

Based on the results of prior preclinical studies and the safety profile demonstrated in clinical trials of psilocybin conducted by third-parties, we believe there is a potential for us to enter into Phase 2 clinical development with limited, or even no, additional preclinical studies or Phase 1 trials, subject to discussion with the FDA. In addition, we are evaluating whether certain nonclinical animal models may be helpful in refining our clinical development plans and may choose to conduct such studies even if not required by the FDA. We intend to request a Type B meeting with the FDA to discuss our proposed approach for each indication we pursue.

In keeping with our strategy of developing drugs that have known safety and/or activity profiles, and which treat diseases with high unmet medical needs, we intend to rely on Section 505(b)(2) of the FDCA, which permits the filing of an NDA where at least some of the information required for approval comes from data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds. The preclinical and clinical data derived from the public domain that we may utilize in our request to open an IND and ultimately incorporate into an NDA may include, but is not limited, the data described in *Preclinical Toxicology Studies* and *Summary of the Safety of Psilocybin in Clinical Trials* below. We also intend to discuss with the FDA the possibility of Orphan Drug, Priority Review, Breakthrough Therapy, Accelerated Approval and/or Fast Track designations for our PFN™ program drug candidates when such designations may be available. See "*Expedited Development and Review Programs*" for descriptions of these designations. We believe that the use of these programs, if available, in addition to the 505(b)(2) regulatory pathway could potentially expedite the development of our PFN™ program candidates.

### *Preclinical Toxicology Studies*

#### Preclinical Toxicology

Preclinical studies to date suggest that psilocybin has very low toxicity, consistent with its reported safety profile in clinical studies, as discussed below. A study of rats found the median lethal dose (LD50) for psilocybin to be between 280-285 mg/kg, which is far higher than a 25-mg dose in humans (0.36 mg/kg in a 70-kg individual). Based on standard human equivalency doses (HED), the LD50 in rodents is approximately 5,000 times the dose that a 70-kg human would receive in our anticipated clinical trials of our PFN™ program drug candidates. The ratio between the LD50 and the median effective dose (ED50) is 641 per the U.S. National Institute for Occupational Safety and Health Registry of Toxic Effects, which compares favorably with many drugs approved for human use (e.g. aspirin has an LD50/ED50 of 199). When administered to awake animals (including rats, mice, rabbits, cats and dogs) at a dose of 10 mg/kg, autonomic effects were induced that included mydriasis, piloerection, irregularities in heart and breathing rate, and hyperglycemia that were time limited and completely resolved following exposure. Similar autonomic effects were observed when psilocybin at a dose of 1-4 mg/kg was administered to baboons.

Although the mutagenicity risk of psilocybin has not been definitively established, a study that utilized the micronucleus test in mice and administered psilocybin dosages of 4-16 mg/kg (significantly higher than a 25 mg dose in humans) found no evidence of genetic abnormalities, based on an absence of chromosome breakage.

### Summary of the Safety of Psilocybin in Clinical Trials

Numerous academic-sponsored studies of psilocybin have been conducted over the last decade, mostly in the areas of depressive and anxiety conditions. These studies have shown psilocybin to be generally well-tolerated, with low toxicity and no serious adverse events (“SAEs”) reported. As described above, the low toxicity profile of psilocybin is corroborated by nonclinical studies that indicate that very high levels of psilocybin are required to induce toxic effects in rodents. Over the course of its clinical development phase, the most commonly reported adverse events associated with psilocybin administration are psychological in nature and include anxiety, the induction of negative emotional states, and paranoid/delusional thinking during psilocybin sessions. Prolonged psychosis in healthy subjects after a single dose of psilocybin is extremely rare and in most cases associated with a psychotic predisposition. Cardiovascular changes, including increased blood pressure and heart rate, nausea, and headaches are also commonly reported with psilocybin administration.

As of November 1, 2020, there were 51 active or completed studies of psilocybin registered with the FDA. A summary of several recent academic-sponsored clinical trials of psilocybin is set forth below. While each used the same API, psilocybin, none of these studies used drugs candidates based on our PFN™ program. We believe that the safety profile of psilocybin exhibited in these and other clinical studies may potentially expedite commencement of clinical trials for drugs from our PFN™ program, as well as potentially lower development cost for our PFN™ program.

	<b>University of California Los Angeles Grob et al (2011)</b>	<b>New York University Ross et al (2016)</b>	<b>Johns Hopkins Griffiths et al (2016)</b>	<b>Imperial College London Carhart-Harris et al (2016, 2018)</b>	<b>Johns Hopkins Griffiths et al (Ongoing)</b>
Disorder	Anxiety related to advanced-stage cancer	Anxiety or depression related to cancer	Anxiety or depression in life-threatening cancer	Treatment-resistant depression	Major depressive disorder
N=(a)	12	29	51	20	21 <sup>(b)</sup>
Design	Double-blinded, placebo-controlled	Randomized, double-blinded, placebo-controlled	Randomized, double-blinded	Open-label	Randomized
Dose	14mg/70kg	21mg/70kg	Low (1 or 3mg/70kg) High (22 or 30mg/70kg)	10mg and subsequently 25mg	20mg/70kg (first) 30mg/70kg (second) <sup>(c)</sup>
Safety findings	No SAEs attributed to psilocybin administration	No SAEs attributed to psilocybin administration	No SAEs attributed to psilocybin administration	No SAEs attributed to psilocybin administration; only mild and transient adverse events	No SAEs attributed to psilocybin administration

Notes:

- (a) “N” indicates the number of patients that completed at least one administration session. In some studies, not all administration sessions and/or follow-up measures were completed for all patients. Reasons provided for patients not completing the studies included patients becoming too ill due to cancer progression, death due to cancer, or resumption of antidepressant medications.
- (b) Data as of December 2019. Study aims to ultimately enroll 24 patients.
- (c) Some patients received the 20mg/70 kg dose again for their second dose.

## TRP-8802 for Fibromyalgia

### *Fibromyalgia*

Fibromyalgia is a chronic pain syndrome that can be considered a neurosensory disorder characterized in part by abnormalities in pain processing by the central nervous system. Patients suffer from widespread pain, stiffness, fatigue, disrupted and unrefreshing sleep, and cognitive difficulties. Patients may also experience symptoms such as headache, anxiety and/or depression, and gastrointestinal distress, all of which lead to impairment of daily activities. Individuals suffering from fibromyalgia often display symptoms without an apparent associated cause, such as tissue inflammation or other damage. The systemic nature of fibromyalgia symptoms suggests that it is a centralized pain disorder with a dysfunction in pain processing within the brain. According to research conducted at the University of Jaén in Spain, the prevalence of fibromyalgia is estimated at 2%–4% in the general population, however prevalence varies among countries due to differences in the ways in which it is diagnosed, as well as differences in sociocultural beliefs and norms. According to the *Journal of Clinical Psychiatry*, it is estimated that fibromyalgia affects more than 5 million people in the United States and presents more frequently in women than in men. Coherent Market Insights estimates that the global fibromyalgia market is expected to reach USD3.6 billion by 2026.

### *Unmet Medical Need*

Two drugs, Cymbalta (duloxetine) and Lyrica (pregabalin), developed by Eli Lilly and Pfizer, respectively, are widely used for chronic pain conditions, including fibromyalgia. Cymbalta, originally developed as an antidepressant, has been approved for multiple chronic pain conditions and before facing generic competition achieved peak annual sales of US\$4.99 billion, as reported in Eli Lilly's 2012 annual report. Lyrica was originally developed for postherpetic neuralgia and painful diabetic peripheral neuropathy, then later expanded into fibromyalgia and pain due to spinal cord injury. Lyrica achieved revenue of US\$5.17 billion in 2014, as reported in Pfizer's 2014 Annual Review.

Despite these treatment options, substantial unmet medical need remains in the treatment of fibromyalgia. For example, according to researchers at Mayo Clinic College of Medicine, opioid use is reported in approximately 30% of fibromyalgia patients, despite the lack of evidence for their effectiveness and the risk of addiction and overdose. Many approved therapies have unclear or partially understood mechanisms of action, or may involve multiple potential mechanisms and targets, leading to inconsistent responses and side effects.

- *Efficacy.* Drugs currently in use lack a mechanism targeted specifically for chronic pain. Most therapies were originally developed as either anticonvulsants or antidepressants. According to researchers at Queen's University in Ontario, Canada, the proportion of patients treated with pharmacotherapy who achieve satisfactory pain reduction (defined as "at least a 50% reduction in pain intensity") is generally only 10% to 25% more than with placebo. This level of efficacy means that only one patient achieves a satisfactory level of pain reduction for every four to ten patients treated.
- *Tolerability.* All of the drugs currently used to treat fibromyalgia exhibit side effect profiles, including somnolence, dizziness, edema, tremors, nausea, constipation, and weight gain.

- *Dosing.* Many of the currently used drugs must be taken two to three times daily in order to maintain a pain relief response, if one is achieved at all. In a chronic condition, dosing multiple times daily can lead to a lack of patient compliance, which in turn leads to overall poor treatment outcomes.
- *Abuse potential.* Abuse of pain medications is commonly associated with opioids, but other chronic pain therapies have been recognized as having abuse potential. Specifically, Lyrica and Cymbalta are both recognized as carrying substantial risk of abuse. Additionally, Lyrica and Cymbalta both have the potential for severe withdrawal symptoms if discontinued abruptly.

Despite the availability of approved medications, only a minority of patients experience substantial benefit, and most will discontinue therapy because of either a lack of efficacy or tolerability problems. Prescription pain and sleep medications are frequently prescribed off-label for symptomatic relief, despite the lack of evidence that such medications provide a meaningful or durable therapeutic benefit, and many of these medications carry significant safety risks and risk of dependence.

#### *Fibromyalgia Clinical Development Plan*

We are developing TRP-8802, which is an oral dosage form of psilocybin for the treatment of fibromyalgia. Our development program includes extensive consultation with leading academic institutions, researchers, and clinicians in the fields of chronic pain and fatigue and the use of psilocybin for the treatment of neuropsychiatric disorders. We believe psilocybin's pharmacologic activity may make it effective in modulating pain through action in the descending pain inhibitory pathway. Effects are thought to be principally mediated through activation of 5-HT<sub>2A</sub> and 5-HT<sub>2C</sub> receptors in the central nervous system. These receptors are involved in peripheral and centrally mediated pain processes and in the regulation of mood, anxiety, and cognition. Additionally, 5-HT<sub>2A</sub> and 5-HT<sub>7</sub> receptors are thought to be involved in antinociceptive actions of the rostral ventromedial medulla of the descending pain inhibitory pathways that inhibit onward transmission of nociceptive information in the spinal cord.

Based on existing preclinical and clinical data regarding psilocybin, including that described in *Our Psilocybin-for-Neuropsychiatry (PFN™) Program – Existing Preclinical and Clinical Safety Data for Psilocybin*, we believe we may be able to initiate a Phase 2 clinical trial of TRP-8802 with minimal or no additional preclinical studies and without conducting a Phase 1 clinical trial, subject to discussion with the FDA.

In order to conduct a clinical trial of a drug candidate, an IND must be filed with the FDA that includes:

- Animal Pharmacology and Toxicology Studies – Preclinical data to permit an assessment as to whether the product is reasonably safe for initial testing in humans. Also included are any previous experiences with the drug in humans.
- Manufacturing Information – Information pertaining to the composition, manufacturer, stability, and controls used for manufacturing the drug substance and the drug product.
- Clinical Protocols and Investigator Information – Detailed protocols for proposed clinical studies to assess whether the initial-phase trials will expose subjects to unnecessary risks.

These requirements are the same for each phase of clinical trial, including Phase 2. FDA allows a trial sponsor to fulfill the requirements of animal pharmacology and toxicology studies through the use of third-party data that is available for reference. As psilocybin has an extensive history of published human safety trials and animal pharmacology and toxicology studies, we believe we may be able to meet the requirements of an

IND through reference to these studies, including those referenced in *Summary of the Safety of Psilocybin in Clinical Trials* above, and a thorough analysis of why the psilocybin in TRP-8802 should exhibit the same toxicology and safety profile of the psilocybin that was used in those studies.

We anticipate that any clinical trials of TRP-8802 will include psychological support from specially trained therapists. Such psychological support in psychedelic therapies is designed to facilitate patient safety and optimal therapeutic outcomes. While any final trial design will incorporate any FDA requirements and input from investigators, KOLs, and our consultants, we expect that treatment of individual patients in a TRP-8802 clinical trial will take place over a period of several weeks and will comprise the following stages:

- **Preparation:** The objectives of the preparation sessions are to establish a therapeutic alliance between the patient and therapist, and to demonstrate and practice the skills of self-directed inquiry and experiential processing.
- **TRP-8802 administration session:** A TRP-8802 administration session is anticipated to last approximately six to eight hours with a therapist and assisting therapist present throughout the session to establish psychological safety, minimize anxiety and encourage openness to all emerging experiences. An administration session will conclude after the acute effects of TRP-8802 subside, at which point patients will be evaluated for safety and discharged.
- **Post-administration integration:** The objectives of integration sessions are to help patients process the range of emotional and physical experiences facilitated by the TRP-8802 administration session and to generate insights that can lead to cognitive and behavioral changes.

We intend to request a Type B meeting to determine whether the FDA concurs with our clinical development plan for TRP-8802, including our ability to proceed directly into a Phase 2 clinical study. Any final clinical trial design will incorporate the requirements of the FDA and the input of investigators, KOLs, and our consultants.

## **TRP-8802 for Hyperphagia in Prader-Willi Syndrome**

### *Prader-Willi Syndrome*

In consultation with leading PWS researchers and clinicians, we are currently evaluating the potential efficacy and safety of psilocybin-based drugs for the treatment of hyperphagia in PWS, as well as potentially relevant animal models and potential clinical trial designs. PWS is a rare, complex metabolic/neuropsychiatric disorder, which is due to the absence of normally active paternally expressed genes from the chromosome 15q11-q13 region. PWS is an imprinted condition with 70-75% of the cases due to a *de novo* deletion in the paternally inherited chromosome 15 11-q13 region, 20-30% from maternal uniparental disomy 15, where the affected individual inherited 2 copies of chromosome from their mother and no copy from their father, and the remaining 2-5% from either microdeletions or epimutations of the imprinting center.

The National Organization for Rare Disorders estimates that 350,000 to 400,000 individuals worldwide have PWS. The American Academy of Pediatrics committee on genetics states that PWS affects both genders equally and occurs in people from all geographic regions; its estimated incidence is 1 in 15,000 to 1 in 25,000 live births. The mortality rate among PWS patients is 3% a year across all ages and 7% in those over 30 years of age. The mean age of death reported from a 40-year mortality study in the United States was  $29.5 \pm 15$  years (range: 2 months - 67 years). Based on its prevalence, we believe that PWS is a rare disease in the

United States and that if we pursue the development of TRP-8802 for PWS-related hyperphagia, it should qualify as an Orphan Drug.

### *Hyperphagia*

Hyperphagia is a hallmark symptom of PWS that is characterized by an extreme and abnormal drive to consume food, which cannot be satisfied. With increasing awareness among families and caregivers leading to significant control of food intake, many PWS patients today may not be obese, however, they remain hyperphagic. Obese PWS patients are more prone to cardiometabolic issues such as abnormal lipid profiles, diabetes and hypertension than non-obese PWS patients. Other complications in PWS patients include greater risk for autistic symptomatology, psychosis, sleep disorders, distress, food stealing and hoarding, withdrawal, sulking, nail-biting, insistence on sameness, and more pronounced attention-deficit hyperactivity disorder symptoms. The reported rates of psychotic symptoms in PWS patients are generally higher than those for individuals with other intellectual disabilities. Individuals with PWS show age-related increases in internalizing problems such as anxiety, sadness and a feeling of low self-esteem. Males are at greater risk for aggressive behavior, depression and dependent personality disorder and overall severity of psychopathology than females. Cognitively, most individuals with PWS function in the mild intellectual disability range with a mean IQ in the 60s to low 70s. The combination of food-related preoccupations and numerous maladaptive behaviors make it difficult for individuals with PWS and their families to live normal lives.

### *Unmet Medical Need*

Currently, there are no approved products to address PWS-associated hyperphagia and behaviors. While there are a number of therapeutic products at various stages of clinical development for the treatment of PWS, including for hyperphagia, several development programs for hyperphagia have recently failed to meet the clinical endpoints of their Phase 2 and Phase 3 clinical trials and some programs have been terminated. The only approved product for PWS is the injectable growth hormone somatropin, which is approved only for growth failure in pediatric PWS patients. It does not address PWS-associated hyperphagia and behaviors.

In a global patient survey conducted by the Foundation for Prader-Willi Research, 96% of respondents rated reducing hunger and 91% rated improving behavior around food as a very important or the most important symptom to be relieved by a new treatment. Among physical function and body composition symptoms, 93% of respondents rated improving metabolic health (reducing fat/increasing muscle) and 81% rated improving activity and stamina as a very important or the most important symptom to be relieved. Among behavioral and cognitive symptoms, 85% of respondents rated reduction of obsessive/compulsive behavior as very important or most important symptom to be relieved.

### *PWS Clinical Development Plan*

While the precise etiology of hyperphagia in PWS is not known, we believe that the promotion of plasticity in the prefrontal cortex, which is believed to be one of the neural mechanisms of psilocybin, combined with ongoing cognitive behavior therapy (“CBT”), may make TRP-8802 a promising candidate for the control or elimination of hyperphagia in certain PWS patients. Studies of psilocybin paired with psychotherapy and/or CBT have shown efficacy in treating cancer-related psychiatric distress, depression and anxiety, treatment-resistant depression, and nicotine or alcohol addiction. Clinical trials are ongoing to evaluate efficacy of



psychedelics in post-trauma disorders and anorexia nervosa, conditions where intrusive thoughts can drive maladaptive and life-threatening behavior. There are parallels between the intrusive thoughts in people with addiction, anorexia nervosa/binge eating, and obsessive-compulsive disorder and those with PWS, where affected individuals ruminate on the potential relief afforded by food, often devising elaborate plans that include lying, stealing, or running away to get food.

Based on existing preclinical and clinical data regarding psilocybin, including that described in *Existing Preclinical and Clinical Safety Data for Psilocybin*, we believe we may be able to initiate a Phase 2 clinical trial of TRP-8802 for the treatment of hyperphagia in PWS patients with minimal or no additional preclinical studies and without a Phase 1 clinical trial, subject to discussion with the FDA. The primary endpoint in Phase 2 and Phase 3 clinical trials for hyperphagia in PWS is typically “change in hyperphagia and food-related behaviors”, as measured by the Hyperphagia Questionnaire for Clinical Trials. We anticipate that this would likely be either the primary or a secondary endpoint of any Phase 2 or Phase 3 clinical trials that we conduct, though we are exploring other possible primary endpoints, including endpoints of a more objective nature, and clinical trial endpoints will be subject to discussion with the FDA. Secondary endpoints in PWS-related hyperphagia clinical studies include, among others, changes in anxiety and distress levels, as measured by the PWS Anxiety and Distress Questionnaire, total body weight, patient global impression of change and severity, quality of life, and physical activity and fatigue.

As with TRP-8802 for fibromyalgia, we anticipate that any clinical trials of TRP-8802 for PWS-related hyperphagia will include psychological support from therapists who are specially trained to facilitate patient safety and optimal therapeutic outcomes and have experience working with PWS patients. We also expect that any clinical trial of TRP-8802 for PWS-related hyperphagia will include preparation, administration and post-administration integration sessions over the course of several weeks.

We intend to request a Type B meeting to determine whether the FDA concurs with our clinical development plan, including our ability to proceed directly into a Phase 2 clinical study. In the event FDA requires us to conduct preclinical studies or if we determine to conduct studies in animal models, initiation of our clinical trials may be delayed.

### **Other Potential Indications for our PFN™ Program**

In addition to TRP-8802 for fibromyalgia and PWS-related hyperphagia, we are in the process of building a pipeline of other therapies that focus on the unique advantages of our PFN™ program across a variety of rare neuropsychiatric disorders and other neuropsychiatric disorders with high unmet medical needs. This may include evaluation of whether changes to our TRP-8802 formulation, dose level, route of administration, or other qualities may result in more efficacy and/or fewer side effects for a particular disorder. Among the classes of disorders we intend to evaluate are chronic pain conditions, where there is significant need for therapies without serious risk of dependency, and eating disorders. In its 2018 National Vital Statistics database, the U.S. Centers for Disease Control and Prevention estimated that, on average, 128 Americans die every day from an opioid overdose. An October 2020 article in the international journal *Drug and Alcohol Dependence* estimated that costs for opioid use disorder and fatal opioid overdose in the United States in 2017 were US\$1.02 trillion. We believe our PFN™ program has the potential to meet the need for safe and effective non-opioid chronic pain therapies.

## **Our Soft Tissue Sarcoma Program**

### ***TRP-1001 for Soft Tissue Sarcoma***

TRP-1001 is an oral formulation of razoxane, which we are evaluating for the treatment of soft tissue sarcoma (“**STS**”). Based on the results of a number of third-party clinical trials, we anticipate that we will initially focus on TRP-1001 in combination with a microtubule target agent from the vinca alkaloid class of compounds and radiation therapy.

#### *Soft Tissue Sarcoma*

Soft tissue sarcomas are a rare and diverse group of tumors that account for about 1% of all cancers in adults and 7% in children. It is estimated that STS consists of more than 100 different subtypes. STS tumors can occur anywhere within the body, including muscle, fat, nerves, vascular tissue, and other connective tissues. Median survival after development of distant metastases is estimated to be 11 to 18 months, but this varies significantly based on primary histologic subtype and treatment paradigms. The American Cancer Society estimates that in 2020 approximately 13,000 new cases of STS will be diagnosed and over 5,000 people will die of STS. The National Cancer Institute estimates that in 2017 there were approximately 150,000 people in the United States living with STS. Based on the prevalence of STS in the United States, we believe it is a rare disease and that TRP-1001 for the treatment of STS should qualify for Orphan Drug status.

Because of the large number of sarcoma subtypes, including malignant and non-malignant pathologies, clinical courses and therapeutic management are widely divergent. Sarcomas have clinical courses ranging from indolent to highly aggressive. Surgery is still the most common treatment, as it remains the best means of curing the disease. In most cases it is not clear what causes sarcoma, but family history and radiation exposure may increase risk.

#### *Unmet Medical Need*

STS patients are typically treated with surgery, followed by radiation therapy and/or chemotherapy. Chemotherapy is a cancer treatment that uses drugs to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing. When chemotherapy is taken by mouth or injected into a vein or muscle, the drugs enter the bloodstream and can reach cancer cells throughout the body. The most common chemotherapy drug used to treat STS is doxorubicin, also known by its brand name, Adriamycin. Doxorubicin is typically given alone as the standard first-line chemotherapy, however some specific types of STS seem to be more sensitive to certain other chemotherapy drugs, which may be used alone or in combination. While the FDA has granted a small number of approvals for new STS drugs in recent years, including Ayvakit (avapritnib), Yondelis (trabectedin), Tazverik (tazemetostat), and Lartruvo (olaratumab), which was subsequently withdrawn from the market, there remains a significant unmet medical need for new STS treatments.

In 2016, following completion of a 133 patient Phase 2 clinical trial, Eli Lilly’s Lartruvo (olaratumab), a platelet-derived growth factor receptor-alpha blocking antibody, was approved by both the FDA and the EMA for use with doxorubicin for the treatment of patients with STS who cannot be cured with radiation or surgery and who have a type of STS for which an anthracycline is an appropriate treatment. Lartruvo was the first new therapy approved by the FDA for the initial treatment of STS since doxorubicin’s approval over 40 years ago. In 2019, Lartruvo was withdrawn from the global market based on results of a Phase 3 post-approval clinical trial. As published on the FDA’s website, Lartruvo in combination with doxorubicin did not

improve overall survival in patients with advanced or metastatic STS as compared to doxorubicin and placebo. In its 2018 annual report, the last full year before withdrawal, Eli Lilly disclosed approximately US\$305 million in global sales of Lartruvo.

### *Razoxane*

Razoxane is multifunctional antineoplastic agent with radiosensitizing abilities in animal systems and in human soft tissue sarcomas. It has been shown to not only have cytostatic properties, but it also acts to normalize tumor vasculature and inhibit topoisomerase II enzymes and the breakdown of collagen of the basic membrane. This in turn reduces metastatic progression, inhibits invasive growth, and enhances the effects of radiation therapy. Because razoxane's oral bioavailability has been shown to be enhanced by smaller, fractionated dosing, TRP-1001 may include proprietary extended-release technologies meant to increase blood levels, reduce patient burden, and increase patient compliance. We believe the modes of action of razoxane may include:

- inhibition of topoisomerase II  $\alpha$ ;
- blocking of the cell cycle at G2/M;
- normalization of tumor neovasculature;
- anti-metastatic activity;
- anti-invasive activity;
- anti-inflammatory activity; and
- metal chelating activity.

These modes of action are known to be associated with:

- reduction of solid tumor hypoxia;
- potentiation of radiation therapy;
- potentiation of chemotherapy (variably); and
- prevention of spontaneous metastases.

### *Cytostatic Activity*

Razoxane has been shown to inhibit the enzyme topoisomerase II without inducing DNA strand breaks. This activity results in the inhibition of DNA synthesis and cell division in the premitotic and early mitotic phases (late G2/M) of the cell cycle, with no discernible inhibitory, toxic, or destructive effect at any other phase of the cell cycle. The cytostatic activity is nonselective, affecting normal dividing and malignant cells alike.

Razoxane's cytostatic activity may make standard measurements of "response" for TRP-1001 inappropriate. Because razoxane blocks the cell cycle after cell division, but prior to separation, tumor cells may significantly increase in size following treatment. While a "response" of reduction in tumor size may be meager and short-lived, we believe that treatment with TRP-1001 may lead to long-term stability of disease with tumors' capacity to grow slowed or even stopped.

A preclinical study published in 1971 evaluated the effects of 18 chemotherapy agents, including doxorubicin, cyclophosphamide, and razoxane, against an experimental breast cancer. In that study, the effect on tumor volume was largely shown to be directly proportional to the effect on survival; i.e., the greater the effect on tumor volume, the greater the effect on survival. The only exception was razoxane, which had the best effect on survival and one of the worst on tumor volume. While razoxane had no significant effect on tumor growth, and thus did not appear to interfere with an increase in tumor cell numbers, its positive effect on survival was greater than with any of the other drugs tested.

In addition to slowing or stopping tumor progression, the G2/M phase of the cell cycle is the most sensitive phase to ionizing irradiation. Blocking of the cell cycle at this phase may be one reason that razoxane, in addition to slowing or stopping tumor progression, appears to enhance the efficacy of radiation therapy. See "*Radiosensitizing Activity*".

#### *Normalization of Tumor Vasculature*

Razoxane has been shown in studies to normalize tumor neovasculature. Neovasculature refers to newly formed blood vessels in a tumor, as opposed to those already in place. This in turn has been shown to increase oxygen levels in the tumor microenvironment, with resulting anti-metastatic, radiosensitizing, and anti-invasive activity.

In solid tumors, the aggressive growth of the neoplastic cell population and associated overexpression of pro-angiogenic factors lead to the development of disorganized blood vessel networks that are structurally and functionally different from normal vasculature. A disorganized labyrinth of vessels that are immature, tortuous and hyperpermeable typifies tumor vasculature. A critical consequence of the inadequate vascular networks in solid tumors is the development of regions of hypoxia. Hypoxia, or low oxygen levels, is a hallmark feature of the tumor microenvironment. It has been estimated that 50 to 60% of solid tumors contain regions of hypoxia and/or anoxia (complete lack of oxygen) that arise as a result of an imbalance between oxygen delivery and oxygen consumption. Within the tumor microenvironment, oxygen delivery is impaired because of abnormalities in the tumor vasculature, including distended capillaries characterized by leaky and sluggish blood flow. At the same time, oxygen consumption rates are high because of the demands of proliferating tumor cells and infiltrating immune cells. Clinically, hypoxia is associated with hypoxia-inducible transcription factors ("**HIF**") activation, metastasis, and resistance to chemotherapy and radiation therapy, as well as poor patient survival.

#### *Radiosensitizing Activity*

STS patients are typically treated with surgery followed by radiation therapy and/or chemotherapy. As described above, the disorganized and structurally defective nature of tumor vascularization can significantly enhance a tumor's resistance to radiation therapy due to low oxygen levels and the resulting areas of hypoxia. In the presence of oxygen, free radical attack enhances radiation-induced DNA damage. Conversely, tumor cells lacking oxygen have been shown to be 2.5–3 times more resistant to radiation than their oxygen-replete counterparts. Studies evaluating razoxane in combination with radiation therapy have shown enhanced results over radiation therapy alone. These enhanced results are thought to be the result of normalization of tumor vasculature by razoxane and the resulting increases in oxygen levels in the tumor microenvironment. There also may be an enhanced effect in radiation therapy due to razoxane's blocking of the cell cycle at the G2/M phase, as discussed in *Cytostatic Activity*.

### *Anti-metastatic Activity*

Metastatic disease is the leading cause of cancer-related deaths and involves critical interactions between tumor cells and the microenvironment. The metastatic cascade can be broadly separated into three main processes: invasion (direct extension and penetration by cancer cells into neighboring tissues), intravasation (invasion of cancer cells through the basement membrane into a blood or lymphatic vessel), and extravasation (movement of cancer cells or a drug out of a blood or lymphatic vessel into tissue). Hypoxia is a potent microenvironmental factor promoting metastatic progression. Clinically, hypoxia and the expression of HIF-1 and HIF-2 are associated with increased distant metastasis and poor survival in a variety of tumor types. HIF signaling in malignant cells influences multiple steps within the metastatic cascade.

Several clinical studies on patients receiving radiotherapy for STS have demonstrated the correlation between tumor oxygenation and the frequency of distant metastases. For example, in a Duke University study of 22 patients with non-metastatic, high-grade STS, 70% of those patients with partial pressure of oxygen (“pO<sub>2</sub>”) in the tumor microenvironment of less than 10 mm Hg developed distant metastases, versus 35% of those with pO<sub>2</sub> greater than 10 mm Hg. The primary tumor was eradicated in all patients regardless of the level of oxygenation. Only the incidence of metastases varied between high and low pO<sub>2</sub> values. These data were subsequently confirmed in a Danish study in which 28 patients with STS exhibited an increased risk of metastatic spread if they possessed low tumor pO<sub>2</sub> values.

### *Anti-invasive Activity*

During the metastatic cascade, the loss of cell-cell adhesion capacity allows malignant tumor cells to dissociate from the primary tumor mass. Changes in cell-matrix interaction enable dissociated tumor cells to invade the surrounding stroma. This is known as the process of invasion. This involves the secretion of substances to degrade the basement membrane and extracellular matrix and also the expression/suppression of proteins involved in the control of motility and migration.

While razoxane is not a tubulin-affinic drug and therefore does not affect cellular motility and deformability, studies have observed that it inhibits the collagen degradation of basement membrane that is induced by a malignant tumor enzyme, thereby decreasing tumor cells’ ability to invade nearby tissue. We believe that this anti-invasive likely represents a further mechanism of action in razoxane’s inhibition of the metastatic cascade.

### *TRP-1001 Clinical Development Plan*

We believe that TRP-1001 represents an opportunity to improve upon both the safety and clinical benefit profiles of approved agents in STS, which to date have demonstrated poor toxicity and produced limited impact on patient survival. We intend to rely on Section 505(b)(2) of the FDCA in our TRP-1001 clinical development plan, which permits the filing of an NDA where at least some of the information required for approval comes from data in the public domain or the FDA’s prior conclusions regarding the safety and effectiveness of approved compounds. We believe this could expedite the development of TRP-1001 by potentially decreasing the amount of preclinical and clinical data that we would need to generate in order to obtain FDA approval. The preclinical and clinical data from the public domain that we may incorporate into an NDA for TRP-1001 may include, but is not limited to, data derived from the studies described in *Razoxane Preclinical and Clinical Safety Data*.

We anticipate that our clinical development plan may include evaluation of TRP-1001 in combination with an FDA-approved vinca alkaloid, or another approved chemotherapeutic compound, and radiation in STS. The low prevalence of STS qualifies it as a rare disease, and we intend to pursue Orphan Drug designation for TRP-1001 for this indication in the United States. Orphan Drug designation provides certain benefits, such as research tax credits, waivers of certain regulatory fees and seven years of marketing exclusivity, but does not provide any assurance of regulatory approval or expedite regulatory review. See “*Government Regulations – Orphan Drug Designation*” for a description of the Orphan Drug program in the United States. As our TRP-1001 program progresses, we also intend to discuss with the FDA the possibility of Breakthrough Therapy designation, Fast Track designation, Priority Review and Accelerated Approval for TRP-1001. See “*Government Regulations – Expedited Development and Review Programs*” for descriptions of these designations.

While there will likely be significant variations in our development plan and our clinical trial designs, we will initially be guided, at least in part, by the clinical development plans and FDA’s recent approval of drugs for the treatment of STS, particularly Lartruvo. In 2016 FDA granted accelerated approval to Lartruvo for the treatment of patients with histologic subtypes of STS for which an anthracycline-containing regimen is appropriate and which are not amenable to curative treatment with radiotherapy or surgery. The Lartruvo approval was based on the results of a Phase 2 randomized, active-controlled clinical trial. In that trial patients were randomized 1:1 to receive Lartruvo plus doxorubicin or doxorubicin alone. The primary endpoint of the study was progression-free survival, with secondary endpoints of objective response rate and median overall survival. It is anticipated that all clinical trials in our TRP-1001 clinical development program will take place in the United States.

The FDA granted the Lartruvo application Breakthrough Therapy designation, Fast Track designation, and Priority Review status because preliminary clinical evidence indicated that it may offer a substantial improvement in effectiveness in the treatment of a serious or life-threatening disease or condition. The FDA approved Lartruvo under its accelerated approval program, which allows approval of a drug to treat a serious or life-threatening disease or condition based on clinical data showing the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. Lartruvo also received Orphan Drug designation, which provides incentives such as tax credits, user fee waivers and eligibility for marketing exclusivity to assist and encourage the development of drugs intended to treat rare diseases. The FDA required a post-approval study of Lartruvo plus doxorubicin versus placebo plus doxorubicin. The Lartruvo arm did not outperform the placebo arm in that study and was subsequently withdrawn from the market.

#### *Razoxane Preclinical and Clinical Safety Data*

Based on existing preclinical and clinical data for razoxane, as well as the regulatory pathway in the FDA’s approval of Lartruvo, we believe we may be able to initiate a Phase 2 clinical trial of TRP-1001 dosed in combination with an FDA-approved vinca alkaloid, or another approved chemotherapeutic compound, and radiation with minimal or no additional nonclinical studies and without a Phase 1 clinical trial. We intend to request a Type B meeting to determine whether FDA concurs with this approach. Any final clinical trial design will be subject to the requirements of the FDA and the input of investigators, KOLs, and our consultants.

Even if the FDA agrees that we can proceed directly to initiating a Phase 2 clinical trial, we may choose to first engage in one or more clinical trials of TRP-1001 that are meant to gather additional data and inform our clinical development plans. These types of clinical trials, if conducted, could be used to confirm the historical safety profile of TRP-1001, as well as gather information regarding optimal dosing levels and

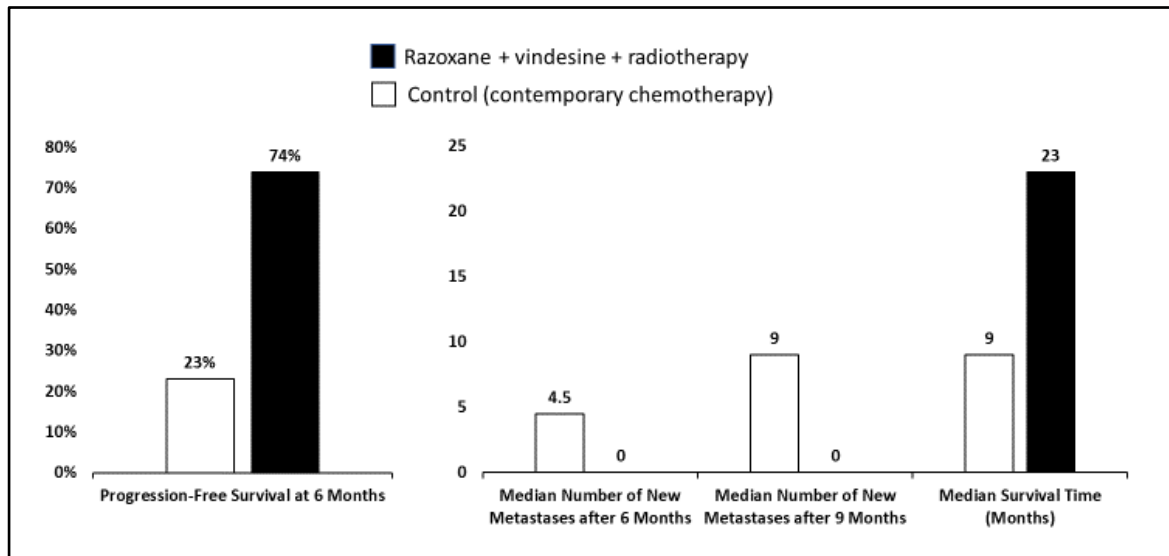
intervals, pharmacokinetics, and pharmacodynamics. These types of studies are sometimes referred to as Phase 1/2a clinical trials.

Razoxane Efficacy Data

Numerous clinical trials evaluating the efficacy of razoxane for the treatment of STS, including when dosed in combination with a vinca alkaloid, have shown promising results. The trials described below highlight the findings of the broader group of clinical trials that have been conducted on the efficacy of razoxane for the treatment of STS.

In a Phase 2 study, the results of which were published in 2008, 23 patients with unresectable ( $n = 7$ ) and oligometastatic ( $n = 16$ ) STS received a basic treatment with razoxane and vindesine (an EMA-approved vinca alkaloid) supported by radiotherapy and occasionally by surgery. 36 patients with comparable stages of STS treated with chemotherapy served as non-randomized, retrospective controls. In patients receiving razoxane and vindesine, the median number of new metastases after six months was 0 (range, 0–40) and after nine months was 0 (0–70). The corresponding results in the control group were 4.5 (range, 0–40) and 9 (0–>100) ( $P < 0.001$ ). The progression-free survival at six months was 74% in the study group and 23% in the control group. The median survival time from the occurrence of the first metastasis or the time of unresectability was 20+ months (range, 8–120+) in the study group versus 9 months (range, 2–252) in the control group ( $P < 0.001$ ). The combined treatment of razoxane and vindesine was associated with a low to moderate toxicity. The results of this study can be seen in Figure 1.

