

**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, 2019**

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**

**INTELGEX TECHNOLOGIES CORP.**

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**

State or Other Jurisdiction of  
Incorporation or Organization

**87-0638336**

I.R.S. Employer Identification No.

**6420 Abrams, Ville Saint Laurent, Quebec, Canada**

Address of Principal Executive Offices

**H4S 1Y2**

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	OTCQX 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 is a shell company (as defined in Rule 12b-2 of the Act). Yes  No

As of June 30, 2019, the aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates of the registrant was \$42,290,549 based on the closing price of the registrant's common stock of U.S. \$0.51, as reported on the OTCQX 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.

<b>Class</b>	<b>Outstanding at March 25, 2020</b>
<b><u>Common Stock, \$0.0001 par value</u></b>	<b><u>110,259,653 shares</u></b>

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 2020 Annual Meeting of Shareholders (the "2020 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 2019 as reported by the Bank of Canada, being U.S. \$1.00 = CA\$1.3268.

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## 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. 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.** 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 uncertainty about the spread of the COVID-19 virus and the impact it will have on IntelGenx' 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 to be launched in 2020. 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 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 U.S. Food and Drug Administration ("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.

Managing our project pipeline is a key success factor for the Company. 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 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 combination.

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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 our VersaFilm™ products in-house as 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 clients and development partners a full service from product conception through to supply of the finished product.

Our website address is [www.intelgenx.com](http://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.

## 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 utilize our VersaFilm™ technology and one utilizes our AdVersa® 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, 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 developed in accordance with a co-development and commercialization agreement with RedHill Biopharma Ltd. ("RedHill"). In the second quarter of 2012 we conducted a pivotal clinical study against Maxalt-MLT®. The study results indicate that the product is safe, and that the 90% confidence intervals of the three relevant parameters Cmax, AUC(0-t) and AUC(0-infinity) are well within the 80 - 125 acceptance range for bioequivalency.

In February 2014 we received a Complete Response Letter ("CRL") from the FDA.

In October 2014 we submitted a Marketing Authorization Application ("MAA") to the German Federal Institute for Drugs and Medical Devices ("BfArM") seeking European marketing approval of our oral thin film formulation of Rizatriptan for acute migraines, under the brand name RIZAPORT®. The MAA was submitted under the European Decentralized Procedure ("DCP") with Germany and Luxemburg as the reference member states.

On September 10, 2015 we announced the positive outcome of the DCP confirming that RIZAPORT® is approvable in Europe. The announcement followed the issuance of the Final Assessment Report from the Reference Member State, BfArM, and the agreement of all the Concerned Member States ("CMS") in DCP that RIZAPORT® is approvable. With the decision, the regulatory process entered its final phase known as the national licensing phase during which the National Agencies in the individual countries will issue the marketing licenses that allow RIZAPORT® to be marketed in each country.

On November 9, 2015 we announced that BfArM has granted marketing authorization of RIZAPORT® 5mg and 10mg, an oral thin film formulation of rizatriptan benzoate for the treatment of acute migraines. The national approval of RIZAPORT® in Germany was granted under the DCP, in which Germany served as the Reference Member State. This authorization was the first national marketing approval of RIZAPORT®.

On February 18, 2016, we announced that the USPTO had granted a patent protecting Rizaport®, an oral thin film formulation of rizatriptan benzoate for the treatment of acute migraines. This patent protects the composition of Rizaport® and will be listed in the Orange Book upon approval of the product by the FDA. The 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 the definitive agreement with Grupo Juste S.A.Q.F. (now Exeltis Healthcare, S.L. ("Exeltis")) for the commercialization of RIZAPORT®, our proprietary oral thin film for the treatment of acute migraines, in the country of Spain. All commercial manufacturing of RIZAPORT® will take place at our new state-of-the-art manufacturing facility in Canada. Grupo Juste (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.

According to the definitive agreement, Grupo Juste (Exeltis) has obtained exclusive rights to register, promote and distribute RIZAPORT® in Spain. In exchange, we and Redhill Biopharma received upfront payments and are entitled to milestone payments, together with a share of the net sales of RIZAPORT®. The initial term of the definitive agreement shall be for ten years from the date of first commercial sale of the product and shall automatically renew for one additional two-year term.

Through our partner Grupo Juste (Exeltis), the product was submitted in Spain in September 2016 for approval using a decentralized procedure.

On December 14, 2016, we, together with our partner RedHill, 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 the agreement, RedHill granted Pharmatronic Co. the exclusive rights to register and commercialize RIZAPORT® in South Korea. IntelGenx and RedHill 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.

In April 2017, we announced the national marketing approval in Luxembourg which completes the approval process of RIZAPORT® under the DCP.

On December 5, 2017 we announced the termination of the Co-development and Commercialization agreement with Redhill, following which Redhill transferred all rights and obligations under the agreement to the Company.

On October 31, 2018 IntelGenx announced that its commercialization partner for RIZAPORT® (10mg) in Spain, Grupo Juste, which is now part of Exeltis Healthcare, received national marketing authorization from the Spanish Agency of Medicines and Medical Devices for the product. Following the approval of the manufacturing site transfer of RIZAPORT® from the European contract manufacturer listed in the initial manufacturing site transfer application to IntelGenx's GMP compliant facility in Montreal, Canada, IntelGenx's marketing partner, Exeltis Healthcare, will be able to commercialize the product in Spain. The Company believes that recently reported results from a successful study, demonstrating that RIZAPORT® is bioequivalent to the European reference, Maxalt®-Lingua, will further support the site transfer application in Spain.

On December 12, 2018 we announced the execution of a definitive licensing, development and supply agreement with Gensco® Pharma, a specialty pharmaceutical company focusing on research, development and marketing of prescription products, for the exclusive commercialization of RIZAPORT® in the United States. Under the Agreement, Gensco® Pharma has been granted the exclusive right to commercialize RIZAPORT® in the United States. In return, IntelGenx is entitled to receive royalty payments based on the net profits of RIZAPORT®. IntelGenx is also eligible to receive milestone payments upon FDA approval and product launch. The agreement also grants Gensco® Pharma exclusivity to develop, market, sell, distribute and fully commercialize products as an IntelGenx 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 the company's Health Canada-certified cGMP manufacturing facility in Montreal, relating to our NDA for RIZAPORT®, a VersaFilm™ oral soluble film for the treatment of acute migraines. At the conclusion of the PAI on January 25, the FDA issued a Form 483 with five inspectional observations.

On March 13, 2019, Japanese Patent No. 6482552 was granted by the Japanese Patent Office.

On April 2019 we received a CRL from the FDA regarding the resubmitted 505(b)(2) NDA for RIZAPORT® VersaFilm™ for the treatment of acute migraines. The deficiencies listed in the CRL relate to the Chemistry, Manufacturing and Controls section of the application. The Agency requested additional information, but no new bioequivalence study.

On July 15, 2019, Mexican Patent No. 366595 was granted by the Mexican Patent Office.

In September 2019 we announced the filing of the response to the CRL followed by the acceptance of the response by the FDA in October. The FDA has assigned a Prescription Drug User Fee Act ("PDUFA") goal date for completion of the review of the RIZAPORT® NDA of March 26, 2020.

On January 13, 2020, we announced the signing of a binding term sheet with Orivas for the commercialization of RIZAPORT®, pursuant to which Orivas will obtain exclusive rights to market and sell RIZAPORT® in Lithuania, Latvia, Estonia and Poland, with the right of first refusal for a predefined term to include the Republic of Belarus and/or Republic of Ukraine, as well as any of the Scandinavian countries (Finland, Denmark, Sweden and Norway). Financial terms of the agreement were not disclosed.

**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., a global leader in cannabis production and distribution. Pursuant to the agreement, the two companies will co-develop and commercialize oral film products infused with adult-use and medical cannabis ("cannabis-infused VersaFilm™"),

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

In connection with the agreement with Tilray, Inc., the parties have also executed a subscription agreement pursuant to which Tilray, Inc. made a strategic investment in IntelGenx by way of a non-brokered private placement ("Private Placement"). Pursuant to the Private Placement, IntelGenx issued 1,428,571 common shares at a subscription price of U.S.\$0.70 per common share for gross proceeds of U.S.\$1,000,000. We intend to use the proceeds of the Private Placement for cannabis-infused VersaFilm™ product development under the agreement with Tilray, Inc.

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

In the spring of 2019, IntelGenx applied for a micro-processing license under the Health Canada Cannabis Act. The micro-processing license allows for processing of under 600kg of cannabis per year, analytical testing, sales and research on cannabis. The license is at its final stage of review at Health Canada.

**INT0007/2006:** We are developing an oral film product based on our VersaFilm™ technology containing the active ingredient Tadalafil. The product is intended for the treatment of erectile dysfunction ("ED"). The results of a phase I pilot study that was 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 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 prior to the expiration of the '166 dosing patent. This license terminates all our current tadalafil-related litigation activities.

On March 28, 2017, we announced that Eli Lilly and Company granted IntelGenx' an exclusive license for tadalafil film product under ED dosing patent, the '166 dosing patent.

On May 08, 2019, we announced the execution of a worldwide collaboration agreement for tadalafil with Aquestive Therapeutics. Under the terms of the Agreement, IntelGenx and Aquestive will each grant to the other exclusive worldwide licenses to their respective intellectual property relating to tadalafil oral film formulation and manufacturing. The companies will jointly undertake further co-development and commercialization of Tadalafil oral film products, and will equally share (50/50) net profits from worldwide product sales. Aquestive previously submitted an NDA for its tadalafil oral film for the treatment of ED to the FDA. In November 2018, Aquestive received a CRL from the FDA requesting additional safety data from healthy volunteers. Both companies are currently working to establish a path to resubmission and approval.

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

On September 12, 2016, we announced that we had entered into a licensing, development and supply agreement with 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 the agreement, Chemo has 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 IntelGenx announced that an Abbreviated New Drug Application ("ANDA") for a generic buccal film product has been submitted to the FDA by its 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. IntelGenx is currently preparing for the upcoming pre approval inspection.

In March 2019 the FDA conducted a pre-approval inspection for the buccal film, and IntelGenx received a 483 form.

In October 2019, a CRL was received. IntelGenx is currently preparing a response for both the 483 and the CRL.

**INT0027/2011:** We developed this oral film product based on our VersaFilm™ technology. In accordance with a co-development and commercialization agreement with Par Pharmaceutical Companies, Inc. ("Par") (now an operating company of Endo International plc), we developed an oral film product based on our proprietary VersaFilm™ technology. The product is a generic formulation of a commercial buprenorphine and naloxone containing sublingual film and is indicated for the treatment of opioid dependence. A bioequivalent film formulation was developed, scaled-up, and pivotal batches were manufactured and tested during a subsequent pivotal clinical study. An ANDA was filed with the FDA by Par in July 2013.



In August 2013 we were notified that, in response to the filing of the ANDA, we were named as a codefendant in a lawsuit pursuant to Paragraph IV of the Hatch Waxman act filed by Reckitt Benckiser Pharmaceuticals and Monosol RX 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<sup>®</sup>. We believe the ANDA product does not infringe those or any other patents. In accordance with the terms of the co-development and commercialization agreement, Par was financially responsible for the costs of the defense. Paragraph IV litigation is a regular part of the ANDA process and did not have any impact on our development schedule. In June 2016, an opinion from the district court was obtained on the validity and infringement of the 3 orange book patents. The court ruled that the product is not infringing on two out of the three patents. Subsequently, appeals were filed by both parties.

