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, 2020 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 Venture Exchange

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. [ ]

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, 2020, the aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates of the registrant was $20,920,883 based on the closing price of the registrant's common stock of U.S. $0.21, 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 24, 2021**
Common Stock, $.00001 par value	111,909,533 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 2021 Annual Meeting of Shareholders (the "2021 Proxy Statement") are incorporated by reference into Part III

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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 2020 as reported by the Bank of Canada, being U.S. $1.00 = CA$1.3412.

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 Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. 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, exchange listings, and the pending transaction with ATAI Life Sciences AG ("atai"). 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 ability to continue as a going concern;
- 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 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 will have reduced ownership and voting interest after the closing of 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 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 our 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 the common stock of the Company (the "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. In addition, there is an ongoing uncertainty about the spread of the COVID-19 virus and the impact it will have on our operations, the demand for its products, global supply chains and economic activity in general.

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, 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 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 expected to be launched in early 2021 and in 2020 we made the decision to enter the psychedelic market. In addition, 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 and, once the viability of a product has been demonstrated, license the commercial rights to our partners in the pharmaceutical industry. In certain cases, we rely upon partners in the pharmaceutical industry to fund the development of licensed products, complete the regulatory approval process with the FDA or other regulatory agencies for the licensed products and assume responsibility for marketing and distributing such products.

In addition, we may choose to pursue the development of certain products until the project reaches the marketing and distribution stage. We will assess the potential for successful development of a product and associated costs, and then determine at which stage it is most prudent to seek a partner, balancing such costs against the potential for additional returns earned by collaborating later in the development process.

Managing our project pipeline is a key Company success factor. 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 §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 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 research and development 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 three delivery platform technologies: (1) VersaFilm™, an oral film technology, (2) AdVersa®, a mucoadhesive tablet technology and (3) the VetaFilm™ technology platform for veterinary applications.

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 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.

Our AdVersa® platform technology allows for the development of oral controlled-release products. It is designed to adhere to the oral mucosa and release the drug to the site of application at a controlled rate. The AdVersa® platform provides the following advantages relative to competing technologies: (i) it avoids the first pass effect, whereby the liver metabolizes the active ingredient and greatly reduces the level of drug reaching the systemic circulation, (ii) it leads to a higher absorption rate in the oral cavity as compared to the conventional oral route, and (iii) it achieves a rapid onset of action for the drug. Our AdVersa® technology is versatile in order to permit the site of application, residence time, and rate of release of the drug to be modulated to achieve the desired results.

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 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 eleven projects currently in our product portfolio, ten 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 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.

In February 2014 we received a Complete Response Letter ("CRL") from the FDA, noting issues the Company needed to address before approval. These issues have all been addressed and the Company is preparing its response to the CRL.

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.

More recently, on March 27, 2020, we received an additional CRL from the FDA. The Agency requested additional information, but no new bioequivalence study. We have addressed the issues raised in the CLR and are currently preparing the CLR response.

On November 9, 2015, BfArM granted marketing authorization of RIZAPORT® 5mg and 10mg for the treatment of acute migraines. This German national approval was granted under the DCP, in which Germany served as the Reference Member State. This authorization was the first national marketing approval of RIZAPORT®. Additionally, in April 2017, RIZAPORT® received national marketing approval in Luxembourg, which completed the approval process under the DCP.

On February 18, 2016, the USPTO granted a patent protecting Rizaport®. This patent protects the composition of Rizaport® and will be listed in the Orange Book (a list of approved drugs upon FDA approval of the product. This patent application, entitled "Instantly Wettable Oral Film Dosage Form Without Surfactant or Polyalcohol" covers rapidly disintegrating film oral dosage forms and is valid until 2034.

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, we 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. More recently, 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.

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

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 have 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.

INT0046/2018: Our first cannabis project based on our VersaFilm™ technology is currently in preparation for launch. We started this project in anticipation of the amended cannabis regulations that would allow adult-use consumers to purchase edible products in Canada.

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 with Tilray, us and Tilray will fund 20% and 80%, respectively, of the costs associated with the development of the cannabis infused Versafilm™ products. We 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, we 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 US$0.70 per share of Common Stock for gross proceeds of US$1,000,000. We used the proceeds of the Tilray Private Placement for cannabis infused VersaFilm™ product development under the agreement with Tilray.

In 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 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 using our VersaFilm® technology for the Canadian and Australian markets. In addition, we received our first purchase order from Heritage for 50,000 CBD Filmstrips. The first shipment of product to Heritage is expected in the second quarter of 2021.

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 November 21, 2016, we announced the signing of a binding term sheet for a license to Eli Lilly and Company's ("Eli Lilly") tadalafil dosing patent, United States Patent No. 6,943,166 (the " '166 dosing patent"). Any exclusivity associated with the tadalafil compound patent is not affected by this agreement. Subject to FDA approval, this license allows us to commercialize a tadalafil ED VersaFilm™ product in the United States before the expiration of the '166 dosing patent. This license terminates all of our current tadalafil-related litigation activities. On March 28, 2017, we announced that Eli Lilly granted us an exclusive license for tadalafil film product under the '166 dosing patent.

On May 8, 2019, we executed a worldwide collaboration agreement for tadalafil with Aquestive Therapeutics, Inc. ("Aquestive"). Under the terms of this agreement, we 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 waiting for FDA's comments on resubmission and approval and are in active discussions with several companies to commercialize the product.

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.

In March 2019, the FDA conducted a pre-approval inspection 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. We are currently preparing a response to both the 483 and the CRL.

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.

In 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.

In 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, us, Par, Indivior, Inc., Indivior UK Limited, and Aquestive (previously Monosol RX) settled all patent litigation related to Suboxone® film. The settlement agreement permits Par to begin selling a generic version of Suboxone® film on January 1, 2023 or earlier under certain circumstances.

Our earlier stage projects:

INT0043/2015: We developed an oral film containing montelukast as the active ingredient based on our proprietary VersaFilm™ edible 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 will be 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. The study is presently on hold due to the COVID-19 pandemic.

INT0040/2014: An oral film product 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 and will receive future milestone payments. Endo and us will share the expected profits of commercialization.

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 is needed, 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 Q4 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 due to the difficulty of sourcing a necessary active pharmaceutical ingredient.

Other projects:

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 a successful feasibility study, we are in discussions to further develop the product with the partner.

On February 8, 2021, we announced that we have 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.

INT0052/2020. On July 7, 2020 we entered into a feasibility agreement with Cybin Corp. for a fast-acting, orally-dissolving psilocybin film. We are currently developing a formulation intended for a clinical phase 1 study.

INT0053/2020. On August 20, 2020 we entered into a feasibility agreement with atai to develop pharmaceutical-grade polymeric film-based psychedelics. Some material was received and we are currently developing a formulation. However, in parallel, both companies are currently working on the required import and export licenses to continue the R&D work.

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 April 5, 2017, we announced signing of a definitive agreement with Tetra Bio-Pharma Inc. ("Tetra") for the development and commercialization of a drug product containing the cannabinoid Dronabinol (the "Tetra Product") for the management of anorexia and cancer chemotherapy-related pain.

Under the definitive agreement, Tetra has exclusive rights to sell the Tetra Product in North America, with a right of first negotiation for territories outside of the United States and Canada. Tetra made an upfront payment to the Issuer, in addition to fixed future milestone and royalty payments, based on the completion of an efficacy study, approvals from the FDA and Health Canada and the commercial launch of the Tetra Product. We are responsible for the research and development of the Tetra Product, including optimization of the prototype, scale-up activities and preparation of a phase II proof of concept clinical study. We are developing the Tetra Product as an oral mucoadhesive tablet based on our proprietary AdVersa ® controlled-release technology. Tetra is responsible for funding the product development, and will own and control all regulatory approvals, including the related applications and any other marketing authorizations. Tetra will also be responsible for all aspects of commercializing the Tetra Product.

On October 21, 2020, we entered into an amended and restated licensing agreement with Tetra Bio-Pharma under which Tetra is purchasing 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.

INT0004/2006: We developed a new, higher strength of the antidepressant Bupropion HCl, the active ingredient in Wellbutrin XL ®, and, in November 2011, the FDA approved the drug for patients with Major Depressive Disorder. In February 2012, we entered into an agreement with Edgemont Pharmaceuticals LLC ("Edgemont") for commercialization of this product in the United States. Under the terms of this agreement, Edgemont obtained certain exclusive rights to market and sell the product in the United States. In exchange, we received a $1 million upfront payment, agreed to launch-related milestone payments totaling up to $4 million and additional milestones of up to a further $23.5 million upon achieving certain sales and exclusivity targets, in addition to tiered double-digit royalties on the net sales of the product.

The product was launched in the United States in October 2012 under the brand name Forfivo XL ®. As of December 31, 2015, we had received an upfront payment of $1 million and a $1 million milestone payment related to the launch. Edgemont reaching $7 million of cumulative net trade sales for this product as of July 2015 over the preceding 12 months triggered a launch-related milestone payment of $3 million from Edgemont.

In August 2013, we announced receipt of a Paragraph IV Certification Letter from Wockhardt Bio AG, advising of the submission of an ANDA to the FDA requesting authorization to manufacture and market generic versions of Forfivo XL® 450 mg tablets in the United States. In November 2014 we announced that the Paragraph IV litigation with Wockhardt had been settled and that, under the terms of the settlement, Wockhardt has been granted the right, with effect from January 15, 2018, to be the exclusive marketer and distributor of an authorized generic of Forfivo XL® in the United States.

In December 2014, Edgemont exercised its right to extend the license for the exclusive marketing of Forfivo XL ® 450 mg tablets. In exchange, we received milestone payments of $650,000 in December 2014 and $600,000 in February 2015. All other financial obligations contained in the Edgemont license agreement, specifically launch-related and sales milestones, together with the contractual royalty rates on net sales of the product, remained in effect.

On August 5, 2016, we sold our United States royalty on future sales of Forfivo XL ® to SWK Holdings Corporation ("SWK") for $6 Million (CA$8 million). Under that agreement, we received $6 million from SKW for: (i) 100% of any and all royalties (as defined in the Edgemont license agreement) or similar royalty amounts received on or after April 1, 2016; (ii) 100% of the $2 million milestone payment due when Edgemont reached annual net sales of $15 million; and (iii) 35% of all potential future milestone payments. Patent protection for Forfivo XL® in the United States expires in 2027.

In the first quarter of 2017, we were informed that Edgemont had assigned its product business, including Forfivo XL ®, to Alvogen Group Holdings 3 LLC. We retained all patent rights to Forfivo XL®, which is sold on the US market.

INT0037/2013: We discontinued this project due to discontinuation of the reference product.

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	Preparing CRL response
INT0046/2018	Adult Use	Preparing for commercial manufacturing
INT0007/2006	Erectile dysfunction	Awaiting FDA's comment for the response to Aquestive's CRL
INT0039/2013	Undisclosed	Undisclosed
INT0027/2011	Opioid addition	Settlement agreement
INT0043/2015	Alzheimer	Study on hold due to COVID-19
INT0040/2014	Undisclosed	Undisclosed
INT0010/2006	Treatment of neuropathic pain and nausea in cancer patients undergoing chemotherapy	Transferred to TetraBio
INT0036/2013	Schizophrenia or bipolar 1 disorder	On hold due to sourcing issues
INT0048/2020	Animal Health	Preparing second phase of the project
INT0052/2020	Undisclosed	Formulation development ongoing
INT0053/2020	Undisclosed	Formulation development ongoing Awaiting import and export permit

Recent Developments

Strategic Development Agreement

On March 14, 2021, IntelGenx Corp. entered into a strategic development agreement (the "Strategic Development Agreement") with atai. Under the Strategic Development Agreement, atai and us will cooperate to conduct research and development projects in areas relating to the parties' respective technologies. A portion of the funds (20%) that we receive through atai's equity investment under the Securities Purchase Agreement described below will be available to be credited against the costs to us of the research and development projects. So long as atai maintains certain levels of its initial equity ownership in us, atai will have exclusive commercialization rights in the field of compounds for the prevention or treatment of mental health diseases or disorders or compounds that have psychedelic, entactogenic and/or oneirophrenic properties, but excluding certain specific compounds and veterinary applications.

The commercialization of any technologies that result from the research and development 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.

Securities Purchase Agreement

On March 14, 2021, we also entered into a securities purchase agreement, as may be amended (the “Securities Purchase Agreement”) with atai. Under the Securities Purchase Agreement, atai has agreed to purchase (A) an aggregate of 37,300,000 units of the Company (the “Initial Units”) at a price of $0.331 per Initial Unit, each Initial Unit to be issued being comprised of one share of Common Stock of the Company (an “Initial Share”) and 0.60 of a warrant (each whole warrant, an “Initial Warrant”) for an aggregate consideration of $12,346,300, and (B) a warrant (in a form to be agreed by the parties reflecting the terms set out in the Securities Purchase Agreement)(the “Additional Units Warrant”) to acquire up to 130,000,000 additional units of the Company (the “Additional Units”), each Additional Unit to be issued being comprised of one share of Common Stock of the Company (an “Additional Share”) and 0.5 of one warrant (each such whole warrant, an “Additional Warrant” and collectively with the Initial Warrants, the “Warrants”), (the “Investment”) following receipt of approval of our shareholders (the “Shareholders”) at our Annual Meeting of the Shareholders (the “Meeting”). Payment for the Additional Units may be in cash or in certain circumstances in, atai equity. Each Initial Warrant will entitle atai to purchase one share of Common Stock at a price of $0.35 for a period of three years from closing of the initial investment.

