UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended **December 31, 2022** or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission file number **000-31187**

IntelGenx Technologies Corp.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**87-0638336**
State or Other Jurisdiction of Incorporation or Organization	I.R.S. Employer Identification No.
6420 Abrams, Ville Saint Laurent , Quebec, Canada	**H4S 1Y2**
Address of Principal Executive Offices	Zip Code

Registrant's telephone number, including area code **(514) 331-7440**

Securities registered pursuant to Section 12(b) of the Act: **None**

Securities registered pursuant to Section 12(g) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.00001 par value	IGXT IGX	OTCQB TSX

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act.
Yes ☐ No ☑

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).
Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐
Non-accelerated filer ☑
Emerging growth company ☐
Accelerated filer ☐
Smaller reporting company ☑

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐[1]

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐[1]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).
Yes ☐ No ☑

As of June 30, 2022, the aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates of the registrant was $21,421,546 based on the closing price of the registrant's common stock of U.S. $0.17, as reported on the OTCQB on that date. Shares of the registrant's common stock held by each officer and director and each person who owns 10% or more of the outstanding common stock of the registrant have been excluded in that such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

Class	Outstanding at March 29, 2023
Common Stock, $.00001 par value	174,646,197 shares

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company's Proxy Statement for its 2023 Annual Meeting of Shareholders (the "2023 Proxy Statement") are incorporated by reference into Part III

[1] Not applicable.

TABLE OF CONTENTS

Terminology and references

In this Annual Report on Form 10-K, the words "Company", "IntelGenx", "we", "us", and "our", refer collectively to IntelGenx Technologies Corp. and IntelGenx Corp., our wholly-owned Canadian subsidiary.

In this Form 10-K, unless otherwise specified, all monetary amounts are in United States dollars, all references to "$", "U.S.$", "U.S. dollars" and "dollars" mean U.S. dollars and all references to "C$", "Canadian dollars" and "CA$" mean Canadian dollars. To the extent that such monetary amounts are derived from our consolidated financial statements included elsewhere in this Form 10-K, they have been translated into U.S. dollars in accordance with our accounting policies as described therein. Unless otherwise indicated, other Canadian dollar monetary amounts have been translated into United States dollars at the average annual exchange rate for 2022 as reported by the Bank of Canada, being U.S. $1.00 = CA$1.3013.

PART I

Cautionary Statement Concerning Forward-Looking Statements

Certain statements included or incorporated by reference in this report constitute forward-looking statements within the meaning of applicable securities laws. All statements contained in this report that are not clearly historical in nature are forward-looking, and the words "anticipate", "believe", "continue", "expect", "estimate", "intend", "may", "plan", "will", "shall" and other similar expressions are generally intended to identify forward-looking statements within the meaning of Section 27A of the United States Securities Act of 1933, as amended ("Securities Act") and Section 21E of the United States Securities Exchange Act of 1934, as amended ("Exchange Act"). All forward-looking statements are based on our beliefs and assumptions based on information available at the time the assumption was made. These forward-looking statements are not based on historical facts but on management's expectations regarding future growth, results of operations, performance, future capital and other expenditures (including the amount, nature and sources of funding thereof), competitive advantages, business prospects and opportunities and exchange listings. Forward-looking statements involve significant known and unknown risks, uncertainties, assumptions and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from those implied by forward-looking statements. These factors should be considered carefully and prospective investors should not place undue reliance on the forward-looking statements. Although the forward-looking statements contained in this report or incorporated by reference herein are based upon what management believes to be reasonable assumptions, there is no assurance that actual results will

be consistent with these forward-looking statements. These forward-looking statements are made as of the date of this report or as of the date specified in the documents incorporated by reference herein, as the case may be. **We undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date on which such statements were made or to reflect the occurrence of unanticipated events, except as may be required by applicable securities laws.**

Forward-looking statements are subject to a variety of known and unknown risks, uncertainties and other factors which could cause actual events or results to differ from those expressed or implied by the forward-looking statements, including, without limitation:

- risks related to our history of losses;
- risks related to the potential need for additional capital;
- risks related to the incurrence of unforeseen costs;
- risks related to our dependence on business partners for clinical trials, regulatory approvals and the marketing and selling of our products;
- the competition in our industry;
- the size and experience of our competitors;
- the laws, regulations and guidelines applicable to cannabinoid-based products;
- risks related to our dependence on suppliers;
- risks related to the manufacturing of our VersaFilm™ products;
- risks related to regulatory approval and regulatory review of our products;
- our ability to expand or enhance our product offerings;
- the market's reception of our products that incorporate drug delivery technologies;
- risks related to environmental regulations;
- the impact of COVID-19;
- risks related to the atai investment (as defined below);
- the risk the Investment is terminated;
- the restrictions on our business activities contained in the Securities Purchase Agreement (as defined below);
- that our existing shareholders ("Shareholders") will have reduced ownership and voting interest if ATAI Life Sciences AG ("atai") chooses to exercise their options to increase the Investment;
- the influence atai may have on our business;
- the risk that the Strategic Development Agreement (as defined below) may not result in commercially viable products;
- risks related to default on our loan agreements;
- risks related to default on our convertible notes ;
- risks related to the developments of compounds that have psychedelic, entactogenic and/or oneirophrenic properties;
- risks related to public controversy with respect to compounds that may contain controlled substances;
- our ability to adequately protect our intellectual property;
- the risk we infringe on the intellectual property rights of third parties;
- the risk that certain of our products may be subject to litigation;
- the risk of litigation in the ordinary course of business;
- risks related to cyber security and the protection of our information systems;

- risks related to the high risk nature of the common stock of the Company (the "Common Stock");
- our failure to achieve and maintain profitability;
- actual or anticipated variations in our quarterly results of operations;
- the application of "penny stock" rules to our Common Stock and its impact on trading and liquidity;
- the lack of public market for certain of our outstanding securities;
- the risk of dilution upon the conversion or exercise of outstanding securities;
- risks related to events of default with respect to our Debentures (as defined below) and Notes (as defined below);
- risks related to foreign currency fluctuations;
- the impact of securities analyst downgrades of our Common stock; and
- risks associated with the prior activities of the public company we merged with.

The factors set forth in Item 1A., "Risk Factors", as well as any cautionary language in this report, provide examples of risks, uncertainties and events that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. Before you invest in our Common Stock, you should be aware that the occurrence of the events described as risk factors and elsewhere in this report could have a material adverse effect on our business, operating results and financial condition.

ITEM 1. BUSINESS.

Corporate History

Our predecessor company, Big Flash Corp., was incorporated in Delaware on July 27, 1999. On April 28, 2006, Big Flash Corp., through its Canadian holding corporation, completed the acquisition of IntelGenx Corp., a Canadian company incorporated on June 15, 2003. The Company did not have any operations prior to the acquisition of IntelGenx Corp. In connection with the acquisition, we changed our name from Big Flash Corp. to IntelGenx Technologies Corp. IntelGenx Corp. has continued operations as our operating subsidiary.

Overview

We are a drug delivery company established in 2003 and headquartered in Montreal, Quebec, Canada. Our focus is on the contract development and manufacturing of novel oral thin film products for the pharmaceutical market. More recently, we have made the strategic decision to

enter the Canadian cannabis market with a non-prescription cannabis infused oral film that launched in early 2021 and in 2020 we made the decision to enter the psychedelic market. As a full service contract development and manufacturing organization ("CDMO"), we are offering partners a comprehensive portfolio of pharmaceutical services, including pharmaceutical research and development ("R&D"), clinical monitoring, regulatory support, tech transfer, manufacturing scale-up and commercial manufacturing.

Our business strategy is to leverage our proprietary drug delivery technologies and develop pharmaceutical products with tangible benefits for patients, for our partners and, once a developed product launches, retain the exclusive manufacturing rights.

Managing our project pipeline is a key Company success factor. We have identified three focus areas; psychedelics, cannabis and animal health where we believe we can establish a leadership position with our drug delivery technology. We have undertaken a strategy under which we will work with pharmaceutical companies in order to apply our oral film technology to pharmaceutical products for which patent protection is nearing expiration, a strategy which is often referred to as "lifecycle management." Under Section 505(b)(2) of the Federal Food, Drug, and Cosmetics Act (the "FDCA") ("Section 505(b)(2)"), the U.S. Food and Drug Administration (the "FDA") may grant market exclusivity for a term of up to three years following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage, dosage form, route of administration or a combination.

The Section 505(b)(2) pathway is also the regulatory approach to be followed if an applicant intends to file an application for a product containing a drug that is already approved by the FDA for a certain indication and for which the applicant is seeking approval for a new indication or for a new use, the approval of which is required to be supported by new clinical trials, other than bioavailability studies. We have implemented a strategy under which we actively look for such so-called "repurposing opportunities" and determine whether our proprietary VersaFilm™ technology adds value to the product. We currently have two such drug repurposing projects in our development pipeline.

We continue to develop the existing products in our pipeline and may also perform R&D on other potential products as opportunities arise.

We have established a state-of-the-art manufacturing facility with the intent to manufacture all of our VersaFilm™ products in-house as we believe that this:

- represents a profitable business opportunity;
- will reduce our dependency upon third-party contract manufacturers, thereby protecting our manufacturing process know-how and intellectual property; and
- allows us to offer our clients and development partners a full service from product conception through to supply of the finished product.

Our website address is www.intelgenx.com.

Technology Platforms

Our main product development efforts are based upon four delivery platform technologies: (1) VersaFilm™, an oral film technology, (2) the VetaFilm™ technology platform for veterinary applications, and (3) DisinteQ™ a disintegrating oral film technology.

VersaFilm™ is a drug delivery platform technology that enables the development of oral thin films, improving product performance through:

- rapid disintegration without the need for water;
- quicker buccal or sublingual absorption;
- potential for faster onset of action and increased bioavailability;
- potential for reduced adverse effects by bypassing first-pass metabolism;
- easy administration for patients who have problems swallowing tablets or capsules; pediatric and geriatric patients as well as patients who fear choking and/or are suffering from nausea (e.g., nausea resulting from chemotherapy, radiotherapy or any surgical treatment);
- pleasant taste; and
- small and thin size, making it convenient for consumers.

Our VersaFilm™ technology consists of a thin (25-35 micron) polymeric film comprised of United States Pharmacopeia components that are approved by the FDA for use in food, pharmaceutical, and cosmetic products. Derived from the edible film technology used for breath strips and initially developed for the instant delivery of savory flavors to food substrates, the VersaFilm™ technology is designed to provide a rapid response and improved bioavailability compared to existing conventional tablets. Our VersaFilm™ technology is intended for indications requiring rapid onset of action, such as migraine, opioid dependence, chronic pain, motion sickness, erectile dysfunction, and nausea or for drug that have a low oral bioavailability and require transmucosal absorption.

Our VetaFilm™ platform technology is designed for the application in companion animals. Dose acceptance and compliance are often a challenge for the care giver which can be overcome with our newly designed VetaFilm™ platform. VetaFilm™ is specifically formulated with flavors that are appealing to pets and to achieve rapid adhesion to the oral mucosa of the animal to achieve compliance.

Our new DISINTEQ™ oral disintegrating film formulations will provide different dissolution characteristics compared to VersaFilm®. Instead of quickly dissolving in the oral cavity, DISINTEQ™ formulations disintegrate at a controlled rate. This will allow a slower release of the drug into the oral cavity thereby avoiding saturation of the oral mucosal membranes and increasing mucosal absorption.

Our Product Portfolio

Our product portfolio includes a blend of generic and branded products based on our proprietary delivery technology ("generic" products are essentially copies of products that have already received FDA approval). Of the twelve projects currently in our product portfolio, eleven use our VersaFilm® technology and one uses our VetaFilm™ technology.

Our most advanced projects:

INT0008/2008: We developed a Rizatriptan oral film product based on our VersaFilm™ technology. In March 2013 we submitted a Section 505(b)(2) New Drug Application ("NDA") to the FDA for our novel oral thin-film formulation of Rizatriptan, which demonstrated to be bioequivalent to the

active drug in Maxalt-MLT® orally disintegrating tablets. Maxalt-MLT® is a leading branded anti-migraine product marketed by Merck & Co. The thin-film formulation of Rizatriptan was originally developed under a co-development and commercialization agreement with RedHill Biopharma Ltd. ("RedHill") which was terminated December 5, 2017, following which Redhill transferred all rights and obligations to us.

On July 5, 2016, we announced the signing of a definitive agreement with Grupo Juste S.A.Q.F. (now Exeltis Healthcare, S.L. ("Exeltis")) for the commercialization of RIZAPORT® for the treatment of acute migraines in Spain. Exeltis is a prominent private Spanish company with over 90 years of experience in the research, development and commercialization of proprietary pharmaceutical products, including migraine and other central nervous system drugs, in Europe, Latin America and other territories.

Under the definitive agreement, Exeltis obtained exclusive rights to register, promote and distribute RIZAPORT® in Spain. In exchange, the Company and Redhill received upfront payments and are entitled to milestone payments, together with a share of the net sales of RIZAPORT® in Spain. The initial term of this agreement is ten years from the date of first commercial sale of the product and shall automatically renew for one additional two-year term. On August 27, 2020, we announced that we had granted Exeltis an exclusive license to manufacture and commercialize RIZAPORT® in the European Union ("EU"). Exeltis will pay us prespecified royalties on net RIZAPORT® sales in the EU. In addition, we have a right of first refusal to manufacture this product for the EU market. Effective September 9, 2020, we signed a technology transfer agreement with LTS Lohmann Therapy Systems for future manufacture and supply of the product for Spain.

On December 14, 2016, we announced the signing of an exclusive license agreement with Pharmatronic Co. for the commercialization of RIZAPORT® in the Republic of Korea ("South Korea"). Under the terms of such agreement, we granted Pharmatronic Co. the exclusive rights to register and commercialize RIZAPORT® in South Korea. IntelGenx received an upfront payment and will be eligible to receive additional milestone payments upon achievement of certain predefined regulatory and commercial targets, as well as tiered royalties. The initial term of the definitive agreement with Pharmatronic Co. is for ten years from the date of first commercial sale and shall automatically renew for an additional two-year term.

On October 31, 2018, we received National marketing authorization from the Spanish Agency of Medicines and Medical Devices for RIZAPORT® (10mg) in Spain.

On December 12, 2018, we announced the execution of a definitive licensing, development and supply agreement with Gensco® Pharma, a specialty pharmaceutical company focusing on research, development and marketing of prescription products, for the exclusive right to commercialize RIZAPORT® in the United States. In return, we are entitled to receive royalty payments based on the net profits of RIZAPORT®. We are also eligible to receive milestone payments upon FDA approval and product launch. This agreement also grants Gensco® Pharma a right of first refusal for the exclusive rights to develop, market, sell, distribute and fully commercialize products as a partner for the People's Republic of China.

On January 30, 2019, we announced that the FDA had performed a Pre-Approval Inspection ("PAI") of our manufacturing facility in Montreal, relating to our NDA for RIZAPORT®. At the conclusion of the PAI on January 25, the FDA issued a Form 483 with five inspectional observations that needed attention before final approval.

On March 27, 2020, we received an additional complete response letter ("CRL") from the FDA. The FDA requested additional information, but no new bioequivalence study.

On September 7, 2021, we announced that Exeltis, our commercialization partner in the EU for RIZAPORT®, a unique for the treatment of acute migraines, launched the product in Spain.

On October 18, 2022, we announced that we responded to the CRL received from the FDA.

On November 22, 2022, we announced that the FDA had accepted for review its Class 2 response to the 2020 CRL and that the FDA had assigned a Prescription Drug User Fee Act (PDUFA) goal date of April 17, 2023 for completion of the review of the RIZAFILM® NDA. (RIZAFILM® is a Registered Trademark of Gensco® Pharma Corporation).

On January 23, 2023, we announced that we entered into an exclusive supply agreement (the " **ARWAN Agreement** ") for RIZAPORT® with ARWAN Pharmaceuticals Industries Lebanon s.a.l. ("**ARWAN**") in various countries in the Middle East and North Africa (" **MENA**") region, including Lebanon, Kuwait, Saudi Arabia, United Arab Emirates, Jordan, Iraq, , Libya, Oman, Yemen, Qatar, Bahrain, Egypt, Sudan, Kenya, Nigeria, Mauritius, Cameroon, Afghanistan, Tajikistan, Kazakhstan, Turkmenistan, and Uzbekistan (the "**Territory**").

Under the terms of the ARWAN Agreement, IntelGenx will supply RIZAPORT ® to ARWAN, which will have the exclusive right to register and commercialize it in the Territory.

INT0046/2018/INT55/2021: Our first cannabis project based on our VersaFilm™ technology contains 10mg CBD/CBDA.

On November 7, 2018 we announced the execution of a definitive license, development and supply agreement with Tilray, Inc. ("Tilray"), a global leader in cannabis production and distribution. Under such agreement, the two companies will co-develop and commercialize oral film products infused with adult-used medical cannabis ("cannabis infused VersaFilm™").

Under the agreement, the Company and Tilray will fund 20% and 80%, respectively, of the costs associated with the development of the cannabis infused Versafilm™ products. The Company will have the exclusive right to manufacture and supply the co-developed products to Tilray, and will also receive a fixed single-digit royalty on net product sales. Tilray will have the exclusive, worldwide marketing and distribution rights for the co-developed products.

In connection with the Tilray agreement, the Company and Tilray also executed a subscription agreement under which Tilray made a strategic investment in IntelGenx through a non-brokered private placement (the "Tilray Private Placement"). As a result, we issued Tilray 1,428,571 shares of Common Stock at a subscription price of $0.70 per share of Common Stock for gross proceeds of $1,000,000. We used the proceeds of the Tilray Private Placement for cannabis infused VersaFilm™ product development under the agreement with Tilray.

On May 2019, we received the first extract from Tilray in sufficient quantities to commence batch production of cannabis-infused VersaFilm® followed by an announcement in October 2019 that the formulation had progressed to the scale-up manufacturing stage. The manufacturing scale-up work was completed successfully in January 2020.

In the spring of 2019, we applied for a micro-processing license under the Canadian *Cannabis Act* (the "Cannabis Act"), which would allow us to process 600kg of cannabis per year, perform analytical testing and begin sales and research on cannabis. On June 5, 2020, we received the cannabis micro-processing license from Health Canada for our Montreal, Quebec facility, in accordance with the Cannabis Act and the regulations thereunder.

On July 20, 2020, we announced that the exclusivity terms of the November 2018 license, development and supply agreement with Tilray had been amended to allow for the Company's co-development and commercialization of cannabidiol ("CBD") products with additional partners. In consideration, we shall pay a royalty to Tilray on all CBD products sold under this amendment. All other terms of such agreement, including those pertaining to Tilray's exclusive, worldwide marketing and distribution rights for non-CBD cannabis infused VersaFilm®, remained unchanged.

On October 29, 2020, we signed a letter of intent with Heritage Cannabis Holding Corp. ("Heritage Cannabis") for long term cannabis filmstrip supply agreement. Shortly after, on January 7, 2021, we announced the execution of a definitive supply agreement with Heritage Cannabis for the manufacturing and supply of filmstrip products containing 10 mg of CBD/CBDA using our VersaFilm® technology for the Canadian and Australian markets.

On August 31, 2021, we announced that we completed a shipment of CBD/CBDA Filmstrips in support of Heritage Cannabis' Canadian market launch of its "CB4 Control" branded product. The product was subsequently successfully launched by Heritage Cannabis in Canada and the relationship is ongoing between the parties.

On December 8, 2021, we announced that we initiated an arbitration proceeding against Tilray, related to an alleged breach of the parties' 2018 license, development and supply agreement, as amended with Tilray for the co-development and commercialization of cannabis-infused VersaFilm® products. The arbitration is currently ongoing.

INT0007/2006: We are developing an oral film product based on our VersaFilm™ technology containing the active ingredient tadalafil. This product is intended for the treatment of erectile dysfunction ("ED"). The results of a phase I pilot study conducted in the second quarter of 2015 confirmed that the product is bioequivalent with the brand product, Cialis®.

On May 8, 2019, we executed a worldwide collaboration agreement for tadalafil with Aquestive Therapeutics, Inc. ("Aquestive"). Under the terms of this agreement, the Company and Aquestive will each grant to the other exclusive worldwide licenses to their respective intellectual property relating to tadalafil oral film formulation and manufacturing. The companies will jointly undertake further co-development and commercialization of tadalafil oral film products, and will equally share (50/50) net profits from worldwide product sales. Aquestive previously submitted an NDA for its tadalafil oral film for the treatment of ED to the FDA. In November 2018, Aquestive received a CRL from the FDA requesting additional safety data from healthy volunteers. Both companies are currently working on responding to the CRL.

On September 29, 2021, we announced that Aquestive, our co-development and commercialization partner for Tadalafil oral films for the treatment of erectile dysfunction and benign prostatic hyperplasia, entered into a definitive license and supply agreement with an undisclosed leading men's health company for the US.

INT0039/2013: This product is based on one of our proprietary technologies and was being developed under another development and commercialization agreement with Par Pharmaceuticals ("Par"). On September 18, 2015, Endo International plc ("Endo") acquired Par. As a result of this acquisition, Par had a conflict and was unable to remain as the partner for this product. Therefore, the product was returned to us with full rights and no requirement for any compensation for work paid by Par.

On September 12, 2016, we entered into a licensing, development and supply agreement with Chemo Group ("Chemo") granting Chemo the exclusive license to commercialize two generic products for the United States market and one product on a worldwide basis. Under the terms of this agreement, Chemo obtained certain exclusive rights to market and sell our products in exchange for upfront and milestone payments, together with a share of the profits of commercialization. Chemo also has a right of first negotiation to obtain the exclusive commercialization rights for two of the products to include any country outside the United States.

On October 4, 2018, we submitted an Abbreviated New Drug Application ("ANDA") to the FDA for a generic buccal film product for our partner, Insud Pharma (formerly Chemo Group). On January 30, 2019, the FDA confirmed the acceptance for review of this ANDA with a GDUFA date of October 18, 2019.

On June 2019, the FDA conducted a PAI for the buccal film that resulted in the FDA issuing us a Form 483, a report from an investigator noting conditions that in their judgment may constitute violations of the FDCA and related acts. Further, in October 2019, we received a CRL in which the FDA declined to approve our product. A CRL does not necessarily indicate that a drug or biologic is not safe or effective. Rather, the FDA issues a CRL when it has reviewed the submitted data and has outstanding questions. A CRL allows the FDA to provide an applicant with a systematic list of deficiencies detected within the submission package sent to the agency that stop short of requiring an entire resubmission. Our updated response to the Form 483 was submitted on April 28 2021 and our response to the CRL was sent to the FDA on May 14, 2021. In February 2022, the FDA conducted a second PAI based on the initial response to the CRL filed earlier in May 2021 which resulted in the issuance of a Form 483 with two observations. Subsequently, on March 14, 2022 the FDA issued a second CRL requesting more information on the product and changes to the labelling

On October 25, 2022, we announced that our previously undisclosed development candidate, Buprenorphine Buccal Film, for which an abbreviated ANDA has been filed by Chemo Research through its agent and affiliate Xiromed, has received a U.S. FDA Generic Drug User Fee Act ("GDUFA") date of April 28, 2023.

INT0043/2015: We developed an oral film containing montelukast as the active ingredient based on our proprietary VersaFilm™ oral film technology, which is in the early clinical trial phase.

We are collaborating with Dr. Ludwig Aigner, a member of our Scientific Advisory Board and head of the Institute of Molecular Regenerative Medicine at the Paracelsus Medical University in Salzburg, Austria. Dr. Aigner has made major contributions in the field of brain and spinal cord regeneration over the last 25 years. He was the first to develop tools to visualize neurogenesis in living animals and identified crucial signaling mechanisms that are involved in limiting brain regeneration. One of these mechanisms, leukotriene signaling, is related to asthma. In consequence, Dr. Aigner and his team recently demonstrated that the anti-asthmatic drug montelukast structurally and functionally rejuvenates the aged brain. His main aim is to develop molecular and cellular therapies for patients with neurodegenerative diseases and for the aged population.

On July 13, 2016, we announced the successful completion of a pilot clinical study for our montelukast VersaFilm™ that demonstrated a significantly improved pharmacokinetic profile compared to the reference product. The study data confirmed that buccal absorption of the drug from the

montelukast film product resulted in a significantly improved bioavailability of the drug compared to the commercial tablet. In addition, the study data confirmed that montelukast crosses the blood brain barrier when administered using our Versafilm™ delivery technology.

In 2017, we announced receiving a no objection letter from Health Canada regarding a Phase IIa proof-of-concept study. The objectives of this 26-week, randomized, double-blind and placebo-controlled Phase IIa proof of concept study to be conducted at eight clinical study sites across Canada will be to evaluate the safety, feasibility, tolerability and efficacy of montelukast buccal film in patients with mild to moderate Alzheimer's Disease ("AD"). The trial design includes testing of up to 70 patients. Based on the outcome of this first efficacy trial in humans, we began actively seeking a partnership or alliance opportunity to further advance developmental work and commercialization of this product.

On September 25, 2018, we announced the beginning of patient recruitment for the proposed AD study. In October 2019, an independent Data Safety Monitoring Board ("DSMB") completed its first interim analysis of the ongoing montelukast AD Phase IIa ("BUENA") clinical trial in patients with mild to moderate AD. The DSMB reviewed compiled safety data from 25 subjects enrolled in the BUENA trial, 13 of whom have completed 26 weeks of daily treatment. The DSMB did not raise any concerns regarding safety and recommended that the trial continue.

Based on additional efficacy testing of montelukast in an AD mouse model, conducted in collaboration with Prof. Dr. Ludwig Aigner's group at the Paracelsus Medical University in Salzburg suggesting that montelukast, when given at higher doses, significantly improves cognition in patients suffering from memory impairment and dementia, a revision of the dosage regiment was requested to Health Canada through the filing of a clinical trial application. Health Canada issued a non-objection letter in January 2020.

On October 12, 2021, we announced our intention to resume patient screening in the ongoing BUENA clinical trial in patients with mild to moderate AD following Health Canada's issuance of a no objection letter in response to IntelGenx's amended Clinical Trial Application.

On January 20, 2022, we announced that patient dosing has resumed in the ongoing BUENA clinical trial in patients with mild to moderate AD under a previously amended protocol using higher doses of Montelukast VersaFilm®.

On September 8, 2022, we announced that patient enrollment in the ongoing BUENA clinical trial in patients with mild to moderate AD had reached the halfway mark.

Currently, this proof-of-concept study includes ten clinical research sites, all of which are expected to enroll a total of approximately 70 patients.

On February 9, 2023, IntelGenx announced a research collaboration with Per Svenningsson, MD, PhD, of the Karolinska Institute, to plan and conduct a multicentre, randomized, double-blind, placebo-controlled clinical study (the "**Study**") to investigate the use of IntelGenx's Montelukast VersaFilm® for the treatment of Parkinson's Disease (" **PD**").

Dr. Svenningsson will serve as the Principal Investigator for the planned Study and will sponsor it through a 20 million Swedish Crowns grant (approx. $2 million USD) awarded by the Swedish Research Council, Sweden's largest governmental research funding body. IntelGenx will supply Dr. Svenningsson with both active and placebo films to be used in the 18-month treatment regimen for study participants. Upon completion of the Study, IntelGenx will retain the intellectual property rights and use the findings to further develop its Montelukast VersaFilm® program for PD treatment. The Study is currently expected to commence in the third quarter of 2023.

PD is one of the most common movement disorders in elderly people and is the second most common neurodegenerative disorder after Alzheimer's disease ("**AD**"). It is a neurodegenerative disorder where misfolded alpha-synuclein-enriched aggregates, called Lewy bodies, are central in pathogenesis. No neuroprotective or disease-modifying treatments are currently available. The current standard treatment of PD motor dysfunction is based on the enhancement of dopaminergic transmission and involves the administration of L-dopa. Evidence from multiple patient studies and animal models has shown a significant immune component during the course of the disease, highlighting immunomodulation as a potential treatment strategy. Montelukast is a $CysLT_1$ antagonist which decreases neuroinflammation by inhibiting $CysLT_1$. Early results have indicated its potential usefulness for the treatment of various neurodegenerative disorders like PD and AD.

Our Psychedelic Programs:

INT0052/2020. On July 7, 2020 we entered into a feasibility agreement with Cybin Corp. for a fast-acting, orally-dissolving psilocybin film. . This project has been discontinued.

INT0053/2020. On August 20, 2020 we entered into a feasibility agreement with atai to develop pharmaceutical-grade polymeric film-based psychedelics.

On October 13, 2022, we provided an update on our collaboration with atai. Pursuant to the feasibility agreement, IntelGenx conducted pre-development, formulation development work and clinical supply manufacturing to provide a product prototype to atai for further clinical investigation. That previously undisclosed candidate, buccal VLS-01, is a buccal film containing a synthetic form of N,N-dimethyltryptamine. atai is developing the product as a novel therapy for treatment-resistant depression ("TRD") in combination with atai's digital therapeutic designed to provide contextual "(mind)set-and-setting" support to patients prior to dosing.

INT0054/2020. On May 12, 2021, we entered into a second feasibility agreement with atai for the development of novel formulations of Salvinorin A, a naturally occurring psychedelic compound being developed for the treatment of TRD and other indications. This program is currently on hold by the partner.

Our Animal Health Programs:

INT0048/2020 VetaFilm: On January 9, 2020 we entered the animal health market by signing a feasibility agreement for its VetaFilm™ platform. We have performed all of our obligations under such agreement and the successfully developed high loading VetaFilm which was sent for evaluation by our partner. Based on the successful feasibility study, we are advancing the product development with the partner.