In December 2014, Reckitt Benckiser Pharmaceuticals and Monosol RX filed a lawsuit for patent infringement in the Delaware Court relating to the Suboxone<sup>®</sup> ANDA product. We were named as a codefendant in this action alleging patent infringement 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 for the process patents was held in November 2016.

On May 14, 2018, we announced that all patent litigation between the Company, Par, Indivior, Inc., Indivior UK Limited, and Aquestive Therapeutics, Inc. (formerly MonoSol Rx, LLC) related to Suboxone<sup>®</sup> film had been settled. The settlement agreement permits Par to begin selling a generic version of Suboxone<sup>®</sup> 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<sup>™</sup> 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 signaling mechanisms that are crucially 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<sup>™</sup> 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<sup>™</sup> delivery technology.

In 2017 we announced receiving the no objection letter from Health Canada regarding a phase II-a proof-of-concept study. The objectives of this 26 week, randomized, double-blind, and placebo controlled Phase IIa proof of concept study which will 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. The trial design includes testing of up to 70 patients.

On January 24, 2018 we announced that we retained the services of Cogstate and JSS Medical Research as the Contract Research Organizations to support the Montelukast VersaFilm<sup>™</sup> study

We are also actively working on securing the IP of our product by filing numerous patent applications. 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 that patient recruitment will commence for the Phase 2a study with Montelukast VersaFilm<sup>™</sup> in patients with mild to moderate Alzheimer's Disease ("AD"). Two research sites (the Centre for Memory and Aging in Toronto, ON and True North Clinical Research in Halifax, NS) are being activated and will be open for patient enrollment as of September 26, 2018, with additional sites planning to initiate patient screening in the near future. This randomized, double-blind, placebo controlled Phase 2a proof of concept study will enroll approximately 70 subjects with mild to moderate AD across eight Canadian research sites. The primary study objectives will be to evaluate the safety, feasibility, tolerability, and efficacy of Montelukast buccal film following daily dosing for 26 weeks.

In 2019 we added of three new sites to its study: the Douglas Mental Health University Institute in Montreal, Quebec, the Kawartha Centre site in Peterborough, Ontario and another site in Ottawa, Ontario. In October an independent Data Safety Monitoring Board ("DSMB") completed its first interim analysis of the ongoing Montelukast VersaFilm® Phase 2a ("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 which 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 regimen was requested to Health Canada through the filing of a clinical trial application. A non-objection letter was issued by Health Canada in January 2020.

**INT0040/2014:** An oral film product based on our proprietary VersaFilm™ technology is currently in the scale up stage. In order to protect our competitive advantage, no further details of the product can be disclosed at this stage.

On December 27, 2016, we announced that we have entered into a co-development and commercialization agreement with Endo Ventures Ltd. for this product utilizing our proprietary VersaFilm™ for the United States market. Under the agreement, Endo has 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 IntelGenx will share the profits of commercialization.

**INT0010/2006:** This product is based on our proprietary AdVersa® technology and is currently in an advanced development stage.

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 the muco-adhesive tablet we developed which is based on our proprietary AdVersa® technology. The study results indicated improved bioavailability and reduced first-pass metabolism of the drug. In the fourth quarter of 2010, we acquired from Cynapsus full control of, and interest in, this project 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 "Product") for the management of anorexia and cancer chemotherapy-related pain. This definitive agreement followed the binding term sheet between the two companies that was announced on February 9, 2017.

Pursuant to the definitive agreement, Tetra has exclusive rights to sell the 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 IntelGenx, in addition to set 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 Product. We are responsible for the research and development of the product, including optimization of the prototype, scale-up activities and preparation of a phase II proof of concept clinical study and are developing the 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 Product.

**INT0036/2013:** This oral film product is based on our proprietary oral film technology VersaFilm™ and is currently in the optimization development stage. Loxapine is indicated for the treatment of anxiety and aggression in patients suffering from schizophrenia or bipolar I disorder. Loxapine oral film will utilize the company's proprietary VersaFilm™ technology, allowing for an improved product to offer patients significant therapeutic benefits compared to existing medications. A fast acting Loxapine oral film dosage form that can be used to effectively treat acute agitation associated with schizophrenia or bipolar I disorder in non-institutionalized patients while reducing the risk of pulmonary problems 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 are working to optimize the film to further improve the time to reach peak plasma concentrations. However, due to the prioritisation of our project line, resources were directed to other projects, which resulted in a temporary hold of the optimization work during 2019. We are now actively working on advancing this project.

On February 10, 2016, we announced the submission of the patent application with the United States patent office for an oral film dosage form containing Loxapine for the treatment of anxiety and aggression in patients suffering from schizophrenia or bipolar I disorder. The application is currently under review.

**Other projects:**

**INT0037/2013:** A product based on one of our proprietary technologies has been developed, but preparations of submission batches and documentation in support of a marketing application to the FDA have been placed on hold.

The product was being developed in accordance with another development and commercialization agreement with Par. On September 18, 2015, Par was acquired by Endo International plc. As a result of this acquisition, there was a conflict for Par to remain as the partner for these products. As such, the product was returned to the Company with full rights and no requirement for any compensation for work paid by Par.

On September 12, 2016, we announced that we had entered into a licensing, development and supply agreement with Chemo Group ("Chemo") granting Chemo the exclusive license to commercialize two generic products for the USA market and one product on a worldwide basis. Under the terms of the agreement, Chemo has 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 USA. As per Chemo's decision, activities in preparation for filing the marketing application for this product have been placed on hold.

**INT0001/2004:** This is the most advanced tablet generic product involving our multilayer tablet technology. Equivalency with the reference product Toprol XL<sup>®</sup> and its European equivalent Beloc-ZOK<sup>®</sup> has been demonstrated *in-vitro*. The product has been tested in phase I studies. In November 2016 we entered into a license and development agreement with Chemo to advance the commercialization of our Versa Tab<sup>™</sup> product. The manufacturing technology transfer to Chemo has not been completed and the project has been discontinued.

**INT0004/2006:** We developed a new, higher strength of the antidepressant Bupropion HCl, the active ingredient in Wellbutrin XL<sup>®</sup>, 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 the product in the United States. Under the terms of the 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, received launch related milestones totaling up to \$4 million, were eligible for additional milestones of up to a further \$23.5 million upon achieving certain sales and exclusivity targets and to also receive 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<sup>®</sup>. As of December 31, 2015 we had received an upfront payment of \$1 million and a \$1 million milestone payment related to the launch. The commercialization of Forfivo XL<sup>®</sup> triggered a launch-related milestone payment of \$3 million from IntelGenx' licensing partner Edgemont due to Edgemont reaching in July 2015, \$7 million of cumulative net trade sales of Forfivo XL<sup>®</sup> over the preceding 12 months.

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<sup>®</sup> 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<sup>®</sup> in the United States.

In December 2014 we announced that Edgemont had exercised its right to extend the license for the exclusive marketing of Forfivo XL<sup>®</sup> 450 mg tablets. In exchange, we received milestone payments of \$650 thousand in December 2014 and \$600 thousand in February 2015. All other financial obligations contained in the license agreement entered into by Edgemont and IntelGenx in February 2012, 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 announced that we had sold our United States royalty on future sales of Forfivo XL<sup>®</sup> to SWK Holdings Corporation ("SWK") for \$6 million (CA\$8 million). Forfivo XL<sup>®</sup> (Bupropion extended-release) is the first 450 mg bupropion HCl tablet indicated for Major Depressive Disorder, approved by the FDA. As per terms of the agreement, we received \$6 million from SKW at closing. In return for, (i) 100% of any and all royalties (as defined in the Edgemont Pharmaceuticals, LLC License Agreement) or similar royalty amounts received on or after April 1, 2016, (ii) 100% of the \$2 million milestone payment upon Edgemont reaching annual net sales of \$15 million, and (iii) 35% of all potential future milestone payments. Patent protection for Forfivo XL<sup>®</sup> in the United States expires in 2027.

In the first quarter of 2017, we were informed that Edgemont Pharmaceuticals, LLC assigned its product business, including Forfivo XL<sup>®</sup>, to Alvogen Group Holdings 3 LLC.

IntelGenx retained all patent rights to the product Forfivo XL<sup>®</sup>, which is sold on the US market.

**The current status of each of our products as of the date of this report is summarized in the following table:**

Product	Indication	Status of Development
INT0008/2008	Migraine	PDUFA March 26 2020
INT0046/2018	Adult Use	Scale-up completed
INT0007/2006	Erectile dysfunction	Responding to Aquestive's CRL
INT0039/2013	Undisclosed	Undisclosed
INT0027/2011	Opioid addiction	Responding to CRL
INT0043/2015	Alzheimer	Preparing sites for new dosage regiment
INT0040/2014	Undisclosed	Undisclosed
INT0010/2006	Treatment of neuropathic pain and nausea in cancer patients undergoing chemotherapy	In progress
INT0036/2013	Schizophrenia or bipolar 1 disorder	In progress
INT0037/2013	Undisclosed	On hold
INT0004/2006	Depression	Approved and on the market

### **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<sup>™</sup>,
- 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<sup>™</sup>, VetaFilm<sup>™</sup> and AdVersa<sup>®</sup> 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 16 patents and have an additional 56 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 the 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.

<b>Patent No.</b>	<b>Title</b>	<b>Subject</b>	<b>Date issued/Expiration</b>
US 6,231,957	Rapidly disintegrating flavor wafer for flavor enrichment	The composition, manufacturing, and use of rapidly disintegrating flavored films for releasing flavors to certain substrates	Issued May 15, 2001 Expires May 6, 2019
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





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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
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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
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US 10,272,038	Film dosage form with extended release mucoadhesive particles	Film containing mucoadhesive particle	Issued April 30, 2019 Expires November 26, 2034
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CA 2,998,223	Loxapine film oral dosage form	Formulation of oral films containing loxapine	Issued October 9, 2018 Expires January 24, 2037
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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
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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
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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
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<b>Patent Application No.</b>	<b>Title</b>	<b>Subject</b>	<b>Date Filed</b>
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. KR20180105184	Loxapine film oral dosage form	Formulation of oral films containing loxapine	Filed January 25, 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 3,427,732	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
EU Appl. EP 3,426,235	Montelukast transmucosal film	Formulation of oral films containing montelukast	Filed March 1, 2017
EU Appl. EP 3,411,024	Loxapine film oral dosage form	Formulation of oral films containing loxapine	Filed January 25, 2017
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. EP 3,600,265	Method of treatment and device for the improved bioavailability of leukotriene receptor antagonists	Formulation of oral films containing montelukast	Filed March 29, 2018

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Chinese Appl.  
CN105530921

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

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Chinese Appl.  
CN108697656

Loxapine film oral dosage form

Formulation of oral films containing  
loxapine

Filed January 25, 2017

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Chinese Appl. CN108778259	Montelukast the mucous membrane the membrane	Formulation of oral films containing montelukast	Filed March 1, 2017
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 bioavailability of improved leukotriene receptor antagonists	Formulation of oral films containing montelukast	Filed March 29, 2018
Canadian Appl. CA2,919,442	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
Mexican Appl. MX2018010755	Montelukast transmucosal film	Formulation of oral films containing montelukast	Filed March 1, 2017
Mexican Appl. MX2018009306	Loxapine film oral dosage form	Formulation of oral films containing loxapine	Filed January 25, 2017
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
Brazilian Appl. BR112016002074	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
Brazilian Appl. BR112018015624	Loxapine film oral dosage form	Formulation of oral films containing loxapine	Filed January 25, 2017