The Additional Units Warrant exercise 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 (“Outstanding Convertibles”), provided that atai may not exercise Additional Warrants to purchase more than the lesser of (x) 44,000,000 shares of Common Stock, and (y) the number of shares of Common Stock issued by the us under Outstanding Convertibles.

Under the Securities Purchase Agreement, we also granted atai a pro-rata equity participation right for any issuances of new securities, subject to certain exceptions.

Following the initial closing, atai will hold approximately 25% (approximately 35% on a partially diluted basis) of the issued and outstanding shares of Common Stock and therefore become a new "Control Person" of us as such term is defined under the policies of the TSX Venture Exchange (the "TSX-V"). Based on the number of issued and outstanding shares of Common Stock and outstanding convertible instruments on March 15, 2021, assuming the full exercise of Additional Units Warrant to acquire the Additional Units and exercise of the Warrants and Additional Warrants, atai would hold approximately 60% (approximately 60% on a partially diluted basis) of the issued and outstanding shares of Common Stock.

Under the Securities Purchase Agreement, we have agreed to use reasonable efforts to list the shares of Common Stock on the Toronto Stock Exchange (the “TSX”) with a target to achieve such listing shortly after the initial closing contemplated by the Securities Purchase Agreement and we intend to promptly submit a listing application to the TSX. There is no assurance that the TSX will approve the listing application and any listing of our shares of Common Stock on the TSX is subject to us meeting all of the listing requirements of and obtaining the approval of the TSX. The Additional Units Warrant is only exercisable if our shares of Common Stock are listed on the TSX.

Purchaser Rights Agreement

On March 14, 2021, we also entered into a purchaser rights agreement (the "Purchaser Rights Agreement") with atai. Under the Purchaser Rights Agreement, atai will have the right to appoint nominees in the same proportion to the number of our board members as the shares of Common Stock then held by atai, registration rights, and financial and other information rights.

We will have the right to terminate the Purchaser Rights Agreement if atai ceases to own a certain amount of our equity.

Term Loan

On March 9, 2021 atai funded a secured loan in the amount of $2,000,000 bearing interest at 8% pursuant to a loan agreement entered into between IntelGenx Corp. and atai (the "Loan Agreement"). The loan is repayable on the date that is 120 days following the date of the Meeting, but in any event not later than September 30, 2021. The Securities Purchase Agreement provides that an amendment is to be entered into at the initial closing of the atai investment under which the maturity date will be following the first closing of a subscription for Additional Units if the proceeds from such subscription amount to at least $3,000,000. The loan provides for the possibility of an additional advance to us of up to $500,000, subject to certain conditions. The loan is guaranteed by IntelGenx Technologies Corp. in a guarantee entered into by IntelGenx Technologies Corp. concurrently with the Loan Agreement and is secured by all of the present and future fixed assets of IntelGenx Corp., excluding any intellectual property or technology controlled or owned by IntelGenx Corp.

IntelGenx Corp. has applied approximately CA$800,000 ($628,000) from the loan to fully repay the outstanding amount on the Company's credit facilities with its Bank. We intend to use the balance of the loan for general working capital purposes.

Growth Strategy

Our primary growth strategy is based on three pillars: (1) out licensing commercial rights of our existing pipeline products, (2) partnering on contract development and manufacturing projects leveraging our various technology platforms, and (3) expanding our current pipeline through:

- identifying lifecycle management opportunities for existing market leading pharmaceutical products,
- developing oral film products that provide tangible patient benefits,
- development of new drug delivery technologies,
- entering the veterinary market with VetaFilm™,
- repurposing existing drugs for new indications, and
- developing generic drugs where high technology barriers to entry exist in reproducing branded films.

Contract Development and Manufacturing based on our various technology platforms

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.

Lifecycle Management Opportunities

We are seeking to position our delivery technologies as an opportunity for lifecycle management of products for which patent protection of the active ingredient is nearing expiration. While the patent for the underlying substance cannot be extended, patent protection can be obtained for a new and improved formulation by filing an application with the FDA under Section 505(b)(2) of the United States Federal Food, Drug and Cosmetic Act. Such applications, known as a "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. A 505(b)(2) NDA may include information regarding safety and efficacy of a proposed drug that comes from studies not conducted by or for the applicant. The first formulation for a respective active ingredient filed with the FDA under a 505(b)(2) application may qualify for up to three years of market exclusivity upon approval. Based upon a review of past partnerships between third party drug delivery companies and pharmaceutical companies, management believes that drug delivery companies which possess innovative technologies to develop these special dosage formulations present an attractive opportunity to pharmaceutical companies. Accordingly, we believe "505(b)(2) products" represent a viable business opportunity for us.

Product Opportunities that provide Tangible Patient Benefits

Our focus will be on developing 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™, and our AdVersa ® mucosal adhesive tablet, are two examples 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.

Repurposing Existing Drugs

We are working on the repurposing of already approved drugs for new indications using our VersaFilm™ film technology. This program represents a viable growth strategy for us as it will allow for reduced development costs, improved success rates and shorter approval times. We believe that through our repurposing program we will be able minimize the risk of developmental failure and create value for us and potential partners.

Generic Drugs with High Barriers to Entry

We plan to pursue the development of generic drugs that have certain barriers to entry, e.g., where product development and manufacturing is complex and can limit the number of potential entrants into the generic market. We plan to pursue such projects only if the number of potential competitors is deemed relatively insignificant.

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 Therapeutics Inc. (formerly Monosol Rx), Tesa-Labtec GmbH, 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 industry partner, we plan to continue to invest in our research and development activities and in our manufacturing technology expertise, in order to further strengthen our technology base and to develop the ability to manufacture our VersaFilm™ products ourselves, and our VersaTab™ and AdVersa® products through our manufacturing partners, at competitive costs.

Our Competitive Strengths

We believe that our key competitive strengths include:

- our comprehensive service portfolio;
- our diversified pipeline;
- 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 20 patents and have an additional 30 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 6,660,292	Rapidly disintegrating film for precooked foods	Composition and manufacturing of flavored films for releasing flavors to precooked food substrates	Issued December 9, 2003 Expires June 19, 2021
US 7,132,113	Flavored film	Composition and manufacturing method of multi-layered films	Issued November 7, 2006 Expires April 16, 2022
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
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
ZL 201480043392.8	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

Patent Application No.	**Title**	**Subject**	**Date Filed**
Korean Appl. KR20167005581	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
Korean Appl. KR20180119627	Montelukast transmucosal film	Formulation of oral films containing montelukast	Filed March 1, 2017
Korean Appl. KR20190071692	Devices and methods for treating diseases associated with neuroinflammation	Formulation of oral films containing montelukast	Filed October 17, 2017
Korean Appl. KR20190128637	Therapeutic Methods and Apparatus for Improved Bioavailability of Leukotriene Receptor Antagonists	Formulation of oral films containing montelukast	Filed March 29, 2018
EU Appl. EP 3,528,796	Device and method of treating conditions associated with neuroinflammation	Formulation of oral films containing montelukast	Filed October 17, 2017
EU Appl.	Film dosage form with extended release mucoadhesive particles	Film containing mucoadhesive particle	Filed May 8, 2018
Chinese Appl. CN109843273	The device and method for treating illness relevant to neuroinflammation	Formulation of oral films containing montelukast	Filed October 17, 2017
Chinese Appl. CN110381931	The treatment method and device of the bioavilability 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
South African Appl. 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
Indian Appl. IN201947014213	Device and method of treating conditions associated with neuroinflammation	Formulation of oral films containing montelukast	Filed October 17, 2017
Indian Appl. IN201947035380	Method of treatment and device for the improved bioavailability of leukotriene receptor antagonists	Formulation of oral films containing montelukast	Filed March 29, 2018
Japanese Appl. JP2019508437	Montelukast transmucosal film	Formulation of oral films containing montelukast	Filed March 1, 2017
Canadian Appl. CA2,998,218	Device and method of treating conditions associated with neuroinflammation	Formulation of oral films containing montelukast	Filed October 17, 2017
Canadian Appl. CA3,015,555	Loxapine film oral dosage form	Formulation of oral films containing loxapine	Filed January 25, 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
Canadian Appl. CA 3,061,086	Lipophilic active oral film formulation and method of making the same	Film containing lipophilic actives	Filed Nov 6, 2019
Australian Appl. AU2017344764	Device and method of treating conditions associated with neuroinflammation	Formulation of oral films containing montelukast	Filed October 17, 2017
Australian Appl. AU2018241534	Method of treatment and device for the improved bioavailability of leukotriene receptor antagonists	Formulation of oral films containing montelukast	Filed March 29, 2018
US Appl. 15/940,288	Method of treatment and device for the improved bioavailability of leukotriene receptor antagonists	Formulation of oral films containing montelukast	Filed March 29, 2018
US Appl. 16/110,737	Film dosage form with extended release mucoadhesive particles	Film containing mucoadhesive particle	Filed August 23, 2018
US Appl. 16/053,383	Loxapine film oral dosage form	Formulation of oral films containing loxapine	Filed August 2, 2018
US Appl. 16/131,995	Method of treatment and device for the improved bioavailability of leukotriene receptor antagonists	Formulation of oral films containing montelukast	Filed September 14, 2018
US Appl. 16/391,430	Film Dosage Forms Containing Amorphous Active Agents	Film containing amorphous agent	Filed April 23, 2019
US Appl. 15/067,309	Lipophilic active oral film formulation and method of making the same		Filed April 15, 2019
US Appl. 17/063,644	Oral film formulation for modulating absorption profile		Filed October 5, 2020
PCT Appln. WO2020093146	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 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 505(b)(2) NDA opportunities. By applying our drug delivery technology to existing drugs, we seek to develop products with lower research & development ("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.

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) of the FDCA. 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 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 505(b)(2) applicant.

Orange Book Listing

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents 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 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 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 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 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 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 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 European Union 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.

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

Our auditors have raised substantial doubts as to our ability to continue as a going concern.

Our financial statements have been prepared under the assumption that we will continue as a going concern. The opinion of our independent registered public accountants on our audited financial statements as of and for the year ended December 31, 2020 contains an explanatory paragraph expressing substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent upon our ability to raise capital from financing transactions and to attain profitable operations. Our 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. However, if adequate funds are not available to us when we need it, we will be required to curtail our operations which would, in turn, further raise substantial doubt about our ability 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.

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 research and development 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 $48,551 thousand since our inception in 2003 through December 31, 2020. To date, these losses have been financed principally through sales of equity securities. Our revenues for the past five years ended December 31, 2020, December 31, 2019, December 31, 2018, December 31, 2017 and December 31, 2016 were $1.5 million, $0.7 million, $1.8 million, $5.2 million and $5.2 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 research and development 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.

We are asking our Shareholders to approve an amendment to our Certificate of Incorporation to increase the number of shares of our common stock that we are authorized to issue from 200,000,000 to 450,000,000. If our Shareholders do not approve such amendment, we may not have the necessary flexibility to utilize shares for various corporate purposes that may be identified in the future, including, but not limited to, potential strategic transactions (such as mergers, acquisitions, and other business combinations), future stock dividends, equity or equity-linked offerings and other capital-raising or financing transactions such as the issuance of convertible debenture, grants and awards under the stock plan, and other types of general corporate purpose transactions.

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 research and development 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 research and development 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 research and development capabilities and greater human resources than we do. Some of these drug delivery competitors include Aquestive Therapeutics Inc (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 future 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. 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 recently received our Drug Establishment License from Health Canada indicating cGMP compliance for manufacturing and packaging activities and anticipate the manufacturing of our products to commence in the first half of 2021.

With our current manufacturing equipment, we are only able to manufacture products that do not contain flammable organic solvents. Since several of our film products are solvent-based, we are in the process of acquiring manufacturing equipment that is capable of handling organic solvents, and 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 research and development 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. In December 2019, a novel strain of the coronavirus emerged in China and the virus has now spread to other countries, including Canada and the U.S., and infections have been reported globally. We are actively assessing and responding where possible to the potential impact of the COVID-19 outbreak. 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.

Risks Related to the Investment

The completion of the Investment is subject to a number of conditions and the Securities Purchase Agreement may be terminated in accordance with its terms. As a result, there is no assurance when or if the Investment will be completed.

We anticipate certain benefits from the cooperation with and investment in us by atai. However, the completion of the Investment is subject to the satisfaction or waiver of a number of conditions as set forth in the Securities Purchase Agreement, as may be amended. These include, among others, (a) the approval of the Investment Resolution (as defined in the securities purchase agreement) and the amendment to our Certificate of Incorporation at the Meeting by the Shareholders; (b) (i) with respect to the Initial Closing (as defined in the securities purchase agreement), conditional acceptance by the TSX-V for the listing of the Initial Shares (as defined in the securities purchase agreement) and the Shares of Common Stock issuable upon due exercise of the Initial Warrants (as defined in the securities purchase agreement); and (ii) with respect to any Additional Closing (as defined in the securities purchase agreement), conditional acceptance by the TSX for the listing of the applicable Additional Shares (as defined in the securities purchase agreement) and the shares of Common Stock issuable upon due exercise of the applicable Additional Warrants; (c) the absence of an event causing a material adverse effect on us; (d) the absence of any preliminary or permanent injunction or other order issued by a governmental body, or statute, rule, regulation or executive order promulgated or enacted by a governmental body, which restrains, enjoins, prohibits or otherwise makes illegal the consummation of the transactions contemplated by the Securities Purchase Agreement; (f) the absence of any pending or threatened action or proceeding, at law or in equity, to restrain, enjoin or prohibit the consummation of the transactions contemplated by the Securities Purchase Agreement; (g) the absence of any order having the effect of suspending the issuance or ceasing the trading of any of the shares of Common Stock issued or made by any governmental body, securities regulator or stock exchange; and (h) compliance with the covenants and agreements in the Securities Purchase Agreement in all material respects. There can be no assurance as to when these conditions will be satisfied or waived, if at all, or that other events will not intervene to delay or result in the failure to close the Investment. In addition, atai may elect to terminate the Securities Purchase Agreement in certain circumstances.