On February 8, 2021, we announced that we had filed a new provisional patent application at the United States Patent and Trademark Office ("USPTO") entitled "High Loading Oral Film Formulation". The patent application covers the incorporation of high concentrations of active ingredients in

products based on IntelGenx's VetaFilm™ proprietary veterinary oral film technology. This higher loading capability enables a formulation with a ratio of active-to-polymer of 1-to-1, thereby pushing the limit of the film capabilities and distinguishing it from known oral film technology.

Other Programs:

INT0027/2011: We developed this oral film product based on our VersaFilm™ technology under a co-development and commercialization agreement with Par (now an operating company of Endo). The product is a generic formulation of a commercial buprenorphine and naloxone-containing sublingual film for the treatment of opioid dependence. With Par, we developed a bioequivalent film formulation, scaled-up to a commercial manufacturing process and manufactured and tested pivotal batches during a subsequent pivotal clinical study. Par filed an ANDA with the FDA in July 2013.

On August 2013, we were notified that, in response to the filing of the ANDA, we were named as a co-defendant in a lawsuit under Paragraph IV of the Hatch-Waxman Act filed by Reckitt Benckiser Pharmaceuticals ("Reckitt") and Monosol RX ("Monosol") in the United States District Court for the District of Delaware (the "Delaware Court") alleging infringement of United States Patent Nos. 8,475,832, 8,603,514 and 8,017,150, each of which relate to Suboxone®. We believe the ANDA product does not infringe those or any other patents. Under the terms of the co-development and commercialization agreement, Par was financially responsible for the costs of the defense. In June 2016, the Delaware Court ruled that our product is not infringing on two out of the three patents. Subsequently, both parties filed appeals.

On December 2014, Reckitt and Monosol filed another lawsuit for patent infringement in the Delaware Court relating to the Suboxone ® ANDA product. We were named as a co-defendant in this action alleging patent infringement of United States Patent Nos. 8,900,497 ("the '497 patent") and 8,906,277 ("the '277 patent"), each of which related to a process for making a uniform oral film (the "process patents"). The trial on the process patents was held in November 2016.

On May 14, 2018, the Company, Par, Indivior, Inc., Indivior UK Limited, and Aquestive (previously Monosol RX) settled all patent litigation related to Suboxone® film. The settlement agreement permitted Par to begin selling a generic version of Suboxone® film on January 1, 2023. The project is presently on hold.

INT0040/2014: This oral film product is based on our proprietary VersaFilm™ technology. On December 27, 2016, we entered into a co-development and commercialization agreement with Endo for this product in the United States market. Under such agreement, Endo obtained certain exclusive rights to market and sell our product in the United States. We received an upfront payment. The project is discontinued due to low sales of the brand product.

INT0036/2013: This oral film product is based on our proprietary oral film technology VersaFilm™. Loxapine is indicated for the treatment of anxiety and aggression in patients suffering from schizophrenia or bipolar 1 disorder. Using our VersaFilm™ technology allows an improved product to offer patients significant therapeutic benefits compared to existing medications. We expect to effectively treat acute agitation associated with schizophrenia or bipolar 1 disorder in non-institutionalized patients while reducing the risk of pulmonary problems. Our product offers an important therapeutic benefit to these patients, as it could substantially reduce the potential risks of violence and injury to patients and others by preventing or reducing the duration and severity of an episode of acute agitation. Our first clinical study on this product, completed in the fourth quarter of 2014, suggested improved bioavailability compared to the currently approved tablet. In late 2015, we completed a second pilot clinical study which demonstrated that buccal absorption of the drug from the Loxapine oral film results in a significantly higher bioavailability of the drug compared to oral tablets. We were working to optimize the film to further improve the time to reach peak plasma concentrations, however, due to the prioritization of our project line, we directed resources to other projects, leading to a temporary hold of the optimization work during 2019. This project is currently on hold.

On February 21, 2023, IntelGenx announced that the United States Patent and Trademark Office (" **USPTO**") granted a Notice of Allowance for U.S. Patent Application 16/053,383, entitled "Loxapine Film Oral Dosage Form."

This film formulation patent covers Loxapine oral film formulations designed for use in patients with anxiety and agitation associated with schizophrenia and bipolar 1 disorder, and is intended to protect IntelGenx Loxapine VersaFilm® product.

INT0010/2006: This product is based on our proprietary AdVersa ® technology and has been transferred to Tetra BioPharma. We initially entered into an agreement with Cynapsus Therapeutics Inc. (formerly Cannasat Therapeutics Inc., "Cynapsus") for the development of a buccal muco-adhesive tablet product containing a cannabinoid-based drug for the treatment of neuropathic pain and nausea in cancer patients undergoing chemotherapy. In 2009, we completed a clinical biostudy on this product. The study results indicated improved bioavailability and reduced first-pass metabolization of the drug. In the fourth quarter of 2010, we acquired full control of, and interest in, this project from Cynapsus going forward. We also obtained worldwide rights to United States Patent 7,592,328 and all corresponding foreign patents and patent applications to exclusively develop and further secure intellectual property protection for this project.

On October 21, 2020, we entered into an amended and restated licensing agreement with Tetra Bio-Pharma under which Tetra purchased the worldwide Adversa® technology rights as it relates to its PPP-002 (Dronabinol) drug product candidate for three undisclosed milestone payments: 45% to be paid on November 15, 2020; 45% to be paid on March 1, 2021, and a final payment of 10% upon successful technology transfer. In addition, Tetra will pay us a royalty on future net sales of Dronabinol mucoadhesive tablets.

The current status of each of our products as of the date of this Annual Report is summarized in the table below.

Product	Indication	Status of Development
INT0008/2008	Migraine	Launched in Spain and pending FDA approval
INT0046/2018 and INT0055/2021	Adult Use	Launched Canada
INT0007/2006	Erectile dysfunction	Working on response to Aquestive's CRL
INT0039/2013	Pain	Pending FDA approval
INT0027/2011	Opioid addiction	Currently on hold
INT0043/2015	Alzheimer	BUENA Study on-going

INT0010/2006	Treatment of neuropathic pain and nausea in cancer patients undergoing chemotherapy	Transferred to TetraBio
INT0036/2013	Schizophrenia or bipolar 1 disorder	Currently on hold
INT0048/2020	Animal Health	Clinical Study
INT0053/2020	Treatment resistant depression (TRD)	Clinical Study
INT0054/2020	Undisclosed	Formulation development on hold

Growth Strategy

Our primary growth strategy is based on providing CDMO services to the pharmaceutical industry by focusing on three key strategic areas: (1) psychedelics, (2) cannabis, and (3) animal health.

We have established a state-of-the-art manufacturing facility for the future manufacture of our VersaFilm™ and VetaFilm™ products. We believe that this (1) represents a profitable business opportunity, (2) will reduce our dependency upon third-party contract manufacturers, thereby protecting our manufacturing process know-how and intellectual property, and (3) allows us to offer our development partners a full service from product conception through to supply of the finished product.

With our current manufacturing equipment, we are only able to manufacture products that do not contain flammable organic solvents. We initiated a project to expand the existing manufacturing facility, the timing of which will be dictated in part by the completion of agreements with our commercial partners. This expansion became necessary following requests by commercial partners to increase manufacturing capacity and provide solvent film manufacturing capabilities. The new facility should create a fivefold increase of our production capacity in addition to offering a one-stop shopping opportunity to our partners and provide better protection of our Intellectual Property.

Product Opportunities that provide Tangible Patient Benefits

In addition to our three key strategic areas we will offer our services to develop oral film products leveraging our VersaFilm™ technology that provide tangible patient benefits versus existing drug delivery forms. Patients with difficulties swallowing medication, pediatrics or geriatrics may benefit from oral films due to the ease of use. Similarly, we are working on oral films to improve bio-availability and/or response time versus existing drugs and thereby reducing side effects.

Development of New Drug Delivery Technologies

The rapidly disintegrating film technology contained in our VersaFilm™ is an example of our efforts to develop alternate technology platforms. As we work with various partners on different products, we seek opportunities to develop new proprietary technologies.

Competition

The pharmaceutical industry is highly competitive and is subject to the rapid emergence of new technologies, governmental regulations, healthcare legislation, availability of financing, patent litigation and other factors. Many of our competitors, including Aquestive (formerly Monosol Rx), Tesa-Labtec GmbH, Collegium Pharmaceutical Inc. (formerly BioDelivery Sciences International, Inc.) and LTS Lohmann Therapy Systems Corp., have longer operating histories and greater financial, technical, marketing, legal and other resources than we have. In addition, many of our competitors have significantly greater experience than we have in conducting clinical trials of pharmaceutical products, obtaining FDA and other regulatory approvals of products, and marketing and selling products that have been approved. We expect that we will be subject to competition from numerous other companies that currently operate or are planning to enter the markets in which we compete.

The key factors affecting the development and commercialization of our drug delivery products are likely to include, among other factors:

- the regulatory requirements;
- the safety and efficacy of our products;
- the relative speed with which we can develop products;
- generic competition for any product that we develop;
- our ability to defend our existing intellectual property and to broaden our intellectual property and technology base;
- our ability to differentiate our products;
- our ability to develop products that can be manufactured on a cost effective basis;
- our ability to manufacture our products in compliance with current Good Manufacturing Practices ("cGMP") and any other regulatory requirements; and
- our ability to obtain financing.

In order to establish ourselves as a viable full service CDMO partner, we plan to continue to invest in our R&D activities, analytical testing and in our manufacturing technology expertise, in order to further strengthen our technology base and to develop the ability to manufacture products based on our drug delivery technologies at competitive costs.

Our Competitive Strengths

We believe that our key competitive strengths include:

- our comprehensive service portfolio;
- our ability to swiftly develop products through to regulatory approval;
- the versatility of our drug delivery technologies, and
- our highly qualified, dedicated professional team.

Dependence on Major Customers

We currently rely on a few major customers for our end products. We also currently depend upon a limited number of partners to develop our products, to provide funding for the development of our products, to assist in obtaining regulatory approvals that are required in order to commercialize these products, and to market and sell our products.

Intellectual Property and Patent Protection

We protect our intellectual property and technology by using the following methods: (i) applying for patent protection in the United States and in the appropriate foreign markets, (ii) non-disclosure agreements, license agreements and appropriate contractual restrictions and controls on the distribution of information, and (iii) trade secrets, common law trademark rights and trademark registrations. We plan to file core technology patents covering the use of our platform technologies in any pharmaceutical products.

We have obtained 38 patents and have 31 published pending patent applications, as described below. The patents expire 20 years after submission of the initial application. In the United States, the term of a patent sometimes extends over the 20-year period. The initial term of 20 years is extended by a period (the "patent term adjustment") determined by the USPTO according to delays in the prosecution of the patent application that are not applicant delays.

Our patent portfolio is dynamic in nature and constantly under review to assess the business priorities, as such any of the currently pending application and issued patent may be abandoned if the expense of pursuing prosecution or maintaining the patent or application active is no longer warranted by our business targets.

Patent No.	Title	Subject	Date issued/Expiration
US 7,674,479	Sustained-release bupropion and bupropion / mecamylamine tablets	Formulation and method of making tablets containing bupropion and mecamylamine	Issued March 9, 2010 Expires July 25, 2027
US 8,691,272	Multilayer tablet	Formulation of multilayered tablets	Issued April 8, 2014 Expires January 28, 2033
US 8,703,191	Controlled release pharmaceutical tablets	Formulation of tablets containing bupropion and mecamylamine	Issued April 22, 2014 Expires January 10, 2032
US 8,735,374	Oral mucoadhesive dosage form	Direct compression formulation for buccal and sublingual dosage forms	Issued May 27, 2014 Expires April 15, 2032
South Africa 2016/00785	Immediately wet oral films dosage forms have no surfactant and a polyhydric alcohol	Formulation of oral films containing active pharmaceutical ingredients	Filed July 30, 2014 Expires July 30, 2034
US 9,301,948	Instantly wettable oral film dosage form without surfactant or polyalcohol	Formulation of oral films containing active pharmaceutical ingredients	Issued April 5, 2016 Expires July 30, 2033
US 9,668,970	Film Dosage Form with Extended Release Mucoadhesive Particles	Film containing mucoadhesive particle	Issued June 6, 2017 Expires November 26, 2034
US 9,717,682	Solid Oral Film Dosage Forms and Methods for Making Same	Optimization of film strip technology	Issued August 1, 2017 Expires September 21, 2031
US 9,949,934	Device and method of treating conditions associated with neuroinflammation	Formulation of oral films containing montelukast	Issued April 24, 2018 Expires October 20, 2036

US 10,272,038	Film dosage form with extended release mucoadhesive particles	Film containing mucoadhesive particle	Issued April 30, 2019 Expires November 26, 2034
US 10,610,528	Solid oral film dosage forms and methods for making same	Formulation of oral films containing tadalafil	Issued April 7, 2020 Expires June 28, 2031
US 10,722,476	Device and method of treating conditions associated with neuroinflammation	Formulation of oral films containing montelukast	Issued July 28, 2020 Expires October 20, 2036
US 10,828,254	Oral film formulation for modulating absorption profile	Formulation of oral films containing tadalafil	Issued November 10, 2020 Expired September 28, 2038
CA 2,998,223	Loxapine film oral dosage form	Formulation of oral films containing loxapine	Issued October 9, 2018 Expires January 24, 2037
CL 61.052	Instantly wettable oral film dosage form without surfactant or polyalcohol	Formulation of oral films containing active pharmaceutical ingredients	Issued October 13, 2020 Expires July 30, 2034
EP 3,027,179	Instantly wettable oral film dosage form without surfactant or polyalcohol	Formulation of oral films containing active pharmaceutical ingredients	Issued October 17, 2018 Expires July 30, 2034
JP 6,482,552	Instantly wettable oral film dosage form without surfactant or polyalcohol	Formulation of oral films containing active pharmaceutical ingredients	Issued March 13, 2019 Expires July 30, 2034
MX 366,595	Instantly wettable oral film dosage form without surfactant or polyalcohol	Formulation of oral films containing active pharmaceutical ingredients	Issued July 15, 2019 Expires July 30, 2034
CN 105530921	Instantly wettable oral film dosage form without surfactant or polyalcohol	Formulation of oral films containing active pharmaceutical ingredients	Issued February 26, 2021 Expires July 30, 2034
Austria AT E1053177	Instantly wettable oral film dosage form without surfactant or polyalcohol	Formulation of oral films containing active pharmaceutical ingredients	Issued February 26, 2021 Expires July 30, 2034
Belgium 3027179	Instantly wettable oral film dosage form without surfactant or polyalcohol	Formulation of oral films containing active pharmaceutical ingredients	Issued February 26, 2021 Expires July 30, 2034

Switzerland 3027179	Instantly wettable oral film dosage form without surfactant or polyalcohol	Formulation of oral films containing active pharmaceutical ingredients	Issued February 26, 2021 Expires July 30, 2034
Denmark 602014034391.0	Instantly wettable oral film dosage form without surfactant or polyalcohol	Formulation of oral films containing active pharmaceutical ingredients	Issued February 26, 2021 Expires July 30, 2034
Spain 3027179	Instantly wettable oral film dosage form without surfactant or polyalcohol	Formulation of oral films containing active pharmaceutical ingredients	Issued February 26, 2021 Expires July 30, 2034
Finland 3027179	Instantly wettable oral film dosage form without surfactant or polyalcohol	Formulation of oral films containing active pharmaceutical ingredients	Issued February 26, 2021 Expires July 30, 2034
France 3027179	Instantly wettable oral film dosage form without surfactant or polyalcohol	Formulation of oral films containing active pharmaceutical ingredients	Issued February 26, 2021 Expires July 30, 2034
UK 3027179	Instantly wettable oral film dosage form without surfactant or polyalcohol	Formulation of oral films containing active pharmaceutical ingredients	Issued February 26, 2021 Expires July 30, 2034
Greece 3027179	Instantly wettable oral film dosage form without surfactant or polyalcohol	Formulation of oral films containing active pharmaceutical ingredients	Issued February 26, 2021 Expires July 30, 2034
Italy 502019000003967	Instantly wettable oral film dosage form without surfactant or polyalcohol	Formulation of oral films containing active pharmaceutical ingredients	Issued February 26, 2021 Expires July 30, 2034
Netherlands 3027179	Instantly wettable oral film dosage form without surfactant or polyalcohol	Formulation of oral films containing active pharmaceutical ingredients	Issued February 26, 2021 Expires July 30, 2034
Norway NO/EP3027179	Instantly wettable oral film dosage form without surfactant or polyalcohol	Formulation of oral films containing active pharmaceutical ingredients	Issued February 26, 2021 Expires July 30, 2034
Sweden 3027179	Instantly wettable oral film dosage form without surfactant or polyalcohol	Formulation of oral films containing active pharmaceutical ingredients	Issued February 26, 2021 Expires July 30, 2034

Denmark 3027179	Instantly wettable oral film dosage form without surfactant or polyalcohol	Formulation of oral films containing active pharmaceutical ingredients	Issued February 26, 2021 Expires July 30, 2034
US 11,033,496	Film dosage form with extended release mucoadhesive particles	Film containing mucoadhesive particle	Issued June 15, 2021 Expires August 23, 2038
CA 2998218	Device and method of treating conditions associated with neuroinflammation	Formulation of oral films containing montelukast	Issued June 15, 2021 Expires October 17, 2037
KR102272442	Instantly wettable oral film dosage form without surfactant or polyalcohol	Formulation of oral films containing active pharmaceutical ingredients	Issued June 28, 2021 Expires July 30, 2034
US 11,471,406	Oral film formulation for modulating absorption profile	Formulation of oral films containing hydroxyethyl cellulose	Issued October 18, 2022 Expires November 11, 2038
BR Appl. BR112016002074-0	Instantly wettable oral film dosage form without surfactant or polyalcohol	Formulation of oral films containing active pharmaceutical ingredients	Issued January 24, 2023 Expires July 30, 2034

Patent Application No.	**Title**	**Subject**	**Date Filed**
EU Appl. 17862398.9	Device and method of treating conditions associated with neuroinflammation	Formulation of oral films containing montelukast	Filed October 17, 2017
Chinese Appl. 201780062591.7	The device and method for treating illness relevant to neuroinflammation	Formulation of oral films containing montelukast	Filed October 17, 2017
Chinese Appl. 201880016281.6	The treatment method and device of the bioavailability of improved leukotriene receptor antagonists	Formulation of oral films containing montelukast	Filed March 29, 2018
Mexican Appl. MX2019004096	Device and method of treating conditions associated with neuroinflammation	Formulation of oral films containing montelukast	Filed October 17, 2017

Mexican Appl. MX2019010573	Method of treatment and device for the improved bioavailability of leukotriene receptor antagonists	Formulation of oral films containing montelukast	Filed March 29, 2018
Mexican Appl. MX2018010755A	Montelukast transmucosal film	Formulation of oral films containing montelukast	Filed March 1, 2017
Canadian Appl. CA3,017,264	Montelukast transmucosal film	Formulation of oral films containing montelukast	Filed March 1, 2017
Canadian Appl. CA3,017,526	Method of treatment and device for the improved bioavailability of leukotriene receptor antagonists	Formulation of oral films containing montelukast	Filed September 14, 2018
Canadian Appl. CA3,056,944	Method of treatment and device for the improved bioavailability of leukotriene receptor antagonists	Formulation of oral films containing montelukast	Filed March 29, 2018

Canadian Appl. CA 3,062,704	Film dosage form with extended release mucoadhesive particles	Film containing mucoadhesive particle	Filed May 8, 2018
EP Appl. 18798869.6	Film dosage form with extended release mucoadhesive particles	Film containing mucoadhesive particle	Filed May 8, 2018
Canadian Appl. CA 3,061,086	Lipophilic active oral film formulation and method of making the same	Film containing lipophilic actives	Filed November 6, 2019
Canadian Appl. CA 3,122,192	Device and method of treating conditions associated with neuroinflammation	Formulation of oral films containing montelukast	Filed October 17, 2017
US Appl. 16/053,383	Loxapine film oral dosage form	Formulation of oral films containing loxapine	Filed August 2, 2018
US Appl. 16/391,430	Film Dosage Forms Containing Amorphous Active Agents	Film containing amorphous agent	Filed April 23, 2019
EP Appl. 19859079.6	Method of treatment and device for the improved bio availability of montelukast, a leukotriene receptor antagonist	Formulation of oral films containing montelukast	Filed September 12, 2019

BR Appl. 112021008649-8	Lipophilic active oral film formulation and method of making the same	Formulation of oral films containing lipophilic actives	Filed November 4, 2019
Canadian Appl. CA 3,118,594	Lipophilic active oral film formulation and method of making the same	Formulation of oral films containing lipophilic actives	Filed November 4, 2019
EP Appl. 19883191.9	Lipophile aktive orale filmformulierung und verfahren zu ihrer herstellung	Formulation of oral films containing lipophilic actives	Filed November 4, 2019
US Appl. 17/291,582	Lipophilic active oral film formulation and method of making the same	Formulation of oral films containing lipophilic actives	Filed May 5, 2021
US Appl. 17/346,874	Film dosage form with extended release mucoadhesive particles	Film containing mucoadhesive particles	Filed June 14, 2021
Australia Appl. 2019374173	Lipophilic active oral film formulation and method of making the same	Formulation of oral films containing lipophilic actives	Filed April 11, 2019
US Appl. 16/383,813	Lipophilic active oral film formulation and method of making the same	Formulation of oral films containing lipophilic actives	Filed April 15, 2019
Canadian Appl. CA 3,150,213	Method of treatment and device for the improved bio availability of montelukast, a leukotriene receptor antagonist	Formulation of oral films containing montelukast	Filed September 12, 2019

Mexican Appl. MX2021005292A	Lipophilic active oral film formulation and method of making the same	Formulation of oral films containing lipophilic actives	Filed July 13, 2021
PCT/CA2022/050171	High loading oral film formulation	Formulation of oral films containing a high amount of actives	Filed February 7, 2022

PCT/CA2022/050212	Novel tryptamine oral film formulation	Formulation of oral films containing tryptamine	Filed February 14, 2022
US Appl. US 17/842,372	Stable Tryptamine Oral Films	Formulation of oral films containing tryptamine	Filed June 16, 2022
US Appl. US 17/732,456	Method Of Treatment And Device For The Improved Bioavailability Of Leukotriene Receptor Antagonists	Formulation of oral films containing montelukast	Filed April 28, 2022
US Appl. US 17/729,442	Method Of Treatment And Device For The Improved Bioavailability Of Leukotriene Receptor Antagonists	Formulation of oral films containing montelukast	Filed April 26, 2022
New Zealand Appl. NZ 775442	Lipophilic active oral film formulation and method of making the same	Formulation of oral films containing lipophilic actives	Filed November 4, 2019

COVID-19

Our operations and financial condition have been affected by the COVID-19 pandemic. Though we were granted an exemption by local authorities which permitted us to continue operations during the COVID-19 pandemic, we nevertheless faced multiple operational and financial challenges. Despite these challenges, we have continually been able to minimize the impact on our overall performance.

In response to the COVID-19 pandemic, we partially reorganized our operations, adopted a remote work policy for employees and management and implemented a compensation deferral program. We also benefited from the Canada Emergency Wage Subsidy as well as the Canada Emergency Commercial Rent Assistance program from our landlord. There is uncertainty as to the duration of these benefits and hence the potential impact.

Throughout the COVID-19 pandemic, we have been, and remain, in compliance with all federal, provincial, and municipal regulations that have been put in place since the beginning of the pandemic. We will continue to monitor any further developments in this regard, with the health and safety of our employees and management as the primary concern.

Government Regulation

The pharmaceutical industry is highly regulated. The products we participate in developing require certain regulatory approvals. In the United States, drugs are subject to rigorous regulation by the FDA. The FDCA, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, record keeping, packaging, labeling, adverse event reporting, advertising, promotion, marketing, distribution, and import and export of pharmaceutical products. Failure to comply with applicable regulatory requirements may subject a company to a variety of administrative or judicially-imposed sanctions and/or the inability to obtain or maintain required approvals or to market drugs. The steps ordinarily required before a new pharmaceutical product may be marketed in the United States include:

- preclinical laboratory tests, animal studies and formulation studies under FDA's good laboratory practices regulations, ("GLPs");
- the submission to the FDA of an investigational new drug application, which must become effective before human clinical trials may begin;
- the completion of adequate and well-controlled clinical trials according to good clinical practice regulations,("GCPs"), to establish the safety and efficacy of the product for each indication for which approval is sought;

- after successful completion of the required clinical testing, submission to the FDA of an NDA, or an ANDA, for generic drugs. In certain cases, an application for marketing approval may include information regarding safety and efficacy of a proposed drug that comes from studies not conducted by or for the applicant. Such applications, known as a Section 505(b)(2) NDA, are permitted for new drug products that incorporate previously approved active ingredients, even if the proposed new drug incorporates an approved active ingredient in a novel formulation or for a new indication;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the product is to be produced, to assess compliance with cGMPs to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA or ANDA.

The cost of complying with the foregoing requirements, including preparing and submitting an NDA or ANDA, may be substantial. Accordingly, we typically rely upon our partners in the pharmaceutical industry to spearhead and bear the costs of the FDA approval process. We also seek to mitigate regulatory costs by focusing on Section 505(b)(2) NDA opportunities. By applying our drug delivery technology to existing drugs, we seek to develop products with lower R&D expenses and shorter time-to-market timelines as compared to regular NDA products.

The preclinical and clinical testing and approval process takes many years and the actual time required to obtain approval, if any, may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLPs. The results of preclinical testing are submitted to the FDA as part of an Investigational New Drug ("IND") application along with other information, including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND application is submitted.

The IND application automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions relating to one or more proposed clinical trials and places the clinical trial on a clinical hold, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. A separate submission to an existing IND application must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board ("IRB"), covering each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and informed consent information for subjects before the trial commences at that site and it must monitor the study until completed. The FDA, the IRB, or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk or for failure to comply with the IRB's requirements, or may impose other conditions. Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator in accordance with GCP requirements, which includes the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Sponsors of clinical trials generally must register and report, at the NIH-maintained website ClinicalTrials.gov, key parameters of certain clinical trials. For purposes of an NDA submission and approval, human clinical trials are typically conducted in the following sequential phases, which may overlap or be combined:

In Phase 1, through the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness.

Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks.

Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency and a statistically persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. Under federal law, the submission of most NDAs is subject to a substantial application user fee, and applicant under an approved NDA is also subject to an annual program fee for each prescription drug product, which beginning in Fiscal Year 2018 replaced the product and establishment fees.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information and is subject to payment of additional user fees. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. Under the Prescription Drug User Fee Act, the FDA has agreed to certain performance goals in the review of NDAs through a two-tiered classification system, Standard Review and Priority Review. Priority Review designation is given to drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists. The FDA endeavors to review applications subject to Standard Review within ten to twelve months, whereas the FDA's goal is to review Priority Review applications within six to eight months.

The FDA may refer applications for proprietary drug products or drug products which present difficult questions of safety or efficacy to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions.

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP requirements. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless it determines that the manufacturing process and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities and possibly conducts a sponsor inspection, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the NDA and may require substantial additional testing, or information, in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA may ultimately decide that an application does not satisfy the regulatory criteria for approval. If, or when, the deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The review by the FDA is two months for a Class I resubmission and six months for a Class 2 resubmission. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

As a condition of NDA approval, the FDA may require a REMS, or Risk Evaluation and Mitigation Strategy, to help ensure that the benefits of the drug outweigh the potential risks. If the FDA determines a REMS is necessary during review of the application, the drug sponsor must agree to the REMS plan at the time of approval. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate healthcare providers of the drug's risks, limitations on who may prescribe or dispense the drug, or other elements to assure safe use, such as special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. In addition, the REMS must include a timetable to periodically assess whether the REMS plan is effective. The requirement for a REMS can materially affect the potential market and profitability of a drug.

Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy, and the FDA has the authority to prevent or limit further marketing of a product based on the results of these post-marketing programs. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label, and, even if the FDA approves a product, it may limit the approved indications for use for the product or impose other conditions, including labeling or distribution restrictions or other risk-management mechanisms.

Further changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses similar procedures in reviewing NDA supplements as it does in reviewing NDAs.

Post-Approval Requirements

Ongoing adverse event reporting and submission of periodic reports are required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging, and labeling procedures must continue to conform to cGMPs and NDA specifications after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA. Accordingly, manufacturers must continue to expend time, money, and training and compliance efforts in the areas of production and quality control to maintain compliance with cGMPs or other applicable laws. Regulatory authorities may require remediation, withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems or new concerns are subsequently discovered. In addition, other regulatory action, including, among other things, warning letters, the seizure of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, civil penalties, and criminal prosecution may be pursued.

The Hatch-Waxman Amendments

ANDA Approval Process

The Hatch-Waxman Amendments established abbreviated FDA approval procedures for drugs that are shown to be equivalent to drugs previously approved by the FDA through its NDA process. Approval to market and distribute these drugs is obtained by submitting an ANDA to the FDA. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. Premarket applications for generic drugs are termed abbreviated because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, a generic applicant must demonstrate that its product is bioequivalent to the innovator drug. In certain situations, an applicant may obtain ANDA approval of a generic product with a strength or dosage form that differs from a referenced innovator drug pursuant to the filing and approval of an ANDA Suitability Petition. The FDA will approve the generic product as suitable for an ANDA application if it finds that the generic product does not raise new questions of safety and effectiveness as compared to the innovator product. A product is not eligible for ANDA approval if the FDA determines that it is not equivalent to the referenced innovator drug, if it is intended for a different use, or if it is not subject to an approved Suitability Petition. However, such a product might be approved under an NDA, with supportive data from clinical trials.

