NUGEN MEDICAL DEVICES INC.

Annual Information Form

For the year ended December 31, 2022

Dated as of October 11, 2023

nuGen MEDICAL DEVICES

TABLE OF CONTENTS

PRELIMINARY NOTES

This annual information form ("**AIF**") of NuGen Medical Devices Inc. (the "**Company**" or "**NuGen**") is prepared in the form prescribed by National Instrument 51-102 – *Continuous Disclosure Obligations* of the Canadian Securities Administrators. All dollar amounts in this AIF are expressed in Canadian dollars unless otherwise indicated. All information in this AIF is as of December 31, 2022, unless otherwise indicated.

FORWARD-LOOKING INFORMATION

Certain statements contained in this AIF, particularly in the sections below entitled "*Description of The Business*" and "*Risk Factors*", contain "forward-looking information" within the meaning of applicable securities laws. 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 strategy, budgets, operations, financial results, taxes, dividend policy, plans, and objectives. In some cases, forward-looking information can be identified by the use of forward-looking terminology such as "plans", "targets", "expects", "does not expect", "is expected", "an opportunity exists", "budget", "scheduled", "estimates", "outlook", "forecasts", "projection", "prospects", "strategy", "intends", "anticipates", "does not anticipate", "believes", or variations of such words and phrases or state that certain actions, events or results "may", "could", "would", "might", "will", "will be taken", "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.

The information contained in this AIF: (a) is provided as at the date hereof, or as otherwise indicated, and is subject to change without notice, (b) does not purport to contain all the information that may be necessary or desirable to fully and accurately evaluate an investment in the Company, and (c) is not to be considered as a recommendation by the Company or any other person on behalf of the Company that any person make an investment in the Company. We disclaim any intention or obligation or undertaking 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.

The forward-looking information contained in this AIF is based on management's opinions, estimates and assumptions in light of its experience and perception of historical trends, current conditions and expected future developments, as well as other factors that we believe to be 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. Certain assumptions are material factors made in preparing the forward-looking information and management's expectations contained in this AIF, including assumptions in respect of the Company's current and future business, products and operations, the general expectations of the Company related thereto, regulatory approvals, and domestic and international markets performance and regulations.

Forward-looking information is subject to known and unknown risks, uncertainties and other factors that may cause the actual results, level of activity, performance or achievements to be materially different from those expressed or implied by such forward-looking information, including but not limited to those referred to under the heading "*Risk Factors*" in this AIF and those identified in our Management's Discussion & Analysis for the year ended December 31, 2022, which is available under our profile on the System for Electronic Document Analysis and Retrieval Plus ("**SEDAR+**") at https://www.sedarplus.ca/.

We caution that the list of risk factors and uncertainties under the heading "*Risk Factors*" is not exhaustive and other factors could also adversely affect our results. Readers are urged to consider the risks, uncertainties and assumptions carefully in evaluating the forward-looking information in this AIF and are cautioned not to place undue reliance on such information.

All of the forward-looking information contained in this AIF is expressly qualified by this cautionary statement.

MARKET AND INDUSTRY DATA

This AIF includes market and industry data obtained from third-party sources, industry publications, scientific journals and publicly available information. NuGen believes that this market and industry data is accurate and that its estimates and assumptions are reasonable, but there can be no assurance as to the accuracy or completeness thereof. The accuracy and completeness of the market and industry data used throughout this AIF are not guaranteed and NuGen does not make any representation as to the accuracy of such information. Although NuGen believes it to be reliable, NuGen has not independently verified any of the data from third-party sources referred to in this AIF, nor analyzed or verified the underlying studies or surveys relied upon or referred to by such sources, or ascertained the underlying economic and other assumptions relied upon by such sources.

TRADEMARKS AND TRADE NAMES

This AIF includes references to certain trademarks, such as "InsuJet" and "PetJet", which are protected under applicable intellectual property laws in Canada and are NuGen's property. Solely for convenience, NuGen's trademarks and trade names may appear in this AIF without the TM symbol, but such references are not intended to indicate, in any way, that NuGen will not assert, to the fullest extent under applicable law, its rights to these trademarks and trade names.

CORPORATE STRUCTURE

Name, Address and Incorporation

The Company was incorporated as BuzBuz Capital Corp. under the laws of the Province of Ontario on February 26, 2018. In connection with the Qualifying Transaction (as defined below under *Three-Year History*), effective October 15, 2021, by articles of amendment, the Company changed its name to NuGen Medical Devices Inc.

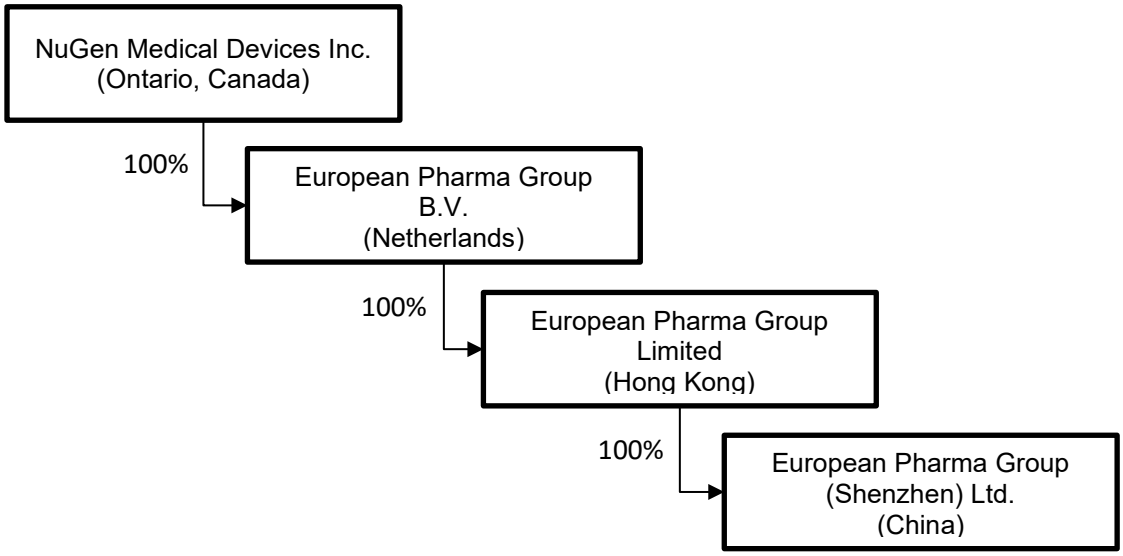
The Company's registered office, corporate head office and principal place of business is located at 1400-18 King Street East, Toronto, Ontario M5C 1C4.

The Company is a reporting issuer in the Provinces of British Columbia, Alberta, Saskatchewan and Ontario.

The common shares of the Company (each, a "**Common Share**") were listed for trading on the TSX Venture Exchange ("**TSXV**") under the symbol "BZBZ.P" as a capital pool company (listed in May 2019). Following the completion of the Qualifying Transaction, the Common Shares were listed for trading on the TSXV under the symbol "NGMD" (listed in November 2021), on the Frankfurt Stock Exchange under the symbol "79O" (listed in March 2022) and on the OTCQB Venture Market in the United States under the symbol "NGMDF" (listed in July 2022). The Company's Common Shares became eligible for book-entry and depositary services on September 9, 2022, through Depositary Trust Company in the United States.

Inter-corporate Relationships

Set out below is the corporate structure of the Company and its subsidiaries, including the jurisdiction of incorporation and the percentage of votes attaching to all voting securities of the subsidiary owned, controlled or directed by the Company.



GENERAL DEVELOPMENT OF THE BUSINESS

NuGen is an emerging specialty medical device company developing the next generation of needle-free technologies and other innovative medical delivery products. The Company's products, which include the InsuJet™ needle-free injection system ("**InsuJet**") and accessories, are designed to improve the lives of millions of people and animals. NuGen continues to receive approval in numerous countries, including Canada. NuGen's products are designed for use in important fields including, but not limited to, diabetes, veterinary medicine, and vaccines.

NuGen's InsuJet needle-free injection device and accessories has received regulatory approvals to be sold and used in over 40 countries and is actively sold in 11 countries through the Company's distributor and wholesale network.

NuGen's mission is reducing the daily burden of diabetes care by providing a needle-free insulin injection device and supplies for each individual's personal needs.

Three-Year History

Qualifying Transaction:

On October 19, 2021, the Company completed a business combination with Inolife R&D Inc. ("**Inolife**") consisting of the indirect acquisition by the Company of all of the issued and outstanding common shares in the capital of Inolife by way of a three-cornered amalgamation pursuant to which a wholly-owned subsidiary of the Company amalgamated with Inolife (the "**Qualifying Transaction**"). The Qualifying Transaction constituted the Company's qualifying transaction under Policy 2.4 – *Capital Pool Companies* of the TSXV. The Qualifying Transaction was carried out in accordance with the terms and conditions of an amalgamation agreement dated October 1, 2020.

In connection with the Qualifying Transaction, Inolife completed the Concurrent Financing (as defined and described below under *Corporate Finance*) on December 30, 2020.

Immediately prior to the completion of the Qualifying Transaction, the Company consolidated its Common Shares on a two for one basis and Inolife consolidated its common shares on a three for one basis. Upon completion of the Qualifying Transaction, each Inolife shareholder received one post-consolidation Common Share for each post-consolidated Inolife common share held. As part of the Qualifying Transaction, common share purchase warrants, stock options and convertible debentures of Inolife were replaced with similar securities of the Company with adjustments to their exercise or conversion terms to reflect the exchange ratio for the Inolife common shares under the Qualifying Transaction.

Following the completion of the Qualifying Transaction, Inolife became a wholly-owned subsidiary of the Company and the directors and management of Inolife became the directors and management of the Company. The Company changed its name to NuGen Medical Devices Inc. and its Common Shares began trading on the TSXV under the symbol "NGMD" on November 8, 2021. An aggregate of 29,576,340 Common Shares were subject to escrow pursuant to TSXV escrow requirements (See *Escrowed Securities*).

For accounting purposes, it has been determined that the Company was the accounting acquiree and Inolife was the accounting acquirer as the former shareholders of Inolife gained control of the Company. The Company continued the business of Inolife as an emerging specialty medical device company focused on developing and commercializing novel drug delivery technologies.

On March 1, 2022, the Company and Inolife completed a vertical amalgamation under the *Business Corporations Act* (Ontario).

Corporate Finance:

Subscription receipts financing (December 30, 2020):

On December 30, 2020, in connection with the Qualifying Transaction, Inolife completed a brokered private placement of 15,000,000 subscription receipts at a price of $0.40 per subscription receipt for aggregate gross proceeds of $6 million (the "**Concurrent Financing**"). Each subscription receipt entitled the holder thereof to receive one unit of Inolife (each, an "**Inolife Unit**") following the satisfaction of the Escrow Release Conditions (as defined below).

Each Inolife Unit was comprised of one common share in the capital of Inolife and one-half of one common share purchase warrant, each whole warrant entitling the holder to acquire one common share in the capital of Inolife at a price of C$0.70 for a period of twelve months following the satisfaction of the Escrow Release Conditions.

On September 30, 2021, the Company announced that it received shareholder and regulatory approvals, including the conditional approval of the TSXV, and satisfied all conditions necessary to complete the Qualifying Transaction (the "**Escrow Release Conditions**"). Upon satisfaction of the Escrow Release Conditions, the subscription receipts of Inolife automatically converted into Inolife Units without the payment of additional consideration or the taking of further action on the part of the subscribers.

All Inolife Units under the Concurrent Financing were exchanged for equivalent securities of the Company in connection with the Qualifying Transaction.

Debt settlement (February 2, 2022):

The Company agreed to settle an aggregate of $500,000 of indebtedness owed to an arm's length creditor with respect to royalty payments due to the creditor through the issuance of an aggregate of 1,644,736 Common Shares at a price of $0.304 per Common Share. All Common Shares issued in connection with the debt settlement were subject to a statutory hold period which expired on June 3, 2022 in accordance with applicable securities legislation.

Private placement of units (July 22, 2022 and September 8, 2022):

The Company closed the first tranche of a non-brokered private placement offering of units on July 22, 2022 through the issuance of 4,118,000 units at a price of $0.10 per unit for gross proceeds of $411,800. A second tranche was closed by the Company on September 8, 2022 through the issuance of 2,285,763 units for gross proceeds of $228,576.30. Each unit was comprised of one Common Share and one Common Share purchase warrant, each warrant entitling the holder to purchase one Common Share for a period of 24 months from closing of the offering at a price of $0.30 per Common Share. Securities issued in connection with this private placement were subject to a statutory hold period which expired four months and one day following closing in accordance with applicable securities legislation.

In connection with the completion of the offering, certain eligible persons were paid an aggregate cash commission of $12,708 equal to 6% of the gross proceeds raised from subscribers introduced to the Company by such eligible persons and issued a total of 127,080 non-transferable broker warrants, each entitling the holder to purchase one Common Share for a period of 24 months from the closing of the offering at a price of $0.30 per Common Share.

Unsecured convertible debentures (September 8, 2022):

The Company completed a non-brokered private placement of 10% unsecured convertible debentures maturing on September 8, 2024 for aggregate gross proceeds of $740,000. The debentures were convertible into Common Shares at the option of the holder at a conversion price equal to $0.25. The debentures were fully repaid by the Company in April 2023.

Warrant amendment (September 30, 2022):

The TSXV approved the Company's application to extend the expiry date and reduce the exercise price of an aggregate of 7,500,000 outstanding common share purchase warrants of the Company. The term of the warrants was extended for an additional 12 months from September 30, 2022 to September 30, 2023, and the exercise price was amended from $0.70 per warrant to $0.40 per warrant. All other provisions of the warrants remained the same.

Private placement of units (December 28, 2022):

The Company closed a non-brokered private placement on December 28, 2022 through the issuance of 2,500,000 units at a price of $0.05 per unit for gross proceeds of $125,000. Each unit was comprised of one Common Share and one Common Share purchase warrant, each warrant entitling the holder to purchase one Common Share for a period of 60 months from closing of the private placement at a price of $0.05 per Common Share.

Securities issued in connection with this private placement were subject to a statutory hold period which expired four months and one day following closing in accordance with applicable securities legislation.

Business Development:

Distribution agreements and partnerships:

To date, NuGen's InsuJet needle-free injection device and accessories has received regulatory approvals to be sold and used in over 40 countries. This has allowed the Company to grow and expand its network of distributors and partners, reaching new markets globally. Below are some notable distribution agreements for InsuJet secured by the Company during the past three years:

Company	Date Announced	Description
Shin-Ya Biotechnology Co., Ltd.	February 1, 2022	Multi-year sales and distribution agreement in Taiwan. The first purchase order for 100 units of InsuJet and consumables was delivered on February 1, 2022 and benefited approximately 100 Taiwanese children diagnosed with juvenile diabetes.
Unifire, Inc.	March 22, 2022	Master distribution and marketing agreement granting Unifire, Inc. exclusive rights to sell InsuJet to various government agencies in the United States, Israel and Australia. Unifire, Inc. further agreed to collaborate with the Company to seek regulatory approval garner political support, introduce non-dilutive government funding, while advising on the necessary manufacturing and supply chain requirements to be eligible to submit to government requests for proposals.
Distributors in Yemen and Iran	March 29, 2022	Distribution agreements in Iran and Yemen with a five-year term. The Company obtained regulatory approval in Iran for InsuJet in February 2022 and received the first purchase order in March 2022. The company has received a second purchase order for Iran in Q3 2023. InsuJet was also approved for use as a medical device in Yemen in November 2022. The company has received it's first purchase order for Yemen with a value of 50,000 CAD, has received payment in full in Q3 2023 and is planning to fulfil the order in Q4 of 2023.

Company	Date Announced	Description
Sol-Millenium Medical Inc. ("Sol-M")	July 5, 2022	Agreement granting Sol-M exclusive rights to promote, sell, and distribute InsuJet in Canada and Brazil. In return, the distributor undertakes to exclusively represent InsuJet in Canada and Brazil. InsuJet was officially launched in Canada in November 2022 at the 2022 Diabetes Canada/Canadian Society of Endocrinology and Metabolism Professional Conference. The distribution agreement with Sol-M on July 25, 2023 to include France, Spain and Portugal, and presently Italy and Switzerland are being negotiated. The first order for Spain was received in Q3 2023. The first large bulk sales in key markets such as Canada are postponed until Q1 2024, as Sol-M will market the needle-free system under their own brand, co-branded with InsuJet.
Science-Link Trading SAPI de CV	October 25, 2022	Master distribution agreement with a term of five years for the distribution of InsuJet in Mexico. The Company estimates that the total value of this agreement in 2023 and 2024 is approximately US$6.2 million with estimated gross margins of 72%.
Trustmed SRL.	June 12, 2023	Agreement to distribute InsuJet over a five-year term in Romania. The first purchase order quantity was 500 starter packs and accessories. The company received payment of $82,000, and the order has been shipped.

Regulatory approvals and operations:

On December 9, 2021, the Company received general use approval from Health Canada for InsuJet and its accessories, introducing InsuJet to the North American market and making it available to consumers in Canada.

On June 1, 2022, the Company launched a new online brand store for InsuJet, making it available to individual purchasers in the European Union.

On June 22, 2022, the Company launched PetJet™, a needle-free injection device specifically designed for domesticated household pets, which allows pet owners and veterinarians to safely and quickly inject various types of medication without the fear of hurting their pets with a traditional hypodermic needle.

On July 21, 2022, InsuJet received approval from Health Canada specifically for the delivery of insulin, bringing more clarity to the intended use of the device and further supporting the Company's marketing initiatives to the diabetic community.