If the Securities Purchase Agreement is terminated or the Investment fails to close, we will not recognize the anticipated benefits of the Investment.

The pendency of the Investment could adversely affect our business, results of operations and financial condition.

The pendency of the Investment could cause disruptions in and create uncertainty surrounding our business, including affecting our relationships with existing and future customers, suppliers, partners in our industry and employees. This could have an adverse effect on our business, results of operations and financial condition, as well as the market price of our shares, regardless of whether the Investment closes. Any adverse effect could be exacerbated by a prolonged delay in closing the Investment.

We could also potentially lose customers, suppliers or business partners; existing customers, suppliers or business partners may seek to change their existing business relationships or renegotiate or terminate their contracts with us; and potential customers, suppliers or business partners could defer entering into contracts with us, each as a result of uncertainty relating to the Investment.

While the Securities Purchase Agreement is in effect, we are subject to restrictions on our business activities.

Under the Securities Purchase Agreement, we are subject to certain restrictions on the conduct of our business and generally must operate our business in the ordinary course prior to completing the initial closing of the Investment. These restrictions may constrain our ability to pursue certain business strategies. The restrictions may also prevent us from pursuing otherwise attractive business opportunities, making acquisitions and investments or making other changes to our business prior to the completion of the Investment or the termination of the Securities Purchase Agreement. Any such lost opportunities may reduce our competitiveness or efficiency and could lead to an adverse effect on our business, financial results, financial condition or share price.

Our existing Shareholders will have a reduced ownership and voting interest after the closing of the Investment.

Following each closing 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 will have the right to nominate directors to 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.

Following the completion of the Investment, atai will be 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 will hold approximately 25% of our issued and outstanding shares. If atai were to acquire all of the Additional Shares and exercise all of the Initial Warrants and Additional Warrants, atai would hold approximately 60% 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 research and development 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 research and development 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 20 patents and have an additional 30 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 has also been listed on the TSX-V under the symbol "IGX" since May 2008.

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 (i) for the warrants issued by the Company in 2018 and (ii) in the United States for the warrants issued by the Company in 2020. 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.

On February 11, 2020 we issued warrants in connection with a Canadian public offering. These warrants were listed on the TSX-V and currently trade under the symbol IGX.WT. We do not intend to apply for listing or quotation of those or any other of the Company's warrants on any other securities exchange or automated quotation system.

Risks related to our outstanding convertible debentures and convertible notes.

Issuance of shares of our Common Stock upon conversion of convertible debentures will dilute the ownership interest of our existing stockholders and could adversely affect the market price of our Common Stock.

Conversions of the 8% Convertible Unsecured Subordinated Debentures due June 30, 2022 (the "Debentures") or the 6% Subordinate Convertible Unsecured Promissory Notes (the "Notes") would reduce a shareholder's percentage voting and ownership interest. The conversion, or potential conversion, of the Debentures or Notes could adversely affect the market price of our Common Stock and the terms on which we could obtain additional financing. In addition, our shareholders may experience further dilution upon our election to repay the Debentures or the interest payable thereon in, or convert the Notes to, shares of Common Stock.

There is no public market for the Company's Debentures in the United States, 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 Debentures in the United States. As a result, a market is unlikely to develop for the Company's Debentures in the United States and holders may not be able to sell the Company's Debentures 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. However, the Debentures are listed on the TSX-V and currently trade under the symbol IGX.DB. We do not intend to apply for listing or quotation of those Debentures on any other securities exchange or automated quotation system.

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 Debentures and Notes could require us to redeem such Debentures or Notes at a loss.

The Debentures provide that, upon the occurrence of an "Event of Default," the Debentures may become immediately due and payable. Events of Default under the Debentures include, among other things the occurrence and continuation of any one or more of the following events with respect to the Debentures: (a) failure for 30 days to pay interest on the Debentures when due; (b) failure to pay principal or premium, if any, when due on the Debentures, whether at maturity, upon redemption, by declaration or otherwise; (c) certain events of bankruptcy, insolvency or reorganization of the Company under bankruptcy or insolvency laws; or (d) default in the observance or performance of any material covenant or condition of the trust indenture dated July 12, 2017, between the Company and TSX Trust Company (the "Debenture Trustee"), as trustee, and continuance of such default for a period of 30 days after notice in writing has been given by the Debenture Trustee to the Company specifying such default and requiring the Company to rectify the same. In addition, upon an Event of Default, the Debentures become, upon receipt of a request in writing signed by the holders of not less than 25% in principal amount of the Debentures then outstanding, immediately due and payable.
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 both the Debentures and 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 Debentures elected to have us redeem their Debentures or 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 redeeming the Debentures or 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 a 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$120 thousand (approximately $94 thousand) per year, which will increase at a rate of CA$0.25 ($0. 20) 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$77 thousand (approximately $60 thousand) per year, which will increase at a rate of CA$0.25 ($0. 20) per square foot, every two years. We use the leased space to manufacture the oral film VersaFilm™.

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 November 15, 2021. 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.

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 the 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, is currently quoted on the OTCQB. Our Common Stock has also been listed on the TSX-V under the symbol "IGX" since May 2008.

On March 24, 2021, 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 2020, 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 2020, we did not sell equity securities without registration under the Securities Act of 1933, as amended, 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[2] (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	928,846[1]	$0.53	946,154[3]
Equity Compensation Plans Not Approved by Security Holders	4,304,818[3]	$0.59	4,188,576[4]
Total	5,233,664	$0.58	5,134,730

(1) Includes shares of our Common Stock issuable pursuant to options granted under the 2006 Stock Option Plan and RSUs awarded under our Performance and Restricted Share Unit Plan ("PRSU Plan").
(2) The weighted average exercise price excludes restricted share unit ("RSU") awards, which have no exercise price.
(3) On May 9, 2016, the Board adopted the 2016 Stock Option Plan which amended and restated the 2006 Stock Option Plan, which expired in August 2016. As a result of the adoption of the 2016 Stock Option Plan, no additional options will be granted under the 2006 Stock Option Plan and all previously granted options will be governed by the 2016 Stock Option Plan. Due to the nature of the changes made to the 2006 Stock Option Plan it was determined that no stockholder approvals were required by the TSX-V. The number represents only securities available under the PRSU Plan.
(4) Represents the maximum number of shares of our Common Stock available for grants under the 2016 Stock Option Plan as of December 31, 2020.

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-V 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-V 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.

The PRSU Plan was approved by Shareholders at the 2018 annual meeting on May 7, 2018. The primary purpose of the PRSU Plan is to provide the Company with a share-related mechanism to attract, retain and motivate qualified executive officers of the Company and its subsidiaries and to reward such executive officers for their contributions toward the long term goals and success of the Company and to enable and encourage such executive officers 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 is listed on the TSX-V, or (b) 2.5% of the issued and outstanding Common Stock, if the Company is listed on the TSX. 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.

On a go-forward basis, the Company intends to primarily compensate executive officers with RSUs and compensate non-executive employees with stock options. No RSUs were granted during fiscal years 2019 and 2020.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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 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 to be launched this year. In addition we are offering partners a comprehensive portfolio of pharmaceutical services, including pharmaceutical R&D, clinical monitoring, regulatory support, tech transfer and 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, and once the viability of a product has been demonstrated, license the commercial rights to partners in the pharmaceutical industry. In certain cases, we rely upon partners in the pharmaceutical industry to fund the development of the licensed products, complete the regulatory approval process with the FDA or other regulatory agencies relating to the licensed products, and assume responsibility for marketing and distributing such products.

In addition, we may choose to pursue the development of certain products until the project reaches the marketing and distribution stage. We will assess the potential for successful development of a product and associated costs, and then determine at which stage it is most prudent to seek a partner, balancing such costs against the potential for additional returns earned by collaborating later in the development process.

Our primary growth strategy is based on three pillars: (1) out licensing commercial rights of our existing pipeline products, (2) partnering on contract development and manufacturing projects leveraging our various technology platforms, (3) expanding our current pipeline through:

- identifying lifecycle management opportunities for existing market leading pharmaceutical products,
- developing oral film products that provide tangible patient benefits,
- development of new drug delivery technologies,
- entering the veterinary market with VetaFilm™
- repurposing existing drugs for new indications, and
- developing generic drugs where high technology barriers to entry exist in reproducing branded films.

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.

Lifecycle Management Opportunities

We are seeking to position our delivery technologies as an opportunity for lifecycle management of products for which patent protection of the active ingredient is nearing expiration. While the patent for the underlying substance cannot be extended, patent protection can be obtained for a new and improved formulation by filing an application with the FDA under Section 505(b)(2) of the U.S. Federal Food, Drug and Cosmetic Act. Such applications, known as a "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. A 505(b)(2) NDA may include information regarding safety and efficacy of a proposed drug that comes from studies not conducted by or for the applicant. The first formulation for a respective active ingredient filed with the FDA under a 505(b)(2) application may qualify for up to three years of market exclusivity upon approval. Based upon a review of past partnerships between third party drug delivery companies and pharmaceutical companies, management believes that drug delivery companies which possess innovative technologies to develop these special dosage formulations present an attractive opportunity to pharmaceutical companies. Accordingly, we believe "505(b)(2) products" represent a viable business opportunity for us.

Product Opportunities that provide Tangible Patient Benefits

Our focus will be on developing 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™, and our AdVersa® mucosal adhesive tablet, are two examples 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.

Repurposing Existing Drugs

We are working on the repurposing of already approved drugs for new indications using our VersaFilm™ film technology. This program represents a viable growth strategy for us as it will allow for reduced development costs, improved success rates and shorter approval times. We believe that through our repurposing program we will be able minimize the risk of developmental failure and create value for us and potential partners.

Generic Drugs with High Barriers to Entry

We plan to pursue the development of generic drugs that have certain barriers to entry, e.g., where product development and manufacturing is complex and can limit the number of potential entrants into the generic market. We plan to pursue such projects only if the number of potential competitors is deemed relatively insignificant.

Corporate

On February 11, 2020, we announced the closing of an offering of 16,317,000 units at a price of C$0.50 per unit for gross proceeds of C$8,158,500. Each unit consisted of one share of Common Stock and one warrant entitling the holder to purchase one share of Common Stock at an exercise price of C$0.75 per share. The warrants will expire on the third anniversary of the date of their issuance.

The units were distributed under a short form prospectus dated January 27, 2020 filed by us in connection with the offering and were registered with the United States Securities and Exchange Commission pursuant to a Form S-1 Registration Statement that was declared effective on January 31, 2020. The offering was conducted, on a best efforts basis, by Echelon Wealth Partners Inc. In consideration for the services rendered by the agent, we paid the agent an agency fee equal to 7% of the gross proceeds of the offering and issued the agent a number of warrants equal to 7% of the number of units issued under the offering, each agent warrant entitling the holder to purchase one share of Common Stock at an exercise price of C$0.75 per share until the third anniversary of the date of their issuance. After the payment of the agent's commissions and the reimbursement of certain of the agent's offering expenses and the payment of other offering expenses, we were left with approximately C$7.4 million.

The warrants were listed on the TSXV under the symbol "IGX.WT" and commenced trading at the opening of the market on Thursday, February 13, 2020.

On October 15, 2020, we announced the closing of an offering by way of private placement to certain investors in the United States of $1,205,00 million principal amount of 8% convertible notes due October 15, 2024. The notes bear interest at a rate of 8% per annum, payable quarterly, and are convertible into shares of Common Stock beginning 6 months after their issuance at a price of U.S.$0.18 per Share. In connection with the offering, we 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 shares of Common Stock at a price of $0.18 per share until October 15, 2022. We used the proceeds of the offering for working capital purposes.

On October 23, 2020, we announced the closing of a second tranche of a private placement to certain investors in the United States of $532,000 principal amount of 8% convertible notes due October 15, 2024. The notes bear interest at a rate of 8% per annum, payable quarterly, and are convertible into shares of Common Stock beginning 6 months after their issuance at a price of $0.18 per share. In connection with the second tranche of the offering, we paid to an agent a cash commission of approximately $37,000 in the aggregate and issued non-transferable warrants to the agent, entitling the holder to purchase 212,800 shares of Common Stock at a price of $0.18 per share until October 15, 2022. We used proceeds of the offering for working capital purposes.

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 research and development 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, research and development 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 of Directors 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, 2020 report an accumulated other comprehensive loss due mainly to foreign currency translation adjustments of $856 due to the fluctuations in the rates used to prepare our financial statements, $20 of which negatively impacted our comprehensive loss for the fiscal year ended December 31, 2020. The following Management Discussion and Analysis takes this into consideration whenever material.