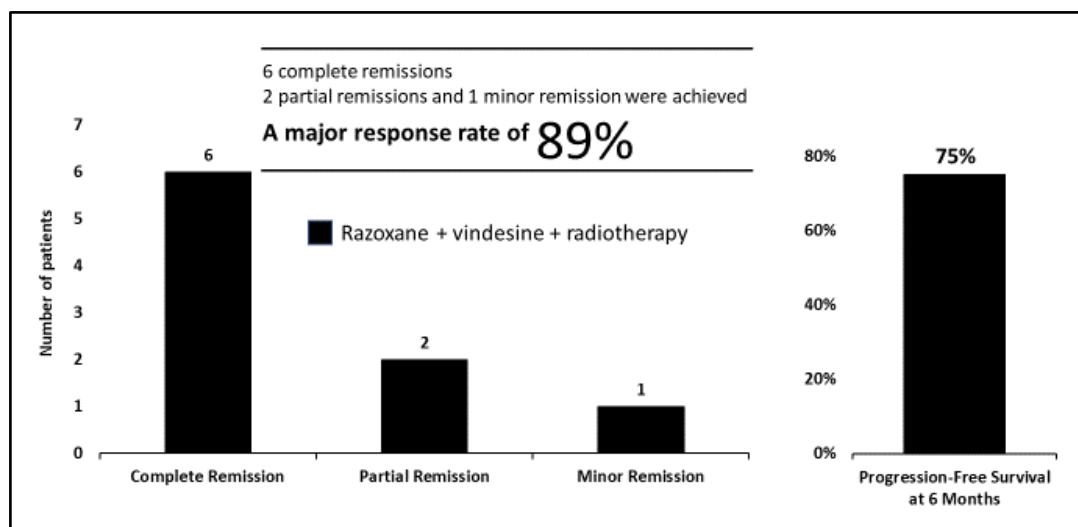
**Figure 1**



In 2008, the Austrian Society of Radiooncology published the results of a Phase 2 clinical trial to evaluate the effectiveness of razoxane and vindesine, together with radiotherapy in STS. Of 13 evaluable patients (ten angiosarcomas and three hemangio-pericytomas), nine had unresectable measurable disease, three showed microscopic residuals, and one had a resection with clear margins. Each patient received a basic treatment with razoxane and vindesine supported by radiation therapy. Outcome measures were objective response rates, survival time, and the incidence of distant metastases. In nine patients with measurable vascular soft tissue sarcomas (eight angiosarcomas and one hemangiopericytoma), six complete remissions, two partial

remissions, and one minor remission were achieved, corresponding to a major response rate of 89%. A maintenance therapy with razoxane and vindesine of one year or longer led to a suppression of distant metastases. The median survival time from the start of the treatment was 23+ months (range, 3-120+) for 12 patients with macroscopic and microscopic residual disease. The progression-free survival at six months was 75%. The combined treatment was associated with a low general toxicity. The results of this study can be seen in Figure 2.

**Figure 2**



## **Manufacturing and Supply**

### ***Pharmaceuticals***

Our manufacturing strategy is to contract with third parties to manufacture our APIs and finished drug products. We intend to file patent applications in the United States and other regions of the world regarding the proprietary formulations and processes used to manufacture our drug candidates. We have agreements with third-party manufacturers that are intended to restrict these manufacturers from using or revealing any unpublished proprietary information other than in the development and manufacturing of our products. In August 2020 we entered into an agreement with AMRI, a leading global contract research, development and manufacturing organization for high potency compounds, pursuant to which AMRI will provide research, development and cGMP manufacturing services for the synthetic psilocybin API we intend to utilize in our PFN™ program.

Our third-party manufacturing partners are independent entities that are subject to their own operational and financial risks over which we have no control. If we or any of these third-party manufacturers fail to perform as required, this could cause delays in our clinical trials, regulatory applications and regulatory submission.

### ***Regulation of Pharmaceutical Manufacturing Processes***

The manufacturing process for pharmaceutical products is highly regulated and regulators may shut down manufacturing facilities that they believe do not comply with regulations. We and our third-party



manufacturers are subject to cGMPs, which are extensive regulations governing manufacturing processes, stability testing, record keeping and quality standards as defined by the FDA and the EMA. Similar regulations and requirements are in effect in other countries.

## **Commercialization**

We are a clinical stage company without a history of revenue or manufacturing, late stage clinical development or marketing experience. Because late stage clinical development, as well as establishing a full manufacturing and commercialization structure, is expensive and time consuming, we intend to explore alternative commercialization strategies, including:

- developing drug candidates up to and through Phase 2 clinical trials with the objectives of rapid, cost effective risk reduction and value creation followed by establishment of strategic partnerships for late stage clinical development and subsequent commercialization;
- developing a robust pipeline of promising drug candidates at various stages of the development process to establish optionality and regular value inflection opportunities and revenue(s), particularly during development activities up to and including Phase 2 clinical studies;
- strategically entering into co-development partnership(s) to retain potential for commercialization rights on selected drug candidate(s) and market opportunities; and
- partnering with industry participants to incorporate our PFN™ program into new and existing drugs.

## **Competition**

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our technology, the expertise of our executive and scientific teams, research, clinical capabilities, development experience and scientific knowledge provide us with competitive advantages, we face increasing competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Drug candidates that we successfully develop and commercialize may compete with existing therapies and new therapies that may become available in the future.

We are aware of other organizations and institutions evaluating the use of psilocybin for the treatment of neuropsychiatric disorders, including COMPASS Pathways. In addition, there are various companies exploring other psychedelic compounds for the treatment of neuropsychiatric disorders.

Many of our competitors, either alone or with their collaborators, have significantly greater financial resources, established presence in the market, expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements

with large and established companies. Additional mergers and acquisitions may result in even more resources being concentrated in our competitors.

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than drugs that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market or make our development more complicated. Further, we are aware of numerous companies that are developing psilocybin-based drug candidates, which may be prescribed off-label for the indications that we are pursuing should they obtain regulatory approval prior to TRP-8802. The key competitive factors affecting the success of all of our programs are likely to be efficacy, safety and convenience.

### ***TRP-8802 for Fibromyalgia***

There are currently several therapies for the treatment of fibromyalgia, including Cymbalta, which is marketed by Eli Lilly; Lyrica, which is marketed by Pfizer; and Savella, which is marketed by Allergan. We are also aware that physicians use a variety of therapies off-label to treat fibromyalgia. Other companies working to develop therapeutics for the treatment of fibromyalgia include Aptinyx; Astellas Pharma; Axsome Therapeutics; Teva Pharmaceutical Industries; Tonix Pharmaceuticals, and Virios Therapeutics.

### ***TRP-8802 for PWS-related Hyperphagia***

Currently, the only approved products for PWS are brands of the growth hormone somatropin (Genotropin, Omnitrope, and Norditropin), which are approved for growth failure in children who have PWS. There are no approved products to address PWS-associated hyperphagia and behaviors, or for any other abnormalities associated with the disease. However, we are aware of other companies working to develop therapeutics for the treatment of PWS, including for hyperphagia. These companies include Consynance Therapeutics; GLWL Research; Inversago Pharma; Levo Therapeutics; Saniona; Soleno Therapeutics; and Rhythm Pharmaceuticals.

### ***TRP-1001 for STS***

There are a number of chemotherapy drugs approved for the treatment of STS. While surgery followed by radiation and/or chemotherapy remains the standard treatment for STS, we are aware of other companies working to develop new drugs for the treatment of STS, including Blueprint Medicines; Deciphera Pharmaceuticals; Eli Lilly; Karyopharm Therapeutics; Pfizer; and TRACON Pharmaceuticals.

Since 2015 the FDA has approved a number new drugs for the treatment of certain sub-types of STS, including Yodelis (trabectedin), Halaven (eribulin), Lartruvo (olaratumab), Ayvakit (avapritinib), and Tazverik (tazemetostat), though Lartruvo was subsequently withdrawn from the market due to failure to show improvement over placebo in a post-approval confirmatory clinical trial.

Additionally, while there is no PD-1 or PD-L1 therapy approved by the FDA for the treatment of STS. Merck's Keytruda (pembrolizumab) has a compendia listing for the treatment of undifferentiated pleomorphic sarcoma ("**UPS**"), and is used off-label for the treatment of patients with UPS. While rare, UPS is the fourth most common sub-type of STS.

## **Intellectual Property**

### ***Patent Applications***

We strive to protect the proprietary technology that we believe is important to our business, including seeking and maintaining patents intended to cover both our broad development programs and individual drug candidates. We seek to obtain domestic and international patent protection, and endeavor to promptly file patent applications for new commercially valuable inventions. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

We plan to continue to expand our intellectual property estate by filing patent applications directed to pharmaceutical compositions, methods of treatment, methods of manufacture, methods for patient selection created or identified from our ongoing development of our drug candidates, as well as discovery based on our proprietary PFN™ program. Our success will depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce any patents that we may obtain, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties. We also rely on know-how and continuing technological innovation to develop and maintain our proprietary position and, in the future, may rely on or leverage in-licensing opportunities.

The patent positions of biopharmaceutical companies like us are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent may be challenged in courts after issuance. Moreover, many jurisdictions permit third parties to challenge issued patents in administrative proceedings, which may result in further narrowing or even cancellation of patent claims. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or at all, whether the claims of any patent applications, should they issue, will cover our drug candidates, or whether the claims of any issued patents will provide sufficient protection from competitors or otherwise provide any competitive advantage. See *“Risk Factors – Risks Related to our Intellectual Property”*.

Because patent applications in the United States and certain other jurisdictions are maintained in secrecy for 18 months or potentially even longer, and because publication of discoveries in the scientific or patent literature often lags behind actual discoveries and patent application filings, we cannot be certain of the priority of inventions covered by pending patent applications. Accordingly, we may not have been the first to invent the subject matter disclosed in some of our patent applications or the first to file patent applications covering such subject matter, and we may have to participate in interference proceedings or derivation proceedings declared by the United States Patent and Trademark Office, or USPTO, to determine priority of invention. Third party pending applications may issue with claims that cover the Company's products or manufacture of the Company's products, or may contain claims of scope that cannot be defined with certainty until issuance.

### ***Patent Portfolio***

Our patent strategy includes pursuing protection for any proprietary forms of synthetic psilocybin that we may develop; large-scale psilocybin manufacturing processes; psilocybin formulations and compositions; razoxane formulations and compositions; and methods of treatment using psilocybin and razoxane. Our patent portfolio includes patent applications in varying stages of prosecution in the United States and

selected ex-U.S. jurisdictions. As of August 31, 2020, our patent portfolio consisted of two pending applications, both of which are owned by us. These patent applications cover therapeutic methods for using psilocybin and compositions and methods to improve the therapeutic benefit of bis-dioxopiperazines, which includes razoxane.

We intend to explore additional opportunities to expand our patent portfolio. We will continue to innovate and strategically protect our innovations in the following three main areas:

- novel manufacturing processes for large-scale manufacture of our APIs;
- novel formulations and unique pharmaceutical compositions; and
- methods of treatment using our APIs.

We have a number of additional indications for our PFN™ program and razoxane under evaluation based on unmet medical need and potential efficacy. As we begin exploratory work on prioritized opportunities, we expect that we and our research and development partners will generate additional intellectual property for which we will file patent applications when appropriate. There may be instances where we determine that certain intellectual property has greater protection as a trade secret and we may choose to not file a patent application in such a circumstance.

### ***Patent Term***

The base term of a U.S. patent is 20 years from the filing date of the earliest-filed non-provisional, patent application from which the patent claims priority. The term of a U.S. patent can be lengthened by patent term adjustment, which compensates the owner of the patent for administrative delays at the USPTO. In some cases, the term of a U.S. patent is shortened by terminal disclaimer that reduces its term to that of an earlier-expiring patent.

The term of a U.S. patent may be eligible for patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Act, to account for at least some of the time the drug is under development and regulatory review after the patent is granted. With regard to a drug for which FDA approval is the first permitted marketing of the active ingredient, the Hatch-Waxman Act allows for extension of the term of one U.S. patent that includes at least one claim covering the composition of matter of such an FDA-approved drug, an FDA-approved method of treatment using the drug and/or a method of manufacturing the FDA-approved drug. The extended patent term cannot exceed the shorter of five years beyond the non-extended expiration of the patent or fourteen years from the date of the FDA approval of the drug, and a patent cannot be extended more than once or for more than a single product. During the period of extension, if granted, the scope of exclusivity is limited to the approved product for approved uses. Some foreign jurisdictions, including Europe and Japan, have analogous patent term extension provisions, which allow for extension of the term of a patent that covers a drug approved by the applicable foreign regulatory agency. In the future, if and when our drug candidates receive FDA approval, we expect to apply, if appropriate, for patent term extension on patents covering those drug candidates, their methods of use and/or methods of manufacture.

### ***Trade Secrets***

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. We typically rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. We protect trade secrets and know-how by

establishing confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and collaborators. These agreements provide that all confidential information developed or made known during the course of an individual or entities' relationship with us must be kept confidential during and after the relationship. These agreements also provide that all inventions resulting from work performed for us or relating to our business and conceived or completed during the period of employment or assignment, as applicable, shall be our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary information by third parties.

## **Government Regulations**

Government authorities in the United States at the federal, state and local level and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug products. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific to each regulatory authority, submitted for review and approved by the regulatory authority.

### ***U.S. Drug Development***

In the United States, the FDA regulates drugs under the FDCA, and its implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Additionally, a manufacturer may need to recall a product from the market. Any agency or judicial enforcement action could have a material adverse effect on us.

Our drug candidates must be approved by the FDA through the NDA process before they may be legally marketed in the United States. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of extensive nonclinical laboratory tests, animal studies and formulation studies in accordance with applicable regulations, including the FDA's good laboratory practice, or good laboratory practices ("**GLP**"), regulations;
- submission to the FDA of an IND application, which must become effective before human clinical studies may begin;
- approval by an independent institutional review board, or IRB, or ethics committee at each clinical study site before each study may be initiated;
- performance of adequate and well-controlled human clinical studies in accordance with applicable IND and other clinical study-related regulations, referred to as good clinical practices ("**GCPs**"), to establish the safety and efficacy of the proposed drug for each proposed indication;

- submission to the FDA of an NDA for a new drug;
- a determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with current good manufacturing practices, or cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA audit of the nonclinical study and/or clinical study sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the United States.

The nonclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our drug candidates will be granted on a timely basis, if at all.

The data required to support an NDA is generated in two distinct development stages: nonclinical and clinical. For new chemical entities, the nonclinical development stage generally involves synthesizing the active component, developing the formulation and determining the manufacturing process, as well as carrying out non-human toxicology, pharmacology and drug metabolism studies in the laboratory, which support subsequent clinical testing. These nonclinical tests include laboratory evaluation of product chemistry, formulation, stability and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The conduct of the nonclinical tests must comply with federal regulations, including GLPs. The sponsor must submit the results of the nonclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. Some nonclinical testing may continue even after the IND is submitted, but an IND must become effective before human clinical studies may begin. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical studies, including concerns that human research subjects will be exposed to unreasonable health risks, and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical studies due to safety concerns or non-compliance. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical studies to begin, or that, once begun, issues will not arise that could cause the study to be suspended or terminated.

The clinical stage of development involves the administration of the drug candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical studies are conducted under protocols detailing, among other things, the objectives of the clinical study, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical study must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical study will be conducted. An IRB is charged

with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical studies are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical study subject or his or her legal representative and must monitor the clinical study until completion. There are also requirements governing the reporting of ongoing clinical studies and completed clinical study results to public registries.

A sponsor who wishes to conduct a clinical study outside the United States may, but need not, obtain FDA authorization to conduct the clinical study under an IND. If a foreign clinical study is not conducted under an IND, the sponsor may submit data from the clinical study to the FDA in support of an NDA so long as the clinical study is conducted in compliance with GCP and the FDA is able to validate the data through an onsite inspection if the agency deems it necessary. There can be no assurance that the FDA will accept data from clinical trials conducted outside of the United States.

### ***Clinical studies***

Clinical studies are generally conducted in three sequential phases that may overlap, known as Phase 1, Phase 2 and Phase 3 clinical studies.

- Phase 1 clinical studies generally involve a small number of healthy volunteers who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical studies is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the drug.
- Phase 2 clinical studies typically involve studies in disease-affected patients to determine the dose required to produce the desired benefits and provide a preliminary evaluation of efficacy. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, as well as identification of possible adverse effects and safety risks.
- Phase 3 clinical studies generally involve large numbers of patients at multiple sites (from several hundred to several thousand subjects) and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for physician labeling. Phase 3 clinical studies may include comparisons with placebo and/or comparator treatments.

Post-approval studies, sometimes referred to as Phase 4 clinical studies, may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical studies as a condition of approval of an NDA.

Progress reports detailing the results of the clinical studies must be submitted at least annually to the FDA. Written IND safety reports must be submitted to the FDA and the investigators within 15 calendar days for serious and unexpected suspected adverse events, findings from other studies or animal or in vitro testing that suggests a significant risk for human subjects, and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Additionally, a sponsor must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days. Phase 1, Phase 2 and Phase 3 clinical studies may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical study at any time on various grounds, including a finding that the research subjects or patients are being exposed to an

unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the institutional review board's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical studies are overseen by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study.

Concurrently with clinical studies, companies often complete additional animal studies in order to gather further information regarding a drug candidate's pharmacokinetic and pharmacodynamic characteristics. Additionally, companies must develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

### ***NDA and FDA Review Process***

The results of the nonclinical studies and clinical studies, together with other detailed information, including extensive manufacturing information and information on the composition of the drug and proposed labeling, are submitted to the FDA in the form of an NDA requesting approval to market the drug for one or more specified indications. The FDA reviews an NDA to determine, among other things, whether a drug is safe and effective for its intended use and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality, and purity. FDA approval of an NDA must be obtained before a drug may be offered for sale in the United States.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each NDA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's fee schedule, effective from October 1, 2020 through September 30, 2021, the user fee for an application requiring clinical data, such as an NDA, is \$2,875,842. PDUFA also imposes an annual prescription drug product program fee for human drugs. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under PDUFA, for drugs that do not contain an NCE, the FDA has ten months from the receipt date in which to complete its initial review of a standard NDA and respond to the applicant, and six months from the receipt date for a priority NDA. For drugs containing an NCE, these ten and six month review timeframes are from the filing date of an NDA. The FDA does not always meet its PDUFA goal dates for standard and



priority NDAs, and the review process is often significantly extended by FDA requests for additional information or clarification.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving an NDA, the FDA may also audit data from clinical studies to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The FDA will likely re-analyze the clinical study data, which could result in extensive discussions between the FDA and the applicant during the review process. The review and evaluation of an NDA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all.

After the FDA evaluates an NDA, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical study(s), and/or other significant and time-consuming requirements related to clinical studies, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may resubmit the NDA addressing all of the deficiencies identified in the letter, withdraw the application, or request an opportunity for a hearing. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical studies are not always conclusive and the FDA may interpret data differently than we interpret the same data.

There is no assurance that the FDA will ultimately approve a drug product for marketing in the United States and we may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings, or precautions be included in the product labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing or clinical studies and surveillance to monitor the effects of approved products. For example, the FDA may require Phase 4 testing which involves clinical studies designed to further assess a drug's safety and efficacy and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA also may place other conditions on approvals including the requirement for a risk evaluation and mitigation strategy, or REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA

without an approved REMS, if required. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory requirements or if problems occur following initial marketing.

### ***Orphan Drug Designation***

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making the product available in the United States for this type of disease or condition will be recovered from sales of the product.

Orphan Drug designation must be requested before submitting an NDA. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan Drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to Orphan Drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years from the date of such approval, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity by means of greater effectiveness, greater safety, or providing a major contribution to patient care or in instances of drug supply issues. Competitors, however, may receive approval of either a different product for the same indication or the same product for a different indication but that could be used off-label in the orphan indication. Orphan Drug exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval before we do for the same product, as defined by the FDA, for the same indication we are seeking approval, or if our product is determined to be contained within the scope of the competitor's product for the same indication or disease. If one of our products designated as an Orphan Drug receives marketing approval for an indication broader than that which is designated, it may not be entitled to Orphan Drug exclusivity.

### ***Expedited Development and Review Programs***

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the drug and the specific indication for which it is being studied. The sponsor of a new drug may request the FDA to designate the drug as a Fast Track product at any time during the clinical development of the product. Unique to a Fast Track product, the FDA may review sections of the marketing application on a rolling basis before the complete NDA is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application. The FDA review period does not begin until after the last section of the NDA has been submitted. Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Any product submitted to the FDA for marketing, including under the Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review. A drug is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or offers a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review.

Additionally, a drug may be eligible for designation as a Breakthrough Therapy if the drug is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinical development. The benefits of Breakthrough Therapy designation include the same benefits as Fast Track designation, plus intensive guidance from FDA to ensure an efficient drug development program. Fast Track designation, priority review, and breakthrough designation do not change the standards for approval but may expedite the development or approval process.

### ***Pediatric Trials***

The FDCA requires that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within sixty days of an end-of-Phase 2 meeting or as may be agreed between the sponsor and the FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical studies and/or other clinical development programs.

### ***Post-marketing Requirements***

Following approval of a new drug, a pharmaceutical company and the approved drug are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the FDA of adverse experiences with the drug, providing the FDA with updated safety and efficacy information, drug sampling and distribution requirements and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use), limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the applicant to develop additional data or conduct additional nonclinical and clinical studies. As with new NDAs, the review process is often significantly extended by FDA's requests for additional information or clarification. Any distribution of prescription drug

products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act, or the PDMA, a part of the FDCA.

In the United States, once a drug is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. NDA holders using contract manufacturers, laboratories or packagers are responsible for the selection and monitoring of qualified firms, and, in certain circumstances, qualified suppliers to these firms. These manufacturers must comply with cGMP regulations that require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. The discovery of violative conditions, including failure to conform to cGMP, could result in enforcement actions that interrupt the operation of any such facilities or the ability to distribute products manufactured, processed or tested by them. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA, including, among other things, recall or withdrawal of the product from the market.

Discovery of previously unknown problems with a drug or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning or untitled letters or Forms 483 from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our drugs under development. Changes in statutes, regulations, or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to drug labeling; (iii) the recall or discontinuation of our drugs; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

### ***Orange Book Listing***

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A Section 505(b)(2) NDA is an application in which the applicant, in part, relies on investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application ("**ANDA**"). An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product. Limited changes must be preapproved by the FDA via a suitability

petition. ANDAs are termed “abbreviated” because they are generally not required to include nonclinical and clinical data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo, or other testing. The generic version must deliver the same amount of active ingredients into a subject’s bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug.

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents having claims that cover the applicant’s product and method of use. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book. These products may be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA.

Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must make patent certifications to the FDA that (1) no patent information on the drug or method of use that is the subject of the application has been submitted to the FDA; (2) the patent has expired; (3) the date on which the patent has expired and approval will not be sought until after the patent expiration; or (4) the patent is invalid or will not be infringed upon by the manufacture, use, or sale of the drug product for which the application is submitted. The last certification is known as a paragraph IV certification. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through a paragraph IV certification or if the applicant is not seeking approval of a patented method of use. If the applicant does not challenge the listed patents or does not indicate that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have expired.

If the competitor has provided a paragraph IV certification to the FDA, the competitor must also send notice of the paragraph IV certification to the holder of the NDA for the reference listed drug and the patent owner within 20 days after the application has been accepted for filing by the FDA. The NDA holder or patent owner may then initiate a patent infringement lawsuit in response to the notice of the paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a paragraph IV certification notice prevents the FDA from approving the ANDA or 505(b)(2) application until the earlier of 30 months from the date of the lawsuit, expiration of the patent, settlement of the lawsuit, a decision in the infringement case that is favorable to the applicant or such shorter or longer period as may be ordered by a court. This prohibition is generally referred to as the 30-month stay.

In instances where an ANDA or 505(b)(2) NDA applicant files a paragraph IV certification, the NDA holder or patent owners regularly take action to trigger the 30-month stay, recognizing that the related patent litigation may take many months or years to resolve. Thus, approval of an ANDA or 505(b)(2) NDA could be delayed for a significant period of time depending on the patent certification the applicant makes and the reference drug sponsor’s decision to initiate patent litigation.

### ***U.S. Marketing Exclusivity***

Marketing exclusivity provisions under the FDCA can also delay the submission or the approval of certain marketing applications. The FDCA provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. This

three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving abbreviated new drug applications, or ANDAs, for drugs containing the active agent for the original indication or condition of use. The FDCA also provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity (“NCE”). A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovator drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. Three-year and five-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the nonclinical studies and adequate and well-controlled clinical studies necessary to demonstrate safety and efficacy. Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued “Written Request” for such a trial.

#### ***U.S. Patent-term Extension***

Depending upon the timing, duration and specifics of FDA approval of our current drug candidates or any future product candidate, some of our U.S. patents may be eligible for limited patent term extension under the Hatch Waxman Act. The Hatch Waxman Act permits extension of the patent term of up to five years as compensation for patent term lost during FDA regulatory review process. Patent term extension, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product’s approval date. The patent term extension period is generally one half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved drug is eligible for the extension (and only those patent claims covering the approved drug, a method for using it or a method for manufacturing it may be extended), and the application for the extension must be submitted prior to the expiration of the patent. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The United States Patent and Trademark Office, or USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension. In the future, we may apply for extension of patent term for our owned patents to add patent life beyond their current expiration date, depending on the expected length of the clinical studies and other factors involved in the filing of the relevant NDA. However, there can be no assurance that the USPTO or FDA will grant us any requested patent term extension, either for the length we request or at all.

#### ***Controlled Substances***

The federal Controlled Substances Act of 1970, or 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 DEA. The DEA is the federal agency 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.

The DEA categorizes controlled substances into one of five schedules — Schedule I, II, III, IV or V — with varying qualifications for listing in each schedule. Schedule I substances by definition have a high potential for abuse, have no currently accepted medical use in treatment in the United States and lack accepted safety for use under medical supervision. Pharmaceutical products having a currently accepted medical use that are otherwise approved for marketing may be listed as Schedule II, III, IV or V substances, with Schedule II substances presenting the highest potential for abuse and physical or psychological dependence, and Schedule V substances presenting the lowest relative potential for abuse and dependence. If any of our PFN™ program products are approved in the United States, will require scheduling by the DEA before it can be marketed.

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

The 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 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. In some cases, Schedule III non-narcotic substances may be subject to the import/export permit requirement, if necessary, to ensure that the United States complies with its obligations under international drug control treaties.

For drugs manufactured in the United States, the 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 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 API and production of dosage forms. The 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 DEA has substantial discretion in whether or not to make such adjustments for individual companies.

The states also 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 our business, operations and financial condition. The 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.

### **Other Regulatory Matters**

Manufacturing, sales, promotion, and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services including the Office of the Inspector General, the U.S. Department of Justice, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local regulatory authorities. In the United States, sales, marketing and scientific/educational programs must also comply with state and federal fraud and abuse laws. These laws include the federal Anti-Kickback Statute, which makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

Although we would not submit claims directly to payors, drug manufacturers can be held liable under the federal civil False Claims Act, which prohibits anyone from knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. The government may deem manufacturers to have “caused” the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, our activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between \$11,665 and \$23,331 for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. If the government were to allege that we were, or convict us of, violating these false claims laws, we could be subject to a substantial fine and may suffer a decline in our share price. In addition, private individuals have the ability to bring actions under the federal False Claims Act and certain states have enacted laws modeled after the federal False Claims Act.



The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal Anti-Kickback Statute 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.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Also, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, to the extent that any of our drug candidates, if approved, are sold in a foreign country, we may be subject to similar foreign laws.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, including the final omnibus rule published on January 25, 2013, mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes HIPAA's security standards directly applicable to business associates, defined as independent contractors or agents of covered entities that create, receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and 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 attorney's fees and costs associated with pursuing federal civil actions. In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and criminal penalties.

Other regulations may affect other aspects of our business. For example, pricing and rebate programs must comply with the Medicaid rebate requirements of the U.S. Omnibus Budget Reconciliation Act of 1990 and more recent requirements in ACA. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, sales, promotion and other activities are also potentially subject to federal and state consumer protection and unfair competition laws. There has also been a recent trend of increased federal and state regulation of payments made to physicians. Certain states mandate implementation of compliance programs, impose restrictions on drug manufacturers' marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and individual imprisonment, any of which could adversely affect our ability to operate our business and our financial results. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

### ***European Union Drug Development***

Similar to the United States, the various phases of preclinical and clinical research in the EU are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated, it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority ("**NCA**"), and one or more Ethics Committees ("**ECs**"). Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

The EU clinical trials legislation currently is undergoing a transition process mainly aimed at harmonizing and streamlining clinical-trial authorization, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency. Recently enacted Clinical Trials Regulation EU No 536/2014 ensures that the rules for conducting clinical trials in the EU will be identical. In the meantime, Clinical Trials Directive 2001/20/EC continues to govern all clinical trials performed in the EU.

### ***European Union Drug Review and Approval***

In the European Economic Area, or EEA, comprising the 28 Member States of the EU plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of marketing authorizations:

The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition

Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State, or RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Member States Concerned).

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

### ***European Union New Chemical Entity Exclusivity***

In the EU, new chemical entities, sometimes referred to as new active substances, qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. The data exclusivity, if granted, prevents regulatory authorities in the EU from referencing the innovator's data to assess a generic application for eight years, after which generic marketing authorization can be submitted, and the innovator's data may be referenced, but not approved for two years. The overall ten year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are determined to bring a significant clinical benefit in comparison with currently approved therapies.

### ***European Union Orphan Designation and Exclusivity***

In the EU, the European Commission, based on the recommendation of the EMA's Committee for Orphan Medicinal Products, grants Orphan Drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the EU community (or where it is unlikely that the development of the medicine would generate sufficient return to justify the investment) and for which no satisfactory method of diagnosis, prevention or treatment has been authorized (or, if a method exists, the product would be a significant benefit to those affected).

In the EU, Orphan Drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following medicinal product approval. This period is extended by two years for compliance with an agreed upon pediatric investigation plan granted at the time of review of the Orphan Drug designation. This period may be reduced to six years if the Orphan Drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time, if (i) the holder of the marketing authorization for the original orphan medicinal product consents to a second orphan medicinal product application, (ii) the holder of the marketing authorization for the original orphan medicinal product cannot supply sufficient quantities of the orphan medicinal product, or (iii) the second applicant can establish that the second medicinal product, although similar, is safer, more effective or otherwise clinically superior to the authorized orphan

medicinal product. Orphan Drug designation must be requested before submitting an application for marketing approval. Orphan Drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

### ***Controlled Drugs Classification in the United Kingdom and European Union***

In the United Kingdom, psilocybin and psilocin are considered Class A drugs under the Misuse of Drugs Act 1971, as amended, and as Schedule 1 drugs under the Misuse of Drugs Regulations 2001, as amended. Class A drugs are considered to be the most potentially harmful, and have the highest level of control exerted over them under the Misuse of Drugs Act 1971. Similarly, Schedule 1 of the Misuse of Drugs Regulations 2001 lists those drugs to which the most restrictive controls apply: they are considered to have no legitimate or medicinal use, and can only be imported, exported, produced, supplied and the like under a license issued by the UK Government's Home Office. If and when granted a marketing authorization by the MHRA in respect of the UK, psilocybin would still remain a Schedule 1 drug until rescheduled by the United Kingdom Government's Home Office. Unless and until psilocybin is rescheduled under the Misuse of Drugs Regulations 2001, and unless a statutory exemption was to be passed for any of our PFN™ program products following the grant of a UK marketing authorization and before rescheduling, any prescribing doctors in the United Kingdom would require a Home Office license to prescribe one of our PFN™ program drugs, and similarly any patients to whom one of our PFN™ program drugs was prescribed would require a Home Office license to possess such a product. There can be no guarantee that such Home Office licenses would be granted or that rescheduling would be successful.

The positions of EU member states is not harmonized: member states have implemented the relevant UN Conventions (the Single Convention of Narcotic Drugs 1961 and the Convention on Psychotropic Substances 1971) into their national legislation, which has led to differences in how controlled substances are regulated in different countries of the EU. It is therefore important to determine at a national level whether a substance is controlled and to comply with the applicable legal requirements. If we are successful in obtaining a marketing authorization in key EU member states, it is likely that rescheduling of psilocybin will also be required to enable prescribing.

### ***Rest of the World Regulation***

For other countries outside of the EU and the United States, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical studies, product licensing, pricing and reimbursement vary from country to country. In all cases the clinical studies must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

### ***Healthcare Reform***

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In March 2010, the Affordable Care Act was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States and significantly affected the pharmaceutical industry. The Affordable Care Act contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and fraud and abuse changes. Additionally, the

Affordable Care Act increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1%; required collection of rebates for drugs paid by Medicaid managed care organizations; required manufacturers to participate in a coverage gap discount program, under which they must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain "branded prescription drugs" to specified federal government programs; implemented a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; expanded eligibility criteria for Medicaid programs; created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. For example, in 2017, Congress enacted the Tax Cuts and Jobs Act, which eliminated the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseparable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the Affordable Care Act are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, although it is unclear when a decision will be made or how the Supreme Court will rule. It is also unclear how other efforts to challenge, repeal or replace the Affordable Care Act will impact the law.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year and reduced payments to several types of Medicare providers, which will remain in effect through 2030 absent additional congressional action. The Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, which was signed into law on March 27, 2020, designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended these reductions from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030.

Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed, among other things, to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for pharmaceutical products. At the federal level, the Trump administration's budget proposal for fiscal year 2021 includes 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 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. Further, the Trump Administration previously released a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase drug 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. Individual states in the United States have also become increasingly active in 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, mechanisms to encourage importation from other countries and bulk purchasing. Furthermore, there has been increased interest by third-party payors and governmental authorities in reference pricing systems and publication of discounts and list prices.

### **Facilities**

We are a virtual company and do not own or lease any facilities. We believe that suitable facilities will be available in the future on commercially reasonable terms, if required.

### **Employees**

As of August 31, 2020, the Company had no employees and six key consultants, including the Company’s Chief Executive Officer and its President and Chief Scientific Officer, each of whom anticipate dedicating approximately 100% of their time to the affairs of the Company. We are a virtual company and our consultants work remotely. In addition to our six key consultants, we utilize independent contractors and other third parties to assist with various aspects of our business.

## **USE OF PROCEEDS**

### **Proceeds**

Under the Offering, assuming the Agent does not exercise the Agent’s Option, the Company will receive estimated net proceeds of \$4,002,000 after deduction of the Commission (assuming no proceeds are raised from President’s List Sales) but before deducting the estimated expenses of the Offering of \$350,000. If the Agent exercises the Agent’s Option in full, the estimated net proceeds to the Company from the Offering will be \$4,602,300 after deduction of the Commission (assuming no proceeds are raised from President’s List Sales) but before deducting the estimated expenses of the Offering of \$350,000.

### **Available Funds**

The working capital of the Company on the last day of the month before filing the Prospectus was \$497,734 (unaudited). That, when combined with the estimated net proceeds of the Offering of \$4,002,000, provides the Company with total estimated available funds of \$4,499,734.

Source of Funds	Amount (\$)
Working Capital as at November 30, 2020	\$497,734
Estimated Net Proceeds from the Offering <sup>(1)</sup>	\$4,002,000
Total Available Funds (unaudited)	\$4,499,794

**Note:**

(1) Assuming the Agent's Option is not exercised.

**Principal Purposes**

The Company intends to use the funds available to it following completion of the Offering as indicated in the following table:

Use of Available Funds	Amount (\$)
Research, Development and IND-Enabling Activities for TRP-8802	\$1,500,000
Research, Development and IND-Enabling Activities for TRP-1001	\$400,000
General and Administrative Expenses <sup>(1)(2)</sup>	\$2,200,000
Unallocated Working Capital <sup>(3)</sup>	\$399,794
Total Available Funds (unaudited)	\$4,499,794

**Notes:**

(1) Includes \$350,000 estimated expenses of the Offering.

(2) Estimated operating expenses for the next 12 months are comprised of: \$660,000 for consulting fees, of which approximately \$464,000 is allocated to executive compensation; \$237,500 for professional services (including accounting and legal services); \$485,000 for investor relations activities; \$245,000 for administrative expenses; \$200,000 related to maintenance and protection of intellectual property; and \$272,500 for other miscellaneous expenses.

(3) Our unallocated working capital is to provide additional contingency for overhead and general and administrative expense overrun.

*Research and Development Activities*

The Company intends to use a portion of the funds raised pursuant to the Offering for research and development purposes as well as IND-enabling activities. The Company anticipates that all or a portion of such research and development and IND-enabling activities will be subcontracted out to third-party organizations. See "*General Development and Business of the Company*".

Major components of the Company's research and development programs include formulation and manufacturing process development; certain preliminary manufacturing activities; development of clinical trial protocols; and preparation for Type B meetings with the FDA.

Key activities and milestones expected to be achieved in 2021 include:

#### TRP-8802

- Develop and validate manufacturing process for API;
- Manufacture API; and
- Initiate development of finished drug product formulation.

Following completion of the activities above, the Company expects to have the API and the chemistry, manufacturing, and controls data necessary for manufacturing of finished drug product and requesting a Type B meeting with the FDA regarding the use of TRP-8802 in the treatment of fibromyalgia. The Company may, at its own discretion, or at the request of the FDA following a Type B meeting, conduct certain preclinical studies prior to initiating a clinical study of TRP-8802. Additional funds will be required to complete finished drug product manufacturing and clinical development activities. The nature and costs of clinical development activities depend heavily on the outcome of the initial clinical study of TRP-8802 and feedback from the FDA.

#### TRP-1001

- Develop and validate manufacturing process for API; and
- Initiate development of finished drug product formulation.

Following completion of the activities above, the Company expects to have the chemistry, manufacturing, and controls data necessary for manufacturing API and conducting finished drug product manufacturing scale-up and stability testing.

If the Agent's Option is exercised either in full or in part, we will use the proceeds received, after deducting the Agent's Commission and expenses of the Offering, to supplement our unallocated working capital.

The Company intends to spend its available funds as set out in this Prospectus. However, there may be situations where, due to changes in the Company's circumstances, business outlook, research results or other reasons, including unforeseen impacts resulting from the COVID-19 pandemic, that a reallocation of funds is necessary in order for the Company to achieve its overall business objectives. Management has, and will continue to have, the discretion to modify the allocation of the Company's available funds, including the net proceeds of the Offering, if necessary. If management determines that a reallocation of funds is necessary, the Company may redirect its available funds, including the net proceeds of the Offering, to purposes other than as described in this Prospectus. The actual amount that the Company spends in connection with each of the intended uses of funds may vary significantly from the amounts specified above and will depend on a number of factors, including those referred to under "Risk Factors".

#### Business Objectives and Milestones

The objectives we expect to accomplish using our available funds in the next 12 months, are as follows:

Business Objective	Milestone that must occur for Business Objective to be Accomplished	Anticipated Timing to achieve Business Objective	Estimated Cost
Manufacture cGMP TRP-8802 API and advance the TRP-8802 R&D program	Develop and validate manufacturing process for API	Calendar Q3/Q4 2021	\$1,500,000



to initiation of finished drug product manufacturing scale-up and stability testing

Initiate development of finished drug product formulation

Request Type B meeting with the FDA

Advance the TRP-1001 R&D program to a stage where we are ready to initiate the cGMP API manufacturing and finished drug product manufacturing scale-up and stability testing phases

Develop and validate manufacturing process for API

Initiate development of finished drug product formulation

Calendar Q3 2021

\$400,000

We expect that with the funds anticipated to be available to the Company following the Offering we will make significant progress in the research and development programs for each of TRP-8802 and TRP-1001. However, there may be situations where, due to changes in the Company's circumstances, business outlook, research results or other reasons, including unforeseen impacts resulting from the COVID-19 pandemic, such progress is delayed. Management has, and will continue to have, the discretion to modify the Company's objectives, if necessary. See *"Risk Factors"*.

#### **Unallocated Funds in Trust or Escrow**

Unallocated funds will be deposited in the Company's bank account and added to the working capital of the Company. Our Chief Financial Officer is responsible for the supervision of all our financial assets. Based on our cash flows requirements, management will determine the appropriate level of liquidity required for operations and will draw down such funds as necessary.