Section 505(b)(2) NDAs

As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2). Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments and permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant. If the Section 505(b)(2) applicant can establish that reliance on FDA's previous findings of safety and effectiveness is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements, including clinical trials, to support the change from the approved branded reference drug. The FDA may then approve the new product candidate for all, or some, of the label indications for which the branded reference drug has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

Orange Book Listing

In seeking approval for a drug through an NDA, including a Section 505(b)(2) NDA, applicants are required to list with the FDA certain patents with claims that cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a Section 505(b)(2) NDA referencing a drug listed in the Orange Book must certify to the FDA that (i) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (ii) such patent has expired; (iii) the date on which such patent expires; or (iv) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or Section 505(b)(2) application refers. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent.

If the reference drug NDA holder and patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. The ANDA or Section 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired as described in further detail below.

Non-Patent Exclusivity

In addition to patent exclusivity, the holder of the NDA for the listed drug may be entitled to a period of non-patent related exclusivity, during which the FDA cannot review, or in some cases, approve an ANDA or Section 505(b)(2) application that relies on the listed drug. For example, a company may obtain five years of non-patent exclusivity upon NDA approval of a new chemical entity ("NCE"), which is a drug that contains an active

moiety that has not been approved by the FDA in any other NDA. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacologic action. During the five-year exclusivity period, the FDA cannot accept for filing any ANDA seeking approval of a generic version of that drug or any Section 505(b)(2) NDA for the same active moiety and that relies on the FDA's findings regarding that drug, except that FDA may accept an application for filing after four years if the follow-on applicant makes a paragraph IV certification.

A drug, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation of a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. Should this occur, the FDA would be precluded from approving any ANDA or Section 505(b)(2) application for the protected modification until after that three-year exclusivity period has run. However, unlike NCE exclusivity, the FDA can accept an application and begin the review process during the exclusivity period.

International Regulation

In addition to regulations in the United States, we are and will be subject to a variety of foreign regulations regarding development, approval, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the necessary approvals by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and can involve additional product testing and additional review periods, and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing, among other things, the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. 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 negatively impact the regulatory process in others. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. In the EU, we may seek marketing authorization under either the centralized authorization procedure or national authorization procedures.

Centralized procedure. The European Medicines Agency, ("EMA"), implemented the centralized procedure for the approval of human medicines to facilitate marketing authorizations that are valid throughout the EU. This procedure results in a single marketing authorization issued by the European Commission following a favorable opinion by the EMA that is valid across the European Union, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human medicines that are: derived from biotechnology processes, such as genetic engineering, contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and officially designated orphan medicines. For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

National authorization procedures. There are also two other possible routes to authorize medicinal products in several EU countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure: the decentralized procedure and the mutual recognition procedure. Under the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country for medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure. Under the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following a national authorization, the applicant may seek further marketing authorizations from other EU countries under a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

In the EU, medicinal products designated as orphan products benefit from financial incentives such as reductions in marketing authorization application fees or fee waivers and 10 years of market exclusivity following medicinal product approval. For a medicinal product to qualify as orphan: (i) it must be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating; (ii) the prevalence of the condition in the EU must not be more than five in 10,000 or it must be unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development; and (iii) no satisfactory method of diagnosis, prevention or treatment of the condition concerned can be authorized, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

Other Regulation

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. While we believe we are in compliance with applicable environmental and other regulations, in each of these areas, as above, the FDA and other government agencies have broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on us.

Canadian Medical and Adult-Use

Medical and adult-use cannabis in Canada is regulated under the federal Cannabis Act and the Cannabis Regulations ("CR") promulgated under the Cannabis Act. Both the Cannabis Act and CR came into force in October 2018, superseding earlier legislation that only permitted commercial distribution and home cultivation of medical cannabis. The following are the highlights of the current federal legislation:

- a federal license is required for companies to cultivate, process and sell cannabis for medical or non-medical purposes;
- Health Canada, federal government entity, is the oversight and regulatory body for cannabis licenses in Canada. As of December 31, 2020, Health Canada has issued approximately 570 active licenses to licensees under the CR ("Licensed Producers");
- allows individuals to purchase, possess and cultivate limited amounts of cannabis for medical purposes and, for individuals over the age of 18 years, for adult-use recreational purposes;
- enables the provinces and territories to regulate other aspects associated with recreational adult-use. In particular, each province or territory may adopt its own laws governing the distribution, sale and consumption of cannabis and cannabis accessory products, and those laws may set lower maximum permitted quantities for individuals and higher age requirements;
- promotion, packaging and labelling of cannabis is strictly regulated. For example, promotion is largely restricted to the place of sale and age-gated environments (i.e., environments with verification measures in place to restrict access to persons of legal age). Promotions that appeal to underage individuals are prohibited;
- since the current federal regime came into force on October 17, 2018, certain classes of cannabis, including dried cannabis and oils, have been permitted for sale into the medical and adult-use markets;
- following amendments to the CR that came into force on October 17, 2019 (often referred to as Cannabis 2.0 regulations);

- other non-combustible form-factors, including edibles, topicals, and extracts (both ingested and inhaled), are permitted in the medical and adult-use markets;
- export is restricted to medical cannabis, cannabis for scientific purposes, and industrial hemp; and
- sale of medical cannabis occurs on a direct-to-patient basis from a federally licensed provider, while sale of adult-use cannabis occurs through retail-distribution models established by provincial and territorial governments.

All provincial and territorial governments have, to varying degrees, enacted regulatory regimes for the distribution and sale of recreational adult-use cannabis within their jurisdiction, including minimum age requirements. The retail-distribution models for adult-use cannabis varies nationwide:

- Quebec, New Brunswick, Nova Scotia and Prince Edward Island have adopted a government-run model for retail and distribution;
- Ontario, British Columbia, Alberta, and Newfoundland and Labrador have adopted a hybrid model with some aspects, including distribution and online retail being government-run while allowing for private licensed retail stores;
- Manitoba and Saskatchewan have adopted a private model, with privately-run retail stores and online sales, with distribution in Manitoba managed by the provincial government; and
- the three northern territories of Yukon, Northwest Territories and Nunavut have adopted a model that mirrors their government-run liquor distribution model.

All provinces and territories have secured supply agreements from Licensed Producers for their respective markets. We are fulfilling adult-use supply agreements and purchase orders from various jurisdictions, consisting of: Quebec, Ontario, British Columbia, Prince Edward Island, Saskatchewan, Manitoba, Alberta, Nova Scotia, New Brunswick, Northwest Territories, and the Yukon.

United States Regulation of Hemp

Hemp products are subject to state and federal regulation in respect to the production, distribution and sale of products intended for human ingestion or topical application. Hemp is categorized as Cannabis sativa L., a subspecies of the cannabis genus. Numerous unique, chemical compounds are extractable from Hemp, including tetrahydrocannabinol ("THC") and CBD. These cannabinoids are responsible for a range of potential psychological and physiological effects. Hemp, as defined in the 2018 Farm Bill, is distinguishable from marijuana, which also comes from the Cannabis sativa L. subspecies, by its absence of more than trace amounts (0.3% or less) of the psychoactive compound THC. Although international standards vary, other countries, such as Canada, use the same THC potency standards to define Hemp.

The 2018 Farm Bill preserves the authority and jurisdiction of the FDA, under the FD&C Act, to regulate the manufacture, marketing, and sale of food, drugs, dietary supplements, and cosmetics, including products that contain Hemp extracts and derivatives, such as CBD. As a result, the FD&C Act will continue to apply to Hemp-derived food, drugs, dietary supplements, cosmetics, and devices introduced, or prepared for introduction, into interstate commerce. As a producer and marketer of Hemp-derived products, the Company must comply with the FDA regulations applicable to manufacturing and marketing of certain products, including food, dietary supplements, and cosmetics.

As a result of the 2018 Farm Bill, federal law dictates that CBD derived from Hemp is not a controlled substance; however, CBD derived from Hemp may still be considered a controlled substance under applicable state law. Individual states take varying approaches to regulating the production and sale of Hemp and Hemp-derived CBD. Some states explicitly authorize and regulate the production and sale of Hemp-derived CBD or otherwise provide legal protection for authorized individuals to engage in commercial Hemp activities, other states, however, maintain drug laws that do not distinguish between marijuana and Hemp and/or Hemp-derived CBD which results in Hemp being classified as a controlled substance under certain state laws.

European Union Medical Use

While each country in the EU has its own laws and regulations, many common practices are being adopted relative to the developing and growing medical cannabis market. For example, to ensure quality and safe products for patients, many EU countries only permit the import and sale of medical cannabis from GMP-certified manufacturers.

The EU requires adherence to GMP standards for the manufacture of active substances and medicinal products, including cannabis products. The EU system for certification of GMP allows a Competent Authority of any EU member state to conduct inspections of manufacturing sites and, if the strict GMP standards are met, to issue a certificate of GMP compliance that is also accepted in other EU member countries.

Competitive Conditions

As of December 31, 2020, Health Canada has issued approximately 570 active licenses to cannabis cultivators, processors and sellers. Health Canada licenses are limited to individual properties. As such, if a Licensed Producer seeks to commence production at a new site, it must apply to Health Canada for a new license. As demand for legal cannabis increases and the number of authorized retail distribution points increases, we believe new competitors are likely to enter the Canadian cannabis market.

We also expect more countries to pass regulation allowing for the use of medical and/or recreational cannabis. While expansion of the global cannabis market will provide more opportunities to grow our international business, we also expect to experience increased global competition.

Psychedelic Regulatory Disclosure

Canada

In Canada, oversight of healthcare is divided between the federal and provincial governments. The federal government is responsible for regulating, among other things, the approval, import, sale, and marketing of controlled substances, whether natural or novel. The provincial/territorial level of government has authority over the delivery of health care services, including regulating health facilities, administering health insurance plans such as the Ontario Health Insurance Plan, distributing prescription drugs within the province, and regulating health professionals such as doctors, psychologists, psychotherapists and nurse practitioners. Regulation is generally overseen by various colleges formed for that purpose, such as the College of Physicians and Surgeons of Ontario.

Certain psychoactive compounds, such as psilocybin, are considered controlled substances under Schedule III of the Controlled Drugs and Substances Act (Canada) (the "CDSA"). The production, possession, sale and distribution of controlled substances is prohibited unless specifically permitted by the government. Notwithstanding the prohibitions on various activities with respect to controlled substances that are set out in the CDSA, there are several avenues through which one can be legally permitted to conduct otherwise-prohibited activities with controlled substances.

For instance, in order to conduct certain kinds of scientific research, including pre-clinical and clinical trials, using controlled substances (including various psychoactive compounds), an exemption granted by the Minister of Health under Section 56 of the CDSA (a "Section 56 Exemption") is required. This exemption allows the person to whom the Section 56 Exemption was issued to perform the activities specified in the Section 56 Exemption in relation to the controlled substance(s) specified in the Section 56 Exemption without being subject to the corresponding restrictions set out in the CDSA. Section 56 Exemptions may be granted by the Minister of Health to individual persons or to particular classes of persons, but only for medical purposes, scientific purposes, or where it is in the public interest.

Additionally, dealer's licences may be applied for and obtained pursuant to various regulations existing under the CDSA. Dealer's licences can authorize the holders thereof (also known as licensed dealers) to possess, produce, assemble, sell, provide, transport, send, deliver, import and/or export one or more controlled substances. Licensed dealers are permitted to engage in all activities that are expressly set out in their respective licences. With respect to psychedelic substances, the primary regulations pursuant to which a person may obtain the appropriate dealer's licence are Part J of the Food and Drug Regulations (Canada)-which applies to "restricted drugs" such as psilocin and psilocybin-and the Narcotic Control Regulations (Canada)-which applies to "narcotics" such as ketamine. In order to receive a dealer's licence, a party must meet all regulatory requirements mandated by the applicable regulations, including (without limitation) having sufficiently secure facilities and other physical infrastructure, and all requisite personnel (e.g., a senior person in charge; a qualified person in charge) that possess the necessary qualifications set out under the applicable regulations.

The Company currently holds a dealer's licence, as issued pursuant to the CDSA, which authorizes the Company to possess, sell, supply, send, transport and deliver various controlled substances, including, among others, 2,2'-bisnaloxone, fentanyl, N,N-dimethyltryptamine, oxycodone, pseudobuprenorphine, psilocin, psilocybin and thebaine. The Company may, from the time to time, apply for approval to perform additional activities under its dealer's licence and/or to perform such activities in relation to additional controlled substances.

United States

In the United States, the FDA and other federal, state, local and foreign regulatory agencies impose substantial requirements upon the clinical development, approval, labeling, manufacture, marketing and distribution of drug products. These agencies regulate, among other things, R&D activities and the testing, approval, manufacture, quality control, safety, effectiveness, labeling, storage, record keeping, advertising and promotion of any prescription drug product candidates or commercial products. The regulatory approval process is generally lengthy and expensive, with no guarantee of a positive result. Moreover, failure to comply with applicable FDA or other requirements may result in civil or criminal penalties, recall or seizure of products, injunctive relief including partial or total suspension of production, or withdrawal of a product from the market. The Company's commercial partners will be responsible for filing the necessary regulatory applications such as Investigational New Drug ("IND") with the FDA following the development by the Company of a prototype containing the psychedelic compound.

Psychoactive compounds such as psilocybin and psilocin, are strictly controlled under the federal Controlled Substances Act, 21 U.S.C. §801, et. seq. (the "CSA") as Schedule I substances. Schedule I substances by definition have no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse. Schedule I and II drugs are subject to the strictest controls under the CSA, including manufacturing and procurement quotas, security requirements and criteria for importation. Anyone wishing to conduct research on substances listed in Schedule I under the CSA must register with the U.S. Drug Enforcement Administration ("DEA"), and obtain DEA approval of the research proposal. Please see "Research and Development - Psychedelics" for additional information concerning the regulation applicable to the process required before prescription drug product candidates may be marketed in the United States.

The FDA also regulates the formulation, manufacturing, preparation, packaging, labeling, holding, and distribution of foods, drugs and dietary supplements under the FDCA and the Dietary Supplement Health and Education Act of 1994 ("DSHEA"). "Dietary supplements" are defined as vitamins, minerals, herbs, other botanicals, amino acids and other dietary substances for human use to supplement the diet, as well as concentrates, metabolites, constituents, extracts or combinations of such dietary ingredients. Generally, under DSHEA, dietary ingredients that were on the market prior to October 15, 1994 may be used in dietary supplements without notifying the FDA. New dietary ingredients (i.e., not marketed in the U.S. prior to October 15, 1994) must be the subject of a new dietary ingredient notification submitted to the FDA unless the ingredient has been "present in the food supply as an article used for food" without being "chemically altered." A new dietary ingredient notification must provide the FDA with evidence of a "history of use or other evidence of safety" establishing that use of the dietary ingredient, when used under the conditions recommended or suggested in the labeling of the dietary supplement, "will reasonably be expected to be safe." A new dietary ingredient notification must be submitted to the FDA at least 75 days before the initial marketing of the new dietary ingredient. There can be no assurance that the FDA will accept the evidence of safety for any new dietary ingredients that the Company may want to market, and the FDA's refusal to accept such evidence could prevent the marketing of such dietary ingredients.

The DSHEA revised the provisions of the FDCA concerning the composition and labeling of dietary supplement ingredients and products. Under the DSHEA, dietary supplement labeling must include the statement of identity (name of the dietary supplement), the net quantity of contents statement (amount of the dietary supplement), the nutrition labeling, the ingredient list, and the name and place of business of the manufacturer, packer, or distributor. The DSHEA also states that dietary supplements may display "statements of nutritional support," provided certain requirements are met. Such statements must be submitted to the FDA within 30 days of first use in marketing and must be accompanied by a label disclosure that "This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease." Such statements may describe how a particular dietary ingredient affects the structure, function or general well-being of the body, or the mechanism of action by which a dietary ingredient may affect body structure, function or well-being, but may not expressly or implicitly represent that a dietary supplement will diagnose, cure, mitigate, treat, or prevent a disease. Any statement of nutritional support the Company makes in labeling must possess scientific evidence substantiating that the statement is truthful and not misleading. If the FDA were to determine that a particular statement of nutritional support was an unacceptable drug claim or an unauthorized version of a health claim about disease risk reduction for a food product, or if the FDA were to determine that a particular claim was not adequately supported by existing scientific data or was false or misleading, the Company would be prevented from using that claim. In addition, the FDA deems promotional and internet materials as labeling; therefore, the Company's promotional and internet materials must comply with FDA requirements and could be the subject of regulatory action by the FDA, or by the Federal Trade Commission (the "FTC") if that agency or other governmental authorities, reviewing the materials as advertising, considers the materials false and misleading.

U.S. laws also require recordkeeping and reporting to the FDA of all serious adverse events involving dietary supplements products. The Company will need to comply with such recordkeeping and reporting requirements, and implement procedures governing adverse event identification, investigation and reporting. As a result of reported adverse events, health and safety risks or violations of applicable laws and regulations, the Company may from time to

time elect, or be required, to recall, withdraw or remove a product from a market, either temporarily or permanently.

The Company's expected nutraceutical products may be considered "food" and must be labeled as such. Within the U.S., this category of products is subject to the federal Nutrition, Labeling and Education Act ("NLEA"), and regulations promulgated under the NLEA. The NLEA regulates health claims, ingredient labeling and nutrient content claims characterizing the level of a nutrient in the product. The ingredients in conventional foods must either be generally recognized as safe by experts for the purposes to which they are put in foods, or be approved as food additives under FDA regulations. If the Company's expected nutraceutical products were regulated as foods, it would be required to comply with the Federal Food Safety & Modernization Act and applicable regulations. The Company would be required to provide foreign supplier certifications evidencing the Company's compliance with FDA requirements.

The FDA has broad authority to enforce the provisions of the FDCA applicable to foods, drugs, dietary supplements, and cosmetics, including powers to issue a public warning letter to a company, to publicize information about illegal or harmful products, to request a recall of products from the market, and to request the United States Department of Justice to initiate a seizure action, an injunction action, or a criminal prosecution in the U. S. courts. The Company could be subject to fines and penalties, including under administrative, civil and criminal laws for violating U.S. laws and regulations, and the Company's expected nutraceutical products could be banned or subject to recall from the marketplace. The Company could also be subject to possible business and consumer claims under applicable statutory, product liability and common laws.

The FTC will exercise jurisdiction over the advertising of the Company's expected nutraceutical products in the United States. The FTC has in the past instituted enforcement actions against several dietary supplement and food companies and against manufacturers of dietary supplement products, including for false and misleading advertising, label claims or product promotional claims. In addition, the FTC has increased its scrutiny of the use of testimonials, which the Company may utilize, as well as the role of endorsements and product clinical studies. The Company cannot be sure that the FTC, or comparable foreign agencies, will not question the Company's advertising, product claims, promotional materials or other operations in the future. The FTC has broad authority to enforce its laws and regulations, including the ability to institute enforcement actions that could result in recall actions, consent decrees, injunctions, and civil and criminal penalties by the companies involved. Failure to comply with the FTC's laws and regulations could impair the Company's ability to market the Company's expected nutraceutical products.

The Company will also be subject to regulation under various state and local laws, ordinances and regulations that include provisions governing, among other things, the registration, formulation, manufacturing, packaging, labeling, advertising, sale and distribution of foods and dietary supplements. In addition, in the future, the Company may become subject to additional laws or regulations administered by the FDA or by other federal, state, local or foreign governmental authorities, to the repeal of laws or regulations that the Company considers favorable, or to more stringent interpretations of current laws or regulations. In the future, the Company believes that the dietary supplement industry will likely face increased scrutiny from federal, state and local governmental authorities. It is difficult to predict the effect future laws, regulations, repeals or interpretations will have on the Company's business. However, such changes could require the reformulation of products, recalls or discontinuance of products, additional administrative requirements, revised or additional labeling, increased scientific substantiation or other requirements. Any such changes could have a material adverse effect on the Company's business or financial performance.

Research and Development - Psychedelics

Canada

Prescription Drugs in Canada

If and as permitted by applicable law, the Company intends to manufacture prescription drugs with which it is authorized to deal pursuant to its dealer's licence. The process required before a prescription drug product candidate may be marketed in Canada generally involves:

Chemical and Biological Research - Laboratory tests are carried out on tissue cultures and with a variety of small animals to determine the effects of the drug. If the results are promising, the manufacturer will proceed to the next step of development.

Pre-Clinical Development - Animals are given the drug in varying amounts over differing periods of time. If it can be shown that the drug causes no serious or unexpected harm at the doses required to have an effect, the manufacturer will proceed to clinical trials.

Clinical Trials - Phase I - The first administration in humans is to test if people can tolerate the drug. If this testing is to take place in Canada, the manufacturer must prepare a clinical trial application for the Therapeutic Products Directorate of Health Canada (the "TPD"). This includes the results of the first two steps and a proposal for testing in humans. If the information is sufficient, the Health Products and Food Branch of Health Canada (the "HPFB") grants permission to start testing the drug, generally first on healthy volunteers.

Clinical Trials - Phase II - Phase II trials are carried out on people with the target condition, who are usually otherwise healthy, with no other medical condition. Trials carried out in Canada must be approved by the TPD. In phase II, the objective of the trials is to continue to gather information on the safety of the drug and begin to determine its effectiveness.

Clinical Trials - Phase III - If the results from phase II show promise, the manufacturer provides an updated clinical trial application to the TPD for phase III trials. The objectives of phase III include determining whether the drug can be shown to be effective, and have an acceptable side effect profile, in people who better represent the general population. Further information will also be obtained on how the drug should be used, the optimal dosage regimen and the possible side effects.

New Drug Submission - If the results from phase III continue to be favourable, the drug manufacturer can submit a new drug submission ("NDS") to the TPD. A drug manufacturer can submit an NDS regardless of whether the clinical trials were carried out in Canada. The TPD reviews all the information gathered during the development of the drug and assesses the risks and benefits of the drug. If it is judged that, for a specific patient population and specific conditions of use, the benefits of the drug outweigh the known risks, the HPFB will approve the drug by issuing a notice of compliance.

United States

The process required before a prescription drug product candidate may be marketed in the United States generally involves:

- completion of extensive non-clinical laboratory tests, animal studies and formulation studies, all performed in accordance with the FDA's Good

Laboratory and/or Manufacturing Practice regulations;

- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an institutional review board or independent ethics committee at each clinical trial site before each trial may be initiated;
- for some products, performance of adequate and well-controlled human clinical trials in accordance with the FDA's regulations, including Good Clinical Practices, to establish the safety and efficacy of the prescription drug product candidate for each proposed indication;
- submission to the FDA of a NDA; and
- FDA review and approval of the NDA prior to any commercial marketing, sale or shipment of the drug.

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

Non-clinical tests include laboratory evaluations of product chemistry, formulation and stability, as well as studies to evaluate toxicity in animals and other animal studies. The results of non-clinical tests, together with manufacturing information and analytical data, are submitted as part of an IND to the FDA. Some non-clinical testing may continue even after an IND is submitted. The IND also includes one or more protocols for the initial clinical trial or trials and an investigator's brochure. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions relating to the proposed clinical trials as outlined in the IND and places the clinical trial on a clinical hold. In such cases, the IND sponsor and the FDA must resolve any outstanding concerns or questions before any clinical trials can begin. Clinical trial holds also may be imposed at any time before or during studies due to safety concerns or non-compliance with regulatory requirements.

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

The Company's commercial partners may plan to seek orphan drug designation for certain indications qualified for such designation. The U.S., E.U. and other jurisdictions may grant orphan drug designation to drugs intended to treat a "rare disease or condition." Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or 200,000 or more individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan drug designation must be requested before submitting an NDA. If a product that has an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, meaning that the applicable regulatory authority may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, for a period of seven years in the U.S. Orphan drug designation does not prevent competitors from developing or marketing different drugs for the same indication or the same drug for different indications. After orphan drug designation is granted, the identity of the therapeutic agent and its potential orphan use are publicly disclosed. Orphan drug designation does not convey an advantage in, or shorten the duration of, the development, review and approval process. However, this designation provides an exemption from marketing and authorization (NDA) fees.

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

Drugs manufactured or distributed pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, reporting of adverse experiences with the product, and complying with promotion and advertising requirements. The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-market testing, including phase IV clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. In addition, drug manufacturers and their subcontractors involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including current Good Manufacturing Practices, which impose certain procedural and documentation requirements. Failure to comply with statutory and regulatory requirements may subject a manufacturer to legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, civil penalties or criminal prosecution. There is also a continuing, annual prescription drug product program user fee.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, requirements for post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a risk evaluation and mitigation strategy.

Controlled Substances

In the United States, the possession and sale of psychedelic and hallucinogenic products are illegal under federal, state, and local laws and regulations. Many psychedelic substances, such as psilocybin, are strictly controlled under the CSA as Schedule I substances. The CSA and its implementing regulations establish a "closed system" of regulations for controlled substances. The CSA imposes registration, security, recordkeeping and reporting, storage, manufacturing, distribution, importation and other requirements under the oversight of the DEA. The DEA is responsible for regulating controlled substances, and requires those individuals or entities that manufacture, import, export, distribute, research, or dispense controlled substances to comply with the regulatory requirements in order to prevent the diversion of controlled substances to illicit channels of commerce.

Facilities that research, manufacture, distribute, import or export any controlled substance must register annually with the DEA. The DEA registration is specific to the particular location, activity(ies) and controlled substance schedule(s). For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized.

The DEA inspects all manufacturing facilities to review security, recordkeeping, reporting and handling prior to issuing a controlled substance registration. The specific security requirements vary by the type of business activity and the schedule and quantity of controlled substances handled. The most stringent requirements apply to manufacturers of Schedule I and Schedule II substances. Required security measures commonly include background

checks on employees and physical control of controlled substances through storage in approved vaults, safes and cages, and through use of alarm systems and surveillance cameras. Once registered, manufacturing facilities must maintain records documenting the manufacture, receipt and distribution of all controlled substances. Manufacturers must submit periodic reports to the DEA of the distribution of Schedule I and II controlled substances, Schedule III narcotic substances, and other designated substances. Registrants must also report any controlled substance thefts or significant losses, and must obtain authorization to destroy or dispose of controlled substances. Imports of Schedule I and II controlled substances for commercial purposes are generally restricted to substances not already available from a domestic supplier or where there is not adequate competition among domestic suppliers. In addition to an importer or exporter registration, importers and exporters must obtain a permit for every import or export of a Schedule I and II substance or Schedule III, IV and V narcotic, and submit import or export declarations for Schedule III, IV and V non-narcotics.

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

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

ITEM 1A. RISK FACTORS.

Our business faces many risks. Any of the risks discussed below, or elsewhere in this report or in our other filings with the Securities and Exchange Commission ("SEC"), could have a material impact on our business, financial condition, or results of operations.

Risks Related to Our Business

We have a history of losses and our revenues may not be sufficient to sustain our operations.

Even though we ceased being a "development stage" company in April 2006, we are still subject to all of the risks associated with having a limited operating history and pursuing the development of new products. Our cash flows may be insufficient to meet expenses relating to our operations and the development of our business, and may be insufficient to allow us to develop new products. We currently conduct R&D using our proprietary platform technologies to develop oral controlled release and other delivery products. We do not know whether we will be successful in the development of such products. We have an accumulated deficit of approximately $68,530 thousand since our inception in 2003 through December 31, 2022. To date, these losses have been financed principally through sales of equity securities. Our revenues for the past five years ended December 31, 2022, December 31, 2021, December 31, 2020, December 31, 2019 and December 31, 2018 were $1 million, $1.5 million, $1.5 million, $0.7 million and $1.8 million, respectively. Revenue generated to date has not been sufficient to sustain our operations. In order to achieve profitability, our revenue streams will have to increase and there is no assurance that revenues will increase to such a level.

We may need additional capital to fulfill our business strategies. Failure to obtain such capital would adversely affect our business.

We will need to expend significant capital in order to continue with our R&D and manufacturing operation expansion by hiring additional research staff and acquiring additional equipment. If our cash flows from operations are insufficient to fund our expected capital needs, or our needs are greater than anticipated, we may be required to raise additional funds in the future through private or public sales of equity securities or the incurrence of indebtedness.

If we borrow additional funds, we likely will be obligated to make periodic interest or other debt service payments and may be subject to additional restrictive covenants. If we raise additional funds through public or private sales of equity securities, the sales may be at prices below the market price of our stock and our Shareholders may suffer significant dilution.

Additional funding may also not be available on favorable terms, or at all. If we fail to obtain sufficient additional capital in the future, we could be forced to curtail our growth strategy by reducing or delaying capital expenditures, selling assets or downsizing or restructuring our operations.

We are dependent on business partners to conduct clinical trials of, obtain regulatory approvals for, and market and sell our products.

We depend heavily on our pharmaceutical partners to pay for part or all of the R&D expenses associated with developing a new product and to obtain approval from regulatory bodies such as the FDA to commercialize these products. We also depend on our partners to distribute these products after receiving regulatory approval. Our revenues from R&D fees, milestone payments and royalty fees are derived from our partners. Our inability to find pharmaceutical partners who are willing to pay us these fees in order to develop new products would negatively impact our business and our cash flows.