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

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 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	**2020**	2019	**2020**	2019
	$	$	$	$
Comprehensive loss	(1,268)	(2,651)	(7,064)	(10,330)
Add (deduct):				
Depreciation	198	195	734	718
Finance costs	321	306	1,202	1,207
Finance income	(17)	(17)	(422)	(97)
Share-based compensation	21	71	193	333
Other comprehensive (income) loss	(9)	(10)	20	(330)
Adjusted EBITDA Loss	**(754)**	(2,106)	**(5,337)**	(8,499)

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

Adjusted EBITDA Loss improved by $1,352 for the three-month period ended December 31, 2020 to ($754) compared to ($2,106) for the three-month period ended December 31, 2019. Adjusted EBITDA Loss improved by $3,162 for the twelve-month period ended December 31, 2020 to ($5,337) compared to ($8,499) for the twelve-month period ended December 31, 2019. The improvement in Adjusted EBITDA of $1,343 for the three-month period ended December 31, 2020 is mainly attributable to an increase in revenues of $722, and decreases in R&D expenses of $542 before consideration of stock-based compensation and SG&A expenses of $88 before consideration of stock-based compensation. The improvement in Adjusted EBITDA of $3,162 for the twelve-month period ended December 31, 2020 is mainly attributable to an increase in revenues of $802, and decreases in R&D expenses of $1,103 before consideration of stock-based compensation and SG&A expenses of $1,257 before consideration of stock-based compensation.

Results of operations for the three month and twelve month periods ended December 31, 2020 compared with the three month and twelve month periods ended December 31, 2019.

Revenue

In U.S.$ thousands	Three-month period ended December 31,		Twelve-month period ended December 31,	
	2020	2019	**2020**	2019
Revenue	$ 790	$ 68	$ 1,544	$ 742
Research and Development Expenses	337	890	2,637	3,774
Selling, General and Administrative Expenses	1,228	1,355	4,437	5,800
Depreciation of tangible assets	198	195	734	718
Operating Loss	**(973)**	(2,372)	**(6,264)**	(9,550)
Net Loss	**(1,277)**	(2,661)	**(7,044)**	(10,660)
Comprehensive Loss	**(1,268)**	(2,651)	**(7,064)**	(10,330)

Revenue

Total revenues for the three-month period ended December 31, 2020 amounted to $790, representing an increase of $722 or 1,062% compared to $68 for the three-month period ended December 31, 2019. Total revenues for the twelve-month period ended December 31, 2020 amounted to $1,544 representing an increase of $802 or 108% compared to $742 for the twelve-month period ended December 31, 2019. The increase for the three-month period ended December 31, 2020 compared to the last year's corresponding period is mainly attributable to an increase in Revenues from Licensing agreements of $671 and R&D revenues of $51. The increase for the twelve-month period ended December 31, 2020 compared to the last year's corresponding period is mainly attributable to an increase in Revenues from Licensing agreements of $982, increase in R&D revenues of $190, offset by a decrease in R&D milestones revenues of $370.

Research and development ("R&D") expenses

R&D expenses for the three-month period ended December 31, 2020 amounted to $337, representing a decrease of $553 or 62%, compared to $890 for the three-month period ended December 31, 2019. R&D expenses for the twelve-month period ended December 31, 2020 amounted to $2,637, representing a decrease of $1,137 or 30%, compared to $3,774 recorded in the same period of 2019.

The decrease in R&D expenses for the three-month period ended December 31, 2020 is mainly attributable to decreases in study costs of $252, analytical costs of $105, consulting fees of $63, R&D scale-up expenses of $63, salary expense of $44, patent expenses of $35 and license fees of $13, offset by an increase in lab supplies of $22. The decrease in R&D expenses for the twelve-month period ended December 31, 2020 is mainly attributable to decreases in study costs of $875, analytical costs of $233, salary expense of $191 (due to the Canada Emergency Wage Subsidy), patent expenses of $101, consulting fees of $92, seminar expenses of $13 and license fees of $11, offset by an increase in R&D scale-up expenses of $254 and a decrease in R&D estimated tax credits of $127.

In the twelve-month period ended December 31, 2020 we recorded estimated Research and Development Tax Credits of $240, compared with $367 that was recorded in the same period of the previous year.

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

SG&A expenses for the three-month period ended December 31, 2020 amounted to $1,228, representing a decrease of $127 or 9%, compared to $1,355 for the three-month period ended December 31, 2019. SG&A expenses for the twelve-month period ended December 31, 2020 amounted to $4,437, representing a decrease of $1,363 or 24%, compared to $5,800 recorded in the same period of 2019.

The decrease in SG&A expenses for the three-month period ended December 31, 2020 is mainly attributable to decreases in business development expenses of $99, the variation of the foreign exchange expense due to the depreciation of the CA dollar vs the US currency of $67, manufacturing expenses of $58, investor relations expenses of $20, travel expenses of $14, rent expense of $9 due to the Canadian government rent relief program related to the COVID-19 pandemic, offset by increases in insurance expense of $62, salaries and compensation expenses of $47 mainly attributable to the revaluation of the DSUs granted to non-employee directors, and professional fees of $41. The decrease in SG&A expenses for the twelve-month period ended December 31, 2020 is mainly attributable to decreases in salaries and compensation expenses of $551 (mainly attributable to the fact that there were no new DSUs granted in 2020 (approximately $200) and due to the Canada Emergency Wage Subsidy), investor related expenses of $326, Laboval deposit write-off of $207 (in 2019), the variation of the foreign exchange expense due to the depreciation of the CA dollar vs the US currency of $189, business development expenses of $120, rent expense of $81 due to the Canadian government rent relief program related to the COVID-19 pandemic, office and general expenses of $70, manufacturing expenses of $57, and travel expenses of $41, offset by an increase in insurance expense of $278.

Depreciation of tangible assets

In the three-month period ended December 31, 2020 we recorded an expense of $198 for the depreciation of tangible assets, compared with an expense of $195 thousand for the same period of the previous year. In the twelve-month period ended December 31, 2020 we recorded an expense of $734 for the depreciation of tangible assets, compared with an expense of $718 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, 2020 amounted to $21 compared to $71 for the three-month period ended December 31, 2019. Share-based compensation warrants and share-based payments expense for the twelve-month period ended December 31, 2020 amounted to $193 compared to $333 for the twelve-month period ended December 31, 2019.

We expensed approximately $156 in the twelve-month period ended December 31, 2020 for options granted to our employees in 2019 and 2020 under the 2016 Stock Option Plans and $37 for options granted to consultants in 2019 and 2020, compared with $285 and $48 respectively that was expensed in the same period of the previous year.

There remains approximately $180 in stock-based compensation to be expensed in fiscal 2021, all of which relates to the issuance of options to our employees during 2019 and 2020. 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, 2020	December 31, 2019	Increase/ (Decrease)	Percentage Increase/ (Decrease)
Current assets	$ 4,305	$ 3,220	$ 1,085	34%
Leasehold improvements and equipment, net	5,851	6,365	(514)	(8%)
Security deposits	252	752	(500)	(66%)
Operating lease right-of-use asset	710	683	27	4%
Current liabilities (excluding convertible debentures and notes)	2,882	2,805	77	3%
Long-term debt	171	470	(299)	(64%)
Convertible debentures	5,461	5,642	(181)	(3%)
Convertible notes	2,991	1,255	1,736	138%
Operating lease liability	482	555	(73)	(13%)
Finance lease liability	84	-	84	100%
Capital Stock	1	1	0	0%
Additional paid-in-capital	48,453	42,635	5,818	14%

Going Concern

We have financed our operations to date 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, research and development revenues and the monetization of future revenues. We have devoted substantially all of our resources to our drug development efforts, conducting clinical trials to further advance the product pipeline, the expansion of our facilities, protecting our intellectual property and general and administrative functions relating to these operations. Our future success is dependent on our ability to develop our product pipeline and ultimately upon our ability to attain profitable operations. As of December 31, 2020, we had cash and short-term investments totaling approximately $2,243. We do not have sufficient existing cash and short-term investments to support operations for the next year following the issuance of these financial statements.

On March 11, 2020, the World Health Organization declared the outbreak of a novel coronavirus ("COVID-19") a global pandemic. We have received the Canada Emergency Wage Subsidy and have benefited from the Canada Emergency Commercial Rent Assistance program from our landlord. There is uncertainty as to the duration and hence the potential impact. As a result, we are unable to estimate the potential impact on our business as of the date of this filing.

These conditions raise substantial doubt about our 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 our control:

- Raise funding through the possible sale of the Common Stock, including public or private equity financings.
- Raise funding through debt financing.
- Continue to seek partners to advance product pipeline.
- Initiate oral film manufacturing activities.
- Initiate contract oral film manufacturing activities.

If we are unable to raise further capital when needed or on attractive terms, or if it is unable to procure partnership arrangements to advance its programs, we would be forced to delay, reduce or eliminate our research and development programs. The current COVID-19 pandemic could continue to have a negative impact on the stock market, including trading prices of our shares and our ability to raise new capital.

The accompanying 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 financial statements do not include any adjustments or classifications that may result from our possible inability to continue as a going concern. Should we be unable to continue as a going concern, we may be unable to realize the carrying value of our assets and to meet our liabilities as they become due.

Current assets

Current assets totaled $4,305 at December 31, 2020 compared with $3,220 at December 31, 2019. The increase of $1,085 is mainly attributable to increases in short term investments of $458, contract asset of $354, investment tax credits receivable of $260, security deposits of $407, offset by decreases in cash of $127, accounts receivable of $121, prepaid expenses of $8, as well as a decrease in inventory of $138.

Cash

Cash totaled $1,205 as at December 31, 2020 representing a decrease of $127 compared with the balance of $1,332 as at December 31, 2019. The decrease in cash on hand relates to net cash used in operating activities of $5,768, net cash used in investing activities of $526 and a negative effect of foreign exchange of $73, partially offset by net cash provided from financing activities of $6,240.

Short term investments

Short term investments totaled $1,038 as at December 31, 2020, representing an increase of $458 compared with the balance of $580 as at December 31, 2019. The increase in short term investments is attributable to acquisition of investments to fund operations.

Accounts receivable

Accounts receivable totaled $260 as at December 31, 2020 representing a decrease of $121 compared with the balance of $381 as at December 31, 2019. The decrease may be explained by the collection of 2019 amounts as well as the fact that most of the revenues invoiced in Q4-2020 had already been collected by year-end or accounted for in contract asset.

Prepaid expenses

As at December 31, 2020, prepaid expenses totaled $162 compared with $170 as of December 31, 2019.

Investment tax credits receivable

R&D investment tax credits receivable totaled approximately $635 as at December 31, 2020 compared with $375 as at December 31, 2019. The increase relates to the accrual estimated and recorded for the twelve-month period ended December 31, 2020 and the fact that the 2019 amounts were not yet received.

Inventory

As at December 31, 2020, inventories totaled $244 compared to a balance of $382 as at December 31, 2019. An amount of $138 was recognized in Research and development expenses.

Leasehold improvements and equipment

As at December 31, 2020, the net book value of leasehold improvements and equipment amounted to $5,851, compared to $6,365 as at December 31, 2019. In the year ended December 31, 2020 additions to assets totaled $120 and mainly comprised of $70 for manufacturing equipment, $32 for leasehold improvements, $13 for laboratory and office equipment, and $5 for computer equipment, offset by depreciation expense of $734 and variation of foreign exchange fluctuation.

Security deposit

A security deposit in the amount of CA$300 ($236) 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, 2020. Security deposits in the amount of CA$16 ($12) for utilities and CA$5 ($4) for Cannabis license were also recorded as at December 31, 2020. Security deposits in the amount of CA$518 ($407) for the term loans were also recorded as at December 31, 2020 but classified as short-term. The difference between the amount as at December 31, 2020 and the amount at December 31, 2019 is related to the US currency fluctuation

Accounts payable and accrued liabilities

Accounts payable and accrued liabilities totaled $1,989 as at December 31, 2020 (December 31, 2019 - $1,941). The increase is mainly attributable to an increase in accrued liabilities as at December 31, 2020.

Long-term debt

Long-term debt totaled $732 as at December 31, 2020 (December 31, 2019 - $1,197). The current portion of long-term debt totaled $561 as at December 31, 2020 (December 31, 2019 - $727). An amount of $732 is attributable to term loan from the lender secured by a first ranking movable hypothec on all our present and future movable property and a 50% guarantee by Export Development Canada, a Canadian Crown corporation export credit agency.

Convertible debentures

Convertible debentures totaled $5,461 as at December 31, 2020 as compared to $5,642 as at December 31, 2019. We issued a total aggregate principal amount of CA$7,600,000 ($5,969,000) of debentures at a price of CA$1,000 ($785) per debenture in July 2017 and August 2017. On June 25, 2020, the debenture holders 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 CA$1.35 ($1.06) to CA$0.50 ($0.39). The convertible debentures have been recorded as a liability as at December 31, 2020

Total transactions costs (including CA$94,000 ($74,000) related to the extension) in the amount of CA$1,331,000 ($1,045,000) were recorded against the liability. The accretion expense for the year ended December 31, 2020 amounts to CA$398,000 ($297,000) (CA$443,000, (334,000) in 2019). The interest on the convertible debentures as at December 31, 2020 amounts to CA$606,000 ($452,000) out of which CA$309 thousand ($218 thousand) was paid in cash on June 25, 2020 and CA$297 thousand ($234 thousand) was paid by issuance of 887,880 shares of Common Stock on December 31, 2020, and is recorded in Financing and interest expense. The interest on the convertible debentures as at December 31, 2019 amounts to CA$606,000 ($457,000) out of which CA$303 thousand ($229 thousand) was paid in cash on June 27, 2019 and CA$303 thousand ($228 thousand) was paid by issuance of 415,179 shares of Common Stock on December 31, 2019, and is recorded in Financing and interest expense. A gain on debt extinguishment based on its present value calculation was recognized in finance and interest income in the amount of $401 for the year ended December 31, 2020, which will be accreted until June 30, 2022.