Brazilian Appl. BR112018068116	Transmucosal film for montelukast administration	Formulation of oral films containing montelukast	Filed March 1, 2017
Brazilian Appl. BR112019007321	Device and method of treating conditions associated with neuroinflammation	Formulation of oral films containing montelukast	Filed October 17, 2017
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

Chilean Appl. 201600160	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. IN201847036315	Montelukast transmucosal film	Formulation of oral films containing montelukast	Filed September 26, 2018
Indian Appl. IN201847030838	Loxapine film oral dosage form	Formulation of oral films containing loxapine	Filed August 17, 2018
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
Japanese Appl. JP2019504099	Loxapine film oral dosage form	Formulation of oral films containing loxapine	Filed January 25, 2017
Japanese Appl. JP2019531310	Device and method of treating pathologies associated with neuroinflammation	Formulation of oral films containing montelukast	Filed October 17, 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

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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

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Canadian Appl. CA 3,062,704	Film dosage form with extended release mucoadhesive particles	Film containing mucoadhesive particle	Filed May 8, 2018
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Australian Appl. AU2017231110	Montelukast transmucosal film	Formulation of oral films containing montelukast	Filed March 1, 2017
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Australian Appl. AU2017214774	Loxapine film oral dosage form	Formulation of oral films containing loxapine	Filed January 25, 2017
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Australian Appl. AU2017344764	Device and method of treating conditions associated with neuroinflammation	Formulation of oral films containing montelukast	Filed October 17, 2017
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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
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US Appl. 15/426,149	Solid Oral Film Dosage Forms and Methods for Making Same	Formulation of oral films containing tadalafil	Filed February 7, 2017
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US Appl. 15/067,309	Montelukast transmucosal film	Formulation of oral films containing montelukast	Filed March 11, 2016
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US Appl. 14/630,699	Film dosage forms containing amorphous active agents	Film containing amorphous agent	Filed February 2, 2015
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US Appl. 15/848,819	Film dosage form with multimodal and particle size distributions	Optimization of film strip technology	Filed December 20, 2017
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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
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US Appl. 16/110,737	Film dosage form with extended release mucoadhesive particles	Film containing mucoadhesive particle	Filed August 23, 2018
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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. 16/353,628	Film Dosage Form with Extended Release Mucoadhesive Particles	Film containing mucoadhesive particle	Filed March 14, 2019
US Appl. 16/441,872	Device and method of treating conditions associated with neuroinflammation	Formulation of oral films containing montelukast	Filed June 14, 2019
US Appl. 16/391,430	Film Dosage Forms Containing Amorphous Active Agents	Film containing amorphous agent	Filed April 23, 2019
US Appl. 16/455,916	Loxapine film oral dosage form	Formulation of oral films containing loxapine	Filed June 28, 2019

## 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 United States Federal Food, Drug, and Cosmetic Act, 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, or Good Laboratory Practices("GLP").
- 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, or 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 R&D expenses and shorter time-to-market timelines as compared to regular NDA products.

#### Cannabis in Canada

On October 17, 2018, the Cannabis Act came into force putting in place, a new, strict framework for controlling cannabis sale, possession, production and distribution. New classes of cannabis were included in the amendment to the Cannabis Act that came into force on October 17, 2019. The amendment allows the production and sale of edible cannabis, cannabis extracts and cannabis topicals, by provincial and territorial retailers and federally licensed sellers of cannabis for medical purposes. As part of the amended regulations, the sale of edible cannabis, cannabis extracts and cannabis topicals was permitted mid-December 2019.

#### Environmental Regulatory Compliance

We believe that we are in compliance with environmental regulations applicable to our research and development and manufacturing facility located in Ville Saint Laurent, Quebec.

#### Employees

As of the date of this filing, we have 48 full-time and 3 part-time employees. None of our employees are covered by collective bargaining agreements. We believe that our relations with our employees are very good.

#### 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, 2019 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 \$41,507 thousand since our inception in 2003 through December 31, 2019. To date, these losses have been financed principally through sales of equity securities. Our revenues for the past five years ended December 31, 2019, December 31, 2018, December 31, 2017, December 31, 2016 and December 31, 2015 were \$0.7 million, \$1.8 million, \$5.2 million, \$5.2 million and \$5.1 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 not receive a waiver of default for outstanding indebtedness for which we may be in default in the future.**

The agreements governing our indebtedness include certain debt service and other financial covenants that we must satisfy. In previous years, we have defaulted on certain of these debt service coverage ratio covenants and have received waivers for the defaults. As of December 31, 2019, we were not in compliance with the required minimum debt service coverage ratio on one of our term loans and obtained a waiver of such default from the lender. We cannot provide any assurance that the lender will provide us with a waiver of the default for any future default. A failure to maintain compliance, along with our lender not agreeing to a waiver for the non-compliance, would cause the outstanding borrowings to be in default and payable on demand, which would raise substantial doubt in our ability to continue as a going concern.

**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 material adverse effect on our financial condition and results of operations.

**We may need additional capital to fulfill our business strategies. We may also incur unforeseen costs. 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. Additional funding may not be available on favorable terms, or at all. 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 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. 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.

**The loss of the services of key personnel would adversely affect our business.**

Our future success depends to a significant degree on the skills, experience and efforts of our executive officers and senior management staff. The loss of the services of existing personnel would be detrimental to our research and development programs and to our overall business.

**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 second half of 2019.

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 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.

**We are subject to environmental regulations, and any failure to comply may result in substantial fines and sanctions.**

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.

**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.

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 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 13 patents and have an additional 41 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 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.

### **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 was quoted on the OTC Bulletin Board under the symbol "IGXT" from January 2007 until June 2012 and, subsequent to our upgrade in June 2012, has been quoted on the OTCQX. Our Common Stock has also been listed on the TSX Venture Exchange 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.

**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.

**Our limited cash resources restrict our ability to pay cash dividends.**

Since our inception, we have not paid any cash dividends on our Common Stock. We currently intend to retain future earnings, if any, 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 of Directors ("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. If we do not pay any dividends on our Common Stock, our shareholders will be able to profit from an investment only if the price of the stock appreciates before the shareholder sells it. Investors seeking cash dividends should not purchase our Common Stock.

**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.

**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-Venture Exchange 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, 2020 (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-Venture Exchange 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 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 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.

**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\$116 thousand (approximately \$89 thousand) per year, which will increase at a rate of CA\$0.25 (\$0.19) 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\$74 thousand (approximately \$57 thousand) per year, which will increase at a rate of CA\$0.25 (\$0.19) 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 patent validity is scheduled to begin on or after September 21, 2020. A trial addressing infringement is scheduled to begin on or after February 1, 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 OTCQX under the symbol "IGXT" since June 2012. Our Common Stock has also been listed on the TSX Venture Exchange under the symbol "IGX" since May 2008.

On March 25, 2020, 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 2019, 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 2019, 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 <sup>(2)</sup> (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	1,153,846 <sup>(1)</sup>	\$0.54	946,154 <sup>(3)</sup>
Equity Compensation Plans Not Approved by Security Holders	2,914,818 <sup>(3)</sup>	\$0.75	3,675,358 <sup>(4)</sup>
Total	4,068,664	\$0.69	4,621,512

- (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 Venture Exchange. 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, 2019.

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

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 Venture Exchange, or (b) 2.5% of the issued and outstanding Common Stock, if the Company is listed on the Toronto Stock Exchange. The Board has the authority to condition the grant of RSUs or PSUs upon the attainment of specified performance goals, or such other factors (which may vary between awards) as the Board determines in its sole discretion. The Board has the authority to determine at the time of grant, in its sole discretion, the duration of the vesting period and other vesting terms applicable to the grant of RSUs or PSUs. In the case of PSUs, such awards may be adjusted in accordance with the applicable PSU award agreement.

On a go-forward basis, the Company intends to primarily compensate executive officers with RSUs and compensate non-executive employees with stock options.

## **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. In addition, there is uncertainty about the spread of the COVID-19 virus and the impact it will have on IntelGenx' operations, the demand for its products, global supply chains and economic activity in general.

### **Company Background**

We are a drug delivery company established in 2003 and headquartered in Montreal, Quebec, Canada. Our focus is on developing 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 in 2020. 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, 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.

We have established a state-of-the-art manufacturing facility for the future manufacture of our VersaFilm™, VetaFilm™ and AdVersa 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.

#### *Corporate*



On December 18, 2019, we filed a preliminary short form prospectus with respect to an offering of units for a minimum of CA\$4,000,000 and a maximum of CA\$10,000,000 aggregate gross proceeds. Each unit consisted of one share of Common Stock and one half of one Common Stock purchase warrant. Each warrant entitled the holder to purchase one share of Common Stock. Concurrently with the filing of the prospectus, we filed a registration statement on Form S-1 with the SEC to register the units and the warrant shares.

On January 27, 2020, we announced the pricing of an agency offering of up to 20,000,000 units, subject to a minimum offering of 10,000,000 units for gross proceeds of between CA\$5,000,000 (initially filed at CA\$4,000,000) and CA\$10,000,000, at a price of CA\$0.50 per unit. Each unit consisted of one share of Common Stock and one warrant (initially filed at one half) to purchase one share of Common Stock at an exercise price of CA\$0.75 per share. The Company also granted the agent an option to increase the size of the offering by up to 15%, exercisable in whole or in part at any time for a period of 30 days after and including the closing date of the offering.

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

The units were distributed under the previously filed short form prospectus dated January 27, 2020 and were registered with the SEC pursuant to the 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 CA\$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, our net proceeds from the offering amounted to approximately CA\$7.4 million.

The warrants commenced trading on the TSX Venture Exchange under the symbol "IGX.WT" on Thursday, February 13, 2020.

We intend to use the net proceeds from the offering for our Phase 2A Montelukast Study and general working capital requirements.

### **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<sup>®</sup>. 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, 2019 report an accumulated other comprehensive loss due mainly to foreign currency translation adjustments of \$836 due to the fluctuations in the rates used to prepare our financial statements, \$330 of which positively impacted our comprehensive loss for the fiscal year ended December 31, 2019. 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. The Company uses adjusted financial measures to assess its 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. The Company uses Adjusted EBITDA to measure its 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 the Company believes it provides meaningful information on the Company's 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. The Company believes 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 the Company's 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 core operating performance of the Company may vary significantly from one period to another. As such, Adjusted EBITDA provides improved continuity with respect to the comparison of the Company's 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	2019	2018	2019	2018
	\$	\$	\$	\$
Comprehensive loss	(2,651)	(2,938)	(10,330)	(10,637)
<b>Add (deduct):</b>				
Depreciation	195	179	718	719
Finance costs	306	300	1,207	1,121
Finance income	(17)	(11)	(97)	(11)
Share-based compensation	71	59	333	370
Other comprehensive (income) loss	(10)	439	(330)	529
<b>Adjusted EBITDA</b>	<b>(2,106)</b>	<b>(1,972)</b>	<b>(8,499)</b>	<b>(7,909)</b>

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

Adjusted EBITDA decreased by \$134 for the three-month period ended December 31, 2019 to (\$2,106) compared to (\$1,972) for the three-month period ended December 31, 2018. Adjusted EBITDA decreased by \$590 for the twelve-month period ended December 31, 2019 to (\$8,499) compared to (\$7,909) for the twelve-month period ended December 31, 2018. The decrease in Adjusted EBITDA of \$134 for the three-month period ended December 31, 2019 is mainly attributable to a decrease in revenues of \$583, an increase in selling, general and administrative ("SG&A") expenses of \$658 before consideration of stock-based compensation offset by a decrease in R&D expenses of \$1,107 before consideration of stock-based compensation. The decrease in Adjusted EBITDA of \$590 for the twelve-month period ended December 31, 2019 is mainly attributable to a decrease in revenues of \$1,082, an increase in SG&A expenses of \$836 before consideration of stock-based compensation offset by a decrease in R&D expenses of \$1,328 before consideration of stock-based compensation.