#### **Negative Operating Cash Flow**

As at August 31, 2020 the Company has incurred a loss of \$422,617 since incorporation. There is no guarantee the Company will ever become profitable. By the nature of our business as a pharmaceutical company focused on discovering and developing novel therapeutics for the treatment of rare diseases and other diseases with high unmet medical needs, the Company has negative cash flow from its operating activities and currently generates no revenue from its activities. The Company anticipates that it will continue to have negative cash flow until such time as commercial production is achieved on one or more of its drug candidates.

Since its inception in September 2019, the Company has generated negative operating cash flows. The Company does not expect to generate positive cash flows until one or more of its drug candidates enters into commercial production. The Company has to this date funded its operations with proceeds from equity financings and expects to raise additional funds through equity financings.

See *"Risk Factors – Risks Related to the Company"*.

#### **DIVIDEND POLICY**

The Company has not, since the date of its incorporation, declared or paid any dividends or other distributions on its Common Shares, and does not currently have a policy with respect to the payment of dividends or other distributions. The Company does not currently pay dividends and does not intend to pay

dividends in the foreseeable future. The declaration and payment of any dividends in the future is at the discretion of the Board and will depend on numerous factors, including compliance with applicable laws, financial performance, working capital requirements of the Company and such other factors as its directors consider appropriate. There can be no assurance that the Company will pay dividends under any circumstances. See “Risk Factors – Risks Related to the Company”.

#### SELECTED FINANCIAL INFORMATION AND MANAGEMENT’S DISCUSSION AND ANALYSIS

The following tables set forth selected financial information with respect to the Company’s audited financial statements for the period from incorporation on September 24, 2019 to August 31, 2020 and have been prepared as at August 31, 2020. The selected financial information has been derived, except where indicated, from the audited financial statements for the period of incorporation on September 24, 2019 to August 31, 2020. The following should be read in conjunction with the said financial statements.

##### Selected Financial Information

	<b>Incorporation (September 24, 2019) to (August 31, 2020) (Audited) (\$)</b>
<b>Statement of Loss</b>	
Revenue	-
Expenses	422,617
Net Loss	(422,617)
Basic and diluted loss per share	(0.02)
<b>As at August 31, 2020 (Audited) (\$)</b>	
<b>Statement of Financial Position</b>	
<b>Assets</b>	
Current Assets	1,047,800
Intangible Assets	960,725
Total Assets	2,035,045
<b>Liabilities</b>	
Current Liabilities	192,708
Total Liabilities	192,708
Shareholders' Equity	1,842,337
Total Liabilities & Shareholders' Equity	2,035,045

## Management Discussion and Analysis

### Overview

This management discussion and analysis (“**MD&A**”) of the operations and financial condition of the Company is dated as of August 31, 2020 and describes the operating and financial results of the Company for the period from incorporation on September 24, 2019 to August 31, 2020. This MD&A supplements, but does not form part of, the audited financial statements of the Company, and should be read in conjunction with the Company’s audited financial statements and related notes for the period from incorporation on September 24, 2019 to August 31, 2020. The Company prepares and files its financial statements in accordance with IFRS. The currency referred to in this MD&A is Canadian Dollars.

### Overall Performance

Tryp is a pharmaceutical company focused on developing compounds with known activity and/or safety profiles for the treatment of rare or orphan diseases and other diseases with high unmet medical needs. The Company’s lead development program, which is referred to as the psilocybin-for-neuropsychiatry, or PFN™, program, is designed to treat neuropsychiatric disorders through the dosing of formulations of synthetic psilocybin. The initial indication for our PFN™ program is fibromyalgia. The Company is also evaluating additional indications for our PFN™ program, including hyperphagia in Prader-Willi Syndrome (PWS) and other neuropsychiatric-based chronic pain conditions and eating disorders.

In addition to our PFN™ program, Tryp intends to pursue non-psychedelic drug candidates with known activity and/or safety profiles that may have utility in the treatment of rare or orphan diseases or other diseases with high unmet medical needs. As part of that program, Tryp’s business objectives include the development of a proprietary formulation of razoxane for the treatment of soft tissue sarcomas. The Company’s continues to evaluate potential additional indications for its existing programs, as well as other drug candidates that meet Tryp’s criteria for development. See “*General Development and Business of the Company*”.

### Results of Operation

#### **Financial Results for the period September 24, 2019 to August 31, 2020**

The Company has no operating revenues during the period from incorporation on September 24, 2019 to August 31, 2020 and relies on external financings to generate capital for its continued operations. As a result of its activities, the Company continues to incur losses.

The Company’s operating results for the period September 24, 2019 to August 31, 2020 were as follows:

	<b>2020</b>
<b>Expenses</b>	
Consulting Fees	\$ 233,640
Office and Administrative	772
Filing fees	123
Research and Development	8,327
Marketing and Corporate Development	27,672

Website, advertising and promotion	14,479
Professional fees	126,193
Travel	11,411
<hr/>	
Total expenses	422,617
<hr/>	
<b>Net loss and comprehensive loss for the year</b>	<b>(422,617)</b>
<hr/>	
<b>Loss per share for the year- basic and diluted</b>	<b>\$ (0.02)</b>
<hr/>	
<b>Weighted average number of shares outstanding</b>	<b>18,998,964</b>

The primary costs included in total expenses included:

Consulting fees (\$233,640) relate to services provided by consultants, including management, of which \$189,640 was compensated through the issuance of common shares for the research and development of the Company's business plan, business advisory services provided to management to assist in the preparation of its going public transaction and related documentation and filing requirements.

Website, advertising and promotion expenses (\$14,479) relate to the design of the corporate logo, presentations, and website development.

Professional fees (\$126,193) include legal fees in connection with the Company's incorporation, going public transaction opportunities, patent applications, and general legal counsel. Also, included are audit fees accrued to the Company's auditors for the August 31, 2020 audit.

Marketing and corporate development expenses (\$27,672) relate to media advisory and marketing campaign.

Travel expenses (\$11,411) are in connection with the attendance of certain conferences related to the Company's business plan.

### ***Summary of Quarterly Results***

Since incorporation, the Company has not prepared quarterly interim financial statements. As a result, the Company is unable to provide a summary or the quarterly results from the date of incorporation on September 24, 2019 to August 31, 2020.

### ***Liquidity and capital resources***

	<b>August 31 2020</b>
<hr/>	
<b>Financial position:</b>	
Cash	\$ 1,019,100
Working capital	\$ 855,092
Total Assets	\$ 2,035,045
Shareholders' equity	\$ 1,842,337
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As at August 31, 2020, the Company's working capital balance was \$855,092 which included prepaid expenditures of \$28,700 for marketing and corporate development.

The intangible assets of \$960,725 represents the capital investment (\$956,520) and further expenditures (\$4,205) for patent applications filing and expenses.

Since incorporation on September 24, 2019 to August 31, 2020 the Company has raised \$1,068,794 and spent approximately \$422,617 on investment activities related to the research and development of its business objectives and milestones as outlined in "*Business Objectives and Milestones*".

The Company believes that its cash and cash equivalents on hand will enable the Company to fund future overhead working capital for the next 12 months. The Company will require additional funding to complete any significant research and development as outline in "*Business Objectives and Milestones*".

### ***Off-Balance Sheet Arrangements***

The Company has no off-balance sheet arrangements.

### ***Key Management and Personnel Compensation***

Key management personnel include those persons having authority and responsibility for planning, directing, and controlling the activities of the Company as a whole. The Company has determined that key management personnel consist of executive and non-executive members of the Company's Board of Directors and corporate officers. Key management personnel compensation for the period from September 24, 2019 to August 31, 2020 included:

	<b>Period from September 24, 2019 (incorporation) to August 31, 2020</b>
Key management personnel compensation comprised:	
Consulting fees <sup>1</sup> :	<b>\$42,500</b>

<sup>1</sup> Included in compensation was the issuance of 500,000 common shares with a fair value of \$25,000 issued for services (See Note 7 to the Company's financial statements for the period from incorporation on September 24, 2019 to August 31, 2020).

As at August 31, 2020, included in trade and other payables are amounts due to officers and directors for fees and expenses of \$41,113.

### ***Related Party Transactions***

#### ***IP Purchase***

On January 9, 2020, the Company and Dr. Garner entered into a purchase and assignment agreement (the "**IP Purchase Agreement**") pursuant to which the Company acquired certain inventions, technical information and the Razoxane Patent Application (the "**Purchased Assets**"). Pursuant to the terms of the IP

Purchase Agreement the Company issued 32,000 common shares at a price of \$0.005 per Common Share for a value of \$160 for the Purchased Assets (on a post-split, post-consolidation basis).

On June 30, 2020, the Company entered into purchase agreements (collectively the “**Additional IP Purchase Agreements**”) with Dr. Garner and Dr. Kuo, pursuant to which to which the Company acquired certain inventions, technical information and the Psilocybin Patent Application (the “**Additional Purchased Assets**”). Pursuant to the terms of the Additional IP Purchase Agreements the Company paid an aggregate of \$956,360 for the Additional Purchased Assets, pursuant to the issuance of an aggregate of 19,127,200 Common Shares at a deemed price of \$0.05 per Common Share.

The Purchased Assets and Additional Purchased Assets (collectively the “**Intellectual Property**”) with an aggregate value of \$956,520 were recorded as intangible assets.

### ***Shares Issued for Services***

On June 23, 2020, the Company issued 500,000 common shares at a price of \$0.05 per share for a value of \$25,000 to an officer of the Company for compensation for services and is included in the amounts recorded as consulting fees (see note 8 to the Company’s financial statements for the period from incorporation on September 24, 2019 to August 31, 2020).

### ***Shareholder Loans***

As at August 31, 2020, cash advances to the Company in the amount of \$4,514 were due and payable to a director and shareholder of the Company. This amount is due on demand, unsecured, and without interest. Subsequent to August 31, 2020, the amount was repaid in full.

### ***Critical Accounting Policies and Estimates***

The Company makes estimates and assumptions about the future that affect the reported amounts of assets and liabilities. Estimates and judgments are continually evaluated based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. In the future, actual experience may differ from these estimates and assumptions. The effect of a change in an accounting estimate is recognized prospectively by including it in loss/income in the year of the change, if the change affects that year only, or in the year of the change and future years, if the change affects both.

Information about critical judgments and estimates in applying accounting policies that have the most significant risk of causing material adjustment to the carrying amounts of assets and liabilities recognized in the financial statements within the next financial year are discussed below:

#### **Critical accounting estimates:**

##### **Recoverability of the carrying value of intangible assets**

Recoverability of the carrying value of intangible assets requires management to determine whether future economic benefits from sale or otherwise are likely. Evaluation may be more complex where activities have not reached a stage that permits a reasonable assessment of the viability of the asset. Management must make certain estimates and assumptions about future events or circumstances including, but not limited to,

the interpretation of research results, as well as the Company's financial ability to continue sales activities and operations.

### **The measurement of deferred income tax assets and liabilities**

Deferred tax assets, including those arising from un-utilized tax losses, require management to assess the likelihood that the Company will generate sufficient taxable earnings in future periods in order to utilize recognized deferred tax assets. Assumptions about the generation of future taxable profits depend on management's estimates of future cash flows. In addition, future changes in tax laws could limit the ability of the Company to obtain tax deductions in future periods. To the extent that future cash flows and taxable income differ significantly from estimates, the ability of the Company to realize the net deferred tax assets recorded at the reporting date could be impacted.

### **Useful lives of intangible assets**

Amortization is recorded on the straight-line basis based upon management's estimate of the useful life and residual value. The estimates are reviewed at least annually and are updated if expectations change as a result of the technical obsolescence or legal and other limits to use. A change in the useful life or residual value will impact the reported carrying value of the intangible assets resulting in a change in related amortization expense. As at August 31, 2020, the Company has not amortized the intangible assets as amortization begins when the intangible assets are available for use.

### **Fair value of consideration for intangible assets acquired**

The Company has applied estimates with respect to the valuation of shares issued for non-cash consideration in the acquisition of intangible assets. Shares are valued at the fair value of the equity instruments granted at the date the Company receives the goods or services for share-based payments made to those other than employees or others providing similar services.

### **Critical accounting judgments:**

#### **Going concern**

The preparation of these financial statements requires management to make judgments regarding the going concern of the Company as discussed in note 2 of the Company's audited financial statements.

#### **Treatment of development costs**

Costs to develop products are capitalized to the extent that the criteria for recognition as intangible assets in IAS 38 *Intangible Assets* are met. Those criteria require that the product is technically and economically feasible, which management assessed based on the attributes of the development project, perceived user needs, industry trends and expected future economic conditions. Management considers these factors in aggregate and applies significant judgment to determine whether the product is feasible. The Company has not capitalized any development costs as at August 31, 2020.

### **Treatment of deferred financing costs**

Professional, consulting, regulatory and other costs directly attributable to financing transactions are recorded as deferred financing costs until the financing transactions are completed, if the completion of the transaction is considered likely; otherwise they are expensed as incurred. Management applies significant judgment to determine whether the completion of the transaction is considered likely.

### **Treatment of acquired intangible assets**

Consideration paid in the acquisition of intangible assets is capitalized to the extent that the definition of an intangible asset and the criteria for recognition as intangible assets in IAS 38 *Intangible Assets* are met. Those criteria require that the intangible asset be identifiable, the Company must have control over it, and it must provide future economic benefits. Management considers these factors in aggregate and applies significant judgment to determine whether the intangible asset should be recognized in the statement of financial position.

At each reporting date, the Company assesses if the intangible assets have indicators of impairment. In determining whether the intangible assets are impaired, the Company assesses certain criteria, including observable decreases in value, significant changes with adverse effect on the entity, evidence of technological obsolescence and future plans.

### ***Future Accounting Pronouncements***

The standards listed below include only those which the Company reasonably expects may be applicable to the Company at a future date. The Company is currently assessing the impact of the standards on the financial statements.

#### ***IFRS 16 Leases***

IFRS 16 specifies how an IFRS reporter will recognize, measure, present and disclose leases. The standard provides a single lessee accounting model, requiring lessees to recognize assets and liabilities for all leases unless the lease term is 12 months or less or the underlying asset has a low value. Lessors continue to classify leases as operating or finance, with IFRS 16's approach to lessor accounting substantially unchanged from its predecessor, IAS 17 *Leases*. The standard is effective for annual periods beginning on or after January 1, 2019, with early adoption permitted for entities that have adopted IFRS 16. The Company has no leases as at August 31, 2020.

### **Financial Instruments**

The Company is exposed to risks that arise from its use of financial instruments. This note describes the Company's objectives, policies and processes for managing those risks and the methods used to measure them. Further quantitative information in respect of these risks is presented throughout these financial statements. The type of risk exposure and the way in which such exposure is managed is provided as follows:



### ***Credit risk***

Credit risk is the risk that one party to a financial instrument will fail to discharge an obligation and cause the other party to incur a financial loss. The Company's primary exposure to credit risk is on its cash held in bank accounts. The majority of cash is deposited in bank accounts held with a major bank in Canada. As most of the Company's cash is held by one bank there is a concentration of credit risk. This risk is managed by using major banks that are high credit quality financial institutions as determined by rating agencies. Credit risk related to cash is assessed as low.

### ***Liquidity risk***

Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they fall due. The Company has a planning and budgeting process in place to help determine the funds required to support the Company's normal operating requirements on an ongoing basis. The Company ensures that there are sufficient funds to meet its short-term business requirements, taking into account its anticipated cash flows from operations and its holdings of cash. As of August 31, 2020, the Company had working capital of \$855,092 to cover short term obligations.

Historically, the Company's sole source of funding has been loans from related parties and private placements. The Company's access to financing is always uncertain. There can be no assurance of continued access to significant equity funding. Liquidity risk is assessed as moderate.

### ***Interest rate risk***

Interest rate risk is the risk that the fair value of future cash flows of a financial instrument will fluctuate because of changes in market interest rates. As at August 31, 2020, the Company did not have any financial instruments subject to interest rate risk.

### ***Fair value***

Financial instruments that are measured subsequent to initial recognition at fair value are grouped in Levels 1 to 3 based on the degree to which the fair value is observable:

- Level 1 – Unadjusted quoted prices in active markets for identical assets or liabilities;
- Level 2 – Inputs other than quoted prices that are observable for the asset or liability either directly or indirectly; and
- Level 3 – Inputs that are not based on observable market data.

As at August 31, 2020, cash is measured as Level 1 financial instruments.

### **Capital Management**

The Company considers its share capital as capital. The Company's objectives when maintaining capital are to maintain a sufficient capital base in order to meet its short-term obligations and at the same time preserve investor's confidence required to sustain future development and production of the business. The Company is not exposed to any externally imposed capital requirements. There were no changes in the Company's approach to capital management during the period.

## **Outstanding Share Data**

The Company's authorized share capital consists of:

- Unlimited Common Shares without par value.
- Unlimited Preferred Shares without par value.

As at the date of this Prospectus the Company had 39,291,722 Common Shares issued and outstanding and no Preferred Shares issued and outstanding. Additionally, the Company has 6,869,684 Options outstanding. See "*Description of the Securities Distributed*".

## **Risks and Uncertainties**

See "*Risk Factors*".

## **DESCRIPTION OF THE SECURITIES DISTRIBUTED**

### **Authorized and Issued Share Capital**

The authorized share capital of the Company consists of an unlimited number of Common Shares without par value of which 39,291,722 Common Shares are issued and outstanding as at the date of this Prospectus and an unlimited number of Preferred Shares, of which none are issued and outstanding as of the date of this Prospectus.

### **Common Shares**

The holders of the Common Shares are entitled to receive notice of and to attend and vote at all meetings of the shareholders of the Company and each Common Share shall confer the right to one vote in person or by proxy at all meetings of the shareholders of the Company. The holders of the Common Shares, subject to the prior rights, if any, of any other class of shares of the Company, are entitled to receive such dividends in any financial year as the Board of Directors of the Company may by resolution determine. In the event of the liquidation, dissolution or winding-up of the Company, whether voluntary or involuntary, the holders of the Common Shares are entitled to receive, subject to the prior rights, if any, of the holders of any other class of shares of the Company, the remaining property and assets of the Company. The Common Shares do not carry any pre-emptive, subscription, redemption or conversion rights, nor do they contain any sinking or purchase fund provisions.

### **Unit Warrants**

The Unit Warrants are governed by the terms and conditions set forth in the Warrant Indenture between the Company and the Warrant Agent, which indenture provides for the creation of the Unit Warrants and includes a form of Unit Warrant certificate. The following is a summary description of certain material provisions of the Warrant Indenture, it does not purport to be a comprehensive summary and is qualified in its entirety by reference to the more detailed provisions of the Warrant Indenture, a copy of which may be

obtained on request without charge from the Company at its registered office or electronically on SEDAR at [www.sedar.com](http://www.sedar.com).

Each Unit Warrant will be exercisable to acquire one Warrant Share at an exercise price of \$0.50 per Warrant Share at any time up to the date which is 12 months from the Closing Date, subject to adjustment in certain events. If, at any time following the date that is 60 days from the Listing Date, the daily volume weighted average trading price of the Common Shares on the CSE, or such other stock exchange on which the Common Shares are listed, if the Common Shares are listed on any stock exchange, is greater than \$0.75 for the preceding 10 consecutive trading days, the Company may, upon providing written notice to the holders of Unit Warrants, accelerate the expiry date of the Unit Warrants to the date that is 30 days following the delivery of such written notice.

The Warrant Indenture provides for adjustment in the number of Warrant Shares issuable upon the exercise of the Unit Warrants and/or the exercise price per Warrant Share upon the occurrence of certain events, including: (i) the subdivision, re-division or change of the outstanding Common Shares into a greater number of Common Shares; (ii) the reduction, combination or consolidation of the outstanding Common Shares into a lesser number of Common Shares; (iii) the issuance of Common Shares or securities exchangeable for or convertible into Common Shares to all or substantially all of the holders of the Common Shares as a stock dividend or other distribution (other than upon exercise of Warrants); and (iv) the fixing of a record date for the issuance or distribution to all or substantially all of the holders of the Common Shares of: (a) securities of any class, whether of the Company or any other trust (other than Common Shares), (b) rights, options or warrants to subscribe for or purchase Common Shares (or other securities convertible into or exchangeable for Common Shares), (c) evidences of its indebtedness, or (iv) any property or other assets.

The Warrant Indenture also provides for adjustments in the class and/or number of securities issuable upon exercise of the Unit Warrants and/or exercise price per security in the event of the following additional events: (i) reclassifications of the Common Shares or a capital reorganization other than as described above; (ii) consolidations, amalgamations, arrangements, or mergers of the Company with or into another entity; or (iii) the sale or conveyance of the property or assets of the Company as an entirety or substantially as an entirety to any other entity.

Notwithstanding the foregoing, no adjustment shall be made in the acquisition rights attached to the Unit Warrants if the issue of Common Shares is being made pursuant to the Warrant Indenture or in connection with: (i) any share incentive plan or restricted share plan or share purchase plan in force from time to time for directors, officers, employees, consultants or other service providers of the Company; or (ii) the satisfaction of existing instruments issued at the Closing Date.

The Company has agreed that, so long as any Unit Warrant remains outstanding, it will give notice to the Warrant Agent and to the holders of Unit Warrants of its intention to fix a record date that is prior to the expiry date of the Unit Warrants for any matter for which an adjustment may be required pursuant to the Warrant Indenture. Such notice is to specify the particulars of such event and the record date for such event, provided that the Company shall only be required to specify in the notice such particulars of the event as shall have been fixed and determined on the date on which the notice is given. The notice is to be given, in each case, not less than 14 days prior to such applicable record date. If notice has been given and the adjustment is not then determinable, the Company shall promptly, after the adjustment is determinable,

file with the Warrant Agent a computation of the adjustment and give notice to the holders of Unit Warrants of such adjustment computation.

Neither the Unit Warrants nor the Common Shares issuable upon exercise of the Unit Warrants have been or will be registered under the U.S. Securities Act or any state securities regulations. Accordingly, the Unit Warrants may not be exercised in the United States or by, or on behalf of, a U.S. Person (as defined in Rule 902(k) of the U.S. Securities Act) or a person in the United States unless exemptions are available from the registration requirements of the U.S. Securities Act and the securities laws of all applicable states.

No fractional Warrant Shares will be issuable upon the exercise of any Unit Warrants, and no cash or other consideration will be paid in lieu of fractional shares. Holders of Unit Warrants will not have any voting or preemptive rights or any other rights that a holder of Common Shares would have.

### **Warrant Shares**

The Warrant Shares issuable pursuant to exercise of the Unit Warrants will have the same rights as the Common Shares. See "*Description of Securities Distributed – Common Shares*" for a description of the rights of holders of Common Shares.

### **Compensation Options**

On the Closing Date, the Company will issue Compensation Options to the Agent. The Compensation Options will be qualified by this Prospectus. Each Compensation Option will be exercisable at a price of \$0.25 per Compensation Option for a period of 12 months from the Listing Date to acquire one Compensation Unit. Each Compensation Unit will consist of one Compensation Unit Share and one-half of one Compensation Unit Warrant. Each Compensation Unit Warrant will entitle the holder to purchase one Compensation Unit Warrant Share at a price of \$0.50 per share for a period of 12 months from the Closing Date, subject to the same acceleration clause as the Unit Warrants.

The certificates representing the Compensation Options and Compensation Unit Warrants will, among other things, include provisions for the appropriate adjustment in the class, number and price of the Compensation Unit Warrants to be issued on exercise of such options upon the occurrence of certain events, including any subdivision, consolidation or reclassification of the Common Shares, the payment of stock dividends, and corporate reorganization of the Company. The issue of Compensation Options will not restrict or prevent the Company from obtaining any other financing, or from issuing additional securities or rights, during the period within which the options may be exercised. This Prospectus qualifies the distribution of the Compensation Options, the Compensation Unit Shares, the Compensation Unit Warrants and the Compensation Unit Warrant Shares issuable upon the exercise thereof. See "*Plan of Distribution*".

### **Agent's Option**

The Company has granted to the Agent the Agent's Option, exercisable in whole or in part, in the sole discretion of the Agent, for a period of 30 days from the Closing Date, to increase the size of the Offering by up to 2,610,000 Agent's Option Units at the Offering Price. If the Agent's Option is exercised in full, the total "Price to the Public", "Agent's Fee" and "Net Proceeds to the Company" will be \$5,002,500, \$400,200 and

\$4,602,300, respectively. This Prospectus qualifies the grant of the Agent’s Option and the distribution of the Agent’s Option Units issuable upon exercise of the Agent’s Option.

### **CONSOLIDATED CAPITALIZATION**

There have been the following material changes in the Company’s share capital since August 31, 2020, the date of its most recently completed financial period (the Company has no loan capital as of the date of this Prospectus):

#### *Shares for Debt*

On September 21, 2020, the Company issued 900,000, Common Shares at a deemed price of \$0.15 per Common Share in satisfaction of outstanding indebtedness of the Company.

#### *Stock Options*

On September 29, 2020, the Company granted an aggregate of 1,600,000 options at a price of \$0.15 to certain consultants of the Company. The options vest over a period three years and expire five years following the date of grant.

On November 2, 2020, the Company granted an aggregate of 5,269,684 options at a price of \$0.15 to certain consultants of the Company. The options vest in periods ranging from six months to three years and expire in periods ranging from five to ten years following the date of grant.

The Company anticipates issuing 17,400,000 Unit Shares pursuant to the Offering (20,010,000) Unit Shares if the Agent’s Option is exercised in full). On completion of the Offering, the Company will have 56,691,722 Common Shares issued and outstanding (59,301,722 Common Shares issued and outstanding if the Agent’s Option is exercised in full). There will be no material change to the Company’s loan capital that will result from the completion of the Offering.

The following table sets forth the consolidated share capitalization of the Company as at August 31, 2020 on an actual basis and on a pro forma basis as adjusted to give effect to the completion of the Offering. Investors should read the following information in conjunction with the Company’s audited financial statements and related notes thereto, along with the associated MD&A, included in this Prospectus.

<b>Description of Security</b>	<b>Amount Authorized</b>	<b>Amount Outstanding as of August 31, 2020</b>	<b>Amount Outstanding as at August 31, 2020 after giving effect to the Offering</b>	<b>Amount Outstanding as at August 31, 2020 after giving effect to the Offering, assuming the exercise of the Agent’s Option in full</b>
Common Shares	Unlimited	\$2,264,954 (38,391,722 Common Shares)	\$6,614,954 (55,791,722 Common Shares)	\$7,267,454 (58,401,722 Common Shares)
Preferred Shares	Unlimited	nil	nil	nil

Description of Security	Amount Authorized	Amount Outstanding as of August 31, 2020	Amount Outstanding as at August 31, 2020 after giving effect to the Offering	Amount Outstanding as at August 31, 2020 after giving effect to the Offering, assuming the exercise of the Agent's Option in full
Options	10% of issued and outstanding Common Shares plus an additional 5,269,684 options	nil	nil	nil

## OPTIONS TO PURCHASE SECURITIES

### Stock Option Plan

Incentive stock options are governed by the Company's stock option plan (the "Plan") approved by the Company's directors on November 2, 2020. The purpose of the Plan is to advance the interests of the Company by encouraging the directors, officers, employees and consultants of the Company, and of its subsidiaries and affiliates, if any, to acquire Common Shares in, thereby increasing their proprietary interest in the Company, encouraging them to remain associated with the Company and furnishing them with additional incentive in their efforts on behalf of the Company in the conduct of its affairs.

The Plan is administered by the Company's directors or by a special committee of directors appointed from time to time by the Board. The material terms of the Plan are as follows:

- The aggregate number of Common Shares issuable upon the exercise of all options granted under the Plan shall not exceed 10% of the issued and outstanding Common Shares of the Company from time to time (the "Rolling 10% Maximum"), other than Common Shares issuable upon the exercise of the Special Consultant Options (as defined herein), which shall be in addition to the Rolling 10% Maximum, provided that such number of Common Shares issuable upon exercise of options granted under the Plan plus the number of Shares reserved for issuance under all other equity incentive plans of the Corporation, shall not exceed 20% of the issued and outstanding Common Shares on a non-diluted basis at any time. If any option granted hereunder, other than a Special Consultant Option, shall expire or terminate for any reason in accordance with the terms of the Plan without being exercised, the unpurchased Common Shares subject thereto shall again be available for the purpose of the Plan. If any Special Consultant Option shall expire or terminate for any reason in accordance with the terms of the Plan without being exercised, the unpurchased Common Shares subject thereto shall not be available for the purpose of the Plan. For the purposes of the Plan, "Special Consultant Options" means the 5,269,684 options of the Company granted to consultants of the Company on November 2, 2020.
- The term of any options granted under the Plan will be fixed by the Board of Directors at the time such options are granted, provided that options will not be permitted to exceed the maximum term permitted by any stock exchange on which the Common Shares are then listed and any other regulatory body having jurisdiction.

- The exercise price of any options granted under the Plan will be determined by the Board of Directors, subject to the approval of any applicable stock exchange. In no event, shall such exercise price be lower than the lowest exercise price permitted by an applicable stock exchange.
- The Board of Directors may impose vesting periods on any options granted.
- Options granted to persons who perform investor relations services in any 12 month period will not exceed the maximum number of Common Shares permitted by an applicable stock exchange.
- All options will be non-assignable and non-transferable unless specifically provided in the Plan or to the extent, if any, permitted by an applicable stock exchange.
- The number of Common Shares subject to an option granted to any one participant shall be determined by the Board, but no one participant shall be granted an option which exceeds such maximum number, if any, permitted by an applicable stock exchange.
- If a participant ceases to be a director, officer, consultant or employee of the Company, for any reason (other than death), such participant may exercise his option to the extent that the participant was entitled to exercise it at the date of such cessation, provided that such exercise must occur within 90 days after the participant ceases to be a director, officer, consultant, employee, unless such participant was engaged in investor relations activities, in which case such exercise must occur within 30 days after the cessation of the participant's services to the Company.

As of the date hereof, there are 6,869,684 options outstanding under the Plan. The options are held as follows:

<b>Category of Optionee</b>	<b>Common Shares under Options Granted</b>	<b>Exercise Price per Common Share</b>	<b>Expiry Date</b>
All executive officers and past executive officers as a group	Nil	N/A	N/A
All directors and past directors who are not also executive officers as a group	Nil	N/A	N/A
Consultants, as a group (7 persons)	6,869,684	\$0.15	Ranging from 5 to 10 years from date of grant
Any other person or company, other than the Agent	Nil	N/A	N/A
Total Options	6,869,684	\$0.15	Ranging from 5 to 10 years from date of grant

## PRIOR SALES

The following table summarizes the issuances of Common Shares and securities that are convertible or exchangeable into Common Shares in the 12 months prior to the date of this Prospectus:

Date	Number and Type of Securities <sup>(1)</sup>	Issue / Exercise Price Per Security
September 24, 2019	1 Common Share <sup>(2)</sup>	\$0.0000001
January 9, 2019	100,000 Common Shares <sup>(3)</sup>	\$0.0000001
June 30, 2020	22,374,000 Common Shares <sup>(4)</sup>	\$0.05
August 4, 2020	11,899,650 Common Shares <sup>(5)</sup>	\$0.05
August 14, 2020	4,038,072 Common Shares <sup>(6)(7)</sup>	\$0.05 - \$0.15
September 21, 2020	900,000 Common Shares <sup>(8)</sup>	\$0.15
September 29, 2020	1,600,000 Options	\$0.15
November 2, 2020	5,269,684 Options	\$0.15

**Notes:**

- (1) 20,292,400 of these Common Shares will be held in escrow in accordance with the terms of the Escrow Agreement (as defined herein).
- (2) Common Share issued on incorporation and subsequently repurchased by the Company on January 9, 2020.
- (3) 40,000 of these Common Shares were issued in connection with the acquisition of the Intellectual Property by the Company. The Common Shares were subsequently split on January 9, 2020 at ratio of 1 (old) for 200 (new), resulting in an aggregate of 20,000,000 Common Shares issued and outstanding as of January 9, 2020. The Common Shares were subsequently consolidated on June 23, 2020 at a ratio of 250 (old) for 1 (new), resulting in an aggregate of 80,000 Common Shares issued and outstanding as of June 23, 2020.
- (4) 19,127,200 of these Common Shares were issued in connection with the acquisition of Intellectual Property by the Company. 3,246,800 of these Common Shares were issued to certain persons on account of past services rendered to the Company.
- (5) 500,000 of these Common Shares were issued in satisfaction of outstanding indebtedness of the Company at a deemed price per share of \$0.05.
- (6) 546,000 of these Common Shares were issued to certain persons on account of past services rendered to the Company at a value of \$0.05.
- (7) 166,667 of these Common Shares were issued in satisfaction of outstanding indebtedness of the Company at a deemed price per share of \$0.15.
- (8) These Common Shares were issued in satisfaction of outstanding indebtedness of the Company at a deemed price per share of \$0.15.

### ESCROWED SECURITIES AND SECURITIES SUBJECT TO RESTRICTION ON TRANSFER

National Policy 46-201 – *Escrow for Initial Public Offerings (“NP 46-201”)* provides that all securities of an issuer owned or controlled by a Principal (as defined in NP 46-201) must be placed in escrow at the time the issuer distributes its securities or convertible securities to the public by prospectus pursuant to an initial public offering, unless the securities held by the Principal or issuable to the Principal upon conversion of convertible securities held by the Principal collectively represent less than 1% of the total issued and outstanding Common Shares of the Company after giving effect to the initial public offering.

The Principals of the Company for the purposes of NP 46-201 are William Garner, James Kuo, James Gilligan, Terese Gieselman, Gage Jull and Peter Molloy (collectively, the “**Escrowed Principals**”).

The following table sets forth, as of the date of this Prospectus, the number of securities of each class of securities of the Company held, to the knowledge of the Company, in escrow or that are subject to a



contractual restriction on transfer and the percentage that number represents of the outstanding securities of that class.

Designation of Class	Number of Escrowed Securities	Percentage of Class
Common Shares	20,292,400	51.65%

On November 13, 2020, the Escrowed Principals entered into an agreement (the “**Escrow Agreement**”) with Computershare Investor Services Inc., as escrow agent (the “**Escrow Agent**”), pursuant to which the Escrowed Principals will collectively deposit 20,292,400 Common Shares into escrow (the “**Escrowed Securities**”) with the Escrow Agent, representing 51.65% of the issued and outstanding Common Shares prior to giving effect to the Offering (or 35.79% of the issued and outstanding Common Shares after giving effect to the Offering, assuming the Agent’s Option is not exercised).

In accordance with NP 46-201, the Escrowed Securities will be subject to a three-year escrow period and subject to the following release schedule:

Date	Amount of Escrowed Securities Released
On the Closing Date	1/10 of the Escrowed Securities
6 months after the Closing Date	1/6 of the Escrowed Securities
12 months after the Closing Date	1/5 of the Escrowed Securities
18 months after the Closing Date	1/4 of the Escrowed Securities
24 months after the Closing Date	1/3 of the Escrowed Securities
30 months after the Closing Date	1/2 of the Escrowed Securities
36 months after the Closing Date	The remaining Escrowed Securities

The Company is an “emerging issuer” as defined in NP 46-201. Should the Company become an “established issuer” as defined in NP 46-201, the release of the remaining Escrowed Securities will be accelerated on a retroactive basis such that 25% would have been released on the Listing Date and an additional 25% would have been released every six months thereafter.

Pursuant to the terms of the Escrow Agreement, the Escrowed Securities may not be transferred or otherwise dealt with during the term of the Escrow Agreement except for certain circumstances, including:

- transfers to continuing or incoming directors and senior officers, subject to the Company’s Board of Directors’ approval;
- transfers to an RRSP or similar trust plan provided that the only beneficiaries are the transferor or the transferor’s spouse or children;
- transfers upon bankruptcy to a trustee in bankruptcy; and
- pledges to a financial institution as collateral for a bona fide loan, provided that upon a realization the securities remain subject to escrow.

The complete text of the Escrow Agreement is available for inspection at the registered and records office of the Company and is also available on SEDAR at [www.sedar.com](http://www.sedar.com).

### Statutory Hold Periods

In addition to the foregoing, securities legislation imposes certain resale restrictions on securities issued within the four months preceding the Offering, such hold periods are governed by NI 45-102 – *Resale of Securities*. All certificates representing securities subject to these restrictions will bear legends indicating the applicable hold periods.

### Securities Subject to Lock-Up Agreement

Pursuant to the Agency Agreement, the Company has agreed to: (i) as a condition of Closing, cause each of the Escrowed Principals and each employee of the Company that holds Common Shares (an “**Employee**”) to enter into a lock-up agreement with the Agent (a “**Lock-up Agreement**”), and (ii) use its commercially reasonable efforts to cause all other holders of its Common Shares (the “**Non-Principals**” and together with the Escrowed Principals and the Employees, the “**Locked-up Persons**”) to enter into Lock-up Agreements. Pursuant to the Lock-up Agreements, each Locked-up Person will agree not to, directly or indirectly, offer, sell, contract to sell, grant or sell any option to purchase, purchase any option or contract to sell, hypothecate, pledge, transfer, assign, lend, swap, or enter into any other agreement to transfer the economic consequences of, or otherwise dispose of or deal with (or agree to or publicly announce any intention to do any of the foregoing) whether through the facilities of a stock exchange, by private placement or otherwise, any Common Shares or other securities of the Company convertible into, exchangeable for or exercisable to acquire, Common Shares, directly or indirectly, unless (i) they first obtain the prior consent of the Agent, such consent not to be unreasonably withheld, conditioned or delayed, or (ii) there occurs a take-over bid or similar transaction involving a change of control of the Company. The Locked-Up Persons and their related lock-up periods are set forth below and shall be measured from the date of listing of the Common Shares on the CSE:

<b>Locked-Up Persons</b>	<b>Lock-up Period</b>
Escrowed Principals	12 months
Employees and Non-Principals	8 months, with Common Shares being released from lock-up in 25% increments at 2, 4, 6 and 8 months

If, at any time following the date of listing of Common Shares on the CSE, the daily volume weighted average trading price of the Common Shares on the CSE is greater than \$0.50 share for the preceding ten (10) consecutive trading days, all Common Shares or other securities of the Company convertible into, exchangeable for or exercisable to acquire, Common Shares, directly or indirectly, held by Non-Principals that remain subject to a lock-up shall immediately be released from such lock-up without any further action on the part of the Non-Principals.

## PRINCIPAL SECURITYHOLDERS

The following table sets forth information regarding ownership of the Common Shares as at the date of this Prospectus by (i) each person or company who, to the Company's knowledge, beneficially owns, or controls or directs, directly or indirectly, Common Shares carrying 10% or more of the voting rights attaching to all issued and outstanding Common Shares.

Name and Municipality of Residence	Prior to the Offering		Following Close of the Offering	
	Number of Shares Owned Directly or Indirectly	Percentage of Shares Held <sup>(1)</sup>	Number of Shares Owned Directly or Indirectly	Percentage of Shares Held <sup>(2)</sup>
William Garner, San Juan, Puerto Rico, USA <sup>(3)</sup>	13,200,000	33.59%	13,200,000	23.28%
James Kuo, La Jolla, California, USA <sup>(4)</sup>	6,000,000	15.27%	6,000,000	10.58%

**Notes:**

- (1) Assumes 39,291,722 Common Shares outstanding prior to the Offering.
- (2) Assumes 56,691,722 Common Shares outstanding following completion of the Offering. If the Agent's Option is exercised in full, Dr. Garner and Dr. Kuo would hold 22.26% and 10.12% of the issued and outstanding Common Shares, respectively.
- (3) On a fully diluted basis, and assuming the Agent's Option is not exercised and that there are no President's List Sales, Dr. Garner would hold 17.85% of the issued and outstanding Common Shares.
- (4) On a fully diluted basis, and assuming the Agent's Option is not exercised and that there are no President's List Sales, Dr. Kuo would hold 8.11% of the issued and outstanding Common Shares.