During the year ended December 31, 2020, CA$141,000 ($111,000) of convertible debentures were converted into 282,000 shares of Common Stock at the option of the holders, resulting in an increase in additional paid-in capital of $103,000. There were no conversions in 2019.

Convertible notes

Convertible notes totaled $2,991 as at December 31, 2020 as compared to $1,255 as at December 31, 2019. On May 8, 2019, the Company issued 320 units at a subscription price of $10,000 per Unit for gross proceeds of $3,200,000. Each Unit was comprised of (i) 7,940 shares of Common Stock, (ii) a $5,000 convertible 6% note, and (iii) 7,690 warrants to purchase Common Stock of the Company. Each Note bears interest at a rate of 6% (payable quarterly, in arrears, with the first payment being due on September 1, 2019), matures on June 1, 2021 and is convertible into Common Stock at a conversion price of $0.80 per share of Common Stock. Each warrant entitles its holder to purchase one share of Common Stock at a price of $0.80 per share of Common Stock until June 1, 2021. The convertible notes were recorded as a liability. Total transactions costs in the amount of $111 thousand were recorded against the liability. The accretion expense for the year ended December 31, 2020 was $231 thousand ($182 thousand in 2019). The interest on the convertible notes as at December 31, 2020 was $96 thousand ($96 thousand in 2019) and was recorded as a financing and interest expense.

On October 15, 2020, we 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 beginning 6 months after their issuance at a price of $0.18 per Share. We intend to use the proceeds of the Offering for working capital purposes. In connection with the Offering, we 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 shares of Common Stock at a price of $0.18 per Share until October 15, 2022. On October 23, 2020, we 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 will bear interest at a rate of 8% per annum, payable quarterly, and will be convertible into shares of Common Stock beginning 6 months after their issuance at a price of $0.18 per Share. In connection with the Offering, we 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 shares of Common Stock 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, 2020 amounts to $11 (2019: $Nil). The warrants have been recorded as equity.

Shareholders' deficit

As at December 31, 2020 we had accumulated a deficit of $48,551 compared with an accumulated deficit of $41,507 as at December 31, 2019. Total assets amounted to $11,118 and shareholders' deficiency totaled $953 as at December 31, 2020, compared with total assets and shareholders' equity of $11,020 and $293 respectively, as at December 31, 2019.

Capital stock

As at December 31, 2020 capital stock amounted to $1.1143 (December 31, 2019: $0.939). 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 $48,453 as at December 31, 2020, as compared to $42,635 at December 31, 2019. Additional paid in capital increased by $5,818 from which $3,912 came from the value of Common Stock issued, $1,207 was the value of the warrants issued, $193 was the stock based compensation attributable to the amortization of stock options granted to employees, $234 was the value of the interest paid by issuance of Common Stock, $169 was the value of agents' warrants issued, and $103 was the value of the conversion of convertible debentures.

Taxation

As at December 31, 2020, the date of our latest annual tax return, we had Canadian and provincial net operating losses of approximately $31,673 (December 31, 2019: $23,101) and $33,905 (December 31, 2019: $25,264) 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 2040. A portion of the net operating losses may expire before they can be utilized.

As at December 31, 2020, we had non-refundable tax credits of $2,802 thousand (2019: $2,486 thousand) of which $8 thousand is expiring in 2026, $10 thousand is expiring in 2027, $177 thousand is expiring in 2028, $155 thousand is expiring in 2029, $132 thousand is expiring in 2030, $141 thousand is expiring in 2031, $176 thousand is expiring in 2032, $117 thousand is expiring in 2033, $89 thousand expiring in 2034, $104 thousand is expiring in 2035, $144 thousand expiring in 2036, $275 thousand is expiring in 2037, $594 thousand expiring in 2038, $359 thousand expiring in 2039, and $298 thousand expiring in 2040 and undeducted research and development expenses of $15,302 thousand (2019: $14,282 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, 2020	December 31, 2019	Increase/ (Decrease)	Percentage Increase/ (Decrease)
Operating Activities	$ (5,768)	$ (8,199)	$ 2,431	30%
Financing Activities	6,240	(690)	6,930	1004%
Investing Activities	(526)	3,205	(3,731)	(116%)
Cash - end of period	1,205	1,332	(127)	(10%)

Statement of cash flows

Net cash used in operating activities was $5,768 for the twelve-month period ended December 31, 2020, compared to net cash used by operating activities of $8,199 for the twelve-month period ended December 31, 2019. For the twelve-month period ended December 31, 2020, net cash used by operating activities consisted of a net loss of ($7,044) (2019: $10,660) before depreciation, stock-based compensation, accretion expense, DSU expense, interest paid by issuance of Common Stock, gain on debt extinguishment and lease non-cash expense in the amount of $1,152 (2019: $1,906) and an increase in non-cash operating elements of working capital of $124 compared with an increase of $555 for the twelve-month period ended December 31, 2019.

The net cash provided by financing activities was $6,240 for the twelve-month period ended December 31, 2020, compared to net cash used in financing activities of $690 for the twelve-month period ended December 31, 2019 For twelve-month period ended December 31, 2020, an amount of $5,564 derives from proceeds from the public offering and an amount of $1,601 derives from the proceeds from convertible notes, offset by repayment of term loans for an amount of $474, the transaction costs related to the public offering of $320, transaction costs related to debt extinguishment of $69, and the transaction costs related to the convertible notes of $62. The financing activities for the year ended December 31, 2019 are for the repayment of term loans in the amount of $711 offset by proceeds from exercise of stock options in the amount of $21.

Net cash used in investing activities amounted to $526 for the twelve-month period ended December 31, 2020 compared to net cash provided by investing activities of $3,205 for the twelve-month period ended December 31, 2019. The net cash used in investing activities for the year ended December 31, 2020 relates to the acquisition of short-term investments of $4,532 (2019: $1,535) and the purchase of fixed assets for $120 (2019: $525), offset by redemption of short-term investments of $4,126 (2019: $5,265).

The balance of cash as at December 31, 2020 amounted to $1,205, compared to $1,332 at December 31, 2019.

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$120 thousand (approximately $94 thousand) per year, which will increase at a rate of CA$0.25 ($0.20) 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$77 thousand (approximately $60 thousand) per year, which will increase at a rate of CA$0.25 ($0.20) per square foot every two years.

The aggregate minimum rentals, exclusive of other occupancy charges, for property leases expiring in 2026, are approximately $831 thousand, as follows:

2021	155
2022	159
2023	161
2024	164
2025	164
Thereafter	28

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 $125 thousand, as follows:

2021	32
2022	32
2023	32
2024	29

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, 2020 an amount of Euro1,425 thousand has been paid with respect to these agreements.

Subsequent events

On January 11, 2021, 150,000 options to purchase shares of Common Stock were granted to an officer under the 2016 Stock Option Plan. The options have an exercise price of $0.27. The options granted vest over a period of 2 years at a rate of 25% every six months and expire 10 years after the grant date.

Subsequent to the end of the year, CA$301,000 ($236,000) of convertible debentures were converted into 602,000 shares of Common Stock at the option of the holders.

On March 15, 2021, we announced a strategic partnership with atai and a proposed TSX graduation. The announcement stated that we had agreed to the terms of a strategic partnership with atai, a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders, including an equity investment by atai, pursuant to which atai will initially acquire an approximate 25% interest in the Company. We also announced that atai had granted to IntelGenx a secured loan in the amount of $2,000,000. As part of the strategic partnership, we will partner with atai to develop compounds for the prevention or treatment of mental health diseases or disorders, including compounds that have psychedelic, entactogenic and/or oneirophrenic properties and atai will have exclusive commercialization rights to those jointly developed products. The partnership and investment are subject to the approval of the TSX Venture Exchange and approval of our shareholders and will be subject to certain customary closing conditions. Shareholders will be asked to consider and vote on the proposed transaction with atai at the Meeting.

Strategic Development Agreement

Under a strategic development agreement, atai and IntelGenx will cooperate to conduct research and development projects in areas relating to the parties' respective technologies. A portion of the funds (20%) that we will receive through atai's equity investment under the securities purchase agreement described below will be available to be credited against the costs of the Company the research and development projects. So long as atai maintains certain levels of its initial equity ownership in us, atai will have exclusive commercialization rights in the field of compounds for the prevention or treatment of mental health diseases or disorders or compounds that have psychedelic, entactogenic and/or oneirophrenic properties, but excluding certain specific compounds and veterinary applications. The commercialization of any technologies that result from the research and development 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.

Securities Purchase Agreement

Under the Securities Purchase Agreement, atai has agreed to purchase (A) an aggregate of 37,300,000 units of the Company at a price of $0.331 per Initial Unit, each Initial Unit to be issued being comprised of one share of common stock of the Company and 0.60 of a warrant for an aggregate consideration of $12,346,300, and (B) a warrant (in a form to be agreed by the parties reflecting the terms set out in the Securities Purchase Agreement) to acquire up to 130,000,000 additional units of the Company, each Additional Unit to be issued being comprised of one share of common stock of the Company and 0.5 of one warrant following receipt of approval of our Shareholders at our Annual Meeting of the Shareholders. Payment for the Additional Units may be in cash or in certain circumstances in, atai equity. Each Initial Warrant will entitle atai to purchase one share of common stock at a price of $0.35 for a period of three years from closing of the initial investment.

The Additional Units Warrant exercise 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 (x) 44,000,000 shares of Common Stock, and (y) the number of shares of Common Stock issued by the us under Outstanding Convertibles. Under the securities purchase agreement, we also granted atai a pro-rata equity participation right for any issuances of new securities, subject to certain exceptions. Following the initial closing, atai will hold approximately 25% (approximately 35% on a partially diluted basis) of the issued and outstanding shares and therefore become a new “Control Person” of IntelGenx as such term is defined under the policies of the TSX Venture Exchange. Based on the number of issued and outstanding shares and outstanding convertible instruments on the date hereof, assuming the full exercise of the Additional Units Warrant to acquire the additional units and exercise of the initial warrants and additional warrants, atai would hold approximately 60% (approximately 60% on a partially diluted basis) of the issued and outstanding Shares.

Proposed Graduation to the Toronto Stock Exchange

Under the Securities Purchase Agreement, we have agreed to use reasonable efforts to list our shares on the TSX with a target to achieve such listing shortly after the initial closing contemplated by the securities purchase agreement and we intend to promptly submit a listing application to the TSX. There is no assurance that the TSX will approve the listing application and any listing of the shares of Common Stock on the TSX is subject to us meeting all of the listing requirements of and obtaining the approval of the TSX. The Additional Units Warrant is only exercisable if our shares of Common Stock are listed on the TSX.

Purchaser Rights Agreement

Under the purchaser rights agreement, atai will have the right to appoint nominees in the same proportion to the number of board members of IntelGenx as the shares then held by atai, registration rights, and financial and other information rights. We will have the right to terminate the purchaser rights agreement if atai ceases to own a certain amount of our equity.

Term Loan

atai has granted to IntelGenx a secured loan in the amount of $2,000,000 bearing interest at 8%. The loan is repayable on the date that is 120 days following the date of the Meeting, but in any event not later than September 30, 2021. The securities purchase agreement provides that an amendment is to be entered into at the initial closing of the atai investment under which the maturity date will be following the first closing of a subscription for additional units if the proceeds from such subscription amount to at least $3,000,000. The loan provides for the possibility of an additional advance to us of up to $500,000, subject to certain conditions. The loan is guaranteed by IntelGenx Technologies Corp. and secured by all of present and future fixed assets of IntelGenx Corp., excluding any intellectual property or technology controlled or owned by IntelGenx Corp.. IntelGenx Corp. has applied approximately CA$800,000 ($628,000) from the loan to fully repay the outstanding amount on our credit facilities with our Bank. We intend to use the balance of the loan for general working capital purposes.

Off-balance sheet arrangements

We have no off-balance sheet arrangements.

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 Securities Exchange Act of 1934, as amended (the "Exchange Act") were effective as of December 31, 2020 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, 2020 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, 2020. 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, 2020 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.

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 2021 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 2021 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 2021Proxy 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 2021 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 2021 Proxy Statement.