**Results of operations for the three month and twelve month periods ended December 31, 2019 compared with the three month and twelve month periods ended December 31, 2018.**

**Revenue**

In U.S.\$ thousands	Three-month period ended December 31,		Twelve-month period ended December 31,	
	2019	2018	2019	2018
Revenue	\$ 68	\$ 651	\$ 742	\$ 1,824
Research and Development Expenses	890	1,998	3,774	5,104
Selling, General and Administrative Expenses	1,355	684	5,800	4,999
Depreciation of tangible assets	195	179	718	719
<b>Operating Loss</b>	<b>(2,372)</b>	<b>(2,210)</b>	<b>(9,550)</b>	<b>(8,998)</b>
<b>Net Loss</b>	<b>(2,661)</b>	<b>(2,499)</b>	<b>(10,660)</b>	<b>(10,108)</b>
<b>Comprehensive Loss</b>	<b>(2,651)</b>	<b>(2,938)</b>	<b>(10,330)</b>	<b>(10,637)</b>

**Revenue**

Total revenues for the three-month period ended December 31, 2019 amounted to \$68, representing a decrease of \$583 or 90% compared to \$651 for the three-month period ended December 31, 2018. Total revenues for the twelve-month period ended December 31, 2019 amounted to \$742 representing a decrease of \$1,082 or 59% compared to \$1,824 for the twelve-month period ended December 31, 2018. The decrease for the three-month period ended December 31, 2019 compared to the last year's corresponding period is mainly attributable to a decrease in R&D revenues of \$583. The decrease for the twelve-month period ended December 31, 2019 compared to the last year's corresponding period is mainly attributable to a decrease in R&D revenues of \$1,454, partially offset by an increase in R&D milestones revenues of \$372.

**Research and development expenses**

R&D expenses for the three-month period ended December 31, 2019 amounted to \$890, representing a decrease of \$1,108 or 55%, compared to \$1,998 for the three-month period ended December 31, 2018. R&D expenses for the twelve-month period ended December 31, 2019 amounted to \$3,774, representing a decrease of \$1,330 or 26%, compared to \$5,104 recorded in the same period of 2018.

The decrease in R&D expenses for the three-month period ended December 31, 2019 is mainly attributable to decreases in lab supplies of \$916, analytical costs of \$171, study costs of \$132 and R&D salary expense of \$64, offset by a decrease in estimated R&D tax credits of \$122. The decrease in R&D expenses for the twelve-month period ended December 31, 2019 is mainly attributable to decreases in lab supplies of \$796, study costs of \$589 and R&D salaries of \$65, offset by a decrease in R&D estimated tax credits of \$71.

In the twelve-month period ended December 31, 2019 we recorded estimated Research and Development Tax Credits of \$367, compared with \$438 that was recorded in the same period of the previous year.

**Selling, general and administrative expenses**

SG&A expenses for the three-month period ended December 31, 2019 amounted to \$1,355, representing an increase of \$671 or 98%, compared to \$684 for the three-month period ended December 31, 2018. SG&A expenses for the twelve-month period ended December 31, 2019 amounted to \$5,800, representing an increase of \$801 or 16%, compared to \$4,999 recorded in the same period of 2018.

The increase in SG&A expenses for the three-month period ended December 31, 2019 is mainly attributable to increases in manufacturing expenses of \$297, a variation of the foreign exchange due to the depreciation of the foreign exchange rate expense due to the depreciation of the Canadian dollar compared to the U.S. dollar of \$207, salaries and compensation expenses of \$177 mainly attributable to the negative revaluation of the deferred share units ("DSUs") granted to non-employee directors which was less impactful than last year, and insurance expense of \$64, partially offset by a decrease in professional fees of \$107 and investor relations expenses of \$29. The increase in SG&A expenses for the twelve-month period ended December 31, 2019 is mainly attributable to the variation of the foreign exchange expense due to the depreciation of the Canadian dollar compared to the U.S. dollar of \$408, the increase in investor relations expenses of \$260 and the expense related to the write-off of the Laboval deposit of \$207 as well as increases in salaries and compensation expenses of \$150 attributable to new hires, and an increase in insurance expense of \$63. These increases were partially offset by a decrease in professional fees of \$273 which was mainly related to costs attributable to the 2018 aborted capital raise as well as costs related to the termination of the Laboval acquisition and a decrease in business development expenses of \$50.

#### **Depreciation of tangible assets**

In the three-month period ended December 31, 2019 we recorded an expense of \$195 for the depreciation of tangible assets, compared with an expense of \$179 thousand for the same period of the previous year. In the twelve-month period ended December 31, 2019 we recorded an expense of \$718 for the depreciation of tangible assets, compared with an expense of \$719 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, 2019 amounted to \$71 compared to \$59 for the three-month period ended December 31, 2018. Share-based compensation warrants and share-based payments expense for the twelve-month period ended December 31, 2019 amounted to \$333 compared to \$370 for the twelve-month period ended December 31, 2018.

We expensed approximately \$285 in the twelve-month period ended December 31, 2019 for options granted to our employees in 2018 and 2019 under the 2016 Stock Option Plans, \$48 for options granted to consultants in 2018 and 2019 and \$Nil for options granted to non-employee directors compared with \$320, \$11 and \$14 respectively that was expensed in the same period of the previous year. In the twelve-month period ended December 31, 2019, an amount of \$Nil was expensed for RSU's granted to the CEO and CFO under the PRSU Plan compared to \$25 in the same period for the previous year.

There remains approximately \$157 in stock-based compensation to be expensed in fiscal 2019 and 2020, \$121 of which relates to the issuance of options to our employees during 2018 and 2019 and \$36 relates to the issuance of options to consultants in 2018. 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, 2019	December 31, 2018	Increase/ (Decrease)	Percentage Increase/ (Decrease)
Current assets	\$ 3,220	\$ 13,063	\$ (9,843)	\$ (75%)
Leasehold improvements and equipment, net	6,365	6,248	117	2%
Security deposits	752	707	45	6%
Operating lease right-of-use asset	683	-	683	100%
Current liabilities (excluding convertible debentures)	3,205	2,722	483	18%
Long-term debt	470	1,140	(670)	(59%)
Convertible debentures	5,642	5,047	595	12%
Convertible notes	1,255	1,073	182	17%
Operating lease liability	555	-	555	100%
Capital Stock	1	1	0	0%
Additional paid-in-capital	42,635	42,048	587	1%

### Going Concern

The Company has financed its operations to date primarily through public offerings of its 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 United States 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, 2019, the Company had cash and short-term investments totaling approximately \$1,912. The Company does not have sufficient existing cash and short-term investments to support operations for the next year following the issuance of these financial statements. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans to alleviate these conditions include pursuing one or more of the following steps to raise additional funding, none of which can be guaranteed or are entirely within the Company's control:

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

On February 11, 2020, the Company announced that it closed its offering of 16,317,000 units at a price of CAD\$0.50 per Unit for a gross proceeds of CAD\$8,158,500.

If the Company is unable to further raise 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 delay, reduce or eliminate its research and development programs.

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 the possible inability of the Company to continue as a going concern. Should the Company be unable to continue as a going concern, it may be unable to realize the carrying value of its assets and to meet its liabilities as they become due.

**Current assets**

Current assets totaled \$3,220 at December 31, 2019 compared with \$13,063 at December 31, 2018. The decrease of \$9,843 is mainly attributable to decreases in cash of \$5,483, short term investments of \$3,600, accounts receivable of \$434, prepaid expenses of \$292, as well as a decrease in investment tax credits receivable of \$41.

**Cash**

Cash totaled \$1,332 as at December 31, 2019 representing a decrease of \$5,483 compared with the balance of \$6,815 as at December 31, 2018. The decrease in cash on hand relates to net cash used in operating activities of \$8,199 and net cash used in financing activities of \$690, partially offset by net cash provided from investing activities of \$3,205.

**Short term investments**

Short term investments totaled \$580 as at December 31, 2019, representing a decrease of \$3,600 compared with the balance of \$4,180 as at December 31, 2018. The decrease in short term investments is attributable to redemptions of investments to fund operations.

**Accounts receivable**

Accounts receivable totaled \$381 as at December 31, 2019 representing a decrease of \$434 compared with the balance of \$815 as at December 31, 2018. The decrease in accounts receivable is attributable to the decrease in revenues accounted for as at December 31, 2019.

**Prepaid expenses**

As at December 31, 2019, prepaid expenses totaled \$170 compared with \$462 as of December 31, 2018. The decrease in prepaid expenses is mainly attributable to the expensing of the Laboval deposit as a result of the termination of the potential acquisition in the amount CA\$275 (\$212) and advance payments in December 2018 of certain expenses that relate to services to be provided in the remainder of the year.

**Investment tax credits receivable**

R&D investment tax credits receivable totaled approximately \$375 as at December 31, 2019 compared with \$416 as at December 31, 2018. The decrease relates to the accrual estimated and recorded for the twelve-month period ended December 31, 2019 offset by the collection of the 2018 tax credits.

**Inventory**

As at December 31, 2019, inventories totaled \$382 compared to a balance of \$375 as at December 31, 2018.

**Leasehold improvements and equipment**

As at December 31, 2019, the net book value of leasehold improvements and equipment amounted to \$6,365, compared to \$6,248 at December 31, 2018. In the year ended December 31, 2019 additions to assets totaled \$525 and mainly comprised of \$351 for manufacturing equipment, \$131 for leasehold improvements, \$29 for laboratory and office equipment, and \$14 for computer equipment, offset by depreciation expense of \$718 and variation of foreign exchange fluctuation.

**Security deposit**

A security deposit in the amount of CA\$300 (\$231) 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, 2019. Security deposits in the amount of CA\$650 (\$500) for the term loans were also recorded as at December 31, 2019. The difference between the amount at December 31, 2019 and the amount at December 31, 2018 is related to the US currency fluctuation.

**Accounts payable and accrued liabilities**

Accounts payable and accrued liabilities totaled \$1,941 as at December 31, 2019 (December 31, 2018 - \$2,030). The decrease is mainly attributable to a decrease in payables related to R&D expenses.

**Long-term debt**

Long-term debt totaled \$1,197 as at December 31, 2019 (December 31, 2018 - \$1,832). The current portion of long-term debt totaled \$727 as at December 31, 2019 (December 31, 2018 - \$692). An amount of \$1,005 is attributable to term loan from the lender secured by a first ranking movable hypothec on all present and future movable property of the Company and a 50% guarantee by Export Development Canada, a Canadian Crown corporation export credit agency.

An amount of \$192 is attributable to a second loan secured by a second ranking on all present and future property of the Company.