## DIRECTORS AND EXECUTIVE OFFICERS

To the Company's knowledge as at the date of this Prospectus, following completion of the Offering, its directors and executive officers as a group (excluding the purchase of any Common Shares by any directors and executive officers under the Offering) will beneficially own, or control or direct, directly or indirectly, 20,292,400 Common Shares, representing approximately 35.79% of the outstanding Common Shares on a non-diluted basis following the completion of the Offering (or approximately 34.22% on a non-diluted basis, assuming the Agent's Option is exercised in full).

### Name, Occupation, and Security Holdings

The following table sets forth the name of each director and executive officer of the Company as at the date of this Prospectus, their province or state and country of residence, their position(s) and office(s) held with the Company, their principal occupation(s) during the preceding five years, the date they became a director or officer of the Company, and the number and percentage of Common Shares they beneficially own, or control or direct, directly or indirectly. Each director's term will expire immediately prior to the first annual meeting of shareholders of the Company.

Name, Residence and Current Position with the Company	Director/Officer Since	Principal Occupation or Employment for the Past Five Years	Number and Percentage of Common Shares Beneficially Owned Directly or Indirectly (at the date of this Prospectus)
William Garner, Executive Chairman and Director San Juan, Puerto Rico, USA	September 24, 2019	Founder of EGB Ventures since 2002. Chairman of InMed Pharmaceuticals since July 2016. Director of Isla Pharmaceuticals since March 2017. Founder and Director of Race Oncology between July 2016 and October 2020. Co-founder and Director of DelMar Pharmaceuticals, Inc. between February 2013 and January 2016. Director of GeneTether since February 2018	13,200,000/ 33.59%
James Kuo, Chief Executive Officer and Director La Jolla, California, USA <sup>(1)</sup>	September 24, 2019	Director and CEO of the Company since August 2019. CEO of OncoTracker, Inc. from May 2018 to April 2019. CEO of FIT Biotech Oy from April 2016 to January 2018	6,000,000 / 15.27%
Gage Jull, Director King City, Ontario, Canada <sup>(1)</sup>	September 25, 2020	Executive Chairman of Arrow Exploration Corp. since March 2020. Chairman of Bordeaux Capital Inc. since November 2015	392,400 / 1.00%
Peter Molloy, Director New York, New York, USA <sup>(1)</sup>	September 25, 2020	President and CEO of Maxsa Group Inc. since January 2019. CEO of Edison Investment Research Inc. between February 2012 and September 2018	200,000 / 0.51%
James Gilligan, President and Chief Scientific Officer Denville, New Jersey, USA	November 2, 2020	Managing Partner of TBG Consulting from March 2018 to November 2020. Consulting CSO of Taurus Development Corp. between February 2018 and December 2019. CSO of Tarsa Therapeutics from October 2009 to February 2018	Nil
Terese Gieselman, Chief Financial Officer and Corporate Secretary Kelowna, British Columbia, Canada	June 11, 2020 <sup>(2)</sup>	Minco Corporate Management Inc. <sup>(3)</sup>	500,000 / 1.27%

**Notes:**

(1) Member of the Audit Committee.

(2) Ms. Gieselman was appointed Corporate Secretary of the Company on June 11, 2020 and Chief Financial Officer on November 2, 2020.

(3) Ms. Gieselman provides consulting services through Minco Corporate Management Inc., a company owned and controlled by Ms. Gieselman. Through Minco Corporate Management Inc., during the past five years Ms. Gieselman has served as CFO of Golden Ridge Resources Ltd., CFO and director of Julian Resources Inc., CFO of Damara Gold Corp., Corporate Secretary of Ridgeline Minerals Corp. and as CFO and corporate secretary of Choom Holdings Inc.

## **Director and Executive Officer Biographies**

The following is a brief description of the background of the Company's key management, directors and promoters.

### *William Garner, Executive Chairman and Director, Age 54*

Dr. Garner is the founder of EGB Ventures, where he has focused on advancing technologies and companies to significant value inflection points, leading to monetization of assets via licensing, mergers and acquisitions or initial public offering transactions. Dr. Garner has extensive director-level and executive management experience, including his current appointment as Non-Executive Chairman of InMed Pharmaceuticals (NASDAQ:INM; TSX:IN), as Founder and Chairman at Isla Pharmaceuticals, and as Founder and Executive Chairman at GeneTether, Inc.; as well as his previous service as Non-Executive Chairman & Founder of Race Oncology (ASX:RAC), as CEO of Invion Limited, and as a co-founder and Director of Del Mar Pharmaceuticals (NASDAQ:DMPI). Dr. Garner brings additional medical affairs experience from his tenure at Hoffmann LaRoche's oncology division. Prior to Roche, Dr. Garner was a healthcare merchant banker in New York City. He has a Master of Public Health from the Harvard T.H. Chan School of Public Health and earned his MD at New York Medical College. Dr. Garner trained in the Anatomic Pathology residency program at Columbia-Presbyterian and is currently a licensed physician in the State of New York.

It is anticipated that Dr. Garner will assist the Company on an as-needed basis. Dr. Garner has entered into a proprietary information, non-competition and inventions assignment agreement with the Company.

### *James Kuo, Chief Executive Officer and Director, Age 56*

Dr. Kuo brings global life science leadership, business development and corporate finance experience to the company. He is presently Chairman of the Board at ImmunoPrecise Antibodies (TSXV: IPA) and has served as Managing Director of Athena Bioventures. He has also been Chief Executive Officer of BioMicro Systems, Synthetic Biologics, Inc. (NYSE: SYN), Discovery Laboratories (NASDAQ: DSCO), OncoTracker, Inc., and FIT Biotech Oy. In addition, Dr. Kuo has headed business development at Myriad Genetics (NASDAQ: MYGN) and was Associate Director of Licensing and Development at Pfizer. He has further been Managing Director of HealthCare Ventures, a \$378 million venture capital fund. He is a founder and Chairman of Monarch Labs, a medical device company commercializing a wound care therapy.

Dr. Kuo received his MD from the Perelman School of Medicine at the University of Pennsylvania and his MBA from the Wharton School of Business. He received his BA in molecular biology from Haverford College.

Dr. Kuo intends to dedicate 100% of his time to the affairs of the Company. Dr. Kuo has entered into a proprietary information, non-competition and inventions assignment agreement with the Company.

### *James Gilligan, President and Chief Science Officer, Age 68*

Dr. Gilligan has over 35 years of experience in the life sciences industry, including R&D, clinical development, international regulatory affairs, and manufacturing. Prior to joining the Company, Dr. Gilligan was a Co-Founder and Managing Partner of The Bracken Group, a life sciences consulting firm providing regulatory and product development support to pharmaceutical and biotech companies. Dr. Gilligan was a co-founder of Unigene Laboratories (now Enteris Biopharma), which develops technology for the recombinant manufacture of peptide hormones, as well as oral and nasal delivery technologies for peptide

based therapeutics. Dr. Gilligan was also a Co-Founder and the Chief Scientific Officer of Tarsa Therapeutics. Additionally, Dr. Gilligan was a consulting Chief Science Officer for Taurus Development Corp. and Managing Partner of TBG Consulting.

Dr. Gilligan earned a PhD from University of Connecticut and a Masters in International Business from Seton Hall University. He continued his post-graduate education at the Roche Institute of Molecular Biology.

Dr. Gilligan intends to dedicate approximately 100% of his time to the affairs of the Company. Dr. Gilligan has entered into a proprietary information, non-competition and inventions assignment agreement with the Company.

*Terese J. Gieselman –Chief Financial Officer and Corporate Secretary, Age 58*

Ms. Gieselman has 34 years of international experience with junior mining and exploration companies listed on the TSX, TSXV, OTCBB, NASDAQ and AMEX, in the roles of CFO, Treasurer, Corporate Secretary and director. During her tenure in the resource sector, Ms. Gieselman has accumulated an extensive background in corporate and financial reporting and compliance for Canada and the United States, including particularly relevant experience in financings, treasury, international corporate structure and financial reporting in Mexico, Peru, Chile, Argentina and Zimbabwe. Ms. Gieselman is currently the CFO, Corporate Secretary of Golden Ridge Resources Ltd (TSXV-listed) and the CFO and a director of Julian Resources Inc. (TSXV-listed), CFO/Secretary of Damara Gold Corp (TSXV-listed), Director of Mind Cure Health Inc. (CSE-listed), President of Minco Corporate Management Inc. and CFO/Secretary of Choom Holdings Inc. (CSE-listed).

Ms. Gieselman will devote approximately 15% of her time to the Company or such greater amount of time as is necessary. Ms. Gieselman has entered into a proprietary information, non-competition and inventions assignment agreement with the Company.

*Gage Jull, Director, Age 61*

Mr. Jull is a co-founder and Chairman of Bordeaux Capital Inc., a Toronto-based mergers & acquisitions advisory firm focused on emerging companies in the natural resources and other sectors. Mr. Jull also holds the position of Executive Chairman for Arrow Exploration. He also acted as a Director and Chairman of the Special Committee for Aldridge Minerals Inc. Prior to Bordeaux Capital, Mr. Jull was a Managing Director, Corporate Finance at Mackie Research Capital Corp., an investment banking, and securities brokerage firm. Mr. Jull has experience working on numerous cross border equity and debt offerings involving energy assets around the world, with capital sourced in Canada, the U.S. and the U.K. At Prudential Bache Mr. Jull was the lead banker on the \$40 million cross border Initial Public Offering of Quadra Logic Technologies a Vancouver based pharmaceutical company. He has completed over 200 financings and M&A transactions in the course of his career.

Mr. Jull holds a BSc degree from the University of Toronto, an MBA from the University of Western Ontario, and holds both PEng and CFA designations.

It is anticipated that Mr. Jull will assist the Company on an as-needed basis. Mr. Jull has entered into proprietary information, non-competition and inventions assignment agreement with the Company.

*Peter Molloy, Director, Age 48*

Peter Molloy has 25 years of experience creating, advising and investing in private and public companies,

with a particular focus on the healthcare sector. Mr. Molloy is currently the President and Chief Executive Officer of Maxsa Group, Inc. He was previously the founder and CEO of Edison Group where he spent 15 years building the company into an international brand with a global team in excess of 100 people, recognized for its world class equity research platform, advisory services, and deep sector expertise. He remains a Director and principle shareholder of Edison. Peter is also the co-founder of various other companies including, most recently, Tarus Therapeutics Inc., an immuno-oncology company with a broad portfolio of adenosine receptor antagonists. He is also currently an director of Taronis Fuels, Inc. Peter's earlier career includes a successful period as an institutional investor, most notably at Hermes Investment Management in London, managing a healthcare and technology focused small/mid-cap portfolio, and with a close involvement in Hermes' shareholder activism initiatives.

Mr. Molloy graduated from Exeter University (UK) with a degree in Economics and is an alumnus of London Business School. He is a member of CFA (UK) and FINRA Series 7.

It is anticipated that Mr. Molloy will assist the Company on an as-needed basis. Mr. Molloy has entered into a proprietary information, non-competition and inventions assignment agreement with the Company.

#### **Cease Trade Orders, Bankruptcies, Penalties or Sanctions**

None of the Company's directors or executive officers is, as at the date hereof, or was within 10 years before the date hereof, a director, chief executive officer or chief financial officer of any company (including the Company) that (a) was subject to a cease trade order, an order similar to a cease trade order or an order that denied the relevant issuer access to any exemption under securities legislation, that was in effect for a period or more than 30 consecutive days (an "Order") that was issued while the director or executive officer was acting in the capacity as director, chief executive officer or chief financial officer of such issuer, or (b) was subject to an Order that was issued after the director or executive officer ceased to be a director, chief executive officer or chief financial officer and which resulted from an event that occurred while that person was acting in the capacity as director, chief executive officer or chief financial officer.

None of the Company's directors or executive officers, nor, to its knowledge, any shareholder holding a sufficient number of its securities to affect materially the control of the Company (a) is, as at the date hereof, or has been within the 10 years before the date hereof, a director or executive officer of any company (including the Company) that, while that person was acting in that capacity, or within a year of that person ceasing to act in that capacity, became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold its assets, or (b) has, within the 10 years before the date hereof, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or become subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold the assets of such director, executive officer or shareholder.

None of the Company's directors or executive officers, nor, to its knowledge, any shareholder holding a sufficient number of its securities to affect materially the control of the Company, has been subject to (a) any penalties or sanctions imposed by a court relating to securities legislation or by a securities regulatory authority or has entered into a settlement agreement with a securities regulatory authority, or (b) any other

penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable investor in making an investment decision.

### **Conflicts of Interest**

To the best of the Company's knowledge, there are no existing or potential material conflicts of interest between the Company and any of its directors or officers as of the date hereof. However, certain of the Company's directors and officers are, or may become, directors or officers of other companies with businesses which may conflict with its business. Accordingly, conflicts of interest may arise which could influence these individuals in evaluating possible acquisitions or in generally acting on the Company's behalf.

Pursuant to the BCBCA, directors and officers of the Company are required to act honestly and in good faith with a view to the best interests of the Company.

Generally, as a matter of practice, directors who have disclosed a material interest in any contract or transaction that the Board is considering will not take part in any board discussion respecting that contract or transaction. If on occasion such directors do participate in the discussions, they will refrain from voting on any matters relating to matters in which they have disclosed a material interest. In appropriate cases, the Company will establish a special committee of independent directors to review a matter in which directors or officers may have a conflict.

See also "*Risk Factors – Risks Related to the Company – The directors and officers may have conflicts of interest with the Company*".

### **Term of Office of Directors**

The term of office of the directors expires annually at the time of the Company's annual general meeting. The term of office of the executive officers expires at the discretion of the Board.

### **Indemnification and Insurance**

The Company intends to obtain a director and officer insurance program to limit the Company's exposure to claims against, and to protect, its directors and officers.

## **EXECUTIVE COMPENSATION**

Prior to obtaining a receipt for this Prospectus from securities regulatory authorities in the Selling Provinces, the Company was not a reporting issuer in any jurisdiction. As a result, certain information required by Form 51-102F6V – *Statement of Executive Compensation – Venture Issuers* ("**Form 51-102F6V**") has been omitted pursuant to Section 1.3(8) of Form 51- 102F6V.

Securities legislation requires the disclosure of the compensation received by each Named Executive Officer of the Company. "Named Executive Officer" is defined by securities legislation to mean: (i) the CEO; (ii) the CFO; (iii) the most highly compensated executive officer of the Company, including any of its subsidiaries, other than the CEO and CFO, at the end of the most recently completed financial year whose total compensation was, individually more than \$150,000 for that financial year; and (iv) each individual who would be a "Named Executive Officer" under paragraph (iii) but for the fact that the individual was neither



an executive officer of the Company or its subsidiaries, nor acting in similar capacity, at the end of the most recently completed financial year.

As at August 31, 2020, the Company had the following Named Executive Officers (collectively, the “**Named Executive Officers**” or “**NEOs**”):

- James Kuo, Chief Executive Officer and a Director
- Terese Gieselman, Corporate Secretary and Chief Financial Officer

## **Compensation Governance**

### ***Philosophy***

In determining the compensation to be paid or awarded to its executives, the Board of Directors seeks to encourage the advancement of the Company’s projects, with a view to enhancing shareholder value. To achieve these objectives, the Company believes it is critical to create and maintain a compensation program that attracts and retains committed, highly qualified personnel by providing appropriate rewards and incentives that align the interest of its executives with those of its shareholders. In addition, as the Company currently has no revenues from operations and operates with limited financial resources, the Board of Directors needs to consider not only the Company’s financial situation at the time of determining executive compensation but also the Company’s estimated financial situation in the mid and long term.

The Company’s executive compensation program consists of a combination of base salary and long-term incentives in the form of participation in the Plan. In making its determinations regarding the various elements of executive incentive stock option grants, the Company will seek to meet the following objectives:

- a) to attract, retain and motivate talented executives who create and sustain the Company’s continued success within the context of compensation paid by other companies of comparable size engaged in similar business in appropriate regions;
- b) to align the interests of the NEOs with the interests of the Company’s shareholders; and
- c) to incent extraordinary performance from our key personnel. The Company is an early stage pharmaceutical company and may not generate revenues from operations for a significant period of time. As a result, the use of traditional performance standards, such as corporate profitability, is not considered by the Company to be appropriate in the evaluation of the performance of its executive officers.

### ***Base Salary***

The base salary for each executive is established by the Board based upon the position held by such executive, competitive market conditions, such executive’s related responsibilities, experience and the NEO’s skill base, the functions performed by such executive and the salary ranges for similar positions in

comparable companies. Individual and corporate performance will also be taken into account in determining base salary levels for executives.

### ***Cash Bonuses***

Cash bonuses do not form a normal part of the Company's executive compensation. However, the Company may elect to utilize such incentives where the role-related context and competitive environment suggest that such a compensation modality is appropriate. When and if utilized, the amount of cash bonus compensation will normally be paid on the basis of timely achievement of specific pre-agreed milestones. Each milestone will be selected based upon consideration of its impact on shareholder value creation and the ability of the Company to achieve the milestone during a specific interval. The amount of bonus compensation will be determined based upon achievement of the milestone, its importance to the Company's near and long term goals at the time such bonus is being considered, the bonus compensation awarded to similarly situated executives in similarly situated early stage pharmaceutical companies or any other factors the Board of Directors may consider appropriate at the time such performance-based bonuses are decided upon. The quantity of bonus will normally be a percentage of base salary not to exceed 100%. However, in exceptional circumstances, the quantity of bonus paid may be connected to the shareholder value creation embodied in the pre-agreed milestones.

### ***Options***

Incentive stock options are a key compensation element for the Company. Because many of the most capable individuals in the pharmaceutical industry work for companies who can offer attractive cash and bonus compensation and a high level of employment security, options represent a compensation element that balances the loss of employment security that such individuals must accept when moving to an early-stage pharmaceutical company such as the Company. Options are also an important component of aligning the objectives of the Company's executive officers and consultants with those of its shareholders, while encouraging them to remain associated with the Company. The Company expects to provide significant option positions to its executive officers and consultants. The precise amount of options to be offered will be governed by the importance of the role within the Company, by the competitive environment within which the Company operates, and by the regulatory limits on option grants that cover organizations such as the Company. When considering an award of options to an executive officer, consideration of the number of options previously granted to the executive may be taken into account, however, the extent to which such prior grants remain subject to resale restrictions will generally not be a factor.

See "*Options to Purchase Securities - Stock Option Plan*" for a summary of the key terms of the Plan.

### ***Compensation Risks***

In making its compensation-related decisions, the Board carefully considers the risks implicitly or explicitly connected to such decisions. These risks include the risks associated with employing executives who are not world class in their capabilities and experience, the risk of losing capable but under-compensated

executives, and the financial risks connected to the Company’s operations, of which executive compensation is an important part.

In adopting the compensation philosophy described above, the principal risks identified by the Company are:

- a) that the Company will be forced to raise additional funding (causing dilution to shareholders) in order to attract and retain the caliber of executive employees that it seeks; and
- b) that the Company will have insufficient funding to achieve its objectives.

***Executive Compensation-Related Fees***

For the financial year ended August 31, 2020, no fees were billed to the Company by any consultant or advisor, or any of its affiliates, for services related to determining compensation for any of the Company’s directors and executive officers or for any other services.

***Hedging Named Executive Officers or Directors***

The Company has no policy with respect to NEOs or directors purchasing financial instruments, including, for greater certainty, prepaid variable forward contracts, equity swaps, collars, or units of exchange funds that are designed to hedge or offset a decrease in market value of equity securities granted as compensation or held, directly or indirectly, by an NEO or director.

***Compensation, Excluding Options and Compensation Securities***

The following table sets out the compensation, excluding options and compensation securities, paid to the individuals who were directors or NEOs from incorporation of the Company on September 24, 2019 to August 31, 2020. The Company anticipates setting compensation for its NEOs for the 2021 fiscal year following completion of the Offering.

<b>TABLE OF COMPENSATION EXCLUDING COMPENSATION SECURITIES</b>							
<b>Name and Position</b>	<b>Year</b>	<b>Salary, Consulting Fee, Retainer or Commission</b>	<b>Bonus</b>	<b>Committee or Meeting Fees</b>	<b>Value of Perquisites</b>	<b>Value of all Other Compensation</b>	<b>Total Compensation</b>
William Garner Executive Chairman and Director	2020	Nil	Nil	Nil	Nil	Nil	Nil

**TABLE OF COMPENSATION EXCLUDING COMPENSATION SECURITIES**

<b>Name and Position</b>	<b>Year</b>	<b>Salary, Consulting Fee, Retainer or Commission</b>	<b>Bonus</b>	<b>Committee or Meeting Fees</b>	<b>Value of Perquisites</b>	<b>Value of all Other Compensation</b>	<b>Total Compensation</b>
James Kuo Chief Executive Officer and Director	2020	\$10,000	Nil	Nil	Nil	Nil	\$10,000
Terese Gieselman Corporate Secretary and Chief Financial Officer	2020	\$32,500 <sup>(1)(2)</sup>	Nil	Nil	Nil	Nil	\$32,500
Gage Jull Director	2020	\$19,620 <sup>(2)</sup>	Nil	Nil	Nil	Nil	\$19,620
Peter Molloy Director	2020	\$10,000 <sup>(2)</sup>	Nil	Nil	Nil	Nil	\$10,000

**Notes:**

(1) Ms. Gieselman provides services through Minco Corporate Management Inc., a company owned and controlled by Ms. Gieselman.

(2) Includes Common Shares issued for past services at a deemed price of \$0.05/share as follows: Terese Gieselman, 500,000 Common Shares (\$25,000), Peter Molloy, 200,000 Common Shares (\$10,000) and Gage Jull, 392,400 Common Shares (\$19,620).

***Stock Options and Other Compensation Securities***

No stock options or other compensation securities were granted or issued to any directors or Named Executive Officers during the period from incorporation on September 24, 2019 to August 31, 2020.

***External Management Companies***

Other than as disclosed herein, the Company has not entered into any agreement with any external management company that employs or retains one or more of the NEOs or Directors and, other than as disclosed below, the Company has not entered into any understanding, arrangement or agreement with any external management company to provide executive management services to the Company, directly or indirectly, in respect of which any compensation was paid by the Company.

Ms. Gieselman provides consulting services through Minco Corporate Management Inc., a company owned and controlled by Ms. Gieselman.

### ***Employment, Consulting and Management Agreements***

During the fiscal period ended August 31, 2020, the Company did not have any written contract, agreement, plan or arrangement that provided for payment to a Named Executive Officer at, following, or in connection with any termination (whether voluntary, involuntary or constructive), resignation, retirement, a change in control of the Company or a change in a director or Named Executive Officer's responsibilities.

On November 2, 2020, the Company entered into a binding term sheet with Dr. Gilligan pursuant to which the Company engaged Dr. Gilligan on an "at will" basis as an independent contractor to perform the services of President and Chief Scientific Officer. Pursuant to the binding term sheet, Dr. Gilligan was issued an aggregate of 2,769,684 stock options and will be entitled to receive an initial annual base salary of \$150,000, to participate in the Plan and will be eligible for annual bonuses as determined by the Board. Pursuant to the term sheet, Dr. Gilligan will be entitled to three months' severance pay if he is terminated without "cause". No severance shall be paid if Dr. Gilligan is terminated for "cause". The term "cause" is defined in the term sheet as malfeasance, material non-performance or materially inadequate performance following written notice or other communication from the Board of such cause and a reasonable period of time to cure it one time. The term sheet does not provide for any change of control payments; however upon a sale of all or substantially all of the assets of the Company, any unvested equity incentive awards (including incentive stock options) granted to Dr. Gilligan shall automatically vest immediately prior to the closing of such transaction.

### ***Pension Plan Benefits***

The Company does not anticipate having any deferred compensation plan or pension plan that provide for payments or benefits at, following or in connection with retirement.

### ***Director Compensation***

Each of Messrs. Jull and Molloy have been granted 200,000 Common Shares at a deemed price of \$0.05/share as compensation for their role as non-executive directors of the Company. The Company contemplates that each independent director, will be entitled to participate in the Plan and any other security-based compensation arrangement or plan adopted by the Company with the approval of the Board and/or the Company's shareholders, as may be required by applicable law or CSE policies.

### ***Directors' and Officers' Liability Insurance and Indemnification***

The Articles provide that the Company may indemnify each director and officer against all costs, charges and expenses reasonably incurred by him or her in respect of any action or proceeding to which he or she is made a party by reason of being a director or officer of the Company, subject to the limitations contained in the Articles.

### **INDEBTEDNESS OF DIRECTORS AND EXECUTIVE OFFICERS**

None of the directors, executive officers or employees of the Company or former directors, executive officers or employees of the Company had any indebtedness outstanding to the Company as at the date hereof and no indebtedness of these individuals to another entity is the subject of a guarantee, support agreement, letter of credit or other similar arrangement or understanding provided by the Company as at the date hereof. Additionally, no individual who is, or at any time during the Company's last financial year

was, a director or executive officer of the Company, proposed management nominee for director of the Company or associate of any such director, executive officer or proposed nominee is as at the date hereof, or at any time since the beginning of the Company's last financial year has been, indebted to the Company or to another entity where the indebtedness to such other entity is the subject of a guarantee, support agreement, letter of credit or other similar arrangement or understanding provided by the Company, including indebtedness for security purchase or any other programs.

#### **AUDIT COMMITTEE**

The Company has formed an Audit Committee comprised of James Kuo, Peter Molloy and Gage Jull (Chair), all of whom are "financially literate" as defined in National Instrument 52-110 – *Audit Committees* ("**NI 52-110**"). Mr. Molloy and Mr. Jull are considered "independent" and Dr. Kuo, as Chief Executive Officer of the Company, is not considered "independent", pursuant to NI 52-110.

The Audit Committee provides assistance to the Board in fulfilling its obligations relating to the integrity of the internal financial controls and financial reporting of the Company. The external auditors of the Company report directly to the Audit Committee. The Audit Committee's primary duties and responsibilities include: (i) reviewing and reporting to the Board on the annual audited financial statements (including the auditor's report thereon) and unaudited interim financial statements and any related management's discussion and analysis, if any, and other financial disclosure related thereto that may be required to be reviewed by the Audit Committee pursuant to applicable legal and regulatory requirements; (ii) reviewing material changes in accounting policies and significant changes in accounting practices and their impact on the financial statements; (iii) overseeing the audit function, including engaging in required discussions with the Company's external auditor and reviewing a summary of the annual audit plan at least annually, overseeing the independence of the Company's external auditor, overseeing the Company's internal auditor, and pre-approving any non-audit services to the Company; (iv) reviewing and discussing with management the appointment of key financial executives and recommending qualified candidates to the Board; (v) reviewing with management and the Company's external auditors, at least annually, the integrity of the internal controls over financial reporting and disclosure; (vi) reviewing management reports related to legal or compliance matters that may have a material impact on the Company and the effectiveness of the Company's compliance policies; and (vii) establishing whistleblowing procedures and investigating any complaints or concerns it deems necessary.

The full text of the Audit Committee Charter is attached to this Prospectus as Schedule "B".

#### **Relevant Education and Experience**

Each proposed member of the Audit Committee has adequate education and experience that is relevant to their performance as an Audit Committee member and, in particular, the requisite education and experience that have provided the member with:

- an understanding of the accounting principles used by the Company to prepare its financial statements and the ability to assess the general application of those principles in connection with estimates, accruals and reserves;
- experience preparing, auditing, analyzing or evaluating financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of

issues that can reasonably be expected to be raised by the Company's financial statements or experience actively supervising individuals engaged in such activities; and

- an understanding of internal controls and procedures for financial reporting.

#### *Gage Jull*

Mr. Jull is a co-founder and Chairman of Bordeaux Capital Inc., a Toronto-based mergers & acquisitions advisory firm focused on emerging companies in the natural resources and other sectors. Prior to Bordeaux Capital, Mr. Jull was a Managing Director, Corporate Finance at Mackie Research Capital Corp., an investment banking and securities brokerage firm. Mr. Jull has experience working on numerous cross border equity and debt offerings involving energy assets around the world, with capital sourced in Canada, the U.S. and the U.K. At Prudential Bache Mr. Jull was the lead banker on the \$40 million cross border initial public offering of Quadra Logic Technologies, a Vancouver-based pharmaceutical company. He has completed over 200 financings and M&A transactions in the course of his career.

Mr. Jull holds a BSc degree from the University of Toronto, an MBA from the University of Western Ontario, and holds both PEng and CFA designations.

Mr. Jull has an understanding of financial reporting requirements respecting financial statements sufficient enough to enable him to discharge his duties as an Audit Committee member.

#### *Peter Molloy*

Peter Molloy has 25 years of experience creating, advising and investing in private and public companies, with a particular focus on the healthcare sector. He was previously the founder and CEO of Edison Group where he spent 15 years building the company into an international brand with a global team in excess of 100 people, recognized for its world class equity research platform, advisory services, and deep sector expertise. He remains a Director and principle shareholder of Edison. Peter is also the co-founder of various other companies including, most recently, Tarus Therapeutics Inc., an immuno-oncology company with a broad portfolio of adenosine receptor antagonists. Peter's earlier career includes a successful period as an institutional investor, most notably at Hermes Investment Management in London, managing a healthcare and technology focused small/mid-cap portfolio, and with a close involvement in Hermes' shareholder activism initiatives.

Mr. Molloy graduated from Exeter University (UK) with a degree in Economics and is an alumni of London Business School. He is a member of CFA (UK) and FINRA Series 7.

Mr. Molloy has an understanding of financial reporting requirements respecting financial statements sufficient enough to enable him to discharge his duties as an Audit Committee member.

#### *James Kuo*

Dr. Kuo brings global life science leadership, business development and corporate finance experience to the company. He is presently Chairman of the Board at ImmunoPrecise Antibodies (TSXV: IPA) and has served as Managing Director of Athena Bioventures. He has also been Chief Executive Officer of BioMicro Systems, Synthetic Biologics, Inc. (NYSE: SYN), Discovery Laboratories (NASDAQ: DSCO), OncoTracker, Inc., and FIT Biotech Oy. In addition, Dr. Kuo has headed business development at Myriad Genetics (NASDAQ: MYGN)

and was Associate Director of Licensing and Development at Pfizer. He has further been Managing Director of HealthCare Ventures, a \$378 million venture capital fund. He is a founder and Chairman of Monarch Labs, a medical device company commercializing a wound care therapy.

Dr. Kuo received his MD from the Perelman School of Medicine at the University of Pennsylvania and his MBA from the Wharton School of Business. He received his BA in molecular biology from Haverford College.

Dr. Kuo has an understanding of financial reporting requirements respecting financial statements sufficient enough to enable him to discharge his duties as an Audit Committee member.

### **Pre-Approval Policies and Procedures**

The Audit Committee mandate requires that the Audit Committee pre-approve any retainer of the auditor of the Company to perform any non-audit services to the Company that it deems advisable in accordance with applicable legal and regulatory requirements and policies and procedures of the Board. The Audit Committee is permitted to delegate pre-approval authority to one of its members; however, the decision of any member of the Audit Committee to whom such authority has been delegated must be presented to the full Audit Committee at its next scheduled meeting.

### **Reliance on Certain Exemptions**

At no time since the commencement of the Company's most recently completed financial year has the Company relied on the following exemptions:

- a) the exemption in section 2.4 of National Instrument 52-110 (*De Minimis Non-audit Services*);
- b) the exemption in subsection 6.1.1(4) of National Instrument 52-110 (*Circumstance Affecting the Business or Operations of the Venture Issuer*);
- c) the exemption in subsection 6.1.1(5) of National Instrument 52-110 (*Events Outside Control of Member*);
- d) the exemption in subsection 6.1.1(6) of National Instrument 52-110 (*Death, Incapacity or Resignation*); or
- e) an exemption from National Instrument 52-110, in whole or in part, granted under Part 8 of National Instrument 52-110 (*Exemption*).

### **External Auditor Service Fees by Category**

The fees billed by the Company's external auditors for audit and non-audit related services provided to the Company for the period from incorporation to August 31, 2020 are as follows:

<u>Audit Fees</u>	<u>Audit Related Fees</u>	<u>Tax Fees</u>	<u>All Other Fees</u>
\$12,500	Nil	Nil	Nil



## Exemption

The Company has relied upon the exemption provided by section 6.1 of NI 52-110, pursuant to which the Company is not required to comply with Part 3 (*Composition of the Audit Committee*) and Part 5 (*Reporting Obligations*) of NI 52-110.

## CORPORATE GOVERNANCE

Corporate governance relates to the activities of the Board of Directors, the members of which are elected by and are accountable to the shareholders, and takes into account the role of the individual members of *management* who are appointed by the Board of Directors and who are charged with day-to-day management of the Company. National Instrument 58-201- *Corporate Governance Guidelines* establishes corporate governance guidelines to be used by issuers in developing their own corporate governance practices. The Board of Directors is committed to sound corporate governance practices, which are both in the interest of its shareholders and contribute to effective and efficient decision making.

In accordance with National Instrument 58-101 *Disclosure of Corporate Governance Practices* (“**NI 58-101**”) the Company’s corporate governance practices are summarized below. The Board of Directors will continue to monitor such practices on an ongoing basis and when necessary implement such additional practices as it deems appropriate.

### Board of Directors

The Company’s Board of Directors is currently composed of four directors – William Garner, Gage Jull, Peter Molloy and James Kuo. The Board facilitates its exercise of independent supervision over management by ensuring sufficient representation by directors independent of management.

NI 58-101 suggests that the board of directors of a public company should be constituted with a majority of individuals who qualify as “independent” directors. An “independent” director is a director who is independent of management and is free from any interest and any business or other relationship which could, or could reasonably be perceived to materially interfere with the director’s ability to act with a view to the best interests of the Company, other than interests and relationships arising from shareholding. In addition, where a company has a significant shareholder, NI 58-101 suggests that the board of directors should include a number of directors who do not have interests in either the company or the significant shareholder. The independent directors would exercise their responsibilities for independent oversight of management and meet independently of management whenever deemed necessary. Each of Gage Jull and Peter Molloy can be considered to be “independent” within the meaning of NI 58-101. James Kuo, by reason of being Chief Executive Officer of the Company and William Garner, by reason of his being Executive Chairman of the Company, cannot be considered to be “independent” within the meaning of NI 58-101.

The independent directors will meet separately from the non-independent directors, as determined necessary from time to time, in order to facilitate open and candid discussion among the independent directors. No separate meetings of the independent directors have been held to date. William Garner acts as the chairman with respect to the conduct of Board meetings. Given the Company’s relatively small size and start-up nature, the Board is satisfied as to the extent of independence of its members. The Board is satisfied that it is not constrained in its access to information, in its deliberations, or in its ability to satisfy the mandate established by law to supervise the business and affairs of the Company, and that there are

sufficient systems and procedures in place to allow the Board to have a reasonable degree of independence from day-to-day management.

Since the Company's incorporation on September 24, 2019 until the date of this Prospectus, the Board has held formal Board meetings and the directors have also approved various matters by consent resolutions.

### **Directorships**

The following directors are also currently directors of the following reporting issuers:

<u>Name of Director</u>	<u>Name of Reporting Issuer</u>	<u>Exchange</u>
William Garner	InMed Pharmaceuticals Inc.	NASDAQ; TSX
James Kuo	ImmunoPrecise Antibodies, Inc.	TSXV
Peter Molloy	Taronis Fuels, Inc.	OTC QB
Gage Jull	Arrow Exploration Corp.	TSXV

### **Orientation and Continuing Education**

The Board of Directors provides an overview of the Company's business activities, systems and business plan to all new directors. New director candidates have free access to any of the Company's records, employees or senior management in order to conduct their own due diligence and will be briefed on the strategic plans, short, medium and long term corporate objectives, business risks and mitigation strategies, corporate governance guidelines and existing policies of the Company. The Directors are encouraged to update their skills and knowledge by taking courses and attending professional seminars.

### **Ethical Business Conduct**

The Board of Directors believes good corporate governance is integral to the success of the Company and to meeting responsibilities to shareholders. Generally, the Board of Directors has found that the fiduciary duties placed on individual directors by the Company's governing corporate legislation and the common law and the restrictions placed by applicable corporate legislation on an individual director's participation in decisions of the Board of Directors in which the director has an interest have been sufficient to ensure that the Board of Directors operates independently of management and in the best interests of the Company. However, to supplement the foregoing, the Company has also adopted a written Code of Ethical Conduct (the "**Code**"), which emphasizes the importance of matters relating to honest and ethical conduct, conflicts of interest, confidentiality of corporate information, protection and proper use of corporate assets and opportunities, compliance with applicable laws, rules and regulations and the reporting of any illegal or unethical behaviour.

The Board of Directors is also responsible for applying governance principles and practices, and tracking development in corporate governance, and adapting "best practices" to suit the needs of the Company. Certain of the Directors of the Company may also be directors and officers of other companies, and conflicts

of interest may arise between their duties. Such conflicts must be disclosed in accordance with, and are subject to such other procedures and remedies as applicable under, the BCBCA.

### **Nomination of Directors**

The Board of Directors has not formed a nominating committee or similar committee to assist the Board of Directors with the nomination of directors for the Company. The Board of Directors considers itself too small to warrant creation of such a committee; and each of the Directors has contacts he can draw upon to identify new members of the Board of Directors as needed from time to time.

The Board of Directors will continually assess its size, structure and composition, taking into consideration its current strengths, skills and experience, proposed retirements and the requirements and strategic direction of the Company. As required, directors will recommend suitable candidates for consideration as members of the Board of Directors.

### **Compensation**

The Board of Directors reviews the compensation of its directors and executive officers annually. The Directors will determine compensation of directors and executive officers taking into account the Company's business ventures and the Company's financial position. See "*Executive Compensation*".

### **Other Board Committees**

The Company has established an Audit Committee. There are no other committees of the Board of Directors.

### **Director Assessment**

The Board of Directors has not implemented a process for assessing its effectiveness. As a result of the Company's small size and the Company's stage of development, the Board of Directors considers a formal assessment process to be inappropriate at this time.

The Board of Directors plans to continue evaluating its own effectiveness on an ad hoc basis. The Board of Directors does not formally assess the performance or contribution of individual Board members or committee members.

## **PLAN OF DISTRIBUTION**

### **Agency Agreement**

Pursuant to the Agency Agreement dated December 8, 2020, among the Company and the Agent, the Company has appointed the Agent to act as its exclusive agent to offer for sale, on a "commercially reasonable efforts" basis, 17,400,000 Common Shares for gross proceeds \$4,350,000, subject to the terms and conditions of the Agency Agreement. The price of the Common Shares was determined by negotiation between the Company and the Agent.

The obligations of the Agent under the Agency Agreement may be terminated by the Agent at its discretion on the basis of its assessment of the state of the financial markets and may also be terminated in certain

stated circumstances and upon the occurrence of certain stated events, including industry standard “market out”, “material adverse change” and “regulatory proceedings out” provisions.

The Company has agreed to grant to the Agent the Agent’s Option to increase the size of the Offering by up to 2,610,000 Agents’ Option Units at the Offering Price for a period of 30 days from the Closing Date, to cover the Agent’s over-allocation position, if any, and for market stabilization purposes. This Prospectus qualifies the distribution of the Agents’ Option and the Agents’ Option Units. A purchaser who acquires Units forming part of the Agent’s over-allocation position acquires those Units under this Prospectus, regardless of whether the over-allocation position is ultimately filled through the exercise of the Agent’s Option or secondary market purchases.