PART IV

ITEM 15. EXHIBITS, 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.
B. Consolidated Balance Sheets as of December 31, 2020 and 2019.
C. Consolidated Statements of Shareholders' Equity for the years ended of December 31, 2020 and 2019.
D. Consolidated Statements of Comprehensive Loss for the years ended of December 31, 2020 and 2019.
E. Consolidated Statements of Cash Flows for the years ended December 31, 2020 and 2019.
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	By-Laws (incorporated by reference to the Form SB-2 (File No. 333-91049) filed on November 16, 1999
3.6	Amended and Restated By-Laws (incorporated by reference to the Form 8-K filed on March 31, 2011)
3.7	Amended and Restated By-Laws (incorporated by reference to the Form 8-K filed on March 21, 2012)
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 8K 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)
10.7	Second Amended 2016 Stock Option Plan, July 16, 2020 (incorporated by reference to the Form 8K on July 17, 2020
10.8+	Employment Agreement Andre Godin, July 2015 (incorporated by reference to the Form 8-K filed on July 20, 2015)
10.9+	Employment Agreement Nadine Paiement, January 2016 (incorporated by reference to the Form 10-K filed on March 30, 2016)
10.10+	Employment Agreement Dana Matzen, March 2016 (incorporated by reference to the Form 10-K filed on March 30, 2016)
10.11+	2016 Stock Option Plan May, 11 2016 (incorporated by reference to the Form S-8 Registration Statement filed on August 3, 2016)
10.12	Amended Principal's Registration Rights Agreement, November 8, 2016 (incorporated by reference to Form 10-Q filed on November 10, 2016)
10.13	Agency Agreement dated June 28, 2017 (incorporated by reference to the Form 8-K filed on July 5, 2017)
10.14+	Deferred Share Unit Plan for non-employee directors (incorporated by reference to the Form 10-K filed on March 29, 2018)
10.15	Placement Agent Agreement dated May 8, 2018 (incorporated by reference to the Form 8-K filed on May 10, 2018)
10.16	Form of Warrant dated May 8, 2018 (incorporated by reference to the Form 8-K filed on May 10, 2018)
10.17	Form of Securities Purchase Agreement dated May 8, 2018 (incorporated by reference to the Form 8-K filed on May 10, 2018)
10.18	Form of Registration Rights Agreement dated May 8, 2018 (incorporated by reference to the Form 8-K filed on May 10, 2018)
10.19	Form of Note dated May 8, 2018 (incorporated by reference to the Form 8-K filed on May 10, 2018)
10.20	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)
10.21	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)
10.22	Form of Warrant (incorporated by reference to the Form 8-K on October 22, 2018)
10.23	Form of Securities Purchase Agreement (incorporated by reference to the Form 8-K filed on October 22, 2018)
10.24	Form of Agent Warrant (incorporated by reference to the Form S-1/A on filed on January 30, 2020)
10.25	Agency Agreement dated January 27, 2020 (incorporated by reference to the Form 8-K filed on January 29, 2020)
10.26*	Loan Agreement dated March 9, 2021
10.27*[#]	Strategic Development Agreement dated March 14, 2021
10.28*±	Securities Purchase Agreement dated March 14, 2021
10.29*	Purchaser Rights Agreement dated March 14, 2021

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*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* 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.]

ITEM 16. FORM 10K 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 25, 2021, 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 25, 2021
By*: /s/Andre Godin* Andre Godin	President and Chief Financial Officer	March 25, 2021
By: /s/ *Bernard Boudreau* J. Bernard Boudreau	Director, Vice Chairman of the Board	March 25, 2021
By: /s/*Bernd Melchers* Bernd J. Melchers	Director	March 25, 2021
By: /s/*John Marinucci* John Marinucci	Director	March 25, 2021
By: /s/*Clemens Mayr* Clemens Mayr	Director	March 25, 2021
By: /s/*Mark Nawacki* Mark Nawacki	Director	March 25, 2021

IntelGenx Technologies Corp.

Consolidated Financial Statements
December 31, 2020 and 2019
(Expressed in U.S. Funds)

IntelGenx Technologies Corp.

Consolidated Financial Statements
December 31, 2020 and 2019
(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, 2020 and 2019, the related consolidated statements of comprehensive loss, shareholders' deficit and cash flows for each of the two years in the period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, 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, 2020, the Company's leasehold improvements and equipment amounted to $5,851 thousands. 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, including the impact of COVID-19,
- 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 (Signed)

Montréal, Quebec
March 25, 2021

IntelGenx Technologies Corp.

Consolidated Balance Sheets
As at December 31, 2020 and 2019
(Expressed in Thousands of U.S. Dollars ($'000) Except Share and Per Share Data)

		2020		2019
Assets				
Current				
Cash	**$**	**1,205**	$	1,332
Short-term investments (note 5)		**1,038**		580
Accounts receivable		**260**		381
Prepaid expenses		**162**		170
Investment tax credits receivable		**635**		375
Contract asset		**354**		-
Security deposits		**407**		-
Inventory (note 6)		**244**		382
Total current assets		**4,305**		3,220
Leasehold improvements and equipment, net (note 7)		**5,851**		6,365
Security deposits		**252**		752
Operating lease right-of-use-asset (note 18)		**710**		683
Total assets	**$**	**11,118**	$	11,020
Liabilities				
Current				
Accounts payable and accrued liabilities		**1,989**		1,941
Current portion of long-term debt (note 9)		**561**		727
Current portion of operating lease liability (note 18)		**141**		137
Current portion of finance lease liability (note 18)		**25**		-
Deferred revenue		**166**		-
Convertible debentures (note 10)		**-**		5,642
Convertible notes (note 11)		**1,486**		-
Total current liabilities		**4,368**		8,447
Long-term debt (note 9)		**171**		470
Convertible notes (note 11)		**1,505**		1,255
Convertible debentures (note 10)		**5,461**		-
Operating lease liability (note 18)		**482**		555
Finance lease liability (note 18)		**84**		-
Total liabilities		**12,071**		10,727
Commitments (note 12)				
Subsequent event (note 21)				
Shareholders' deficit				
Capital stock, common shares, $0.00001 par value; 200,000,000 shares authorized; 111,429,532 shares issued and outstanding (2019: 93,942,652 common shares) (note 13)		**1**		1
Additional paid-in capital (note 14)		**48,453**		42,635
Accumulated deficit		**(48,551)**		(41,507)
Accumulated other comprehensive loss		**(856)**		(836)
Total shareholders' deficit		**(953)**		293
	$	**11,118**	$	11,020

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, 2019
(Expressed in Thousands of U.S. Dollars ($'000) Except Share and Per Share Data)

	Capital Stock		Additional Paid-In		Accumulated Other	
	Number	Amount	Capital	Accumulated Deficit	Comprehensive Loss	**Total Shareholders' Equity**
Balance - December 31, 2018	93,477,473	$ 1	$ 42,048	$ (30,896)	$ (1,166)	**$ 9,987**
Modified retrospective adjustment upon adoption of ASC 842	-	-	-	49	-	**49**
Other comprehensive income	-	-	-	-	330	**330**
Interest paid by issuance of common shares (note 10)	415,179	-	233	-	-	**233**
Options exercised (note 13)	50,000	-	21	-	-	**21**
Stock-based compensation (note 13)	-	-	333	-	-	**333**
Net loss for the year	-	-	-	(10,660)	-	**(10,660)**
Balance - December 31, 2019	**93,942,652**	**$ 1**	**$ 42,635**	**$ (41,507)**	**$ (836)**	**$ 293**

See accompanying notes

IntelGenx Technologies Corp.

Consolidated Statement of Shareholders' Deficit
For the Year Ended December 31, 2020
(Expressed in Thousands of U.S. Dollars ($'000) Except Share and Per Share Data)

	Capital Stock		Additional Paid-In		Accumulated Other	
	Number	Amount	Capital	Accumulated Deficit	Comprehensive Loss	**Total Shareholders' Deficit**
Balance - December 31, 2019	93,942,652	$ 1	$ 42,635	$ (41,507)	$ (836)	**$ 293**
Other comprehensive loss	-	-	-	-	(20)	**(20)**
Common stock issued, net of transaction costs of $778 (note 13)	16,317,000	-	3,912	-	-	**3,912**
Warrants issued, net of transaction costs of $240 (note 13)	-	-	1,207	-	-	**1,207**
Agents' warrants issued (notes 11 and 13)	-	-	169	-	-	**169**
Conversion of convertible debentures (note 10)	282,000	-	103	-	-	**103**
Interest paid by issuance of common shares (note 10)	887,880	-	234	-	-	**234**
Stock-based compensation (note 13)	-	-	193	-	-	**193**
Net loss for the year	-	-	-	(7,044)	-	**(7,044)**
Balance - December 31, 2020	**111,429,532**	**$ 1**	**$ 48,453**	**$ (48,551)**	**$ (856)**	**$ (953)**

See accompanying notes

IntelGenx Technologies Corp.

Consolidated Statements of Comprehensive Loss
For the Years Ended December 31, 2020 and 2019
(Expressed in Thousands of U.S. Dollars ($'000) Except Share and Per Share Data)

		2020		2019
Revenues (note 16)	**$**	**1,544**	$	742
Total revenues		**1,544**		742
Expenses				
Research and development expense		**2,637**		3,774
Selling, general and administrative expense		**4,437**		5,800
Depreciation of tangible assets		**734**		718
Total expenses		**7,808**		10,292
Operating loss		**(6,264)**		(9,550)
Interest income		**422**		97
Financing and interest expense		**(1,202)**		(1,207)
Net financing and interest expense		**(780)**		(1,110)
Loss before income taxes		**(7,044)**		(10,660)
Income taxes (note 15)		**-**		-
Net loss		**(7,044)**		(10,660)
Other comprehensive (loss) income				
Change in fair value		102		46
Foreign currency translation adjustment		(122)		284
		(20)		330
Comprehensive loss	**$**	**(7,064)**	$	(10,330)
Basic and diluted:				
Weighted average number of shares outstanding		**108,440,888**		93,525,413
Basic and diluted loss per common share (note 20)	**$**	**(0.07)**	$	(0.11)

See accompanying notes

IntelGenx Technologies Corp.

Consolidated Statements of Cash Flows
For the Year Ended December 31, 2020 and 2019
(Expressed in Thousands of U.S. Dollars ($'000) Except Share and Per Share Data)

		2020		2019
Funds (used) provided -				
Operating activities				
Net loss	**$**	**(7,044)**	$	(10,660)
Depreciation of tangible assets		**734**		718
Stock-based compensation		**193**		333
Accretion expense		**539**		514
DSU expense		**(142)**		105
Interest paid by issuance of common shares		**234**		228
Gain on debt extinguishment (note 10)		**(401)**		-
Lease non-cash expense		(5)		8
		(5,892)		(8,754)
Changes in non-cash items related to operations:				
Accounts receivable		**121**		426
Prepaid expenses		**8**		292
Investment tax credits receivable		**(260)**		41
Contract asset		**(354)**		-
Inventory		**138**		-
Security deposits		**113**		-
Accounts payable and accrued liabilities		**192**		(204)
Deferred revenues		**166**		-
Net change in non-cash items related to operations		**124**		555
Net cash used in operating activities		**(5,768)**		(8,199)
Financing activities				
Repayment of long-term debt		**(474)**		(711)
Proceeds from exercise of warrants and stock options		**-**		21
Net proceeds from public offering		**5,564**		-
Transaction costs of public offering		**(320)**		-
Net proceeds from convertible notes		**1,601**		-
Transaction costs of convertible notes		**(62)**		-
Transaction costs of debt extinguishment		**(69)**		
Net cash provided by (used in) financing activities		**6,240**		(690)
Investing activities				
Additions to leasehold improvements and equipment		**(120)**		(525)
Acquisitions of short-term investments		**(4,532)**		(1,535)
Redemptions of short-term investments		**4,126**		5,265
Net cash (used in) provided by investing activities		**(526)**		3,205
Decrease in cash		**(54)**		(5,684)
Effect of foreign exchange on cash		**(73)**		201
Cash				
Beginning of year		**1,332**		6,815
End of year	**$**	**1,205**	$	1,332

See accompanying notes

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, bank loans, royalty, up-front and milestone payments, license fees, proceeds from exercise of warrants and options, research and development revenues and the sale of U.S. royalty on future sales of Forfivo XL®. 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, 2020, the Company had cash and short-term investments totaling approximately $2,243. 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.

On March 11, 2020, the World Health Organization declared the outbreak of a novel coronavirus ("COVID-19") as a global pandemic. The Company is aware of the impact on its business as a result of COVID-19 but uncertain as to the extent of this impact on its consolidated financial statements. The Company has received the Canada Emergency Wage Subsidy and has benefited from the Canada Emergency Commercial Rent Assistance program from its landlord. There is uncertainty as to the duration and hence the potential impact. As a result, we are unable to estimate the potential impact on our business as of the date of this filing.

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 common stock, including public or private equity financings.
- Raise funding through debt financing.
- Continue to seek partners to advance product pipeline.
- Initiate oral film manufacturing activities.
- Initiate contract oral film manufacturing activities.

2. Going Concern (Cont'd)

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 discontinue some of its operations. The current COVID-19 pandemic could continue to have a negative impact on the stock market, including trading prices of the Company's shares and its ability to raise new capital.

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 development and manufacturing of novel oral thin film products for the pharmaceutical market. More recently, the Company has made the strategic decision to enter the Canadian cannabis market with a non-prescription cannabis infused oral film and in 2020 we made the decision to enter the psychedelic market. In addition, IntelGenx is offering partners a comprehensive portfolio of pharmaceutical services, including pharmaceutical research and development, clinical monitoring, regulatory support, technology transfer and 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) AdVersa®, a mucoadhesive tablet technology and (3) the VetaFilm™ technology platform for veterinary applications.

The Company's opportunity assessment and product development strategies primarily focus on addressing unmet market needs and utilize the U.S. Food and Drug Administration's ("FDA") 505(b)(2) approval process to obtain more timely and efficient approval of new formulations of previously approved products. The Company's primary growth strategy is based on three pillars: (1) out licensing commercial rights of existing pipeline products, (2) partnering in contract development and manufacturing projects leveraging its various technology platforms, and (3) expanding its current pipeline.