### **Convertible debentures**

Convertible debentures totaled \$5,642 as at December 31, 2019 as compared to \$5,047 as at December 31, 2018. The Corporation issued a total aggregate principal amount of CAD\$7,600,000 (\$5,852,000) of debentures at a price of CAD\$1,000 (\$770) per debenture in July 2017 and August 2017. The convertible debentures have been recorded as a short term liability as at December 31, 2019 as it matures in June 2020. Total transactions costs in the amount of CAD\$1,237,000 (\$952,000) were recorded against the liability. The accretion expense for the year ended December 31, 2019 amounts to CAD\$443,000 (\$334,000) (CAD\$383,000, \$296,000 in 2018). The interest on the convertible debentures as at December 31, 2019 amounts to CAD\$606,000 (\$457,000) (CAD\$607,000, \$468,000 in 2018) and is recorded in Financing and interest expense.

### **Convertible notes**

Convertible notes totaled \$1,255 as at December 31, 2019 as compared to \$1,073 as at December 31, 2018. On May 8, 2018, 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 common shares of the Corporation, (ii) a \$5,000 convertible 6% note, and (iii) 7,690 warrants to purchase Common Stock. 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 Stock 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. 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, 2019 was \$182 thousand (\$98 thousand in 2018). The interest on the convertible notes as at December 31, 2019 was \$96 thousand (\$63 thousand in 2018) and was recorded as a financing and interest expense.

### **Shareholders' equity**

As at December 31, 2019 we had accumulated a deficit of \$41,507 compared with an accumulated deficit of \$30,896 as at December 31, 2018. Total assets amounted to \$11,020 and shareholders' equity totaled \$293 as at December 31, 2019, compared with total assets and shareholders' equity of \$20,018 and \$9,987 respectively, as at December 31, 2018.

### **Capital stock**

As at December 31, 2019 capital stock amounted to \$0.939 (December 31, 2018: \$0.935). 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 \$42,635 as at December 31, 2019, as compared to \$42,048 at December 31, 2018. Additional paid in capital increased by \$587 from which \$333 came from stock based compensation attributable to the amortization of stock options granted to employees, \$231 was the value of the interest paid by issuance of Common Stock, and \$21 from proceeds from exercise of stock options.

### **Taxation**

As at December 31, 2019, the date of our latest annual tax return, we had Canadian and provincial net operating losses of approximately \$23,101 (December 31, 2018: \$14,934) and \$25,264 (December 31, 2018: \$16,498) 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 2039. A portion of the net operating losses may expire before they can be utilized.

As at December 31, 2019, we had non-refundable tax credits of \$2,486 thousand (2018: \$1,981 thousand) of which \$8 thousand is expiring in 2026, \$10 thousand is expiring in 2027, \$174 thousand is expiring in 2028, \$152 thousand is expiring in 2029, \$130 thousand is expiring in 2030, \$138 thousand is expiring in 2031, \$173 thousand is expiring in 2032, \$115 thousand is expiring in 2033, \$87 thousand expiring in 2034, \$102 thousand is expiring in 2035, \$141 thousand expiring in 2036, \$270 thousand is expiring in 2037, \$582 thousand expiring in 2038 and \$404 thousand expiring in 2039 and undeducted research and development expenses of \$14,282 thousand (2018: \$10,663 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, 2019	December 31, 2018	Increase/ (Decrease)	Percentage Increase/ (Decrease)
Operating Activities	\$ (8,199)	\$ (8,530)	\$ 331	4%
Financing Activities	(690)	16,404	(17,094)	(104)%
Investing Activities	3,205	(2,177)	5,382	247%
Cash - end of period	1,332	6,815	(5,483)	(80)%

### Statement of cash flows

Net cash used in operating activities was \$8,199 for the twelve-month period ended December 31, 2019, compared to net cash used by operating activities of \$8,530 for the twelve-month period ended December 31, 2018. For the twelve-month period ended December 31, 2019, net cash used by operating activities consisted of a net loss of (\$10,660) (2018: \$10,108) before depreciation, stock-based compensation, accretion expense, DSU expense, interest paid by issuance of Common Stock and lease non-cash expense in the amount of \$1,906 (2018: \$1,860) and an increase in non-cash operating elements of working capital of \$555 compared with a decrease of \$282 for the twelve-month period ended December 31, 2018.

The net cash used in financing activities was \$690 for the twelve-month period ended December 31, 2019, compared to net cash provided by financing activities of \$16,404 for the twelve-month period ended December 31, 2018. 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. For twelve-month period ended December 31, 2018, an amount of \$11,405 derives from proceeds from the public offering, an amount of \$4,004 derives from the proceeds of a private placement and an amount of \$2,328 derives from proceeds from exercise of warrants and stock options offset by repayment of term loans for an amount of \$749 and the transaction costs related to the private placement of \$82 and the transaction costs related to the public offering of \$502.

Net cash provided by investing activities amounted to \$3,205 for the twelve-month period ended December 31, 2019 compared to net cash used in investing activities of \$2,177 for the twelve-month period ended December 31, 2018. The net cash provided by investing activities for the year ended December 31, 2019 relates to the redemptions of short-term investments of \$5,265 (2018: \$3,192) offset by the purchase of fixed assets for \$525 (2018: \$1,096) as well as acquisitions of short-term investments of \$1,535 (2018: \$4,273).

The balance of cash as at December 31, 2019 amounted to \$1,332, compared to \$6,815 at December 31, 2018.

### Commitments

On April 24, 2015, the Company 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 the Company has retained two options to extend the lease, with each option being for an additional five years. Under the terms of the lease the Company will be required to pay base rent of approximately CA\$116 thousand (approximately \$89 thousand) per year, which will increase at a rate of CA\$0.25 (\$0.19) per square foot, every two years.

On March 6, 2017, the Company into an agreement to lease 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 the Company has retained two options to extend the lease, with each option being for an additional five years. Under the terms of the lease the Company will be required to pay base rent of approximately CA\$74 thousand (approximately \$57 thousand) per year, which will increase at a rate of CA\$0.25 (\$0.19) per square foot, every two years.



The aggregate minimum rentals, exclusive of other occupancy charges, for property leases expiring in 2026, are approximately \$965 thousand, as follows:

2020	150
2021	152
2022	156
2023	158
2024	161
Thereafter	188

The Company has initiated a project to expand the existing manufacturing facility. The Company has signed agreements in the amount of Euro1,911 thousand with three suppliers with respect to equipment for solvent film manufacturing. As at December 31, 2019 an amount of Euro1,425 thousand has been paid with respect to these agreements.

#### **Subsequent events**

On February 11, 2020, the Company closed its offering of 16,317,000 units at a price of C\$0.50 per unit. Each unit consisted of one share of Common Stock and one warrant entitling the holder to purchase one share of Common Stock of the Company at an exercise price of \$0.75 per share. The offering was conducted on a commercially reasonable best efforts basis pursuant to that certain Agency Agreement dated as of January 27, 2020 by and between the Company and Echelon Wealth Partners Inc. The warrants are exercisable immediately and expire on February 11, 2023. The warrants are governed by that certain Warrant Indenture dated as of February 11, 2020 between the Company and TSX Trust Company.

On March 11, 2020, the World Health Organization declared the outbreak of a novel coronavirus ("COVID-19") as a global pandemic, which continues to spread throughout Canada and around the world. On March 23, 2020, the government of Quebec ordered the closure of all non-essential businesses effective March 25, 2020, through April 13, 2020. Because of the nature of its operations, the Company is only partially affected by this order. As of March 26, 2020, 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. This partial disruption, even temporary, may impact our operations and overall business by delaying the progress of our research and development programs and production activities. 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.

#### **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, 2019 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, 2019 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, 2019. 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, 2019 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 2020 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 2020 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 2020 Proxy Statement.

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

Certain information required by this Item 13 relating to certain relationships and related transactions, and director independence is incorporated by reference herein from the 2020 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 2020 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, 2019 and 2018.
- C. Consolidated Statements of Shareholders' Equity for the years ended of December 31, 2019 and 2018.
- D. Consolidated Statements of Comprehensive Loss for the years ended of December 31, 2019 and 2018.
- E. Consolidated Statements of Cash Flows for the years ended December 31, 2019 and 2018.
- 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
<a href="#">2.1</a>	<a href="#">Share exchange agreement dated April 10, 2006 (incorporated by reference to the Form 8-K/A filed on May 5, 2006)</a>
<a href="#">3.1</a>	<a href="#">Certificate of Incorporation (incorporated by reference to the Form SB-2 (File No. 333-90149) filed on November 16, 1999)</a>
<a href="#">3.2</a>	<a href="#">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)</a>
<a href="#">3.3</a>	<a href="#">Amendment to the Certificate of Incorporation (incorporated by reference to the Form DEF 14C filed on April 20, 2007)</a>
<a href="#">3.4</a>	<a href="#">Amendment to the Certificate of Incorporation (incorporated by reference to the Form S-1/A filed on May 12, 2017)</a>
<a href="#">3.5</a>	<a href="#">By-Laws (incorporated by reference to the Form SB-2 (File No. 333-91049) filed on November 16, 1999)</a>
<a href="#">3.6</a>	<a href="#">Amended and Restated By-Laws (incorporated by reference to the Form 8-K filed on March 31, 2011)</a>
<a href="#">3.7</a>	<a href="#">Amended and Restated By-Laws (incorporated by reference to the Form 8-K filed on March 21, 2012)</a>
<a href="#">4.1</a>	<a href="#">Trust Indenture with TSX Trust Company, dated July 12, 2017 (incorporated by reference to the Form 8-K filed on July 12, 2017)</a>
<a href="#">4.2</a>	<a href="#">Warrant Indenture dated February 11, 2020 (incorporated by reference to the Form 8-K filed on February 12, 2020)</a>
<a href="#">4.3*</a>	<a href="#">Description of the Company's Securities Registered Under Section 12 of the Securities Exchange Act of 1934</a>
<a href="#">9.1</a>	<a href="#">Voting Trust agreement (incorporated by reference to the Form 8-K/A filed on May 5, 2006)</a>