We have limited experience in manufacturing, marketing and selling pharmaceutical products. Accordingly, if we cannot maintain our existing partnerships or establish new partnerships with respect to our other products in development, we will have to establish our own capabilities or discontinue the commercialization of the affected product. Developing our own capabilities would be expensive and time consuming and could delay the commercialization of the affected product. There can be no assurance that we would be able to develop these capabilities.

Our existing agreements with pharmaceutical industry partners are generally subject to termination by the counterparty on short notice upon the occurrence of certain circumstances, including, but not limited to, the following: a determination that the product in development is not likely to be successfully developed or not likely to receive regulatory approval; our failure to satisfy our obligations under the agreement, or the occurrence of a bankruptcy event. If any of our partnerships are terminated, we may be required to devote additional resources to the product, seek a new partner on short notice, or abandon the product development efforts. The terms of any additional partnerships or other arrangements that we establish may not be favorable to us.

We are also at risk that these partnerships or other arrangements may not be successful. Factors that may affect the success of our partnerships include the following:

- our partners may incur financial and cash-flow difficulties that force them to limit or reduce their participation in our joint projects;
- our partners may be pursuing alternative technologies or developing alternative products that are competitive to our product, either on their own or in partnership with others;
- our partners may reduce marketing or sales efforts, or discontinue marketing or sales of our products, which may reduce our revenues received on the products;
- our partners may have difficulty obtaining the raw materials to manufacture our products in a timely and cost effective manner or experience delays in production, which could affect the sales of our products and our royalty revenues earned;
- our partners may terminate their partnerships with us. This could make it difficult for us to attract new partners, and it could adversely affect how the business and financial communities perceive us;
- our partners may pursue higher priority programs or change the focus of their development programs, which could affect the partner's commitment to us. Pharmaceutical and biotechnology companies historically have re-evaluated their priorities from time to time, including following mergers and consolidations, a common occurrence in recent years; and
- our partners may become the target of litigation for purported patent or intellectual property infringement, which could delay or prohibit commercialization of our products and which would reduce our revenue from such products.

We face competition in our industry, and several of our competitors have substantially greater experience and resources than we do.

We compete with other companies within the drug delivery industry, many of which have more capital, more extensive R&D capabilities and greater human resources than we do. Some of these drug delivery competitors include Aquestive (formerly Monosol Rx), Tesa-Labtec GmbH, BioDelivery Sciences International, Inc. and LTS Lohmann Therapy Systems Corp. Our competitors may develop new or enhanced products or processes that may be more effective, less expensive, safer or more readily available than any products or processes that we develop, or they may develop proprietary positions that prevent us from being able to successfully commercialize new products or processes that we develop. As a result, our products or processes may not compete successfully, and research and development by others may render our products or processes obsolete or uneconomical. Competition may increase as technological advances are made and commercial applications broaden.

The laws, regulations and guidelines applicable to cannabinoid-based products in Canada and in other countries may change in ways that impact our ability to continue our business as currently conducted or proposed to be conducted.

Our operations are subject to various laws, regulations and guidelines relating to the manufacture, management, transportation, storage and disposal of cannabinoid-based products as well as laws and regulations relating to health and safety, the conduct of operations and the protection of the environment. The successful execution of our cannabis business objectives is contingent upon compliance with all applicable laws and regulatory requirements in Canada and other jurisdictions and obtaining all required regulatory approvals for the production, sale, import and export of our cannabinoid-based products. The administration, application and enforcement of the laws of Canada and other countries, may significantly delay or impact our ability to participate in the Canadian cannabis market or cannabis markets outside Canada, and our ability to develop, produce and sell cannabinoid-based products.

Further, the regulatory authorities in Canada and in other countries in which we may operate in the future or to which we may export our products may change their administration, interpretation or application of the applicable laws, rules and regulations or their compliance or enforcement procedures at any time. Any such changes could require us to revise our ongoing compliance procedures, requiring us to incur increased compliance costs and expend additional resources. There is no assurance that we will be able to comply or continue to comply with applicable laws, rules and regulations.

We rely upon third-party manufacturers, which puts us at risk for supplier business interruptions.

In certain instances, we may have to enter into agreements with third party manufacturers to manufacture certain of our products once we complete development and after we receive regulatory approval. If our third-party manufacturers fail to perform, our ability to market products and to generate revenue would be adversely affected. Our failure to deliver products in a timely manner could lead to the dissatisfaction of our distribution partners and damage our reputation, causing our distribution partners to cancel existing agreements with us and to stop doing business with us.

Any third-party manufacturers that we depend on to manufacture our products are required to adhere to FDA regulations regarding cGMP, which include testing, control and documentation requirements. Ongoing compliance with cGMP and other regulatory requirements is monitored by periodic inspection by the FDA and comparable agencies in other countries. Failure by our third-party manufacturers to comply with cGMP and other regulatory requirements could result in actions against them by regulatory agencies and jeopardize our ability to obtain products on a timely basis.

We have established our own manufacturing facility for the manufacture of VersaFilm™ products, which required considerable financial investment. If we are unsuccessful to manufacture our VersaFilm™ products adequately and at an acceptable cost, this could have a material adverse effect on our business, financial condition or results of operations.

We currently manufacture products only for clinical and testing purposes in our own facility and we do not yet manufacture products for commercial use to the exception of our CBD film which was launched in Q1 2021. In order to establish ourselves as a full-service partner for our thin film products, we invested approximately $6.5 million to establish a state-of-the-art manufacturing facility for the commercial manufacture of products developed using our VersaFilm™ drug delivery technology.

We project to exceed our current manufacturing capacity by 2025; therefore, we ordered new manufacturing equipment that will increase our capacity approximately fourfold. We are expanding our manufacturing facility in order to create the space required for this new manufacturing equipment

We have limited expertise in establishing and operating a manufacturing facility and although we have contracted with architects, engineers and

construction contractors specialized in the planning and construction of pharmaceutical facilities, there can be no guarantee that the project can be completed within the time or budget allocated. In addition, we may be unable to attract suitably qualified personnel for our manufacturing facility at acceptable terms and conditions of employment.

In addition, before we can begin commercial manufacture of our VersaFilm™ products for sale in the United States, we must obtain FDA regulatory approval for the product, which requires a successful inspection of our manufacturing facilities, processes and quality systems. Further, pharmaceutical manufacturing facilities are continuously subject to inspection by the FDA and other health authorities before and after product approval. Due to the complexity of the processes used to manufacture our VersaFilm™ products, we may be unable initially or at any future time to pass federal, state or international regulatory inspections in a cost effective manner. If we are unable to comply with manufacturing regulations, we may be subject to fines, unanticipated compliance expenses, recall or seizure of any approved products, total or partial suspension of production and/or enforcement actions, including injunctions, and criminal or civil prosecution.

The manufacture of our products is heavily regulated by governmental health authorities, including the FDA. We must ensure that all manufacturing processes comply with current cGMP and other applicable regulations. If we fail to comply fully with these requirements and the health authorities' expectations, then we could be required to shut down our production facilities or production lines, or could be prevented from importing our products from one country to another. This could lead to product shortages, or to our being entirely unable to supply products to patients for an extended period of time. Such shortages or shut downs could lead to significant losses of sales revenue and to potential third-party litigation. In addition, health authorities have in some cases imposed significant penalties for such failures to comply with cGMP. A failure to comply fully with cGMP could also lead to a delay in the approval of new products to be manufactured at our manufacturing facility.

Any disruption in the supply of our future products could have a material adverse effect on our business, financial condition or results of operations.

We have no timely ability to replace our future VersaFilm™ manufacturing capabilities.

If our manufacturing facility suffers any type of prolonged interruption, whether caused by regulator action, equipment failure, critical facility services, fire, natural disaster or any other event that causes the cessation of manufacturing activities, we would be exposed to long-term loss of sales and profits. There are no facilities capable of contract manufacturing our VersaFilm™ products at short notice. If we suffer an interruption to our manufacturing of VersaFilm™ products, we may have to find a contract manufacturer capable of supplying our needs, although this would require completing a Manufacturing Site Change process, which takes considerable time and is costly. Replacement of our manufacturing capabilities will have a material adverse effect on our business and financial condition or results of operations.

We depend on a limited number of suppliers for Active Pharmaceutical Ingredients ("API"). Generally, only a single source of API is qualified for use in each product due to the costs and time required to validate a second source of supply. Changes in API suppliers must usually be approved through a Prior Approval Supplement by the FDA.

Our ability to manufacture products is dependent, in part, upon ingredients and components supplied by others, including international suppliers. Any disruption in the supply of these ingredients or components or any problems in their quality could materially affect our ability to manufacture our products and could result in legal liabilities that could materially affect our ability to realize profits or otherwise harm our business, financial, and operating results. As the API typically comprises the majority of a product's manufactured cost, and qualifying an alternative is costly and time-consuming, API suppliers must be selected carefully based on quality, reliability of supply and long-term financial stability.

We are subject to extensive government regulation including the requirement of approval before our products may be marketed. Even if we obtain marketing approval, our products will be subject to ongoing regulatory review.

We, our partners, our products, and our product candidates are subject to extensive regulation by governmental authorities in the United States and other countries. Failure to comply with applicable requirements could result in warning letters, fines and other civil penalties, delays in approving or refusal to approve a product candidate, product recall or seizure, withdrawal of product approvals, interruption of manufacturing or clinical trials, operating restrictions, injunctions, and criminal prosecution.

Our products cannot be marketed in the United States without FDA approval. Obtaining FDA approval requires substantial time, effort, and financial resources, and there can be no assurance that any approval will be granted on a timely basis, if at all. With most of our products, we rely on our partners for the preparation of applications and for obtaining regulatory approvals. If the FDA does not approve our product candidates in a timely fashion, or does not approve them at all, our business and financial condition may be adversely affected. Further, the terms of approval of any marketing application, including the labeling content, may be more restrictive than we desire and could affect the marketability of our or our partner`s products. Subsequent discovery of problems with an approved product may result in restrictions on the product or its withdrawal from the market. In addition, both before and after regulatory approval, we, our partners, our products, and our product candidates are subject to numerous FDA requirements regarding testing, manufacturing, quality control, cGMP, adverse event reporting, labeling, advertising, promotion, distribution, and export. Our partners and we are subject to surveillance and periodic inspections to ascertain compliance with these regulations. Further, the relevant law and regulations may change in ways that could affect us, our partners, our products, and our product candidates. Failure to comply with regulatory requirements could have a material adverse impact on our business.

Regulations regarding the manufacture and sale of our future products are subject to change. We cannot predict what impact, if any, such changes may have on our business, financial condition or results of operations. Failure to comply with applicable regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

Additionally, the time required for obtaining regulatory approval is uncertain. We may encounter delays or product rejections based upon changes in FDA policies, including cGMP, during periods of product development. We may encounter similar delays in countries outside of the United States. We may not be able to obtain these regulatory acceptances on a timely basis, or at all.

The failure to obtain timely regulatory acceptance of our products, any product marketing limitations, or any product withdrawals would have a material adverse effect on our business, financial condition and results of operations. In addition, before it grants approvals, the FDA or any foreign regulatory authority may impose numerous other requirements with which we must comply. Regulatory acceptance, if granted, may include significant limitations on the indicated uses for which the product may be marketed. FDA enforcement policy strictly prohibits the marketing of accepted products for unapproved uses. Product acceptance could be withdrawn or civil and/or criminal sanctions could be imposed for our failure to comply with regulatory standards or the occurrence of unforeseen problems following initial marketing.

We may not be able to expand or enhance our existing product lines with new products limiting our ability to grow.

If we are not successful in the development and introduction of new products, our ability to grow will be impeded. We may not be able to identify products to enhance or expand our product lines. Even if we can identify potential products, our investment in R&D might be significant before we can bring the products to market. Moreover, even if we identify a potential product and expend significant dollars on development, we may never be able to bring the product to market or achieve market acceptance for such product. As a result, we may never recover our expenses.

The market may not be receptive to products incorporating our drug delivery technologies.

The commercial success of any of our products that are approved for marketing by the FDA and other regulatory authorities will depend upon their acceptance by the medical community and third party payers as clinically useful, cost-effective and safe. To date, only two products based upon our technologies have been marketed in the United States, which limits our ability to provide guidance or assurance as to market acceptance.

Factors that we believe could materially affect market acceptance of these products include:

- the timing of the receipt of marketing approvals and the countries in which such approvals are obtained;
- the safety and efficacy of the product as compared to competitive products;
- the relative convenience and ease of administration as compared to competitive products;
- the strength of marketing distribution support; and
- the cost-effectiveness of the product and the ability to receive third party reimbursement.

The impact of the COVID-19 outbreak on our operations, and the operations of our partners, suppliers and logistics providers, could significantly disrupt our operations and may materially and adversely affect our business and financial conditions.

Our business could be adversely impacted by the effects of the coronavirus or other epidemics. The extent to which the COVID-19 impacts our business, including our operations and the market for our securities, will depend on future developments, which are highly uncertain and cannot be predicted at this time, and include the duration, severity and scope of the outbreak and the actions taken to contain or treat the coronavirus outbreak. In particular, the continued spread of the coronavirus globally could materially and adversely impact our business including without limitation, employee health, workforce productivity, increased insurance premiums, limitations on travel, the availability of industry advisers and personnel, and other factors that will depend on future developments beyond our control, which may have a material and adverse effect on our business, financial condition and results of operations. Likewise, the continued spread of the virus locally and regionally and the resulting preventative measures that have been put in place by the provincial and local administrations may impact our ability to hire qualified staff.

Hence, there can be no assurance that our personnel will not be impacted by these pandemic diseases and ultimately see our workforce productivity reduced or incur increased medical costs / insurance premiums as a result of these health risks.

In addition, a significant outbreak of coronavirus could result in a widespread global health crisis that could adversely affect global economies and financial markets resulting in an economic downturn.

The war in Ukraine and Russia may continue to have a material adverse impact on us and our companies.

On February 24, 2022, the President of Russia, Vladimir Putin, announced a military invasion of Ukraine. In response, countries worldwide, including the United States, have imposed sanctions against Russia on certain businesses and individuals, including, but not limited to, those in the banking, import and export sectors. This invasion has led, is currently leading, and for an unknown period of time will continue to lead to disruptions in local, regional, national, and global markets and economies affected thereby. These disruptions caused by the invasion have included, and may continue to include, political, social, and economic disruptions and uncertainties and material increases in certain commodity prices that may affect our business operations or the business operations of our subsidiaries.

Risks Related to the atai Investment

Our existing Shareholders will have a reduced ownership and voting interest after any potential future atai investment

Following any potential future atai investment under the Securities Purchase Agreement, the existing Shareholders other than atai will hold a percentage ownership in us that is smaller than the Shareholders' current percentage ownership. This dilution will be proportional to the percentage rate by which we increase our issued and outstanding shares. In addition, as of immediately following the initial closing of the Investment, atai had the right to nominate directors to the Board of Directors of the Company (the "Board"), which right is proportionate to the shares of Common Stock then held by atai. As a result, existing Shareholders will have less influence on our management and policies than they currently have, which influence will also further diminish if atai's ownership stake increases following additional closings.

Atai is in a position to exert substantial influence on us and the interests pursued by atai could differ from the interests of our other Shareholders, and if it acquires a majority of our shares, it will be able to approve most corporate actions requiring shareholder approval by written consent.

Following the completion of the initial Investment, atai held approximately 25% of our issued and outstanding shares. Since then atai's ownership has been reduced to 21% following additional issuance of shares by the Company to Shareholders other than atai. If atai were to acquire all of the Additional Shares and exercise all of the Initial Warrants and Additional Warrants, atai would hold approximately 56% of our issued and outstanding shares. As a result, atai may be in a position to exert substantial influence at our annual shareholder meeting or any special meeting of the shareholders and, consequently, over matters decided by the annual shareholder meeting or any special meeting of the shareholders, including the appointment of members of the directors of the Board, particularly if attendance is low among other Shareholders. If atai acquires more than 50% of our outstanding Common Stock, atai generally will be able to determine the outcome of corporate actions requiring shareholder approval. In this regard, the interests of atai could deviate from, and even be to the detriment of, the interests of our other Shareholders.

The Strategic Development Agreement may not result in the development of commercially viable products or the generation of significant future revenues.

Under the Strategic Development Agreement, we will cooperate with atai to conduct R&D projects in areas relating to our respective technologies. The success of our cooperation is dependent on a number of factors, including with respect to research and development, manufacturing and quality assurance. Even if our development and clinical trial efforts succeed, the FDA or other regulatory agencies may not approve the developed products or may require additional product testing and clinical trials before approving the developed products, which would result in product launch delays and additional expense. Even if approved by the FDA or other regulatory agencies, the developed products may not be accepted in the marketplace.

The commercialization of any technologies that result from the R&D projects under the strategic development agreement will be subject to agreements to be negotiated, as well as to specified pricing and royalty terms for manufacturing conducted by us or third parties. There is no guarantee that we will be able to enter into such an agreement on commercially reasonable terms or at all.

If we default under the Loan Agreement, all or a portion of our assets could be subject to forfeiture.

IntelGenx Technologies Corp. has guaranteed the repayment obligations of IntelGenx Corp. under the Loan Agreement and the loan is also secured by all of present and future fixed assets of IntelGenx Corp., excluding any intellectual property or technology controlled or owned by IntelGenx Corp. If IntelGenx Technologies Corp. defaults on the Loan Agreement and is unable to cure the default pursuant to the terms of the agreement or is unable to repay or refinance the loan when due, atai could take possession of any or all assets in which it holds a security interest, and dispose those assets to the extent necessary to pay off the debts, which may have a significant impact on our ability to operate our business.

Risks related to the development of compounds for the prevention or treatment of mental health diseases or disorders, including compounds that have psychedelic, entactogenic and/or oneirophrenic properties.

Under the Strategic Development Agreement, we aim to develop compounds for the prevention or treatment of mental health diseases or disorders, including compounds that have psychedelic, entactogenic and/or oneirophrenic properties. The success of our ability to develop and commercialize such compounds will depend on numerous factors, including the following:

- successful completion of clinical trials and preclinical studies;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- receiving regulatory approvals or clearance for conducting our planned clinical trials or future clinical trials;
- successful patient enrollment in and completion of clinical trials;
- positive data from our clinical trials that support an acceptable risk-benefit profile of the compound for the intended populations;
- receipt and maintenance of regulatory and marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection and/or regulatory exclusivity for any compounds we develop;
- successfully launching commercial sales of any compounds we develop, if approved;
- acceptance of our compounds' benefits and uses, if approved, by patients, the medical community and third-party payors;
- maintaining a continued acceptable safety profile of any compound we develop following approval;
- effectively competing with companies developing and commercializing other compounds in the indications which our compounds target;
- obtaining and maintaining healthcare coverage and adequate reimbursement from third-party payors;
- enforcing and defending intellectual property rights and claims; and
- complying with laws and regulations, including laws applicable to controlled substances.

If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our compounds we develop, which would materially harm our business.

The compounds we may develop in the future may be subject to controlled substance laws and regulations in the territories where the product will be marketed, such as the United States, Canada, and Europe, and failure to comply with these laws and regulations, or the cost of compliance with these laws and regulations, may adversely affect the results of our business operations, both during clinical development and post approval, and our financial condition. In addition, during the review process of any compound, and prior to approval, the FDA and/or other regulatory bodies may require additional data, including with respect to whether such compound has abuse potential. This may delay approval and any potential rescheduling process.

Certain compounds may contain controlled substances, the use of which may generate public controversy.

Compounds containing controlled substances may generate public controversy. Political and social pressures and adverse publicity could lead to delays in approval of, and increased expenses for, any compounds we may develop. Adverse publicity from misuse may adversely affect the commercial success or market penetration achievable by any compound we develop.

If any compounds are approved for commercial sale, we will be highly dependent upon consumer perceptions regarding safety and quality. We may face limited adoption if healthcare providers, and patients are unwilling to try novel compounds, which could have a material adverse impact on our business, prospects, financial condition and results of operations.

Future adverse events in research into depression and mental health diseases, or the pharmaceutical industry more generally, could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals. Any increased scrutiny could delay or increase the costs of obtaining regulatory approvals.

Risks Related to Our Intellectual Property

If we are not able to adequately protect our intellectual property, we may not be able to compete effectively.

Our success depends, to a significant degree, upon the protection of our proprietary technologies. While we currently own 38 patents and have an additional 31 published pending patent applications in several jurisdictions, we will need to pursue additional protection for our intellectual property as we

develop new products and enhance existing products. We may not be able to obtain appropriate protection for our intellectual property in a timely manner, or at all. Our inability to obtain appropriate protections for our intellectual property may allow competitors to enter our markets and produce or sell the same or similar products.

If we are forced to resort to legal proceedings to enforce our intellectual property rights, the proceedings could be burdensome and expensive. In addition, our proprietary rights could be at risk if we are unsuccessful in, or cannot afford to pursue, those proceedings.

We also rely on trade secrets and contract law to protect some of our proprietary technology. We have entered into confidentiality and invention agreements with our employees and consultants. Nevertheless, these agreements may not be honored and they may not effectively protect our right to our un-patented trade secrets and know-how. Moreover, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets and know-how.

We may need to obtain licenses to patents or other proprietary rights from third parties. We may not be able to obtain the licenses required under any patents or proprietary rights or they may not be available on acceptable terms. If we do not obtain required licenses, we may encounter delays in product development or find that the development, manufacture or sale of products requiring licenses could be foreclosed. We may, from time to time, support and collaborate in research conducted by universities and governmental research organizations. We may not be able to acquire exclusive rights to the inventions or technical information derived from these collaborations, and disputes may arise over rights in derivative or related research programs conducted by us or our partners.

If we infringe on the rights of third parties, we may not be able to sell our products, and we may have to defend against litigation and pay damages.

If a competitor were to assert that our products infringe on its patent or other intellectual property rights, we could incur substantial litigation costs and be forced to pay substantial damages. Such litigation costs could be as a result of direct litigation against us, or as a result of litigation against one or more of our partners to whom we have contractually agreed to indemnify in the event that our intellectual property is the cause of a successful litigious action against our partner. Third-party infringement claims, regardless of their outcome, would not only consume significant financial resources, but would also divert our management's time and attention. Such claims could also cause our customers or potential customers to purchase competitors' products or defer or limit their purchase or use of our affected products until resolution of the claim. If any of our products are found to violate third-party intellectual property rights, we may have to re-engineer one or more of our products, or we may have to obtain licenses from third parties to continue offering our products without substantial re-engineering. Our efforts to re-engineer or obtain licenses could require significant expenditures and may not be successful.

Our controlled release products that are generic versions of branded controlled release products that are covered by one or more patents may be subject to litigation, which could delay FDA approval and commercial launch of our products. We are also subject to litigation and other legal proceedings and may be involved in disputes with other parties in the future which may result in litigation

We expect to file or have our partners file NDAs or ANDAs for our controlled release products under development that are covered by one or more patents of the branded product. It is likely that the owners of the patents covering the brand name product or the sponsors of the NDA with respect to the branded product will sue or undertake regulatory initiatives to preserve marketing exclusivity. Any significant delay in obtaining FDA approval to market our products as a result of litigation, as well as the expense of such litigation, whether or not we or our partners are successful, could have a materially adverse effect on our business, financial condition and results of operations.

The causes of potential future litigation and legal proceedings cannot be known and may arise from, among other things, business activities, the Investment, environmental laws, permitting and licensing activities, volatility in stock prices, or alleged failure to comply with disclosure obligations. The results of litigation and proceedings cannot be predicted with certainty and may include injunctions pending the outcome of such litigation and proceedings. Failure to resolve any such disputes favorably may have a material adverse impact on our financial performance, cash flow and results of operations.

If we are unable to protect our information systems against service interruption, misappropriation of data or breaches of security, our operations could be disrupted, we may suffer financial losses and our reputation may be damaged.

If we or third parties with which we do business were to fall victim to successful cyber-attacks or experience other cybersecurity incidents, including the loss of individually identifiable customer or other sensitive data, we may incur substantial costs and suffer other negative consequences, which may include: remediation costs, such as liability for stolen assets or information, repairs of system damage or replacement of systems, and incentives to customers or business partners in an effort to maintain relationships after an attack; increased cybersecurity protection costs, which may include the costs to continue to make organizational changes, deploy additional personnel and protection technologies, train employees, and engage third party consultants; lost revenues resulting from the unauthorized use of proprietary information or the failure to retain or attract customers following an attack; litigation and legal risks, including regulatory actions by state and federal governmental authorities; increased cybersecurity and other insurance premiums; reputational damage that adversely affects customer or investor confidence; and damage to our competitiveness, stock price, and long-term stockholder value.

Risks Related to Our Securities:

The price of our Common Stock could be subject to significant fluctuations.

Any of the following factors could affect the market price of our Common Stock:

- our failure to achieve and maintain profitability;
- changes in earnings estimates and recommendations by financial analysts;
- actual or anticipated variations in our quarterly results of operations;
- changes in market valuations of similar companies;
- announcements by us or our competitors of significant contracts, new products, acquisitions, commercial relationships, joint ventures or capital commitments;

- the loss of major customers or product or component suppliers;
- the loss of significant partnering relationships; and
- general market, political and economic conditions.

We have a significant number of convertible securities outstanding that could be exercised in the future. Subsequent resale of these and other shares could cause our stock price to decline. This could also make it more difficult to raise funds at acceptable levels pursuant to future securities offerings.

Our Common Stock is a high risk investment.

Our Common Stock has been quoted on OTC Markets under the symbol "IGXT" since January 2007. Beginning in June 2012, our Common Stock was quoted on the OTCQX and, since April 2020, has been quoted on the OTCQB. Our Common Stock was also listed on the TSX Venture Exchange (the "TSX-V") from May 2008 until our graduation to the Toronto Stock Exchange (the "TSX") in October 2021 where our Common Stock is now trading under the under the symbol "IGX".

There is a limited trading market for our Common Stock, which may affect the ability of Shareholders to sell our Common Stock and the prices at which they may be able to sell our Common Stock.

The market price of our Common Stock has been volatile and fluctuates widely in response to various factors which are beyond our control. The price of our Common Stock is not necessarily indicative of our operating performance or long term business prospects. In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our Common Stock.As a result of the foregoing, our Common Stock should be considered a high risk investment.

The application of the "penny stock" rules to our Common Stock could limit the trading and liquidity of our Common Stock, adversely affect the market price of our Common Stock and increase stockholder transaction costs to sell those shares.

As long as the trading price of our Common Stock is below $5.00 per share, the open market trading of our Common Stock will be subject to the "penny stock" rules, unless we otherwise qualify for an exemption from the "penny stock" definition. The "penny stock" rules impose additional sales practice requirements on certain broker-dealers who sell securities to persons other than established customers and accredited investors (generally those with assets in excess of $1,000,000 or annual income exceeding $200,000 or $300,000 together with their spouse). These regulations, if they apply, require the delivery, prior to any transaction involving a penny stock, of a disclosure schedule explaining the penny stock market and the associated risks. Under these regulations, certain brokers who recommend such securities to persons other than established customers or certain accredited investors must make a special written suitability determination regarding such a purchaser and receive such purchaser's written agreement to a transaction prior to sale. These regulations may have the effect of limiting the trading activity of our Common Stock, reducing the liquidity of an investment in our Common Stock and increasing the transaction costs for sales and purchases of our Common Stock as compared to other securities.

There is no public market for certain Company warrants, which could limit their respective trading price or a holder's ability to sell them.

There is currently no trading market in the United States for the warrants issued by the Company in 2020 and 2021. As a result, a market is unlikely to develop for the Company's warrants in the United States and holders may not be able to sell the Company's warrants in the United States. Future trading prices of the Company's warrants will depend on many factors, including the market for similar securities, general economic conditions and our financial condition, performance and prospects. Accordingly, holders may be required to bear the financial risk of an investment in the Company's warrants for an indefinite period of time until they expire.

Risks related to our outstanding convertible notes.

There is no public market for the Company's Notes, which could limit their respective trading price or a holder's ability to sell them.

There is currently no trading market for the Company's Notes. As a result, a market is unlikely to develop for the Company's Notes and holders may not be able to sell the Company's Notes. Future trading prices of the Company's Notes will depend on many factors, including the market for similar securities, general economic conditions and our financial condition, performance and prospects. Accordingly, holders may be required to bear the financial risk of an investment in the Company's Notes for an indefinite period of time until their maturity.

Our failure to avoid events of default as defined in the Notes could require us to redeem such Notes at a loss.

The Notes provide that, upon the occurrence of an "Event of Default," the Notes may become immediately due and payable. Events of Default under the Notes include, the occurrence of any of the following events with respect to the Notes: (a) failure for 10 business days to pay any of the principal amount or interest on the Notes when due; (b) voluntary or involuntary bankruptcy or insolvency proceedings; or (c) the Company breaches any representation or covenant in the Note that could reasonably be expected to have a material adverse effect and such breach is not cured within 30 days after the notice thereof. Upon an Event of Default for non-payment, voluntary bankruptcy or insolvency or involuntary bankruptcy or insolvency, the Notes become immediately due and payable with the written consent of the holders of a majority in interest of investors. Upon an Event of Default for a Company breach of a representation or covenant, all outstanding Notes automatically become immediately due and payable.

Our ability to avoid such Events of Default under the Notes may be affected by changes in our business condition or results of our operations, or other events beyond our control. If we were to experience an Event of Default and the holders of the Notes became immediately due and payable, we may not have sufficient resources to do so, and we may have to seek additional debt or equity financing to cover the costs of paying the Notes. Any additional debt or equity financing that we may need may not be available on terms favorable to us, or at all. Furthermore, to the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our Shareholders.

General Risk Factors

We may incur losses associated with foreign currency fluctuations.