The Company's product pipeline currently consists of 11 products in various stages of development from inception through commercialization, including products for the treatment of Alzheimer's disease, opioid dependence, erectile dysfunction, migraine, schizophrenia and pain management. Of the products currently under development, 10 utilize the *VersaFilm™* technology and one utilizes the *VetaFilm™* technology.

4. Summary of Significant Accounting Policies

Adoption of New Accounting Policies

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-13, Financial Instruments - Credit Losses (Topic 326). The ASU introduces a new credit loss methodology, Current Expected Credit Losses ("CECL"), which requires earlier recognition of credit losses, while also providing additional transparency about credit risk. Since its original issuance in 2016, the FASB has issued several updates to the original ASU.

The CECL methodology utilizes a lifetime "expected credit loss" measurement objective for the recognition of credit losses for loans, held to maturity securities and other receivables at the time the financial asset is originated or acquired. The expected credit losses are adjusted each period for changes in expected lifetime credit losses. The methodology replaces the multiple existing impairment methods in Accounting principles generally accepted in the United States ("U.S. GAAP"), which generally require that a loss be incurred before it is recognized.

For financial assets measured at amortized cost (e.g., cash and receivables from clients), the Company has concluded that there are de minimus expected credit losses based on the nature and contractual life or expected life of the financial assets and immaterial historic and expected losses.

On January 1, 2020, the Company adopted Topic 326 using the modified retrospective approach for all in scope assets, which did not result in an adjustment to the opening balance in retained earnings.

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.

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

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.

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.

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

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.

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, 2020 totaled $Nil (2019: $416).

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.

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

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.

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 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.

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

In April 2020, the FASB issued a Staff Question-and-Answer ("Q&A") to clarify whether lease concessions related to the effects of COVID-19 require the application of the lease modification guidance under the new lease standard, which the Company adopted on January 1, 2019. Under the new leasing standard, an entity would have to determine, on a lease by lease basis, if a lease concession was the result of a new arrangement reached with the tenant, which would be accounted for under the lease modification framework, or if the lease concession was under the enforceable rights and obligations that existed in the original lease, which would be accounted for outside the lease modification framework. The Q&A provides entities with the option to elect to account for lease concessions as though the enforceable rights and obligations existed in the original lease as long as the total cash flows from the modified lease are substantially similar to the cash flows in the original lease. The Company has elected to use this option and, to the extent that a rent concession is granted as a deferral of payments but total payments are substantially the same, the Company will account for the concession as if no change has been made to the original 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.

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.

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.

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.

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.

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

Recent Accounting Pronouncements

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.

These amendments are effective for fiscal years beginning after December 15, 2021. The Company is currently evaluating the impact of this Statement on its consolidated financial statements.

ASU 2019-12 Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes

The FASB issued ASU 2019-12 which removes specific exceptions to the general principles in Topic 740 in Generally Accepted Accounting Principles (GAAP). It eliminates the need for an organization to analyze whether the following apply in a given period:

-Exception to the incremental approach for intraperiod tax allocation;

-Exceptions to accounting for basis differences when there are ownership changes in foreign investments; and

-Exception in interim period income tax accounting for year-to-date losses that exceed anticipated losses.

The ASU also improves financial statement preparers' application of income tax-related guidance and simplifies GAAP for:

-Franchise taxes that are partially based on income;

-Transactions with a government that result in a step up in the tax basis of goodwill;

-Separate financial statements of legal entities that are not subject to tax; and

-Enacted changes in tax laws in interim periods.

These amendments are effective for fiscal years beginning after December 15, 2020. The Company is currently evaluating the impact of this Statement on its consolidated financial statements.

5. Short-term investments

As at December 31, 2020, short-term investments consisted of investments in mutual funds of $1 million (CAD$1.3 million) (2019 - $580 thousand (CAD$754 thousand)) and are with a Canadian financial institution having a high credit rating.

(Expressed in U.S. Funds)

6. Inventory

Inventory as at December 31, 2020 consisted of raw materials in the amount of $244 thousand (2019 - $382 thousand). An amount of $138 was recognized in Research and development expenses.

7. Leasehold Improvements and Equipment

	Cost	Accumulated Depreciation	**2020 Net Carrying Amount**	2019 Net Carrying Amount
Manufacturing equipment	$ 4,819	$ 1,195	**$ 3,624**	$ 3,778
Laboratory and office equipment	1,409	993	**416**	498
Computer equipment	133	100	**33**	40
Leasehold improvements	3,424	1,646	**1,778**	2,049
	$ 9,785	$ 3,934	**$ 5,851**	$ 6,365

From the balance of manufacturing equipment, an amount of $1,824 thousand (2019 - $1,788 thousand) represents assets which are still under construction as at December 31, 2020 and are consequently not depreciated. The commitment of the Company for the remainder of the project is as disclosed in note 12.

8. Bank Indebtedness

The Company's credit facility is subject to review annually and consists of an operating demand line of credit of up to CAD$250 thousand ($196 thousand) and corporate credits cards of up to CAD$75 thousand ($59 thousand), and foreign exchange contracts limited to CAD$425 thousand ($334 thousand). Borrowings under the operating demand line of credit bear interest at the Bank's prime lending rate plus 2%. The credit facility and term loan (see note 9) are secured by a first ranking movable hypothec on all present and future movable property of the Company for an amount of CAD$4,250,000 ($3,338,000) plus 20%, and a 50% guarantee by Export Development Canada, a Canadian Crown corporation export credit agency. The terms of the banking agreement require the Company to comply with certain debt service coverage and debt to net worth financial covenants on an annual basis at the end of the Company's fiscal year. As at December 31, 2020, the Company was not in compliance with its financial covenants and has not drawn on its credit facility. The Company has obtained a waiver from the lender.

(Expressed in U.S. Funds)

9. Long-Term Debt

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

	December 31, 2020 $	December 31, 2019 $
Term loan facility	732	1,005
Secured loan	-	192
Total debt	732	1,197
Less: current portion	561	727
Total long-term debt	171	470

The Company's term loan facility consists of a total of CAD$4 million ($3.14 million) bearing interest at the Bank's prime lending rate plus 2.50%, with monthly principal repayments of CAD$62 thousand ($49 thousand). In April 2020, as a result of the global pandemic, the lender granted the Company an automatic six-month moratorium of capital repayments. The term loan is subject to the same security and financial covenants as the bank indebtedness (see note 8).

Principal repayments due in each of the next two years are as follows:

2020	561 (CAD 714)
2021	171 (CAD 218)

The secured loan was repaid in full during the year.

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 ($5,371,000). Pursuant to the Offering, the Corporation issued an aggregate principal amount of CAD$6,838,000 ($5,371,000) of Debentures at a price of CAD$1,000 ($785) 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 will be 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 will be CAD$1.35 ($1.06) (the "Conversion Price") per common share of the Corporation ("Share"), being a conversion rate of approximately 740 Shares per CAD$1,000 ($785) 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 ($598,000).

(Expressed in U.S. Funds)

10. Convertible Debentures (Cont'd)

Together with the principal amount of CAD$6,838,000 ($5,371,000) of Debentures issued on July 12, 2017, the Company issued a total aggregate principal amount of CAD$7,600,000 ($5,969,000) of Debentures at a price of CAD$1,000 ($785) 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 ($1.06) to CAD$0.50 ($0.39). This extension was accounted for as an extinguishment and the debenture were re-measured at fair value on June 30, 2020. This re-measurement resulted in a gain on extinguishment in the amount of CAD$547,000 ($401,000) recognized in finance and interest income.

The components of the convertible debentures subsequent to the extension are as follows:

		December 31, 2020
Face value of the convertible debentures	$	5,848
Gain on extinguishment		(430)
Transaction costs		(74)
Accretion		117
Convertible debentures	$	5,461

The convertible debentures have been recorded as a liability. The accretion expense for the year ended December 31, 2020 amounts to CAD$398,000 ($297,000), compared to CAD$443,000 ($334,000) for the comparative period in 2019.

During the year ended December 31, 2020, CAD$141,000 ($111,000) of convertible debentures were converted into 282,000 common shares at the option of the holders, resulting in an increase in additional paid-in capital of $103 thousand.

Interest accrued during the year ended December 31, 2020 on the convertible debentures amounts to CAD$606 thousand ($452 thousand) out of which CAD$309 thousand ($218 thousand) was paid in cash on June 25, 2020 and CAD$297 thousand ($234 thousand) was paid by issuance of 887,880 common shares on December 31, 2020. Interest accrued during the year ended December 31, 2019 on the convertible debentures amounts to CAD$606 thousand ($457 thousand) out of which CAD$303 thousand ($229 thousand) was paid in cash on June 27, 2019 and CAD$303 thousand ($228 thousand) was paid by issuance of 415,179 common shares on December 31, 2019.

11. Convertible Notes

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.

(Expressed in U.S. Funds)

11. Convertible Notes (Cont'd)

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), matures 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.

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**

The convertible notes have been recorded as a liability. Total transactions costs in the amount of $111 thousand were recorded against the liability. The accretion expense for the year ended December 31, 2020 amounts to $231,000 (2019: $182,000). The warrants have been recorded as equity.

The components of the convertible notes are as follows:

	December 31, 2020	December 31, 2019
Attributed value of net proceeds to convertible notes	**$ 975**	$ 975
Accretion	**511**	280
Convertible note	**$ 1,486**	$ 1,255

The interest on the convertible notes for the year ended December 31, 2020 amounts to $96,000 (2019: $96,000) and is recorded in financing and interest expense.

The proceeds of the Units are attributed to liability and equity components based on the fair value of each component. Management has determined the value attributed to the common stock is $1,460 and $437 for the warrants issued, resulting in an increase in additional paid-in-capital of $1,897.

(Expressed in U.S. Funds)

11. Convertible Notes (Cont'd)

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.

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 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. 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, 2020 amounts to $11. The warrants have been recorded as equity.

The components of the convertible notes are as follows:

		December 31, 2020
Attributed value of net proceeds to convertible notes	**$**	**1,494**
Accretion		**11**
Convertible note	**$**	**1,505**

The interest on the convertible notes for the year ended December 31, 2020 amounts to $29,000 (2019: $Nil) and is recorded in financing and interest expense.

(Expressed in U.S. Funds)

12. 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 with three suppliers with respect to equipment for solvent film manufacturing. As at December 31, 2020 an amount of Euro 1,425 thousand has been paid with respect to these agreements (note 8).

13. Capital Stock

	2020	2019
Authorized -		
200,000,000 common shares of $0.00001 par value		
20,000,000 preferred shares of $0.00001 par value		
Issued -		
111,429,532 (December 31, 2019: 93,942,652) common shares	**$ 1**	$ 1

Public Offering

On February 11, 2020, IntelGenx announced the closing of 16,317,000 units (the "Units") at a price of CAD$0.50 ($0.37) for gross proceeds of CAD$8,158,500 ($6,137,000).

Each Unit consists of one share of common stock of the Company and one warrant entitling the holder to purchase one share of common stock of the Company at an exercise price of CAD$0.75 ($0.56) per share. The Warrants are exercisable immediately and will expire on the third anniversary of the date of their issuance. Management has determined the value attributed to common stock is $3,912 thousand and $1,207 thousand for the warrants issued, resulting in an increase in additional paid-in-capital of $5,119 thousand.

In connection with the Offering, the Company paid to the Agents a cash commission of approximately CAD$763,000 ($572,000) in the aggregate and issued non-transferable agents' warrants to the Agents, entitling the Agents to purchase 1,142,190 common shares at a price of CAD$0.75 ($0.56) per share until February 11, 2023. Management has determined the value of the agents' warrants to be $125,000, resulting in an increase in additional paid-in-capital of $125,000.

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

	Gross proceeds	**Transaction costs**	**Net proceeds**
Common stock	**$ 4,690**	**$ 778**	**$ 3,912**
Warrants	**1,447**	**240**	**1,207**
	$ 6,137	**$ 1,018**	**$ 5,119**

13. Capital Stock (Cont'd)

Stock options

During the year ended December 31, 2020 there were no stock options exercised.

During the year ended December 31, 2019 a total of 50,000 stock options were exercised for 50,000 common shares having a par value of $0 thousand in aggregate, for cash consideration of $21 thousand, resulting in an increase in additional paid-in capital of $21 thousand.

Stock-based compensation of $193 thousand and $333 thousand was recorded during the year ended December 31, 2020 and 2019 respectively. An amount of $156 thousand (2019 - $286 thousand) expensed relates to stock options granted to employees and an amount of $37 thousand (2019- $47 thousand) relates to stock options granted to consultants during the year ended December 31, 2019. As at December 31, 2020 the Company has $180 thousand (2019 - $157 thousand) of unrecognized stock-based compensation, of which $Nil (2019 - $36) relates to options granted to consultants.

14. Additional Paid-In Capital

Stock Options

On May 9, 2016, the Board of Directors of the Company adopted the 2016 Stock Option Plan which amended and restated the 2006 Stock Option. As a result of the adoption of the 2016 Stock Option Plan, no additional options will be granted under the 2006 Stock Option Plan and all previously granted options will be governed by the 2016 Stock Option Plan. The 2016 Stock Option Plan permits the granting of options to officers, employees, directors and eligible consultants of the Company. A total of 9,347,747 shares of common stock were reserved for issuance under this plan, which includes stock options granted under the previous 2006 Stock Option Plan. 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-V. 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.