<a href="#"><u>10.1 +</u></a>	<a href="#"><u>Horst Zerbe employment agreement dated October 1, 2014 (incorporated by reference to the Form 10-Q filed on November 12, 2014)</u></a>
<a href="#"><u>10.2</u></a>	<a href="#"><u>Registration rights agreement (incorporated by reference to the Form SB-2 (File No. 333-135591) filed on July 3, 2006)</u></a>
<a href="#"><u>10.3</u></a>	<a href="#"><u>Principal's registration rights agreement (incorporated by reference to the Form SB-2 (File No. 333-135591) filed on July 3, 2006)</u></a>
<a href="#"><u>10.4 +</u></a>	<a href="#"><u>2006 Stock Option Plan (incorporated by reference to the Form S-8 filed on November 21, 2006)</u></a>
<a href="#"><u>10.5 +</u></a>	<a href="#"><u>Amended and Restated 2006 Stock Option Plan, May 29, 2008 (incorporated by reference to the Form 10-K filed on March 25, 2009)</u></a>
<a href="#"><u>10.6 +</u></a>	<a href="#"><u>Amended and Restated 2006 Stock Option Plan (incorporated by reference to the Form S-8 filed on November 15, 2010)</u></a>
<a href="#"><u>10.7</u></a>	<a href="#"><u>License and Asset Transfer Agreement with Edgemont Pharmaceuticals (incorporated by reference to the Form 10Q filed on May 15, 2012)</u></a>
<a href="#"><u>10.8</u></a>	<a href="#"><u>Development Services and Commercialization Agreement with PAR Pharmaceuticals, dated December 19, 2011 (incorporated by reference to the Form 10-K filed on March 11, 2014)</u></a>
<a href="#"><u>10.9+</u></a>	<a href="#"><u>Employment Agreement Andre Godin, July 2015 (incorporated by reference to the Form 8-K filed on July 20, 2015)</u></a>
<a href="#"><u>10.10+</u></a>	<a href="#"><u>Employment Agreement Nadine Paiement, January 2016 (incorporated by reference to the Form 10-K filed on March 30, 2016)</u></a>
<a href="#"><u>10.11+</u></a>	<a href="#"><u>Employment Agreement Dana Matzen, March 2016 (incorporated by reference to the Form 10-K filed on March 30, 2016)</u></a>
<a href="#"><u>10.12+</u></a>	<a href="#"><u>2016 Stock Option Plan May, 11 2016 (incorporated by reference to the Form S-8 Registration Statement filed on August 3, 2016)</u></a>
<a href="#"><u>10.13</u></a>	<a href="#"><u>Amended Principal's Registration Rights Agreement, November 8, 2016 (incorporated by reference to Form 10-Q filed on November 10, 2016)</u></a>
<a href="#"><u>10.14</u></a>	<a href="#"><u>Agency Agreement dated June 28, 2017 (incorporated by reference to the Form 8-K filed on July 5, 2017)</u></a>
<a href="#"><u>10.15+</u></a>	<a href="#"><u>Deferred Share Unit Plan for non-employee directors (incorporated by reference to the Form 10-K filed on March 29, 2018)</u></a>
<a href="#"><u>10.16</u></a>	<a href="#"><u>Placement Agent Agreement dated May 8, 2018 (incorporated by reference to the Form 8-K filed on May 10, 2018)</u></a>
<a href="#"><u>10.17</u></a>	<a href="#"><u>Form of Warrant dated May 8, 2018 (incorporated by reference to the Form 8-K filed on May 10, 2018)</u></a>
<a href="#"><u>10.18</u></a>	<a href="#"><u>Form of Securities Purchase Agreement dated May 8, 2018 (incorporated by reference to the Form 8-K filed on May 10, 2018)</u></a>
<a href="#"><u>10.19</u></a>	<a href="#"><u>Form of Registration Rights Agreement dated May 8, 2018 (incorporated by reference to the Form 8-K filed on May 10, 2018)</u></a>
<a href="#"><u>10.20</u></a>	<a href="#"><u>Form of Note dated May 8, 2018 (incorporated by reference to the Form 8-K filed on May 10, 2018)</u></a>
<a href="#"><u>10.21</u></a>	<a href="#"><u>Placement Agent Agreement between the Company and H.C. Wainwright &amp; Co., LLC dated October 18, 2018 (incorporated by reference to the Form 8-K filed on October 22, 2018)</u></a>
<a href="#"><u>10.22</u></a>	<a href="#"><u>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)</u></a>
<a href="#"><u>10.23</u></a>	<a href="#"><u>Form of Warrant (incorporated by reference to the Form 8-K on October 22, 2018)</u></a>
<a href="#"><u>10.24</u></a>	<a href="#"><u>Form of Securities Purchase Agreement (incorporated by reference to the Form 8-K filed on October 22, 2018)</u></a>
<a href="#"><u>10.25</u></a>	<a href="#"><u>Form of Agent Warrant (incorporated by reference to the Form S-1/A on filed on January 30, 2020)</u></a>
<a href="#"><u>10.26</u></a>	<a href="#"><u>Agency Agreement dated January 27, 2020 (incorporated by reference to the Form 8-K filed on January 29, 2020)</u></a>
<a href="#"><u>21.1</u></a>	<a href="#"><u>Subsidiaries of the small business issuer (incorporated by reference to the Form SB-2 (File No. 333-135591) filed on July 3, 2006)</u></a>
<a href="#"><u>23.1*</u></a>	<a href="#"><u>Consent of Richter LLP</u></a>
<a href="#"><u>31.1*</u></a>	<a href="#"><u>Certification of Horst G. Zerbe, President and Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u></a>
<a href="#"><u>31.2*</u></a>	<a href="#"><u>Certification of Andre Godin, Executive Vice President and Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u></a>
<a href="#"><u>32.1*</u></a>	<a href="#"><u>Certification of Horst G. Zerbe, President and Chief Executive Officer, pursuant to 18 U.S.C. Section 1350</u></a>
<a href="#"><u>32.2*</u></a>	<a href="#"><u>Certification of Andre Godin, Executive Vice President and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350</u></a>

\* Filed herewith.

+ Indicates management contract or employee compensation plan.

++ Portions of this exhibit have been omitted based on an application for confidential treatment from the SEC. The omitted portions of these exhibits have been submitted separately with the SEC.

**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 26, 2020, thereunto duly authorized.

### INTELGEX 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.

<b>Signature</b>	<b>Position</b>	<b>Date</b>
By: <i>/s/ Horst G. Zerbe</i> Horst G. Zerbe	Chief Executive Officer and Chairman of the Board	March 26, 2020
By: <i>/s/Andre Godin</i> Andre Godin	President and Chief Financial Officer	March 26, 2020
By: <i>/s/ Bernard Boudreau</i> J. Bernard Boudreau	Director, Vice Chairman of the Board	March 26, 2020
By: <i>/s/Bernd Melchers</i> Bernd J. Melchers	Director	March 26, 2020
By: <i>/s/John Marinucci</i> John Marinucci	Director	March 26, 2020
By: <i>/s/Clemens Mayr</i> Clemens Mayr	Director	March 26, 2020
By: <i>/s/Mark Nawacki</i> Mark Nawacki	Director	March 26, 2020

**IntelGenx Technologies Corp.**

**Consolidated Financial Statements**  
**December 31, 2019 and 2018**  
**(Expressed in U.S. Funds)**

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# IntelGenx Technologies Corp.

**Consolidated Financial Statements**  
**December 31, 2019 and 2018**  
**(Expressed in U.S. Funds)**

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# 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, 2019 and 2018, the related consolidated statements of comprehensive loss, shareholders' equity and cash flows for each of the two years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with the standards of the Public Company Accounting Oversight Board (United States).

### *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.

### *Change in Accounting Principle*

As discussed in Note 4 to the financial statements, the Company has changed its method of accounting for leases in 2019 due to the adoption of Financial Accounting Standards Board Accounting Standards Codification Topic 842, *Leases*.

### *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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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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 include 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.

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

Montréal, Quebec  
March 26, 2020

<sup>1</sup>CPA auditor, CA, public accountancy permit No. A112505

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# IntelGenx Technologies Corp.

## Consolidated Balance Sheets

As at December 31, 2019 and 2018

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

	2019	2018
<b>Assets</b>		
<b>Current</b>		
Cash	\$ 1,332	\$ 6,815
Short-term investments (note 6)	580	4,180
Accounts receivable	381	815
Prepaid expenses	170	462
Investment tax credits receivable	375	416
Inventory (note 7)	382	375
<b>Total current assets</b>	<b>3,220</b>	<b>13,063</b>
<b>Leasehold improvements and equipment, net</b> (note 8)	<b>6,365</b>	<b>6,248</b>
<b>Security deposits</b>	<b>752</b>	<b>707</b>
<b>Operating lease right-of-use-asset</b> (note 19)	<b>683</b>	<b>-</b>
<b>Total assets</b>	<b>\$ 11,020</b>	<b>\$ 20,018</b>
<b>Liabilities</b>		
<b>Current</b>		
Accounts payable and accrued liabilities	1,941	2,030
Current portion of long-term debt (note 10)	727	692
Current portion of operating lease liability (note 19)	137	-
Convertible debentures (note 11)	5,642	-
<b>Total current liabilities</b>	<b>8,447</b>	<b>2,722</b>
<b>Deferred lease obligations</b>	<b>-</b>	<b>49</b>
<b>Long-term debt</b> (note 10)	<b>470</b>	<b>1,140</b>
<b>Convertible debentures</b> (note 11)	<b>-</b>	<b>5,047</b>
<b>Convertible notes</b> (note 12)	<b>1,255</b>	<b>1,073</b>
<b>Operating lease liability</b> (note 19)	<b>555</b>	<b>-</b>
<b>Total liabilities</b>	<b>10,727</b>	<b>10,031</b>
<b>Commitments (note 13)</b>		
<b>Subsequent event (note 22)</b>		
<b>Shareholders' equity</b>		
Capital stock, common shares, \$0.00001 par value; 200,000,000 shares authorized; 93,942,652 shares issued and outstanding (2018: 93,477,473 common shares) (note 14)	1	1
Additional paid-in capital (note 15)	42,635	42,048
Accumulated deficit	(41,507)	(30,896)
Accumulated other comprehensive loss	(836)	(1,166)
<b>Total shareholders' equity</b>	<b>293</b>	<b>9,987</b>
	<b>\$ 11,020</b>	<b>\$ 20,018</b>

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, 2018

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

	Capital Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Shareholders' Equity
	Number	Amount				
<b>Balance - December 31, 2017</b>	67,031,467	\$ 1	\$ 25,253	\$ (20,788)	\$ (637)	\$ 3,829
Other comprehensive loss	-	-	-	-	(529)	(529)
Common stock issued, net of transaction costs of \$1,906 (note 14)	22,017,295	-	11,647	-	-	11,647
Warrants issued, net of transaction costs of \$322 (note 14)	-	-	1,873	-	-	1,873
Agents' warrants issued (note 14)	-	-	330	-	-	330
Interest paid by issuance of common shares (note 11)	307,069	-	231	-	-	231
Conversion of convertible debentures (note 11)	17,036	-	16	-	-	16
Warrants exercised (note 14)	4,044,606	-	2,295	-	-	2,295
Options exercised (note 14)	60,000	-	33	-	-	33
Stock-based compensation (note 14)	-	-	370	-	-	370
Net loss for the year	-	-	-	(10,108)	-	(10,108)
<b>Balance - December 31, 2018</b>	<b>93,477,473</b>	<b>\$ 1</b>	<b>\$ 42,048</b>	<b>\$ (30,896)</b>	<b>\$ (1,166)</b>	<b>\$ 9,987</b>

See accompanying notes

# 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 Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Shareholders' Equity
	Number	Amount				
<b>Balance - December 31, 2018</b>	93,477,473	\$ 1	\$ 42,048	\$ (30,896)	\$ (1,166)	\$ 9,987
Modified retrospective adjustment upon adoption of ASC 842 (note 4)	-	-	-	49	-	49
Other comprehensive income	-	-	-	-	330	330
Interest paid by issuance of common shares (note 11)	415,179	-	233	-	-	233
Options exercised (note 14)	50,000	-	21	-	-	21
Stock-based compensation (note 14)	-	-	333	-	-	333
Net loss for the year	-	-	-	(10,660)	-	(10,660)
<b>Balance - December 31, 2019</b>	<b>93,942,652</b>	<b>\$ 1</b>	<b>\$ 42,635</b>	<b>\$ (41,507)</b>	<b>\$ (836)</b>	<b>\$ 293</b>

See accompanying notes

# IntelGenx Technologies Corp.

Consolidated Statements of Comprehensive Loss  
For the Years Ended December 31, 2019 and 2018  
(Expressed in Thousands of U.S. Dollars (\$'000) Except Share and Per Share Data)