On July 27, 2022, the Company's Common Shares commenced trading on the OTCQB under the symbol "NGMDF", increasing accessibility for American investors interested in participating in the Company's growth.

On October 18, 2022, the Company announced that its wholly-owned subsidiary, European Pharma Group B.V. ("**EPG**") obtained the approval under its ISO 13485 QMS certificate to manufacture InsuJet at its site in the Netherlands in addition to its existing site in China. The additional manufacturing site allows NuGen to better serve markets in Europe, the Middle East and the Americas with lower logistical costs as well as reduced trade barriers and supply chain uncertainty It also positions the Company to utilize a well-established European supply chain for many of its critical components.

Events Subsequent to Year Ended December 31, 2022:

Subsequent to year end, the Company has made efforts to strengthen its leadership team with the incorporation of professionals whose knowledge and experience is allowing the Company to harness the potential of its products through an overhaul of the Company's marketing and sales strategy with the goal of reaching, and positively impacting the lives of, millions of diabetics globally.

Name	Position	Date Announced	Background
Richard Buzbuzian	President, Chief Executive Officer and Director	February 22, 2023	Capital markets executive with over 25 years of experience in Canada and Europe. Mr. Buzbuzian sits on the boards of public, private, and non-profit organizations including Give-A-Mile and the Richard and Jacob Buzbuzian Family Foundation. He holds a degree from the University of Toronto.
Tony Di Benedetto	Executive Chairman and Director	February 28, 2023	Canadian technology entrepreneur with over 30 years of hands-on experience in building, operating, and divesting technology companies. Mr. Di Benedetto has also co-founded technology companies including system integration/managed services businesses, hosting, and a large fixed wireless broadband network company in Ontario, all of which he successfully divested. Mr. Di Benedetto holds a degree from York University.
Philip Cortese	Director	January 26, 2023	Seasoned Banker with over 30 years of experience in the financial institution industry and has held senior managerial positions at RBC, TD Bank and CIBC for over half of those years. He led TD Bank's Real Estate Financing Commercial Mortgage-Backed Securities origination group as Vice President for the Quebec region. He joined a real estate investor and branded the development company now known as Brivia Group. Mr. Cortese is a former Canadian Securities Institute graduate and a licensed Commercial Real Estate Broker.
Chris Irwin	Director	June 23, 2023	Graduate of Bishop's University (B.A., 1990), the University of New Brunswick (Bachelor of Laws, 1994) and Osgoode Hall Law School (Master of Laws, 2009). Mr. Irwin was called to the Bar of Ontario in 1996. He represents, is an officer and/or director, and has served on the audit committee of several public companies.
Veronique Laberge	Chief Financial Officer and Corporate Secretary	March 10, 2023	Chartered professional accountant and holder of the title of auditor. With more than 17 years of experience in professional practice, she is specialized in certification mandates, general accounting and as a consultant for public and private companies.

The Company closed a non-brokered private placement on February 14, 2023 through the issuance of 50,000,000 units at a price of $0.05 per unit for gross proceeds of $2,500,000. Each unit was comprised of one Common Share and one Common Share purchase warrant exercisable at a price of $0.05 per Common Share for a period of 24 months from the date of issuance. Securities issued in connection with this private placement were subject to a statutory hold period which expired four months and one day following closing in accordance with applicable securities legislation. In connection with the closing of the private placement, the Company paid certain eligible persons a cash commission of $103,400 in the aggregate.

On February 28, 2023 and May 29 2023, the Company announced the engagement of bullVestor Medien GmbH ("**bullVestor**") to provide digital marketing services to the Company for a period ending in June 2023 including the creation of content, strategic planning, digital marketing, digital advertisement placement, investor relation and promotional services and building awareness of the Company to a wider European audience and overseeing progress and results of digital campaigns. In consideration for providing the services, the Company has agreed to pay bullVestor $500,000. Consideration offered to bullVestor does not include any securities of the Company.

On March 29, 2023, the Company announced the launch of its e-commerce sales platform for InsuJet targeting the European market, including a subscription-based offering at www.insujet.com, allowing customers to directly purchase InsuJet devices, consumables or subscribe to 1-or 3 year InsuJet plans.

On April 3, 2023, the Company announced the appointment of Louise Cresswell as the Commercial Lead for the United Kingdom. Ms. Cresswell has an extensive background working in the United Kingdom's health sector both as a registered nurse and in commercial, sales and marketing roles with international manufacturers and suppliers of medical technologies. Ms. Cresswell is responsible for growth of NuGen's InsuJet needle free injection device for insulin administration in the United Kingdom, leading commercial activities and accelerating growth to the National Health Services (the "**NHS**") and private hospitals.

On April 10, 2023, the Company announced that it engaged Basic Pharma Technologies, a pharmaceutical company located in the Netherlands, to perform an assessment and feasibility study, which will include validation testing of semaglutide if administered using InsuJet. Semaglutide is the drug known as Ozempic® and it is currently administered by a pen-needle method. Integrity testing of semaglutide being administered via InsuJet will be conducted over a seven-to-eight-month period comprised of three phases.

The Company completed a non-brokered private placement on April 25, 2023 through the issuance of 22,222,222 units at a price of $0.18 per unit for aggregate gross proceeds of $4 million. In order to accommodate investors that were not in a position to close on April 25, 2023, the Company completed an additional non-brokered private placement on May 18, 2023 through the issuance of 2,500,000 units at a price of $0.18 per unit for aggregate gross proceeds of $450,000. Each unit consisted of one Common Share and one Common Share purchase warrant entitling the holder to purchase one Common Share at a price of $0.24 for a period of 24 months from closing. Should the closing price at which the Common Shares trade on the TSXV (or any such other stock exchange in Canada as the Common Shares may trade at the applicable time) exceed $0.28 for 10 consecutive trading days at any time following the date that is four months and one day after the date of issuance, the Company may, at its option, within 10 business days following such 10-day period, accelerate the warrant expiry such that the warrants shall expire on the date which is 30 days following the date a press release is issued by the Company announcing the new warrant expiry date. In connection with the closing of the offerings, the Company paid certain eligible persons a cash commission of $266,662.94 in the aggregate and issued an aggregate of 1,497,992 broker warrants, each entitling the holder to acquire one unit for a period of two years from the date of issuance, subject to the reduced warrant term.

On June 2, 2023, the Company announced that it received its first bulk purchase order from Science-Link Trading SAPI de CV for 500 InsuJet devices and accessories for the Mexican market. Payment for the order was received by the Company on June 23, 2023.

On June 6, 2023, the Company engaged Dsrupt Media Inc., direct-to-consumer growth marketing company, to develop product awareness and grow sales of InsuJet through content for paid media. The Company further announced that it aimed at commencing business-to-business sales in the United Kingdom, France and Spain, where InsuJet is approved for sale as a medical device.

On June 9, 2023, the Company announced that InsuJet was registered for supply through the NHS Drug Tariff. InsuJet was officially listed by the NHS on its website on June 23, 2023. Items listed on the NHS Drug Tariff are funded by the Government of the United Kingdom through the Department of Health. Diabetic patients will receive the device free of charge via an NHS prescription provided through their clinician which includes general practitioners, diabetes specialist nurses, and diabetes specialist doctors.

The Company further announced that it engaged Reliance Medical Ltd., a trade distributor of high-quality surgical dressings, healthcare products, medical equipment and first aid supplies, as its third-party logistics partner and distributor in the United Kingdom. The first shipment of InsuJet devices and consumables were delivered by the Company to Reliance Medical Ltd. on June 30, 2023.

All patients in the United Kingdom with a confirmed diagnosis of diabetes are eligible for free of charge diabetes medication and equipment. The decision of what medication and insulin delivery device is prescribed sits with the clinician based on national and local diabetes care pathways and treatment guidelines. Informed patients may request specific devices, including InsuJet. However, the prescription has to be initiated by the clinician who will align prescribing to their local medicines formulary which lists the devices authorized for prescription by clinicians in the hospital/community healthcare region.

On June 12, 2023, the Company reported that it sold 500 units of InsuJet to Trustmed SRL. InsuJet is registered and authorized for use in Romania as a medical device.

On June 14, 2023, the Company announced the engagement of Porter Media, a growth marketing team that specializes in scaling online businesses, to develop product awareness and grow sales of InsuJet. Porter Media is responsible for the creation and delivery of a comprehensive direct-to-consumer digital marketing strategy that looks to expedite sales growth of InsuJet.

On June 12, 2023, the Company reported the that it sold 800 units of InsuJet to Rosheta for Medicines and Medical Supplies in Yemen. InsuJet is registered and authorized for use in Yemen as a medical device. The lifetime value of this sale was estimated by the Company at $720,000 with margins of approximately 72%.

On July 25, 2023, the Company announced that it entered into a new distribution agreement with Sol-M for a term of five years. Sol-M is now the preferred distributor of InsuJet in Canada, Brazil, France and Spain where Sol-M has an extensive existing business footprint in the safety syringe and the diabetic supply business and where InsuJet is approved for sale as a medical device. Sol-M will be required to fulfill minimum yearly purchases to maintain its five-year distribution rights which NuGen estimates to be approximately $132 million dollars based on an estimated lifetime value per unit of InsuJet, plus consumables, of approximately $900 over the span of 3.5 years. National country-wide rollout of InsuJet in Canada, Spain, France and Brazil, is expected to occur in Q1 2024. InsuJet is expected to be available for purchase in all major pharmacies, grocery stores, hospitals, diabetic clinics and offices of endocrinologists and diabetic nurse practitioners.

On September 11, 2023, the Company announced that it received $1,302,000 through the exercise of 25,290,000 warrants at an exercise price of $0.05 and 750,000 options exercised at an exercise price of $0.05. A total of 26,040,000 common shares were issued by the Company. An additional 1,000,000 warrants at an exercise price of $0.05 were exercised on September 29, 2023.

Significant Acquisitions

There were no significant acquisitions completed by the Company during its most recently completed financial year for which disclosure would be required under Part 8 of National Instrument 51-102 – *Continuous Disclosure Obligations*.

DESCRIPTION OF THE BUSINESS

Overview

NuGen is an emerging specialty medical device company focused on developing and commercializing novel drug delivery technologies. NuGen's principal business is the research, development and commercialization of innovative needle-free injection devices and systems for the administration of subcutaneous medication.

The Company is developing products using its novel needle-free delivery technology in important fields including, but not limited to, diabetes, semaglutide, growth and fertility hormone as well as DNA and conventional/pediatric vaccines.

NuGen is focusing its development efforts in needle free devices in the area of liquid jet delivery through the InsuJet platform.

InsuJet

The InsuJet device is a re-usable needle-free spring-powered subcutaneous liquid jet, developed as a "self-injectable" treatment for chronic diseases such as diabetes, for people who take medicine injections or administer injections to others. A special needle-free nozzle is the key feature of the InsuJet system. The operating principle of jet-stream injection technology is to press liquid through a small orifice of this special needle-free nozzle. The spring integrated into the injector produces the required energy to deliver a fine stream of medication through a microscopic hole in the subcutaneous tissue without using a needle, making it virtually pain-free. The system dispenses the medication uniformly in a spray like pattern, in less than 1/10 of a second. Due to the small radius of the jet stream, the fluid is deposited just under the epidermis in the subcutaneous layer, where most vascularization resides. In the subcutaneous tissue, the liquid follows the path of least resistance, resulting in a larger spread compared with a (bulk) droplet needle - 31 - administration. Both the favourable position (just under the skin, as well as the larger area over which the liquid drug is spread) makes the InsuJet jet-stream injection technology particularly suitable for the administration of drugs that requires a relatively fast onset.

The InsuJet liquid injector device is easy to use, and it eliminates needlestick injuries and does not lead to tissue damage on long-term use. InsuJet injectors are reusable, which utilize disposable ampoules and other accessories, and come with a full lifetime replacement warranty. The devices' single-use ampoules can be disposed as domestic waste and are completely recyclable.

InsuJet is used by diabetics for insulin therapy. Diabetics who require insulin supplementation, usually require multiple insulin injections a day. The current version of the InsuJet (InsuJet V5) injector can be used for up to 5,000 injections, and most people can use the device between 3 to 4 years. The InsuJet injector uses sterile consumables: nozzles which can be used for 14 days, and adaptors (filling device) which are installed upon the insulin container. The number of adaptors sold per year per injector depends on the type of insulin cartridges/vials used. Adaptors are customizable to each brand of insulin. As per NuGen's razor/ razor blade model, the consumables are required for the usage of the device since they need to be replaced at regular intervals.

InsuJet jet administration system		
InsuJet injector (v5)	Sterile consumables	
	Nozzle	Adaptor
		

InsuJet administration improves the action of onset of the insulin, opening a complete range of possibilities:

- **Non-invasive**: InsuJet is a non-invasive way to administer insulin and an effective treatment for type-1 and type-2 diabetes.

- **Improved pharmacokinetics**: The pharmacokinetics of regular insulins that are administered with the InsuJet are virtually identical to the more expensive fast acting insulins (analogues) that are injected with a needle-based system (see study 1 in the table above).

- **Fast acting**: The injection of a fast action insulin with InsuJet creates the fastest acting insulin currently available, quickly lowering the glucose exposure after a sugar-rich meal (see study 2 in the table above).

These two advantages are particularly beneficial for patients with high body mass index as research shows that there is a strong association between body mass index and rate of insulin absorption in healthy subjects, arguing a role for greater subcutaneous tissue thickness.[1]

Needle-phobia (trypanophobia) typically develops in childhood with as many as 2 in 3 children and 1 in 4 adults having strong fear of needles, and 1 in 10 adults having full blown needle phobia[2] that can interfere with life-saving treatment. Needle fear and anxiety around self-injection is highly common in patients requiring insulin to control their diabetes and can be a barrier to the initiation of insulin. InsuJet's needle-free delivery avoids the negative association between needles and life-saving treatment.

Potential benefits and possible uses of InsuJet also include:

- **Better protection of innovative products**: Pharma companies spend a significant amount of their resources on development and testing of new drugs, which will run out of patent within a relatively short time span. Using jetstream injection technology, these companies can create a line extension of existing product or make a unique drug-device combination that significantly raises the entry barrier for competing drugs.

- **Software patient management systems**: Electronic operation and Bluetooth connectivity opens up a new range of possibilities for disease treatment management systems:

[1] See de Galan, B. E., Engwerda, E. E., Abbink, E. J., & Tack, C. J. (2013). Body mass index and the efficacy of needle-free jet injection for the administration of rapid-acting insulin analogs, a post hoc analysis. Diabetes, obesity & metabolism, 15(1), 84–86. https://doi.org/10.1111/j.1463-1326.2012.01666.x

[2] McLenon J, Rogers MAM. The fear of needles: A systematic review and meta-analysis. J Adv Nurs. 2019 Jan;75(1):30-42. doi: 10.1111/jan.13818. Epub 2018 Sep 11. PMID: 30109720. The fear of needles: A systematic review and meta-analysis - PubMed (nih.gov)

- Providing in-depth knowledge of compliance and use for healthcare payers;
- Push notifications and instructions for user; and
- Home distance monitoring.

NuGen's InsuJet has been certified in multiple countries and as of the date of this AIF has the following certificates:

Country/Region	Certification
Europe	CE
Australia and New Zealand	TGA
Canada	HC
Brazil	ANVISA

Additional local certifications exist for Kingdom of Saudi Arabia, Jordan, Iraq, Iran, Yemen, Taiwan, Malaysia, and Hong Kong.

In the two most recently completed financial years, sales of InsuJet generated $152,358 in 2022 and $137,648 in 2021.

Currently, the insurance coverage for InsuJet V5 device is provided by National Health Service in the United Kingdom country-wide and by private insurance in the Netherlands.

Principal markets:

InsuJet is approved for sale in 42 counties and is actively sold in 11 countries, most importantly, the United Kingdom where it is covered by the NHS drug tariff, but also in the Netherlands, Australia, Taiwan and certain countries in East Europe and the middle East, through the Company's distributor and wholesale network. There is a global market for needle-free injector devices. Injections are a common healthcare procedure, administered to billions every day but the technique is increasingly going needle-free.

NuGen intends to focus its sales efforts through its subscription offering and distributor network in Europe, Canada and Australia. This includes 30 countries, with a total addressable market of 11.6 million insulin-dependent diabetics. Needle fear and anxiety around self-injection is highly common in patients requiring insulin to control their diabetes and can be a barrier to the initiation of insulin. InsuJet's innovative needle-free delivery avoids the negative association between needles and life-saving treatment.

NuGen's InsuJet needle-free injection system has a variety of benefits for insulin-dependent diabetics such as:

1. proven technology;
2. portable, all-in-one design;
3. flexible dosage setting due to incremental dose system;
4. safe, two-step automatic release system: safety switch combined with minimum counter pressure;
5. clinical proof of efficacy platform;
6. over 40% faster insulin uptake[3];
7. higher acceptance among patients with needle-phobia;
8. reduced chance of needle-stick injuries and cross contamination; and
9. reduced chance of intra-muscular injections.

[3] de Wit, H.M., Engwerda, E.E.C., Tack, C.J. and de Galan, B.E. (2015), Insulin administered by needle free jet injection corrects marked hyperglycaemia faster in overweight or obese patients with diabetes. Diabetes Obes Metab, 17: 1093-1099. https://doi.org/10.1111/dom.12550

Distribution methods:

Subscription offering:

Utilizing fulfilment centers across Europe and Canada, new purchases are made online via a smart phone or at our e-commerce website www.insujet.com, are paid within two "clicks", and then routed to fulfilment based upon the member's IP address. The member's starter kit is then picked, packed, and shipped within hours allowing for a highly scalable virtual business model.