The majority of our expenses are paid in Canadian dollars, while a significant portion of our revenues are in U.S. dollars. Our financial results are subject to the impact of currency exchange rate fluctuations. Adverse movements in exchange rates could have an adverse effect on our financial condition and

results of operations.

Our operations are subject to Canadian and international environmental laws and regulations governing, among other things, emissions to air, discharges to waters and the generation, handling, storage, transportation, treatment and disposal of raw materials, waste and other materials. Many of these laws and regulations provide for substantial fines and criminal sanctions for violations. We believe that we are and have been operating our business and facility in a manner that complies in all material respects with environmental, health and safety laws and regulations; however, we may incur material costs or liabilities if we fail to operate in full compliance. We do not maintain environmental damage insurance coverage with respect to the products which we manufacture.

The decision to establish commercial film manufacturing capability may require us to make significant expenditures in the future to comply with evolving environmental, health and safety requirements, including new requirements that may be adopted or imposed in the future. To meet changing licensing and regulatory standards, we may have to make significant additional site or operational modifications that could involve substantial expenditures or reduction or suspension of some of our operations. We cannot be certain that we have identified all environmental and health and safety matters affecting our activities and in the future our environmental, health and safety problems, and the costs to remediate them, may be materially greater than we expect.

If we are the subject of securities analyst reports or if any securities analyst downgrades our Common Stock or our sector, the price of our Common Stock could be negatively affected.

Securities analysts may publish reports about us or our industry containing information about us that may affect the trading price of our Common Stock. In addition, if a securities or industry analyst downgrades the outlook for our stock or one of our competitors' stocks, the trading price of our Common Stock may also be negatively affected.

We became public by means of a reverse merger, and as a result we are subject to the risks associated with the prior activities of the public company with which we merged.

Additional risks may exist because we became public through a "reverse merger" with a shell corporation. Although the shell did not have any operations or assets and we performed a due diligence review of the public company, there can be no assurance that we will not be exposed to undisclosed liabilities resulting from the prior operations of our company.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

On April 24, 2015, we entered into an agreement to lease approximately 17,000 square feet in a property located at 6420 Abrams, St-Laurent, Quebec. The lease has a 10 year and 6-month term which commenced on September 1, 2015 and we have retained two options to extend the lease, with each option being for an additional five years. Under the terms of the lease we will be required to pay base rent of approximately CA$125 thousand (approximately $92 thousand) per year, which will increase at a rate of CA$0.25 ($0.18) per square foot, every two years. Approximately 9,500 square feet of the new facility is being used to establish manufacturing capabilities for our VersaFilm™ thin film products, approximately 4,000 square feet for our R&D activities, and approximately 3,500 square feet for administration.

On March 6, 2017, we entered into an agreement to lease additional approximately 11,000 square feet in a property located at 6410 Abrams, St-Laurent, Quebec. The lease has an 8 year and 5-month term commencing on October 1, 2017 and we have retained two options to extend the lease, with each option being for an additional five years. Under the terms of the lease we will be required to pay base rent of approximately CA$80 thousand (approximately $59 thousand) per year, which will increase at a rate of CA$0.25 ($0.18) per square foot, every two years. We use the leased space to manufacture the oral film VersaFilm™.

On August 31, 2021, we entered into an agreement to lease additional approximately 15,000 square feet in a property located at 6400 Abrams, St-Laurent, Quebec. The lease has a 4 year and 6-month term commencing on September 1, 2021 and we have retained two options to extend the lease, with each option being for an additional five years. Under the terms of the lease we will be required to pay base rent of approximately CA$146 thousand (approximately $108 thousand) per year, which will increase at a rate of CA$0.50 ($0.37) per square foot, every two years. We are currently using the space for warehousing.

ITEM 3. LEGAL PROCEEDINGS

On March 1, 2019, a complaint for patent infringement was filed in United States District Court for the District of Delaware against Chemo Research, S.L., Insud Pharma S.L., IntelGenx Corp., and IntelGenx Technologies Corp. (collectively, the "Defendants") by BioDelivery Sciences International, Inc., and Arius Two, Inc., (collectively, the "Plaintiffs"), asserting that the Defendants infringed upon BioDelivery Sciences International, Inc. Orange Book listed patents for BELBUCA, including United States Patent Nos. 8,147,866 and 9,655,843, both expiring in July of 2027, and United States Patent No. 9,901,539 expiring December of 2032. See *BioDelivery Sciences International, Inc. et al v. Chemo Research, S.L. et al* , No. 1:19-cv-00444-CFC-CJB (D. Del.). Plaintiffs seek to enjoin Defendants from commercially manufacturing, using, offering for sale, or selling Defendants' generic buprenorphine buccal film within the United States, or importing Defendants' generic buprenorphine buccal film into the United States, until the expiration of U.S. Patent Nos. 8,147,866, 9,655,843, and 9,901,539. Plaintiffs are not seeking damages. Discovery is ongoing. A trial addressing infringement is scheduled to begin on or after April 25, 2022. We believe that we will ultimately be successful in our defense of these matters.

This complaint followed the receipt by BioDelivery Sciences International, Inc. of a notice letter by Chemo Research S.L. on January 31, 2019, stating that it had filed with the FDA an ANDA containing a Paragraph IV Patent Certification, for a generic version of BELBUA Buccal Film in strengths 75 mcg, 150 mcg, 300 mcg, 450 mcg, and 900 mcg. Since the Plaintiffs initiated a patent infringement suit to defend the patents identified in the notice letter within 45 days after receipt, the FDA is prevented from approving the ANDA until the earlier of (i) 30 months or (ii) a decision which determines whether the patents were infringed or invalid.

On March 15, 2019, Plaintiffs filed their same complaint for patent infringement in the United States District Court for the District of New Jersey. See *BioDelivery Sciences International, Inc. et al v. Chemo Research, S.L. et al* , No. 2:19-cv-08660-KM-MAH (D.N.J.). Plaintiffs voluntarily dismissed their New Jersey case on April 25, 2019.

On December 8, we initiated an arbitration proceeding against Tilray related to an alleged breach of the parties' 2018 license, development and supply agreement, as amended (the "Agreement"), with Tilray for the co-development and commercialization of cannabis-infused VersaFilm® products.

The action follows a press release issued by Tilray announcing its launch of medical cannabis oral strips in THC and CBD-rich varieties based on a competitive oral thin film technology to IntelGenx's VersaFilm® platform. We believe this represents a material breach of the Agreement. The arbitration is ongoing.

On September 12, 2022, BioDelivery Sciences International, Inc., and Arius Two, Inc., (collectively, the "Plaintiffs) filed a second complaint for patent infringement against Chemo Research, S.L., Insud Pharma S.L., IntelGenx Corp., and IntelGenx Technologies Corp. and Xiromed, LLC (collectively, the "Defendants") alleging infringement of the same patents based on Defendants' generic buprenorphine buccal film, 600 mcg and 750 mcg doses. *See BioDelivery Sciences International, Inc. et al v. Chemo Research, S.L. et al*, No. 1:22-cv-01196-CFC (D. Del.). Plaintiffs seek to enjoin Defendants from commercially manufacturing, using, offering for sale, or selling Defendants' generic buprenorphine buccal film within the United States, or importing Defendants' generic buprenorphine buccal film into the United States, until the expiration of U.S. Patent Nos. 8,147,866, 9,655,843, and 9,901,539. Plaintiffs are not seeking damages. Currently, there is no trial date set in for both cases (*BioDelivery Sciences International, Inc. et al v. Chemo Research, S.L. et al*, No. 1:22-cv-01196-CFC (D. Del.) and *BioDelivery Sciences International, Inc. et al v. Chemo Research, S.L. et al* , No. 1:19-cv-00444-CFC-CJB (D. Del.))

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our Common Stock has been quoted on OTC Markets under the symbol "IGXT" since January 2007. Beginning in June 2012, our Common Stock was quoted on the OTCQX and, since April 2020, has been quoted on the OTCQB. Our Common Stock was also listed on the TSX-V from May 2008 until our graduation to the TSX in October 2021 where our Stock is now trading under the under the symbol "IGX".

On March 29, 2023, there were approximately 48 holders of record of our Common Stock, one of which was Cede & Co., a nominee for Depository Trust Company, and one of which was The Canadian Depository for Securities Limited ("CDS"). All of our Common Stock held by brokerage firms, banks and other financial institutions in the United States and Canada as nominees for beneficial owners are considered to be held of record by Cede & Co. in respect of brokerage firms, banks and other financial institutions in the United States, and by CDS in respect of brokerage firms, banks and other financial institutions located in Canada. Cede & Co. and CDS are each considered to be one shareholder of record.

Dividend Policy

We have never declared or paid any cash dividends on our Common Stock. We currently intend to retain any earnings to support operations and to finance the growth and development of our business. Therefore, we do not expect to pay cash dividends in the foreseeable future. Any future determination relating to our dividend policy will be made at the discretion of our Board and will depend on a number of factors, including future earnings, capital requirements, financial conditions and future prospect and other factors that the Board may deem relevant.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

During the fourth quarter of 2022, there were no purchases or repurchases of our equity securities by us or any affiliated purchasers.

Unregistered Sales of Equity Securities and Use of Proceeds

During fiscal year ended 2022, we did not sell equity securities without registration under the Securities Act, except as disclosed on a Current Report on Form 8-K.

Equity Compensation Plan Information

	Number of Securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights(3) (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity Compensation Plans Approved by Security Holders	4,441,164[(1)(2)]	$0.56	10,366,394(4)
Equity Compensation Plans Not Approved by Security Holders	0	—	0
Total	4,441,164	$0.56	10,366,394

Footnotes:

(1) Includes shares of our Common Stock issuable pursuant to options granted under the 2006, 2016 and 2022 versions of the Stock Option Plans and RSUs awarded under our PRSU Plan.
(2) At the 2022 Annual Meeting of Shareholders, shareholders approved the 2022 Amended and Restated Stock Option Plan, which was adopted by the Board on March 21, 2022.
(3) The weighted average exercise price excludes RSUs, which have no exercise price.
(4) Represents the maximum number of shares of our Common Stock available for grants under the 2022 Amended and Restated Stock Option Plan

as of December 31, 2022. No registration statement has been filed for the additional 6,117,382 shares of common stock that were available to be granted under the 2016 Stock Option Plan (now known as the SOP) pursuant to the amendments from July 2020 and May 2022.

2022 Amended and Restated Stock Option Plan

The 2016 Stock Option Plan was adopted by the Board in order to make the terms of the Company's stock option plan more consistent with the requirements of the TSX Venture Exchange and to remove certain provisions which would have enabled the Company to grant incentive stock options in compliance with Section 422 of the Internal Revenue Code. The 2016 Stock Option Plan permits the granting of options to officers, employees, directors and eligible consultants of the Company. A total of 6,361,525 shares of Common Stock were reserved for issuance under this plan, which includes stock options granted under the previous 2006 Stock Option Plan. In August 2018, the Board approved the amendment of the 2016 Stock Option Plan to increase the total number of shares of Common Stock reserved under the plan to 9,347,747 and in July 2020, the number of shares reserved was increased to 11,025,965. Options may be granted under the 2016 Stock Option Plan on terms and at prices as determined by the Board except that the options cannot be granted at less than the market closing price of the Common Stock on the TSX Venture Exchange on the date prior to the grant. Each option will be exercisable after the period or periods specified in the option agreement, but no option may be exercised after the expiration of 10 years from the date of grant. The 2016 Stock Option Plan provides the Board with more flexibility when setting the vesting schedule for options which was otherwise fixed in the 2006 Stock Option Plan. On March 21, 2022, the Board adopted further amendments to the 2016 Stock Option Plan, which were approved by shareholders at the 2022 Annual Meeting of Shareholders.

PRSU Plan

The PRSU Plan was approved by Shareholders at the 2018 annual meeting on May 7, 2018. The primary purpose of this PRSU Plan is to provide the Company with a share-related mechanism to attract, retain and motivate qualified executive officers and senior managers of the Company and its Subsidiaries and to reward such officers and senior managers for their contributions toward the long-term goals and success of the Company and to enable and encourage such officers and senior managers to acquire shares of Common Stock as long-term investments and proprietary interests in the Company.

The PRSU Plan permits the Board to grant RSU awards to employees, consultants or directors of the Company and Performance Share Unit ("PSU") awards to employees and consultants of the Company. In each case, the award of RSUs or PSUs are subject to restrictions in connection with the termination of employment, engagement or term in office. The Board may, in its sole discretion, grant the majority of the awards to insiders of the Company. The number of shares of Common Stock reserved for issuance under this plan is equal to a number that: (a) does not exceed 1,000,000 shares if, and for so long as the Company was listed on the TSX Venture Exchange, or (b) 2.5% of the issued and outstanding Common Stock of the Company, since the Company is listed on the Toronto Stock Exchange. The Board has the authority to condition the grant of RSUs or PSUs upon the attainment of specified performance goals, or such other factors (which may vary between awards) as the Board determines in its sole discretion. The Board has the authority to determine at the time of grant, in its sole discretion, the duration of the vesting period and other vesting terms applicable to the grant of RSUs or PSUs. In the case of PSUs, such awards may be adjusted in accordance with the applicable PSU award agreement.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITIONS AND RESULTS OF OPERATIONS

Introduction to Management's Discussion and Analysis

The purpose of this section, Management's Discussion and Analysis of Financial Condition and Results of Operations, is to provide a narrative explanation of the financial statements that enables investors to better understand our business, to enhance our overall financial disclosure, to provide the context within which our financial information may be analyzed, and to provide information about the quality of, and potential variability of, our financial condition, results of operations and cash flows. Unless otherwise indicated, all financial and statistical information included herein relates to our continuing operations. Unless otherwise indicated or the context otherwise requires, the words, "IntelGenx", "Company", "we", "us", and "our" refer to IntelGenx Technologies Corp. and its subsidiaries, including IntelGenx Corp. This information should be read in conjunction with the accompanying audited Consolidated Financial Statements and Notes thereto.

Company Background

We are a drug delivery company established in 2003 and headquartered in Montreal, Quebec, Canada. Our focus is on the contract development and manufacturing of novel oral thin film products for the pharmaceutical market. More recently, we have made the strategic decision to enter the Canadian cannabis market with non-prescription cannabis infused oral film that launched in early 2021 and in 2020 we made the decision to enter the psychedelic market. As a full service CDMO, we are offering partners a comprehensive portfolio of pharmaceutical services, including pharmaceutical R&D, clinical monitoring, regulatory support, tech transfer, manufacturing scale-up and commercial manufacturing.

Our business strategy is to leverage our proprietary drug delivery technologies and develop pharmaceutical products with tangible benefits for patients, for our partners and, once a developed product launches, retain the exclusive manufacturing rights.

Our primary growth strategy is based on providing CDMO services to the pharmaceutical industry by focusing on three key strategic areas: (1) psychedelics, (2) cannabis, and (3) animal health.

We have established a state-of-the-art manufacturing facility for the future manufacture of our VersaFilm™ and VetaFilm™ products. We believe that this (1) represents a profitable business opportunity, (2) will reduce our dependency upon third-party contract manufacturers, thereby protecting our manufacturing process know-how and intellectual property, and (3) allows us to offer our development partners a full service from product conception through to supply of the finished product.

We initiated a project to expand the existing manufacturing facility, the timing of which will be dictated in part by the completion of agreements with our commercial partners. This expansion became necessary in order to meet expected production volumes from our commercial partners. The new facility should create a fourfold increase of our production capacity in addition to offering a one-stop shopping opportunity to our partners and provide better protection of our Intellectual Property.

Product Opportunities that provide Tangible Patient Benefits

In addition to our three key strategic areas we will offer our services to develop oral film products leveraging our VersaFilm™ technology that provide tangible patient benefits versus existing drug delivery forms. Patients with difficulties swallowing medication, pediatrics or geriatrics may benefit from oral films due to the ease of use. Similarly, we are working on oral films to improve bio-availability and/or response time versus existing drugs and thereby reducing side effects.

Development of New Drug Delivery Technologies

The rapidly disintegrating film technology contained in our VersaFilm™, is an example of our efforts to develop alternate technology platforms. As we work with various partners on different products, we seek opportunities to develop new proprietary technologies.

Corporate

On February 1, 2022, the Company announced that its wholly-owned subsidiary, IntelGenx Corp. received a third term loan in the amount of U.S. $3 million pursuant to its amended and restated secured loan agreement with atai Life Sciences. The obligations under the Third Loan are guaranteed by the Company.

On July 5, 2022, the Company announced that, in accordance with the terms of the trust indenture governing the Debentures, as supplemented, issued (i) 19,381,223 shares of common stock of the Company at a deemed price of C$0.2812 in payment of the outstanding C$5,450,000 aggregate principal amount of the Company's convertible unsecured subordinated debentures due June 30, 2022 and (ii) 573,684 Shares at a deemed price of C$0.38 per Share in payment of an aggregate of C$218,000 interest also due on the Debentures as of June 30, 2022. The Convertible Debentures, listed on the TSX under the symbol IGX.DB, were delisted from trading as of the close of business on June 30, 2022.

Subsequent to the end of the year, on January 9, 2023, the Company announced that it has received a fourth and final term loan for $3 million pursuant to its amended and restated secured loan agreement with atai.
On March 21, 2023, the Company announced the closing of an offering by way of a private placement (the "Offering") to certain investors in the United States of convertible notes due March 1, 2027 (the "Notes") for aggregate gross proceeds of approximately $760,000. The Notes will bear interest at a rate of 10% per annum, payable quarterly, and will be convertible into shares of common stock of the Company beginning six months after their issuance at a price of $0.20 per share. The Company intends to use the proceeds of the Offering to finance the Company's Rizaport and Buprenorphine programs as well as for working capital. In connection with the Offering, the Company paid a cash commission of approximately $53,000 in the aggregate and issued non-transferable agent warrants, entitling the agent to purchase 304,000 shares at a price of $0.20 per share until March 21, 2025.

Liquidity Risk

Liquidity risk is the risk that we will not be able to meet our financial obligations as they fall due. We require continued access to capital markets to support our operations, as well as to achieve our strategic plans. Any impediments to our ability to access capital markets, including the lack of financing capability or an adverse perception in capital markets of our financial condition or prospects, could have a materially adverse effect on us. In addition, our access to financing is influenced by the economic and credit market environment. We manage liquidity risk through the management of our capital structure.

Our objective in managing capital is to ensure a sufficient liquidity position to finance our R&D activities, scale up activities, regulatory activities, including product pipeline development general and administrative expenses, working capital and overall capital expenditures. Since inception, we financed our liquidity needs primarily through public offerings of our Common Stock, convertible debentures, convertible notes, bank loans, royalty, up-front and milestone payments, license fees, proceeds from exercise of warrants and options, R&D revenues and the sale of U.S. royalty on future sales of Forfivo XL®. When possible, we try to optimize our liquidity needs by non-dilutive sources, including research tax credits, grants, interest income, as well as with proceeds from collaboration and research agreements or product licensing agreements.

In addition, we manage liquidity risk by continuously monitoring actual and projected cash flows. The Board reviews, approves and monitors our annual operating and capital budgets, as well as any material transactions.

Currency Rate Fluctuations

Our operating currency is Canadian dollars, while our reporting currency is U.S. dollars. Accordingly, our results of operations and balance sheet position have been affected by currency rate fluctuations. In summary, our financial statements for the fiscal year ended December 31, 2022 report an accumulated other comprehensive loss due to foreign currency translation adjustments and changes in fair values of $2,234 primarily due to the fluctuation in the rates and fair values used to prepare our financial statements, $863 of which negatively impacted our comprehensive loss for the fiscal year ended December 31, 2022. The following Management Discussion and Analysis takes this into consideration whenever material.

Reconciliation of Comprehensive Loss to Adjusted Earnings (Loss) before Interest, Taxes, Depreciation and Amortization (Adjusted EBITDA (Loss))

Adjusted EBITDA is a non-US GAAP financial measure. A reconciliation of the Adjusted EBITDA is presented in the table below. We use adjusted financial measures to assess our operating performance. Securities regulations require that companies caution readers that earnings and other measures adjusted to a basis other than US-GAAP do not have standardized meanings and are unlikely to be comparable to similar measures used by other companies. Accordingly, they should not be considered in isolation. We use Adjusted EBITDA to measure our performance from one period to the next without the variation caused by certain adjustments that could potentially distort the analysis of trends in our operating performance, and because we believe it provides meaningful information on our financial condition and operating results.

IntelGenx obtains its Adjusted EBITDA measurement by adding / (deducting) to comprehensive loss, finance income and costs, depreciation and amortization, income taxes and foreign currency translation adjustment incurred during the period. IntelGenx also excludes the effects of certain non-monetary transactions recorded, such as share-based compensation, for its Adjusted EBITDA calculation. We believe it is useful to exclude these items as they are either non-cash expenses, items that cannot be influenced by management in the short term, or items that do not impact core operating performance. Excluding these items does not imply they are necessarily nonrecurring. Share-based compensation costs are a component of employee and consultant's remuneration and can vary significantly with changes in the market price of our shares. Foreign currency translation adjustments are a component of other comprehensive income and can vary significantly with currency fluctuations from one period to another. In addition, other items that do not impact our core operating performance may vary significantly from one period to another. As such, Adjusted EBITDA provides improved continuity with respect to the comparison of our operating results over a period of time. Our method for calculating Adjusted EBITDA may differ from that used by other corporations.

Reconciliation of Non-U.S.-GAAP Financial Information

	Three-month period ended December 31,		Twelve-month period ended December 31,	
In U.S.$thousands	**2022**	2021	**2022**	2021
	$	$	$	$
Comprehensive loss	(2,314)	(2,857)	(11,553)	(9,827)
Add (deduct):				
Depreciation	190	202	777	791
Finance costs	218	354	1,281	1,488
Finance income	(2)	—	(4)	(152)
Deferred income tax	—	(3)	—	(6)
Share-based compensation	19	26	113	107
Other comprehensive (income) loss	(430)	(1)	863	515
Adjusted EBITDA Loss	**(2,319)**	(2,279)	**(8,523)**	(7,084)

Adjusted Earnings before Interest, Taxes, Depreciation and Amortization (Adjusted EBITDA (Loss))

Adjusted EBITDA Loss increased by $40 for the three-month period ended December 31, 2022 to ($2,319) compared to ($2,279) for the three-month period ended December 31, 2021. Adjusted EBITDA Loss increased by $1,439 for the twelve-month period ended December 31, 2022 to ($8,523) compared to ($7,084) for the twelve-month period ended December 31, 2021. The increase in Adjusted EBITDA Loss of $40 for the three-month period ended December 31, 2022 is mainly attributable to a decrease in revenues of $321, offset by decreases in Manufacturing expenses of $173 before consideration of stock-based compensation, R&D expenses of $67 before consideration of stock-based compensation, and SG&A expenses of $41 before consideration of stock-based compensation. The increase in Adjusted EBITDA Loss of $1,439 for the twelve-month period ended December 31, 2022 is mainly attributable to a decrease in revenues of $585, and increases in SG&A expenses of $931 before consideration of stock-based compensation, and R&D expenses of $305 before consideration of stock-based compensation, offset by decreases in Manufacturing expenses of $382 before consideration of stock-based compensation.

Results of operations for the three month and twelve month periods ended December 31, 2022 compared with the three month and twelve month periods ended December 31, 2021.

In U.S.$thousands	Three-month period ended December 31, **2022**	2021	Twelve-month period ended December 31, **2022**	2021
Revenue	$ 173	$ 494	$ 950	$ 1,535
Research and Development Expenses	742	807	3,031	2,717
Manufacturing Expenses	477	658	1,858	2,256
Selling, General and Administrative Expenses	1,292	1,334	4,697	3,753
Depreciation of tangible assets	190	202	777	791
Operating Loss	**(2,528)**	(2,507)	**(9,413)**	(7,982)
Net Loss	**(2,744)**	(2,858)	**(10,690)**	(9,312)
Comprehensive Loss	**(2,314)**	(2,857)	**(11,553)**	(9,827)

Revenue

Total revenues for the three-month period ended December 31, 2022 amounted to $173, representing a decrease of $321 or 65% compared to $494 for the three-month period ended December 31, 2021. Total revenues for the twelve-month period ended December 31, 2022 amounted to $950 representing a decrease of $585 or 38% compared to $1,535 for the twelve-month period ended December 31, 2021. The decrease for the three-month period ended December 31, 2022 compared to the last year's corresponding period is mainly attributable to decreases in Revenues from Licensing agreements of $249, R&D Revenues of $43 and Product Revenues of $36, offset by an increase in Royalties on Product Sales of $7. The decrease for the twelve-month period ended December 31, 2022 compared to the last year's corresponding period is mainly attributable to decreases in Sales Milestone Revenue of $320, Revenues from Licensing agreements of $249, and Product Revenues of $189, offset by increases in R&D Revenues of $125 and Royalties on Product Sales of $48.

Research and development expenses

R&D expenses for the three-month period ended December 31, 2022 amounted to $742, representing a decrease of $65 or 8%, compared to $807 for the three-month period ended December 31, 2021. R&D expenses for the twelve-month period ended December 31, 2022 amounted to $3,031, representing an increase of $314 or 12%, compared to $2,717 recorded in the same period of 2021.

The decrease in R&D expenses for the three-month period ended December 31, 2022 is mainly attributable to decreases in salary expenses of $101, the allocation of the 20% credit of $80 as per the strategic development agreement with atai, analytical costs of $55, lab supplies of $36, and an increase in R&D estimated tax credits of $39, offset by increases in study costs of $223 and consulting fees of $26.

The increase in R&D expenses for the twelve-month period ended December 31, 2022 is mainly attributable to increases in study costs of $773, the allocation of the 20% credit of $150 as per the strategic development agreement with atai, consulting fees of $96, repairs and maintenance of $32, and a decrease in R&D estimated tax credits of $65, offset by decreases in R&D batch development expenses of $350, analytical costs of $253, lab supplies of $93, salary expenses of $57, and patent expenses of $49.

In the twelve-month period ended December 31, 2022 we recorded estimated Research and Development Tax Credits of $118, compared with $183 that was recorded in the same period of the previous year.

Manufacturing expenses

Manufacturing expenses for the three-month period ended December 31, 2022 amounted to $477, representing a decrease of $181 or 28%, compared to $658 for the three-month period ended December 31, 2021. Manufacturing expenses for the twelve-month period ended December 31, 2022 amounted to $1,858 representing a decrease of $398 or 18%, compared to $2,256 for the twelve-month period ended December 31, 2021.

The decrease in Manufacturing expenses for the three-month period ended December 31, 2022 is mainly attributable to decreases in salary expenses of $246 due to employee departures, supplies and consumables of $39, offset by increases in storage fees of $87, consulting fees of $10 and quality expenses of $8.

The decrease in Manufacturing expenses for the twelve-month period ended December 31, 2022 is mainly attributable to decreases in supplies and consumables of $378 and salary expenses of $242 due to employee departures, offset by increases in storage costs of $87, repairs and maintenance of $64, quality expenses of $46 and consulting fees of $26.

Selling, general and administrative ("SG&A") expenses

SG&A expenses for the three-month period ended December 31, 2022 amounted to $1,292, representing a decrease of $42 or 3%, compared to $1,334 for the three-month period ended December 31, 2021. SG&A expenses for the twelve-month period ended December 31, 2022 amounted to $4,697, representing an increase of $944 or 25%, compared to $3,753 recorded in the same period of 2021.

The decrease in SG&A expenses for the three-month period ended December 31, 2022 is mainly attributable to decreases in filing fees of $146, salaries and compensation expenses of $43, business development expenses of $15, travel expenses of $10, and office supplies of $7, offset by increases in professional fees of $122 and insurance expense of $59.

The increase in SG&A expenses for the twelve-month period ended December 31, 2022 is mainly attributable to the variation of the foreign exchange due to the depreciation of the CA dollar vs US currency in the amount of $841 and increases in professional fees of $403 (including recruiting fees), insurance expense of $191, leasehold expenses of $67, investor relations expenses of $20, business development expenses of $13, offset by decreases in salaries and compensation expenses of $477, mainly attributable to the fact that there was no bonus awarded in 2022 and the revaluation of previously issued DSUs which was caused by the decrease in the Company's share price during the twelve-month period ended December 31, 2022 and filing fees of $113.

Depreciation of tangible assets

In the three-month period ended December 31, 2022 we recorded an expense of $190 for the depreciation of tangible assets, compared with an expense of $202 thousand for the same period of the previous year. In the twelve-month period ended December 31, 2022 we recorded an expense of $777 for the depreciation of tangible assets, compared with an expense of $791 for the same period of the previous year

Share-based compensation expense, warrants and stock based payments

Share-based compensation warrants and share-based payments expense for the three-month period ended December 31, 2022 amounted to $19 compared to $26 for the three-month period ended December 31, 2021. Share-based compensation warrants and share-based payments expense for the twelve-month period ended December 31, 2022 amounted to $113 compared to $107 for the twelve-month period ended December 31, 2021.

We expensed approximately $101 in the twelve-month period ended December 31, 2022 for options granted to our employees in 2021 and 2022 under the 2016 Stock Option Plans and $12 for options granted to consultants, compared with $107 and $Nil, respectively that was expensed in the same period of the previous year.