In consideration for the services provided by the Agent in connection with the Offering, and pursuant to the terms of the Agency Agreement, the Company will pay the Agent the Commission, equal to the sum of (i) 8.0% of the gross proceeds of the Offering (including any gross proceeds raised on exercise of the Agent’s Option), other than the gross proceeds raised from President’s List Sales and (ii) 4.0% of the gross proceeds raised from President’s List Sales, payable in cash from the proceeds of the Offering. The Agent will also receive, as additional compensation, Compensation Options to purchase that number of Units that is equal to 8.0% of the Units sold pursuant to the Offering (including any Agent’s Option Units sold pursuant to the exercise of the Agent’s Option), but excluding the Units sold pursuant to President’s List Sales. In connection with the President’s List Sales, the Agent will receive Compensation Options to purchase that number of Units that is equal to 4.0% of the Units sold pursuant to the President’s List Sales. Each Compensation Option is exercisable to purchase one Compensation Unit at the Offering Price for a period of 12 months from the Listing Date.

The Company has also agreed to pay the Agent a corporate finance fee which shall be satisfied by issuing to the Agent such number of Corporate Finance Fee Units that is equal to 5.0% of the number of Units issued pursuant to the Offering (including any Agent’s Option Units sold pursuant to the exercise of the Agent’s Option). Each Corporate Finance Fee Unit consists of one Corporate Finance Fee Unit Share and one-half of one Corporate Finance Fee Unit Warrant. Each Corporate Finance Fee Unit Warrant will entitle the holder to acquire one Corporate Finance Fee Warrant Share at a price of \$0.50 per Corporate Finance Fee Warrant Share for a period of 12 months following the Closing, subject to the same acceleration clause as is applicable to the Unit Warrants.

Applicable securities rules provide that a prospectus may only qualify securities issued or paid as compensation to the Agent for acting as the agent in respect of the Offering in an amount up to 10% of the Offering (on an as-if-converted basis and including the Agent’s Option). The Agent’s Compensation Options (and the Compensation Unit Shares and the Compensation Unit Warrant Shares issuable upon the exercise of the underlying Compensation Unit Warrants) and the Corporate Finance Fee Units (and the Corporate Finance Fee Unit Shares and the Corporate Finance Fee Unit Warrant Shares issuable upon the exercise of the underlying Corporate Finance Fee Unit Warrants) are qualified by this Prospectus.

The Company has also agreed to pay the Agent’s reasonable expenses, including legal fees and disbursements, in connection with the Offering. See: “*Use of Proceeds*”.

The Company will also indemnify the Agent, its affiliates and their respective partners, directors, officers and employees (the “**Indemnified Parties**”) against certain claims with which the Indemnified Parties may

become involved in any capacity in so far as the claims relate to performance of the professional services of the Agent pursuant to the Agency Agreement.

No securities offered under this Prospectus have been or will be registered under the U.S. Securities Act, or any state securities laws, and accordingly may not be offered, sold or delivered within the United States except in transactions exempt from the registration requirements of the U.S. Securities Act and applicable state securities laws. The Agent will not offer, sell or deliver the Units within the United States.

The Company has agreed not to, directly or indirectly, issue, sell, offer, grant an option or right in respect of (or agree to or publicly announce any intention to do any of the foregoing) any additional Common Shares or any securities convertible or exchangeable into Common Shares, other than: (i) pursuant to the Offering, (ii) pursuant to the grant or exercise of stock options and other similar issuances pursuant to any stock option plan or similar share compensation arrangements, (iii) the issuance of Common Shares upon the exercise of convertible securities, warrants, options or obligations outstanding prior to the date of the Agency Agreement, or (iv) in connection with any arm's length property acquisition transaction or other corporate acquisitions by the Company, for a period commencing on the Closing Date and ending 90 days from the Listing Date without the prior written consent of the Agent, such consent not to be unreasonably withheld, conditioned or delayed.

If the Company does not complete the Offering, but the Company or any affiliate or subsidiary thereof completes any debt or equity financing transaction (excluding a bank loan from commercial bank lenders) prior to the date that is 180 days after the termination of the Agency Agreement (any such transaction, an "**Alternative Transaction**") in respect of which the Agent is not the sole lead underwriter, placement agent, arranger or initial purchaser, or in respect of which the Agent does not receive at least the same amount of compensation pursuant to the Alternative Transaction as to which it would have been entitled under the Offering, the Agent shall be entitled to receive immediately upon the completion of such Alternative Transaction the lesser of (i) the amount of compensation assuming completion of the maximum Offering, and (ii) the commissions and Compensation Options calculated based on the amount raised pursuant to the Alternative Transaction; provided, however, that the Agent shall not be entitled to any amount in the event the Agent voluntarily terminated the Agency Agreement (other than as a result of a material breach by the Company of its obligations hereunder) or the Company voluntarily terminates the Agency Agreement as a result of a material breach by the Agent of its obligations hereunder. If the Company and the Agent, acting reasonably and in good faith, are unable to complete the Offering due to market conditions or otherwise and the Company voluntarily terminates the Agency Agreement, the Agent shall only be entitled to the compensation described above in connection with proceeds raised in an Alternative Transaction from investors introduced to the Company by the Agent in the process of the Offering.

The Agent, or registered sub-agents who assist the Agent in the distribution of the Units offered hereunder, conditionally offer the Units, subject to prior sale, if, as and when issued by the Company and accepted by the Agent in accordance with the conditions contained in the Agency Agreement and subject to the approval of certain legal matters, on behalf of the Company by Pushor Mitchell LLP, and on behalf of the Agents by Borden Ladner Gervais LLP. Subscriptions for Units will be payable to the Company against delivery of the Units. Subscriptions for Units will be received subject to rejection or allotment in whole or in part and the right is reserved to close the subscription books at any time without notice. Closing of the Offering is expected to occur on or about December 16, 2020 or such other date as is mutually agreed by the Company and the Agent. If subscriptions for a minimum of 17,400,000 Units have not been received within 90 days after a receipt is obtained for this Prospectus, this Offering may not continue and subscription proceeds will

be returned to subscribers, without interest or deduction, unless consent is obtained from those who have subscribed for Units on or before such date.

Except in certain limited circumstances: (i) the Units will be registered and represented electronically through the NCI system of CDS in "book-entry only" form; (ii) no certificates evidencing the Units will be issued to purchasers of Units unless specifically requested; and (iii) purchasers of Units will receive only a customer confirmation from the Agent or other registered dealer who is a CDS participant and from or through whom a beneficial interest in the Units is purchased. Such request will need to be made through a CDS participant through whom the beneficial interest in the securities are held at the time of request.

Prior to the Offering, there has been no public market for the Common Shares. The sale of a substantial number of the Common Shares in the public market after the Offering, or the perception that such sales may occur, could adversely affect the prevailing market price of the Common Shares. All of the Common Shares will be freely tradable in Canada without restriction or further registration under applicable Canadian securities laws.

The Company has applied to list the Unit Shares on the CSE. The CSE provided its conditional approval of the listing on December 7, 2020. Listing is subject to the Company fulfilling all of the requirements of the CSE, including meeting all minimum listing requirements. There is no guarantee that the CSE will provide approval for the listing of the Common Shares. The Company has not applied and does not intend to list the Unit Warrants.

As at the date of this Prospectus, the Company does not have any of its securities listed or quoted, has not applied to list or quote any of its securities, and does not intend to apply to list or quote any of its securities, on the Toronto Stock Exchange, Aequitas NEO Exchange Inc., a U.S. marketplace, or a marketplace outside Canada and the United States of America (other than the Alternative Investment Market of the London Stock Exchange or the PLUS markets operated by PLUS Markets Group plc).

There is no market through which the Common Shares may be sold, and purchasers may not be able to resell the Unit Shares (or the Warrant Shares acquired upon due exercise of the Unit Warrants) purchased under this Prospectus. This may affect the pricing of the Common Shares in the secondary market, the transparency and availability of trading prices, the liquidity of the Common Shares, and the extent of issuer regulation. See "*Risk Factors*".

## **RISK FACTORS**

*Investing in our securities involves a high degree of risk. Before you invest in our Common Shares, you should carefully consider the following risks, as well as general economic and business risks, and all of the other information contained in this prospectus. Many of the following risks and uncertainties are, and will be, exacerbated by the coronavirus disease 2019, or COVID-19, pandemic and any worsening of the global business and economic environment as a result. The occurrence of any of the events or developments described below could materially and adversely affect our business, financial condition, results of operations and prospects. In such an event, the market price of the Common Shares could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.*

## **Risks Related to the Offering and this Prospectus**

### ***Forward-looking statements may prove to be inaccurate.***

The forward-looking information and statements included in this Prospectus relating to, among other things, our future results, performance, achievements, prospects, targets, plans, objectives, goals, milestones, intentions or opportunities or the markets in which we operate is based on opinions, assumptions and estimates made by management in light of experience and perception of historical trends, current conditions and expected future developments, as well as other factors that we believe are appropriate and reasonable in the circumstances. However, there can be no assurance that such estimates and assumptions will prove to be correct. Our actual results in the future may vary significantly from estimated or expected results and those variations may be material. We make no representation that our actual results in the future will be the same, in whole or in part, as those included in this Prospectus.

### ***Our management retains discretion in the use of proceeds from this Offering.***

Our management will have broad discretion concerning the use of the proceeds of the Offering as well as the timing of their expenditures. As a result, an investor will be relying on the judgment of management for the application of the proceeds of the Offering. Management may use the net proceeds of the Offering in ways that an investor may not consider desirable. The results and the effectiveness of the application of the proceeds are uncertain. If the proceeds are not applied effectively, the Company's results of operations may suffer.

### ***The market price of our Common Shares is expected to be volatile.***

The trading price of our Common Shares is likely to be volatile. Our stock price could be subject to wide fluctuations in response to a variety of factors, including the following:

- our ability to conduct and achieve positive outcomes from our preclinical studies and clinical trials;
- contracting with third parties such as academic institutions and various CROs who will perform such studies, or the potential lack of performance of such organizations;
- acceptance of INDs by the FDA or similar regulatory filing by comparable foreign regulatory authorities for the conduct of clinical trials of our drug candidates and our proposed design of future clinical trials;
- the inherently uncertain outcome of clinical trials;
- delays in publications of research findings;
- significant lawsuits, including patent or shareholder litigation;
- inability to obtain additional funding or funding on favorable terms;
- failure to successfully develop and commercialize our drug candidates;
- failure of patent applications to issue;
- failure of patent applications to issue with a reasonable scope;
- changes in laws or regulations applicable to our drug candidates;

- inability to obtain adequate supply of our drug candidates, or the inability to do so at acceptable prices or in an acceptable timeframe;
- unanticipated serious safety concerns related to any of our drug candidates;
- adverse regulatory decisions;
- introduction of new products or technologies by our competitors;
- off-label prescription of the psilocybin drug products of our competitors;
- adverse events or results for our competitors or our drug candidate target areas that could generally adversely affect us or our industry;
- failure to meet or exceed drug development or financial projections we provide to the public;
- failure to meet or exceed the estimates, expectations and projections of the investment community and our shareholders;
- the perception of the pharmaceutical industry by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our drugs;
- additions or departures of key scientific or management personnel;
- changes in the market valuations of similar companies;
- general economic and market conditions and overall fluctuations in the Canadian and U.S. equity markets;
- sales of our Common Shares by us or our shareholders in the future;
- trading volume of our Common Share;
- period-to-period fluctuations in our financial results;
- any real or perceived weakness in our internal control over financial reporting, which, while we believe we have taken appropriate steps to minimize any such material weakness, there can be no assurance that the steps we are taking will be sufficient to eliminate any real or perceived weakness or prevent future weaknesses or significant deficiencies from occurring;
- changes in the structure of healthcare payments;
- changes in the listing status of our Common Shares on the applicable stock exchange; and
- recommendations of equity analysts covering our Common Shares.

In addition, the stock market, and equity values of early stage pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our Common Shares, regardless of our actual operating performance. Further, a decline in the financial markets and related factors beyond our control may cause our share price to decline rapidly and unexpectedly.



In the past, following periods of volatility in the market price of a company's securities, shareholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

***Our executive officers, directors and certain significant shareholders will continue to own a substantial number of our Common Shares and, as a result, may be able to exercise control over us, including the outcome of shareholder votes.***

Upon the completion of this Offering, our executive officers, directors, 10% holders and their affiliates will represent beneficial ownership, in the aggregate, of approximately 35.79% of our total outstanding Common Shares (exclusive of any Common Shares that may be purchased by members of this group as part of this Offering and assuming the Agent's Option is not exercised and there are no President's List Sales). As a result, these parties may be able to determine all matters requiring shareholder approval. For example, these shareholders may be able to exert control over our business, including significant corporate actions such as mergers, schemes of arrangement, sales of substantially all of our assets, and election, re-election and removal of directors. This may prevent or discourage unsolicited acquisition proposals or offers for our Common Shares, or other such changes in control, that you may feel are in your best interest. The interests of this group of shareholders may not always coincide with your interests or the interests of other shareholders and they may act in a manner that advances their best interests and not necessarily those of who purchase Common Shares in this offering, including seeking a premium value for their Common Shares, and might affect the prevailing market price for our Common Shares.

***If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, our share price and trading volume could decline.***

The trading market for our Common Shares depends, in part, on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable research about our business, our share price would likely decline. In addition, if our operating results fail to meet the forecast of analysts, our share price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our Common Shares could decrease, which might cause our share price and trading volume to decline.

***Sales of a substantial number of shares of our Common Shares in the public market by our shareholders or future issuances of our Common Shares or rights to purchase our Common Shares could cause our share price to fall.***

Sales of a substantial number of Common Shares by our existing shareholders in the public market, or the perception that these sales might occur, could depress the market price of our Common Shares and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our Common Shares.

***We may never pay dividends on our Common Shares, so any returns would be limited to the appreciation of our stock.***

We currently anticipate that we will retain any future earnings for the development, operation and expansion of our business and do not anticipate we will declare or pay any cash dividends for the foreseeable future. In addition, the terms of any future debt agreements may preclude us from paying dividends. Any return to shareholders will therefore be limited to the appreciation of their Common Shares.

***Our Common Shares lack a liquid, public market and a one may not develop in the near future or at all.***

There has been no public market for our Common Shares and there can be no assurance that a liquid, public market will develop for our Common Shares. This may affect the pricing of our Common Shares in the secondary market, the transparency and availability of trading prices, the liquidity of the Common Shares and the extent of issuer regulation. There can be no assurance that an active trading market for our securities will develop or, if developed, that any such market, including for the Common Shares, will be sustained. The Offering Price may not be indicative of the market price of the Common Shares following a listing on the CSE or other stock exchange. In the absence of an active trading market for the Common Shares, investors may have difficulty selling their Common Shares. We cannot predict the prices at which the Common Shares will trade.

***Purchasers of our Common Shares in this Offering could be subject to significant dilution from subsequent financings.***

The Articles permit the Company to issue an unlimited number of Common Shares and an unlimited number of Preferred Shares for such consideration and on such terms and conditions as established by the Board, in many cases, without the approval of the Company's shareholders. The Company may issue additional Common Shares or Preferred Shares in subsequent offerings (including through the sale of securities convertible into or exchangeable for Common Shares, or Preferred Shares). The Company cannot predict the size of future issuances of Common Shares or Preferred Shares or the effect that future issuances and sales of such securities will have on the market price of the Common Shares, should such a market develop. Issuances of a substantial number of additional Common Shares or Preferred Shares or the perception that such issuances could occur, may adversely affect prevailing market prices for the Common Shares, if any. With any additional issuance of Common Shares investors will suffer dilution to their voting power and the Company may experience dilution in its earnings per share.

### **Risks Related to the Company**

***We have a very limited operating history, are not currently profitable, do not expect to become profitable in the near future, and may never become profitable.***

We have no meaningful historical operations upon which to evaluate our business and prospects and have not yet demonstrated an ability to obtain marketing approval for any of our drug candidates or successfully overcome the risks and uncertainties frequently encountered by companies in the pharmaceutical industry. We also have not generated any revenues from collaboration and licensing agreements or product sales to date and continue to incur research and development and other expenses. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our shareholders' deficit and working capital, and our future success is subject to significant uncertainty. As we have not begun generating revenue, it is extremely difficult to make accurate predictions and forecasts of our finances and

this is compounded by the fact that we intend to operate in the psychedelic industry, which is a relatively new and rapidly transforming industry.

For the foreseeable future, we expect to continue to incur losses, which will increase significantly from recent historical levels as we expand our drug development activities, seek regulatory approvals for our drug candidates and begin to commercialize them if they are approved by the FDA, the EMA or comparable foreign authorities. Even if we succeed in developing and commercializing one or more drug candidates, we may never become profitable.

***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.***

We have a limited operating history. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, filing patent applications, identifying potential drug candidates, and establishing arrangements with third parties for the manufacture of initial quantities of our drug candidates and component materials. We have not yet demonstrated our ability to successfully complete any clinical trials, obtain marketing approvals, manufacture a commercial-scale drug or arrange for a third party to do so on our behalf, or enter into agreements with third parties to conduct sales, marketing and distribution activities necessary for successful commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

***We operate in a relatively new industry and this industry may not succeed in the long term.***

Our PFN™ program operates in the psychedelic industry and there is no assurance that the industry and market will continue to exist and grow as currently estimated or anticipated or function and evolve in the manner consistent with management's expectations and assumptions. Any event or circumstance that adversely affects the psychedelic industry and market could have a material adverse effect on our business, financial condition and results of operations.

The psychedelic market will face specific marketing challenges given the products' status as a controlled substance which resulted in past and current public perception that the products have negative health and lifestyle effects and have the potential to cause physical and social harm due to psychoactive and potentially addictive effects. Any marketing efforts will need to overcome this perception to build consumer confidence, brand recognition and goodwill. In addition, due to the nature of our business and the fact that our contracts involve psilocybin, we may face difficulties in enforcing our contracts. The inability to enforce any of our contracts could have a material adverse effect on our business, operating results, financial condition or prospects.

Research regarding the medicinal benefits, viability, safety, efficacy, addictiveness, dosing and social acceptance of psychedelic products derived from psilocybin remains in early stages. There have been relatively few clinical trials on the benefits of such products. Although we believe that the articles, reports and studies support the medical benefits, viability, safety, efficacy, dosing and social acceptance of psychedelic products derived from psilocybin, future research and clinical trials may prove such statements to be incorrect, or could raise concerns regarding, and perceptions relating to, psychedelic products derived from psilocybin. Given these risks, uncertainties and assumptions, readers should not place undue reliance on such articles and reports. Future research studies and clinical trials may draw opposing conclusions to

those stated in this Prospectus or reach negative conclusions regarding the medical benefits, viability, safety, efficacy, dosing, social acceptance or other facts and perceptions related to psychedelic products derived from psilocybin, which could have a material adverse effect on the potential future demand for our drug candidates with the potential to lead to a material adverse effect on our business, financial condition and results of operations.

***We will have increased costs after becoming a publicly traded company.***

If we successfully list on the CSE, we will incur significant additional legal, accounting and filing fees that at present, are not required. Securities legislation and the rules and policies of the CSE require listed companies to, among other things, adopt corporate governance and related practices, and to continuously prepare and disclose material information all of which will significantly increase legal and financial compliance costs. We expect to have significant costs associated with being a public, reporting company. Our ability to continue as a going concern will depend on positive cash flow, if any, from future operations and on our ability to raise additional funds through equity or debt financing. If we are unable to achieve the necessary results or raise or obtain funding to cover the costs of operating as a public, reporting company, we may be forced to discontinue operations.

***Other clinical trials or studies may have negative results or reveal adverse safety events.***

From time to time, studies or clinical trials on various aspects of biopharmaceutical products are conducted by academic researchers, competitors or others. The results of these studies or trials, when published, may have a significant effect on the market for the biopharmaceutical products that are the subject of the study. The publication of negative results of studies or clinical trials or adverse safety events related to our drug candidates, or the therapeutic areas in which our drug candidates compete, could adversely affect our share price and ability to finance future development of our drug candidates, and could materially and adversely affect our business and financial results.

***We are highly dependent on the success of our initial drug candidates and we cannot be certain that any of them will receive regulatory approval or be commercialized.***

To date, we have not submitted an IND to the FDA, and we have not commenced clinical trials for any of our drug candidates. All of our drug candidates will require additional development, clinical trials, and regulatory clearances before they can be commercialized. Positive results obtained during early development do not necessarily mean later development will succeed or that regulatory clearances will be obtained. Our drug development efforts may not lead to commercial drugs, either because our drug candidates are not deemed safe and effective, because of competitive or market forces, intellectual property issues or because we have inadequate financial or other resources to advance our drug candidates through the clinical development and approval processes. If any of our drug candidates fail to demonstrate safety or efficacy at any time or during any phase of development, we would experience potentially significant delays in, or be required to abandon, development of the drug candidate.

We do not anticipate that any of our current drug candidates will be eligible to receive regulatory approval from the FDA, the EMA or comparable foreign authorities and begin commercialization for a number of years, if ever. Even if we ultimately receive regulatory approval for any of these drug candidates, we or our potential future partners, if any, may be unable to commercialize them successfully for a variety of reasons. These include, for example, the availability of alternative treatments, lack of cost-effectiveness, the cost of

manufacturing the drug on a commercial scale and competition with other drugs. The success of our drug candidates may also be limited by the prevalence and severity of any adverse side effects. If we fail to commercialize one or more of our current drug candidates, we may be unable to generate sufficient revenues to attain or maintain profitability, and our financial condition may decline.

We have never commercialized a drug candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize our therapies on our own or with suitable collaborators.

***If development of our drug candidates does not produce favorable results, we and our collaborators, if any, may be unable to commercialize these drug candidates.***

To receive regulatory approval for the commercialization of any drug candidates that we may develop, adequate and well-controlled clinical trials must be conducted to demonstrate safety and efficacy in humans to the satisfaction of the FDA, the EMA and comparable foreign authorities. In order to support marketing approval, these agencies typically require successful results in one or more Phase 3 clinical trials, which our current drug candidates have not yet reached and may never reach. The development process is expensive, can take many years and has an uncertain outcome. Failure can occur at any stage of the process. We may experience numerous unforeseen events during, or as a result of, the development process that could delay or prevent approval and commercialization of our current or future drug candidates, any of which may be exacerbated by unforeseen impacts related to the ongoing COVID-19 pandemic. These events may include the following:

- preclinical studies conducted with drug candidates for potential clinical development to evaluate their toxicology, carcinogenicity and pharmacokinetics and optimize their formulation, among other things, may produce unfavorable results;
- patient recruitment and enrollment in clinical trials may be slower than we anticipate;
- clinical trials may produce negative or inconclusive results;
- costs of development may be greater than we anticipate;
- the potential advantages of our drug candidates may not materialize and thus would confer no benefits to patients over other parties' products that may emerge;
- the potential that our competitors develop psilocybin drug products for the same indications or for other indications with off-label use;
- our drug candidates may cause undesirable side effects that delay or preclude regulatory approval or limit their commercial use or market acceptance, if approved;
- collaborators who may be responsible for the development of our drug candidates may not devote sufficient resources to the preclinical studies or clinical trials studies of these candidates or conduct them in a timely manner; or
- we may face delays in obtaining regulatory approvals to commence one or more clinical trials.

Success in early development does not mean that later development will be successful because, for example, drug candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy despite having progressed through initial clinical trials.

We or any potential future collaborative partner will be responsible for establishing the targeted endpoints and goals for development of our drug candidates. These targeted endpoints and goals may be inadequate to demonstrate the safety and efficacy levels required for regulatory approvals. Even if we believe data collected during the development of our drug candidates are promising, such data may not be sufficient to support marketing approval by the FDA, the EMA or comparable foreign authorities. Further, data generated during development can be interpreted in different ways, and the FDA, the EMA or comparable foreign authorities may interpret such data in different ways than we or our collaborators. Our failure to adequately demonstrate the safety and efficacy of any of our drug candidates would prevent our receipt of regulatory approval, and such failure would ultimately prevent the potential commercialization of these drug candidates.

Since we do not currently possess the resources necessary to independently develop and commercialize our drug candidates or any other drug candidates that we may develop, we will seek to enter into collaborative agreements to assist in the development and potential future commercialization of some or all of these drug candidates as a component of our strategic plan. Our discussions with potential collaborators, however, may not lead to the establishment of collaborations on acceptable terms, if at all, or it may take longer than expected to establish new collaborations, leading to development and potential commercialization delays, which would adversely affect our business, financial condition and results of operations.

***We expect to incur significant research and development expenses, which may make it difficult for us to attain profitability.***

We expect to expend substantial funds in research and development, including preclinical studies and clinical trials for our drug candidates, as well as for working capital requirements and other operating and general corporate purposes. Moreover, an increase in our headcount would dramatically increase our costs in the near and long-term.

Such spending may not yield any commercially viable drugs. Due to our limited financial and managerial resources, we must focus on a limited number of drug candidates and on specific indications. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities.

Because the successful development of our drug candidates is uncertain, we are unable to precisely estimate the actual funds we will require to develop and potentially commercialize them. In addition, we may not be able to generate sufficient revenue, even if we are able to commercialize any of our drug candidates, to become profitable.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic.

***We may expend our limited resources to pursue a particular drug candidate or indication and fail to capitalize on drug candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

Because we have limited financial and managerial resources, we will initially develop our lead drug candidates for particular diseases. As a result, we may forego or delay pursuit of opportunities in other

diseases that may prove to have greater treatment potential. Likewise, we may forego or delay the pursuit of opportunities with other potential drug candidates that may prove to have greater commercial potential.

Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and drug candidates for specific indications may not yield any commercially viable drug candidates. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other similar arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the drug candidate.

***Given our lack of current cash flow, we will need to raise additional capital; however, it may be unavailable to us or, even if capital is obtained, may cause dilution or place significant restrictions on our ability to operate our business.***

Since we will be unable to generate sufficient, if any, cash flow to fund our operations for the foreseeable future, we will need to seek additional equity or debt financing to provide the capital required to maintain or expand our operations.

There can be no assurance that we will be able to raise sufficient additional capital on acceptable terms or at all. If such additional financing is not available on satisfactory terms, or is not available in sufficient amounts, we may be required to delay, limit or eliminate the development of business opportunities, and our ability to achieve our business objectives, our competitiveness, and our business, financial condition and results of operations may be materially adversely affected. In addition, we may be required to grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves. Our inability to fund our business could lead to the loss of your investment.

Our future capital requirements will depend on many factors, including, but not limited to:

- the scope, rate of progress, results and cost of our preclinical studies, clinical trials and other related activities;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the timing of, and the costs involved in, obtaining regulatory approvals for any of our current or future drug candidates;
- the number and characteristics of the drug candidates we seek to develop or commercialize;
- the cost of manufacturing clinical supplies of our drug candidates;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing possible patent claims, including litigation costs and the outcome of any such litigation.

Any capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop our drug candidates. Moreover, if we raise additional capital by issuing equity

securities, the percentage ownership of our existing shareholders may be reduced, and accordingly these shareholders may experience substantial dilution. We may also issue equity securities that provide for rights, preferences and privileges senior to those of our Common Shares. Given our need for cash and that equity issuances are the most common type of fundraising for similarly situated companies, the risk of dilution is particularly significant for our shareholders. Furthermore, the incurrence of indebtedness would 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 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 otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our drug 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.

***There is substantial doubt about our ability to continue as a going concern.***

We had a negative operating cash flow for the period ended August 31, 2020. There is no assurance that sufficient revenues will be generated in the near future, if at all. The report of our independent registered public accounting firm on our August 31, 2020 audited financial statements includes an explanatory paragraph referring to our ability to continue as a going concern. As of August 31, 2020, we had a cash balance of approximately \$1,019,100. In addition, we had outstanding accounts payable and accrued liabilities of \$188,194 as of August 31, 2020. Additional funding will be required to continue our R&D and other operating activities as we have not reached successful commercialization of our product candidates. These circumstances cast significant doubt as to our ability to continue as a going concern. The inclusion in our financial statements of a going concern opinion may also negatively impact our ability to raise future financing and achieve future revenue.

***We may not be successful in our efforts to build a pipeline of drug candidates.***

A key element of our strategy is to build a pipeline of drug candidates for the treatment of rare diseases and diseases with high unmet medical needs, including through the use of our PFN™ program, and progress those drug candidates through clinical development. Even if we are successful in building a drug candidate pipeline, the potential drug candidates that we identify may not be suitable for clinical development for a number of reasons, including causing harmful side effects or demonstrating other characteristics that indicate a low likelihood of receiving marketing approval or achieving market acceptance. If our methods of identifying potential drug candidates fail to produce a pipeline of potentially viable drug candidates, then our success as a business will be dependent on the success of fewer potential drug candidates, which introduces risks to our business model and potential limitations to any success we may achieve.

***We are significantly dependent on the success of our PFN™ program and our drug candidates that are based on this program. A failure of any of these drug candidates in clinical development would adversely affect our business and may require us to discontinue development of other drug candidates that are based on our PFN™ program.***

We have invested, and we expect to continue to invest, significant efforts and financial resources in the development of drug candidates that are based on our PFN™ program. Our ability to generate meaningful revenue, which may not occur for the foreseeable future, if ever, will depend heavily on the successful development, regulatory approval and commercialization of one or more of these drug candidates. We will not be able to develop new drug candidates if it is found that the PFN™ program does not create drug candidates that are effective and safe for use in humans.



***Our drug candidates that are based on our PFN™ program will be subject to controlled substance laws and regulations in the territories where the drug will be marketed and failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations, may adversely affect the results of our business operations, both during clinical development and post approval, and our financial condition. In addition, during the review process of drugs that are based on our PFN™ program, and prior to approval, the FDA and/or other regulatory bodies may require additional data, including with respect to whether those drugs have abuse potential. This may delay approval and any potential rescheduling process.***

In the United States, psilocybin and its active metabolite, psilocin, are listed by the DEA as “Controlled Substances” or scheduled substances, under the Comprehensive Drug Abuse Prevention and Control Act of 1970, also known as the Controlled Substances Act, or 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 no 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 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 FDA for medical use in the United States that contain psilocybin or psilocin should be placed in Schedules II-V, since approval by the FDA satisfies the “accepted medical use” requirement. If and when drug candidates that are based on our PFN™ program receive FDA approval, we anticipate that the DEA will make a scheduling determination and place it in a schedule other than Schedule I in order for it to be prescribed to patients in the United States. This scheduling determination will be dependent on FDA approval and the FDA’s recommendation as to the appropriate schedule. During the review process, and prior to approval, the FDA may determine that it requires additional data, either from non-clinical or clinical studies, including with respect to whether, or to what extent, the substance has abuse potential. This may introduce a delay into the approval and any potential rescheduling process. That delay would be dependent on the quantity of additional data required by the FDA. This scheduling determination will require DEA to conduct notice and comment rule making including issuing an interim final rule. Such action will be subject to public comment and requests for hearing which could affect the scheduling of these substances. There can be no assurance that the DEA will make a favorable scheduling decision. Even assuming categorization as a Schedule II or lower controlled substance (i.e., Schedule III, IV or V), at the federal level, such substances would also require scheduling determinations under state laws and regulations.

If approved by the FDA, and if the finished dosage form of any drugs that are based on our PFN™ program are listed by the DEA as a Schedule II, III, or IV controlled substance, their manufacture, importation,

exportation, domestic distribution, storage, sale and legitimate use will continue to be subject to a significant degree of regulation by the DEA. In addition, the scheduling process may take significantly longer than the 90-day deadline set forth in the CSA, thereby delaying the launch of our PFN™ program drugs in the United States. Furthermore, the FDA, DEA, or any foreign regulatory authority could require us to generate more clinical or other data than we currently anticipate to establish whether or to what extent the substance has an abuse potential, which could increase the cost and/or delay the launch of drugs that are based on our PFN™ program therapies. In addition, therapeutic candidates containing controlled substances are subject to DEA regulations relating to manufacturing, storage, distribution, and physician prescription procedures, including:

- **DEA registration and inspection of 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 drugs that are based on our PFN™ program. 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 our 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.** Individual U.S. states have also established controlled substance laws and regulations. Though state-controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs that are based on our PFN™ program. While some states automatically schedule a drug based on federal action, other states schedule drugs through rule making or a legislative action. State scheduling may delay commercial sale of any drug for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such drug. We or our partners must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.
- **Clinical trials.** To conduct clinical trials with our drug candidates that are based on our PFN™ program in the United States prior to approval, each of our 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 those drug candidates. 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 we could lose clinical trial sites.
- **Manufacture in the United States.** Contract manufacturers for our PFN™ program drug candidates are subject to the DEA's annual manufacturing and procurement quota requirements. Additionally, regardless of the scheduling of our PFN™ program drug candidates, the active ingredient in the final dosage form is currently a Schedule I controlled substance and may be subject to such quotas, as

this substance could remain listed on Schedule I. The annual quota allocated to us or our contract manufacturers for the active ingredient in our drug candidates that are based on our PFN™ program may not be sufficient to complete clinical trials or meet commercial demand. Consequently, any delay or refusal by the DEA in establishing our, or our contract manufacturers', procurement and/or production quota for controlled substances could delay or stop our clinical trials or drug launches, which could have a material adverse effect on our business, financial position and results of operations.

- **Distribution in the United States.** If our PFN™ program drug candidates are scheduled as Schedule II, III or IV, anyone engaged in commercial sales of such drug candidate following FDA approval would also need to identify wholesale distributors with the appropriate DEA registrations and authority to distribute those drug candidates. These distributors would need to obtain Schedule II, III or IV distribution registrations. This limitation in the ability to distribute our drugs that are based on our PFN™ program more broadly may limit commercial uptake and could negatively impact our prospects. The failure to obtain, or delay in obtaining, or the loss of any of those registrations could result in increased costs to us. If any of our drug candidates that are based on our PFN™ program are, upon approval, Schedule II drugs, participants in our 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 drug. In addition, our drug candidates that are based on our PFN™ program may be determined to have a high potential for abuse and therefore required to be administered at our trial sites, which could limit commercial uptake. Furthermore, state and federal enforcement actions, regulatory requirements, and legislation intended to reduce prescription drug abuse, such as the requirement that physicians consult a state prescription drug monitoring program, may make physicians less willing to prescribe, and pharmacies to dispense, Schedule II products.

***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 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 FDA and DEA. The 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 FDCA. The 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 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 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.

***Our drug candidates that are based on our PFN™ program contain controlled substances, the use of which may generate public controversy. Adverse publicity or public perception regarding psilocybin or our current or future investigational therapies using psilocybin may negatively influence the success of these therapies.***

Therapies containing controlled substances may generate public controversy. Political and social pressures and adverse publicity could lead to delays in approval of and increased expenses for our drug candidates that are based on our PFN™ program. Opponents of these therapies may seek restrictions on marketing and withdrawal of any regulatory approvals. In addition, these opponents may seek to generate negative publicity in an effort to persuade the medical community to reject these therapies. For example, we may face media-communicated criticism directed at our clinical development program. Adverse publicity from psilocybin misuse may adversely affect the commercial success or market penetration achievable by our drug candidates that are based on our PFN™ program. Anti-psychedelic protests have historically occurred and may occur in the future and generate media coverage. Political pressures and adverse publicity could lead to delays in, and increased expenses for, and limit or restrict the introduction and marketing of, our drug candidates that are based on our PFN™ program.

If any of our drug candidates that are based on our PFN™ program are approved for commercial sale, their success will be highly dependent upon consumer perceptions of their safety and quality. They may face limited adoption if third-party therapy sites, therapists, and patients are unwilling to try such novel treatments. There has been a history of negative media coverage regarding psychedelic substances, including psilocybin, which may affect the public's perception of drug candidates that are based on our PFN™ program. In addition, psilocybin elicits intense psychological experiences, and this could deter patients from choosing this course of treatment. We could be adversely affected if we were subject to negative publicity or if any of our drug candidates that are based on our PFN™ program or any similar drugs distributed by other companies prove to be, or are asserted to be, harmful to patients. Because of our dependence upon consumer perception, any adverse publicity associated with illness or other adverse effects resulting from patients' use or misuse of drugs that are based on our PFN™ program or any similar drugs distributed by other companies could have a material adverse impact on our business, prospects, financial condition and results of operations.

Future adverse events in research into neuropsychiatric disorders, or the pharmaceutical industry more generally, could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our drug candidates. Any increased scrutiny could delay or increase the costs of obtaining regulatory approval for drug candidates that are based on our PFN™ program or any of our other drug candidates, including razoxane.

***Razoxane, the active ingredient in TRP-1001, has been identified by certain third-party researchers as potentially carrying a risk of secondary malignancies when dosed systemically over a long period of time.***

Razoxane, the active ingredient in TRP-1001, has been identified by certain third-party researchers as potentially carrying a risk of secondary malignancies when dosed systemically over a long period of time. While our internal review and research by unaffiliated third parties leads us to believe that risk is limited, adverse events of unanticipated severity or frequency could interrupt, delay or halt clinical trials of TRP-1001, and could result in the FDA or other regulatory authorities denying or withdrawing approval of TRP-1001. The FDA, other regulatory authorities, or we may suspend or terminate clinical trials at any time. We may also be required to update the package inserts based on reports of adverse events or safety concerns

or implement a risk evaluation and mitigation strategy, or REMS, which could adversely affect TRP-1001's acceptance in the market. In addition, the public perception of TRP-1001 might be adversely affected, which could harm our business and results of operations and cause the market price of our common stock to decline.

***The pharmaceutical industry is intensely competitive and involves a high degree of risk. If we are unable to compete effectively with existing drugs, new treatment methods and new technologies, we or our partners, if any may be unable to successfully commercialize any drug candidates that we develop.***

The pharmaceutical market is intensely competitive and rapidly changing. Many large pharmaceutical and biotechnology companies, academic institutions, governmental agencies and other public and private research organizations, both in the United States and worldwide, are pursuing the development of novel drugs for the same diseases that we are targeting or expect to target. Many of our competitors have, either alone or with strategic partners:

- much greater financial, research, technical and human resources than we have at every stage of the discovery, development, manufacture and commercialization of products and drug candidates;
- more extensive experience in designing and conducting preclinical studies and clinical trials, obtaining regulatory approvals, and in manufacturing, marketing and selling pharmaceutical products and drug candidates;
- products and drug candidates that have been approved or are in late stages of development; and
- collaborative arrangements in our target markets with leading companies and research institutions.

We will face intense competition from drugs that have already been approved and accepted by the medical community for the treatment of the conditions for which we may develop drug candidates. We also expect to face competition from new drugs that enter the market. These drugs may be more effective, safer, less expensive, introduced to market earlier, or marketed and sold more effectively or on a more cost-effective basis, than any drug candidates we develop. It is possible that the potential advantages of any of our drug candidates will not materialize.

Our competitors may develop or commercialize products with significant advantages over any drug candidates we are able to develop and commercialize based on many different factors, including:

- the safety and effectiveness of our drug candidates relative to alternative therapies, if any;
- the timing and scope of regulatory approvals for these drug candidates;
- the availability and cost of manufacturing, marketing and sales capabilities;
- price;
- reimbursement coverage from governments and other third-party payors; and
- patent position and intellectual property protection.

Our commercial opportunity could be reduced or eliminated if existing products or products developed and commercialized by our competitors are viewed as safer, more effective, more convenient or less expensive than any drugs that we may develop. Our competitors may also obtain FDA or other regulatory approval for their competing products more rapidly than we may obtain approval for any of our drug candidates, which

could result in our competitors establishing a strong market position before we are able to enter the market. Further, we expect that we will also compete with others when recruiting clinical trial sites and subjects for our clinical trials and when recruiting and retaining qualified scientific and management personnel.