New members subscribe for either a 1–or 3–year plan and pay for the first month before the products even leave the warehouse. Monthly billings follow based on each member's specific subscription (i.e., nozzle and adaptor supplies customized to their insulin brand and injection schedule). Each member receives their consumables based upon their own customized needs.

Some of the highlights of NuGen's subscription offering include:

- Subscription plan with quarterly home delivery of InsuJet supplies.
- Personalized and customizable to the individual's specific diabetic needs.
- One and three-year subscriptions starting at €23 per month.
- Purchase on smart phone or online at our exclusive ecommerce website.
- 24/7 customer support.

Distributor and wholesale network:

In addition to our subscription offering model, InsuJet is provided to end-customers through conventional channels such as pharmacies for patients who have a prescription for the device.

We have carefully selected a few distributors in key markets to support sales via off-line, complementary sales channels to ensure more patients can get access to the InsuJet. They may also target markets where subscription offerings sales are currently not as well established.

Our main distribution partner is Sol-M, a global medical supply company focusing on safe medication delivery systems. Sol-M has an extensive existing business footprint in the safety syringe and the diabetic supply business and is the exclusive distributor of InsuJet in Canada, Brazil, France and Spain.

In the United Kingdom, InsuJet is registered for supply through the NHS Drug Tariff. Devices are sold to pharmaceutical wholesalers and hospitals through Reliance Medical Ltd., our third-party logistics partner and distributor, and are funded by the Government of the United Kingdom through the Department of Health.

In terms of warehousing and order fulfilment, EPG has its own facility in the Netherlands, which can supply orders to distributors and/or end-customers in the Netherlands, the United Kingdom and other European countries. For Asia and Oceania, European Pharma Group (Shenzhen) Ltd. ("**EPG Shenzhen**") keeps inventory in its warehouse in China. In addition, in the United Kingdom, further warehousing and fulfilment is done by our partner Reliance Medical Ltd., a large supplier to the NHS. In the future, NuGen may establish relationships with additional distribution partners.

International shipping between EPG Shenzhen and EPG is done by either air (FedEx) or sea freight depending on available rates and order lead-times. For larger bulk shipments, in 2023 the Company started working with EXSAN | Sany, an international shipping agent, and has used their sea-freight services for the first container shipments (less than container load or full container load) between China and the Netherlands.

Although Incoterms for sales to distributors are often Ex works from factory, meaning the distributor will cover the shipping costs, most distributors ask for shipping as a service, so shipping can be invoiced to the distributor. For road shipping to distributors, we started working with Nunner Logistics, which has an extensive network of locations and agents throughout Europe and the middle-east. For e-commerce sales, commercial agreements are made with both FedEx and DHL express, providing favorable rates for express shipment throughout Europe and the middle east. Software integrations between the online e-commerce platform (Shopify) and DHL express allow for the seamless fulfilment of online sales orders with a minimal amount of work.

Research and development:

NuGen continues to develop and design future iterations of the InsuJet. Anticipating future developments in needle-free medication delivery technologies, the Company is currently working on improvements for InsuJet which will be introduced in the V6, V7 and V8 models of the system.

NuGen may seek external assistance for the following matters:

- Complicated mechanical engineering
- Industrial design (mainly esthetics, product look & feel)
- Electronic hardware design
- Software design

The above is undertaken with close collaboration of NuGen's internal team. NuGen's staff remains responsible for the overall design solutions, design specifications, design for manufacturing, design verification & validation, usability engineering, risk management, design transfer activities, etc. NuGen has previously outsourced certain R&D and engineering work to a Swiss engineering firm. They have historically been involved in the development of InsuJet V7 and V8 devices. NuGen may require additional support from the firm but the involvement is for specific and isolated mandates.

The Company's major design projects are focused on two areas: (i) the current InsuJet platform that allows small incremental improvements, which includes the current InsuJet V5 and the future InsuJet V6, and (ii) the next generations of the device with additional features and a higher degree of innovation that are intended to be included for the InsuJet V7 and V8.

- **InsuJet V6**

The InsuJet V6 device is an incremental improvement of InsuJet V5, and has some improvements in the housing design, ergonomics and usability features. The next phase of development will include design for manufacturing, and design transfer.

- **InsuJet V7**

The InsuJet V7 device will have more innovations, where smart & connective features are added by the incorporation of electronics (e.g., Bluetooth LE.) The device will be positioned as a more high-end version of the device, targeting mainly developed countries, with better monitoring and traceability of user data.

- **InsuJet V8**

The InsuJet V8 device will feature more innovations to enhance the overall usability of the product by eliminating the need to use separate adaptors for the filling of the device dose chamber (nozzle) with insulin prior to each injection.

The table below summarizes the current R&D initiatives being advanced by the Company, which are dependant on funding and investments from external partners:

Description	Stage of Development	Estimated Timing	Subcontractors (if applicable)	Additional steps to commercial production, cost and timing
InsuJet V6	Technology Readiness Level: 8	12 months - 3 months R&D - 3 months tooling - 3 months verification & validation - 3 months approval.	Subcontractors include existing suppliers of tooling and injection molding and test labs	Refer to estimated timing. Estimated Costs: $150,000
InsuJet V7	Technology Readiness Level: 8	24 months - 6 months R&D, - 6 months tooling, - 6 months verification & validation, - 6 months approval.	Subcontractors include existing suppliers for engineering, software design, tooling , injection molding, machining and test labs	Refer to estimated timing. Estimated Costs: $500,000
InsuJet V8	Technology Readiness Level: 5	36 months - 9 months R&D, - 9 months tooling, - 9 months verification & validation, - 9 months approval.	Subcontractors include existing suppliers for engineering, software design, tooling, injection molding, machining and test labs	Refer to estimated timing. Estimated Costs: $750,000

The R&D activities with respect to the InsuJet product line are primarily performed in Amsterdam and Shenzhen with Canadian strategic direction and oversight.

Foreign Operations

The Company has active operations in the Netherlands and China through its subsidiaries EPG and EPG Shenzhen correspondingly. The manufacturing activities with respect to the InsuJet product line are primarily performed in the Netherlands and in China with Canadian strategic direction and oversight. European Pharma Group Limited ("**EPG Hong Kong**") serves as a flow-through company inherited from the Qualifying Transaction and has no operations.

EPG and EPG Shenzhen design, manufacture, perform quality control and packaging of InsuJet systems. In addition, EPG covers the product release, sales and distribution, clinical evaluation and post market surveillance of InsuJet. All activities carried out by EPG and EPG Shenzhen are supervised and directed by the management of the Company.

Production

NuGen's operations in China (the "**China Operations**") are based in Shenzhen and operate under the name of EPG Shenzhen which conducts the following activities: design, development, manufacturing, assembly, quality assurance, and testing.

The China Operations adhere to ISO 13485:2016, the global standard for medical device manufacturing companies. ISO 13485:2016 is designed to be used by organizations involved in the design, production, installation and servicing of medical devices and related services. The operating procedures of the China Operations are not only established and based on the requirements of ISO 13485:2016, but also the EU Medical Device Directive 93/42/EEC, the new EU regulation MDR 2017/745, and other applicable standards.

The China Operations are audited annually by the designated notified body, LNE/GMED, to ensure compliance with the ISO 13485:2016 standard and for the maintenance of EPG's products' CE Mark. GMED is one of the few global notified bodies that has been accredited by national competent authorities to perform conformity assessment procedures to the European Regulation (EU) 2017/745 on medical devices and 93/42/EEC as amended by Directive 2007/47/EC- Medical Devices (MD). These are the applicable directives and regulations for CE Mark for medical devices on the EU market (https://lne-gmed.com/accreditations). Audits are conducted onsite by European staff from GMED over multiple days.

The sterilization process is performed by a major health services company based in China, approved by the Food and Drug Administration of the United States ("**FDA**").

Components

The three principal categories of components involved in the production of InsuJet are:

- **Injectors**: EPG acquires all parts from third party manufacturers, then assembles, tests and packages them. EPG Shenzhen defines the design spec, does the supplier evaluation, does the part verification, and does quality control, packaging and final release.

- **Nozzles (syringes)**: Manufactured, assembled and packaged by third-party contract manufacturers with multiple global locations.

- **Cartridge/Vial Adaptors**: Manufactured, assembled and packaged by third party contract manufacturers with multiple global locations.

NuGen outsources certain key manufacturing processes to industry experts including sterilization suppliers, suppliers of components which come into direct or indirect contact with drug or breached skin, and consumable assembly suppliers.

All current primary suppliers have been providing products and services to NuGen (and before that to Inolife) for 5-10 years. The medical device industry typically relies on long term cooperation. However, in the event of termination of a primary supplier, the supplier can be replaced as NuGen/EPG has the ownership of all the production assets & manufacturing procedures/information. Estimated time for replacement is 3-6 months. In the event of a possible termination, it is common business practice to announce the termination in advance, so that the manufacturer can adjust its production planning accordingly and build up sufficient stock to bridge the transfer period.

It is important to note that NuGen/EPG works with global contract manufacturers which have manufacturing sites globally. These sites typically use the same machines and procedures, and in case of an unexpected shutdown at their China plant, assets could be transferred to an alternative plant to minimize the disruptions in supply. Additionally, NuGen/EPG has a very complete manufacturing file, and maintains relations with back-up suppliers in case unforeseen events warrant a transfer in supplier.

As part of the China Operations, EPG Shenzhen collaborates with various global companies, including:

- the contract manufacturer that moulds nozzle parts and assembles them along with the sterile packaging of the nozzles is the Chinese subsidiary of a global company headquartered in Germany with production sites and locations in 15 countries spread across three continents. It has been a primary supplier to EPG Shenzhen since 2011; and

- the contract manufacturer that moulds adaptor parts is the Chinese subsidiary of a global contract manufacturing organization/contract development manufacturing organization with its medical division headquartered in the USA with 11 manufacturing operations and more than 1,500 associates worldwide. It operates ISO 13485:2016 certified quality systems and FDA registered sites are located throughout the Americas, Europe, and Asia. It has been a primary supplier for EPG Shenzhen since 2011.

These contract manufacturers work with global procedures and infrastructure, allowing unobstructed movement of plastic injection tools from one site to another.

Below is the list of suppliers who are used for the manufacturing of the InsuJet V5 device and sterile accessories.

Supplier	Item supplied	Certification held - expiration dates	Signed agreement in place
Various suppliers located in China	Components for injectors	ISO 9001	For some suppliers yes, otherwise – purchase orders are used.
Secondary suppliers in Europe		ISO 14001	
A global contract manufacturing company headquartered in Germany	Medical grade injection molding for disposable nozzles (syringes)	ISO13485:2016 exp. 2024/6/3	Yes
A global contract manufacturing organization with its medical division headquartered in the USA	Medical grade injection molding for disposable vial adaptor parts	ISO13485:2016 exp. 2026/8/30	Yes
A global sterilization company	Sterilization for consumables	ISO13485:2016 exp. 2024/3/31	Yes

Specialized Skill and Knowledge

The business of the Company requires personnel with specialized skills and knowledge in the medical devices, healthcare and general management fields. These skills include regulatory compliance, health expertise, manufacturing, mergers & acquisitions and managing direct sales teams. The Company's research and development work involves highly qualified personnel and the Company has a highly skilled management team in place.

The Company believes that it has adequate personnel with the specialized skills and knowledge to successfully carry out the Company's business and operations. See "*Risk Factors – Qualified Employees*" for a discussion of the risks of losing such specialized skills and knowledge.

Competition

NuGen competes with other companies that research and develop needle-free medication administration devices in various markets. Although all offer needle-free solutions, many of the competitors: (i) have significant differences in their method of delivery, or (ii) are a drug/device combination, or (iii) are owned and distributed by a specific pharmaceutical company for a specific application, or (iv) have not yet been commercialized.

The competitive advantage of InsuJet is that it has the only reusable spring-powered injector which has the following features:

- integrated spring setting mechanism with no need of an external tools to reset spring;
- integrated dosing mechanism with dose window, no external tools needed to set the target dose inside the nozzle/dose chamber that allows variable dose capabilities if required (i.e., insulin injections); and
- counter pressure safety mechanism that ensures the device only activates when the appropriate force is placed against the target injection site, which results in consistent injection quality.

The combination of features results in a compact design and perhaps the most user-friendly needle-free injector on the market, most suitable for self-injection.

New Products

A needle-free device with the trademark PetJet was launched by the Company in June 2022 to target the global animal market. To demonstrate the efficacy of the use of needle-free delivery systems for the delivery of various vaccines and medications to animals, the Company has conducted two animal studies. The first study was performed with an inactivated polio vaccine (IPV), which showed injection with needle-free injection (NFI) is non inferior to needle-injections. The second study was performed with an oncolytic virus vaccine, which is a new form of drug therapy targeted to treat different kind of cancers. This study also demonstrated that needle-free injections is a suitable alternative and non-inferior to needle injections in terms of efficacy. Furthermore, the Company is conducting case studies with oncolytic viruses vaccines for the treatment of animal melanomas which have favorable results. The first orders of PetJet devices for the United States market have been placed, and distribution agreements with prospect distributors in major markets including in the USA and Mexico are under discussion.

Intellectual Property

NuGen currently holds, directly or indirectly, intellectual property rights in connection with its needle-free drug delivery systems. InsuJet products are sold under the InsuJet trademark.

Most of the patents applied for in the past are used to protect the manufacturer from being copied. Only 1 patent is filed in the Netherlands and internationally via PCT application, which is for a critical innovation which allows the drug to be stored within the device itself which is the key benefit of the InsuJet V8. None of the needle-free injectors on the market have such a feature and if brought to the market it is expected to significantly increase the safety and usability of the device and therefore enhance/spearhead market adoption of InsuJet injectors. More patents are expected to be filed for this technology, as well as to protect the technology used in the development of InsuJet V7 device. Below is a summary table of the patents directly or indirectly held by Nugen:

Patent name	Patent application number/patent number	Remarks	Patentee	Inventor	Filing date	Authorized	Jurisdiction
High precision nozzle mold	ZL 2017 2 0942863.X	Nozzle mold patent	European Pharma Group (Shenzhen) Ltd.	Nicky Canton, Boudewijn van Limpt	July 31, 2017	June 5, 2018	China
Sterile improved safety cartridge adaptor	201710640166.3	3mL adaptor innovation patent	European Pharma Group (Shenzhen) Ltd.	Nicky Canton, Boudewijn van Limpt	July 31, 2017	Pending, substantive examination is in process since 29 Nov.2017.	China
Sterile improved safety cartridge adaptor	ZL 2017 2 0942832.4	3mL adaptor utility patent	European Pharma Group (Shenzhen) Ltd.	Nicky Canton, Boudewijn van Limpt	July 31, 2017	January 29, 2019	China
Sterile vial adaptor	ZL 2017 2 0942864.4	10mL adaptor utility patent	European Pharma Group (Shenzhen) Ltd.	Nicky Canton, Boudewijn van Limpt	July 31, 2017	January 11, 2019	China
Electronic needle-free injector	2018 11130825.X	An electric liquid Injector innovation patent	European Pharma Group (Shenzhen) Ltd	Nicky Canton, Lily Li	Sep 27, 2018	Pending, substantive examination is in process since 27 Feb.2019.	China
Refilling system for medical device using jet delivery principle	N2025322 / 80771NL9-2	Refilling utility patent	European Pharma Group B.V.	Nicky Canton, Frederick J. C. Grimmeli-khuijsen	Apr 09, 2020	Pending	Netherland
Mechanism for puncturing a gas cartridge	2,858,485	Nanojex	NuGen	Martin Brouillette Steven Dion Christian Hebert	Dec 15, 2011	Jan. 22, 2019	Canada
Mechanism for puncturing a gas cartridge	3,029,492	Nanojex	NuGen	Martin Brouillette Steven Dion Christian Hebert	Dec 15, 2011	Sept. 10, 2019	Canada
Mechanism for puncturing a gas cartridge	9,255,665 / 61570911	Nanojex	NuGen	Martin Brouillette Steven Dion Christian Hebert	Dec 15, 2011	PCT Application	United States
Needless syringe and method for delivering therapeutic particles	10,279,113	Nanojex	NuGen	Martin Brouillette Christian Hebert	May 17, 2013	PCT Application	United States

Patent name	Patent application number/patent number	Remarks	Patentee	Inventor	Filing date	Authorized	Jurisdiction
Needless syringe for the subcutaneous delivery of therapeutic agents	2,423,647	Nanojex	NuGen	Martin Brouillette	Oct 20, 2000	Dec 22, 2009	Canada
Needless syringe for the subcutaneous delivery of therapeutic agents	7,320,677	Nanojex	NuGen	Martin Brouillette	Oct 20, 2000	PCT Application	United States

Economic Dependence

The Company has entered into a limited number of supply or sales agreements for the sale of its products. Until additional supply agreements are executed by the Company, the Company's revenues stemming from its distributor and wholesales network will be dependent on such agreements. If such agreements are terminated, or if less of the Company's product than anticipated is purchased pursuant to such agreements, this could have a material adverse impact on the Company's distributor and wholesales sales model and its operations and results.

Environmental Protection

For the current financial year, the Company does not expect any material financial or operational effects based on environmental protection requirements.

Employees

As of the date of this AIF, the Company has 15 staff consisting of 12 employees and 3 consultants.