There remains approximately $39 in stock-based compensation to be expensed in fiscal 2023, of which $12 relates to the issuance of options to a consultant during 2021. We anticipate the issuance of additional options and warrants in the future, which will continue to result in stock-based compensation expense

Key items from the balance sheet

	December 31, 2022	December 31, 2021	Increase/ (Decrease)	PercentageIncrease/ (Decrease)
Current Assets	$ 3,788	$ 11,437	$ (7,649)	(67%)
Leasehold improvements and Equipment, net	4,425	5,213	(788)	(15%)
Security Deposits	245	252	(7)	(3%)
Operating lease right-of-use asset	732	1,003	(271)	(27%)
Current Liabilities (excluding convertible debentures)	2,374	2,773	(399)	(14%)

Long-term debt	5,500	2,500	3,000	120%
Convertible debentures	—	4,247	(4,247)	(100%)
Convertible notes	4,272	3,709	563	15%
Operating lease liability	425	642	(217)	(34%)
Finance lease liability	42	84	(42)	(50%)
Capital Stock	1	1	0	0%
Additional Paid-in Capital	67,340	63,104	4,236	7%

Going concern

The Company has financed its operations to date primarily through public offerings of its common stock, proceeds from issuance of convertible notes and debentures, bank loans, royalty, up-front and milestone payments, license fees, proceeds from exercise of warrants and options, and research and development revenues. The Company has devoted substantially all of its resources to its drug development efforts, conducting clinical trials to further advance the product pipeline, the expansion of its facilities, protecting its intellectual property and general and administrative functions relating to these operations. The future success of the Company is dependent on its ability to develop its product pipeline and ultimately upon its ability to attain profitable operations. As of December 31, 2022, the Company had cash and short-term investments totaling approximately $2,527. The Company does not have sufficient existing cash and short-term investments to support operations for the next year following the issuance of these financial statements. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans to alleviate these conditions include pursuing one or more of the following steps to raise additional funding, none of which can be guaranteed or are entirely within the Company's control:

- Raise funding through the possible sale of the Company's common stock, including public or private equity financings.
- Raise funding through debt financing.
- Continue to seek partners to advance product pipeline.
- Expand oral film manufacturing activities.
- Initiate contract oral film manufacturing activities.

If the Company is unable to raise further capital when needed or on attractive terms, or if it is unable to procure partnership arrangements to advance its programs, the Company would be forced to potentially delay, reduce or eliminate some of its research and development programs and commercial activities.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The accompanying consolidated financial statements do not include any adjustments or classifications that may result from the possible inability of the Company to continue as a going concern. Should the Company be unable to continue as a going concern, it may be unable to realize the carrying value of its assets and to meet its liabilities as they become due.

Current assets

Current assets totaled $3,788 at December 31, 2022 compared with $11,437 at December 31, 2021. The decrease of $7,649 is mainly attributable to decreases in cash of $2,735, short-term investments of $4,687, investment tax credits receivable of $277, and security deposits of $11, offset by increases in accounts receivable of $29 and prepaid expenses of $32.

Cash

Cash totaled $1,210 as at December 31, 2022 representing a decrease of $2,735 compared with the balance of $3,945 as at December 31, 2021. The decrease in cash on hand relates to net cash used in operating activities of $9,516, offset by net cash provided by financing activities of $2,965, net cash provided by investing activities of $3,509 and a positive effect of foreign exchange of $307.

Short term investments

Short term investments totaled $1,317 as at December 31, 2022, representing a decrease of $4,687 compared with the balance of $6,004 as at December 31, 2021. The decrease in short term investments is attributable to redemption of investments to fund operations.

Accounts receivable

Accounts receivable totaled $709 as at December 31, 2022 representing an increase of $29 compared with the balance of $680 as at December 31, 2021. The increase is related to the invoicing of revenues incurred in the three month period ended December 31, 2022, offset by the collection of receivables.

Prepaid expenses

As at December 31, 2022, prepaid expenses totaled $137 compared with $105 as of December 31, 2021. The increase may be explained by advance payments made in December 2022.

Investment tax credits receivable

R&D investment tax credits receivable totaled approximately $159 as at December 31, 2022 compared with $436 as at December 31, 2021. The decrease is attributable to the collection of the 2020 and 2021 amounts, offset by the accrual estimated and recorded for the twelve month period ended December 31, 2022.

Leasehold improvements and equipment

As at December 31, 2022, the net book value of leasehold improvements and equipment amounted to $4,425, compared to $5,213 as at December 31, 2021. In the year ended December 31, 2022 additions to assets totaled $271 and mainly comprised of $161 for laboratory and office equipment, $50 for manufacturing equipment, $50 for leasehold improvements and $10 for computer equipment, offset by variation of foreign exchange fluctuation and depreciation expense of $777.

Security deposit

A security deposit in the amount of CA$300 ($222) in respect of an agreement to lease approximately 17,000 square feet in a property located at 6420 Abrams, St-Laurent, Quebec, Canada was recorded as at December 31, 2022. Security deposits in the amount of CA$26 ($19) for utilities and CA$5 ($4) for Cannabis license were also recorded as at December 31, 2022. Security deposit in the amount of CA$263 ($194) for Company credit cards was also recorded as at December 31, 2022 but classified as short-term.

Accounts payable and accrued liabilities

Accounts payable and accrued liabilities totaled $2,102 as at December 31, 2022 (December 31, 2021 - $2,299). The decrease is mainly attributable to a decrease in payroll related accruals as at December 31, 2022.

Loan payable

Loan payable totaled $5,500 as at December 31, 2022 compared with $2,500 as at December 31, 2021. atai has granted to the Company a secured loan in the amount of $5,500, bearing interest at 8%. In September 2021, the Company entered into an amended and restated secured loan agreement with atai pursuant to which atai has made two additional term loans available to the Company for $3,000 each, which will mature on January 5, 2024. The first loan was received on January 7, 2022 and the second loan was received on January 6, 2023. The Loan Agreement also extends the maturity date for the current loans, in an aggregate amount of $5,500, to January 2024. The loan is guaranteed by the Company and secured by all present and future movable property, rights and assets of the Company, excluding any intellectual property or technology controlled or owned by the Company. The loan bears interest at 8%. The interest for the twelve-month period ended December 31, 2022 amounts to $423 (2021: $156) and is recorded in financing and interest expense.

Convertible debentures

Convertible debentures totaled $Nil as at December 31, 2022 as compared to $4,247 as at December 31, 2021. The Corporation issued a total aggregate principal amount of CAD$7,600,000 ($5,611,000) of debentures at a price of CAD$1,000 ($738) per debenture in July 2017 and August 2017. On September 25, 2021, the debenture holders approved the extension of the maturity date of the convertible debentures from September 30, 2021 to September 30, 2022 and the conversion price was reduced from CAD$1.35 ($1.00) to CAD$0.50 ($0.37). On September 30, 2022, the Company issued 19,381,223 shares of common stock in payment of the outstanding CAD$5,450,000 ($4,229,000) aggregate principal amount of the convertible debentures. The convertible debentures, listed on the TSX under the symbol IGX.DB, were delisted from trading as of the close of business on June 30, 2022.

The convertible debentures were recorded as a liability. The accretion expense for the year ended December 31, 2022 amounts to CA$125,000 ($96,000) (CA$288,000, (230,000) in 2021). The interest on the convertible debentures as at December 31, 2022 amounts to CA$218,000 ($171,000) and was paid by issuance of 573,684 shares of Common Stock on July 5, 2022. The interest on the convertible debentures as at December 31, 2021 amounts to CA$549,000 ($438,000) and is recorded in Financing and interest expense.

During the year ended December 31, 2022, CA$60,000 ($48,000) of convertible debentures were converted into 120,000 shares of Common Stock at the option of the holders, resulting in an increase in additional paid-in capital of $48,000.

During the year ended December 31, 2021, CAD$1,926,000 ($1,519,000) of convertible debentures were converted into 3,852,000 shares of common stock at the option of the holders, resulting in an increase in additional paid-in capital of $1,498,000.

Convertible notes

Convertible notes totaled $4,272 as at December 31, 2022 as compared to $3,709 as at December 31, 2021. The convertible notes have been recorded as a liability. The accretion expense for the year ended December 31, 2022 amounts to $175 compared to $247 for the comparative period in 2021. The interest on the convertible notes for the year ended December 31, 2022 amounts to $380 ($302 in 2021) and is recorded in Financing and interest expense.

During the year ended December 31, 2021, $712,000 of convertible notes were converted into 1,985,847 shares of common stock at the option of the holders, resulting in an increase in additional paid-in capital of $632,000.

Shareholders' deficit

As at December 31, 2022 we had accumulated a deficit of $68,530 compared with an accumulated deficit of $57,863 as at December 31, 2021. Total assets amounted to $9,190 and shareholders' deficit totaled $3,423 as at December 31, 2022, compared with total assets and shareholders' equity of $17,905 and $3,871 respectively, as at December 31, 2021.

Capital stock

As at December 31, 2022 capital stock amounted to $1.746 (December 31, 2021: $1.545). Capital stock is disclosed at its par value with the excess of proceeds shown in Additional Paid-in-Capital.

Additional paid-in-capital

Additional paid-in capital totaled $67,340 as at December 31, 2022, as compared to $63,104 at December 31, 2021. Additional paid in capital increased by $4,236. The increase is due to the issuance of Common Stock of $4,229, interest paid by issuance of Common Stock of $171, stock-based compensation attributable to the amortization of stock options granted to employees of $113, and the value of the conversion of the convertible debentures of $48, offset by $325 for the adoption of ASU 606-20 where the previously accounted beneficial conversion feature in the amount of $325 was derecognized from the value of the convertible notes on a retroactive basis as at January 1, 2022.

Taxation

As at December 31, 2022, the date of our latest annual tax return, we had Canadian and provincial net operating losses of approximately $45,041 (December 31, 2021: $39,823) and $52,004 (December 31, 2021: $43,482) respectively, which may be applied against earnings of future years. Utilization of the net operating losses is subject to significant limitations imposed by the change in control provisions. Canadian and provincial losses will be expiring between 2026 and 2042. A portion of the net operating losses may expire before they can be utilized.

As at December 31, 2022, the Company had non-refundable tax credits of $3,004 thousand (2021: $2,912 thousand) of which $8 thousand is expiring in 2026, $10 thousand is expiring in 2027, $166 thousand is expiring in 2028, $146 thousand is expiring in 2029, $124 thousand is expiring in 2030, $132 thousand is expiring in 2031, $166 thousand is expiring in 2032, $110 thousand is expiring in 2033, $84 thousand expiring in 2034, $98 thousand is expiring in 2035, $136 thousand expiring in 2036, $259 thousand is expiring in 2037, $558 thousand expiring in 2038, $338 thousand expiring in 2039, $220 thousand expiring in 2040, $225 thousand expiring in 2041, and $224 expiring in 2042 and undeducted research and development expenses of $17,031 thousand (2021: $16,566 thousand) with no expiration date.

The deferred tax benefit of these items was not recognized in the accounts as it has been fully provided for.

Key items from the statement of cash flows

In U.S.$thousands	December 31, 2022	December 31, 2021	Increase/ (Decrease)	Percentage Increase/ (Decrease)
Operating Activities	$ (9,516)	$ (7,173)	$ (2,343)	$ 33%
Financing Activities	2,965	15,492	(12,527)	(81%)
Investing Activities	3,509	(5,074)	8,583	(169%)
Cash - end of period	1,210	3,945	(2,735)	(69%)

Statement of cash flows

Net cash used in operating activities was $9,516 for the year ended December 31, 2022, compared to net cash used by operating activities of $7,173 for the year ended December 31, 2021. For the year ended December 31, 2022, net cash used by operating activities consisted of a net loss of ($10,690) (2021: $9,312) before depreciation, stock-based compensation, accretion expense, DSU expense, interest paid by issuance of Common Stock and lease non-cash expense in the amount of $1,228 (2021: $1,450) and a decrease in non-cash operating elements of working capital of $54 compared with an increase of $689 for the year ended December 31, 2021.

The net cash provided by financing activities was $2,965 for the year ended December 31, 2022, compared to net cash provided by financing activities of $15,492 for the year ended December 31, 2021. For the year ended December 31, 2022, an amount of $Nil (2021: $12,346) derives from proceeds from issuance of shares, an amount of $3,000 (2021: $2,500) derives from the issuance of a loan, and an amount of $Nil (2021: $1,897) derives from the net proceeds from convertible notes, offset by repayment of term loans for an amount of $Nil (2021: $737), the transaction costs related to share issuance of $Nil (2021: $422), transaction costs related to debt extinguishment of $Nil (2021: $29), the transaction costs related to the convertible notes of $Nil (2021: $34), and finance lease payments of $35 (2021: $29).

Net cash provided by investing activities amounted to $3,509 for the year ended December 31, 2022 compared to net cash used in investing activities of $5,074 for the year ended December 31, 2021. The net cash provided by investing activities for the year ended December 31, 2022 relates to the redemption of short-term investments of $9,519 (2021: $1,034), offset by the acquisition of short-term investments of $5,739 (2021: $6,000) and the purchase of leasehold improvements and equipment of $271 (2021: $108).

The balance of cash as at December 31, 2022 amounted to $1,210, compared to $3,945 at December 31, 2021.

Commitments

On April 24, 2015 we entered into an agreement to lease approximately 17,000 square feet in a property located at 6420 Abrams, St-Laurent, Québec. The lease has a 10 year and 6-month term commencing September 1, 2015. IntelGenx has retained two options to extend the lease, with each option being for an additional five years. Under the terms of the lease we are required to pay base rent of approximately CA$125 thousand (approximately $92 thousand) per year, which will increase at a rate of CA$0.25 ($0.18) per square foot, every two years.

On March 6, 2020 IntelGenx executed an agreement to lease approximately an additional 11,000 square feet in a property located at 6410 Abrams, St-Laurent, Quebec. The Lease has an 8 year and 5-month term commencing on October 1, 2020 and IntelGenx has retained two options to extend the Lease, with each option being for an additional five years. Under the terms of the Lease we will be required to pay base rent of approximately CA$80 thousand (approximately $59 thousand) per year, which will increase at a rate of CA$0.25 ($0.18) per square foot every two years.

On August 31, 2021 we entered into an agreement to lease additional approximately 15,000 square feet in a property located at 6400 Abrams, St-Laurent, Québec. The lease has a 4 year and 6-month term commencing September 1, 2021 and we have retained two options to extend the lease, with each option being for an additional five years. Under the terms of the lease we are required to pay base rent of approximately CA$146 thousand (approximately $108 thousand) per year, which will increase at a rate of CA$0.50 ($0.37) per square foot, every two years.

The aggregate minimum rentals, exclusive of other occupancy charges, for property leases expiring in 2026, are approximately $837 thousand, as follows:

2023	259
2024	267
2025	267
2026	44

Substantially all our finance lease right-of-use assets and finance lease liability represents leases for laboratory equipment to conduct our business.

The aggregate minimum lease payments for laboratory equipment are approximately $84 thousand, as follows :

2023	40
2024	38
2025	6

We have initiated a project to expand the existing manufacturing facility. We have signed agreements in the amount of Euro1,911 thousand with three suppliers with respect to equipment for solvent film manufacturing. As at December 31, 2022 an amount of Euro1,490 thousand has been paid with respect to these agreements.

IT Infrastructure

We have an IT Infrastructure Disaster Recovery Plan in place. In the event of a disaster (cyber attack), a full recovery of our IT system is estimated to be recovered within a week. During the year ended December 31, 2022, the disaster recovery plans were tested. All recovery tests were successful.

Contingencies

The government authorities have assessed the Company with respect to sales taxes claimed on certain expenses between 2017 and 2020, which the government is denying. The sales tax assessments amount to $314,000 (including interest and penalties of $33,000), which was paid to avoid further interest and penalties. The Company disagrees with the government's position and the sales tax assessments are under appeal. In the event the Company is unsuccessful in its appeal, sales taxes expenses would increase by $281,000 and net earnings would decrease by $281,000.

Subsequent events

Subsequent to the end of the year, on January 9, 2023, the Company announced that it has received a fourth and final term loan for $3 million pursuant to its amended and restated secured loan agreement with atai.

On March 21, 2023, the Company announced the closing of an offering by way of a private placement (the "Offering") to certain investors in the United States of convertible notes due March 1, 2027 (the "Notes") for aggregate gross proceeds of approximately $760,000. The Notes will bear interest at a rate of 10% per annum, payable quarterly, and will be convertible into shares of common stock of the Company beginning six months after their issuance at a price of $0.20 per share. The Company intends to use the proceeds of the Offering to finance the Company's Rizaport and Buprenorphine programs as well as for working capital. In connection with the Offering, the Company paid a cash commission of approximately $53,000 in the aggregate and issued non-transferable agent warrants, entitling the agent to purchase 304,000 shares at a price of $0.20 per share until March 21, 2025.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements and supplementary data of the Company required in this item are set forth beginning on page F-1 of this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

a. Evaluation of Disclosure Controls and Procedures

Based on an evaluation under the supervision and with the participation of our management, our Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act were effective as of December 31, 2022 to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms and (ii) accumulated and communicated to the Company's management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

b. Changes in Internal Controls over Financial Reporting

Our Chief Executive Officer and Chief Financial Officer have concluded that there were no changes in the Company's internal controls over financial reporting during the quarter ended December 31, 2022 that have materially affected or are reasonably likely to materially affect the Company's internal controls over financial reporting.

c. Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control system was designed to provide reasonable assurance to our management and the Board regarding the preparation and fair presentation of published financial statements.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can

provide only reasonable assurance with respect to financial statement preparation and presentation.

Our management, including the Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2022. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated Framework (2013). Based on our processes and assessment, as described above, management has concluded that, as of December 31, 2022 our internal control over financial reporting was effective.

This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the company's registered public accounting firm pursuant to rules of the SEC, as the Company qualifies as a "smaller reporting company".

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGRADING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Certain information required by this Item 10 relating to our directors, executive officers, audit committee and corporate governance is incorporated by reference herein from the 2023 Proxy Statement.

ITEM 11. EXECUTIVE COMPENSATION

Certain information required by this Item 11 relating to remuneration of directors and executive officers and other transactions involving management is incorporated by reference herein from the 2023 Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Certain information required by this Item 12 relating to security ownership of certain beneficial owners and management, and the equity compensation plan information, is incorporated by reference herein from the 2023 Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Certain information required by this Item 13 relating to certain relationships and related transactions, and director independence is incorporated by reference herein from the 2023 Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Certain information required by this Item 14 regarding principal accounting fees and services is set forth under "Audit Fees" in the 2023 Proxy Statement.

PART IV

ITEM 15. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES

(a) Financial Statements and Schedules

1. *Financial Statements*

The following financial statements are filed as part of this report under Item 8 of Part II "Financial Statements and Supplementary Data:

A. Report of Independent Registered Public Accounting Firm Richter LLP, PCAOB ID# 989, Montreal, Quebec
B. Consolidated Balance Sheets as of December 31, 2022 and 2021.
C. Consolidated Statements of Shareholders' Equity for the years ended of December 31, 2022 and 2021.
D. Consolidated Statements of Comprehensive Loss for the years ended of December 31, 2022 and 2021.
E. Consolidated Statements of Cash Flows for the years ended December 31, 2022 and 2021.
F. Notes to Consolidated Financial Statements.

2. *Financial Statement Schedules*

Financial statement schedules not included herein have been omitted because they are either not required, not applicable, or the information is otherwise included herein.

(b) Exhibits.

EXHIBIT INDEX

Exhibit No.	Description
2.1	Share exchange agreement dated April 10, 2006 (incorporated by reference to the Form 8-K/A filed on May 5, 2006)
3.1	Certificate of Incorporation (incorporated by reference to the Form SB-2 (File No. 333-90149) filed on November 16, 1999)

3.2	Amendment to the Certificate of Incorporation (incorporated by reference to amendment No. 2 to Form SB-2 (File No. 333-135591) filed on August 28, 2006)
3.3	Amendment to the Certificate of Incorporation (incorporated by reference to the Form DEF 14C filed on April 20, 2007)
3.4	Amendment to the Certificate of Incorporation (incorporated by reference to the Form S-1/A filed on May 12, 2017)
3.5	Third Amended and Restated By-Laws (incorporated by reference to the Form 8-K filed on March 21, 2022)
4.1	Trust Indenture with TSX Trust Company, dated July 12, 2017 (incorporated by reference to the Form 8-K filed on July 12, 2017)
4.2	Warrant Indenture dated February 11, 2020 (incorporated by reference to the Form 8-K filed on February 12, 2020)
4.3	Description of the Company's Securities Registered Under Section 12 of the Securities Exchange Act of 1934 (incorporated by reference to the Form 10-K filed on March 26, 2020)
4.4	Second Supplemental Trust Indenture, June 25, 2020.(incorporated by reference to the Form 8-K on December 23, 2020)
9.1	Voting Trust agreement (incorporated by reference to the Form 8-K/A filed on May 5, 2006)
10.1+	Horst Zerbe employment agreement dated October 1, 2014 (incorporated by reference to the Form 10-Q filed on November 12, 2014)
10.2	Registration rights agreement (incorporated by reference to the Form SB-2 (File No. 333-135591) filed on July 3, 2006)
10.3	Principal's registration rights agreement (incorporated by reference to the Form SB-2 (File No. 333-135591) filed on July 3, 2006)
10.4+	2006 Stock Option Plan (incorporated by reference to the Form S-8 filed on November 21, 2006)
10.5+	Amended and Restated 2006 Stock Option Plan, May 29, 2008 (incorporated by reference to the Form 10-K filed on March 25, 2009)
10.6+	Amended and Restated 2006 Stock Option Plan (incorporated by reference to the Form S-8 filed on November 15, 2010)
10.8	Second Amended 2016 Stock Option Plan, July 16, 2020 (incorporated by reference to the Form 8-K on July 17, 2020)
10.9+	Employment Agreement Andre Godin, July 2015 (incorporated by reference to the Form 8-K filed on July 20, 2015)
10.10+	Employment Agreement Nadine Paiement, January 2016 (incorporated by reference to the Form 10-K filed on March 30, 2016)

10.11+	Employment Agreement Dana Matzen, March 2016 (incorporated by reference to the Form 10-K filed on March 30, 2016)
10.12+	2016 Stock Option Plan May, 11 2016 (incorporated by reference to the Form S-8 Registration Statement filed on August 3, 2016)
10.13	Amended Principal's Registration Rights Agreement, November 8, 2016 (incorporated by reference to Form 10-Q filed on November 10, 2016)
10.14	Agency Agreement dated June 28, 2017 (incorporated by reference to the Form 8-K filed on July 5, 2017)
10.15+	Deferred Share Unit Plan for non-employee directors (incorporated by reference to the Form 10-K filed on March 29, 2018)
10.16	Placement Agent Agreement dated May 8, 2018 (incorporated by reference to the Form 8-K filed on May 10, 2018)
10.17	Form of Warrant dated May 8, 2018 (incorporated by reference to the Form 8-K filed on May 10, 2018)
10.18	Form of Securities Purchase Agreement dated May 8, 2018 (incorporated by reference to the Form 8-K filed on May 10, 2018)
10.19	Form of Registration Rights Agreement dated May 8, 2018 (incorporated by reference to the Form 8-K filed on May 10, 2018)
10.20	Form of Note dated May 8, 2018 (incorporated by reference to the Form 8-K filed on May 10, 2018)
10.21	Placement Agent Agreement between the Company and H.C. Wainwright & Co., LLC dated October 18, 2018 (incorporated by reference to the Form 8-K filed on October 22, 2018)
10.22	Placement Agent Agreement between the Company and Echelon Wealth Partners Inc. dated October 18, 2018 (incorporated by reference to the Form 8-K filed on October 22, 2018)
10.23	Form of Warrant (incorporated by reference to the Form 8-K on October 22, 2018)
10.24	Form of Securities Purchase Agreement (incorporated by reference to the Form 8-K filed on October 22, 2018)
10.25	Form of Agent Warrant (incorporated by reference to the Form S-1/A on filed on January 30, 2020)
10.26	Agency Agreement dated January 27, 2020 (incorporated by reference to the Form 8-K filed on January 29, 2020)
10.27	Loan Agreement dated March 9, 2021 (incorporated by reference to the Form 10-K filed on March 25, 2021)
10.28[#]	Strategic Development Agreement dated March 14, 2021(incorporated by reference to the Form 10-K filed on March 25, 2021) ,
10.29±	Securities Purchase Agreement dated March 14, 2021(incorporated by reference to the Form 10-K filed on March 25, 2021)
10.30	Purchaser Rights Agreement dated March 14, 2021(incorporated by reference to the Form 10-K filed on March 25, 2021)
10.31	Amended and Restated Securities Purchase Agreement dated May 14, 2021 (incorporated by reference to the Form 8-K filed on May 17, 2021)
10.32	First Amendment to Loan Agreement dated May 14, 2021 (incorporated by reference to the Form 8-K filed on May 17, 2021)
10.33	Amendment No. 1 to 6% Subordinated Convertible Unsecured Promissory Note dated May 24, 2021 (incorporated by reference to the Form 8-K filed on May 25, 2021)
10.34	Form of Initial Warrant dated May 14, 2021 (incorporated by reference to the Form 10-Q filed on August 4, 2021)
10.35	Form of Additional Unit Warrant dated May 14, 2021 (incorporated by reference to the Form 10-Q filed on August 4, 2021)
10.36	Form of Note (incorporated by reference to the Form 8-K filed on August 11, 2021)
10.37+	Employment Agreement Dr. David Kideckel, March 2023 (incorporated by reference to the Form 8-K filed on March 24, 2023)
10.38	Form of Note (incorporated by reference to the Form 8-K filed on March 24, 2023)
21.1	Subsidiaries of the small business issuer (incorporated by reference to the Form SB-2 (File No. 333-135591) filed on July 3, 2006)
23.1*	Consent of Richter LLP
31.1*	Certification of Horst G. Zerbe, Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

31.2*	Certification of Andre Godin, President and Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Horst G. Zerbe, Chief Executive Officer, pursuant to 18 U.S.C. Section 1350
32.2*	Certification of Andre Godin, President and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350
101.INS	Inline XBRL Instance Document–the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in the Exhibit 101 attachments)

* Filed herewith.

+ Indicates management contract or employee compensation plan.

[# Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10). The omitted information is not material and would likely cause competitive harm to the Company if publicly disclosed. The Company agrees to furnish an unredacted copy to the SEC upon its request.]

±Certain schedules and exhibits have been omitted in compliance with Regulation S-K Item 601(a)(5). The Company agrees to furnish a copy of any omitted schedule or exhibit to the SEC upon its request.

ITEM 16. FORM 10-K SUMMARY.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned on March 29, 2023, thereunto duly authorized.

INTELGENX TECHNOLOGIES CORP.

By: */s/ Horst G. Zerbe*
Horst G. Zerbe
Chief Executive Officer
(Principal Executive Officer)

By: */s/ Andre Godin*
Andre Godin
President and Chief Financial Officer
(Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed by the following persons in the capacities and on the dates indicated.

Signature	Position	Date
By: /s/ *Horst G. Zerbe* Horst G. Zerbe	Chief Executive Officer and Chairman of the Board	March 29, 2023
By*: /s/Andre Godin* Andre Godin	President and Chief Financial Officer	March 29, 2023
By: /s/ *Bernard Boudreau* J. Bernard Boudreau	Director, Vice Chairman of the Board	March 29, 2023
By: /s/*Bernd Melchers* Bernd J. Melchers	Director	March 29, 2023
By: /s/*Clemens Mayr* Clemens Mayr	Director	March 29, 2023
By: /s/*Mark Nawacki* Mark Nawacki	Director	March 29, 2023
By: /s/ *Frank Stegert* Frank Stegert	Director	March 29, 2023
By: /s/ *Srinivas Rao* Srinivas Rao	Director	March 29, 2023
By: /s/*Monika Trzcinska* Monika Trzcinska	Director	March 29, 2023

IntelGenx Technologies Corp.

Board of Directors and Executive Officers

as of March 29, 2023

BOARD OF DIRECTORS
(the "Board")

Dr. Horst G. Zerbe	Chairman of the Board and Chief Executive Officer of IntelGenx Technologies Corp.
J. Bernard Boudreau	Vice Chairman of the Board Former Vice-President of Pharmeng International Inc.
Bernd J. Melchers	Former Managing Director of 3M Dyneon Holding GmbH, Germany; former Global Chief Financial Officer of 3M Dyneon Group
Clemens Mayr	Partner of McCarthy Tétrault LLP, Montreal
Mark Nawacki	President, CEO and Director of Searchlight Pharma Inc.
Frank Stegert	Strategic Advisor to ATAI Life Sciences AG
Dr. Srinivas Rao	Co-Founder and Chief Scientific Officer at ATAI Life Sciences AG
Monika Trzcinska	Partner and co-founder of Bluestar BioAdvisors, LLC, New York

EXECUTIVE OFFICERS

Dr. Horst G. Zerbe	Chief Executive Officer
Andre Godin	President and Chief Financial Officer
Dr. David Kideckel	Senior Vice President, Head of Corporate Development & Strategic Alliances of IntelGenx Corp.,
Nadine Paiement	Vice President, Research and Development of IntelGenx Corp.
Tommy Kenny	Vice President, IP and Legal Affairs, General Counsel of IntelGenx Corp.
Ingrid Zerbe	Corporate Secretary; Director of IntelGenx Corp.

IntelGenx Technologies Corp.

Consolidated Financial Statements
December 31, 2022 and 2021
(Expressed in U.S. Funds)

IntelGenx Technologies Corp.

Consolidated Financial Statements
December 31, 2022 and 2021
(Expressed in U.S. Funds)

Contents

RICHTER

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of
IntelGenx Technologies Corp.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of IntelGenx Technologies Corp. (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of comprehensive loss, shareholders' deficit and cash flows for each of the two years in the period ended December 31, 2022, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States ("US GAAP").