***Any collaboration arrangement that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our current and potential future drug candidates.***

We may seek collaboration arrangements with pharmaceutical companies for the development or commercialization of our current and potential future drug candidates. To the extent that we decide to enter into collaboration agreements, we will face significant competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, execute and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we choose to enter into such arrangements, and the terms of the arrangements may not be favorable to us. If and when we collaborate with a third party for development and commercialization of a drug candidate, we can expect to relinquish some or all of the control over the future success of that drug candidate to the third party. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. As such, our inability to control our collaborators, and the potentially adverse results of our collaborators, may materially and adversely affect our drug candidates and we may not be able to conduct our program in the manner or on the time schedule it currently contemplates, which could negatively impact our business.

If our potential future collaborations do not result in the successful development and commercialization of drugs or if one of our collaborators terminates our agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our program technology and drug candidates could be delayed and we may need additional resources to develop drug candidates and our technology.

Disagreements between parties to a collaboration arrangement can lead to delays in developing or commercializing the applicable drug candidate and can be difficult to resolve in a mutually beneficial manner. In some cases, collaborations with pharmaceutical companies and other third parties are terminated or allowed to expire by the other party. Any such termination or expiration could adversely affect our business, financial condition and results of operations.

***We, or any future collaborators, may not be able to obtain Orphan Drug designation or orphan drug exclusivity for our drug candidates.***

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an Orphan Drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. In the United States and Europe, obtaining orphan drug approval may allow us to obtain financial incentives, such as an extended period of exclusivity during which only we are allowed to market the orphan drug for the orphan indications that we are developing. While we may seek orphan drug designation from the FDA for any of our drug candidates, we, or any future collaborators, may not be granted orphan drug designations for our drug candidates in the United States or in other jurisdictions.

Even if we or any future collaborators obtain orphan drug designation for a drug candidate, we or such collaborators may not be able to obtain orphan drug exclusivity for that drug candidate. Generally, a drug with orphan drug designation only becomes entitled to orphan drug exclusivity if it receives the first marketing approval for the indication for which it has such designation, in which case the FDA or the EMA will be precluded from approving another marketing application for the same drug for that indication for the applicable exclusivity period. The applicable exclusivity period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we or any future collaborators obtain orphan drug exclusivity for a drug, that exclusivity may not effectively protect the drug from competition because the FDA has taken the position that, under certain circumstances, another drug with the same active chemical and pharmacological characteristics, or moiety, can be approved for the same condition. Specifically, the FDA's regulations provide that it can approve another drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

***If we seek and obtain a Fast Track or Breakthrough Therapy designation or accelerated approval by the FDA for any of our drug candidates, such designations may not actually lead to a faster development or regulatory review or approval process or any other material benefits.***

We may in the future seek Fast Track designation for some of our drug candidates that reach the regulatory review process. If a drug candidate is intended for the treatment of a serious or life-threatening condition and the drug candidate demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply to the FDA for a Fast Track designation for the drug candidate. If Fast Track designation is obtained, the FDA may initiate review of sections of an NDA before the application is complete. This "rolling review" is available if the applicant provides and the FDA approves a schedule for the remaining information. In addition, a Fast Track product may be eligible for accelerated approval, as described below. The FDA has broad discretion over whether to grant a Fast Track designation and, as a result, even our drug candidates that may be eligible for such a designation may not receive it. Even if we were to receive Fast Track designation for any of our drug candidates, the designation may not result in a materially faster development process, review or approval compared to conventional FDA procedures. The FDA can withdraw a Fast Track designation if it believes that the designation is no longer supported by data from the clinical development program.

Additionally, we may in the future seek a Breakthrough Therapy designation for our drug candidates. The Food and Drug Administration Safety and Innovation Act established the Breakthrough Therapy designation for drugs intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and that, as indicated by preliminary clinical evidence, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies by the FDA are eligible for accelerated approval and increased interaction and communication with the FDA designed to expedite the development and review process.

As with Fast Track designation, designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe one of our drug candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and may determine not to grant such a designation. Even if we receive a Breakthrough Therapy designation for any of our drug candidates, the designation may not result in a materially faster development process, review or approval compared to conventional FDA procedures. Further, obtaining a Breakthrough Therapy designation does not assure or increase the likelihood of the FDA's approval of the applicable drug candidate. The FDA can determine that a drug candidate no longer meet the conditions for the designation or determine not to shorten the time period for FDA review or approval.

We may also in the future seek accelerated approval for some of our drug candidates. Under the FDA's accelerated approval regulations, the FDA may approve a drug for a serious or life-threatening disease or condition that provides meaningful therapeutic benefit to patients over existing treatments and demonstrates an effect based upon a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. In clinical trials, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or sooner than clinical endpoints. As with Fast Track designation and Breakthrough Therapy designation, the FDA has broad discretion over whether to grant approval based on a surrogate endpoint. Accordingly, even if we believe one of our drug candidates meets the criteria for accelerated approval, the FDA may disagree and may determine not to grant such approval.

In addition, a drug candidate approved on such an accelerated basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to validate the surrogate endpoint or otherwise confirm a clinical benefit during post-marketing studies, would allow the FDA to withdraw the drug from the market on an expedited basis.

***If the FDA does not conclude that certain of our drug candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such drug candidates under Section 505(b)(2) are not as we expect, the approval pathway for those drug candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.***

We are developing drug candidates for which we intend to seek FDA approval through the Section 505(b)(2) regulatory pathway. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the FDCA. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from trials that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to the FDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our drug candidates by potentially decreasing the amount of clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as we anticipated, we may need to conduct



additional clinical trials, provide additional data and information and meet additional standards for regulatory approval.

Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our drug candidates will receive the requisite approvals for commercialization. In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved drug to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing drugs. If successful, such petitions can significantly delay, or even prevent, the approval of the new drug. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no there is no guarantee this would ultimately lead to accelerated drug development or earlier approval.

Moreover, even if our drug candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the drugs may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the drugs.

***If any of our drug candidates obtain regulatory approval, additional competitors could enter the market with generic versions of such drugs, which may result in a material decline in sales of affected drugs.***

Under the Hatch-Waxman Act, a pharmaceutical manufacturer may file an abbreviated new drug application, or ANDA, seeking approval of a generic copy of an approved, small-molecule innovator drug. A manufacturer may also submit an NDA under Section 505(b)(2) of the FDCA that references the FDA's prior approval of the innovator drug. A 505(b)(2) NDA drug may be for a new or improved version of the original innovator drug. The Hatch-Waxman Act also provides for certain periods of regulatory exclusivity, which preclude FDA approval (or in some circumstances, FDA filing and reviewing) of an ANDA or 505(b)(2) NDA. These include, subject to certain exceptions, the period during which an FDA-approved drug is subject to orphan drug exclusivity. For example, a drug that is granted regulatory approval may be eligible for five years of marketing exclusivity in the United States following regulatory approval if that drug is classified as a new chemical entity, or NCE. A drug can be classified as a NCE if the FDA has not previously approved any other drug containing the same active moiety.

In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, drug formulation or an approved use of the drug, which would be listed with the drug in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." If there are patents listed in the Orange Book, a generic or 505(b)(2) applicant that seeks to market its drug before expiration of the patents must include in the ANDA a "Paragraph IV certification," challenging the validity or enforceability of, or claiming non-infringement of, the listed patent or patents. Appropriate notice of the certification must be given to the innovator, too, and if within 45 days of receiving such notice the innovator sues to protect its patents, approval of the ANDA is stayed for 30 months, or as lengthened or shortened by the court.

Accordingly, if any of our drug candidates are approved, competitors could file ANDAs for generic versions of our drugs or 505(b)(2) NDAs that reference our drugs, respectively. If there are patents listed for our drugs

in the Orange Book, those ANDAs and 505(b)(2) NDAs would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict which, if any, patents in our current portfolio or patents we may obtain in the future will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents, or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection for products and technologies we develop or license. Moreover, if any of our owned or in-licensed patents that are listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected drug could immediately face generic competition and its sales would likely decline rapidly and materially.

***We are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our drug candidates.***

The process of manufacturing our drug candidates is complex, highly regulated, and subject to several risks. For example, the process of manufacturing our drug candidates is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing processes for any of our drug candidates could result in reduced production yields, product defects, and other supply disruptions. If microbial, viral, or other contaminations are discovered in our drug candidates or in the manufacturing facilities in which our drug candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. In addition, the manufacturing facilities in which our drug candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors. It may be difficult or impossible to find Current Good Manufacturing Practice (cGMP) grade manufacturers, manufacturing may be cost prohibitive, we or our third-party manufacturers may not be able to manufacture drug candidates in a timely manner, or manufacturing may not be available to fulfill regulatory requirements. In addition, we or our third-party manufacturers may not be able to manufacture our drug candidates in a timely manner.

Product manufacturers and distributors are sometimes required to recall or initiate returns of their products for various reasons, including product defects such as contaminations, unintended harmful side effects or interactions with other products, packaging safety and inadequate or inaccurate labeling disclosure. If any of our future products are recalled, we could incur unexpected expense relating to the recall and any legal proceedings that might arise in connection with the recall. We may lose significant revenue due to loss of sales and may not be able to compensate for or replace that revenue.

In addition, any adverse developments affecting manufacturing operations for our drug candidates may result in shipment delays, inventory shortages, lot failures, withdrawals or recalls, or other interruptions in the supply of our drug candidates. We also may need to take inventory write-offs and incur other charges and expenses for drug candidates that fail to meet specifications, undertake costly remediation efforts or seek costlier manufacturing alternatives.

***We rely, and will continue to rely, predominantly, on third parties to manufacture our preclinical and clinical drug supplies and our business, financial condition and results of operations could be harmed if those third parties fail to provide us with sufficient quantities of drug product, or fail to do so at acceptable quality levels, prices, or timelines.***

We do not currently have, nor do we plan to acquire, the infrastructure or capability internally to manufacture our clinical drug supplies for use in our preclinical studies or clinical trials, and we lack the resources and the capability to manufacture any of our drug candidates on a clinical or commercial scale. We rely on our manufacturers to purchase from third-party suppliers the materials necessary to produce our drug candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our drug candidates, and there may be a need to identify alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our drug candidates for our clinical trials, and, if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Any significant delay or discontinuity in the supply of a drug candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials and potential regulatory approval of our drug candidates, which could harm our business, financial condition and results of operations.

***If we are unable to enter into agreements with third parties to sell and market our drug candidates, it may be necessary to develop our own commercial organization.***

We do not have a sales and marketing organization, and we have no experience as a company in the sales, marketing and distribution of pharmaceutical products. If any of our drug candidates are approved for commercialization and we are unable to make arrangements with a third party to perform sales and marketing services, we may be required to develop our own sales, marketing and distribution capabilities. Developing a sales force for any drug is expensive and time consuming and could delay any drug launch. We may be unable to establish and manage an effective sales force in a timely or cost-effective manner, if at all, and any sales force we do establish may not be capable of generating sufficient demand for our drug candidates. To the extent that we enter into arrangements with collaborators or other third parties to perform sales and marketing services, our revenues are likely to be lower than if we marketed and sold our drug candidates independently. If we are unable to establish adequate sales and marketing capabilities, independently or with others, we may not be able to generate significant revenues and may not become profitable.

***We are exposed to non-clinical and clinical liability risks, which could adversely affect our operations should lawsuits be filed against us.***

Our business exposes us to potential liabilities that are inherent in the testing, manufacturing and marketing of pharmaceutical formulations and products. Because we do not currently have any clinical trials ongoing and do not currently sell products, we do not currently carry liability insurance. We anticipate obtaining such insurance upon initiation of our clinical development activities; however, we may be unable to obtain liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful liability claim or series of claims brought against us could adversely affect our results of operations and business if judgments therewith exceed our insurance coverage.

***If we fail to retain current members of our management, or to attract and keep additional key personnel, we may be unable to successfully develop or commercialize our drug candidates.***

Our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. As of August 31, 2020, we had no full-time employees and six key consultants, including the Company's Chief Executive Officer and its President and Chief Scientific Officer, each of whom anticipate dedicating approximately 100% of their time to the affairs of the Company. We will rely primarily on outsourcing research, development and clinical trial activities, and manufacturing operations, as well as other functions critical to our business. We believe this approach enhances our ability to focus on our core opportunities, allocate resources efficiently to different projects and allocate internal resources more effectively. Competition for qualified personnel is intense. We may not be successful in attracting qualified personnel to fulfill our future needs. In the event we are unable to fill critical open employment positions, we may need to delay our operational activities and goals, including the development of our drug candidates, and may have difficulty in meeting our obligations as a public company. We do not maintain "key person" insurance on any of our key consultants.

The loss of the services of any of our key personnel, the inability to attract or retain highly qualified personnel in the future or delays in hiring such personnel, particularly senior management and other technical personnel, could materially and adversely affect our business, financial condition and results of operations. In addition, the replacement of key personnel likely would involve significant time and costs, and may significantly delay or prevent the achievement of our business objectives.

From time to time, our management seeks the advice and guidance of certain scientific advisors and consultants regarding clinical and regulatory development programs and other customary matters. These scientific advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our scientific advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with us.

***Any failure to maintain an effective system of internal controls may result in material misstatements of our financial statements or cause us to fail to meet our reporting obligations or fail to prevent fraud; and in that case, our shareholders or other investors could lose confidence in our financial reporting, which would harm our business and could negatively impact the price of our Common Shares.***

Effective internal controls are necessary for us to provide reliable financial reports and prevent fraud. If we fail to maintain an effective system of internal controls, we might not be able to report our financial results accurately or prevent fraud; and in that case, our shareholders or other investors could lose confidence in our financial reporting, which would harm our business and could negatively impact the price of our common shares. As a result of our limited administrative staffing levels, internal controls which rely on segregation of duties in many cases are not possible. Due to resource constraints and the present stage of our development, we do not have sufficient size and scale to warrant the hiring of additional staff to address this potential weakness at this time. To help mitigate the impact of this, we are highly reliant on the performance of compensating procedures and senior management's review and approval. Even if we conclude that our internal control over financial reporting provides reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with IFRS, because of its inherent limitations, internal control over financial reporting may not prevent or detect fraud or misstatements. Failure to implement required new or improved controls, or difficulties encountered in their

implementation, could harm our results of operations or cause us to fail to meet our future reporting obligations.

If we fail to timely achieve and maintain the adequacy of our internal control over financial reporting, we may not be able to produce reliable financial reports or help prevent fraud. Our failure to achieve and maintain effective internal control over financial reporting could prevent us from complying with our reporting obligations on a timely basis, which could result in the loss of shareholder or other investor confidence in the reliability of our financial statements, harm our business and negatively impact the trading price of our Common Shares.

***The directors and officers may have conflicts of interest with the Company.***

Most of the Company's directors and officers do not devote their full time to the affairs of the Company. All of the directors and officers of the Company are also directors, officers and shareholders of other companies, and as a result they may find themselves in a position where their duty to another company conflicts with their duty to the Company. Although the Company has policies which address such potential conflicts and the BCBCA has provisions governing directors in the event of such a conflict, none of the Company's constating documents or any of its other agreements contain any provisions mandating a procedure for addressing such conflicts of interest. There is no assurance that any such conflicts will be resolved in favor of the Company. If any such conflicts are not resolved in favor of the Company, the Company may be adversely affected.

***We could be held liable for fraudulent or illegal activity by employees, contractors and consultants resulting in significant financial losses.***

We are exposed to the risk that employees, independent contractors and consultants may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities that violates: (i) government regulations; (ii) manufacturing standards; (iii) healthcare fraud and abuse laws and regulations; or (iv) laws that require the true, complete and accurate reporting of financial information or data. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions taken to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could have a material adverse effect on our business, financial condition and results of operations.

***Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our cyber security or cyber security of our collaborators or partners.***

Given our limited operating history, we are still in the process of implementing our internal security measures. Our computer systems, and those of current and future third parties on which we rely, may fail and are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war, pandemics and telecommunications and electrical failure. In addition, any information technology or other internal infrastructure systems we may put in place in the future, including corporate firewalls, servers,

leased lines and connection to the Internet, face the risk of systemic failure that could disrupt our operations. While we have not, to our knowledge, experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our drug candidates or any future candidates could be hindered or delayed. Furthermore, we may incur additional costs to remedy the damage caused by these disruptions or security breaches.

***Business disruptions such as natural disasters could seriously harm our future revenues and financial condition and increase our costs and expenses.***

We and our suppliers may experience a disruption in our and their business as a result of natural disasters. A significant natural disaster, such as an earthquake, hurricane, flood or fire, could severely damage or destroy our headquarters or facilities or the facilities of our manufacturers or suppliers, which could have a material and adverse effect on our business, financial condition and results of operations. In addition, terrorist acts or acts of war could cause damage or disruption to us, our employees, facilities, partners and suppliers, which could have a material adverse effect on our business, financial condition and results of operations.

***A pandemic, epidemic, or outbreak of an infectious disease, such as the COVID-19 pandemic, may materially and adversely affect our business, including our preclinical studies, clinical trials, third parties on whom we rely, our supply chain, our ability to raise capital, our ability to conduct regular business and our financial results.***

We are subject to risks related to public health crises such as the COVID-19 pandemic. The COVID-19 pandemic originated in Wuhan, China in December 2019 and has since spread to a large number of countries, including the United States and most European countries. The pandemic and policies and regulations implemented by governments in response to the pandemic, often directing businesses and governmental agencies to cease non-essential operations at physical locations, prohibiting certain nonessential gatherings and ceasing non-essential travel have had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, facilities and production have been suspended, and demand for certain goods and services, such as medical service and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The full extent to which COVID-19 will ultimately impact our business will depend on future developments, which are highly uncertain and cannot be accurately predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others. Global health concerns, such as the COVID-19 pandemic, could also result in social, economic, and labor instability in the countries in which we or the third parties with whom we engage operate.

If the COVID-19 pandemic continues and persists for an extended period of time, we expect there could be significant and material disruptions to our supply chain and operations, and associated delays in the manufacturing and supply of our drug candidates. Any such supply disruptions would adversely impact our business, financial condition, results of operations and growth prospects.

As COVID-19 continues to be present and spread around the globe, we may experience additional disruptions that could severely impact our business and clinical trials, including:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials;
- interruption of key clinical trial activities;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing;
- limitations in employee resources that would otherwise be focused on conducting our clinical trials;
- delays in receiving authorizations from regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or the discontinuation of the clinical trials altogether;
- interruptions or delays in preclinical studies due to restricted or limited operations at research and development laboratory facilities;
- interruptions or delays in efforts to acquire data needed to support patent claims or otherwise expand the Company's intellectual property portfolio;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- refusal of the FDA, the EMA, the MHRA or the other regulatory bodies to accept data from clinical trials in affected geographies outside the United States or the EU or other relevant local geography.

Any negative impact the COVID-19 pandemic has on patient enrollment or treatment or the development of our drug candidates could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our drug candidates, if approved, increase our operating expenses, and have a material adverse effect on our financial results. The COVID-19 pandemic has also caused significant volatility in public equity markets and disruptions to the United States and global economies. This increased volatility and economic dislocation may make it more difficult for us to raise capital on favorable terms, or at all. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also heighten many of the other risks described in this "Risk Factors" section, such as those relating to the timing and completion of our clinical trials and our ability to obtain future financing.

***We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.***

From time to time, we may consider strategic transactions, such as spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Additional potential

transactions that we may consider include a variety of different business arrangements, including acquisitions of companies, asset purchases and out-licensing or in-licensing of drugs, drug candidates or technologies. Any such transaction may require us to incur non-recurring or other charges, may increase our near- and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our business, financial condition and results of operations. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired drugs, drug candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for any of these transactions;
- higher-than-expected transaction and integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses or product lines with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses or product lines due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks, and could have a material adverse effect on our business, financial condition and results of operations.

***The estimates and judgments we make, or the assumptions on which we rely, in preparing our financial statements could prove inaccurate.***

Our financial statements have been prepared in accordance with International Financial Reporting Standards. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, revenues and expenses, the amounts of charges accrued by us and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. We cannot assure, however, that our estimates, or the assumptions underlying them, will not change over time or otherwise prove inaccurate. For example, our estimates as they relate to anticipated timelines and milestones for our preclinical development or clinical trials may prove to be inaccurate. If this is the case, we may be required to restate our financial statements, which could, in turn, subject us to securities class action litigation or regulatory investigation or action. Defending against such potential litigation or regulatory action relating to a restatement of our financial statements would be expensive and would require significant attention and resources of our management. Moreover, our insurance to cover our obligations with respect to the ultimate resolution of any such litigation or regulatory action may be inadequate. As a result of these factors, any such potential litigation or regulatory action could have a material adverse effect on our financial results or harm our business.



## **Risks Related to Our Intellectual Property**

### ***We may not be successful in obtaining or maintaining rights to drug candidates through acquisitions and in-licenses.***

We may need to acquire or in-license intellectual property in the future. We may be unable to acquire or in-license any compositions, methods of use, processes or other intellectual property rights from third parties that we identify as necessary for our existing drug candidates or for new drug candidates that we intend to develop. We face competition with regard to acquiring and in-licensing third-party intellectual property rights, including from a number of more established companies. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license intellectual property rights to us. We also may be unable to acquire or in-license third-party intellectual property rights on terms that would allow it to make an appropriate return on our investment, and we may not be able to market products or perform research and development or other activities covered by these patents.

We may enter into collaboration agreements with U.S. and foreign academic institutions to accelerate development of our current or future preclinical drug candidates. Typically, these agreements include an option for the company to negotiate a license to the institution's intellectual property rights resulting from the collaboration. Even with such an option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to license rights from a collaborating institution, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our desired program.

If we are unable to successfully obtain required third-party intellectual property rights or maintain our existing intellectual property rights, we may need to abandon development of the related program and our business, financial condition and results of operations could be materially and adversely affected.

### ***If we fail to comply with our obligations in the agreements under which we in-license intellectual property and other rights from third parties or otherwise experiences disruptions to our business relationships with our licensors, we could lose intellectual property rights that are important to our business.***

We may enter into license agreements for compositions, methods of use, processes or other intellectual property rights in the future. We expect that any future license agreements will impose various royalties, sublicensing fees and other obligations on us. If we fail to comply with our obligations under these agreements, we may be required to make certain payments to the licensor, we may lose the exclusivity of our license, or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Additionally, the royalties and other payments associated with these licenses could materially and adversely affect our business, financial condition and results of operations.

In some cases, patent prosecution of licensed technology may be controlled solely by the licensor. If a licensor fails to obtain and maintain patent or other protection for the proprietary intellectual property we in-license, then we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we may control the prosecution of patents resulting from licensed technology. In the event we breach

any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise regarding intellectual property subject to a licensing agreement, including, but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

If disputes over intellectual property and other rights that we may in-license in the future prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected drug candidates. If we fail to comply with any such obligations to our licensor, such licensor may terminate their licenses to us, in which case we would not be able to market products covered by these licenses. The loss of any licenses could have a material adverse effect on our business, financial condition and results of operations.

***We may not be able to protect our proprietary or licensed technology in the marketplace.***

We depend on our ability to protect our proprietary or licensed technology. We rely on trade secret, patent, and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our success depends in large part on our ability and any licensor's or licensee's ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary or licensed technology and drug candidates. We may in-license additional intellectual property rights in the future. We cannot be certain that patent enforcement activities by future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. We also cannot be certain that future licensors will allocate sufficient resources or prioritize their or our enforcement of such patents. Even if we are not a party to these legal actions, an adverse outcome could prevent us from continuing to license intellectual property that we may need to operate our business, which would have a material adverse effect on our business, financial condition and results of operations.

We believe we will be able to obtain, through prosecution of patent applications covering our owned technology and technology licensed from others, adequate patent protection for our drug candidates. However, we have not completed any patentability searches in relation to our current patent applications, and have not received any formal opinions regarding patentability or freedom to operate in relation to, the subject matter disclosed and claimed in the patent applications. There is no guarantee that the patent applications will issue. If our patent applications do not issue or if we are compelled to spend significant time and money protecting or enforcing our future patents we may own or license, designing around patents held by others, or licensing or acquiring patents or other proprietary rights held by others, our business,

financial condition and results of operations may be materially and adversely affected. If we are unable to effectively protect the intellectual property that we own or license, other companies may be able to offer the same or similar products for sale, which could materially adversely affect our business, financial condition and results of operations. The patents of others from whom we may license technology, and any future patents we may own, may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing the same or similar products or limit the length of term of patent protection that we may have for our drugs.

***Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection for licensed patents, licensed pending patent applications and potential future patent applications and patents could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or patent applications will be due to be paid to the U.S. Patent and Trademark Office (USPTO) and various governmental patent agencies outside of the United States in several stages over the lifetime of the applicable patent and/or patent application. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If this occurs with respect to our existing patent applications, patent applications we may file in the future or patents we may in-license in the future, our competitors might be able to use our technologies, which would have a material adverse effect on our business, financial condition and results of operations.

The patent positions of pharmaceutical products are often complex and uncertain. The breadth of claims allowed in pharmaceutical patents in the United States and many jurisdictions outside of the United States is not consistent. For example, in many jurisdictions, the support standards for pharmaceutical patents are becoming increasingly strict. Some countries prohibit method of treatment claims in patents. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our licensed or owned intellectual property or create uncertainty. In addition, publication of information related to our current drug candidates and potential drug candidates may prevent us from obtaining or enforcing patents relating to these drug candidates and potential drug candidates.

Patents that we may own or license in the future do not necessarily ensure the protection of our licensed or owned intellectual property for a number of reasons, including, without limitation, the following:

- the patents may not be broad or strong enough to prevent competition from other products that are identical or similar to our drug candidates;
- there can be no assurance that the term of a patent can be extended under the provisions of patent term extensions afforded by U.S. law or similar provisions in foreign countries, where available;
- the issued patents and patents that we may obtain or license in the future may not prevent generic entry into the market for our drug candidates;
- we, or third parties from whom we in-license or may license patents, may be required to disclaim part of the term of one or more patents;

- there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim;
- there may be prior art of which we are aware, which we do not believe affects the validity or enforceability of a patent claim, but which, nonetheless, ultimately may be found to affect the validity or enforceability of a patent claim;
- there may be other patents issued to others that will affect our freedom to operate;
- if the patents are challenged, a court could determine that they are invalid or unenforceable;
- there might be a significant change in the law that governs patentability, validity and infringement of our licensed patents or any future patents we may own that adversely affects the scope of our patent rights;
- a court could determine that a competitor's technology or product does not infringe our licensed patents or any future patents we may own; and
- the patents could irretrievably lapse due to failure to pay fees or otherwise comply with regulations or could be subject to compulsory licensing.

If we encounter delays in our development or clinical trials, the period of time during which we could market our potential products under patent protection would be reduced.

Our competitors may be able to circumvent patents we may own or license in the future by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may seek to market generic versions of any approved products by submitting abbreviated new drug applications to the FDA in which our competitors claim that our licensed patents or any future patents we may own are invalid, unenforceable or not infringed. Alternatively, our competitors may seek approval to market their own products similar to or otherwise competitive with our drug candidates. In these circumstances, we may need to defend or assert any patents we may own or license in the future, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find the patents we may own or license in the future invalid or unenforceable. We may also fail to identify patentable aspects of our research and development before it is too late to obtain patent protection. Even if we own or in-license valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

The issuance of a patent is not conclusive as to its inventorship, scope, ownership, priority, validity or enforceability. In this regard, third parties may challenge our licensed patents or any future patents we may own in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and potential drugs. In addition, given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such drug candidates might expire before or shortly after such drug candidates are commercialized.

***Any claims or lawsuits relating to infringement of intellectual property rights brought by or against us will be costly and time consuming and may adversely affect our business, financial condition and results of operations.***

We may be required to initiate litigation to enforce or defend our owned or licensed intellectual property. Lawsuits to protect our intellectual property rights can be very time consuming and costly. There is a substantial amount of litigation involving patent and other intellectual property rights in the pharmaceutical industry generally. Such litigation or proceedings could substantially increase our operating expenses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

In any infringement litigation, any award of monetary damages we receive may not be commercially valuable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are resolved. Further, any claims we assert against a perceived infringer could provoke these parties to assert counterclaims against us alleging that we have infringed their patents. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

In addition, our patent applications, and patents and patent applications that we may apply for, own or license in the future, could face other challenges, such as interference proceedings, opposition proceedings, re-examination proceedings and other forms of post-grant review. Any of these challenges, if successful, could result in the invalidation of, or in a narrowing of the scope of, any of our licensed patents and patent applications and patents and patent applications that we may apply for, own or license in the future subject to challenge. Any of these challenges, regardless of their success, would likely be time-consuming and expensive to defend and resolve and would divert our management and scientific personnel's time and attention, may adversely affect our ability to raise funds or may otherwise cause public relations problems.

***Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our drug candidates or, upon any approval, drug products.***

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involves both technological and legal complexity and is costly, time-consuming and inherently uncertain. For example, the United States previously enacted and is currently implementing wide-ranging patent reform legislation. Specifically, on September 16, 2011, the Leahy-Smith America Invents Act (the Leahy-Smith Act) was signed into law and included a number of significant changes to U.S. patent law, and many of the provisions became effective in March 2013. However, it may take the courts years to interpret the provisions of the Leahy-Smith Act, and the implementation of the statute could increase the uncertainties and costs surrounding the prosecution of our licensed and future patent applications and the enforcement or defense of our licensed and future patents, all of which could have a material adverse effect on our business, financial condition and results of operations. In addition, the U.S. 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 our 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 U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we might obtain in the future.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting and defending patents on drug candidates throughout the world would be prohibitively expensive. Competitors may use our licensed and owned technologies in jurisdictions where we have not licensed or obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain or license patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our drug candidates in jurisdictions where we do not have any issued or licensed patents, and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of any patents we may own in the future, or marketing of competing products in violation of our proprietary rights generally. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our licensed and owned intellectual property both in the United States and abroad. Proceedings to enforce our future patent rights, if any, in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

***We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.***

Due to our expected reliance on third parties throughout the development and manufacturing of our products, we may share trade secrets with such third parties. In order to protect our proprietary technology and processes, we rely in part on confidentiality agreements with our corporate partners, employees, consultants, manufacturers, outside scientific collaborators and sponsored researchers and other advisors. These agreements may not effectively prevent disclosure of our confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

***We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.***

We expect to employ individuals who were previously employed at other pharmaceutical companies. Although we have no knowledge of any such claims against us, we may be subject to claims that us or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

***We may be subject to claims challenging the inventorship of any patents we may own in the future and other intellectual property.***

Although we are not currently experiencing any claims challenging the inventorship of our intellectual property, we may in the future be subject to claims that former employees, collaborators or other third parties have an interest in patents we may own or other licensed or owned intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our drug candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business, financial condition and results of operations. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

***If we do not obtain additional protection under the Hatch-Waxman Amendments and similar foreign legislation extending the terms of our licensed patents and any future patents we may own, our business, financial condition and results of operations may be materially and adversely affected.***

Depending upon the timing, duration and specifics of FDA regulatory approval for our drug candidates, U.S. patents that we may license or own may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during drug development and the FDA regulatory review process. This period is generally one-half the time between the effective date of an IND (falling after issuance of the patent) and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Patent term restorations, however, cannot extend the remaining term of a patent beyond a total of 14 years from the date of approval by the FDA.

The application for patent term extension is subject to approval by the USPTO, in conjunction with the FDA. It takes at least six months to obtain approval of the application for patent term extension. We may not be granted 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 applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our drug will be shortened and our competitors may obtain earlier approval of competing products, and our ability to generate revenues could be materially adversely affected.

#### **Risks Related to Government Regulation**

***We are very early in our development efforts. If we are unable to advance our drug candidates to clinical development, obtain regulatory approval and ultimately commercialize our drug candidates through partnerships, sales or on our own, or experience significant delays in doing so, our business will be materially harmed.***

We are very early in our development efforts. Our ability to generate revenues, which we do not expect will occur for many years, if ever, will depend on the successful development and eventual sale, out-license, or

commercialization of our drug candidates, which may never occur. We currently generate no revenue and we may never be able to develop or commercialize a marketable product. The success of our drug candidates will depend on several factors, including the following:

- successful completion of any necessary preclinical studies;
- submission of INDs prior to commencement of our clinical trials;
- successful enrollment in, and completion of, clinical trials;
- receipt of regulatory approvals from applicable regulatory authorities;
- establishing manufacturing capabilities;
- obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our drug candidates;
- commercial launch of our drug candidates, if and when approved, whether by a purchaser, collaborator or alone;
- acceptance of our drug candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining third-party insurance coverage and adequate reimbursement;
- enforcing and defending intellectual property rights and claims; and
- maintaining a continued acceptable safety profile of the drug candidates following approval, if approved.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our drug candidates, which would materially harm our business. If we do not receive regulatory approvals for our drug candidates, we may not be able to continue our operations.

***Preclinical and clinical trials are expensive, time-consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.***

Before we can commence clinical trials, certain of our drug candidates may require preclinical studies that support our planned INDs in the United States or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of any preclinical studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. It is also impossible to predict when or if any of our drug candidates will complete clinical trials evaluating their safety and effectiveness in humans or will receive regulatory approval. To obtain the requisite regulatory approvals to market and sell any of our drug candidates, we must demonstrate through extensive clinical trials, and potentially preclinical studies, that our drug candidates are safe and effective in humans for use in each target indication. To date, we have never advanced a drug candidate into a clinical trial. Preclinical and clinical testing is expensive and can take many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the preclinical or clinical trial process. Delays or failures in our preclinical or clinical programs would



adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all, which would have an adverse effect on our business, financial condition and results of operations.

Additionally, the results of preclinical studies and future clinical trials of drug candidates may not be predictive of the results of later-stage clinical trials. Drug candidates in later stages of clinical trials may fail to show the desired safety and efficacy results despite having progressed through preclinical studies and initial clinical trials. Many companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to adverse safety profiles or lack of efficacy, notwithstanding promising results in earlier studies. Similarly, our future clinical trial results may not be successful for these or other reasons.

Drug candidate development risk is heightened by any changes in the anticipated clinical trials compared to the completed clinical trials. As drug candidates are developed from preclinical through early to late stage clinical trials towards approval and commercialization, it is customary that various aspects of the development program, such as manufacturing and methods of administration, are altered along the way in an effort to optimize processes and results. While these types of changes are common and are intended to optimize the drug candidates for late stage clinical trials, approval and commercialization, such changes carry the risk that they will not achieve these intended objectives.

Any of these changes could make the results of our anticipated clinical trials or other future clinical trials we may initiate less predictable and could cause our drug candidates to perform differently, including causing toxicities, which could delay completion of our clinical trials, delay approval of our drug candidates, and/or jeopardize our ability to generate revenues.

***We may rely on third parties to conduct investigator-sponsored clinical trials of our drug candidates. Any failure by a third party with respect to the clinical development of our drug candidates may delay or impair our ability to obtain regulatory approvals.***

We may rely on academic and private non-academic institutions to conduct and sponsor preclinical and clinical trials relating to our drug candidates. We will not control the design or conduct of the investigator-sponsored trials, and it is possible that the FDA or non-U.S. regulatory authorities will not view these investigator-sponsored trials as providing adequate support for future preclinical and clinical trials, whether controlled by us or third parties, for any one or more reasons, including elements of the design or execution of the trials or safety concerns or other trial results. For example, we may collaborate with, and rely on, academic centers to conduct preclinical and non-investigator-sponsored research and it is possible that the interests of such academic centers may not be aligned with our interests.

Such arrangements will likely provide us certain information rights resulting from the investigator-sponsored trials, including access to and the ability to use and reference the data, including for our own regulatory filings. However, we would not have control over the timing and reporting of the data from investigator-sponsored trials, nor would we own the data from the investigator-sponsored trials. If we are unable to confirm or replicate the results from the investigator-sponsored trials or if negative results are obtained, we would likely be further delayed or prevented from advancing further clinical development of our drug candidates. Further, if investigators or institutions breach their obligations with respect to the clinical development of our drug candidates, or if the data proves to be inadequate compared to the first-hand knowledge we might have gained had the investigator-sponsored trials been sponsored and conducted by us, then our ability to design and conduct any future preclinical or clinical trials ourselves may be adversely affected.

Additionally, the FDA or non-U.S. regulatory authorities may disagree with the sufficiency of our right of reference to the preclinical, manufacturing or clinical data generated by these investigator-sponsored trials, or our interpretation of preclinical, manufacturing or clinical data from these investigator-sponsored trials. If so, the FDA or other non-U.S. regulatory authorities may require us to obtain and submit additional preclinical, manufacturing, or clinical data before we may initiate our anticipated trials and/or may not accept such additional data as adequate to initiate our anticipated trials.

***We intend to rely on third parties to conduct our preclinical studies and clinical trials and perform other tasks. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our drug candidates and our business, financial condition and results of operations could be substantially harmed.***

We intend to rely upon third-party CROs, medical institutions, clinical investigators and contract laboratories to monitor and manage data for our preclinical and clinical programs. Nevertheless, we maintain responsibility for ensuring that each of our preclinical studies are, and anticipated clinical studies will be, conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on these third parties does not relieve the Company of our regulatory responsibilities. The Company and our CROs and other vendors are required to comply with current requirements on cGMP, GCP and GLP, which are a collection of laws and regulations enforced by the FDA, the EMA and comparable foreign authorities for all of our drug candidates in clinical development. Regulatory authorities enforce these regulations through periodic inspections of preclinical study and clinical trial sponsors, principal investigators, preclinical study and clinical trial sites, and other contractors. If we or any of our CROs or vendors fails to comply with applicable regulations, the data generated in our preclinical studies and clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign authorities may require us to perform additional preclinical studies and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with products produced consistent with cGMP regulations. Our failure to comply with these regulations may require it to repeat clinical trials, which would delay the development and regulatory approval processes.

We may also not be able to enter into arrangements with CROs on commercially reasonable terms, or at all. In addition, our CROs will not be our employees, and except for remedies available to us under our agreements with such CROs, we will not be able to control whether or not they devote sufficient time and resources to our ongoing preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. CROs may also generate higher costs than anticipated. As a result, our business, financial condition and results of operations and the commercial prospects for our drug candidates could be materially and adversely affected, our costs could increase, and our ability to generate revenue could be delayed.

Switching or adding CROs, medical institutions, clinical investigators or contract laboratories involves additional cost and requires management time and focus. In addition, there is a natural transition period

when a new CRO commences work replacing a previous CRO. As a result, delays occur, which can materially impact our ability to meet our desired development timelines. There can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse effect on our business, financial condition or results of operations.

***Our drug candidates may cause undesirable side effects that could delay or prevent their regulatory approval or commercialization or have other significant adverse implications on our business, financial condition and results of operations.***

Undesirable side effects observed in preclinical studies or in clinical trials with our drug candidates could interrupt, delay or halt their development and could result in the denial of regulatory approval by the FDA, the EMA or comparable foreign authorities for any or all targeted indications or adversely affect the marketability of any drug candidates that receive regulatory approval. In turn, this could eliminate or limit our ability to commercialize our drug candidates.

Our drug candidates may require a risk management program that could include patient and healthcare provider education, usage guidelines, appropriate promotional activities, a post-marketing observational study and ongoing safety and reporting mechanisms, among other requirements. Prescribing could be limited to physician specialists or physicians trained in the use of the drug, or could be limited to a more restricted patient population. Any risk management program required for approval of our drug candidates could potentially have an adverse effect on our business, financial condition and results of operations.