Other

The Company and its subsidiaries have not been subject to bankruptcies, receiverships, or similar proceedings, nor have there been any material reorganizations of the Company or any of its subsidiaries during the three most recently completed financial years or completed during or proposed for the current financial year. The business of the Company is not cyclical. The Company does not have an investment policy, or lending and investment restrictions in place.

RISK FACTORS

The risks described below are not the only risks and uncertainties the Company faces. Additional risks not currently known to the Company or that it currently considers immaterial also may impair its operations. If any of the following risks actually occur, the Company's business, results of operations and financial condition could be materially adversely affected. In that case, the trading price of the Common Shares could decline, and investors could lose all or part of their investment. There is no assurance that risk management steps taken will avoid future loss due to the occurrence of the risks described in this AIF or other unforeseen risks. See also "*Risks and Uncertainties*" in the Company's most recent Management's Discussion & Analysis, which is available on SEDAR+ (https://www.sedarplus.ca/).

Risks Related to NuGen's Business and Industry

Regulatory Approvals and Agencies:

Even if regulatory approval is obtained, a regulatory agency may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. The products of the Company will also be subject to ongoing requirements governing the labeling, packaging, storage, advertising, promotion, record keeping and submission of safety and other post market information. In addition, manufacturers of drug products and their facilities may be subject to continual review and periodic inspections by the regulatory authorities for compliance with current good manufacturing practices regulations. If the Company or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturer or the Company, including requiring withdrawal of the product from the market or suspension of manufacturing.

If the Company, the product candidates or the manufacturing facilities for such product candidates fail to comply with applicable regulatory requirements, a regulatory agency may: issue warning letters or untitled letters; impose civil or criminal penalties; suspend regulatory approval; suspend any ongoing clinical trials; refuse to approve pending applications or supplements to applications filed by the Company; impose restrictions on operations; or seize or detain products or require a product recall.

In particular, the European Union regulatory bodies have finalized a new Medical Device Regulation ("**MDR**"), which replaced the existing Medical Device Directives ("**MDD**") and provided a multiyear framework for transition and compliance. The MDR will change certain aspects of the existing regulatory framework, such as updating clinical data requirements and introducing new ones, such as Unique Device Identification. There are currently a limited number of Notified Bodies qualified to oversee compliance to the new MDR. We may face significant uncertainties and delays as the MDR is rolled out and enforced by the European Union's Competent Authorities, creating risks in areas, including the CE Marking process and data transparency, in the upcoming years.

Approval Procedures in other Countries:

Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain Health Canada and FDA clearance or approval. The regulatory approval process in other countries may include all of the risks detailed herein regarding clearance or approval 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 or setback in obtaining such approval could have the same adverse effects detailed. Such effects include the risks that the product candidates may not be approved for all indications requested, which could limit the uses of the product candidates and have an adverse effect on their commercial potential or require costly, post-marketing follow-up studies.

Product Liability:

The use of InsuJet equipment and product candidates in clinical trials and the sale of any products for which the Company may obtain marketing approval can expose the company to the risk of product liability claims. Product liability claims might be brought against the Company by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with its products. For example, pharmaceutical companies have been subject to claims that the use of some pediatric vaccines has caused personal injuries, including brain damage, central nervous system damage and autism, and these companies have incurred material costs to defend these claims.

If the Company cannot successfully defend itself against product liability claims, the Company could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in: decreased demand for the product candidates; impairment of the Company's business reputation; withdrawal of clinical trial participants; costs of related litigation; distraction of management's attention from the company's primary business; substantial monetary awards to patients or other claimants; loss of revenues; and inability to commercialize the products.

The Company has obtained product liability insurance coverage for clinical trials, but the insurance coverage may not be sufficient to reimburse the Company for any expenses or losses it may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, the Company may not be able to maintain adequate insurance coverage at a reasonable cost or in sufficient amounts to protect itself against losses due to liability.

On occasion, large judgments have been awarded in class action lawsuits based on products that had unanticipated side effects. A successful product liability claim or series of claims brought against the Company could cause its stock price to decline and, if judgments exceed the insurance coverage, could adversely affect its business.

Market Acceptance of the Products:

The commercial success of the InsuJet equipment and product candidates for which the Company has obtained marketing approval from the regulatory authorities will depend upon the acceptance of these products by both the medical community and patient population. Coverage and reimbursement of the product candidates by third-party payors, including government payors, generally is also necessary for optimal commercial success.

The degree of market acceptance of any of the approved products will depend on a number of factors, including the Company's ability to provide acceptable evidence of safety and efficacy; the relative convenience and ease of administration; the prevalence and severity of any actual or perceived adverse side effects; limitations or warnings contained in a product's approved labeling; pricing and cost effectiveness; and the willingness of patients to pay out of pocket in the absence of third-party coverage. If the InsuJet equipment and product candidates are approved but do not achieve an adequate level of acceptance by physicians, health care payors and patients, the Company may not generate sufficient revenue from these products, and the Company may not become or remain profitable. In addition, the efforts to educate the medical community and third-party payors on the benefits of the product candidates may require significant resources and may never be successful.

There is a risk that physicians/clinicians may misuse our products, such as not following the instructions for use, not using our products on the intended patient population, using our products with unapproved or modified hardware or software, or misuse by inadequately trained staff. Physicians/clinicians may also initiate their own clinical studies which may be poorly designed or controlled, and may result in adverse safety or efficacy results. Any of the foregoing could result in negative publications, negative sentiment or adverse events or regulatory actions in respect of our products, thereby limiting market acceptance and sales of our products, which could have a material adverse effect on our business, financial condition and results of operations.

Clinical trials and testing:

Clinical testing is expensive and can take many years to complete, and its outcome is uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical studies and early clinical trials of the Company's products may not be predictive of the results of later-stage clinical trials. Results from one study may not be reflected or supported by the results of similar studies. Results of an animal study may not be indicative of results achievable in human studies. Human-use equipment and product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical testing.

The time required to obtain approval by the regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials, depending upon numerous factors. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change.

In addition, ongoing clinical trials may not be completed on schedule, or at all. The commencement and completion of clinical trials can be delayed for a number of reasons. Clinical trials may also be delayed as a result of ambiguous or negative interim results. In addition, a clinical trial may be suspended or terminated by the Company, the medical and ethical regulatory bodies, any of the clinical trial sites with respect to that site, or other regulatory authorities due to a number of factors.

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 a product candidate. Further, delays in the commencement or completion of clinical trials may adversely affect the trading price of the Common Shares.

Acquisition, Development and Commercialization of Additional Product Candidates:

The success of acquiring, developing and commercializing additional products or product candidates depends partly upon the ability of the Company to identify, select and acquire promising product candidates and products. The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with us for the license or acquisition of product candidates and approved products. The Company will have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into its current infrastructure. Moreover, the Company may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or the Company may fail to realize the anticipated benefits of such efforts. The Company may not be able to acquire the rights to additional product candidates on terms that it finds acceptable, or at all.

Further, any product candidate that the Company acquires may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the applicable regulatory authorities. All product candidates are prone to risks of failure typical of product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities.

Future growth may also depend on, among other factors, our ability to successfully develop new product candidates and make product improvements to meet evolving market needs. The Company may not be able to successfully expand its product portfolio to generate new revenue opportunities in the future. Although the Company believes it has the scientific and technical resources available to improve its products and develop new products, future products will nevertheless be subject to the risks of failure inherent in the development of products based on innovative technologies. In addition, any such research and development activities may involve significant capital expenditures. There can be no assurance that the Company will be able to successfully develop future products and tests, which would prevent it from introducing new products in the marketplace and negatively impact its ability to grow revenues and become profitable.

Collaborators, Partners and Manufacturers:

The Company will have entered into, or may enter into, distribution, co-promotion, partnership, sponsored research and other arrangements for development, manufacturing, sales, marketing and other commercialization activities relating to the products of the Company. If any of the current or future collaborators breaches or terminates their agreements, or fails to conduct themselves in a collaborative and timely manner, the commercialization of products could be diminished or blocked completely.

Disputes could also arise between the Company and existing or future collaborators as to a variety of matters, including financial and intellectual property matters or other obligations. These disputes could be both expensive and time-consuming and may result in delays in the development and commercialization of the products of the Company or could damage the relationship with such collaborator or partner.

The Company manufactures some components of the InsuJet systems and utilizes the services of contract manufacturers to manufacture the remaining components of these systems and the product supplies for clinical trials. The manufacture of the systems and products supplies requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls.

Manufacturers often encounter difficulties in production, particularly in scaling up for commercial production. These problems include difficulties with production costs and yields, quality control, including stability of the equipment and product candidates and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced applicable regulations.

If the Company or the manufacturers were to encounter any of these difficulties, the ability of the Company to provide the InsuJet systems and equipment to partners and products to patients in clinical trials or to commercially launch another product could be jeopardized.

In addition, all manufacturers of the Company's products must comply with requirements enforced by the regulatory authorities such as, among other things, quality control, quality assurance and the generation and maintenance of records and documentation. The Company has little control over its manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval.

If the safety of any product is compromised due to the Company or its manufacturers' failure to adhere to applicable laws or for other reasons, the Company may not be able to obtain regulatory approval for or successfully commercialize the products, and the Company may be held liable for any injuries sustained as a result. Furthermore, if the manufacturers fail to deliver the required commercial quantities on a timely basis, pursuant to provided specifications and at commercially reasonable prices, the Company may be unable to meet demand for the products and would lose potential revenues.

Competition:

The Company faces competition and new competitors will continue to emerge throughout the world. Future products offered by the Company’s competitors may take a larger market share than anticipated, which could cause revenue generated from the Company’s products and services to fall below expectations. It is expected that competition in these markets will continue to intensify.

If competitors of the Company develop and market more successful products or services, offer competitive products or services at lower price points, or if the Company does not produce consistently high-quality and well-received products and services, revenues, margins, and profitability of the Company will decline.

There can be no assurance that NuGen will be in a position to continue being competitive as other organizations emerge and existing competitors continue to grow and form cooperative relationships and partnerships. Other numerous factors could affect the Company’s competitiveness. The Company’s business and results may be materially negatively affected as a consequence.

Technological advancement:

The areas in which the Company is commercializing, distributing, and/or selling products involve rapidly developing technology. There can be no assurance that the Company will be able to establish itself in such fields, or, if established, that it will be able to maintain its position. There can be no assurance that the development by others of new or improved products will not make the Company's present and future products, if any, superfluous or obsolete.

Risks Related to NuGen's Operations

Development and expansion of business in emerging markets:

The Company's business objectives involve the proposed expansion of its target market into emerging markets. Emerging markets have greater political and economic volatility and are far more susceptible to labour disruptions than established markets. This expansion presents challenges related to more volatile economic conditions, competition from companies that are already present in the market, the need to identify correctly and leverage appropriate opportunities for sales and marketing, poor protection of intellectual property, inadequate protection against crime (including counterfeiting, corruption and fraud), inadvertent breaches of local laws or regulations and difficulties in recruiting sufficient personnel with appropriate skills and experience.

Political and other risks associated with operating in foreign jurisdictions:

The Company will have operations in China and may have operations in additional emerging markets in the future. Changes, if any, in investment policies or shifts in political attitude in the countries in which the Company operates may adversely affect the Company's operations or profitability. Operations may be affected in varying degrees by government regulations with respect to, but not limited to, restrictions on production, price controls, export controls, currency remittance, importation of product and supplies, income and other taxes, royalties, the repatriation of profits, expropriation of property, foreign investment, maintenance of concessions, licenses, approvals and permits, environmental matters, land use, land claims of local people, water use and workplace safety. The Company will continue to monitor developments and policies in the emerging markets in which it will operate and assess the impact thereof to its operations; however, such developments cannot be accurately predicted and could have an adverse effect on the Company's operations or profitability.

Inflation in emerging markets:

In the past, high levels of inflation have adversely affected emerging economies and financial markets. Moreover, governmental measures to curb inflation and speculation could contribute to the negative economic impact of inflation and could create general economic uncertainty. The emerging markets in which the Company operates or may operate may experience high levels of inflation in the future. Inflationary pressures may weaken investor confidence in such countries and lead to further government intervention in the economy. If countries in which the Company operates experience high levels of inflation in the future and/or price controls are imposed, the Company may not be able to adjust the rates the Company charges its customers to fully offset the impact of inflation on the Company's cost structures, which could adversely affect the Company's results of operations or financial condition.

Risks relating to auditor oversight:

The Company's marketing plan and strategy involves expansion into select emerging markets in the Middle East and Latin America. Expansion into select emerging markets could result in the use of component auditors that are not participating audit firms with the Canadian Public Accountability Board ("**CPAB**"), while public accounting firms that audit Canadian reporting issuers must participate in CPAB's oversight program.

The work of a component auditor outside Canada can impact the execution of quality audits if the work is not executed in accordance with the group auditor's direction and carefully supervised and evaluated by the group auditor. CPAB's inspection activity of reporting issuers with foreign operations is often limited to engagement files accessible only in Canada as it currently has no legal means to compel access to work completed by component auditors. Without access to component auditor working papers in foreign jurisdictions, CPAB is restricted in fulfilling its mandate.

CPAB inspects selected high-risk sections of public accounting firm audit engagement files and evaluates the quality management systems of those firms. Investors should be concerned when foreign laws and regulations impede or reduce the level of auditor oversight that they have come to expect in Canada. Certain countries, including China and Mexico, continue to prevent CPAB from inspecting the audit work of Canadian public companies conducted in their jurisdictions. CPAB has Memorandums of Understanding (MOUs) with audit regulators in nine countries including the Netherlands, however, even with the MOU agreements currently in place, CPAB has no legal authority to compel cooperation from foreign audit regulators or component auditors.

Corruption and anti-bribery law violations:

The Company's business is subject to Canadian laws which generally prohibit companies and employees from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business. In addition, the Company is subject to the anti-corruption and anti-bribery laws of any other countries in which it conducts business now or in the future. The Company’s employees or other agents may, without its knowledge and despite its efforts, engage in prohibited conduct under the Company’s policies and procedures and anti-corruption and anti-bribery laws for which the Company may be held responsible. Although the Company has policies and procedures in place that are designed to promote legal and regulatory compliance, the employees, business partners and consultants of the Company could take actions that violate applicable anti-bribery and anti-corruption laws or regulations. Violations of these laws, or allegations of such violations, could result in loss, reduction or expropriation and/or have a material adverse effect on the Company's business, results of operations or financial condition.

Limited operating history:

NuGen has a limited operating history on which to base an evaluation of its respective business, financial performance and prospects. As such, the Company’s business and prospects must be considered in light of the risks, expenses and difficulties frequently encountered by companies in the early stage of development.

As the Company is in an early stage, its revenues may be materially affected by the decisions, including timing decisions, of a relatively consolidated customer base. There can be no assurance that the Company will be successful in addressing these risks, and the failure to do so in any one area could have a material adverse effect on the Company’s business, prospects, financial condition and results of operations.

Forecasting the revenues and profitability for new business models is inherently uncertain and volatile. The Company's actual revenues and profits for its business models may be significantly less than the Company's forecasts. Additionally, these new business models could fail for one or more of the Company's products and/or services, resulting in the loss of the Company's investment in the development and infrastructure needed to support the new business models.

Conflicts of interest:

Because directors and officers of the Company are or may become directors or officers of other reporting companies or have significant shareholdings in other medical devices companies, the directors and officers of the Company may have a conflict of interest in conducting their duties. The Company and its directors and officers will attempt to minimize such conflicts.

In the event that such a conflict of interest arises at a meeting of the directors of the Company, a director who has such a conflict will abstain from voting for or against the approval of such participation or such terms. 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.

In determining whether or not the Company will participate in a particular program and the interest therein to be acquired by it, the directors will primarily consider the potential benefits to the Company, the degree of risk to which the Company may be exposed and its financial position at that time. Other than as indicated, the Company has no other procedures or mechanisms to deal with conflicts of interest. Executive officers and directors may have rights to indemnification including directors' and officers' liability insurance that will survive consummation of their agreements.

Insurance:

The Company will be affected by a number of operational risks and the Company may not be adequately insured for certain risks. While the Company may obtain insurance to protect its assets, employees and operations, insurance policies may contain exclusions, coverage limits and various terms and conditions and may not be available to cover risks and events relevant to the Company's business. In the event that insurance policies do cover risks and events to which the Company is exposed, there is no guarantee that policy would cover the totality of eventual claims. Furthermore, there is no assurance that such insurance will be available or continue to be available in the future. A material adverse effect to the Company's operations and financial position could arise from substantial liabilities not covered by insurance or in excess of policy limits.

The cost of insurance, including director and officer, worker's compensation, property, product liability and general liability insurance, has risen significantly in recent years and is expected to continue to increase. In particular, the Company's product liability insurance is subject to price increases if it experiences product liability claims. In response, the Company may increase deductibles and/or decrease certain coverages to mitigate these costs. These increases, and the Company's increased risk due to increased deductibles and reduced coverages, could have a negative impact on its business, financial condition and results of operations.

Intellectual Property Related Risks:

The commercial success of the Company will depend in part on obtaining and maintaining patent, trademark, trade secret, and other intellectual property protection relating to the InsuJet equipment and product candidates, as well as successfully defending these intellectual property rights against third party challenges.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. The laws and regulations regarding the breadth of claims allowed in biotechnology patents has evolved over recent years and continues to undergo review and revision, both in the United States and Canada. The biotechnology patent situation outside those countries can be even more uncertain depending on the country. Changes in either the patent laws or in interpretations of patent laws in the United States and Canada and other countries may diminish the value of the intellectual property owned by the Company. The degree of future protection for the intellectual property rights of the Company is uncertain, because legal decision making can be unpredictable, thereby often times resulting in limited protection, which may not adequately protect the rights of the Company or to allow it to gain or keep its competitive advantage, or resulting in an invalid or unenforceable patent.