Going concern uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company does not have sufficient existing cash and short-term investments to support operations for at least the next year following the issuance of these financial statements which raises doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Impairment of leasehold improvements and equipment

As reflected in the Company's consolidated financial statements, at December 31, 2022, the Company's leasehold improvements and equipment amounted to $4,425 million. Long-lived assets must be reviewed for possible impairment if circumstances indicate the carrying amount of the asset may not be recoverable. Given that the plant is not currently operating at capacity, the Company evaluated its leasehold improvements and equipment for recoverability and concluded that they were not impaired. Auditing the Company's impairment assessment involved subjective auditor judgment due to

the significant estimation involved in determining the fair value, including the forecasted cash flows used to evaluate the recoverability and the significant assumptions used in estimating the fair values of long-lived assets. We therefore identified the impairment of leasehold improvements and equipment as a critical audit matter.

The primary procedures we performed to address this critical audit matter included:

- Obtaining an understanding of the impairment process and the controls relating to management's impairment test,
- Reviewing the valuation methodology to assess whether the methodology was widely recognized and appropriate for use in the valuation of leasehold improvements and equipment,
- Testing management's process for determining the forecasted future cash flows used to evaluate the recoverability. We evaluated the reasonableness of management's forecasts of future manufacturing and operating margin by comparing the Company's plans and forecasts to current industry and economic trends,
- Evaluating whether the data and assumptions used were reasonable by considering the past performance, industry and third-party market data, and whether such assumptions were consistent with evidence obtained in other areas of the audit,
- Performing sensitivity analysis on the significant data and assumptions used.

We have served as the Company's auditors since 2005.

Richter LLP

Montréal, Quebec
March 29, 2023

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IntelGenx Technologies Corp.

Consolidated Balance Sheets
As at December 31, 2022 and 2021
(Expressed in Thousands of U.S. Dollars ($'000) Except Share and Per Share Data)

	December 31, 2022	December 31, 2021
Assets		
Current		
Cash	**$ 1,210**	$ 3,945
Short-term investments (note 5)	**1,317**	6,004
Accounts receivable	**709**	680
Prepaid expenses	**137**	105
Investment tax credits receivable	**159**	436
Security deposits	**194**	205
Inventory (note 6)	**62**	62
Total current assets	**3,788**	11,437
Leasehold improvements and equipment, net (note 7)	**4,425**	5,213
Security deposits	**245**	252
Operating lease right-of-use-asset	**732**	1,003
Total assets	**$ 9,190**	$ 17,905
Liabilities		
Current		
Accounts payable and accrued liabilities	**2,102**	2,299
Current portion of operating lease liability (note 18)	**236**	249
Current portion of finance lease liability (note 18)	**36**	36
Deferred revenue	**-**	189
Convertible debentures (note 10)	**-**	4,247
Total current liabilities	**2,374**	7,020
Loan payable (note 9)	**5,500**	2,500
Convertible notes (note 11)	**4,272**	3,709
Operating lease liability (note 18)	**425**	642

Finance lease liability (note 18)	**42**	84
Deferred income tax liability (notes 4 and 11)	**-**	79
Total liabilities	**12,613**	14,034
Contingencies (note 12)		
Subsequent event (note 21)		
Shareholders' deficit		
Capital stock, common shares, $0.00001 par value; 450,000,000 shares authorized; 174,646,196 shares issued and outstanding (2021: 154,571,289 common shares) (note 13)	**1**	1
Additional paid-in capital (note 14)	**67,340**	63,104
Accumulated deficit	**(68,530)**	(57,863)
Accumulated other comprehensive loss	**(2,234)**	(1,371)
Total shareholders' (deficit) equity	**(3,423)**	3,871
	$ 9,190	$ 17,905

See accompanying notes

Approved on Behalf of the Board:

/s/ Bernd J. Melchers Director

/s/ Horst G. Zerbe Director

IntelGenx Technologies Corp.

Consolidated Statement of Shareholders' Equity
For the Year Ended December 31, 2021
(Expressed in Thousands of U.S. Dollars ($'000) Except Share and Per Share Data)

	Capital Stock Number	Capital Stock Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	**Total Shareholders' Equity**
Balance - December 31, 2020	111,429,532	$ 1	$ 48,453	$ (48,551)	$ (856)	**$ (953)**
Other comprehensive loss	-	-	-	-	(515)	**(515)**
Issuance of shares to atai Life Sciences (net of transaction costs of $297) (note 13)	37,300,000	-	8,398	-	-	**8,398**
Issuance of warrants to atai Life Sciences (net of transaction costs of $125) (note 13)	-	-	3,526	-	-	**3,526**
Agents' warrants issued (note 11)	-	-	164			**164**
Conversion of convertible notes (note 11)	1,985,847	-	632	-	-	**632**
Conversion of convertible debentures (note 10)	3,852,000	-	1,498	-	-	**1,498**
Interest paid by issuance of common shares (note 11)	3,910		1			**1**
Stock-based compensation (note 13)	-	-	107	-	-	**107**
Beneficial conversion feature, net of a deferred income tax liability of $86 (note 11)	-	-	325	-	-	**325**
Net loss for the period	-	-	-	(9,312)	-	**(9,312)**
Balance - December 31, 2021	**154,571,289**	**$ 1**	**$ 63,104**	**$ (57,863)**	**$ (1,371)**	**$ 3,871**

See accompanying notes

IntelGenx Technologies Corp.

Consolidated Statement of Shareholders' Deficit
For the Year Ended December 31, 2022
(Expressed in Thousands of U.S. Dollars ($'000) Except Share and Per Share Data)

	Capital Stock		Additional		Accumulated Other	
	Number	Amount	Paid-In Capital	Accumulated Deficit	Comprehensive Loss	**Total Shareholders' Deficit**
Balance - December 31, 2021	154,571,289	$ 1	$ 63,104	$ (57,863)	$ (1,371)	**$ 3,871**
Modified retrospective adjustment upon adoption of ASU 2020-06 (note 4)	-	-	(325)	23	-	**(302)**
Other comprehensive loss	-	-	-	-	(863)	**(863)**
Conversion of convertible debentures (note 10)	120,000	-	48	-	-	**48**
Repayment of convertible debentures in shares (note 10)	19,381,223	-	4,229	-	-	**4,229**
Interest paid by issuance of common shares (note 10)	573,684	-	171	-	-	**171**
Stock-based compensation (note 13)	-	-	113	-	-	**113**
Net loss for the period	-	-	-	(10,690)	-	**(10,690)**
Balance - December 31, 2022	**174,646,196**	**$ 1**	**$ 67,340**	**$ (68,530)**	**$ (2,234)**	**$ (3,423)**

See accompanying notes

IntelGenx Technologies Corp.

Consolidated Statements of Comprehensive Loss
For the Years Ended December 31, 2022 and 2021
(Expressed in Thousands of U.S. Dollars ($'000) Except Share and Per Share Data)

	2022	2021
Revenues (note 16)	**$ 950**	$ 1,535
Total revenues	**950**	1,535
Expenses		
Research and development expense	**3,031**	2,717
Manufacturing expense	**1,858**	2,256
Selling, general and administrative expense	**4,697**	3,753
Depreciation of tangible assets	**777**	791
Total expenses	**10,363**	9,517
Operating loss	**(9,413)**	(7,982)
Finance and interest income	**4**	152
Financing and interest expense	**(1,281)**	(1,488)
Net financing and interest expense	**(1,277)**	(1,336)
Loss before income taxes	**(10,690)**	(9,318)
Deferred income tax	**-**	6
Net loss	**(10,690)**	(9,312)
Other comprehensive (loss) income		
Change in fair value	(869)	(7)
Foreign currency translation adjustment	6	(508)
	(863)	(515)
Comprehensive loss	**$ (11,553)**	$ (9,827)
Basic and diluted:		
Weighted average number of shares outstanding	**164,746,054**	137,003,313

Basic and diluted loss per common share (note 20)	**$**	**(0.07)**	$	(0.07)

See accompanying notes

IntelGenx Technologies Corp.

Consolidated Statements of Cash Flows
For the Year Ended December 31, 2022 and 2021
(Expressed in Thousands of U.S. Dollars ($'000) Except Share and Per Share Data)

		2022		2021
Funds (used) provided -				
Operating activities				
Net loss	**$**	**(10,690)**	$	(9,312)
Depreciation of tangible assets		**777**		791
Stock-based compensation		**113**		107
Accretion expense		**271**		477
DSU expense		**(106)**		224
Interest paid by issuance of common shares		**171**		1
Gain on debt extinguishment (notes 10 and 11)		**-**		(151)
Lease non-cash expense		**2**		7
Deferred income tax		**-**		(6)
		(9,462)		(7,862)
Changes in non-cash items related to operations:				
Accounts receivable		**(29)**		(420)
Prepaid expenses		**(32)**		57
Investment tax credits receivable		**277**		199
Contract asset		**-**		354
Inventory		**-**		182
Security deposits		**(9)**		206
Accounts payable and accrued liabilities		**(72)**		88
Deferred revenues		**(189)**		23
Net change in non-cash items related to operations		**(54)**		689
Net cash used in operating activities		**(9,516)**		(7,173)
Financing activities				
Repayment of long-term debt		**-**		(737)
Issuance of loan		**3,000**		2,500
Finance lease payments		**(35)**		(29)
Proceeds from issuance of shares		**-**		12,346
Transaction costs of share issuance		**-**		(422)
Net proceeds from convertible notes		**-**		1,897
Transaction costs of convertible notes		**-**		(34)
Transaction costs of debt extinguishment		**-**		(29)
Net cash provided by financing activities		**2,965**		15,492
Investing activities				
Additions to leasehold improvements and equipment		**(271)**		(108)
Acquisitions of short-term investments		**(5,739)**		(6,000)
Redemptions of short-term investments		**9,519**		1,034
Net cash provided by (used in) investing activities		**3,509**		(5,074)
(Decrease) increase in cash		**(3,042)**		3,245
Effect of foreign exchange on cash		**307**		(505)
Cash				
Beginning of year		**3,945**		1,205
End of year	**$**	**1,210**	$	3,945

See accompanying notes

IntelGenx Technologies Corp.

Notes to Consolidated Financial Statements
December 31, 2022 and 2021
(Expressed in U.S. Funds)

1. Basis of Presentation

IntelGenx Technologies Corp. (and collectively with IntelGenx Corp., our wholly-owned Canadian subsidiary, "IntelGenx" or the "Company") prepares its consolidated financial statements in accordance with accounting principles generally accepted in the United States of America ("USA"). This basis of accounting involves the application of accrual accounting and consequently, revenues and gains are recognized when earned, and expenses and losses are recognized when incurred.

The consolidated financial statements include the accounts of IntelGenx Technologies Corp. and IntelGenx Corp. On consolidation, all inter-entity transactions and balances have been eliminated.

The financial statements are expressed in U.S. funds.

2. Going Concern

The Company has financed its operations to date primarily through public offerings of its common stock, proceeds from issuance of convertible notes and debentures, bank loans, royalty, up-front and milestone payments, license fees, proceeds from exercise of warrants and options, and research and development revenues. The Company has devoted substantially all of its resources to its drug development efforts, conducting clinical trials to further advance the product pipeline, the expansion of its facilities, protecting its intellectual property and general and administrative functions relating to these operations. The future success of the Company is dependent on its ability to develop its product pipeline and ultimately upon its ability to attain profitable operations. As of December 31, 2022, the Company had cash and short-term investments totaling approximately $2,527. The Company does not have sufficient existing cash and short-term investments to support operations for the next year following the issuance of these financial statements. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans to alleviate these conditions include pursuing one or more of the following steps to raise additional funding, none of which can be guaranteed or are entirely within the Company's control:

- Raise funding through the possible sale of the Company's common stock, including public or private equity financings.
- Raise funding through debt financing.
- Continue to seek partners to advance product pipeline.
- Expand oral film manufacturing activities.
- Initiate contract oral film manufacturing activities.

If the Company is unable to raise further capital when needed or on attractive terms, or if it is unable to procure partnership arrangements to advance its programs, the Company would be forced to potentially delay, reduce or eliminate some of its research and development programs and commercial activities.

The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The accompanying consolidated financial statements do not include any adjustments or classifications that may result from the possible inability of the Company to continue as a going concern. Should the Company be unable to continue as a going concern, it may be unable to realize the carrying value of its assets and to meet its liabilities as they become due.

3. Nature of Business

IntelGenx was incorporated in the State of Delaware as Big Flash Corp. on July 27, 1999. On April 28, 2006 Big Flash Corp. completed, through the Canadian holding corporation, the acquisition of IntelGenx Corp., a company incorporated in Canada on June 15, 2003 and headquartered in Montreal, Quebec. IntelGenx Corp. has continued operations as our operating subsidiary.

IntelGenx Corp. is a drug delivery company focused on the contract development and manufacturing of novel oral thin film products for the pharmaceutical market. More recently, IntelGenx made the strategic decision to enter the Canadian cannabis market with a non-prescription cannabis infused oral film that launched in early 2021 and in 2020 made the decision to enter the psychedelic market. As a full service contract development and manufacturing organization ("CDMO") IntelGenx is offering partners a comprehensive portfolio of pharmaceutical services, including pharmaceutical research and development, clinical monitoring, regulatory support, technology transfer, manufacturing scale-up, and commercial manufacturing. The Company's main product development efforts are based upon three delivery platform technologies: (1) VersaFilm™, an oral film technology, (2) the VetaFilm™ technology platform for veterinary applications and (3) DisinteQ™ a disintegrating oral film technology.

The Company's business strategy is to leverage its proprietary drug delivery technologies and develop pharmaceutical products with tangible benefits for patients, for partners and, once the product launches, retain the exclusive manufacturing rights.

Managing the project pipeline is a key Company success factor. Three focus areas have been identified; psychedelics, cannabis and animal health where the Company believes it can establish a leadership position with its drug delivery technology. The Company has undertaken a strategy under which it will work with pharmaceutical companies in order to apply its oral film technology to pharmaceutical products for which patent protection is nearing expiration, a strategy which is often referred to as "lifecycle management." Under §505(b)(2) of the Food, Drug, and Cosmetics Act (the "FDCA"), the FDA may grant market exclusivity for a term of up to three years following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage, dosage form, route of administration or a combination.

The Company's product portfolio includes a blend of generic and branded products based on its proprietary delivery technology ("generic" products are essentially copies of products that have already received FDA approval). Of the 12 projects currently in the Company's portfolio, 11 use the *VersaFilm™* technology and one uses the *VetaFilm™* technology.

IntelGenx Technologies Corp.

Notes to Consolidated Financial Statements
December 31, 2022 and 2021
(Expressed in U.S. Funds)

4. Summary of Significant Accounting Policies

Adoption of New Accounting Policies

ASU 2020-06-Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity

The FASB issued ASU 2020-06,1 which simplifies the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity.

In August 2020, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2020-06, Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40) ("ASU 2020-06") to simplify accounting for certain financial instruments. ASU 2020-06 eliminates the current models that require separation of beneficial conversion and cash conversion features from convertible instruments and simplifies the derivative scope exception guidance pertaining to equity classification of contracts in an entity's own equity. The new standard also introduces additional disclosures for convertible debt and freestanding instruments that are indexed to and settled in an entity's own equity. ASU 2020-06 amends the diluted earnings per share guidance, including the requirement to use the if-converted method for all convertible instruments. ASU 2020-06 is effective January 1, 2022 and should be applied on a full or modified retrospective basis, with early adoption permitted beginning on January 1, 2021. The Company adopted ASU 2020-06 effective January 1, 2022. The adoption of AASU 2020-06 had a substantial impact on the Company's balance sheet. The August 2021 convertible notes (note 10) contained a beneficial conversion feature. Under the new requirements, the beneficial conversion feature no longer requires to be recognized separately and the convertible notes are treated as a single financial liability. As such, the most significant impact were the reversals of the beneficial conversion feature and the deferred income tax liability.

The impact of the adoption of ASU 2020-06 on the balance sheet as at December 31, 2021 was:

	As reported December 31, 2021	Adoption of ASC 2020-06 Increase (Decrease)	Balance January 1, 2022
Convertible notes	$ 3,709	$ 388	$ 4,097
Deferred income tax liability	79	(79)	-
Total liabilities	14,034	309	14,343
Additional paid-in capital	63,104	(325)	62,779
Accumulated deficit	(57,863)	23	(57,840)
Total shareholders' equity	3,871	(309)	3,562
Total liabilities and shareholders' equity	17,905	-	17,905

IntelGenx Technologies Corp.

Notes to Consolidated Financial Statements
December 31, 2022 and 2021
(Expressed in U.S. Funds)

4. Summary of Significant Accounting Policies (Cont'd)

Revenue Recognition

The Company may enter into licensing and collaboration agreements for product development, licensing, supply and manufacturing for its product pipeline. The terms of the agreements may include non-refundable signing and licensing fees, milestone payments and royalties on any product sales derived from collaborations. These contracts are analyzed to identify all performance obligations forming part of these contracts. The transaction price of the contract is then determined. The transaction price is allocated between all performance obligations on a residual standalone selling price basis. The stand-alone selling price is estimated based on the comparable market prices, expected cost plus margin and the Company's historical experience.

Revenue is measured based on a consideration specified in a contract with a customer, and excludes any sales incentives and amounts collected on behalf of third parties. The Company recognizes revenue when it satisfies a performance obligation by transferring control over a product or service to a customer.

Taxes assessed by a governmental authority that are both imposed on and concurrent with a specific revenue-producing transaction, that are collected by the Company from a customer, are excluded from revenue.

The following is a description of principal activities - separated by nature - from which the Company generates its revenue.

Product revenue

The Company recognizes revenue from the sale of its products when the following conditions are met; delivery has occurred; the price is fixed or determinable; the collectability is reasonable assured and persuasive evidence of an arrangement exists.

Research and Development Revenue

Revenues with corporate collaborators are recognized as the performance obligations are satisfied over time, and the related expenditures are incurred pursuant to the terms of the agreement.

Licensing and Collaboration Arrangements

Licenses are considered to be right-to-use licenses. As such, the Company recognizes the licenses revenues at a point in time, upon granting the licenses.

Milestone payments are considered variable consideration. As such, the Company estimates variable consideration at the most likely amount to which we expect to be entitled. The estimated amounts are included in the transaction price to the extent it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect license, research and other revenues in the period during which the adjustment is recognized. The process of successfully achieving the criteria for the milestone payments is highly uncertain. Consequently, there is significant risk that the Company may not earn all of the milestone payments for each of its contracts.

4. Summary of Significant Accounting Policies (Cont'd)

Royalties are typically calculated as a percentage of net sales realized by the Company's licensees of its products (including their sub-licensees), as specifically defined in each agreement. The licensees' sales generally consist of revenues from product sales of the Company's product pipeline and net sales are determined by deducting the following: estimates for chargebacks, rebates, sales incentives and allowances, returns and losses and other customary deductions in each region where the Company has licensees. Revenues arising from royalties are considered variable consideration. As such, the Company estimates variable consideration at the most likely amount to which we expect to be entitled. The estimated amounts are included in the transaction price to the extent it is probable that a significant reversal of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved.

Use of Estimates

The preparation of financial statements in conformity with US GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. The financial statements include estimates based on currently available information and management's judgment as to the outcome of future conditions and circumstances. Significant estimates in these financial statements include the useful lives and impairment of long-lived assets, stock-based compensation costs, and the investment tax credits receivable. Changes in the status of certain facts or circumstances could result in material changes to the estimates used in the preparation of the financial statements and actual results could differ from the estimates and assumptions.

Financial instruments - Credit losses

The Company accounts for estimated credit losses on financial assets measured at an amortized cost basis and certain off-balance sheet credit exposures in accordance with FASB Accounting Standards Codification ("ASC") 326 20, Financial Instruments - Credit Losses. FASB ASC 326 20 requires the Company to estimate expected credit losses over the life of its financial assets and certain off-balance sheet exposures as of the reporting date based on relevant information about past events, current conditions, and reasonable and supportable forecasts.

The Company records the estimate of expected credit losses as an allowance for credit losses. For financial assets measured at an amortized cost basis the allowance for credit losses is reported as a valuation account on the balance sheet that is deducted from the asset's amortized cost basis. Changes in the allowance for credit losses are reported in Credit Loss expense, included in Selling, General and Administrative Expenses.

Accounts Receivable

The Company's accounts receivable relate to licensing and collaboration agreements for product development, licensing, supply and manufacturing agreements. These accounts receivable are short term in nature. The Company estimates expected credit losses over the life of the financial assets as of the reporting date based on relevant information about past events, current conditions, and reasonable and supportable forecasts.

Investment Tax Credits

Investment tax credits relating to qualifying expenditures are recognized in the accounts at the time at which the related expenditures are incurred and there is reasonable assurance of their realization. Management has made estimates and assumptions in determining the expenditures eligible for investment tax credits claimed. Investment tax credits received in the year ended December 31, 2022 totaled $378 (2021: $382).

IntelGenx Technologies Corp.

Notes to Consolidated Financial Statements
December 31, 2022 and 2021
(Expressed in U.S. Funds)

4. Summary of Significant Accounting Policies (Cont'd)

Inventory

The Company values inventory at the lower of cost and net realizable value where net realizable value represents the expected sale price upon disposition less make-ready costs and the costs of disposal and transportation and determines the cost of raw material inventory using the average-cost method. The Company analyzes its inventory levels quarterly and adjusts inventory to its net realizable value, if required, for obsolete, or has a cost basis in excess of its expected net realizable value.

Leasehold Improvements and Equipment

Leasehold improvements and equipment are recorded at cost. Provisions for depreciation are based on their estimated useful lives using the methods as follows:

On the declining balance method -

Laboratory and office equipment	20%
Computer equipment	30%

On the straight-line method -

Leasehold improvements	over the lease term
Manufacturing equipment	5 - 10 years

Upon retirement or disposal, the cost of the asset disposed of and the related accumulated depreciation are removed from the accounts and any gain or loss is reflected in income. Expenditures for repair and maintenance are expensed as incurred.

Leases

Leases are classified as either finance leases or operating leases. A lease is classified as a finance lease if any one of the following criteria are met: the lease transfers ownership of the asset by the end of the lease term, the lease contains an option to purchase the asset that is reasonably certain to be exercised, the lease term is for a major part of the remaining useful life of the asset or the present value of the lease payments equals or exceeds substantially all of the fair value of the asset. A lease is classified as an operating lease if it does not meet any one of these criteria.

Substantially all of the Company's operating leases are comprised of office space and property leases. The finance leases are comprised of laboratory equipment leases.

For all leases at the lease commencement date, a right-of-use asset and a lease liability are recognized. The right-of-use asset represents the right to use the leased asset for the lease term. The lease liability represents the present value of the lease payments under the lease.

4. Summary of Significant Accounting Policies (Cont'd)

The right-of-use asset is initially measured at cost, which primarily comprises the initial amount of the lease liability, plus any initial costs incurred, consisting mainly of brokerage commissions, less any lease incentives received. All right-of-use assets are reviewed for impairment. The lease liability is initially measured as the present value of the lease payments, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, the Company's secured incremental borrowing rate for the same term as the underlying lease.

Lease payments included in the measurement of the lease liability comprise the following: the fixed noncancelable lease payments, payments for optional renewal periods where it is reasonably certain the renewal period will be exercised, and payments for early termination options unless it is reasonably certain the lease will not be terminated early.

Lease modifications result in remeasurement of the lease liability.

Lease expense for operating leases consists of the lease payments plus any initial direct costs, primarily brokerage commissions, and is recognized on a straight-line basis over the lease term. Included in lease expense are any variable lease payments incurred in the period that were not included in the initial lease liability.

The Company has elected not to recognize right-of-use assets and lease liabilities for short-tern leases that have a term of 12 months or less. The effect of short-term leases on our right-of-use asset and lease liability was not material.

Impairment of Long-lived Assets

Long-lived assets held and used by the Company are reviewed for possible impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of the assets to the estimated undiscounted cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds the fair value thereof.

Security Deposits

Security deposits represent a refundable deposit paid to the landlord in accordance with the lease agreement and deposits held as guarantees by the Company's lenders in accordance with the lending facilities. The deposits will be repaid to the Company at the end of the lease.

4. Summary of Significant Accounting Policies (Cont'd)

Foreign Currency Translation

The Company's reporting currency is the U.S. dollar. The Canadian dollar is the functional currency of the Company's Canadian operations, which is translated to the United States dollar using the current rate method. Under this method, accounts are translated as follows:

Assets and liabilities - at exchange rates in effect at the balance sheet date;

Revenue and expenses - at average exchange rates prevailing during the year;

Equity - at historical rates.

Gains and losses arising from foreign currency translation are included in other comprehensive income.

Income Taxes

The Company accounts for income taxes in accordance with FASB ASC 740 "Income Taxes". Deferred taxes are provided on the liability method whereby deferred tax assets are recognized for deductible temporary differences, and deferred tax liabilities are recognized for taxable temporary differences. Temporary differences are the differences between the reported amounts of assets and liabilities and their tax bases. Deferred tax assets are reduced by a valuation allowance when, in the opinion of management, it is more likely than not that some portion or all of the deferred tax assets will be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment.

Unrecognized Tax Benefits

The Company accounts for unrecognized tax benefits in accordance with FASB ASC 740 "Income Taxes". ASC 740 prescribes a recognition threshold that a tax position is required to meet before being recognized in the financial statements and provides guidance on de-recognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition issues. ASC 740 contains a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained upon ultimate settlement with a taxing authority, including resolution of related appeals or litigation processes, if any. The second step is to measure the tax benefit as the largest amount that is more than 50% likely of being realized upon ultimate settlement.

Additionally, ASC 740 requires the Company to accrue interest and related penalties, if applicable, on all tax positions for which reserves have been established consistent with jurisdictional tax laws. The Company elected to classify interest and penalties related to the unrecognized tax benefits in the income tax provision.

Share-Based Payments

The Company accounts for share-based payments to employees in accordance with the provisions of FASB ASC 718 "Compensation-Stock Compensation" and accordingly recognizes in its financial statements share-based payments at their fair value. In addition, the Company will recognize in the financial statements an expense based on the grant date fair value of stock options granted to employees. The expense will be recognized on a straight-line basis over the vesting period and the offsetting credit will be recorded in additional paid-in capital. Upon exercise of options, the consideration paid together with the amount previously recorded as additional paid-in capital will be recognized as capital stock. The Company uses the Black-Scholes option pricing model to determine the fair value of the options.

4. Summary of Significant Accounting Policies (Cont'd)

The Company measures compensation expense for its non-employee stock-based compensation under ASC 718, "Compensation-Stock Compensation" and accordingly recognizes in its financial statements share-based payments at their fair value. In addition, the Company will recognize in the financial statements as expense over the service period, as if the Company had paid cash for the services.

Loss Per Share

Basic loss per share is calculated based on the weighted average number of shares outstanding during the year. Any antidilutive instruments are excluded from the calculation of diluted loss per share.

Fair Value Measurements

ASC 820 applies to all assets and liabilities that are being measured and reported on a fair value basis. ASC 820 requires disclosure that establishes a framework for measuring fair value in US GAAP, and expands disclosure about fair value measurements. This statement enables the reader of the financial statements to assess the inputs used to develop those measurements by establishing a hierarchy for ranking the quality and reliability of the information used to determine fair values. The statement requires that assets and liabilities carried at fair value be classified and disclosed in one of the following three categories:

Level 1: Quoted market prices in active markets for identical assets or liabilities.
Level 2: Observable market based inputs or unobservable inputs that are corroborated by market data.
Level 3: Unobservable inputs that are not corroborated by market data.

(Expressed in U.S. Funds)

In determining the appropriate levels, the Company performs a detailed analysis of the assets and liabilities that are subject to ASC 820. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs are classified as Level 3. Short-term investments are classified Level 1.

Fair Value of Financial Instruments

The fair value represents management's best estimates based on a range of methodologies and assumptions. The carrying value of receivables and payables arising in the ordinary course of business and the investment tax credits receivable approximate fair value because of the relatively short period of time between their origination and expected realization.

5. Short-term investments

As at December 31, 2022, short-term investments consisted of investments in mutual funds of $ 1.3 million (2021 - $6 million) and are with a Canadian financial institution having a high credit rating.

6. Inventory

Inventory as at December 31, 2022 consisted of raw materials in the amount of $ 62 thousand (2021 - $62 thousand). An amount of $19 thousand ($190 in 2021) was recognized in Manufacturing expenses and an amount of $ Nil (2021 - $44 thousand) was recognized in Research and development expenses.

7. Leasehold Improvements and Equipment

	Cost	Accumulated Depreciation	**2022 Net Carrying Amount**	2021 Net Carrying Amount
Manufacturing equipment	$ 4,589	$ 1,695	**$ 2,894**	$ 3,349
Laboratory and office equipment	1,536	1,117	**419**	382
Computer equipment	152	118	**34**	39
Leasehold improvements	3,267	2,189	**1,078**	1,443
	$ 9,544	$ 5,119	**$ 4,425**	$ 5,213

As at December 31, 2022, no depreciation has been recorded on manufacturing equipment in the amount of $ 1,715 thousand (2021 - $1,832 thousand) as this equipment is not yet in use. The commitment of the Company for the remainder of the project is as disclosed in note 12. In addition, no depreciation has been recorded on laboratory and office equipment in the amount $22 thousand (2021 - $Nil) as this equipment is not yet in use and on $48 thousand (2021 - $Nil) of leasehold improvements that have not been fully completed as at December 31, 2022.