Undesirable side effects involving our drug candidates may have other significant adverse implications on our business, financial condition and results of operations. For example:

- we may be unable to obtain additional financing on acceptable terms, if at all;
- our collaborators may terminate any development agreements covering these drug candidates;
- if any development agreements are terminated, we may determine not to further develop the affected drug candidates due to resource constraints and may not be able to establish additional collaborations for their further development on acceptable terms, if at all;
- if we were to later continue the development of these drug candidates and receive regulatory approval, earlier findings may significantly limit their marketability and thus significantly lower our potential future revenues from their commercialization;
- we may be subject to product liability or shareholder litigation; and
- we may be unable to attract and retain key employees.

In addition, if any of our drug candidates receive marketing approval and we or others later identify undesirable side effects caused by the drug:

- regulatory authorities may withdraw their approval of the drug, or we or our partners may decide to cease marketing and sale of the drug voluntarily;

- we may be required to change the way the drug is administered, conduct additional preclinical studies or additional clinical trials after initial clinical trials regarding the drug, change the labeling of the drug, or change the drug's manufacturing facilities; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected drug and could substantially increase the costs and expenses of commercializing the drug, which in turn could delay or prevent us from generating significant revenues from the sale of the drug.

***Delays in the commencement or completion of clinical trials could result in increased costs to us and delay our ability to establish strategic collaborations.***

Delays in the commencement or completion of clinical trials could significantly impact our drug development costs. We do not know whether anticipated clinical trials will begin on time or be completed on schedule, if at all. The commencement of clinical trials can be delayed for a variety of reasons, including, but not limited to, delays related to:

- obtaining regulatory approval to commence one or more clinical trials;
- reaching agreement on acceptable terms with prospective third-party contract research organizations (CROs) and clinical trial sites;
- manufacturing sufficient quantities of a drug candidate or other materials necessary to conduct clinical trials;
- obtaining institutional review board approval to conduct one or more clinical trials at a prospective site;
- recruiting and enrolling patients to participate in one or more clinical trials; and
- the failure of our collaborators to adequately resource our drug candidates due to their focus on other programs or as a result of general market conditions.

In addition, once a clinical trial has begun, it may be suspended or terminated by us, our collaborators, the institutional review boards or data safety monitoring boards charged with overseeing our clinical trials, the FDA, the EMA or comparable foreign authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols;
- inspection of the clinical trial operations or clinical trial site by the FDA, the EMA or comparable foreign authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues;
- lack of adequate funding to continue the clinical trials; and
- lack of patient enrollment in clinical studies.

If we experience delays in the completion, or the termination, of any clinical trial of our drug candidates, the commercial prospects of our drug candidates will be harmed, and our ability to commence sales and generate revenues from any of our drug candidates will be delayed. In addition, any delays in completing

our clinical trials will increase our costs and slow down our drug candidate development and approval process. Delays in completing our clinical trials could also allow our competitors to obtain marketing approval before we do or shorten the patent protection period during which we may have the exclusive right to commercialize our drug candidates. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many 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 our drug candidates.

***If we experience delays in the enrollment of patients in our clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.***

We may not be able to initiate or continue clinical trials for our drug candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or other regulatory authorities. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating.

If we fail to enroll and maintain the number of patients for which the clinical trial was designed, the statistical power of that clinical trial may be reduced, which would make it harder to demonstrate that the drug candidate being tested in such clinical trial is safe and effective. Additionally, enrollment delays in our clinical trials may result in increased development costs for our drug candidates, which would cause our value to decline and limit our ability to obtain additional financing. Our inability to enroll a sufficient number of patients for any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

***Our drug candidates are subject to extensive regulation under the FDA, the EMA or comparable foreign authorities, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals to commercialize our drug candidates.***

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, export, marketing and distribution of our drug candidates are subject to extensive regulation by the FDA and other U.S. regulatory agencies, the EMA or comparable authorities in foreign markets. In the United States, neither we nor our collaborators are permitted to market our drug candidates until we or our collaborators receive approval of an NDA from the FDA or receive similar approvals abroad. The process of obtaining these approvals is expensive, often takes many years, and can vary substantially based upon the type, complexity and novelty of the drug candidates involved. Approval policies or regulations may change and may be influenced by the results of other similar or competitive products, making it more difficult for us to achieve such approval in a timely manner or at all. In addition, as a company, we have not previously filed NDAs with the FDA or filed similar applications with other foreign regulatory agencies. This lack of experience may impede our ability to obtain FDA or other foreign regulatory agency approval in a timely manner, if at all, for our drug candidates for which development and commercialization is our responsibility.

Despite the time and expense invested, regulatory approval is never guaranteed. The FDA, the EMA or comparable foreign authorities can delay, limit or deny approval of a drug candidate for many reasons, including:

- a drug candidate may not be deemed safe or effective;
- agency officials of the FDA, the EMA or comparable foreign authorities may not find the data from preclinical studies or clinical trials generated during development to be sufficient;
- the FDA, the EMA or comparable foreign authorities may not approve our third-party manufacturers' processes or facilities; or
- the FDA, the EMA or a comparable foreign authority may change their approval policies or adopt new regulations.

Our inability to obtain these approvals would prevent our drug candidates from being commercialized.

***Even if our drug candidates receive regulatory approval in the United States, they may never receive approval outside of the United States.***

In order to market any drug outside of the United States, compliance with numerous and varying regulatory requirements of other countries regarding safety and efficacy is required. Approval procedures vary among countries and can involve additional drug candidate testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay seeking or obtaining such approval would impair our ability to develop foreign markets for our drug candidates.

***Even if any of our drug candidates receive regulatory approval, our drug candidates may still face future development and regulatory difficulties.***

If any of our drug candidates receive regulatory approval, the FDA, the EMA or comparable foreign authorities may still impose significant restrictions on the indicated uses or marketing of the drug candidates or impose ongoing requirements for potentially costly post-approval studies and trials. In addition, regulatory agencies subject a drug, its manufacturers and the manufacturers' facilities to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a drug, including adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured, a regulatory agency may impose restrictions on that drug, our collaborators or us, including requiring withdrawal of the drug from the market. Our drug candidates will also be subject to ongoing FDA, EMA or comparable foreign authorities' requirements for the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. If our drug candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning or untitled letters, Forms 483 or other notices of possible violations;
- impose civil or criminal penalties or fines or seek disgorgement of revenue or profits;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us or our collaborators;

- withdraw any regulatory approvals;
- impose restrictions on operations, including costly new manufacturing requirements, or shut down our manufacturing operations; or
- seize or detain drugs or require a recall of the drug.

***We and our potential contract manufacturers are subject to significant regulation with respect to manufacturing our drug candidates. The manufacturing facilities on which we will rely may not continue to meet regulatory requirements.***

All entities involved in the preparation of drugs for clinical trials or commercial sale, including our potential contract manufacturers for our drug candidates, are subject to extensive regulation. Components of a finished drug product approved for commercial sale or used in clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures and the implementation and operation of quality systems to control and assure the quality of investigational drugs and drugs approved for sale. Poor control of production processes can lead to the introduction of contaminants or to inadvertent changes in the properties or stability of our drug candidates that may not be detectable in final testing. We or our potential contract manufacturers must supply all necessary documentation in support of an NDA or marketing authorization application (“MAA”) on a timely basis and must adhere to cGMP regulations enforced by the FDA, the EMA or comparable foreign authorities through their facilities inspection program. The facilities and quality systems of some or all of our potential third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our drug candidates or any of our other potential drug candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our drug candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. Although we plan to oversee the contract manufacturers, we cannot control the manufacturing process of, and will be completely dependent on, our contract manufacturing partners for compliance with applicable regulatory requirements. If these facilities do not pass a pre-approval plant inspection, regulatory approval of the drug candidates may not be granted or may be substantially delayed until any violations are corrected to the satisfaction of the regulatory authority, if ever.

The regulatory authorities also may, at any time following approval of a drug for sale, audit the manufacturing facilities of our potential third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our drug specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly or time consuming for us or a third party to implement, and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we may contract could materially harm our business, financial condition and results of operations.

If we or any of our potential third-party manufacturers fail to maintain regulatory compliance, the FDA, the EMA or comparable foreign authorities can impose regulatory sanctions including, among other things, refusal to approve a pending application for a drug candidate, withdrawal of an approval, or suspension of production. As a result, our business, financial condition and results of operations may be materially and adversely affected.

Additionally, if supply from one manufacturer is interrupted, an alternative manufacturer would need to be qualified through an NDA supplement or MAA variation, or equivalent foreign regulatory filing, which could result in further delay. The regulatory agencies may also require additional studies or trials if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause us to incur higher costs and could cause the delay or termination of clinical trials, regulatory submissions, required approvals, or commercialization of our drug candidates. Furthermore, if our suppliers fail to meet contractual requirements and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

***Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our drug candidates and could have a material adverse effect on our business.***

In the United States, the EU and other foreign jurisdictions, there have been a number of legislative and regulatory changes to the healthcare system that could affect our 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. pharmaceutical industry.

Among the provisions of the ACA of importance to our drug candidates are the following:

- 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 we expect 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 Trump Administration has 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. We cannot predict what affect further changes to the ACA would have on our 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 our our 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 our drugs candidates and, accordingly, the results of our financial operations.

***Changes in government funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, properly administer drug innovation, or prevent our drug candidates from being developed or commercialized, which could negatively impact our business, financial condition and results of operations.***

The ability of the FDA to review and approve new products can be affected by a variety of factors, including budget and funding levels, ability to hire and retain key personnel, 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 other agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

In December 2016, the 21st Century Cures Act was signed into law. This new legislation is designed to advance medical innovation and empower the FDA with the authority to directly hire positions related to drug and device development and review. However, government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. These budgetary pressures may result in a reduced ability by the FDA to perform their respective roles; including the related impact to academic institutions and research laboratories whose funding is fully or partially dependent on both the level and timing of funding from government sources.

Disruptions at the FDA and other agencies may also slow the time necessary for our drug candidates to be reviewed or approved by necessary government agencies, which could adversely affect our business, financial condition and results of operations.

***If we face allegations of noncompliance with the law and encounter sanctions, our reputation, revenues and liquidity may suffer, and any of our drug candidates that are ultimately approved for commercialization could be subject to restrictions or withdrawal from the market.***

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to generate revenues from any of our drug candidates that are ultimately approved for commercialization. If regulatory sanctions are applied or if regulatory approval is withdrawn, our business, financial condition and results of operations will be adversely affected. Additionally, if we are unable to generate revenues from drug sales, our potential for achieving profitability will be diminished and our need to raise capital to fund our operations will increase.

#### **ELIGIBILITY FOR INVESTMENT**

In the opinion of Ryan Shewchuk Professional Corporation, tax counsel to the Company, and Borden Ladner Gervais LLP, legal counsel to the Agent, based on the provisions of the *Income Tax Act* (Canada) and the regulations thereunder (collectively, the “**Tax Act**”) in force as of the date hereof and all proposals to amend the Tax Act publicly announced by or on behalf of the Minister of Finance (Canada) prior to the date hereof, the Unit Shares, if issued on the date hereof, the Unit Warrants and the Warrant Shares, if issued on the date hereof, will be qualified investments for a trust governed by a registered retirement savings plan (“**RRSP**”), a registered retirement income fund (“**RRIF**”), a registered education savings plan (“**RESP**”), a deferred profit sharing plan, a registered disability savings plan (“**RDSP**”) and a tax-free savings account (“**TFSA**”) as each of those terms is defined in the Tax Act provided that the Unit Shares are listed on a “designated stock exchange” as defined in the Tax Act (which currently includes the Exchange) or is otherwise a “public corporation” within the meaning of the Tax Act and provided further that, with respect

to the Unit Warrants, the Company is not, and deals at arm's length with each person that is an annuitant, a beneficiary, an employer or a subscriber under, or a holder of such fund or plan, as the case may be.

The Common Shares of the Company have been conditionally listed on the Exchange. Listing is subject to the Company fulfilling all of the requirements of the Exchange. The Company will rely upon the Exchange to unconditionally list the Common Shares on the Exchange as of the day before the Closing Date and otherwise proceed in the manner described above to render the Common Shares issued on the Closing Date to be listed on a "designated stock exchange" within the meaning of the Tax Act at the time of issuance. If the Exchange does not proceed with the listing as anticipated, the Unit Shares, Unit Warrants and Warrant Shares will not be "qualified investments" for the purposes of the Tax Act at the Closing Date.

Notwithstanding that the Unit Shares, Unit Warrants and Warrant Shares may be a qualified investment for a trust governed by an RRSP, RRIF, RESP, RDSP, or TFSA (each, a "**Registered Plan**"), the annuitant of an RRSP or RRIF, the subscriber under an RESP or the holder of a TFSA or RDSP, as the case may be, (the "**Controlling Individual**") will be subject to a penalty tax in respect of Unit Shares, Unit Warrants and Warrant Shares held in the Registered Plan if the Unit Shares, Unit Warrants and Warrant Shares are a "prohibited investment" (as defined in the Tax Act) for the particular Registered Plan. The Unit Shares, Unit Warrants and Warrant Shares will be a "prohibited investment" for a Registered Plan if the Controlling Individual (i) does not deal at arm's length with the Company for purposes of the Tax Act, or (ii) has a "significant interest" (as defined in subsection 207.01(4) of the Tax Act) in the Company. Generally, a Controlling Individual will not be considered to have a "significant interest" in the Company provided that the Controlling Individual, together with persons with whom the Controlling Individual does not deal at arm's length, does not own, directly or indirectly, at any time in the year 10% or more of the issued shares of any class of the Company or of any corporation related to the Company (for purposes of the Tax Act). In addition, the Unit Shares, Unit Warrants and Warrant Shares will not be a "prohibited investment" if the Unit Shares, Unit Warrants and Warrant Shares are "excluded property" as defined in the Tax Act for a Registered Plan.

**Investors who are considering holding Unit Shares, Unit Warrants or Warrant Shares within a Registered Plan should consult their own tax advisors in regard to the application of these rules in their particular circumstances.**

#### **PROMOTERS**

William Garner and James Kuo took the initiative in founding the Company and, accordingly, may be considered promoters of the Company within the meaning of applicable securities legislation in British Columbia. Dr. Garner beneficially owns or controls, directly or indirectly, an aggregate of 13,200,000 Common Shares. Dr. Kuo beneficially owns or controls, directly or indirectly, an aggregate of 6,000,000 Common Shares. See "*Executive Compensation*" for disclosure regarding the compensation paid by the Company to Dr. Garner and Dr. Kuo.

On January 9, 2020, the Company acquired the Purchased Assets from Dr. Garner pursuant to the IP Purchase Agreement in consideration of the issuance of 40,000 Common Shares. See "*Selected Financial Information and Management's Discussion and Analysis*" and "*Prior Sales*".

On August 12, 2020, the Company acquired the Additional Purchased Assets from Dr. Garner and Dr. Kuo pursuant to the Additional IP Purchase Agreements in consideration of the issuance of an aggregate of 19,127,200 Common Shares. See "*Selected Financial Information and Management's Discussion and Analysis*" and "*Prior Sales*".

## LEGAL PROCEEDINGS AND REGULATORY ACTIONS

### Legal Proceedings

There are no legal proceedings outstanding, threatened or pending as of the date of this Prospectus by or against the Company or to which it is a party or its business or any of its assets is the subject of, nor to the knowledge of the directors and officers of the Company are any such legal proceedings contemplated which could become material to a purchaser of the Company's securities.

### Regulatory Actions

There have not been any penalties or sanctions imposed against the Company by a court relating to provincial or territorial securities legislation or by a securities regulatory authority, nor have there been any other penalties or sanctions imposed by a court or regulatory body against the Company, and the Company has not entered into any settlement agreements before a court relating to provincial or territorial securities legislation or with a securities regulatory authority.

## INTERESTS OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

Except as disclosed in this Prospectus, no director, executive officer or principal shareholder of the Company, or associate or affiliate of any of the foregoing, has had any material interest, direct or indirect, in any transaction within the preceding three years or in any proposed transaction that has materially affected or will materially affect the Company.

On January 9, 2020, the Company acquired the Purchased Assets from Dr. Garner pursuant to the IP Purchase Agreement in consideration of the issuance of 40,000 Common Shares. Dr. Garner developed the intellectual property forming the Purchased Assets and filed the related patent application independently and did not acquire it from a third party. See *"Selected Financial Information and Management's Discussion and Analysis"* and *"Prior Sales"*.

On August 12, 2020, the Company acquired the Additional Purchased Assets from Dr. Garner and Dr. Kuo pursuant to the Additional IP Purchase Agreements in consideration of the issuance of an aggregate of 19,127,200 Common Shares. Dr. Garner and Dr. Kuo developed the intellectual property forming the Additional Purchased Assets and filed the related patent application independently and did not acquire it from a third party. See *"Selected Financial Information and Management's Discussion and Analysis"* and *"Prior Sales"*.

## RELATIONSHIP BETWEEN ISSUER AND UNDERWRITER

The Company is not a "related issuer" or a "connected issuer" of or to the Agent (as such terms are defined in National Instrument 33-105 – *Underwriting Conflicts*).

## AUDITOR, TRANSFER AGENT AND REGISTRAR

The auditor of the Company is Smythe LLP, located at 1700 – 475 Howe Street, Vancouver, British Columbia V6C 2B3. Smythe LLP is independent of the Company within the meaning of the Code of Professional

Conduct of Chartered Professional Accountants of British Columbia. Smythe LLP was first appointed as auditor of the Company on May 21, 2020.

The transfer agent and registrar for the Common Shares is Computershare Investor Services Inc. at its principal office in Vancouver, British Columbia.

#### **MATERIAL CONTRACTS**

Other than contracts made in the ordinary course of business, the following are the only material contracts entered into or proposed to be entered into, by the Company since its incorporation:

- a) the IP Purchase Agreement;
- b) the Additional IP Purchase Agreements;
- c) the Escrow Agreement;
- d) the Warrant Indenture;
- e) the Transfer Agent, Registrar and Dividend Disbursing Agent Agreement dated October 30, 2020; and
- f) the Agency Agreement.

#### **EXPERTS**

The following persons are named as having prepared or certified a report, valuation, statement or opinion in this Prospectus:

- Smythe LLP, the auditor of the annual financial statements of the Company included in this Prospectus, has advised the Company that it is independent of the Company in accordance with the Code of Professional Conduct of the Chartered Professional Accountants of British Columbia.
- Ryan Shewchuk Professional Corporation, whose opinion has been relied upon by the Company in connection with the inclusion of the information under the heading "*Eligibility for Investment*" in this Prospectus.
- Borden Ladner Gervais LLP is the Agent's counsel in connection with the inclusion of the information under the heading "*Eligibility for Investment*" in this Prospectus.

Based on information provided by the relevant persons above, none of such persons or companies have received or will receive direct or indirect interests in the property of the Company or have any beneficial ownership, direct or indirect, of securities of the Company.

In addition, none of the aforementioned persons nor any director, officer or employee of any of the aforementioned persons, is or is expected to be elected, appointed or employed as, a director, senior officer

or employee of the Company or of an associate or affiliate of the Company, or as a promoter of the Company or an associate or affiliate of the Company.

#### **OTHER MATERIAL FACTS**

There are no other material facts other than as disclosed herein.

#### **FINANCIAL STATEMENT DISCLOSURE**

The audited financial statements of the Company for the fiscal year ended August 31, 2020 are included as Schedule "A" to this Prospectus.

#### **RIGHTS OF WITHDRAWAL AND RESCISSION**

Securities legislation in certain of the provinces of Canada provides purchasers with the right to withdraw from an agreement to purchase securities. This right may be exercised within two business days after receipt or deemed receipt of a prospectus and any amendment. In several of the provinces, the securities legislation further provides a purchaser with remedies for rescission or, in some jurisdictions, damages if the prospectus and any amendment contains a misrepresentation or is not delivered to the purchaser, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province. **The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province for the particulars of these rights or consult with a legal advisor.**

In an offering of warrants, investors are cautioned that the statutory right of action for damages for a misrepresentation contained in the prospectus is limited, in certain provincial securities legislation, to the price at which the warrants are offered to the public under the prospectus offering. This means that, under the securities legislation of certain provinces, if the purchaser pays additional amounts upon exercise of the warrants, those amounts may not be recoverable under the statutory right of action for damages that applies in those provinces. **The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for the particulars of this right of action for damages or consult with a legal advisor.**

#### **LIST OF EXEMPTIONS FROM INSTRUMENT**

The Company has not applied for or received any exemption from NI 41-101, regarding this Prospectus or the distribution of the Units under this Prospectus.

**SCHEDULE "A"**  
**FINANCIAL STATEMENTS OF THE COMPANY**

*[See attached]*



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**FINANCIAL STATEMENTS**

**(Expressed in Canadian dollars)**

**For the period September 24, 2019 (incorporation) to August 31, 2020**



## INDEPENDENT AUDITORS' REPORT

### TO THE SHAREHOLDERS OF TRYP THERAPEUTICS INC.

#### *Opinion*

We have audited the financial statements of Tryp Therapeutics Inc. (the "Company"), which comprise:

- the statement of financial position as at August 31, 2020;
- the statement of comprehensive loss for the 343-day period ended August 31, 2020;
- the statement of changes in shareholders' equity for the 343-day period ended August 31, 2020;
- the statement of cash flows for the 343-day period ended August 31, 2020; and
- the notes to the financial statements, including a summary of significant accounting policies.

In our opinion, the accompanying financial statements present fairly, in all material respects, the financial position of the Company as at August 31, 2020, and its financial performance and cash flows for the 343-day period ended August 31, 2020 in accordance with International Financial Reporting Standards ("IFRS").

#### *Basis for Opinion*

We conducted our audit in accordance with Canadian generally accepted auditing standards. Our responsibilities under those standards are further described in the *Auditors' Responsibilities for the Audit of the Financial Statements* section of our report. We are independent of the Company in accordance with the ethical requirements that are relevant to our audit of the financial statements in Canada, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### *Material Uncertainty Related to Going Concern*

We draw attention to Note 2 in the financial statements, which indicates that the Company incurred a net loss of \$422,617 during the 343-day period ended August 31, 2020. As stated in Note 2, these events or conditions, along with other matters as set forth in Note 2, indicate that a material uncertainty exists that may cast significant doubt on the Company's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

#### *Other Information*

Management is responsible for the other information. The other information comprises Management's Discussion and Analysis.

Our opinion on the financial statements does not cover the other information and we do not express any form of assurance conclusion thereon. In connection with our audit of the financial statements, our responsibility is to read the other information identified above and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated.

We obtained Management's Discussion and Analysis prior to the date of this auditors' report. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

## *Responsibilities of Management and Those Charged with Governance for the Financial Statements*

Management is responsible for the preparation and fair presentation of the financial statements in accordance with IFRS, and for such internal control as management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless management either intends to liquidate the Company or to cease operations, or has no realistic alternative but to do so.

Those charged with governance are responsible for overseeing the Company's financial reporting process.

## *Auditors' Responsibilities for the Audit of the Financial Statements*

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditors' report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with Canadian generally accepted auditing standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements. As part of an audit in accordance with Canadian generally accepted auditing standards, we exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- ♦ Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- ♦ Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control.
- ♦ Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.
- ♦ Conclude on the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditors' report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditors' report. However, future events or conditions may cause the Company to cease to continue as a going concern.
- ♦ Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.



We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide those charged with governance with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

The engagement partner on the audit resulting in this independent auditors' report is Sukhjit Gill.

*Smythe LLP*

Chartered Professional Accountants

Vancouver, British Columbia  
December 8, 2020

**TRYP THERAPEUTICS INC.**  
**STATEMENT OF FINANCIAL POSITION**  
As at August 31, 2020  
(Expressed in Canadian Dollars)

	Note	2020
<b>ASSETS</b>		
Current		
Cash		\$ 1,019,100
Prepays		28,700
Total current assets		1,047,800
Non current		
Deferred financing costs	15	26,520
Intangible assets	5,7,9	960,725
<b>Total Assets</b>		<b>\$ 2,035,045</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
Current		
Trade and other payables	6	188,194
Loans from shareholders	9	4,514
		192,708
<b>Shareholders' Equity</b>		
Share Capital	7	2,264,954
Deficit		(422,617)
Total Shareholders' Equity		1,842,337
<b>Total Liabilities and Shareholders' Equity</b>		<b>\$ 2,035,045</b>

**Nature of operations** (note 1) and **going concern** (note 2)  
**Events after the reporting period** (note 15)

Approved on behalf of the Board:

*"James Kuo" (signed)*

Director

*"William Garner" (signed)*

Director

*The accompanying notes are an integral part of these financial statements*

**TRYP THERAPEUTICS INC.****STATEMENT OF COMPREHENSIVE LOSS**

For the period of incorporation on September 24, 2019 to August 31, 2020

(Expressed in Canadian Dollars)

	Note	2020
<b>Expenses</b>		
Consulting fees	8	\$ 233,640
Office and administrative		772
Filing fees		123
Research and development		8,327
Marketing and corporate development		27,672
Website, advertising and promotion		14,479
Professional fees		126,193
Travel		11,411
Total expenses		422,617
<b>Net loss and comprehensive loss for the period</b>		<b>(422,617)</b>
<b>Loss per share for the period - basic and diluted</b>		<b>\$ (0.02)</b>
<b>Weighted average number of shares outstanding</b>		<b>18,998,964</b>

*The accompanying notes are an integral part of these financial statements*

**TRYP THERAPEUTICS INC.****STATEMENT OF CASH FLOWS**

For the period of incorporation on September 24, 2019 to August 31, 2020

(Expressed in Canadian Dollars)

	Note	2020
<b>OPERATING ACTIVITIES</b>		
Loss for the period		\$ (422,617)
Items not affecting cash		
Shares issued for consulting fees	7	189,640
Shares issued for debt	7,10	21,300
Changes in non-cash working capital		
Trade and other payables		175,365
<b>Cash used in operating activities</b>		<b>(36,312)</b>
<b>INVESTING ACTIVITY</b>		
Purchase of intangible assets	5	(4,205)
<b>Cash used in investing activity</b>		<b>(4,205)</b>
<b>FINANCING ACTIVITIES</b>		
Proceeds from private placements and incorporation	7	1,068,794
Proceeds from shareholder loans	9	4,514
Deferred financing costs		(13,691)
<b>Net cash provided by financing activities</b>		<b>1,059,617</b>
<b>Increase in cash during the period</b>		<b>1,019,100</b>
<b>Cash, beginning of period</b>		<b>-</b>
<b>Cash, end of period</b>		<b>\$ 1,019,100</b>

Supplemental cash flow information – Note 10

*The accompanying notes are an integral part of these financial statements*

**TRYP THERAPEUTICS INC.****STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY**

For the period of incorporation on September 24, 2019 to August 31, 2020

(Expressed in Canadian Dollars)

	Note	Share Capital			
		Number	Amount	Deficit	Total
Balance, September 24, 2019 (date of incorporation)	7	1	\$ 1	\$ -	-
Repurchase and cancellation of incorporation share	7	(1)	(1)	-	-
Shares issued to founders	7	48,000	1	-	-
Shares issued for debt	7	666,667	50,000	-	50,000
Shares issued for services	7,9	3,792,800	189,640	-	189,640
Shares issued for cash	7	14,725,055	1,068,793	-	1,068,794
Shares issued for intangible assets	7,9	19,159,200	956,520	-	956,520
Net loss for the period		-	-	(422,617)	(422,617)
<b>Balance, August 31, 2020</b>		<b>38,391,722</b>	<b>\$ 2,264,954</b>	<b>\$ (422,617)</b>	<b>\$ 1,842,337</b>

*The accompanying notes are an integral part of these financial statements*

**TRYP THERAPEUTICS INC.**  
**NOTES TO FINANCIAL STATEMENTS**  
For the period from September 24, 2019 to August 31, 2020  
(Expressed in Canadian Dollars)

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## 1. CORPORATION INFORMATION

### Nature of Operations

The Company was incorporated under *the BC Business Corporations Act* on September 24, 2019 under the name “Artos Pharma Corp.” (the “Company”). On June 30, 2020, the Company changed its name to “Tryp Therapeutics Inc”. On January 9, 2020, the Company split the common shares on the basis of two hundred (200) new shares for every one (1) common share held. On June 23, 2020, the Company consolidated the common shares on the basis of one (1) new share for every two hundred and fifty (250) common shares held. All common share information in these financial statements has been presented on a post-split and post-consolidation basis.

The Company is a clinical stage pharmaceutical company focused on developing compounds with known activity and/or safety profiles for the treatment of rare or orphan diseases and other diseases with high unmet medical needs. Our lead development program, which we refer to as our psilocybin-for-neuropsychiatry, or PFN™, program, is designed to treat neuropsychiatric disorders through the dosing of formulations of synthetic psilocybin. The initial indication for our PFN™ program is fibromyalgia. We are also evaluating additional indications for our PFN™ program, including hyperphagia in Prader-Willi Syndrome (“PWS”) and other neuropsychiatric-based chronic pain conditions and eating disorders.

In addition to our PFN™ program, we intend to pursue non-psychedelic drug candidates with known activity and/or safety profiles that may have utility in the treatment of rare or orphan diseases or other diseases with high unmet medical needs. As part of that program, we are developing a proprietary formulation of razoxane for the treatment of soft tissue sarcomas. We continue to evaluate additional indications for our existing programs, as well as other drug candidates that meet our criteria for development.

The Company’s principal address, records office and registered address are located at 335 – 1632 Dickson Avenue Kelowna, BC V1Y 7T2.

## 2. BASIS OF PRESENTATION AND GOING CONCERN

These financial statements have been prepared in accordance with International Financial Reporting Standards (“IFRS”), as issued by the International Accounting Standards Board (“IASB”). The financial statements were authorized for issue by the Board of Directors on December 8, 2020.

These financial statements have been prepared on the historical cost basis except for certain financial instruments, which have been measured at fair value. In addition, these financial statements have been prepared using the accrual basis of accounting, except for cash flow information.

The financial statements are presented in Canadian dollars, which is the functional currency of the Company.

The preparation of the financial statements in compliance with IFRS requires management to make certain critical accounting estimates. It also requires management to exercise judgment in applying the Company’s accounting policies. The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to these financial statements are disclosed in note 4.



## **2. BASIS OF PRESENTATION AND GOING CONCERN (cont'd)**

### **Going Concern**

The Company is in the development stage and currently has no sources of cash from operations. Further funds will be required to successfully develop the Company's business and there is no certainty that these funds will be available. As at August 31, 2020, the Company has accumulated net losses of \$422,617 since inception. The operations of the Company have primarily been funded by the issuance of common shares. The Company's continuation as a going concern is dependent upon its ability to raise equity capital or borrowings sufficient to meet current and future obligations, development and ultimately achieve profitable operations.

These financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern. Such adjustments could be material.

In March 2020, the World Health Organization declared coronavirus COVID-19 a global pandemic. This contagious disease outbreak, which has continued to spread, and any related adverse public health developments, has adversely affected workforces, economies and financial markets globally, potentially leading to an economic downturn. It is not possible for the Company to predict the duration or magnitude of the adverse results of the outbreak and its effects on the Company's business or results of operations at this time.

## **3. SIGNIFICANT ACCOUNTING POLICIES**

### **Intangible assets**

Intangible assets acquired separately are measured on initial recognition at fair value. Following initial recognition, intangible assets with finite useful lives are stated at cost less accumulated amortization (note 5). The Company has capitalized direct costs that were directly attributable to the acquisition of its intellectual property and patents (note 5). Those capitalized direct costs include costs incurred during the application and infrastructure of its patents.

Intangible assets with finite lives are amortized over their useful economic lives and assessed for impairment whenever there is an indication that the intangible asset may be impaired. The amortization periods and the amortization methods for an intangible asset with a finite useful life are reviewed at least at the end of each reporting period. Changes in the expected useful lives or the expected pattern of consumption of future economic benefits embodied in the asset are accounted for by changing the remaining amortization periods or methods, as appropriate, and are treated as changes in accounting estimates.

### **Research and development expenditures**

Research and development costs are expensed, except in cases where development costs meet certain identifiable criteria for deferral, including technical and economic feasibility. Development costs are capitalized only if the expenditures can be measured reliably, the product or process is technically and commercially feasible, future economic benefits are probable, and the Company intends to, and has sufficient resources to, complete development and to use or sell the asset. As at August 31, 2020, the Company has not capitalized any research and development costs.

### **3. SIGNIFICANT ACCOUNTING POLICIES (cont'd)**

#### **Financial instruments**

##### Classification

The Company classifies its financial instruments in the following categories: at fair value through profit and loss ("FVTPL"), at fair value through other comprehensive income (loss) ("FVTOCI"), or at amortized cost. The Company determines the classification of financial assets at initial recognition. The classification of debt instruments is driven by the Company's business model for managing the financial assets and their contractual cash flow characteristics. Equity instruments that are held for trading are classified as FVTPL. For other equity instruments, on the day of acquisition the Company can make an irrevocable election (on an instrument-by-instrument basis) to designate them as at FVTOCI. Financial liabilities are measured at amortized cost, unless they are required to be measured at FVTPL (such as instruments held for trading or derivatives) or the Company has opted to measure them at FVTPL.

##### Measurement

##### Financial assets and liabilities at amortized cost

Financial assets and liabilities at amortized cost are initially recognized at fair value plus or minus transaction costs, respectively, and subsequently carried at amortized cost less any impairment. The Company's cash and trade and other payables are classified as amortized cost.

##### Financial assets and liabilities at FVTPL

Financial assets and liabilities carried at FVTPL are initially recorded at fair value and transaction costs are expensed in the statement of comprehensive loss. Realized and unrealized gains and losses arising from changes in the fair value of the financial assets and liabilities held at FVTPL are included in profit or loss.

##### Financial assets at FVTOCI

Financial assets at FVTOCI are initially recorded at fair value adjusted for transaction costs. Dividends are recognized as income in the statement of comprehensive loss unless the dividend clearly represents a recovery of part of the cost of the investment. Gains or losses recognized on the sale of FVOTCI investment are recognized in other comprehensive income (loss) and are never reclassified to profit or loss.

##### Impairment

An 'expected credit loss' impairment model applies which requires a loss allowance to be recognized based on expected credit losses. The estimated present value of future cash flows associated with the asset is determined and an impairment loss is recognized for the difference between this amount and the carrying amount as follows: the carrying amount of the asset is reduced to estimated present value of the future cash flows associated with the asset, discounted at the financial asset's original effective interest rate, either directly or through the use of an allowance account and the resulting loss is recognized in profit or loss for the period.

### **3. SIGNIFICANT ACCOUNTING POLICIES (cont'd)**

In a subsequent period, if the amount of the impairment loss related to financial assets measured at amortized cost decreases, the previously recognized impairment loss is reversed through profit or loss to the extent that the carrying amount of the investment at the date the impairment is reversed does not exceed what the amortized cost would have been had the impairment not been recognized.

#### Derecognition

##### Financial assets

The Company derecognizes financial assets only when the contractual rights to cash flows from the financial assets expire, or when it transfers the financial assets and substantially all of the associated risks and rewards of ownership to another entity. Gains and losses on derecognition are generally recognized in the statement of comprehensive loss.

##### **Impairment of non-financial assets**

Impairment tests of non-financial assets are undertaken whenever events or changes in circumstances indicate that their carrying amount may not be recoverable. Where the carrying value of an asset exceeds its recoverable amount, which is the higher of value in use and fair value less costs to sell, the asset is written down accordingly.

Where it is not possible to estimate the recoverable amount of an individual asset, the impairment test is carried out on the asset's cash-generating unit, which is the lowest group of assets in which the asset belongs for which there are separately identifiable cash inflows that are largely independent of the cash inflows from other assets.

##### **Share capital**

Common shares are classified as equity. Transaction costs directly attributable to the issue of common shares and share options are recognized as a deduction from equity, net of any tax effects. Common shares issued for consideration other than cash are valued at the fair value of the assets received or the services rendered. If the fair value of the assets received or services rendered cannot be reliably measured, common shares issued for consideration will be valued at their fair value on the date of issuance.

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 measurable component. The Company considers the fair value of common shares issued in a unit private placement to be the more easily measurable component and the common shares are valued at their fair value, as determined by the closing quoted bid price on the issued date. The balance, if any, is allocated to the attached warrants. Any value attributed to the warrants is recorded as reserves.

Professional, consulting, regulatory and other costs directly attributable to financing transactions are recorded as deferred financing costs until the financing transactions are completed, if the completion of the transaction is considered likely; otherwise they are expensed as incurred. Share issue costs are charged to share capital when the related shares are issued. Deferred financing costs related to financing transactions that are not completed are expensed.

### **3. SIGNIFICANT ACCOUNTING POLICIES (cont'd)**

#### **Share-based compensation**

The fair value, at the grant date, of equity-settled share option awards is charged to profit or loss over the period for which the benefits of employees and others providing similar services are expected to be received. The corresponding accrued entitlement is recorded in contributed surplus. The amount recognized as an expense is adjusted to reflect the number of share options expected to vest. The fair value of awards is calculated using the Black-Scholes option pricing model which considers the following factors:

- Exercise price
- Expected life of the award
- Forfeiture rate
- Current market price of the underlying shares
- Risk-free interest rate
- Expected volatility

#### **Contributed surplus**

Contributed surplus consists of the fair value of stock options and warrants granted since inception, less amounts transferred to share capital for exercised stock options and warrants. If granted options or warrants vest and then subsequently expire or are forfeited, no reversal of contributed surplus is recognized.

#### **Loss per share**

Basic loss per share is computed by dividing net loss available to common shareholders by the weighted average number of common shares outstanding during the reporting period. Diluted loss per share is computed similarly to basic loss per share except that the weighted average common shares outstanding are increased to include additional shares for the assumed exercise of share options and share purchase warrants, if dilutive. The number of additional common shares is calculated by assuming that outstanding share options and share purchase warrants were exercised and that the proceeds from such exercises were used to acquire common shares at the average market price during the reporting periods.

Shares held in escrow, other than where their release is subject to the passage of time, are not included in the calculation of the weighted average number of common shares outstanding.

#### **Income taxes**

Tax provisions are recognized when it is considered probable that there will be a future outflow of funds to a taxing authority. In such cases, a provision is made for the amount that is expected to be settled, where this can be reasonably estimated. This requires the application of judgment as to the ultimate outcome, which can change over time depending on facts and circumstances. A change in estimate of the likelihood of a future outflow and/or in the expected amount to be settled would be recognized in income in the period in which the change occurs.

### **3. SIGNIFICANT ACCOUNTING POLICIES (cont'd)**

Deferred tax assets or liabilities, arising from temporary differences between the tax and accounting values of assets and liabilities, are recorded based on tax rates expected to be enacted when these differences are reversed. Deferred tax assets are recognized only to the extent it is considered probable that those assets will be recovered. This involves an assessment of when those deferred tax assets are likely to be realized, and a judgment as to whether there will be sufficient taxable profits available to offset the tax assets when they do reverse. This requires assumptions regarding future profitability and is therefore inherently uncertain. To the extent assumptions regarding future profitability change, there can be an increase or decrease in the amounts recognized in respect of deferred tax assets, as well as in the amounts recognized in income in the period in which the change occurs.

Tax provisions are based on enacted or substantively enacted laws. Changes in those laws could affect amounts recognized in income both in the period of change, which would include any impact on cumulative provisions, and in future periods.

#### **Foreign currency transactions**

Foreign currency accounts are translated into Canadian dollars as follows:

At the transaction date, each asset, liability, revenue and expense denominated in a foreign currency is translated into Canadian dollars by the use of the exchange rate in effect at that date. At the year-end date, unsettled monetary assets and liabilities are translated into Canadian dollars by using the exchange rate in effect at the year-end date and the related translation differences are recognized in net loss. Exchange gains and losses on non-monetary financial assets form part of the overall gain or loss recognized in respect of that financial instrument.