The Company depends, in part, on licensors and collaborators to protect a portion of its intellectual property rights. In such cases, licensors and collaborators of the Company may be primarily or wholly responsible for the maintenance of patents and prosecution of patent applications relating to important areas of its business. If any of these parties fail to adequately protect these products with issued patents, the Company's business and prospects would be harmed significantly. The Company also may rely on trade secrets to protect its technology, especially where it does not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect.

Although the Company will use reasonable efforts to protect its trade secrets, its employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose trade secrets to competitors. Enforcing a claim that a third-party entity illegally obtained and is using any of the trade secrets of the Company is expensive and time-consuming, and the outcome is unpredictable.

If the Company or its licensors fail to obtain or maintain patent protection or trade secret protection for the product candidates or the technologies, third parties could use said proprietary information, which could impair the Company's ability to compete in the market and adversely affect its ability to generate revenues and attain profitability.

Infringement by the Company of intellectual property rights:

The Company may become subject to claims that its technologies infringe upon the intellectual property or other proprietary rights of third parties. Any claims, with or without merit, could be time-consuming and expensive, and could divert the Company's management's attention away from the execution of its business plan. Moreover, any settlement or adverse judgment resulting from these claims could require the Company to pay substantial amounts or obtain a license to continue to use the disputed technology, or otherwise restrict or prohibit the Company's use of the technology.

The Company cannot assure that it would be able to obtain a license from the third party asserting the claim on commercially reasonable terms, if at all; that the Company would be able to develop alternative technology on a timely basis, if at all; or that the Company would be able to obtain a license to use a suitable alternative technology to permit the Company to continue offering, and the Company's customers to continue using, the Company's affected products and services. An adverse determination also could prevent the Company from offering its products and services to others. Infringement claims asserted against the Company may have a material adverse effect on its business, products, results of operations or financial condition.

Legal proceedings:

The Company may, from time to time in the future, become subject to legal proceedings, claims, litigation and government investigations or inquiries, which could be expensive, lengthy and disruptive to normal business operations. In addition, the outcome of any legal proceedings, claims, litigation, investigations or inquiries may be difficult to predict and could have a material adverse effect on the Company's business, prospects, operating results or financial condition. In the future, the Company may also be subject to class actions, derivative actions and other securities litigation and investigations. The Company may be required to pay substantial awards, settlements or penalties and incur legal and other expenses causing a material adverse effect on its financial position, reputation, operations and liquidity.

Investors' ability to exercise statutory rights and remedies under Canadian securities laws:

The Company is incorporated in the province of Ontario in Canada. However, the subsidiaries of the Company, EPG, EPG Hong Kong and EPG Shenzhen are organized under the laws of jurisdictions outside of Canada and certain officers and directors of the Company, Nicky Canton and Karen Dunlap, reside outside of Canada. Furthermore, the Company's marketing plan and strategy involves the expansion into select emerging markets in the Middle East and Latin America. This may limit an investor's ability to exercise statutory rights and remedies under Canadian laws. In particular, a Canadian court may determine that it does not have jurisdiction over a claim by an investor against one of the Company's subsidiaries and/or its officers and directors, or that another international jurisdiction is the more convenient forum to adjudicate the claim.

Difficulty in enforcement of judgments:

The Company has subsidiaries incorporated in China, Hong Kong and the Netherlands. Certain directors and officers, including the Company's Chief Operating Officer Nicky Canton and the Company's director and Interim Chief Customer Officer Karen Dunlap, reside outside of Canada and substantially all of the assets of these persons are located outside of Canada. It may not be possible for shareholders to effect service of process against the Company's directors and officers who are not resident in Canada. In the event a judgment is obtained in Canada against one or more of our directors or officers for violations of Canadian securities laws or otherwise, it may not be possible to enforce such judgment against those directors and officers not resident in Canada.

Additionally, it may be difficult for an investor, or any other person or entity, to assert Canadian securities law claims or otherwise in original actions instituted in China, Hong Kong, the Netherlands, Middle East or Latin America. Courts in these jurisdictions may refuse to hear a claim based on a violation of Canadian securities laws or otherwise on the grounds that such jurisdiction is not the most appropriate forum to bring such a claim. Even if a court in an international jurisdiction agrees to hear a claim, it may determine that the local law, and not Canadian law, is applicable to the claim. If Canadian law is found to be applicable, the content of applicable Canadian law must be proven as a fact, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by the law in the relevant international jurisdiction.

Public health threats, economic and political conditions:

Worldwide financial and economic cycles or conditions are uncertain, and recovery from a business downturn or recession could be very slow and have a significant impact on the Company’s business. The Company’s business is sensitive to changes in economic and political conditions, including interest rates, currency issues, energy prices, trade issues, international or domestic conflicts or political crises, and epidemics or pandemics, such as the strain of COVID-19.

There can be no assurance that the Company’s personnel will not be impacted by these pandemic diseases and ultimately see its workforce productivity reduced or incur increased medical costs/insurance premiums as a result of these health risks. As well, there can be no assurance that the Company will not be impacted by adverse consequences that may be brought about by pandemics or public health crises on global financial markets which may reduce resources, share prices and financial liquidity that may severely limit the financing capital available in the industry that the Company operates in and the retail industry generally.

The credit and financial markets have experienced extreme volatility and disruptions due to the current conflict between Ukraine and Russia. The conflict is expected to have further global economic consequences, including but not limited to the possibility of severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in inflation rates and uncertainty about economic and political stability.

In addition, the United States and other countries have imposed sanctions on Russia which increases the risk that Russia, as a retaliatory action, may launch cyberattacks against the United

States, its government, infrastructure and businesses. Any of the foregoing consequences, including those we cannot yet predict, may cause our business, financial condition, results of operations and the price of our ordinary shares to be adversely affected.

Brexit Risk:

The United Kingdom has officially withdrawn its membership from the European Union ("**Brexit**"). The consequences of Brexit and the terms of the future trade agreements and other relationships with the European Union continue to be highly uncertain. Brexit could potentially disrupt the free movement of goods, services and people between the United Kingdom and the European Union, undermine bilateral cooperation in key geographic areas and significantly disrupt trade between the United Kingdom and the European Union or other nations as the United Kingdom pursues independent trade relations. Because this is an unprecedented event, it remains unclear what long-term economic, financial, trade and legal implications Brexit will have and how it will affect the regulation applicable to our business globally and in the region.

The impact on the Company will depend, in part, on the outcome of tariff, trade, regulatory and other negotiations. Any of these developments, along with any political, economic, and regulatory changes that may occur, could cause political and economic uncertainty in Europe and internationally and could adversely affect our sales in Europe and in the United Kingdom. Brexit's impact on the Company will depend, in part, on the outcome of tariff, trade, regulatory and other negotiations.

Finally, Brexit could lead to legal uncertainty and potentially divergent national laws and regulations as the United Kingdom determines which European Union laws to replace or replicate, and those laws and regulations may be cumbersome, difficult, or costly in terms of compliance. In addition, Brexit may lead other European Union member countries to consider referendums regarding their European Union membership. Any of these effects of Brexit, and others we cannot anticipate, could adversely affect our business, results of operations, financial condition, and cash flows.

Reliance on management and key employees:

The Company's future success depends substantially on the continued services of its executive officers and its key personnel. If one or more of its executive officers or key personnel were unable or unwilling to continue in their present positions, the Company might not be able to replace them easily or at all.

In addition, if any of its executive officers or key employees joins a competitor or forms a competing company, the Company may lose know-how, key professionals and staff members as well as business partners. These executive officers and key employees could develop technologies or business models that could compete with and take customers, market share and market opportunity away from the Company.

The Company believes that there are only a limited number of people with the requisite skills to serve in many key positions and it is difficult to hire and retain these people. The loss of one or more of these key personnel may have a significant adverse effect on the Company's sales, operations and profits.

The Company's success is partially dependent on its ability to attract and retain key personnel. There can be no assurance that these business relationships will continue to be maintained or that new ones will be successfully formed. A breach or disruption in these relationships or failure to engage contractors could be detrimental to the future business, operating results and/or profitability of the Company.

Management of growth:

The Company may experience a period of significant growth in the number of personnel which will place a strain upon its management systems and resources. Its future will depend in part on the ability of its officers and other key employees to implement and improve financial and management controls, reporting systems and procedures on a timely basis and to expand, train, motivate and manage the workforce. The Company's current and planned personnel, systems, procedures and controls may be inadequate to support its future operations.

Ability to complete favourable acquisitions:

As part of the Company's overall business strategy, the Company may pursue select strategic acquisitions that would provide additional product or service offerings, additional industry expertise, and a stronger industry presence in both existing and new jurisdictions. Future acquisitions may expose it to potential risks, including risks associated with: (a) the integration of new operations, services and personnel; (b) unforeseen or hidden liabilities; (c) the diversion of resources from the Company's existing business; (d) potential inability to generate sufficient revenue to offset new costs; (e) the expenses of acquisitions; or (f) the potential loss of or harm to relationships with both employees and existing users resulting from its integration of new businesses. In addition, any proposed acquisitions may be subject to regulatory approval.

The Company may attempt to acquire businesses that it believes are a strategic fit with its business. However, the Company may not be able to complete such acquisitions on favourable terms, or at all. Any future acquisitions may result in unforeseen operating difficulties and expenditures, and may absorb significant management attention that would otherwise be available for ongoing development of its business. Since the Company may not be able to accurately predict these difficulties and expenditures, these costs may outweigh the value it realizes from a future acquisition.

Future acquisitions could result in issuances of securities that would dilute shareholders' ownership interest, the incurrence of debt, contingent liabilities, amortization of expenses related to other intangible assets, and the incurrence of large, immediate write-offs.

Difficulties integrating acquisitions:

The benefits of an acquisition or strategic investment of the Company may require considerable time to develop, and the Company cannot be certain that its acquisitions will produce the intended benefits or any benefits at all. The Company's past and future acquisition of other businesses and technologies could result in adverse effects to the Company's financial position.

Marketing risks:

Achieving market success will require substantial marketing efforts and the expenditure of funds to inform potential customers of the distinctive benefits and characteristics of the Company's products and services.

The Company's long-term success will depend on its ability to expand current marketing capabilities. The Company will, among other things, need to attract and retain experienced marketing and sales personnel. No assurance can be given that the Company will be able to attract and retain such personnel or that any efforts undertaken by such personnel will be successful.

Any negative publicity about the Company or its industry, the quality and reliability of the Company's technologies, products and services, the Company's risk management processes, changes to the Company's technologies, products and services, its ability to effectively manage and resolve customer complaints, its privacy and security practices, litigation, regulatory activity, and the experience of sellers and buyers with the Company's products or services, could adversely affect the Company's reputation and the confidence in and use of the Company's technologies, products and services.

Privacy Protection:

As a routine element of the Company's business, the Company or its third-party service providers collect, analyze, and retain substantial amounts of data and sensitive personal information relating to clients, suppliers, contractors, and employees. Any perceived, attempted, or actual unauthorized disclosure of client data or sensitive personal information could constitute a breach of contract, harm the Company's reputation and credibility, reduce the Company's ability to attract and retain clients and could result in litigation against the Company or the imposition of significant fines or penalties.

The Company believes that it has taken appropriate measures to protect against unauthorized disclosure of client data and sensitive personal information; however, those measures may not adequately protect computer systems from a breach. The Company's risk and exposure to these matters cannot be fully mitigated because of, among other things, the evolving nature of these threats. As a result, cyber security and the continued development and enhancement of controls, processes and practices designed to protect systems, computers, software, data and networks from attack, damage or unauthorized access is a priority. As cyber threats continue to evolve, the Company may be required to expend additional resources to continue to modify or enhance protective measures or to investigate and remediate any security vulnerabilities.

Forward-looking information may prove inaccurate:

Readers are cautioned not to place undue reliance on forward-looking information. By its nature, forward-looking information involves numerous assumptions, known and unknown risks and uncertainties, of both a general and specific nature, that could cause actual results to differ materially from those suggested by the forward-looking information or contribute to the possibility that predictions, forecasts or projections will prove to be materially inaccurate. Additional information on the risks, assumptions and uncertainties can be found in this AIF under the heading "*Forward-Looking Information*".

Risks Related to Doing Business in China

Conditions in China:

A portion of the Company's operations (including manufacturing) are carried out in China. Accordingly, the Company's business, financial condition and financial performance may be influenced by the political, economic and legal environments in China, and by the general state of the Chinese economy. The Company's business may be influenced by changes in governmental policies with respect to laws and regulations, anti-inflationary measures, currency conversion and remittance abroad, and rates and methods of taxation, among other things.

The Chinese government imposes controls on the convertibility of Renminbi ("**RMB**") into foreign currencies and, in certain cases, the remittance of currency out of China. The Company anticipates that in future a portion of its revenues will be in RMB, which is currently not a freely convertible currency. Under existing Chinese foreign exchange regulations, payment of current account items, including profit distributions, interest payments and expenditures, can be made in foreign currencies without prior approval from the China State Administration of Foreign Exchange by complying with certain procedural requirements. However, approval from appropriate governmental authorities is required where RMB is to be converted into foreign currency and remitted out of China to pay capital account items, such as the repayment of loans denominated in foreign currencies. The Chinese government may also at its discretion restrict access in the future to foreign currencies for current account transactions.

The Chinese legal system is a system based on written statutes. They are interpreted by the Supreme Peoples' Court and prior court decisions may be cited for reference. Since 1979, the Chinese government has been developing a comprehensive system of commercial laws, and considerable progress has been made in introducing laws and regulations dealing with economic matters such as foreign investment, corporate organization and governance, commerce, taxation and trade. However, because these laws and regulations are relatively new, and because of the limited volume of published cases and their non-binding nature, the interpretation and enforcement of these laws and regulations involve uncertainties. This may result in the outcome of dispute resolutions not being consistent or predictable as compared to more developed jurisdictions. Furthermore, laws and regulations may have a retroactive effect such that the Company is not aware of any violation by it until sometime after the violation has occurred. As the Chinese legal system develops, changes in such laws and regulations, their interpretation, or their enforcement, may have a material effect on the Company.

Intellectual property rights in China are still developing and there are uncertainties involved in intellectual property rights protection and the enforcement of such protection. The Company must pay special attention to protecting its intellectual property and trade secrets. Failure to do so could lead to the loss of a competitive advantage that may not be compensated for by a damages award.

In China, companies with a foreign ownership component could be required to work within a framework which is different from that imposed on local companies. The Chinese government is opening up opportunities for foreign investment and this process is expected to continue, especially as a result of China's entry into the World Trade Organization. If the Chinese government reverses the current trend of permitting foreign investment and imposes greater restrictions on foreign companies, the Company's ability to conduct business in China could be negatively affected.

Changes, if any, in investment policies or shifts in political attitude in China may adversely affect the Company's business, results of operations and financial condition. Operations may be affected in varying degrees by government regulations with respect to, but not limited to, restrictions on production, price controls, income taxes, foreign investment, bank lending, export controls, and usage and costs of state-controlled transportation services and nationalization or expropriation of property or business. Any events resulting in an adverse impact on the Chinese economy may have an adverse effect on the Company's profitability and prospects.

The economy of China has experienced significant growth in the past 20 years, however, growth has been uneven, both geographically and among various sectors of the economy. The Chinese government has implemented various measures from time to time in order to try and encourage or control economic growth and guide the allocation of resources, including certain measures which were put in place to restrict bank lending. Some of these measures may negatively affect the Company. In addition, such control measures may have a general adverse impact on the Chinese economy that would, in turn, likely have an adverse impact on the Company's business, results of operations and financial condition. Rapid economic growth can lead to growth in the supply of money and rising inflation. If the Company's costs rise disproportionately to its product prices, the Company's business may be materially and adversely affected.

Permits and Business Licenses:

EPG Shenzhen holds various permits, business licenses and approvals authorizing their operations and activities, which are subject to periodic review and reassessment by the Chinese authorities. Standards of compliance necessary to pass such reviews change from time to time and differ from jurisdiction to jurisdiction, leading to a degree of uncertainty. If renewals, or new permits, business licenses or approvals required in connection with existing or new facilities or activities, are not granted or are delayed, or if existing permits, business licenses or approvals are revoked or substantially modified, the Company could suffer a material adverse effect. If new standards are applied to renewals or new applications, it could prove costly to the Company to meet any new level of compliance.

Misuse of China Chops

In China, a “chop” is a stamp with the company name as it appears on its Business License. The chop is used by the company to stamp the documents it gives to third parties. In Hong Kong, there is no legal obligation to create, register or use chops, and the use of chops depends on the specific requirements of a contract being executed by the company; as such, an authorized signature prevails over the chop. Under the Chinese laws, each company is required to create and register the company's official chop after its establishment. The chop needs to be engraved by a qualified agency in China and registered in the local police department. Only the registered official chop has legal effect to bind the company.

EPG Shenzhen and EPG Hong Kong (the “**Chinese Subsidiaries**”) have such chops (the “**China Chops**”) which are essential to doing business in China, including entering into contracts, conducting banking activities and undertaking day-to-day business activities.

Under Chinese laws, in the event a chop is lost, stolen or misplaced, the legal representative will: (i) cause the company who owned the lost chop in China to publish an announcement of the loss of chops in designated newspapers; (ii) apply to the local Public Security Bureau for the carving of new chops; and (iii) carve the new chops at places designated by the Public Security Bureau. As the chop replacement process would take approximately five business days, there can be no assurance that there would be no adverse effect on the business, results of operations or financial condition of the Company due to such disruptions of business.