(Expressed in U.S. Funds)

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

The fair value of options granted 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 and directors during the years ended:

	2020	2019
Exercise price	0.27	0.69
Expected volatility	77%	64%
Expected life	5.63 years	5.63 years
Risk-free interest rate	0.39%	2.18%
Dividend yield	Nil	Nil

The weighted average fair value of the options granted to employees during the year ended December 31, 2020 is $0.13 (2019 - $0.40).

Information with respect to employees and directors stock option activity for 2019 and 2020 is as follows:

	Number of options	**Weighted average exercise price $**
Outstanding - January 1, 2019	3,854,818	0.68
Granted	100,00	0.69
Forfeited	(37,500)	(0.66)
Expired	(402,500)	(0.67)
Exercised	(50,000)	(0.41)
Outstanding - December 31, 2019	3,464,818	0.68
Granted	1,390,000	0.27
Expired	(225,000)	(0.61)
Outstanding - December 31, 2020	4,629,818	0.56

(Expressed in U.S. Funds)

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

Information with respect to consultant's stock option activity for 2019 and 2020 is as follows:

	Number of options	Weighted average exercise price $
Outstanding - January 1, 2019 and 2020	550,000	0.72
Outstanding - December 31, 2019 and 2020	550,000	0.72

Details of stock options outstanding as at December 31, 2020 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 $
0.27	1,390,000	2.66	0.07		-	0.00	
0.41	275,000	0.01	0.02		275,000	0.03	
0.58	600,000	0.52	0.07		600,000	0.09	
0.66	200,000	0.28	0.03		200,000	0.04	
0.69	100,000	0.16	0.01		75,000	0.01	
0.70	475,000	0.18	0.06		475,000	0.09	
0.73	525,000	0.53	0.07		525,000	0.10	
0.76	905,000	1.27	0.13		905,000	0.18	
0.77	359,818	0.46	0.05		359,818	0.07	
0.78	100,000	0.01	0.02		100,000	0.02	
0.89	250,000	0.29	0.04		250,000	0.06	
	5,179,818	6.37	0.57	-	3,764,818	0.69	-

(Expressed in U.S. Funds)

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

Stock-based compensation expense recognized in 2020 with regards to the stock options was $193 thousand (2019: $333 thousand). As at December 31, 2020 the Company has $180 thousand (2019 - $157 thousand) of unrecognized stock-based compensation, of which $Nil (2019 - $36 thousand) relates to options granted to consultants. The amount of $180 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 directors to accelerate and would result in $180 thousand being charged to stock-based compensation expense.

Warrants

Information with respect to warrant activity for 2019 and 2020 is as follows:

	Number of warrants (All Exercisable)	Weighted average exercise price $
Outstanding - January 1, 2019 and 2020	12,904,397	0.9470
Granted	18,163,990	0.5453
Outstanding - December 31, 2020	31,068,387	0.7125

Deferred Share Units ("DSUs")

Effective February 7, 2018, the Board approved a Deferred Share Unit Plan (DSU Plan) to compensate non-employee directors as part of their annual remuneration. 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. On March 27, 2019, 271,740 DSUs have been granted under the DSU Plan, accordingly, an amount of $128 thousand has been recognized in general and administrative expenses. No DSUs were granted in 2020.

(Expressed in U.S. Funds)

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

Performance and Restricted Share Units ("PRSUs")

At the Annual Meeting on May 8, 2018, the shareholders approved the IntelGenx Technologies Corp. Performance and Restricted Share Unit Plan (PRSU Plan) which the Board of Directors had approved on March 19, 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 of the Company and its Subsidiaries and to reward such executive officers for their contributions toward the long-term goals and success of the Company and to enable and encourage such executive officers to acquire shares of Common Stock as long-term investments and proprietary interests in the Company. As at December 31, 2020, 53,846 rewards have been issued under the PRSU Plan, accord. No rewards were granted under the PRSU Plan in 2019 and 2020.

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:

		2020		2019
Statutory income taxes	**$**	**(1,716)**	$	(2,398)
Net operating losses for which no tax benefits have been recorded		**1,048**		1,189
Deficiency of depreciation over capital cost allowance		**(28)**		(178)
Non-deductible expenses		**455**		667
Undeducted research and development expenses		**409**		820
Investment tax credit		**(168)**		(100)
	$	**-**	$	-

(Expressed in U.S. Funds)

15. Income Taxes (Cont'd)

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

		2020		2019
Leasehold improvements and equipment	**$**	**445**	$	440
Net operating losses carryforward		**8,684**		6,396
Undeducted research and development expenses		**3,534**		2,903
Non-refundable tax credits carryforward		**2,506**		2,082
		15,169		11,821
Valuation allowance		**(15,169)**		(11,821)
	$	**-**	$	-

As at December 31, 2020, 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 $31,673 thousand (2019: $23,101 thousand) and $33,905 thousand (2019: $25,265 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 2040. A portion of the net operating losses may expire before they can be utilized.

As at December 31, 2020, the Company had non-refundable tax credits of $2,802 thousand (2019: $2,486 thousand) of which $8 thousand is expiring in 2026, $10 thousand is expiring in 2027, $177 thousand is expiring in 2028, $155 thousand is expiring in 2029, $132 thousand is expiring in 2030, $141 thousand is expiring in 2031, $176 thousand is expiring in 2032, $117 thousand is expiring in 2033, $89 thousand expiring in 2034, $104 thousand is expiring in 2035, $144 thousand expiring in 2036, $275 thousand is expiring in 2037, $594 thousand expiring in 2038, $359 thousand expiring in 2039 and $298 thousand expiring in 2040 and undeducted research and development expenses of $15,302 thousand (2019: $14,282 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.

(Expressed in U.S. Funds)

15. Income Taxes (Cont'd)

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, 2020:

Tax Jurisdictions	Tax Years
Federal - Canada	2016 and onward
Provincial - Quebec	2016 and onward
Federal USA	2016 onward

16. Revenues

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

	December 31, 2020	December 31, 2019
Research and development agreements	**$ 562**	$ 742
Licensing agreements	**982**	-
	$ 1,544	$ 742

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

	December 31, 2020	December 31, 2019
Product and services transferred at point in time	**$ 1,185**	$ 372
Products and services transferred over time	**359**	370
	$ 1,544	$ 742

16. Revenues (Cont'd)

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

	December 31, 2020	December 31, 2019
Europe	**$ 795**	534
Canada	**708**	208
United States	**41**	-
	$ 1,544	$ 742

Remaining performance obligations

As at December 31, 2020, the aggregate amount of the transaction price allocated to the remaining performance obligation is $1,425 representing research and development agreements, the majority of which is expected to be recognized in the next twelve months. The Company is also eligible to receive up to $2,558 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	**2020**	2019
Additional Cash Flow Information:		
Interest paid	**$ 441**	$ 465

(Expressed in U.S. Funds)

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, 2020 included in general and administrative expenses is $87 thousand. The cash outflows from operating leases for the year ended December 31, 2020 was $91 thousand.

During the year ended December 31, 2020, the Company was granted a rent concession by the landlord due to the COVID-19 pandemic that resulted in a negative variable lease expense in the amount of $64 thousand.

The weighted average remaining lease term and the weighted average discount rate for operating leases at December 31, 2020 were 5.2 years and 10%, respectively.

The following table reconciles the undiscounted cash flows for the operating leases as et December 31, 2020 to the operating lease liabilities recorded on the balance sheet:

	Operating Leases
2021	$ 155
2022	159
2023	161
2024	164
2025	164
Thereafter	28
Total undiscounted lease payments	831
Less: Interest	208
Present value of lease liabilities	$ 623

Current portion of operating lease liability	$141
Operating lease liability	$482

(Expressed in U.S. Funds)

18. Leases (Cont'd)

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, 2020 was $2 thousand.

The weighted average remaining lease term and the weighted average discount rate for finance leases at December 31, 2020 were 4 years and 6.43%, respectively.

The following table reconciles the undiscounted cash flows for the finance leases as et December 31, 2020 to the finance lease liabilities recorded on the balance sheet:

	Finance Leases
2021	$ 32
2022	32
2023	32
2024	29
Total undiscounted lease payments	125
Less: Interest	16
Present value of lease liabilities	$ 109

Current portion of finance lease liability	$25
Finance lease liability	$84

19. Related Party Transactions

Included in management salaries are $20 thousand (2019 - $67 thousand) for options granted to the Chief Executive Officer, $51 thousand (2019 - $50 thousand) for options granted to the President and Chief Financial Officer, $10 thousand (2019 - $29) for options granted to the Vice-President, Research and Development, $10 thousand (2019 - $29) for options granted to the Vice-President, Business and Corporate Development, and $30 thousand (2019 - $36) for options granted to the Vice-President, Operations under the 2016 Stock Option Plans.

Included in general and administrative expenses are director fees of $233 thousand (2019: $231 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 11, 2021, 150,000 options to purchase common stock were granted to an employee under the 2016 Stock Option Plan. The options have an exercise price of $0.27. The options granted vest over a period of 2 years at a rate of 25% every six months and expire 10 years after the grant date.

Subsequent to the end of the year, CAD$301,000 ($236,000) of convertible debentures were converted into 602,000 common shares at the option of the holders.

On March 15, 2021, the Company announced a strategic partnership with Atai Life Sciences and a proposed TSX graduation. The announcement stated that the Company had agreed to the terms of a strategic partnership with Atai Life Sciences ("**atai**"), a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders, including an equity investment by atai, pursuant to which atai will initially acquire an approximate 25% interest in the Company. The Company also announced that atai had granted to IntelGenx a secured loan in the amount of $2,000,000. As part of the strategic partnership, the Company will exclusively partner with atai 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 partnership and investment are subject to the approval of the TSX Venture Exchange and approval of the shareholders of the Company and will be subject to certain customary closing conditions. Shareholders will be asked to consider and vote on the proposed transaction with atai at the Company's annual meeting of shareholders on May 11, 2021.

21. Subsequent Events (Cont'd)

Strategic Development Agreement

Under a strategic development agreement, atai and IntelGenx will cooperate to conduct research and development projects in areas relating to the parties' respective technologies. A portion of the funds (20%) that we will receive through atai's equity investment under the securities purchase agreement described below will be available to be credited against the costs of the Company the research and development projects. So long as atai maintains certain levels of its initial equity ownership in us, atai will have exclusive commercialization rights in the field of compounds for the prevention or treatment of mental health diseases or disorders or compounds that have psychedelic, entactogenic and/or oneirophrenic properties, but excluding certain specific compounds and veterinary applications. The commercialization of any technologies that result from the research and development 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.

Securities Purchase Agreement

Under a securities purchase agreement, atai has agreed to purchase 37,300,000 shares of common stock of the Company and 22,380,000 warrants for aggregate gross proceeds of $12,346,300 following receipt of shareholders' approval at the meeting. 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 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 (x) 44,000,000 common shares of the Company, and (y) the number of common shares issued by the Company under outstanding convertibles. Under the securities purchase agreement, the Company also granted atai a pro-rata equity participation right for any issuances of new securities, subject to certain exceptions. Following the initial closing, atai will hold approximately 25% (approximately 35% on a partially diluted basis) of the issued and outstanding shares and therefore become a new "Control Person" of the Company as such term is defined under the policies of the Exchange. Based on the number of issued and outstanding shares and outstanding convertible instruments on the date hereof, assuming the full exercise of its option to acquire the additional units and exercise of the initial warrants and additional warrants, atai would hold approximately 60% (approximately 60% on a partially diluted basis) of the issued and outstanding Shares.

21. Subsequent Events (Cont'd)

Proposed Graduation to the Toronto Stock Exchange

Under the Securities Purchase Agreement, we have agreed to use reasonable efforts to list our shares on the TSX with a target to achieve such listing shortly after the initial closing contemplated by the securities purchase agreement and we intend to promptly submit a listing application to the TSX. There is no assurance that the TSX will approve the listing application and any listing of the shares of Common Stock on the TSX is subject to us meeting all of the listing requirements of and obtaining the approval of the TSX. The Additional Units Warrant is only exercisable if our shares of Common Stock are listed on the TSX.

Purchaser Rights Agreement

Under the purchaser rights agreement, atai will have the right to appoint nominees in the same proportion to the number of board members of the Company as the shares then held by atai, registration rights, and financial and other information rights. The Company will have the right to terminate the purchaser rights agreement if atai ceases to own a certain amount of the Company's equity.

Term Loan

atai has granted to the Company a secured loan in the amount of $2,000,000, bearing interest at 8%. The loan is repayable on the date that is 120 days following the date of the Meeting, but in any event not later than September 30, 2021. The securities purchase agreement provides that an amendment is to be entered into at the initial closing of the atai investment under which the maturity date will be following the first closing of a subscription for additional units if the proceeds from such subscription amount to at least $3,000,000. The loan provides for the possibility of an additional advance to the Company of up to $500,000, subject to certain conditions. The loan is guaranteed by the Company and secured by all of present and future fixed assets of the Company, excluding any intellectual property or technology controlled or owned by the Company. The Company has applied approximately CA$800,000 ($628,000) from the loan to fully repay the outstanding amount on the Company’s credit facilities with its Bank. The Company intends to use the balance of the loan for general working capital purposes.