8. Bank Indebtedness

The Company's credit facility is subject to review annually and consists of corporate credits cards of up to CAD$ 75 thousand ($55 thousand) and $60 thousand, and foreign exchange contracts limited to CAD$425 thousand ($314 thousand).

9. Loan Payable

atai Life Sciences ("atai") has granted to the Company a secured loan in the amount of $ 5,500,000, bearing interest at 8%. In September 2021, the Company entered into an amended and restated secured loan agreement with atai pursuant to which atai has made two additional term loans available to the Company for $3,000,000 each, which will mature on January 5, 2024. The first loan was received on January 7, 2022 and the second loan was received on January 6, 2023. The Loan Agreement also extends the maturity date for the current loans, in an aggregate amount of $5,500,000, to January 2024. The loan is guaranteed by the Company and secured by all present and future movable property, rights and assets of the Company, excluding any intellectual property or technology controlled or owned by the Company. The loan bears interest at 8%. The interest for the year ended December 31, 2022 amounts to $423,000 and is recorded in financing and interest expense (2021 - $ 156,000).

9. Loan Payable (Cont'd)

The components of the Company's debt are as follows:

	December 31, 2022	**December 31, 2021**
	$	**$**

Loan payable to atai	5,500	2,500
Total debt	5,500	2,500
Less: current portion	-	-
Total long-term debt	5,500	2,500

10. Convertible Debentures

On July 12, 2017, the Company closed its previously announced prospectus offering (the "Offering") of convertible unsecured subordinated debentures of the Corporation (the "Debentures") for gross aggregate proceeds of CAD$6,838,000 ($5,049,000). Pursuant to the Offering, the Corporation issued an aggregate principal amount of CAD$6,838,000 ($5,049,000) of Debentures at a price of CAD$ 1,000 ($738) per Debenture. The Debentures had a maturity date June 30, 2020 and interest at an annual rate of 8% payable semi-annually on the last day of June and December of each year, commencing on December 31, 2017. The interest may be paid in common shares at the option of the Corporation. The Debentures were convertible at the option of the holders at any time prior to the close of business on the earlier of June 30, 2020 and the business day immediately preceding the date specified by the Corporation for redemption of Debentures. The conversion price was CAD$1.35 ($1.00) (the "Conversion Price") per common share of the Corporation ("Share"), being a conversion rate of approximately 740 Shares per CAD$1,000 ($738) principal amount of Debentures, subject to adjustment in certain events.

On August 8, 2017, the Company closed a second tranche of its prospectus Offering of convertible unsecured subordinated debentures of the Corporation for which a first closing took place on July 12, pursuant to which it had raised additional gross proceeds of CAD$762,000 ($563,000).

Together with the principal amount of CAD$ 6,838,000 ($5,049,000) of Debentures issued on July 12, 2017, the Company issued a total aggregate principal amount of CAD$7,600,000 ($5,611,000) of Debentures at a price of CAD$ 1,000 ($738) per Debenture.

On June 25, 2020, the debentureholders approved the extension of the maturity date of the convertible debentures from June 30, 2020 to June 30, 2022 and the conversion price was reduced from CAD$1.35 ($1.00) to CAD$0.50 ($0.37). This extension was accounted for as an extinguishment and the debentures were re-measured at fair value on June 30, 2020.

On June 30, 2022, the Company issued 19,381,223 shares of common stock in payment of the outstanding CAD$ 5,450,000 ($4,229,000) aggregate principal amount of the convertible debentures. The convertible debentures, listed on the Toronto Stock Exchange under the symbol IGX.DB, were delisted from trading as of the close of business on June 30, 2022.

10. Convertible Debentures (Cont'd)

The components of the convertible debentures are as follows:

	December 31, 2022	December 31, 2021
Face value of the convertible debentures	**$ 3,866**	$ 3,977
Transaction costs	**(73)**	(74)
Accretion	**436**	344
Repayment in shares	**(4,229)**	-
Convertible debentures	**$ -**	$ 4,247

The convertible debentures were recorded as a liability. The accretion expense for the year ended December 31, 2022 amounts to CAD$ 125,000 ($96,000), compared to CAD$ 288,000 ($230,000) for the comparative period in 2021.

During the year ended December 31, 2022, CAD$ 60,000 ($48,000) of convertible debentures were converted into 120,000 common shares at the option of the holders, resulting in an increase in additional paid-in capital of $48 thousand.

During the year ended December 31, 2021, CAD$ 1,926,000 ($1,519,000) of convertible debentures were converted into 3,852,000 common shares at the option of the holders, resulting in an increase in additional paid-in capital of $1,498.

The interest accrued on the convertible debentures for the year ended December 31, 2022 amounts to CAD$ 218 thousand ($171 thousand) and was paid by issuance of 573,684 common shares on July 5, 2022.

Interest accrued on the convertible debentures for the year ended December 31, 2021 amounts to CAD$ 549 thousand ($438 thousand) and is recorded in financing and interest expense.

11. Convertible Notes

On August 5, 2021, the Company announced the closing of an offering by way of private placement to certain investors in the United States of $ 2.1 million principal amount of 8% convertible notes due July 31, 2025. The Notes bear interest at a rate of 8% per annum, payable quarterly, and are convertible into shares of common stock of the Company beginning 6 months after their issuance at a price of $0.40 per Share. The Company intends to use the proceeds of the Offering for the Montelukast clinical program. In connection with the Offering, the Company paid to an agent a cash commission of approximately $199,525 in the aggregate and issued non-transferable warrants to the agent, entitling the holder to purchase 613,000 common shares at a price of $ 0.40 per Share until August 4, 2023.

Management has determined the value of the agents' warrants to be $ 164,000.

IntelGenx Technologies Corp.

Notes to Consolidated Financial Statements
December 31, 2022 and 2021
(Expressed in U.S. Funds)

11. Convertible Notes (Cont'd)

The convertible notes have been recorded as a liability. Total transactions costs in the amount of $ 403 thousand were recorded against the liability. The accretion expense for the year ended December 30, 2022 amounts to $85,000 (2021: $58,000). The warrants have been recorded as equity. The Company recognized the value of the embedded beneficial conversion feature of $411 thousand as additional paid-in capital. Upon adoption of ASU 606-20, the beneficial conversion feature was reversed on January 1, 2022.

The components of the convertible notes are as follows:

	December 31, 2022	December 31, 2021
Face value of the convertible notes	$ 2,101	$ 2,101
Transaction costs	(403)	(403)
Accretion	119	58
Beneficial conversion feature	-	(411)
Convertible notes	$ 1,817	$ 1,345

The interest on the convertible notes for the year ended December 31, 2022 amounts to $ 168,000 (2021: $68,000) and is recorded in financing and interest expense.

On May 8, 2018, the Company closed its previously announced offering by way of private placement (the "Offering"). In connection with the Offering, the Company issued 320 units (the "Units") at a subscription price of $ 10,000 per Unit for gross proceeds of $ 3,200,000. A related party of the Company participated in the Offering and subscribed for an aggregate of two Units.

Each Unit is comprised of (i) 7,940 common shares of the Corporation ("Common Shares"), (ii) a $ 5,000 convertible 6% note (a "Note"), and (iii) 7,690 warrants to purchase common shares of the Corporation ("Warrants"). Each Note bears interest at a rate of 6% (payable quarterly, in arrears, with the first payment being due on September 1, 2018), matured on June 1, 2021 and is convertible into Common Shares at a conversion price of $0.80 per Common Share. Each Warrant entitles its holder to purchase one Common Share at a price of $ 0.80 per Common Share until June 1, 2021.

In connection with the Offering, the Company paid to the Agents a cash commission of approximately $ 157,800 in the aggregate and issued non-transferable agents' warrants to the Agents, entitling the Agents to purchase 243,275 common shares at a price of $ 0.80 per share until June 1, 2021. Management has determined the value of the agents' warrants to be $50,000.

IntelGenx Technologies Corp.

Notes to Consolidated Financial Statements
December 31, 2022 and 2021
(Expressed in U.S. Funds)

11. Convertible Notes (Cont'd)

The proceeds of the Units are attributed to liability and equity components based on the fair value of each component as follows:

	Gross proceeds	Transaction costs	Net proceeds
Common stock	$ 1,627	$ 167	$ 1,460
Convertible notes	1,086	111	975
Warrants	487	50	437
	$ 3,200	$ 328	$ 2,872

On May 19, 2021, the noteholders approved the amendment of the terms of the convertible notes. The maturity date of the convertible notes was extended from June 1, 2021 to October 31, 2024, the interest rate of the notes increased from 6% to 8%, and the conversion price was reduced from $0.80 to $0.44. These amendments were accounted for as an extinguishment and the notes were re-measured at fair value on June 1, 2021. This re-measurement resulted in a gain on extinguishment in the amount of $151,000 recognized in finance and interest income.

The components of the convertible notes subsequent to the amendments are as follows:

	December 31, 2022	December 31, 2021
Face value of the convertible notes	$ 909	$ 909
Transaction costs	(29)	(29)
Accretion	52	21
Convertible notes	$ 932	$ 901

The convertible notes have been recorded as a liability. Total transactions costs in the amount of $ 29 thousand were recorded against the liability. The accretion expense for the year ended December 31, 2022 amounts to $31,000 (2021: $135,000).

During the year ended December 31, 2021, $600,000 of convertible notes were converted into 1,363,625 common shares at the option of the holders, resulting in an increase in additional paid-in capital of $535 thousand.

The interest on the convertible notes for the year ended December 31, 2022 amounts to $ 80 thousand (2021: $99 thousand) and is recorded in financing and interest expense.

On October 15, 2020, the Company announced the closing of an offering by way of private placement to certain investors in the United States of $1.2 million principal amount of 8% convertible notes due October 15, 2024. The Notes will bear interest at a rate of 8% per annum, payable quarterly, and will be convertible into shares of common stock of the Company beginning 6 months after their issuance at a price of $0.18 per Share. The Company intends to use the proceeds of the Offering for working capital purposes. In connection with the Offering, the Company paid to an agent a cash commission of approximately $85,000 in the aggregate and issued non-transferable warrants to the agent, entitling the holder to purchase 482,000 common shares at a price of $ 0.18 per Share until October 15, 2022.

11. Convertible Notes (Cont'd)

On October 23, 2020, the Company announced the closing of a second tranche of the Notes to certain investors in the United States of $ 557 thousand principal amount of 8% convertible notes due Oct 15, 2024. The Notes bear interest at a rate of 8% per annum, payable quarterly, and are convertible into shares of common stock of the Company beginning 6 months after their issuance at a price of $0.18 per Share. In connection with the Offering, the Company paid to an agent a cash commission of approximately $39,000 in the aggregate and issued non-transferable warrants to the agent, entitling the holder to purchase 222,800 common shares at a price of $ 0.18 per Share until October 15, 2022.

Management has determined the value of the agents' warrants to be $ 44,000.

The convertible notes have been recorded as a liability. Total transactions costs in the amount of $ 268 thousand were recorded against the liability. The accretion expense for the year ended December 31, 2022 amounts to $59 thousand (2021: $54 thousand). The warrants have been recorded as equity.

During the year ended December 31, 2021, $112,000 of convertible notes were converted into 622,222 common shares at the option of the holders, resulting in an increase in additional paid-in capital of $97 thousand.

The components of the convertible notes are as follows:

	December 31, 2022	December 31, 2021
Attributed value of net proceeds to convertible notes	**$ 1,397**	**$ 1,397**
Accretion	**126**	**66**
Convertible note	**$ 1,523**	**$ 1,463**

The interest on the convertible notes for the year ended December 31, 2021 amounts to $ 132,000 (2021: $137,000, out of which $1,000 was paid by issuance of 3,910 common shares). The interest is recorded in financing and interest expense.

12. Commitments and Contingencies

Commitments

The Company has initiated a project to expand the existing manufacturing facility. The Company has signed agreements in the amount of Euro 1,911 thousand (2,040 thousand) with three suppliers with respect to equipment for solvent film manufacturing. As at December 31, 2022 an amount of Euro 1,490 thousand (1,591 thousand) has been paid with respect to these agreements (note 6).

Contingencies

The government authorities have assessed the Company with respect to sales taxes claimed on certain expenses between 2017 and 2020, which the government is denying. The sales tax assessments amount to $314,000 (including interest and penalties of $ 33,000), which was paid to avoid further interest and penalties. The Company disagrees with the government's position and the sales tax assessments are under appeal. In the event the Company is unsuccessful in its appeal, sales taxes expenses would increase by $281,000 and net earnings would decrease by $ 281,000.

IntelGenx Technologies Corp.

Notes to Consolidated Financial Statements
December 31, 2022 and 2021
(Expressed in U.S. Funds)

13. Capital Stock

	2022	2021
Authorized -		
450,000,000 common shares of $0.00001 par value		
20,000,000 preferred shares of $0.00001 par value		
Issued -		

(Expressed in U.S. Funds)

174,646,196 (December 31, 2021: 154,571,289) common shares	**$**	**1**	$	1

On May 11, 2021, the shareholders approved a resolution to amend IntelGenx's Certificate of Incorporation to increase the total number of shares of common stock that IntelGenx is authorized to issue from 200,000,000 shares to 450,000,000 shares.

Atai Life Sciences

On May 11, 2021, the Company announced that a significant majority of its shareholders had approved the resolution approving the previously announced investment in IntelGenx by atai Life Sciences, pursuant to which atai acquired an approximate 25% interest in IntelGenx.

On May 14, 2021, the Company reported that the previously announced $ 12,346,300 investment in IntelGenx by atai Life Sciences had been completed. As a result of the investment, atai held 25% of the issued and outstanding common stock of IntelGenx.

Under the securities and purchase agreement, atai purchased Initial Units composed of 37,300,000 shares of common stock of the Company and 22,380,000 warrants for aggregate gross proceeds of $ 12,346,300. Each warrant will entitle atai to purchase one share at a price of $ 0.35 for a period of three years from closing of the initial investment.

The proceeds of the transaction are attributed to equity components based on the fair value of each component as follows:

		Gross proceeds		Transaction costs		Net proceeds
Common stock	**$**	**8,695**	**$**	**297**	**$**	**8,398**
Warrants		**3,651**		**125**		**3,526**
	$	**12,346**	**$**	**422**	**$**	**11,924**

13. Capital Stock (Cont'd)

The securities purchase agreement also provides atai with the right to subscribe (in cash, or in certain circumstances, atai equity) for up to 130,000,000 additional units for a period of three years from the closing of the initial investment. Each additional unit will be comprised of (i) one share of common stock and (ii) one half of one warrant. The price for the additional units will be (i) until the date which is 12 months following the closing, $0.331 (subject to certain exceptions), and (ii) following the date which is 12 months following the closing, the lower of (A) a 20% premium to the market price on the date of purchase, and (B) $0.50 if purchased in the second year following closing and $0.75 if purchased in third year following closing. Each additional warrant will entitle atai, for a period of three years from the date of issuance, to purchase one share at the lesser of either (i) a 20% premium to the price of the corresponding additional share, or (ii) the price per share under which shares of the Company are issued under convertible instruments that were outstanding on February 16, 2021, the date on which the parties entered into a non-binding letter of intent to enter into a definitive securities purchase agreement, provided that atai may not exercise additional warrants to purchase more than the lesser of 44,000,000 common shares of the Company, and the number of common shares issued by the Company under outstanding convertibles.

Stock options

During the years ended December 31, 2022 and 2021 there were no stock options exercised.

Stock-based compensation of $ 113 thousand and $107 thousand was recorded during the years ended December 31, 2022 and 2021 respectively. An amount of $101 thousand (2021 - $107 thousand) expensed relates to stock options granted to employees and an amount of $ 12 (2021- $Nil thousand) relates to stock options granted to a consultant during the year ended December 31, 2021. As at December 31, 2022 the Company has $39 thousand (2021 - $146 thousand) of unrecognized stock-based compensation, of which $ 12 thousand (2021 - $24) relates to options granted to consultants.

14. Additional Paid-In Capital

Stock Options

The fair value of options granted to employees has been estimated according to the Black-Scholes valuation model and based on the weighted average of the following assumptions for options granted to employees during the years ended:

	2022	2021
Exercise price	0.16	0.35
Expected volatility	84%	81%
Expected life	5.63 years	5.63 years
Risk-free interest rate	3.47%	0.83%
Dividend yield	Nil	Nil

The weighted average fair value of the options granted to employees during the year ended December 31, 2022 is $ 0.11 (2021 - $0.23).

(Expressed in U.S. Funds)

14. Additional Paid-In Capital (Cont'd)

On December 22, 2021, the Company granted 100,000 options to purchase common stock to a consultant. The options have an exercise price of $0.35. The options granted vest over 2 years at a rate of 25% every six months and expire 10 years after the grant date. The stock options were accounted for at their fair value, as determined by the Black-Scholes valuation model, of approximately $24 thousand.

	2021
Exercise price	0.35
Expected volatility	83%
Expected life	5.63 years
Risk-free interest rate	1.23%
Dividend yield	Nil

Information with respect to employees' stock option activity for 2021 and 2022 is as follows:

	Number of options	Weighted average exercise price $
Outstanding - January 1, 2021	4,629,818	0.56
Granted	275,000	0.35
Expired	(387,500)	(0.49)
Forfeited	(105,000)	(0.27)
Outstanding - December 31, 2021	4,412,318	0.56
Granted	150,000	0.16
Expired	(266,250)	(0.62)
Forfeited	(58,750)	(0.32)
Outstanding - December 31, 2022	4,237,318	0.54

14. Additional Paid-In Capital (Cont'd)

Information with respect to consultant's stock option activity for 2021 and 2022 is as follows:

	Number of options	Weighted average exercise price $
Outstanding - January 1, 2021	550,000	0.72
Granted	100,000	0.35
Expired	(550,000)	(0.72)
Outstanding - December 31, 2021 and December 31, 2022	100,000	0.35

Details of stock options outstanding as at December 31, 2022 are as follows:

	Outstanding options				Exercisable options		
Exercise prices $	Number of options	Weighted average remaining contractual life (years)	Weighted average exercise price $	Aggregate intrinsic value $	Number of options	Weighted average exercise price $	Aggregate intrinsic value $
0.12	125,000	0.28	0.00		-	-	
0.27	1,322,500	2.41	0.08		1,295,000	0.09	
0.34	25,000	0.05	0.00		6,250	0.00	
0.35	100,000	0.21	0.01		50,000	0.00	
0.44	100,000	0.21	0.01		50,000	0.01	
0.58	600,000	0.35	0.08		600,000	0.09	
0.66	125,000	0.15	0.02		150,000	0.02	
0.69	100,000	0.14	0.02		100,000	0.02	
0.73	475,000	0.41	0.08		475,000	0.09	

0.76	805,000	0.98	0.14		805,000	0.15	
0.77	359,818	0.39	0.06		359,818	0.07	
0.89	200,000	0.19	0.04		200,000	0.04	
	4,337,318	5.77	0.54	10,000	4,166,068	0.58	-

14. Additional Paid-In Capital (Cont'd)

Stock-based compensation expense recognized in 2022 with regards to the stock options was $ 113 thousand (2021: $107 thousand). As at December 31, 2022 the Company has $39 thousand (2021 - $146 thousand) of unrecognized stock-based compensation, of which $ 12 thousand (2021 - $24) relates to options granted to consultants. The amount of $ 39 thousand will be recognized as an expense over a period of two years. A change in control of the Company due to acquisition would cause the vesting of the stock options granted to employees and consultants to accelerate and would result in $39 thousand being charged to stock-based compensation expense.

Warrants

Information with respect to warrant activity for 2021 and 2022 is as follows:

	Number of warrants (All Exercisable)	Weighted average exercise price $
Outstanding - January 1, 2021	31,068,387	0.71
Granted	22,993,000	0.35
Expired	(12,904,397)	(0.95)
Outstanding - December 31, 2021	41,156,990	0.20
Expired	(704,800)	(0.18)
Outstanding - December 31, 2022	40,452,190	0.20

Deferred Share Units ("DSUs")

Under the DSU Plan, the Board may grant Deferred Share Units ("DSUs") to the participating directors at its discretion and, in addition, each participating director may elect to receive all or a portion of his or her annual cash stipend in the form of DSUs. To the extent DSUs are granted, the amount of compensation that is deferred is converted into a number of DSUs, as determined by the market price of our Common Stock on the effective date of the election. These DSUs are converted back into a cash amount at the expiration of the deferral period based on the market price of our Common Stock on the expiration date and paid to the director in cash in accordance with the payout terms of the DSU Plan. As the DSUs are on a cash-only basis, no shares of Common Stock will be reserved or issued in connection with the DSUs. During the year ended December 31, 2022, 543,478 DSUs have been granted under the DSU Plan (2021 - 390,625), accordingly, an amount of $ 197 thousand has been recognized in general and administrative expenses (2021 - $219 thousand).

During the year ended December 31, 2022, 298,640 DSUs were converted back into a cash amount of CAD $ 64 thousand (49 thousand) and paid to the director.

Performance and Restricted Share Units ("PRSUs")

As at December 31, 2022, 53,846 rewards have been issued under the PRSU Plan. No rewards were granted under the PRSU Plan in 2021 and 2022.

IntelGenx Technologies Corp.

Notes to Consolidated Financial Statements
December 31, 2022 and 2021
(Expressed in U.S. Funds)

15. Income Taxes

Income taxes reported differ from the amount computed by applying the statutory rates to net income (losses). The reasons are as follows:

	2022	2021
Statutory income taxes	**$ (3,062)**	$ (2,115)
Net operating losses for which no tax benefits have been recorded	**1,785**	1,040
Deficiency of depreciation over capital cost allowance	**(52)**	(32)
Non-deductible expenses	**918**	839
Undeducted research and development expenses	**455**	383
Investment tax credit	**(44)**	(115)
	$ -	$ -

The major components of the deferred tax assets classified by the source of temporary differences are as follows:

	2022	2021
Leasehold improvements and equipment	$ 184	$ 225
Net operating losses carryforward	12,789	11,017
Undeducted research and development expenses	4,122	3,868
Non-refundable tax credits carryforward	2,780	2,729
	19,875	17,839
Valuation allowance	(19,875)	(17,839)
	$ -	$ -

As at December 31, 2022, management determined that enough uncertainty existed relative to the realization of deferred income tax asset balances to warrant the application of a full valuation allowance. Management continues to believe that enough uncertainty exists relative to the realization of the remaining deferred income tax asset balances such that no recognition of deferred income tax assets is warranted.

There were Canadian and provincial net operating losses of approximately $ 45,041 thousand (2021: $39,823 thousand) and $52,004 thousand (2021: $43,482 thousand) respectively, that may be applied against earnings of future years. Utilization of the net operating losses is subject to significant limitations imposed by the change in control provisions. Canadian and provincial losses will be expiring between 2026 and 2042. A portion of the net operating losses may expire before they can be utilized.

15. Income Taxes (Cont'd)

As at December 31, 2022, the Company had non-refundable tax credits of $ 3,004 thousand (2021: $2,912 thousand) of which $8 thousand is expiring in 2026, $10 thousand is expiring in 2027, $166 thousand is expiring in 2028, $146 thousand is expiring in 2029, $124 thousand is expiring in 2030, $132 thousand is expiring in 2031, $166 thousand is expiring in 2032, $110 thousand is expiring in 2033, $84 thousand expiring in 2034, $98 thousand is expiring in 2035, $136 thousand expiring in 2036, $259 thousand is expiring in 2037, $558 thousand expiring in 2038, $338 thousand expiring in 2039, $220 thousand expiring in 2040, $225 thousand expiring in 2041, and $224 expiring in 2042 and undeducted research and development expenses of $17,031 thousand (2021: $16,566 thousand) with no expiration date.

The deferred tax benefit of these items was not recognized in the accounts as it has been fully provided for.

Unrecognized Tax Benefits

The Company does not have any unrecognized tax benefits.

Tax Years and Examination

The Company files tax returns in each jurisdiction in which it is registered to do business. For each jurisdiction a statute of limitations period exists. After a statute of limitations period expires, the respective tax authorities may no longer assess additional income tax for the expired period. Similarly, the Company is no longer eligible to file claims for refund for any tax that it may have overpaid. The following table summarizes the Company's major tax jurisdictions and the tax years that remain subject to examination by these jurisdictions as of December 31, 2021:

Tax Jurisdictions	Tax Years
Federal - Canada	2017 and onward
Provincial - Quebec	2017 and onward
Federal - USA	2017 onward

IntelGenx Technologies Corp.

Notes to Consolidated Financial Statements
December 31, 2022 and 2021
(Expressed in U.S. Funds)

16. Revenues

The following table presents our revenues disaggregated by revenue source. Sales and usage-based taxes are excluded from revenues:

	December 31, 2022	December 31, 2021
Research and development agreements	$ 824	$ 699
Product revenue	78	267
Sales milestone revenue	-	320
Royalties on product sales	48	-
Licensing agreements	-	249
	$ 950	$ 1,535

The following table presents our revenues disaggregated by timing of recognition:

	December 31, 2022	December 31, 2021

Product and services transferred at point in time	**$**	**271**	$	836
Products and services transferred over time		**679**		699
	$	**950**	$	1,535

The following table presents our revenues disaggregated by geography, based on the billing addresses of our customers:

		December 31, 2022		December 31, 2021
Europe	**$**	**701**	$	1,023
Canada		**104**		263
United States		**145**		249
	$	**950**	$	1,535

Remaining performance obligations

As at December 31, 2022, the aggregate amount of the transaction price allocated to the remaining performance obligation is $ 1,453 representing research and development agreements. The Company is also eligible to receive up to $2,553 in research and development milestone payments, approximately 100% of which is expected to be recognized in the next three years; up to $ 433 in commercial sales milestone payments which are wholly dependent on the marketing efforts of our development partners. In addition, the Company is entitled to receive royalties on potential sales.

The Company applies the practical expedient in paragraph 606-10-50-14 and does not disclose information about the remaining performance obligations that have original expected durations of one year or less.

17. Statement of Cash Flows Information

In US$thousands	**2022**	2021
Additional Cash Flow Information:		
Interest paid	**$ 396**	$ 807

18. Leases

Operating leases

Substantially all our operating lease right-of-use assets and operating lease liability represents leases for office space and property to conduct our business.

The operating lease expense for the year ended December 31, 2022 included in general and administrative expenses is $ 269 thousand (2021: $200 thousand). The cash outflows from operating leases for the year ended December 31, 2022 was $267 thousand (2021: $194 thousand).

The weighted average remaining lease term and the weighted average discount rate for operating leases at December 31, 2022 were 3.2 years and 10%, respectively.

The following table reconciles the undiscounted cash flows for the operating leases as at December 31, 2022 to the operating lease liabilities recorded on the balance sheet:

	Operating Leases
2023	259
2024	267
2025	267
2026	44
Total undiscounted lease payments	837
Less: Interest	176
Present value of lease liabilities	$ 661

Current portion of operating lease liability	$ 236
Operating lease liability	$ 425

18. Leases (Cont'd)

(Expressed in U.S. Funds)

Finance leases

Substantially all our finance lease right-of-use assets and finance lease liability represents leases for laboratory equipment to conduct our business.

The cash outflows from finance leases for the year ended December 31, 2022 was $ 35 thousand (2021: $29 thousand).

The weighted average remaining lease term and the weighted average discount rate for finance leases at December 31, 2022 were 2 years and 6.35%, respectively.

The following table reconciles the undiscounted cash flows for the finance leases as at December 31, 2022 to the finance lease liabilities recorded on the balance sheet:

	Finance Leases
2023	$ 40
2024	38
2025	6
Total undiscounted lease payments	84
Less: Interest	6
Present value of lease liabilities	$ 78

Current portion of operating lease liability	$	36
Operating lease liability	$	42

19. Related Party Transactions

Included in management salaries are $ 12 thousand (2021 - $13 thousand) for options granted to the Chief Executive Officer, $ 12 thousand (2021 - $13 thousand) for options granted to the President and Chief Financial Officer, $ 6 thousand (2021 - $7) for options granted to the Vice-President, Research and Development, $6 thousand (2021 - $7) for options granted to the Vice-President, Business and Corporate Development, $ 3 thousand (2021 - $12) for options granted to the Vice-President, Operations, and $ 17 (2021 - $18) for options granted to the Vice-President Intellectual Property and Legal Affairs under the 2016 Stock Option Plans.

Included in general and administrative expenses are director fees of $ 229 thousand (2021: $236 thousand).

The above related party transactions have been measured at the exchange amount which is the amount of the consideration established and agreed upon by the related parties.

20. Basic and Diluted Loss Per Common Share

Basic and diluted loss per common share is calculated based on the weighted average number of shares outstanding during the year. Common equivalent shares from stock options, warrants and convertible debentures are also included in the diluted per share calculations unless the effect of the inclusion would be antidilutive.

21. Subsequent Events

On January 9, 2023, the Company announced that it has received a fourth and final term loan for $ 3 million pursuant to its amended and restated secured loan agreement with atai.

On March 21, 2023, the Company announced the closing of an offering by way of a private placement (the "Offering") to certain investors in the United States of convertible notes due March 1, 2027 (the "Notes") for aggregate gross proceeds of approximately $760,000. The Notes will bear interest at a rate of 10% per annum, payable quarterly, and will be convertible into shares of common stock of the Company beginning six months after their issuance at a price of $0.20 per share. The Company intends to use the proceeds of the Offering to finance the Company's Rizaport and Buprenorphine programs as well as for working capital. In connection with the Offering, the Company paid a cash commission of approximately $53,000 in the aggregate and issued non-transferable agent warrants, entitling the agent to purchase 304,000 shares at a price of $ 0.20 per share until March 21, 2025.