The China Chops are essential to the Chinese Subsidiaries’ ability to enter into contracts, conduct banking activities and undertake day-to-day corporate and business activities. Although the Company has implemented such internal control procedures as it feels necessary to monitor the authorized personnel and the use of the China Chops, there is no assurance that such procedures will prevent all instances of abuse or negligence. Accordingly, if any of the Chinese Subsidiaries’ authorized personnel misuse or misappropriate the chops, the Company could experience significant disruption to operations until the Chinese Chops are replaced.

If, in particular, during any period the Company loses effective control of the Chinese Subsidiaries as a result of such misuse or misappropriation, the business activities and economic contribution of such entity could be severely disrupted and the Company may not be able to recover corporate assets that are sold or transferred out of the Company’s control in the event of such misappropriation and the Company may not have the financial resources to recover such assets or take appropriate legal action. Funds will be sent to China to fund EPG Shenzhen's working capital requirements as and when needed, and in alignment with the Company’s corporate controls for items ranging from working capital to research and development. The funds will be kept in a bank account at the Bank of China. The Company currently estimates that not more than $100,000 will be kept in China at any given time, except as may be related to inter-company loans received in excess of such amount in the ordinary course of business, to ensure that the Company is able to continue as a going concern should they need to recover corporate assets of the Chinese Subsidiaries.

In addition, while the Company has procedures in place with its banks in China such that no funds can be transferred with the use of the Finance Chop alone (as an authorized signature from Nicky Canton, the Company's Chief Operating Officer, is also required), if the Company loses effective control of the Finance Chop, the legal representative will promptly notify the relevant bank that the Finance Chop has been lost, misplaced or stolen and if one of the authorized signatories is implicated, that such individual is no longer an authorized signatory. In addition, the Company will be able to assume control over the Chinese Subsidiaries' bank accounts through the combined use of the Company Chop and the Legal Representative Chop. Despite the foregoing, however, the Chinese Subsidiaries may experience temporary delays in accessing bank accounts in China.

This risk is significantly mitigated by the requirement for the signatures in conjunction with the use of the Finance Chop in banking matters. Additionally, the Company's external auditor may be unable to access documents and information from such entities that may be necessary to complete an audit of the consolidated financial statements of the Company.

Cost of Labour:

The labour and employment market in China is dynamic. Labour costs in China have traditionally been significantly less than those in other more developed countries; however, such costs have begun to rise and there is no guarantee that they will not continue to rise. Any such increased cost could have an adverse effect on the Company as a result of manufacturing operations in China. Also, in the future, changes in the labour and employment market in China may be imposed or labour disputes may arise. Such events may increase costs of operation and affect the Company's business, results of operations and financial condition.

Enforcing Rights and Judgements in China:

EPG Shenzhen is subject to Chinese company law and regulations. Company law in general and, in particular, provisions for the protection of shareholder's rights and access to information are less developed than those applicable to companies in some other countries. China does not have a treaty with Canada providing for the reciprocal recognition and enforcement of judgments of courts and as such, recognition and enforcement in China of judgments of a Canadian court in relation to any matter not subject to a binding arbitration provision may be difficult or impossible. Investors may be effectively prevented from pursuing remedies against the Company under Canadian securities laws or otherwise.

Risks Related to the Securities of the Company

Requirements of being a public company:

Compliance with applicable securities legislation of the jurisdictions in which the Company is a reporting issuer, listing requirements of the TSXV and other rules and regulations pertaining to continuous disclosure and internal management of the Company may require significant resources and management oversight. Additional employees and consultants, and enhanced controls and procedures may be required to comply with these requirements, increasing the Company's costs and expenses.

Continued uncertainty may arise from changing laws, regulations and standards in connection with the Company's securities or its corporate governance, increasing its legal and financial compliance costs.

Share price volatility risk:

The Company being listed on the TSXV, external factors outside of the Company's control, such as announcements of quarterly variations in operating results, revenues and costs, and sentiments toward stocks, may have a significant impact on the market price of the Common Shares. Global stock markets, including the TSXV, have experienced extreme price and volume fluctuations from time to time. There can be no assurance that an active or liquid market will develop or be sustained for Common Shares.

Resale of Common Shares:

There can be no assurance that the publicly traded market price of the Common Shares will be high enough to create a positive return for shareholders. Further, there can be no assurance that the Common Shares will be sufficiently liquid so as to permit shareholders to sell their equity position in the Company without adversely affecting the stock price. In such event, the probability of resale of the Common Shares would be diminished.

As well, the continued operation of the Company will be dependent upon its ability to procure additional financing in the short term and to generate operating revenues in the longer term. There can be no assurance that any such financing can be obtained or that revenues can be generated. If the Company is unable to obtain such additional financing or generate such revenues, shareholders may be unable to sell their Common Shares and any investment in the Company may be lost.

Speculative nature of investment:

An investment in the shares of the Company carries a high degree of risk and should be considered as a speculative investment. The Company has no history of earnings, limited cash reserves, a limited operating history, has not paid dividends, and is unlikely to pay dividends in the immediate or near future.

Market risk for securities:

There can be no assurance that an active trading market for the Common Shares will be established and sustained and the market price for the Common Shares could be subject to wide fluctuations. Factors such as government regulation, interest rates, share price movements of peer companies and competitors, as well as overall market movements, may have a significant impact on the market price of the Company’s securities. The stock market has from time-to-time experienced extreme price and volume fluctuations, which have often been unrelated to the operating performance of particular companies.

Global financial conditions:

Current global financial conditions have been subject to increased volatility and access to financial markets has been restricted. These factors may impact the ability of the Company to obtain equity or debt financing in the future and, if obtained, on terms favourable to the Company. If these levels of volatility and market instability continue, the Company's operations could be adversely impacted, and the value and the price of the Common Shares could continue to be adversely affected.

Uncertainty and adverse changes in the economy:

Adverse changes in the economy could negatively impact the Company’s business and the value and price of the Common Shares. Future economic distress may result in a decrease in demand for the Company’s products or services, which could have a material adverse impact on the Company’s operating results and financial condition.

Uncertainty and adverse changes in the economy could also increase costs associated with developing and publishing products, increase the cost and decrease the availability of sources of financing, and increase the Company's exposure to material losses from bad debts, any of which could have a material adverse impact on the financial condition and operating results of the Company.

The demand for entertainment and leisure activities tends to be highly sensitive to changes in consumers' disposable income, and thus can be affected by changes in the economy and consumer tastes, both of which are difficult to predict and beyond the Company's control. Unfavorable changes in general economic conditions, including recessions, economic slowdown, sustained high levels of unemployment, and increasing fuel or transportation costs, may reduce customers' disposable income or result in fewer individuals engaging in entertainment and leisure activities. As a result, the Company cannot ensure that demand for the products or services of its investees will remain constant.

Continued or renewed adverse developments affecting economies throughout the world, including a general tightening of availability of credit, decreased liquidity in many financial markets, increasing interest rates, increasing energy costs, acts of war or terrorism, transportation disruptions, natural disasters, declining consumer confidence, sustained high levels of unemployment or significant declines in stock markets, could lead to a further reduction in discretionary spending on leisure activities, such as gaming. Any significant or prolonged decrease in consumer spending on entertainment or leisure activities could adversely affect the Company's investment returns, cash flows, revenues and the value of the Company's Common Shares.

Dilution from further equity financing and declining share price:

The Company is authorized to issue an unlimited number of Common Shares for such consideration and on such terms and conditions as shall be established by the directors without the approval of shareholders, except as may be required by the securities laws or regulations. The Company may also make future acquisition and issue securities as consideration. Accordingly, holders of Common Shares may suffer dilution.

If the Company raises additional financing through the issuance of equity securities (including securities convertible into or exchangeable for equity securities) or completes an acquisition or merger by issuing additional equity securities, such issuance may substantially dilute the interests of shareholders and reduce the value of their investment. The market price of the Common Shares could decline as a result of issuances of new equity securities or sales by existing shareholders of Common Shares in the market or the perception that such sales could occur. We cannot predict the effect, if any, that future public sales of equity securities or the availability of those securities for sale will have on the market price of the Common Shares. If the market price of the Common Shares were to drop as a result, this might impede our ability to raise additional capital and might cause the remaining shareholders to lose all or part of their investment. Sales by shareholders might also make it more difficult for the Company itself to sell equity securities at a time and price that it deems appropriate.

If additional funds are raised through the issuance of preferred stock or debt securities, these securities are likely to have rights, preferences and privileges senior to Common Shares and may involve significant fees, interest expense, restrictive covenants and the granting of security interests in the Company's assets.

Uncertainty of use of proceeds:

Although the Company has set out its intended use of proceeds from private placements, these intended uses are estimates only and subject to change. While management does not contemplate any material variation, management does retain broad discretion in the application of such proceeds. The failure by the Company to apply these funds effectively could have a material adverse effect on the Company's business, including the ability to achieve its stated business objectives.

Variable revenues and earnings:

The revenues and earnings of the Company may fluctuate from quarter to quarter, which could affect the market price of Common Shares. Revenues and earnings may vary quarter to quarter as a result of a number of factors, including the timing of releases of new products or services, competitors' activities, cyclical fluctuations related to the evolution of the industry and technologies, transition periods associated with the migration to new technologies, impairment of goodwill or intangible assets which may result in a significant change to earnings in the period in which an impairment is determined, and operating expenses that are generally fixed in the short-term and therefore difficult to rapidly adjust to different levels of business.

Any of the factors listed above could cause significant variations to the Company's revenues, gross margins and earnings in any given quarter.

Tax considerations:

Each prospective investor should consult with its own tax advisor with respect to the Canadian and non-Canadian income tax consequences of acquiring, holding, and disposing of the Company's Common Shares, based on each prospective investor's particular circumstances.

Dividends:

To date, the Company has not paid any dividends on its outstanding Common Shares and presently has no intention of paying dividends. Any decision to pay dividends on the Common Shares will be made by the board of directors of the Company on the basis of its earnings, financial requirements and other conditions.

Financial Risk Factors

Liquidity and future financing:

Although the Company expects to become profitable, there is no guarantee that will happen, and it may never become profitable. The Company currently has a negative operating cash flow and may continue to have that for the foreseeable future. To date, the Company has modest revenues, and a large portion of its expenses are fixed, including expenses related to facilities, equipment, contractual commitments and personnel. As a result, the Company expects its net losses from operations to improve.

The Company will likely operate at a loss until its business becomes established and the Company will require additional financing in order to fund future operations and expansion plans. The Company's ability to secure any required financing to sustain operations will depend in part upon prevailing capital market conditions and business success. There can be no assurance that the Company will be successful in its efforts to secure any additional financing or additional financing on terms satisfactory to management. If additional financing is raised by issuance of additional shares from treasury, control may change and shareholders may suffer dilution. If adequate funds are not available, or are not available on acceptable terms, the Company may be required to scale back its current business plan or cease operations.

Conducting the costly and time-consuming research, pre-clinical and clinical testing necessary to obtain regulatory approvals and bringing the needle-free medical technology and products to market will require a commitment of substantial funds in excess of the Company's current capital. The Company's future capital requirements will depend on many factors, including, among others:

- the progress of current and new product development programs;
- the progress, scope and results of pre-clinical and clinical testing;
- the time and cost involved in obtaining regulatory approvals;
- the cost of manufacturing existing products and new products;
- the cost of prosecuting, enforcing and defending against patent infringement claims and
- other intellectual property rights;
- competing technological and market developments; and
- the Company's ability to establish and maintain collaborative and other arrangements with third parties to assist in potentially bringing our products to market.

Additional financing may not be available on acceptable terms, or at all. Domestic and international capital markets have been experiencing heightened volatility and turmoil, making it more difficult to raise capital through the issuance of equity securities. Furthermore, as a result of the recent volatility in the capital markets, the cost and availability of credit has been and may continue to be adversely affected by illiquid credit markets and wider credit spreads. Concern about the stability of the markets generally and the strength of counterparties specifically has led many lenders and institutional investors to reduce, and in some cases cease to provide, funding to borrowers.

Fluctuating interest rates could also increase the costs of any debt financing. Raising capital through a licensing or other transaction involving the Company's intellectual property could require the Company to relinquish valuable intellectual property rights and thereby sacrifice long-term value for short-term liquidity.

The Company's failure to successfully address ongoing liquidity requirements would have a substantially negative impact on its business. If the Company is unable to obtain additional capital on acceptable terms when needed, it may need to take actions that adversely affect its business, stock price and ability to achieve cash flow in the future, including possibly surrendering its rights to some technologies or product opportunities, delaying clinical trials or curtailing or ceasing operations.

Going-concern:

As the Company is still in its development phase working on developing markets and finding distribution networks, the Company will likely operate at a loss until its business becomes established, and the Company will require additional financing in order to fund future operations and expansion plans. These conditions indicate the existence of a material uncertainty that may cast significant doubt about the Company's ability to continue as a going concern.

Tax risk:

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

Credit risk:

Credit risk is the risk of loss associated with a counterparty's inability to fulfill its payment obligations. The Company's credit risk is primarily attributable to cash, and accounts receivable. Cash consists of cash on hand deposited with reputable financial institutions which is closely monitored by management. Management believes credit risk with respect to financial instruments included in cash and accounts receivable is minimal. The Company's maximum exposure to credit risk as at the date of this AIF is the carrying value of its cash and receivables.

Liquidity risk:

Liquidity risk is the risk that the Company will encounter difficulty in satisfying its financial obligations. The Company manages its liquidity risk by forecasting it operations and anticipating its operating and investing activities.

Foreign currency:

The Company is exposed to transactional foreign currency risk to the extent that there is a mismatch between the currencies in which sales, purchases, receivables and borrowings are denominated and the respective functional currencies of the Company's subsidiaries. The functional currencies of the Company's subsidiaries are primarily Canadian dollars, Euros and RMB.

This risk is mitigated by timely payment of creditors and monitoring of foreign exchange fluctuations by management. The Company is exposed to unrealized foreign exchange risk through its U.S. dollar, and Euros cash holdings, as well as receivables, payables, long-term debt and convertible debenture in Euros.

Fluctuations in the exchange rate between the Canadian dollar and other currencies such as Euros or the RMB may also have a material adverse effect on the Company's business, prospects, financial condition and operating results in the future. The Company intends to continue to expand operations globally so it may be subject to additional gains and losses against additional currencies. The Company does not currently have a foreign exchange hedging program in place.

However, in the future, it may establish a program to hedge a portion of its foreign currency exposure with the objective of minimizing the impact of adverse foreign currency exchange movements. However, even if the Company develops a hedging program, it may not hedge its entire exposure to any one foreign currency and it may not hedge its exposure at all with respect to certain foreign currencies.

Interest rate risk:

Interest rate risk consists of a) the extent that payments made or received on the Company's monetary assets and liabilities are affected by changes in the prevailing market interest rates, and b) to the extent that changes in prevailing market rates differ from the interest rate in the Company's monetary assets and liabilities. The Company is not exposed to any significant interest rate price risk.

DIVIDENDS AND DISTRIBUTIONS

The Company has never paid any dividends or distributions on any of its securities and presently has no intention of paying dividends. The future dividend policy will be determined by the board of directors of the Company on the basis of earnings, financial requirements and other relevant factors.

DESCRIPTION OF CAPITAL STRUCTURE

General

The authorized share capital of the Company consists of an unlimited number of Common Shares without par value issuable in series. As at December 31, 2022, there were 96,563,460 Common Shares issued and outstanding, and as of the date hereof there are 198,325,682 Common Shares issued and outstanding.

Common Shares

Each Common Share is entitled to one vote at meetings of shareholders and carries with it equal rights with respect to dividends, if any, and residual interests upon dissolution of the Company. Holders of the Common Shares have no pre-emptive rights, nor any right to convert their Common Shares into other securities. There is no restriction on the ability of the Company to pay dividends other than cash flow considerations. Any dividend payments in the future will depend on the Company's ability to continue as a going concern and to generate earnings, as well as capital investment requirements.

Warrants

As of the date of this AIF, the Company currently has the following warrants outstanding on the terms set out below:

Number of Warrants[1]	Exercise Price	Expiry Date
4,239,080[2]	$0.30	July 22, 2024
2,291,763[3]	$0.30	September 8, 2024
23,710,000	$0.05	February 14, 2025
22,222,222	$0.24	April 25, 2025[5]
1,306,624[4]	$0.18	April 25, 2025[5]
2,500,000	$0.24	May 18, 2025[5]
174,835[4]	$0.18	May 18, 2025[5]
2,500,000	$0.05	December 28, 2027
TOTAL: 58,944,524		

Notes:

(1) Except as otherwise indicated in the following notes, each warrant is exercisable into one Common Share.

(2) 4,118,000 warrants and 121,080 broker warrants.

(3) 2,285,763 warrants and 6,000 broker warrants.

(4) Broker warrants, each exercisable into one unit of the Company comprised of one Common Share and one Common Share purchase warrant exercisable at a price of $0.24 per Common Share.

(5) Subject to acceleration in certain events.