### **4. SIGNIFICANT ACCOUNTING JUDGMENTS, ESTIMATES AND ASSUMPTIONS**

The Company makes estimates and assumptions about the future that affect the reported amounts of assets and liabilities. Estimates and judgments are continually evaluated based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. In the future, actual experience may differ from these estimates and assumptions. The effect of a change in an accounting estimate is recognized prospectively by including it in loss/income in the year of the change, if the change affects that year only, or in the year of the change and future years, if the change affects both.

Information about critical judgments and estimates in applying accounting policies that have the most significant risk of causing material adjustment to the carrying amounts of assets and liabilities recognized in the financial statements within the next financial year are discussed below:

#### **Critical accounting estimates:**

##### **Recoverability of the carrying value of intangible assets**

Recoverability of the carrying value of intangible assets requires management to determine whether future economic benefits from sale or otherwise are likely. Evaluation may be more complex where activities have not reached a stage that permits a reasonable assessment of the viability of the asset. Management must make certain estimates and assumptions about future events or circumstances including, but not limited to, the interpretation of research results, as well as the Company's financial ability to continue sales activities and operations.

#### **4. SIGNIFICANT ACCOUNTING JUDGMENTS, ESTIMATES AND ASSUMPTIONS (cont'd)**

##### **The measurement of deferred income tax assets and liabilities**

Deferred tax assets, including those arising from un-utilized tax losses, require management to assess the likelihood that the Company will generate sufficient taxable earnings in future periods in order to utilize recognized deferred tax assets. Assumptions about the generation of future taxable profits depend on management's estimates of future cash flows. In addition, future changes in tax laws could limit the ability of the Company to obtain tax deductions in future periods. To the extent that future cash flows and taxable income differ significantly from estimates, the ability of the Company to realize the net deferred tax assets recorded at the reporting date could be impacted.

##### **Useful lives of intangible assets**

Amortization is recorded on the straight-line basis based upon management's estimate of the useful life and residual value. The estimates are reviewed at least annually and are updated if expectations change as a result of the technical obsolescence or legal and other limits to use. A change in the useful life or residual value will impact the reported carrying value of the intangible assets resulting in a change in related amortization expense. As at August 31, 2020, the Company has not amortized the intangible assets as amortization begins when the intangible assets are available for use.

##### **Fair value of consideration for intangible assets acquired**

The Company has applied estimates with respect to the valuation of shares issued for non-cash consideration in the acquisition of intangible assets. Shares are valued at the fair value of the equity instruments granted at the date the Company receives the goods or services for share-based payments made to those other than employees or others providing similar services.

##### **Critical accounting judgments:**

###### **Going concern**

The preparation of these financial statements requires management to make judgments regarding the going concern of the Company as discussed in note 2.

###### **Treatment of development costs**

Costs to develop products are capitalized to the extent that the criteria for recognition as intangible assets in IAS 38 *Intangible Assets* are met. Those criteria require that the product is technically and economically feasible, which management assessed based on the attributes of the development project, perceived user needs, industry trends and expected future economic conditions. Management considers these factors in aggregate and applies significant judgment to determine whether the product is feasible. The Company has not capitalized any development costs as at August 31, 2020.

###### **Treatment of deferred financing costs**

Professional, consulting, regulatory and other costs directly attributable to financing transactions are recorded as deferred financing costs until the financing transactions are completed, if the completion of the transaction is considered likely; otherwise they are expensed as incurred. Management applies significant judgment to determine whether the completion of the transaction is considered likely.

**TRYP THERAPEUTICS INC.**  
**NOTES TO FINANCIAL STATEMENTS**  
For the period from September 24, 2019 to August 31, 2020  
(Expressed in Canadian Dollars)

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**4. SIGNIFICANT ACCOUNTING JUDGMENTS, ESTIMATES AND ASSUMPTIONS (cont'd)**

**Treatment of acquired intangible assets**

Consideration paid in the acquisition of intangible assets is capitalized to the extent that the definition of an intangible asset and the criteria for recognition as intangible assets in IAS 38 *Intangible Assets* are met. Those criteria require that the intangible asset be identifiable, the Company must have control over it, and it must provide future economic benefits. Management considers these factors in aggregate and applies significant judgment to determine whether the intangible asset should be recognized in the statement of financial position.

At each reporting date, the Company assesses if the intangible assets have indicators of impairment. In determining whether the intangible assets are impaired, the Company assesses certain criteria, including observable decreases in value, significant changes with adverse effect on the entity, evidence of technological obsolescence and future plans.

**5. INTANGIBLE ASSETS**

During the period ended August 31, 2020, the Company invested \$960,725 in intellectual property as described in note 9 as follows:

	<u>Intellectual Property</u>
<b>Costs</b>	
Balance, September 24, 2019 (date of incorporation)	\$ -
<b>Additions</b>	<b>960,725</b>
<b>Balance, August 31, 2020</b>	<b>\$ 960,725</b>

**6. TRADE AND OTHER PAYABLES**

	<u>August 31, 2020</u>
Trade payables	\$147,081
Due to related parties - Note 8	41,113
<b>Total</b>	<b>\$188,194</b>

**7. SHARE CAPITAL**

**Authorized share capital**

The Company's authorized share capital consists of:

Unlimited common shares without par value.

Unlimited preferred shares without par value.

As at August 31, 2020, the Company had 38,391,722 common shares issued and outstanding and no preferred shares issued and outstanding.

**TRYP THERAPEUTICS INC.**  
**NOTES TO FINANCIAL STATEMENTS**  
For the period from September 24, 2019 to August 31, 2020  
(Expressed in Canadian Dollars)

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## **7. SHARE CAPITAL (cont'd)**

### **Issued and outstanding**

On September 24, 2019, the Company issued an incorporation share at \$1 per share.

On September 24, 2019, the Company repurchased and cancelled the incorporation share and issued 48,000 founder's shares at \$0.000001 per share for total proceeds of \$1.

On January 3, 2020, the Company issued 32,000 common shares at \$0.005 per common share with a value of \$160 for intellectual property purchased (note 9).

On June 30, 2020, the Company issued 3,792,800 common shares at \$0.05 per common share with a fair value of \$189,640 for past services to consultants, and an officer (note 9).

On June 30, 2020 the Company issued 19,127,200 common shares at \$0.05 per common share with a fair value of \$956,360 for Intellectual Property purchased as described in notes 5 and 9.

On August 4, 2020 the Company completed a non-brokered private placement of 11,399,650 common shares at a price of \$0.05 per common share for gross proceeds of \$569,982.

On August 4, 2020 the Company issued 500,000 common shares at \$0.05 per common share with a fair value of \$25,000 as shares for debt for marketing and corporate development services.

On August 14, 2020 the Company issued 166,667 common shares at \$0.15 per common share with a value of \$25,000 as shares for debt for marketing and corporate development services.

In August 2020, the Company completed a non-brokered private placement in two tranches for an aggregate of 3,325,405 common shares at a price of \$0.15 per common share as follows:

- i) August 14, 2020 – 2,825,405 for gross proceeds of \$423,811; and
- ii) August 31, 2020 – 500,000 common shares for gross proceeds of \$75,000.

### **Stock options**

On January 9, 2020, the Company implemented an Incentive Stock Option Plan (the "Stock Option Plan"). Pursuant to the Stock Option Plan, the Company will grant stock options to directors, officers, employees and consultants for services, provided that the number of common shares reserved for issuance shall not exceed 10% of the issued and outstanding common shares exercisable for a period of up to 10 years. The exercise price and vesting terms of the options granted under the Stock Option Plan will be determined by the Board of Directors. The Company did not grant any stock options during the period ended August 31, 2020.



**TRYP THERAPEUTICS INC.**  
**NOTES TO FINANCIAL STATEMENTS**  
For the period from September 24, 2019 to August 31, 2020  
(Expressed in Canadian Dollars)

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## 8. KEY MANAGEMENT AND PERSONNEL COMPENSATION

Key management personnel include those persons having authority and responsibility for planning, directing, and controlling the activities of the Company as a whole. The Company has determined that key management personnel consist of executive and non-executive members of the Company's Board of Directors and corporate officers. Key management personnel compensation for the period from September 24, 2019 (date of incorporation) to August 31, 2020, including Company officers, directors, and private companies controlled by officers and directors, was as follows:

	Period from September 24, 2019 (incorporation) to August 31, 2020
Key management personnel compensation comprised:	
Consulting fees <sup>1</sup> :	<b>\$42,500</b>

<sup>1</sup> Included in compensation was the issuance of 500,000 common shares with a fair value of \$25,000 issued for services (notes 7 and 9).

As at August 31, 2020, included in trade and other payables are amounts due to officers and directors for fees and expenses of \$41,113.

Amounts due to related parties included in trade and other payables are unsecured, non-interest bearing and are without fixed terms of repayment.

## 9. RELATED PARTY TRANSACTIONS

### Intellectual property purchase

On January 9, 2020, the Company and a director entered into a purchase and assignment agreement (the "IP Purchase Agreement") pursuant to which the Company acquired certain inventions, technical information and patent application (the "Purchase Assets"). Pursuant to the terms of the IP Purchase Agreement, the Company issued 32,000 common shares at a price of \$0.005 per common share for a value of \$160 for the Purchased Assets.

On June 23, 2020 the Company entered into purchase agreements (collectively the "Additional IP Purchase Agreements") with the directors of the Company pursuant to which to which the Company acquired certain inventions, technical information and patent application (the "Additional Purchase Assets"). Pursuant to the terms of the Additional IP Purchase Agreements the Company issued and aggregate of 19,127,200 common shares at a price of \$0.05 per common share for an aggregate value of \$956,360 for the Additional Purchased Assets.

The Purchased Assets and Additional Purchased Assets (collectively the "Intellectual Property") with an aggregate value of \$960,725 (including \$4,205 in patent application and filing fees) was recorded as intangible assets (note 5).

### Shares issued for services

On June 23, 2020 the Company issued 500,000 common shares at a price of \$0.05 per share for a value of \$25,000 to an officer of the Company for compensation for services and is included in the amounts recorded as consulting fees (note 8).

**TRYP THERAPEUTICS INC.**  
**NOTES TO FINANCIAL STATEMENTS**  
For the period from September 24, 2019 to August 31, 2020  
(Expressed in Canadian Dollars)

**9. RELATED PARTY TRANSACTIONS (cont'd)**

**Shareholder loans**

As at August 31, 2020 cash advances to the Company in the amount of \$4,514 was due and payable to a director and shareholder of the Company. This amount is due on demand, unsecured, and without interest. Subsequent to August 31, 2020 the amount was repaid in full.

**10. SUPPLEMENTAL CASH FLOW INFORMATION**

	Note	August 31 2020
Non-cash investing and financing activities	(i)	\$189,640
	(ii)	956,520
	(iii)	28,700
	(iv)	12,829

(i) As outlined in note 7, the Company issued a total of 3,792,800 common shares of the Company with a fair value of \$189,640 in connection with compensation for consulting services with various consultants, and officers, which was expensed to consulting fees:

(ii) As outlined in note 5, the Company issued an aggregate 19,159,200 common shares of the Company with a fair value of \$956,520 as consideration for the purchase of Intellectual Property, which was capitalized as intangible assets; and

(iii) As outlined in note 7, the Company issued a total of 666,667 common shares of the Company with a fair value of \$50,000 for marketing and development fees. At August 31, 2020, \$28,700 of this amount remains in prepaids while \$21,300 was included in marketing and corporate development expenses during the period ended August 31, 2020.

(iv) Deferred financing costs included in trade and other payables.

**11. INCOME TAXES**

A reconciliation of the income taxes at statutory rates to reported taxes is as follows:

		Period from September 24, 2019 (incorporation) to August 31, 2020
Net loss	\$	422,617
Statutory tax rate		27%
Expected income tax recovery at the statutory tax rate	\$	114,107
Non-deductible items and other		(56,975)
Change in unrecognized deductible temporary differences		(57,132)
Income tax recovery	\$	-

**TRYP THERAPEUTICS INC.**  
**NOTES TO FINANCIAL STATEMENTS**  
For the period from September 24, 2019 to August 31, 2020  
(Expressed in Canadian Dollars)

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## 11. INCOME TAXES (cont'd)

The Company has the following deductible temporary differences for which no deferred tax asset has been recognized:

		Period from September 24, 2019 (incorporation) to August 31, 2020
Non-capital loss carry forwards	\$	57,132
Income tax recovery	\$	-

The Company has non-capital losses of approximately \$211,601 that will commence expiring in the year 2040.

## 12. FINANCIAL INSTRUMENTS

The Company is exposed to risks that arise from its use of financial instruments. This note describes the Company's objectives, policies and processes for managing those risks and the methods used to measure them. Further quantitative information in respect of these risks is presented throughout these financial statements. The type of risk exposure and the way in which such exposure is managed is provided as follows:

### Credit risk

Credit risk is the risk that one party to a financial instrument will fail to discharge an obligation and cause the other party to incur a financial loss. The Company's primary exposure to credit risk is on its cash held in bank accounts. The majority of cash is deposited in bank accounts held with a major bank in Canada. As most of the Company's cash is held by one bank there is a concentration of credit risk. This risk is managed by using major banks that are high credit quality financial institutions as determined by rating agencies. Credit risk related to cash is assessed as low.

### Liquidity risk

Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they fall due. The Company has a planning and budgeting process in place to help determine the funds required to support the Company's normal operating requirements on an ongoing basis. The Company ensures that there are sufficient funds to meet its short-term business requirements, taking into account its anticipated cash flows from operations and its holdings of cash. As of August 31, 2020, the Company had working capital of \$855,092 to cover short term obligations.

Since incorporation, Company's sole source of funding has been loans from related parties and private placements. The Company's access to financing is always uncertain. There can be no assurance of continued access to significant equity funding. Liquidity risk is assessed as moderate.

### Market risk

Market risk is the risk that the fair value of future cash flows of a financial instrument will fluctuate due to changes in market prices. Market risk comprises three types of risk: foreign currency risk, interest rate risk and other price risk. The Company is not exposed to significant market risk.

**TRYP THERAPEUTICS INC.**  
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## **12. FINANCIAL INSTRUMENTS (cont'd)**

### Fair value

Financial instruments that are measured subsequent to initial recognition at fair value are grouped in Levels 1 to 3 based on the degree to which the fair value is observable:

- Level 1 – Unadjusted quoted prices in active markets for identical assets or liabilities;
- Level 2 – Inputs other than quoted prices that are observable for the asset or liability either directly or indirectly; and
- Level 3 – Inputs that are not based on observable market data.

As at August 31, 2020 cash and trade and other payables are measured as Level 1 financial instruments.

## **13. CAPITAL MANAGEMENT**

The Company considers its share capital as capital. The Company's objectives when maintaining capital are to maintain a sufficient capital base in order to meet its short-term obligations and at the same time preserve investor's confidence required to sustain future development and production of the business.

The Company is not exposed to any externally imposed capital requirements. There were no changes in the Company's approach to capital management during the period.

## **14. SEGMENTED INFORMATION**

The Company operates in one business segment being the clinical stage pharmaceutical research and development company. All assets of the Company are located in Canada.

## **15. EVENTS AFTER THE REPORTING DATE**

### **Shares for Debt**

On September 21, 2020, the Company issued 900,000 common shares in exchange for marketing and development consulting fees with a fair value of \$135,000.

### **Stock Options**

On September 29, 2020 the Company granted 1,600,000 stock options at an exercise price of \$0.15 for a period of 5 years to consultants of the Company. The options vest monthly over a period of 36 months.

### **Initial Public Offering**

On December 8, 2020, the Company submitted a prospectus (the "Prospectus") for an initial public offering on a best efforts for 17,400,000 units (the "Units") at a price of \$0.25 per Unit (the "Offering Price") for gross proceeds of \$4,350,000 (the "Offering") and pursuant to the terms of an agency agreement (the "Agency Agreement") dated December 8, 2020, between Canaccord Genuity Corp. (the "Agent") and the Company. Each Unit consists of one common share of the Company and one-half of one common share purchase warrant of the Company with an exercise price of \$0.50 for a period of 12 months following the Closing Date.

Pursuant to the terms and conditions of the Agency Agreement, the Company has agreed to pay the Agent a cash fee (the "Agent's Fee") equal to 8% of the gross proceeds of the Offering plus a corporate finance fee of 5% of the of the aggregate number of Units issued pursuant to the Offering (the "Corporate Finance Fee").

The Agents will receive warrants (the "Agents' Warrants") exercisable at any time prior to the date that is 12 months from the date of listing on the Canadian Securities Exchange to acquire that number of Units which is equal to 8.0% of the number of Units issued pursuant to the Offering, at an exercise price equal to the Issue Price.

The Company shall provide a president's list of investors (the "President's List") that may subscribe for up to \$1,000,000 of the Offering. The compensation to the Agents on these subscriptions will be reduced to 4.0% Agent Fee and 4.0% Agents' Warrants.

As at August 31, 2020, included in deferred financing costs is an amount of \$26,520 for professional fees incurred in relation to the Prospectus.

**SCHEDULE “B”  
AUDIT COMMITTEE CHARTER**

**TRYP THERAPEUTICS INC.  
(the “Company”)**

**PURPOSE**

Tryp Therapeutics Inc. (the “**Company**”) shall appoint an audit committee (the “**Committee**”) to assist the board of directors (the “**Board**”) of the Company in fulfilling its responsibilities of oversight and supervision of the accounting and financial reporting practices and procedures on behalf of the Company and its direct and indirect subsidiaries, the adequacy of internal accounting controls and procedures, and the quality and integrity of the financial statements of the Company. In addition, the Committee is responsible for overseeing the audits of the financial statements of the Company, for directing the auditors’ examination of specific areas, for the selection of the independent external auditors of the Company and for the approval of all non-audit services for which the auditors of the Company may be engaged.

**I. STRUCTURE AND OPERATIONS**

The Committee shall be comprised of at least three members, each of whom shall be a director of the Company, and at least a majority of which shall meet the independence requirements of National Instrument 52-110 – *Audit Committees* (“**NI 52-110**”).

Each member of the Committee shall satisfy, or work towards satisfying, the “financial literacy” requirement of NI 52-110, by having the ability to read and understand a set of financial statements that present a breadth and level of complexity of accounting issues that can reasonably be expected to be raised by the financial statements of the Company.

The members of the Committee shall be annually appointed by the Board and shall serve until such member’s successor is duly elected and qualified or until such member’s earlier resignation or removal. The members of the Committee may be removed, with or without cause, by a majority of the Board.

**II. CHAIR OF THE COMMITTEE**

Unless the Board elects a Chair of the Committee, the members of the Committee shall designate a Chair by the majority vote of the full Committee membership.

The Chair of the Committee shall:

- (a) call and conduct the meetings of the Committee;
- (b) be entitled to vote to resolve any ties;
- (c) prepare and forward to members of the Committee the agenda for each meeting of the Committee, and include, in the agenda, any items proposed for inclusion in the agenda by any member of the Committee;
- (d) review with the Chief Financial Officer (“**CFO**”) and the auditors for the Company any matters referred to the Chair by the CFO or the auditors of the Company;

- (e) appoint a secretary, who need not be a member of the Committee, to take minutes of the meetings of the Committee; and
- (f) act in a manner that the Committee meetings are conducted in an efficient, effective and focused manner.

### **III. MEETINGS**

The Committee shall meet at least quarterly or more frequently as circumstances dictate. As part of its goal to foster open communication, the Committee shall periodically meet with management and the external auditors in separate sessions to discuss any matters that the Committee or each of these groups believes should be discussed privately. The Committee may meet privately with outside counsel of its choosing and the CFO of the Company, as necessary. In addition, the Committee shall meet with the external auditors and management quarterly to review the Company's financial statements in a manner consistent with that outlined in this Charter.

The Committee may invite to its meetings any partners of the Company, management and such other persons as it deems appropriate in order to carry out its responsibilities. The Committee may exclude from its meetings any persons it deems appropriate in order to carry out its responsibilities.

A majority of the Committee members, but not less than two, shall constitute a quorum. A majority of members present at any meeting at which a quorum is present may act on behalf of the Committee. The Committee may meet by telephone or videoconference and may take action by unanimous written consent with respect to matters that may be acted upon without a formal meeting.

The Committee shall maintain minutes or other records of meetings and activities of the Committee.

Notice of the time and place of every meeting shall be given in writing or electronic communication to each member of the Committee at least 24 hours prior to the time fixed for such meeting provided however, that a member may in any manner waive a notice of a meeting. Attendance of a member at a meeting is a waiver of notice of the meeting, except where a member attends a meeting for the express purpose of objecting to the transaction of any business on the grounds that the meeting is not lawfully called.

### **IV. RESPONSIBILITIES, DUTIES AND AUTHORITY**

The following functions shall be the common recurring activities of the Committee in carrying out its responsibilities outlined in this Charter. These functions should serve as a guide with the understanding that the Committee may carry out additional functions and adopt additional policies and procedures as may be appropriate in light of changing business, legislative, regulatory, legal and other conditions. The Committee shall also carry out any other responsibilities and duties delegated to it by the Board from time to time related to the purposes of this Committee.

The Committee in discharging its oversight role is empowered to investigate any matter of interest or concern that the Committee deems appropriate. In this regard, the Committee shall have the authority to retain outside counsel, accounting or other advisors for this purpose, including authority to approve the fees payable to such advisors and other terms of retention. In addition, the Committee shall have the authority to communicate directly with both external and internal auditors of the Company.

The Committee shall be given full access to the Board, management, employees and others, directly and indirectly responsible for financial reporting, and external auditors, as necessary, to carry out these responsibilities. While acting within the scope of this stated purpose, the Committee shall have all the authority of the Board.

The Committee shall be responsible for assessing the range of financial and other risks to the business and affairs of the Company that the Board shall focus on, and make recommendations to the Board about how appropriate responsibilities for continuing to identify, monitor and manage these risks are to be delegated. The Committee shall review and discuss with management and the internal and external auditors all major financial risk exposures and the steps management has taken to monitor/control those exposures. In addition, the Committee shall encourage continuous improvement of, and foster adherence to, the Company's financial policies, procedures and practices at all levels in the organization; and provide an avenue of communication among the external auditors, management and the Board.

Absent actual knowledge to the contrary (which shall promptly reported to the Board), each member of the Committee shall be entitled to rely on: (i) the integrity of those persons or organizations within and outside the Company from which it receives information; (ii) the accuracy of the financial and other information provided to the Committee by such persons or organizations; and (iii) representations made by management and the external auditors, as to any information technology, internal audit and other non-audit services provided by the external auditors to the Company and its subsidiaries.

## **V. SPECIFIC RESPONSIBILITIES AND ACTIVITIES**

### **A. Document Reports/Reviews**

1. *Annual Financial Statements.* The Committee shall review with management and the external auditors, both together and separately, prior to public dissemination:
  - (a) the annual audited financial statements;
  - (b) the external auditors' review of the annual financial statements and their report;
  - (c) any significant changes that were required in the external audit plan;
  - (d) any significant issues raised with management during the course of the audit, including any restrictions on the scope of activities or access to information; and
  - (e) those matters related to the conduct of the audit that are required to be discussed under generally accepted auditing standards applicable to the Company.

Following completion of the matters contemplated above and in Section 15, the Committee shall make a recommendation to the Board with respect to the approval of the annual financial statements with such changes contemplated and further recommended, as the Committee considers necessary.

2. *Interim Financial Statements.* The Committee shall review with management and may review with the external auditors, both together and separately, prior to public dissemination, the interim unaudited financial statements of the Company, including to the extent the Committee considers appropriate, a discussion with the external auditors of those matters required to be discussed under generally accepted auditing standards applicable to the Company.



3. *Management's Discussion and Analysis.* The Committee shall review with management and the external auditors, both together and separately prior to public dissemination, the annual Management's Discussion and Analysis of Financial Condition and Results of Operations ("**MD&A**") and the Committee shall review with management and may review with the external auditors, interim MD&A.
4. *Approval of Annual MD&A, Interim Financial Statements and Interim MD&A.* The Committee shall make a recommendation to the Board with respect to the approval of the annual MD&A with such changes contemplated and further recommended by the Committee as the Committee considers necessary. In addition, the Committee shall approve the interim financial statements and interim MD&A of the Company, if the Board has delegated such function to the Committee. If the Committee has not been delegated this function, the Committee shall make a recommendation to the Board with respect to the approval of the interim financial statements and interim MD&A with such changes contemplated and further recommended as the Committee considers necessary.
5. *Press Releases.* With respect to press releases by the Company:
  - (a) The Committee shall review the Company's financial statements, MD&A and annual and interim earnings press releases before the Company publicly discloses this information.
  - (b) The Committee shall review with management, prior to public dissemination, the annual and interim earnings press releases (paying particular attention to the use of any "pro forma" or "adjusted non-IFRS" information) as well as any financial information and earnings guidance provided to analysts and rating agencies.
  - (c) The Committee shall be satisfied that adequate procedures are in place for the review of the Company's public disclosure of financial information extracted or derived from the Company's financial statements, other than public disclosure referred to in Section V.A.4 of this Charter, and periodically assess the adequacy of those procedures.
6. *Reports and Regulatory Returns.* The Committee shall review and discuss with management, and the external auditors to the extent the Committee deems appropriate, such reports and regulatory returns of the Company as may be specified by law.
7. *Other Financial Information.* The Committee shall review the financial information included in any prospectus, annual information form or information circular with management and, at the discretion of the Committee, the external auditors, both together and separately, prior to public dissemination, and shall make a recommendation to the Board with respect to the approval of such prospectus, annual information form or information circular with such changes contemplated and further recommended as the Committee considers necessary.
- B. *Financial Reporting Processes*
8. *Establishment and Assessment of Procedures.* The Committee shall satisfy itself that adequate procedures are in place for the review of the public disclosure of financial information extracted or derived from the financial statements of the Company and assess the adequacy of these procedures annually.

9. *Application of Accounting Principles.* The Committee shall assure itself that the external auditors are satisfied that the accounting estimates and judgements made by management, and their selection of accounting principles reflect an appropriate application of such accounting principles.
  10. *Practices and Policies.* The Committee shall review with management and the external auditors, together and separately, the principal accounting practices and policies of the Company.
- C. External Auditors
11. *Oversight and Responsibility.* In respect of the external auditors of the Company:
    - (a) The Committee, in its capacity as a committee of the Board, shall be directly responsible for, or if required by Canadian law shall make recommendations to the Board with respect to, the appointment, compensation, retention and oversight of the work of the external auditors engaged for the purpose of preparing or issuing an auditor's report or performing other audit, review or attest services for the Company, including the resolution of disagreements between management and the external auditors regarding financial reporting.
    - (b) The Committee is directly responsible for overseeing the work of the external auditors engaged for the purpose of preparing or issuing an auditor's report or performing other audit, review or attest services for the Company, including the resolution of disagreements between management and the external auditors regarding financial reporting.
  12. *Reporting.* The external auditors shall report directly to the Committee and are ultimately accountable to the Committee.
  13. *Annual Audit Plan.* The Committee shall review with the external auditors and management, together and separately, the overall scope of the annual audit plan and the resources the external auditors will devote to the audit. The Committee shall annually review and approve the fees to be paid to the external auditors with respect to the annual audit.
  14. *Non-Audit Services.*
    - (a) "Non-audit services" means all services performed by the external auditors other than audit services. The Committee shall pre-approve all non-audit services to be provided to the Company or its subsidiaries by the Company's external auditor and permit all non-audit services, other than non-audit services where:
      - (i) the aggregate amount of all such non-audit services that were not pre-approved is reasonably expected to constitute no more than five per cent of the total amount of fees paid by the Company and its subsidiaries to the Company's external auditor during the fiscal year in which the services are provided;
      - (ii) the Company or its subsidiary, as the case may be, did not recognize the services as non-audit services at the time of the engagement; and
      - (iii) the services are promptly brought to the attention of the Committee and approved, prior to the completion of the audit, by the Committee or by one or more of its members to whom authority to grant such approvals had been delegated by the Committee.

- (b) The Committee may delegate to one or more members of the Committee the authority to grant such pre-approvals for non-audited services. The decisions of such member(s) regarding approval of “non-audit” services shall be reported by such member(s) to the full Committee at its first scheduled meeting following such pre-approval.
- (c) The Committee shall adopt specific policies and procedures for the engagement of the non-audit services if:
  - (i) the pre-approval policies and procedures are detailed as to the particular services;
  - (ii) the Committee is informed of each non-audit service; and
  - (iii) the procedures do not include delegation of the Committee’s responsibilities to management.

15. *Independence Review.* The Committee shall review and assess the qualifications, performance and independence of the external auditors, including the requirements relating to such independence of the law governing the Company. At least annually, the Committee shall receive from the external auditors, a formal written statement delineating all relationships between the Company the external auditors, actively engage in a dialogue with the external auditors with respect to any disclosed relationships or services that may impact the objectivity and independence of the auditor, and, if necessary, recommend that the Board takes appropriate action to satisfy themselves of the external auditors’ independence and accountability to the Committee. In evaluating the performance of the external auditors, the Audit Committee shall evaluate the performance of the external auditors’ lead partner and shall ensure the rotation of lead partners as required by law.

D. Internal Controls.

Management shall be required to provide the Committee, at least annually, a report on internal controls, including reasonable assurance that such controls are adequate to facilitate reliable and timely financial information. The Committee shall also review and follow-up on any areas of internal control weakness identified by the external auditors with the auditors and management.

E. Reports to Board

16. *Reports.* In addition to such specific reports contemplated elsewhere in this Charter, the Committee shall report regularly to the Board regarding such matters, including:

- (a) with respect to any issues that arise with respect to the quality or integrity of the financial statements of the Company, compliance with legal or regulatory requirements by the Company, or the performance and independence of the external auditors of the Company;
- (b) following meetings of the Committee; and
- (c) with respect to such other matters as are relevant to the Committee’s discharge of its responsibilities.

17. *Recommendations.* In addition to such specific recommendations contemplated elsewhere in this Charter, the Committee shall provide such recommendations as the Committee may deem appropriate.

The report to the Board may take the form of an oral report by the Chair or any other member of the Committee designated by the Committee to make such report.

F. Whistle Blowing

18. *Procedures.* The Committee shall establish procedures for:

- (a) the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls, or auditing matters; and
- (b) the confidential, anonymous submission by employees of the Company of concerns regarding questionable accounting or auditing matters.

19. *Notice to Employees.*

- (a) To comply with the above, the Committee shall ensure each of the Company and its subsidiaries advises all employees, by way of a written code of business conduct and ethics (the “**Code**”), or if such Code has not yet been adopted by the respective board, by way of a written or electronic notice, that any employee who reasonably believes that questionable accounting, internal accounting controls, or auditing matters have been employed by the Company or their external auditors is strongly encouraged to report such concerns by way of communication directly to the Chair. Matters referred may be done so anonymously and in confidence.
- (b) None of the Company or its subsidiaries shall take or allow any reprisal against any employee for, in good faith, reporting questionable accounting, internal accounting, or auditing matters. Any such reprisal shall itself be considered a very serious breach of this policy.
- (c) All reported violations shall be investigated by the Committee following rules of procedure and process as shall be recommended by outside counsel.

G. General

20. *Access to Advisers and Funding.* The Committee shall have the authority to engage independent counsel and other advisers, as it determines necessary to carry out its duties. The Company shall provide appropriate funding, as determined by the Committee, for payment of (a) compensation to any external auditors engaged for the purpose of preparing or issuing an audit report or performing other audit, review or attest services for the Company; (b) compensation to any advisers employed by the Committee; and (c) ordinary administrative expenses of the Committee that are necessary or appropriate in carrying out its duties.

21. *Hiring of Partners and Employees of External Auditors.* The Committee shall annually review and approve the Company’s hiring policies regarding partners, employees and former partners and employees of the present and former external auditors of the Company.

22. *Forward Agenda.* The Committee may annually develop a calendar of activities or forward agenda to be undertaken by the Committee for each ensuing year and to submit the calendar/agenda in the appropriate format to the Board of Directors following each annual general meeting of shareholders.

23. *Annual Performance Evaluation.* The Committee shall perform a review and evaluation, annually, of the performance of the Committee and its members, including a review of the compliance of the Committee with this Charter. In addition, the Committee shall evaluate, annually, the adequacy of this Charter and recommend any proposed changes to the Board.
24. *Related Party Transactions.* The Committee shall annually review transactions involving directors and officers, including a review of travel expenses and entertainment expenses, related party transactions and any conflicts of interests.

***General. The Committee shall perform such other duties and exercise such powers as may, from time to time, be assigned or vested in the Committee by the Board, and such other functions as may be required of an audit committee by law, regulations or applicable stock exchange rules.***

**CERTIFICATE OF THE CORPORATION**

Dated: December 8, 2020

This prospectus constitutes full, true and plain disclosure of all material facts relating to the securities offered by this prospectus as required by the securities legislation of the Provinces of Alberta, British Columbia and Ontario.

*"James Kuo" (signed)*

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James Kuo  
Chief Executive Officer

*"Terese Gieselman" (signed)*

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Terese Gieselman  
Chief Financial Officer

**ON BEHALF OF THE BOARD**

*"William Garner" (signed)*

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William Garner  
Director

*"Gage Jull" (signed)*

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Gage Jull  
Director

**CERTIFICATE OF THE PROMOTERS**

Dated: December 8, 2020

This prospectus constitutes full, true and plain disclosure of all material facts relating to the securities offered by this prospectus as required by the securities legislation of the Provinces of Alberta, British Columbia and Ontario.

*"William Garner" (signed)*

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William Garner

*"James Kuo" (signed)*

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James Kuo

**CERTIFICATE OF THE AGENT**

Dated: December 8, 2020

To the best of our knowledge, information and belief, this prospectus constitutes full, true and plain disclosure of all material facts relating to the securities offered by this prospectus as required by the securities legislation of the Provinces of Alberta, British Columbia and Ontario.

**CANACCORD GENUITY CORP.**

By: "Graham Saunders" (*signed*)

Graham Saunders  
Vice Chairman, Managing Director  
Head of Capital Markets Origination



**Appendix B:  
Capitalization**

14.1 Prepare and file the following chart for each class of securities to be listed

**Issued Capital**

	<b>Number of Securities (non-diluted)</b>	<b>Number of Securities (fully- diluted)</b>	<b>% of Issued (non- diluted)</b>	<b>% of Issued (fully diluted)</b>
<u>Public Float</u>				
Total outstanding (A)	60,302,222	79,841,956	100.00%	100.00%
Held by Related Persons or employees of the Company or Related Person of the Company, or by persons or companies who beneficially own or control, directly or indirectly, more than a 5% voting position in the Company (or who would beneficially own or control, directly or indirectly, more than a 5% voting position in the Company upon exercise or conversion of other securities held) (B)	20,292,400	23,062,084	33.65%	28.88%
Total Public Float (A-B)	40,009,822	56,779,872	66.35%	71.12%
<u>Freely-Tradeable Float</u>				
Number of outstanding securities subject to resale restrictions, including restrictions imposed by pooling or other arrangements or in a shareholder agreement and securities held by control block holders (C)	36,391,722	40,661,406	60.35%	50.93%
Total Tradeable Float (A-C)	23,910,500	39,180,550	39.65%	49.07%

Public Securityholders (Registered)

**Instruction:** For the purposes of this report, "public securityholders" are persons other than persons enumerated in section (B) of the previous chart. List registered holders only.

**Class of Security**

<u>Size of Holding</u>	<u>Number of holders</u>	<u>Total number of securities</u>
1 – 99 securities	_____	_____
100 – 499 securities	_____	_____
500 – 999 securities	_____	_____
1,000 – 1,999 securities	_____	_____
2,000 – 2,999 securities	_____	_____
3,000 – 3,999 securities	_____	_____
4,000 – 4,999 securities	_____	_____
5,000 or more securities	32	40,009,822
	=====	=====

Public Securityholders (Beneficial)

**Instruction:** Include (i) beneficial holders holding securities in their own name as registered shareholders; and (ii) beneficial holders holding securities through an intermediary where the Issuer has been given written confirmation of shareholdings. For the purposes of this section, it is sufficient if the intermediary provides a breakdown by number of beneficial holders for each line item below; names and holdings of specific beneficial holders do not have to be disclosed. If an intermediary or intermediaries will not provide details of beneficial holders, give the aggregate position of all such intermediaries in the last line.

**Class of Security**

<u>Size of Holding</u>	<u>Number of holders</u>	<u>Total number of securities</u>
1 – 99 securities	_____	_____
100 – 499 securities	_____	_____
500 – 999 securities	_____	_____
1,000 – 1,999 securities	_____	_____
2,000 – 2,999 securities	_____	_____
3,000 – 3,999 securities	_____	_____
4,000 – 4,999 securities	<u>1</u>	<u>4,000</u>
5,000 or more securities	<u>199</u>	<u>20,006,000</u>
Unable to confirm	_____	_____

## Non-Public Securityholders (Registered)

**Instruction:** For the purposes of this report, "non-public securityholders" are persons enumerated in section (B) of the issued capital chart.

### **Class of Security**

<u>Size of Holding</u>	<u>Number of holders</u>	<u>Total number of securities</u>
1 – 99 securities	_____	_____
100 – 499 securities	_____	_____
500 – 999 securities	_____	_____
1,000 – 1,999 securities	_____	_____
2,000 – 2,999 securities	_____	_____
3,000 – 3,999 securities	_____	_____
4,000 – 4,999 securities	_____	_____
5,000 or more securities	5	20,292,400
	=====	=====

14.2 Provide the following details for any securities convertible or exchangeable into any class of listed securities

<b>Description of Security (include conversion / exercise terms, including conversion / exercise price)</b>	<b>Number of convertible / exchangeable securities outstanding</b>	<b>Number of listed securities issuable upon conversion / exercise</b>
Warrants exercisable at a price of \$0.50 until December 17, 2021	10,005,000	10,005,000 shares
Agent's Compensation Options exercisable at a price of \$0.25 for 12 months from the Listing Date	1,443,200	1,443,200 shares  721,600 warrants (721,600 warrant shares)
Agent's Corporate Finance Fee Unit Warrants exercisable at a price of \$0.50 expiring on Closing	500,250	500,250
Share purchase options exercisable at a price of \$0.15 for a period ending September 29, 2025	1,600,000	1,600,000

Share purchase options exercisable at a price of \$0.15 for a period ending November 2, 2030	3,769,684	3,769,684
Share purchase options exercisable at a price of \$0.15 for a period ending November 2, 2025	1,500,000	1,500,000

14.3 The Company does not have any listed securities reserved for issuance that are not included in Section 14.2 above

## CERTIFICATE OF THE COMPANY

Pursuant to a resolution duly passed by its Board of Directors, Tryp Therapeutics Inc., hereby applies for the listing of the above mentioned securities on the Exchange. The foregoing contains full, true, and plain disclosure of all material information relating to Tryp Therapeutics Inc. It contains not untrue statement of material fact and does not omit to state a material fact that is required to be stated or that is necessary to prevent a statement that is made from being false or misleading in light of the circumstances in which it was made.

Dated at: Kelowna, British Columbia this the 17 day of December, 2020.

*"James Kuo" (signed)*

\_\_\_\_\_  
James Kuo  
Chief Executive Officer and Director

*"William Garner" (signed)*

\_\_\_\_\_  
William Garner  
Executive Chairman and Director

*"Philip Jull" (signed)*

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Philip Jull  
Director

*"Peter Molloy" (signed)*

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Peter Molloy  
Director