Stock Options

As of the date of this AIF, the Company currently has the following stock options outstanding, each such stock option exercisable for one Common Share, on the terms set out below:

Number of options	Exercise price	Expiry date
1,270,000	$0.40	December 1, 2023
700,000	$0.40	December 1, 2026
750,000	$0.40	January 24, 2024
1,000,000	$0.05	February 24, 2024
200,000	$0.20	June 2, 2024

Number of options	Exercise price	Expiry date
2,250,000	$0.05	December 13, 2027
2,000,000	$0.05	December 21, 2027
5,725,000	$0.20	February 28, 2028
2,000,000	$0.20	June 26, 2028
350,000	$0.20	July 24, 2028
TOTAL: 16,245,000		

Options outstanding were issued pursuant to the Company's stock option plan (the "**Stock Option Plan**"). The Stock Option Plan permits the reservation of a maximum of 10% of the issued and outstanding Common Shares at any given time. The number of Common Shares reserved for issue in any 12-month period shall not exceed (i) five percent of the issued and outstanding Common Shares to any one director, officer, employee, management company employee or consultant (a "**Service Provider**"); (ii) two percent of the issued and outstanding Common Shares to any one consultant retained by the Company; or (iii) two percent of the issued and outstanding Common Shares to any one Service Provider of the Company conducting "Investor Relations Activities".

The board of directors of the Company determines the price per Common Share and the number of Common Shares which may be allotted to each director, officer, employee and consultant and all of other terms and conditions of the stock option, subject to the rules of the TSXV. The exercise price per Common Share set by the board of directors of the Company may not be less than the Discounted Market Price (as such term is defined in Policy 1.1. of the TSXV.

Stock options under the Stock Option Plan are non-assignable. Stock options must be exercised within 90 days of termination of employment with the Company, provided that such options vested before the termination date. If the cessation of office, directorship, consulting arrangement or employment was by reason of death, stock options must be exercised within 12 months after such death, subject to the expiry of such stock option. In the case of an optionee being dismissed from employment or service for Cause (as defined in the Stock Option Plan), stock options, whether vested or not, will immediately terminate on the date of cessation without right to exercise same.

MARKET FOR SECURITIES

Trading Price and Volume

Common Shares:

The following table sets out the high and low closing market prices and the volume traded of the Common Shares on the TSXV for each month of the financial year ended December 31, 2022:

Month (2022)	High ($)	Low ($)	Volume
January	0.31	0.18	1,420,733
February	0.29	0.18	1,198,709
March	0.29	0.20	2,300,472
April	0.25	0.20	484,736
May	0.21	0.15	532,132
June	0.15	0.08	978,006
July	0.15	0.095	575,742
August	0.12	0.06	706,437
September	0.09	0.06	595,973
October	0.09	0.06	241,630
November	0.10	0.065	332,710
December	0.06	0.04	859,789

Prior Sales

The following table summarizes details of all issuances of securities of the Company, other than Common Shares, in the year ended December 31, 2022, being the most recently completed financial year of the Company:

Issue Date	Securities	Issue Price	Number of Securities
July 22, 2022	Warrants	$0.10	4,118,000
July 22, 2022	Broker Warrants	$0.30(1)	121,080
September 8, 2022	Warrants	$0.10	2,285,763
September 8, 2022	Broker Warrants	$0.30(1)	6,000
December 14, 2022	Options	$0.05(1)	4,000,000
December 22, 2022	Options	$0.05(1)	2,000,000
December 28, 2022	Warrants	$0.05(1)	2,500,000

Notes:
(1) Exercise price.

ESCROWED SECURITIES

Class of Shares	Number of Securities Subject to Restrictions on Transfer	Percentage of Class
Common Shares	11,519,687	5.81%

The escrowed securities are Common Shares issued by the Company in connection with the Qualifying Transaction. 3,468,750 Common Shares are currently held in escrow pursuant to a value security escrow agreement dated November 2, 2021 (the "**Value Escrow Agreement**") and 8,050,937 Common Shares are currently held in escrow pursuant to a surplus security escrow agreement dated November 2, 2021 (the "**Surplus Escrow Agreement**"). Computershare Investor Services Inc. acts as escrow agent for all escrowed securities.

The escrowed securities will be released in accordance with the following schedules:

Escrowed securities – Qualifying Transaction Value Security Escrow Agreement		
Release Date	**Percentage of total escrowed securities to be released**	**Number of escrowed securities to be released**
November 4, 2023	15%	1,156,250
May 4, 2024	15%	1,156,250
November 4, 2024	15%	1,156,250

Escrowed securities – Qualifying Transaction Surplus Security Escrow Agreement		
Release Date	**Percentage of total escrowed securities to be released**	**Number of escrowed securities to be released**
November 4, 2023	15%	1,725,201
May 4, 2024	15%	1,725,200
November 4, 2024	40%	4,600,536

DIRECTORS AND OFFICERS

Name, Occupation and Security Holdings

The following table sets out the name, province or state and country of residence, position(s) and office(s) held with the Company and principal occupations during the preceding five years of each director and executive officer of the Company.

Name, Province or State and Country of Residence	Position/Title with the Company	Principal Occupation During Preceding Five Years	Served as Director of the Company since
Richard Buzbuzian (1) Ontario, Canada	President, Chief Executive Officer, and Director	President, Chief Executive Officer, and Director of the Company. Capital markets executive with over 25 years of experience in Canada and Europe. Previously, Mr. Buzbuzian was President of Drone Delivery Canada Corp. Mr. Buzbuzian sits on the boards of certain public, private, and nonprofit organizations including Give-A-Mile and the Richard and Jacob Buzbuzian Family Foundation.	February 22, 2023

Name, Province or State and Country of Residence	Position/Title with the Company	Principal Occupation During Preceding Five Years	Served as Director of the Company since
Tony Di Benedetto Ontario, Canada	Executive Chairman and Director	Executive Chairman and Director of the Company. Chief Executive Officer of Launch Capital Inc. Mr. Di Benedetto was the co-founder of Drone Delivery Canada Corp. Mr. Di Benedetto has also cofounded technology companies including Data Centers Canada – a colocation data center facility in Vaughan, Ontario.	February 22, 2023
Karen Dunlap California, United States	Interim Chief Customer Officer and Director	Interim Chief Customer Officer of the Company and president and member of the board of directors of KLD & Associates.	October 19, 2021
John Leombruno(1) Ontario, Canada	Director	Pharmacist and Chief Executive Officer of Leven Systems Inc. / OkRx.(2)	October 19, 2021
Philip Cortese(1) Quebec, Canada	Director	Real Estate Consultant at OVCO Group Inc. banker with over 30 years of experience in the Financial Institution Industry. He has held senior managerial positions at RBC, TD Bank and CIBC for over half of those years.	January 24, 2023
Chris Irwin Ontario, Canada	Director	Partner at Irwin Lowy LLP.(3)	June 20, 2023
Nicky Canton Netherlands	Chief Operating Officer	Chief Operating Officer of the Company. Mr. Canton has been working for the Company's subsidiary, EPG, for the past 13 years.	Not applicable
Veronique Laberge Quebec, Canada	Chief Financial Officer and Secretary	Chief Financial Officer of the Company since May 3, 2021. Mrs. Laberge has been working as a fractional CFO for multiple public and private companies since 2018. She was CFO of Dunton Rainville LLP from 2016 to 2018.	Not applicable.

Notes:
(1) Member of the Audit Committee.
(2) The principal occupation of Mr. Leombruno is acting as Chief Executive Officer of Leven Systems Inc., a healthcare consulting and software development company.
(3) The principal occupation of Mr. Irwin is acting as Partner at Irwin Lowy LLP, a boutique securities law firm.

Each director holds office until the next annual meeting of shareholders following his or her election unless his or her office is earlier vacated in accordance with the by-laws of the Company.

As at the date of this AIF, the directors and executive officers of the Company, as a group, beneficially owned, controlled or directed, directly or indirectly, 16,275,214 Common Shares, representing approximately 8.21% of the outstanding Common Shares.

Cease Trade Orders, Bankruptcies, Penalties or Sanctions

Cease Trade Orders:

For the purposes of this section "**Order**" means:

(a) a cease trade order;

(b) an order similar to a cease trade order; or

(c) an order that denied the relevant company access to any exemption under securities legislation;

that was in effect for more than 30 days.

Except as disclosed below with respect to Mr. Irwin, no director or executive officer of the Company, within 10 years before the date of this AIF, has been a director, chief executive officer or chief financial officer of any company that was subject to an Order that was issued:

(a) while the proposed director was acting in the capacity as director, chief executive officer or chief financial officer; or

(b) after the proposed director 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.

Mr. Irwin was a director from June 2015 to December 2017 and Secretary from September 2015 to April 2016 of Playground Ventures Inc. (formerly, Blocplay Entertainment Inc.), which was subject to:

(a) a management cease trade order resulting from a failure to file financial statements as issued on May 2, 2016 by the British Columbia Securities Commission and May 4, 2016 and May 16, 2016 by the Ontario Securities Commission. These cease trade orders were revoked on July 5, 2016 by the British Columbia Securities Commission and July 6, 2016 by the Ontario Securities Commission; and

(b) a management cease trade order resulting from a failure to file financial statements as issued on May 2, 2017 by the British Columbia Securities Commission and May 4, 2017 by the Ontario Securities Commission. These cease trade orders were revoked on July 5, 2017 by the British Columbia Securities Commission and July 6, 2017 by the Ontario Securities Commission.

Mr. Irwin is President, Chief Executive President, Secretary and a Director of Playground Ventures Inc. (formerly, Blocplay Entertainment Inc.), which was subject to a management cease trade order resulting from a failure to file financial statements as issued on December 3, 2018 and amended on December 4, 2018 by the British Columbia Securities Commission and December 4, 2018 by the Ontario Securities Commission. These cease trade orders were revoked on February 6, 2019.

Mr. Irwin is a director and an officer of Intercontinental Gold and Metals Ltd., which was subject to:

(a) a management cease trade order resulting from a failure to file financial statements as issued by the British Columbia Securities Commission on July 30, 2015. The cease trade order was revoked on September 22, 2015.

(b) a management cease trade order resulting from a failure to file financial statements as issued on August 2, 2018 by the British Columbia Securities Commission. Intercontinental was subject to a cease trade order from a failure to file financial statements as issued on October 5, 2018 by the British Columbia Securities Commission. These cease trade orders were revoked on October 9, 2018.

(c) a cease trade order resulting from a failure to file its annual financial statements and accompanying management’s discussion and analysis for the period ended December 31, 2021, within the prescribed time period under applicable securities laws, issued on May 6, 2022 by the British Columbia Securities Commission. As of the date of this personal information form, this cease trade order has not been revoked.

Mr. Irwin was a director of Wolf’s Den Capital Corp., which was subject to a cease trade order issued by the British Columbia Securities Commission and Ontario Securities Commission on December 5, 2019 for failure to file its condensed interim financial statements and accompanying management's discussion and analysis for the period ended September 30, 2019, within the prescribed time period under applicable securities laws. The cease trade orders were revoked on January 6, 2020.

Mr. Irwin was a director of American Aires Inc., which was subject to a cease trade order issued by the Ontario Securities Commission on May 6, 2022 for failure to file its annual financial statements and accompanying management's discussion and analysis for the period ended December 31, 2021, within the prescribed time period under applicable securities laws. The cease trade order was revoked on March 10, 2023.

Mr. Irwin is a director and an officer of SBD Capital Corp., which was subject to a cease trade order issued by the Ontario Securities Commission on August 5, 2022 for failure to file its annual financial statements and accompanying management's discussion and analysis for the period ended March 31, 2022, within the prescribed time period under applicable securities laws. The cease trade order was revoked on September 27, 2022.

Mr. Irwin is President, Chief Executive Officer, Secretary and a Director of Playground Ventures Inc., which was subject to a cease trade order issued by the Ontario Securities Commission on May 5, 2023 for failure to file its annual financial statements and accompanying management's discussion and analysis for the period ended December 31, 2022, within the prescribed time period under applicable securities laws. As of the date hereof, the cease trade order has not been revoked.

Mr. Irwin is a Director of Minnova Corp., which was subject to a management cease trade order resulting from a failure to file financial statements as issued on August 2, 2023 by the Ontario Securities Commission. As of the date hereof, the management cease trade order has not been revoked.

Bankruptcies:

No director or executive officer of the Company, or shareholders holding a sufficient number of securities to materially affect control of the Company has:

(a) as at the date of the AIF, or within 10 years before the date of the AIF, been a director or executive officer of any company that, while the proposed director was acting in that capacity, or within a year of the proposed director 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) within 10 years before the date of the AIF, 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 person.

Penalties and Sanctions:

None of the directors or executive officers of the Company, or shareholders holding a sufficient number of securities to materially affect control of the Company, has, as at the date of the AIF, or within 10 years before the date of the AIF, 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

There are no known existing or potential conflicts of interest among the Company, or any of its subsidiaries, and the directors and officers of the Company as a result of their outside business interests except that certain of the directors and officers may serve as directors, officers, promoters and members of management of other companies and therefore it is possible that a conflict may arise between their duties as a director and officer of the Company and their duties as a director, officer, promoter or member of management of such other companies.

The directors and officers of the Company have been advised of the existence of laws governing accountability of directors and officers regarding corporate opportunity and requiring disclosures by directors of conflicts of interest, and the Company will rely upon such laws in respect of any directors' and officers' conflicts of interest or in respect of any breaches of duty by any of the directors or officers. All such conflicts shall be disclosed by such directors or officers and treated in accordance with the applicable laws of Ontario and the Company's constating documents.

PROMOTERS

No person or company has been, within the two most recently completed financial years or during the current financial year, a promoter of the Company.

LEGAL PROCEEDINGS AND REGULATORY ACTIONS

Legal Proceedings

The Company was not subject to any material legal proceedings during its most recently completed financial year, nor is the Company or any of its properties a party to or the subject of any such proceedings, and no such proceedings are known to be contemplated. The Company may be involved in routine, non-material litigation arising in the ordinary course of business, from time to time.

Regulatory Actions

There were no penalties or sanctions imposed against the Company by a court relating to provincial and territorial securities legislation or by a securities regulatory authority during its most recently completed financial year, 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 and territorial securities legislation or with a securities regulatory authority.

INTERESTS OF MANAGEMENT IN MATERIAL TRANSACTIONS

No director or executive officer of the Company, person or company that beneficially owns, controls or directs, directly or indirectly, more than 10% of the Common Shares, or any associate or affiliate of any such persons, has or had any material interest, direct or indirect, in any transaction within the Company's three most recently completed financial years or during the current financial year which has materially affected or is reasonably expected to materially affect the Company or any of its subsidiaries other than as set out herein.

TRANSFER AGENT AND REGISTRAR

The registrar and transfer agent of the Company is Computershare Investor Services Inc., located at 510 Burrard Street, 3rd Floor, Vancouver, British Columbia V6C 3B9.

MATERIAL CONTRACTS

The Company did not enter into any material contracts during the year ended December 31, 2022 or before the year ended December 31, 2022 that is still in effect as at the date of this AIF.

EXPERTS AND INTERESTS OF EXPERTS

The auditor of the Company, KPMG LLP, has informed the Company that it is independent with respect to the Company within the meaning of the Code of Professional Conduct of Chartered Professional Accountants of Ontario.

AUDIT COMMITTEE INFORMATION

Audit Committee Charter

The directors of the Company have adopted a charter (the "**Charter**") for the audit committee (the "**Audit Committee**"), which sets out the Audit Committee's mandate, organization, powers and responsibilities. The full text of the Charter is attached hereto as Appendix "A" to this AIF.

Composition of the Audit Committee

The Audit Committee members are currently Richard Buzbuzian (Chairman), John Leombruno and Philip Cortese, each of whom is a director and financially literate. Messrs. Leombruno and Cortese are deemed to be independent (as defined in National Instrument 52-110 — *Audit Committees* ("**NI 52-110**") adopted by the Canadian Securities Administrators), while Mr. Buzbuzian, President and Chief Executive Officer of the Company, is not considered to be independent in accordance with NI 52-110.

To be considered independent, a member of the Audit Committee must not have any direct or indirect "material relationship" with the Company. A "material relationship" is a relationship which could. in the view of the board of directors of the Company. be reasonably expected to interfere with the exercise of a member's independent judgment.

To be considered financially literate. a member of the Audit Committee must have the ability to read and understand a set of financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of the issues that can reasonably be expected to be raised by the Company's financial statements.

Relevant Education and Experience

The following is a description of the education and experience of each member of the Audit Committee that is relevant to the performance of his responsibilities as an Audit Committee member and, in particular, any education or experience that would provide the member with:

1. an understanding of the accounting principles used by the Company to prepare its financial statements;

2. the ability to assess the general application of such accounting principles in connection with the accounting for estimates, accruals and reserves;

3. 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 one or more persons engaged in such activities; and

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

Richard Buzbuzian (Chair), President, Chief Executive Officer and Director

Richard Buzbuzian is a capital markets executive with over 25 years of experience in Canada and Europe. Previously, Mr. Buzbuzian was President of Drone Delivery Canada (TSXV: FLT), which he co-founded, took public and raised over CND$120M in equity financings achieving market capitalization in excess of $550M. Mr. Buzbuzian sits on the boards of public, private, and non-profit organizations including Give-A-Mile and the Richard and Jacob Buzbuzian Family Foundation. He holds a degree from the University of Toronto.

Dr. John Leombruno, Director

Canadian Pharmaceutical and Medical Device Patient Support Program systems and operations expert. Dr. Leombruno has executive-level experience in many areas of the pharmaceutical industry, including market access, medical information, pharmacovigilance, medical affairs, and business development. He co-founded Patient Direct (a patient support and specialty pharmacy provider) and GMD Distribution (a pharmaceutical distribution, patient support and specialty pharmacy services firm), both of which were acquired by McKesson Canada between 2010 and 2017. In 2019, Dr. Leombruno started OkRx, a Canadian Healthcare software company focusing on helping patients, prescribers, insurers, and pharmaceutical companies manage specialty medications. Dr. Leombruno is formally trained as a pharmacist and has earned an MBA from Queen's University and a PhD in Pharmacoepidemiology from the University of Toronto.

Philip Cortese, Director

Mr. Cortese is a seasoned banker with over 30 years of experience in the financial institution industry and has held senior managerial positions at RBC, TD Bank and CIBC for over half of those years. In 2002, he was recruited by TD Bank to head the Quebec office of its real estate financing commercial mortgage-backed securities (CMBS) origination group as vice president for the Quebec region. The CMBS group originated close to $1 billion of new commercial mortgages over a period of just 4 years. In October 2012, he joined a local real estate investor, Kheng Ly, and together branded the development company now known as Brivia Group. Mr. Cortese is a former Canadian Securities Institute graduate and a licensed commercial real estate broker.

Audit Committee Oversight

Since the commencement of the Company's most recently completed financial year, there has not been a recommendation of the Audit Committee to nominate or compensate an external auditor which was not adopted by the Board.

Reliance on Exemptions in NI 52-110

Since the commencement of the Company's most recently completed financial year, the Company has not relied on:

1. the exemption in section 2.4 (*De Minimis Non-audit Services*) of NI 52-110 (which exempts all non-audit services provided by the Company's auditor from the requirement to be pre-approved by the Audit Committee if such services are less than 5% of the auditor's annual fees charged to the Company, are not recognized as non-audit services at the time of the engagement of the auditor to perform them and are subsequently approved by the Audit Committee prior to the completion of that year's audit);

2. the exemption in subsection 6.1.1(4) (*Circumstance Affecting the Business or Operations of the Venture Issuer*) of NI 52-110 (an exemption from the requirement that a majority of the members of the Audit Committee must not be executive officers, employees or control persons of the Company or of an affiliate of the Company if a circumstance arises that affects the business or operations of the Company and a reasonable person would conclude that the circumstance can be best addressed by a member of the Audit Committee becoming an executive officer or employee of the Company);

3. the exemption in subsection 6.1.1(5) (*Events Outside Control of Member*) (an exemption from the requirement that a majority of the members of the Audit Committee must not be executive officers, employees or control persons of (i) the Company; (ii) an affiliate of the Company if an Audit Committee member becomes a control person of the Company; or (iii) an affiliate of the Company for reasons outside the member's reasonable control);

4. the exemption in subsection 6.1.1(6) (*Death, Incapacity or Resignation*) (an exemption from the requirement that a majority of the members of the Audit Committee must not be executive officers, employees or control persons of the Company or of an affiliate of the Company if a vacancy on the Audit Committee arises as a result of the death, incapacity or resignation of an Audit Committee member and the Board was required to fill the vacancy); or

5. an exemption from the requirements of NI 52-110, in whole or in part, granted by a securities regulator under Part 8 (*Exemptions*) of NI 52-110.

The Company is a "venture issuer" for the purposes of NI 52-110. Accordingly, the Company is relying upon the exemption in section 6.1 of NI 52-110 providing that the Company is exempt from the application of Part 3 (*Composition of the Audit Committee*) and Part 5 (*Reporting Obligations*) of NI 52-110.

Pre-Approval Policies and Procedures

The Audit Committee has adopted specific policies and procedures for the engagement of non-audit services as described in the Audit Committee Charter.

Audit Fees

The following table provides details in respect of audit, audit-related, tax and other fees billed by the external auditor of the Company for professional services rendered to the Company during the fiscal years ended December 31, 2022, and December 31, 2021:

Year	Audit Fees [1] ($)	Audit Related Fees [2] ($)	Tax Fees [3] ($)	All Other Fees [4] ($)
Year ended December 31, 2022	206,445	Nil	Nil	Nil
Year ended December 31, 2021	211,850	Nil	19,750	65,810

Notes:

(1) Aggregate fees billed for professional services rendered by the auditor for the audit of the Company's annual consolidated financial statements as well as services provided in connection with statutory and regulatory filings.

(2) Aggregate fees billed for professional services rendered by the auditor and were comprised primarily of audit procedures performed related to the review of quarterly consolidated financial statements and related documents.

(3) Aggregate fees billed for tax compliance, tax advice and tax planning professional services. These services included reviewing tax returns and assisting in responses to government tax authorities.

(4) Aggregate fees billed for professional services which included accounting advice and association fees.

ADDITIONAL INFORMATION

Additional information relating to the Company may be found through a database search at SEDAR+ at https://www.sedarplus.ca/.

Additional information on the Company, including directors' and officers' remuneration and indebtedness, principal holders of the Company's securities, securities authorized for issue under equity compensation plans and audit committee disclosure, is contained in the Company's management information circular dated May 12, 2023 ("**Circular**"), and which is available under the Company's profile on SEDAR+ at https://www.sedarplus.ca/. Financial information is provided in the Company's audited consolidated financial statements for the years ended December 31, 2022 and 2021, and management's discussion and analysis thereon, which are available under the Company's profile on SEDAR+ at https://www.sedarplus.ca/.

Additional information relating to the Company's Audit Committee may be found in the Company's most recent Circular, available under the Company's profile on SEDAR+ at https://www.sedarplus.ca/. In addition, the Company's Audit Committee Charter is attached hereto as Schedule Appendix "A".

APPENDIX "A"
CHARTER OF THE AUDIT COMMITTEE

NUGEN MEDICAL DEVICES INC.

CHARTER OF THE AUDIT COMMITTEE OF THE BOARD OF DIRECTORS

1. PURPOSE

1.1 The primary functions of the Audit Committee of NuGen Medical Devices Inc. (the "**Company**") are to fulfill its responsibilities in relation to reviewing the integrity of the Company's financial statements, financial disclosures and internal controls over financial reporting; monitoring the system of internal control; monitoring the Company's compliance with legal and regulatory requirements; selecting the external auditors for shareholder approval; and reviewing the qualifications, independence and performance of the external auditors.

2. MEMBERSHIP AND ORGANIZATION

2.1 Composition - Subject to paragraph 2.6, the Audit Committee shall consist of not less than three independent members of the Board. At the invitation of the Audit Committee, members of the Company's management and others may attend Audit Committee meetings as the Audit Committee considers necessary or desirable.

2.2 Appointment and Removal of Audit Committee Members - Each member of the Audit Committee shall be appointed by the Board on an annual basis and shall serve at the pleasure of the Board, or until the earlier of (a) the close of the next annual meeting of shareholders of the Company at which the member's term of office expires, (b) the death of the member or (c) the resignation, disqualification or removal of the member from the Audit Committee or from the Board. The Board may fill a vacancy in the membership of the Audit Committee.

2.3 Chair - At the time of the annual appointment of the members of the Audit Committee, the Board shall appoint a Chair of the Audit Committee. The Chair shall be a member of the Audit Committee, preside over all Audit Committee meetings, coordinate the Audit Committee's compliance with this mandate, work with management to develop the Audit Committee's annual work plan and provide reports of the Audit Committee to the Board. The Chair may vote on any matter requiring a vote and shall provide a second vote in the case of a tie vote.

2.4 Independence - Subject to paragraph 2.6, each member of the Audit Committee shall be an "independent" (as such term is used in National Instrument 52-110 - Audit Committees ("**NI 52-110**").

2.5 Financial Literacy - Subject to paragraph 2.6, members of the Audit Committee shall be financially literate or agree to become financially literate within a reasonable period of time following the member's appointment. An individual is financially literate if he or she has the ability to read and understand a set of financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of the issues that can reasonably be expected to be raised by the Company's financial statements.

2.6 Venture Issuer - For so long as the Company is a "venture issuer" as defined in NI 52-110, it is not required to comply with the provisions of paragraph 2.1 "Composition", 2.4 "Independence" or 2.4 "Financial Literacy" above. In the event the Company cannot comply with all or a part of these provisions, then the Committee shall be comprised of not less than three members of the Board, a majority of whom are not officers or employees of the Company or a subsidiary of the Company.

3. MEETINGS

3.1 Meetings - The members of the Audit Committee shall hold meetings as are required to carry out this mandate and in any case no less than four meetings annually. The external auditors are entitled to attend and be heard at each Audit Committee meeting. The Chair, any member of the Audit Committee, the external auditors, the Chairman of the Board or the President and CEO may call a meeting of the Audit Committee. The Chair shall chair all Audit Committee meetings that he or she attends, and in the absence of the Chair, the members of the Audit Committee present may appoint a Chair from their number for a meeting.

3.2 Secretary and Minutes - The Secretary, his or her designate or any other person the Audit Committee requests, shall act as secretary at Audit Committee meetings. Minutes of Audit Committee meetings shall be recorded and maintained by the Corporate Secretary and subsequently presented to the Audit Committee for approval.

3.3 Quorum - A majority of the members of the Audit Committee shall constitute a quorum. If a quorum cannot be obtained for an Audit Committee meeting, members of the Board who would qualify as members of the Audit Committee may, at the request of the Chair or the Chairman of the Board, serve as members of the Audit Committee for that meeting.

3.4 Access to Management and Outside Advisors - The Audit Committee shall have unrestricted access to management and employees of the Company, and, from time to time may hold meetings with the external auditor, the CFO or the President and CEO. The Audit Committee shall have the authority to retain and terminate external legal counsel, consultants or other advisors to assist it in fulfilling its responsibilities and to set and pay the respective compensation for these advisors without consulting or obtaining the approval of the Board or any officer of the Company. The Company shall provide appropriate funding, as determined by the Audit Committee, for the services of these advisors.

3.5 Meetings Without Management - The Audit Committee shall hold unscheduled or regularly scheduled meetings, or portions of regularly scheduled meetings, at which management is not present.

4. FUNCTIONS AND RESPONSIBILITIES

The Audit Committee shall have the functions and responsibilities set out below as well as any other functions that are specifically delegated to the Audit Committee by the Board. In addition to these functions and responsibilities, the Audit Committee shall perform the duties required of an audit committee by applicable corporate securities laws, the binding requirements of the stock exchanges on which the securities of the Company are listed, and all other applicable laws.

4.1 Financial Reports

(a) **General** - The Audit Committee is responsible for reviewing the integrity of the Company's financial statements and financial disclosures. Management is responsible for the preparation, presentation and integrity of the Company's financial statements and financial disclosures and for the appropriateness of the accounting principles and the reporting policies used by the Company. The external auditors are responsible for auditing the Company's annual consolidated financial statements and, if requested by the Company, for reviewing the Company's unaudited interim financial statements.

(b) **Review of Annual Financial Reports** - The Audit Committee shall review the annual consolidated audited financial statements of the Company, the external auditors' report thereon and the related management's discussion and analysis of the Company's financial condition and results of operation to determine whether they present fairly, in all material respects in accordance with Canadian generally accepted accounting principles, or any other generally accepted accounting principles in which the financial statements of the Company are prepared from time to time, the financial condition, results of operations and cash flows of the Company. After completing its review, if advisable, the Audit Committee shall approve and recommend for Board approval the annual financial statements and the related MD&A.

(c) **Review of Interim Financial Reports** - The Audit Committee shall review the interim consolidated financial statements of the Company, the external auditors review report thereon, if applicable, and the related MD&A to determine whether they present fairly, in all material respects in accordance with IFRS, the financial condition, results of operations and cash flows of the Company. After completing its review, if advisable, the Audit Committee shall, if so authorized by the Board, approve the interim financial statements and the related MD&A, or if not authorized by the Board, then approve and recommend for Board approval.

(d) **Review Considerations** - In conducting its review of the annual financial statements or the interim financial statements, the Audit Committee shall:

(i) meet with management and the external auditors to discuss the financial statements and MD&A;

(ii) review the disclosures in the financial statements;

(iii) review the audit report or review report prepared by the external auditors;

(iv) discuss with management, the external auditors and legal counsel, as requested, any litigation claim or other contingency that could have a material effect on the financial statements;

(v) review critical accounting and other significant estimates and judgments underlying the financial statements as presented by management;

(vi) review any material effects of regulatory accounting initiatives or off-balance sheet structures on the financial statements as presented by management;

(vii) review any material changes in accounting policies and any significant changes in accounting practices and their impact on the financial statements as presented by management;

(viii) review management's report on the effectiveness of internal controls over financial reporting;

(ix) review results of the Company's whistleblowing program; and

(x) review any other matters, related to the financial statements, that are brought forward by the external auditors, management or which are required to be communicated to the Audit Committee under accounting policies, auditing standards or applicable law.

4.2 Approval of Other Financial Disclosures - The Audit Committee shall review and, if advisable, approve and recommend for Board approval financial disclosure in a prospectus or other securities offering document of the Company, press releases disclosing financial results of the Company and any other material financial disclosure, including in Management Information Circulars and Annual Information Forms.

4.3 External Auditors

a) **General** -The Audit Committee shall be responsible for oversight of the work of the external auditors in auditing and reviewing the Company's financial statements and internal controls over financial reporting.

b) **Appointment and Compensation** - The Audit Committee shall review and, if advisable, select and recommend (i) for shareholder approval, the appointment of the external auditors and (ii) for shareholder or Board approval, as applicable, the compensation of the external auditors.

c) **Annual Review Report** - At least annually, the Audit Committee shall obtain and review a report by the external auditors describing: (i) their internal quality-control procedures and (ii) any material issues raised by their most recent internal quality-control review, peer review or by any inquiry or investigation by governmental or professional authorities within the preceding five years respecting one or more independent audits carried out by the external auditors and any steps taken to deal with any of these issues.

d) **Audit Plan** - At least annually, the Audit Committee shall review a summary of the external auditors' annual audit plan. The Audit Committee shall consider and review with the external auditors any material changes to the scope of the plan.

e) **Quarterly Review Report** - If the external auditors review the Company's unaudited interim financial statements, then the Audit Committee shall review a quarterly review report prepared by the external auditors in respect of each of the interim financial statements of the Company.

f) **Independence of External Auditors** - At least annually, and before the external auditors issue their report on the annual financial statements, the Audit Committee shall obtain from the external auditors a formal written statement describing all relationships between the external auditors and the Company, discuss with the external auditors any disclosed relationships or services that may affect the objectivity and independence of the external auditors, and obtain written confirmation from the external auditors that they are objective and independent within the meaning of the Rules of Professional Conduct/Code of Ethics adopted by the provincial institute or order of chartered accountants to which it belongs.

g) **Evaluation and Rotation of Lead Partner** - At least annually, the Audit Committee shall review the qualifications and performance of the lead partners of the external auditors. The Audit Committee shall obtain a report from the external auditors annually verifying that the lead partner of the external auditors has served in that capacity for no more than five fiscal years of the Company and that the engagement team collectively possesses the experience and competence to perform an appropriate audit.

h) **Pre-Approval of Non-Audit Services** - The Audit Committee shall pre-approve any retainer of the external auditors for any non-audit service to the Company in accordance with applicable law and Board approved policies and procedures. The Audit Committee may delegate pre-approval authority to a member of the Audit Committee. The decisions of any member of the Audit Committee to whom this authority has been delegated must be presented to the full Audit Committee at its next scheduled Audit Committee meeting.

i) **Hiring Practices** - The Audit Committee shall review and approve guidelines regarding the hiring of employees or former employees of the external auditors.

4.4 Internal Controls

(a) **General** - The Audit Committee shall monitor the system of internal control.

(b) **Establishment, Review and Approval** - The Audit Committee shall require management to implement and maintain appropriate systems of internal control in accordance with applicable laws, regulations and guidance, including internal control over financial reporting and disclosure and to review, evaluate and approve these procedures. At least annually, the Audit Committee shall consider and review with management and the external auditors: (i) the effectiveness of, or weaknesses or deficiencies in: the design or operation of the Company's internal controls (including computerized information system controls and security); the overall control environment for managing business risks; and accounting, financial and disclosure controls (including, without limitation, controls over financial reporting), non financial controls, and legal and regulatory controls and the impact of any identified weaknesses in internal controls on management's conclusions; (ii) any significant changes in internal control over financial reporting that are disclosed, or considered for disclosure, including those in the Company's periodic regulatory filings; (iii) any material issues raised by any inquiry or investigation by the Company's regulators; (iv) any related significant issues and recommendations of the external auditors together with management's responses thereto, including the timetable for implementation of recommendations to correct weaknesses in internal controls over financial reporting and disclosure controls.

4.5 Whistleblowing Procedures - The Audit Committee shall review and approve the establishment by management of procedures for the receipt, retention and treatment of complaints received by the Company from employees or others, regarding accounting, internal accounting controls, or auditing matters.

4.6 Succession Planning - In consultation with the Board, the Audit Committee shall review succession plans for the CFO and the Chief Accountant or Controller of the Company. The Audit Committee shall review candidates for the position of CFO of the Company and make recommendations to the Board with respect to the appointment of a CFO.

4.7 Adverse Investments and Transactions - The Audit Committee shall review any investments and transactions that could adversely affect the well-being of the Company.

4.8 Audit Committee Disclosure - The Audit Committee shall review and approve any audit committee disclosures required by securities regulators in the Company's disclosure documents.

4.9 Assessment of Regulatory Compliance - The Audit Committee shall review management's assessment of compliance with laws and regulations as they pertain to responsibilities under this mandate, report its findings to the Board and recommend changes it considers appropriate.

4.10 Delegation - The Audit Committee may designate a sub-committee to review any matter within this mandate as the Audit Committee deems appropriate.

5. REPORTING TO THE BOARD

5.1 The Chair shall report to the Board, as required by applicable law or as deemed necessary by the Audit Committee or as requested by the Board, on matters arising at Audit Committee meetings and, where applicable, shall present the Audit Committee's recommendation to the Board for its approval.