	2019	2018
<b>Revenues (note 17)</b>	<b>\$ 742</b>	<b>\$ 1,824</b>
<b>Total revenues</b>	<b>742</b>	<b>1,824</b>
<b>Expenses</b>		
Research and development expense	3,774	5,104
Selling, general and administrative expense	5,800	4,999
Depreciation of tangible assets	718	719
<b>Total expenses</b>	<b>10,292</b>	<b>10,822</b>
<b>Operating loss</b>	<b>(9,550)</b>	<b>(8,998)</b>
<b>Interest income</b>	<b>97</b>	<b>11</b>
<b>Financing and interest expense</b>	<b>(1,207)</b>	<b>(1,121)</b>
<b>Net financing and interest expense</b>	<b>(1,110)</b>	<b>(1,110)</b>
<b>Loss before income taxes</b>	<b>(10,660)</b>	<b>(10,108)</b>
Income taxes (note 16)	-	-
<b>Net loss</b>	<b>(10,660)</b>	<b>(10,108)</b>
<b>Other comprehensive income (loss)</b>		
Change in fair value	46	3
Foreign currency translation adjustment	284	(532)
	330	(529)
<b>Comprehensive loss</b>	<b>\$ (10,330)</b>	<b>\$ (10,637)</b>
<b>Basic and diluted:</b>		
<b>Weighted average number of shares outstanding</b>	<b>93,525,413</b>	<b>74,121,922</b>
<b>Basic and diluted loss per common share (note 21)</b>	<b>\$ (0.11)</b>	<b>\$ (0.14)</b>

See accompanying notes

# IntelGenx Technologies Corp.

## Consolidated Statements of Cash Flows

For the Year Ended December 31, 2019 and 2018

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

	2019	2018
<b>Funds (used) provided -</b>		
<b>Operating activities</b>		
Net loss	\$ (10,660)	\$ (10,108)
Depreciation of tangible assets	718	719
Stock-based compensation	333	370
Accretion expense	514	396
DSU expense	105	160
Interest paid by issuance of common shares	228	231
Lease non-cash expense	8	-
Conversion of convertible debentures	-	(16)
	<b>(8,754)</b>	<b>(8,248)</b>
Changes in non-cash items related to operations:		
Accounts receivable	426	(192)
Prepaid expenses	292	(259)
Investment tax credits receivable	41	(102)
Inventory	-	(375)
Security deposits	-	(11)
Accounts payable and accrued liabilities	(204)	658
Deferred lease obligations	-	(1)
<b>Net change in non-cash items related to operations</b>	<b>555</b>	<b>(282)</b>
<b>Net cash used in operating activities</b>	<b>(8,199)</b>	<b>(8,530)</b>
<b>Financing activities</b>		
Repayment of long-term debt	(711)	(749)
Proceeds from exercise of warrants and stock options	21	2,328
Net proceeds from private placement	-	4,004
Transaction costs of private placement	-	(82)
Net proceeds from public offering	-	11,405
Transaction costs of public offering	-	(502)
<b>Net cash (used in) provided by financing activities</b>	<b>(690)</b>	<b>16,404</b>
<b>Investing activities</b>		
Additions to leasehold improvements and equipment	(525)	(1,096)
Acquisitions of short-term investments	(1,535)	(4,273)
Redemptions of short-term investments	5,265	3,192
<b>Net cash provided by (used in) investing activities</b>	<b>3,205</b>	<b>(2,177)</b>
<b>(Decrease) Increase in cash</b>	<b>(5,684)</b>	<b>5697</b>
<b>Effect of foreign exchange on cash</b>	<b>201</b>	<b>(473)</b>
<b>Cash</b>		
<b>Beginning of year</b>	<b>6,815</b>	<b>1,591</b>
<b>End of year</b>	<b>\$ 1,332</b>	<b>\$ 6,815</b>

See accompanying notes

# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2019 and 2018

(Expressed in U.S. Funds)

### 1. Basis of Presentation

IntelGenx Technologies Corp. ("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 the Company and its subsidiary companies. 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<sup>®</sup>. 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, 2019, the Company had cash and short-term investments totaling approximately \$1,912. The Company does not have sufficient existing cash and short-term investments to support operations for the next year following the issuance of these financial statements. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans to alleviate these conditions include pursuing one or more of the following steps to raise additional funding, none of which can be guaranteed or are entirely within the Company's control:

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

On February 11, 2020, the Company announced that it has closed its offering (the "Offering") of 16,317,000 units (the "Units") at a price of CAD\$0.50 per Unit (the "Offering Price") for gross proceeds of CAD\$8,158,500.

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 delay, reduce or eliminate its research and development programs.

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.

# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2019 and 2018

(Expressed in U.S. Funds)

### 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. 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, idiopathic pulmonary fibrosis, and pain management. Of the products currently under development, 10 utilize the *VersaFilm*™ technology and one utilizes the *AdVersa*™ technology.

### 4. Adoption of New Accounting Standards

The Company adopted Topic 842 Leases with a date of the initial application of January 1, 2019. As a result, the Company has changed its accounting policy for leases as detailed below.

The Company adopted Topic 842 using a modified retrospective approach with a date of initial application of January 1, 2019, which requires the recognition of the right-of-use assets and related operating and finance lease liabilities on the balance sheet. As a result, the consolidated balance sheet prior to January 1, 2019 was not restated, continues to be reported under ASC Topic 840, Leases, or ASC 840, which did not require the recognition of operating lease liabilities on the balance sheet, and is not comparative. Under ASC 842, all leases are required to be recorded on the balance sheet and are classified as either operating or finance leases. The lease classification affects the expense recognition in the income statement. Operating lease charges are recorded entirely in selling, general and administrative expense. Finance lease charges are split, where amortization of the right-of-use asset is recorded in selling, general and administrative expense and an implied interest component is recorded in financing and interest expense. At the moment of initial application, the Company did not hold any finance leases. The expense recognition for operating leases under ASC 842 is substantially consistent with ASC 840. As a result, there is no significant difference in our results of operations presented in our consolidated income statement and consolidated statement of comprehensive loss for each period presented.



# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2019 and 2018

(Expressed in U.S. Funds)

### 4. Adoption of New Accounting Standards (Cont'd)

The adoption of ASC 842 had a substantial impact on the Company's balance sheet. The most significant impact was the recognition of the operating lease right-of-use asset and operating lease liability. Upon adoption, leases that were classified as operating leases under ASC 840 were classified as operating leases under ASC 842, and the Company recorded an adjustment of \$726 to operating lease right-of-use asset and the related operating lease liability. The operating lease liability is based on the present value of the remaining minimum lease payments, determined under ASC 840, discounted using our secured incremental borrowing rate at the effective date of January 1, 2019, using the original lease term and the tenor. As permitted under ASC 842, the Company elected to use the practical expedient that permits to use hindsight in determining the lease term. The application of the practical expedients did not have a significant impact on the measurement of the operating lease liability.

The impact of the adoption of ASC 842 on the balance sheet as at December 31, 2018 was:

	As reported <u>December 31,</u> 2018	Adoption of ASC 842 <u>Increase</u> <u>(Decrease)</u>	Balance <u>January 1, 2019</u>
Operating lease right-of-use assets	\$ -	\$ 726	\$ 726
Total assets	20,018	726	20,744
Total current liabilities	2,722	127	2,849
Deferred lease obligations	49	(49)	-
Operating lease liability	-	599	599
Total liabilities	10,031	677	10,708
Total shareholders' equity	9,987	49	10,036
Total liabilities and shareholders' equity	20,018	726	20,744

The FASB issued ASU 2018-07 to expand the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from non-employees. These amendments are effective for a public business entity for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The adoption of this statement did not have a material effect on the Company's financial position of results.

### 5. Summary of Significant Accounting Policies

#### 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.

# IntelGenx Technologies Corp.

Notes to Consolidated Financial Statements  
December 31, 2019 and 2018  
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## 5. Summary of Significant Accounting Policies (Cont'd)

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.

### *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.

# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2019 and 2018

(Expressed in U.S. Funds)

### 5. Summary of Significant Accounting Policies (Cont'd)

#### 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.

#### Accounts Receivable

The Company accounts for trade receivables at original invoice amount less an estimate made for doubtful receivables based on a review of all outstanding amounts on a quarterly basis. Management determines the allowance for doubtful accounts by regularly evaluating individual customer receivables and considering a customer's financial condition, credit history and current economic conditions. The Company writes off trade receivables when they are deemed uncollectible and records recoveries of trade receivables previously written off when they receive them. Management has determined that no allowance for doubtful accounts is necessary in order to adequately cover exposure to loss in its December 31, 2019 accounts receivable (2018: \$Nil). A bad debt expense in the amount of \$Nil (2018: \$Nil) is recorded in the year ended December 31, 2019.

#### 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, 2019 totaled \$416 thousand (2018: \$289).

#### 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.

# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2019 and 2018

(Expressed in U.S. Funds)

### 5. 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 and the Company does not hold any finance 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.

# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2019 and 2018

(Expressed in U.S. Funds)

### 5. Summary of Significant Accounting Policies (Cont'd)

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-term 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.

#### 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.

# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2019 and 2018

(Expressed in U.S. Funds)

### 5. Summary of Significant Accounting Policies (Cont'd)

#### 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.

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.

# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2019 and 2018

(Expressed in U.S. Funds)

### 5. Summary of Significant Accounting Policies (Cont'd)

#### 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.

#### Recent Accounting Pronouncements

##### 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:

# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

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(Expressed in U.S. Funds)

### 5. Summary of Significant Accounting Policies (Cont'd)

- 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.

#### **ASU 2019-11 Codification Improvements to Topic 326, Financial Instruments - Credit Losses**

The FASB issued ASU 2019-11 which clarifies guidance around how to report expected recoveries. "Expected recoveries" describes a situation in which an organization recognizes a full or partial writeoff of the amortized cost basis of a financial asset, but then later determines that the amount written off, or a portion of that amount, will in fact be recovered. This ASU permits organizations to record expected recoveries on PCD assets.

These amendments are effective for fiscal years beginning after December 15, 2019. The Company is currently evaluating the impact of this Statement on its consolidated financial statements.

#### **ASU 2019-08 Compensation - Stock Compensation (Topic 718) and Revenue from Contracts with Customers (Topic 606): Codification Improvements - Share-Based Consideration Payable to a Customer**

The FASB issued ASU 2019-08 which requires companies to measure and classify (on the balance sheet) share-based payments to customers by applying the guidance in Topic 718, Compensation-Stock Compensation. As a result, the amount recorded as a reduction in revenue would be measured based on the grant-date fair value of the share-based payment.

These amendments are effective for fiscal years beginning after December 15, 2019. The Company is currently evaluating the impact of this Statement on its consolidated financial statements.

#### **ASU 2019-05 Credit Losses (Topic 326): Targeted Transition Relief**

The FASB issued ASU 2019-05 which provides entities that have certain instruments within the scope of Subtopic 326-20, Financial Instruments - Credit Losses - Measured at Amortized Cost, with an option to irrevocably elect the fair value option in Subtopic 825-10, Financial Instruments - Overall, applied on an instrument-by-instrument basis for eligible instruments, upon adoption of Topic 326. The fair value option election does not apply to held-to-maturity debt securities. An entity that elects the fair value option should subsequently apply the guidance in Subtopics 820-10, Fair Value Measurement - Overall, and 825-10.

These amendments are effective for fiscal years beginning after December 15, 2019. The Company is currently evaluating the impact of this Statement on its consolidated financial statements.



# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2019 and 2018

(Expressed in U.S. Funds)

### 5. Summary of Significant Accounting Policies (Cont'd)

#### ASU 2018-19 Codification Improvements to Topic 326, Financial Instruments-Credit Losses

The FASB issued ASU 2018-19 which mitigates transition complexity by requiring entities other than public business entities, including not-for-profit organizations and certain employee benefit plans, to implement the credit losses standard issued in 2016, for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. This aligns the implementation date for their annual financial statements with the implementation date for their interim financial statements. The guidance also clarifies that receivables arising from operating leases are not within the scope of the credit losses standard, but rather, should be accounted for in accordance with the leases standard.

These amendments are effective for fiscal years beginning after December 15, 2019. The Company is currently evaluating the impact of this Statement on its consolidated financial statements.

#### ASU 2018-18 Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606

The FASB issued ASU 2018-18 which provides guidance on how to assess whether certain transactions between collaborative arrangement participants should be accounted for within the revenue recognition standard.

The ASU also provides more comparability in the presentation of revenue for certain transactions between collaborative arrangement participants. It accomplishes this by allowing organizations to only present units of account in collaborative arrangements that are within the scope of the revenue recognition standard together with revenue accounted for under the revenue recognition standard. The parts of the collaborative arrangement that are not in the scope of the revenue recognition standard should be presented separately from revenue accounted for under the revenue recognition standard.

These amendments are effective for fiscal years beginning after December 15, 2019. The Company is currently evaluating the impact of this Statement on its consolidated financial statements.

#### ASU 2018-13 - Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement

The FASB issued ASU 2018-13 which modifies the disclosure requirements in Topic 820 as follows:

##### *Removals*

- The amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy;
- The policy for timing of transfers between levels;
- The valuation processes for Level 3 fair value measurements; and
- For nonpublic entities, the changes in unrealized gains and losses for the period included in earnings for recurring Level 3 fair value measurements held at the end of the reporting period.

# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2019 and 2018

(Expressed in U.S. Funds)

### 5. Summary of Significant Accounting Policies (Cont'd)

#### *Modifications*

-In lieu of a rollforward for Level 3 fair value measurements, a nonpublic entity is required to disclose transfers into and out of Level 3 of the fair value hierarchy and purchases and issues of Level 3 assets and liabilities;

-For investments in certain entities that calculate net asset value, an entity is required to disclose the timing of liquidation of an investee's assets and the date when restrictions from redemption might lapse only if the investee has communicated the timing to the entity or announced the timing publicly; and

-The amendments clarify that the measurement uncertainty disclosure is to communicate information about the uncertainty in measurement as of the reporting date

#### *Additions*

-The changes in unrealized gains and losses for the period included in other comprehensive income for recurring Level 3 fair value measurements held at the end of the reporting period; and

- The range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. For certain unobservable inputs, an entity may disclose other quantitative information (such as the median or arithmetic average) in lieu of the weighted average if the entity determines that other quantitative

information would be a more reasonable and rational method to reflect the distribution of unobservable inputs used to develop Level 3 fair value measurements.

These amendments are effective for fiscal years beginning after December 15, 2019. The Company is currently evaluating the impact of this Statement on its consolidated financial statements.

### 6. Short-term investments

As at December 31, 2019, short-term investments consisted of investments in mutual funds of \$580 thousand (CAD\$754 thousand) (2018 - \$4,180 (CAD\$5,703 million)) and are with a Canadian financial institution having a high credit rating.

### 7. Inventory

Inventory as at December 31, 2019 consisted of raw materials in the amount of \$382 thousand (2018 - \$375 thousand).

# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

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(Expressed in U.S. Funds)

### 8. Leasehold improvements and Equipment

	Cost	Accumulated Depreciation	2019 Net Carrying Amount	2018 Net Carrying Amount
Manufacturing equipment	\$ 4,657	\$ 879	\$ 3,778	\$ 3,512
Laboratory and office equipment	1,368	870	498	562
Computer equipment	125	85	40	39
Leasehold improvements	3,325	1,276	2,049	2,135
	\$ 9,475	\$ 3,110	\$ 6,365	\$ 6,248

From the balance of manufacturing equipment, an amount of \$1,788 thousand (2018 - \$1,703 thousand) represents assets which are still under construction as at December 31, 2019 and are consequently not depreciated. The commitment of the Company for the remainder of the project is as disclosed in note 13.

### 9. 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 (\$192 thousand) and corporate credits cards of up to CAD\$75 thousand (\$58 thousand), and foreign exchange contracts limited to CAD\$425 thousand (\$327 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 10) 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 (\$3,272,000) 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, 2019, 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.

# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2019 and 2018

(Expressed in U.S. Funds)

### 10. Long-term debt

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

	December 31, 2019 \$	December 31, 2018 \$
Term loan facility	1,005	1,502
Secured loan	192	330
Total debt	1,197	1,832
Less: current portion	727	692
Total long-term debt	470	1,140

The Company's term loan facility consists of a total of CAD\$4 million (\$3.08 million) bearing interest at the Bank's prime lending rate plus 2.50%, with monthly principal repayments of CAD\$62 thousand (\$48 thousand). The term loan is subject to the same security and financial covenants as the bank indebtedness (see note 9).

The secured loan has a principal balance authorized of CAD\$1 million (\$770 thousand) bearing interest at prime plus 7.3%, reimbursable in monthly principal payments of CAD\$17 thousand (\$13 thousand). The loan is secured by a second ranking on all present and future property of the Company. 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, 2019, the Company was not in compliance with its financial covenants. The Company has obtained a waiver from the lender.

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

2020	727 (CAD 945)
2021	470 (CAD 610)

### 11. 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 (\$5,265,000). Pursuant to the Offering, the Corporation issued an aggregate principal amount of CAD\$6,838,000 (\$5,265,000) of Debentures at a price of CAD\$1,000 (\$770) per Debenture. The Debentures will mature on June 30, 2020 and bear interest at 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 (\$1.04) (the "Conversion Price") per common share of the Corporation ("Share"), being a conversion rate of approximately 740 Shares per CAD\$1,000 (\$770) principal amount of Debentures, subject to adjustment in certain events.

# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2019 and 2018

(Expressed in U.S. Funds)

### 11. Convertible Debentures (Cont'd)

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 (\$587,000).

Together with the principal amount of CAD\$6,838,000 (\$5,265,000) of Debentures issued on July 12, 2017, the Corporation issued a total aggregate principal amount of CAD\$7,600,000 of Debentures at a price of CAD\$1,000 (\$770) per Debenture.

The convertible debentures have been recorded as a liability. Total transactions costs in the amount of CAD\$1,237,000 (\$952,000) were recorded against the liability. The accretion expense for the year ended December 31, 2019 amounts to CAD\$443,000 (\$334,000) compared to CAD\$383,000 (\$296,000) for the year ended December 31, 2018.

During the year ended December 31, 2018, CAD\$23,000 (\$17,000) of convertible debentures were converted into 17,036 common shares at the option of the holders, resulting in an increase in additional paid-in capital of \$16 thousand.

The components of the convertible debentures are as follows:

	December 31, 2019	December 31, 2018
Face value of the convertible debentures	\$ 5,835	\$ 5,556
Transaction costs	(952)	(907)
Accretion	759	398
Convertible debentures	\$ 5,642	\$ 5,047

Interest accrued during the year ended December 31, 2019 on the convertible debentures amounts to CAD\$606 thousand (\$457 thousand) out of which and 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.

Interest accrued during the year ended December 31, 2018 on the convertible debentures amounts to CAD\$607 thousand (\$468 thousand) out of which CAD\$304 thousand (\$231 thousand) was paid by issuance of 307,069 common shares on July 3, 2018 and CAD\$303 thousand (\$237 thousand) was paid in cash on December 28, 2018.

### 12. 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.

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),

# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2019 and 2018

(Expressed in U.S. Funds)

### 12. Convertible Notes (Cont'd)

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, 2019 amounts to \$182,000 (2018: \$98,000). The warrants have been recorded as equity.

The components of the convertible notes are as follows:

	December 31, 2019	December 31, 2018
Attributed value of net proceeds to convertible notes	\$ 975	\$ 975
Accretion	280	98
Convertible note	\$ 1,255	\$ 1,073

The interest on the convertible notes for the year ended December 31, 2019 amounts to \$96,000 (2018: \$63,000) 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.

# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2019 and 2018

(Expressed in U.S. Funds)

### 13. Commitments

The Company has initiated a project to expand the existing manufacturing facility. The Company has signed agreements in the amount of Euro1,911 thousand with three suppliers with respect to equipment for solvent film manufacturing. As at December 31, 2019 an amount of Euro1,425 thousand has been paid with respect to these agreements (note 8).

### 14. Capital Stock

	2019	2018
Authorized -		
200,000,000 common shares of \$0.00001 par value		
20,000,000 preferred shares of \$0.00001 par value		
Issued -		
93,942,652 (December 31, 2018: 93,477,473) common shares	\$ 1	\$ 1

#### Private placement

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

Each Unit is comprised of (i) 7,940 common shares of the Corporation ("Common Shares"), (ii) a \$5,000 convertible 6% note (a "Note"), and (iii) 7,690 warrants to purchase common shares of the Corporation ("Warrants"). Each Note bears interest at a rate of 6% (payable quarterly, in arrears, with the first payment being due on September 1, 2018), 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, resulting in an increase in additional paid-in-capital of \$50 thousand.

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

# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2019 and 2018

(Expressed in U.S. Funds)

### 14. Capital Stock (Cont'd)

#### Private Placement Financing

On November 13, 2018, the Company announced the closing of Tilray Inc.'s strategic investment in IntelGenx by way of a private placement. Pursuant to the private placement, the Company issued 1,428,571 common shares at a subscription price of \$0.70 per common share for gross proceeds of \$1,000,000, resulting in an increase in additional paid-in capital of \$1,000,000.

#### Public Offering

On October 22, 2018, IntelGenx announced the closing of 17,144,314 units at a price of US\$0.70 for gross proceeds of approximately US\$12 million in the United States and the Canadian provinces of Alberta, British Columbia, Manitoba, Ontario and Quebec.

On October 26, 2018 IntelGenx announced that Echelon Wealth Partners Inc., who acted as the Company's exclusive placement agent in Canada in connection with the Offering, had exercised its option to place a further 903,610 Units pursuant to its over-allotment option, resulting in additional gross proceeds to the Company of US\$632,527.

Each Unit will consist of one share of common stock of the Company and one half of one warrant, each whole Warrant to purchase one share of common stock of the Company at an exercise price of US\$1.00 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 \$9,187 and \$1,436 for the warrants issued, resulting in an increase in additional paid-in-capital of \$10,623.

In connection with the Offering, the Company paid to the Agents a cash commission of approximately \$560,000 in the aggregate and issued non-transferable agents' warrants to the Agents, entitling the Agents to purchase 1,226,360 common shares at a price of \$0.875 per share until June 1, 2021. Management has determined the value of the agents' warrants to be \$280,000, resulting in an increase in additional paid-in-capital of \$280 thousand.

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	\$	10,926	\$	1,739	\$ 9,187
Warrants		1,708		272	1,436
	\$	12,634	\$	2,011	\$ 10,623



# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2019 and 2018

(Expressed in U.S. Funds)

### 14. Capital Stock (Cont'd)

#### Stock options

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.

During the year ended December 31, 2018 a total of 60,000 stock options were exercised for 60,000 common shares having a par value of \$0 thousand in aggregate, for cash consideration of \$33 thousand, resulting in an increase in additional paid-in capital of \$33 thousand.

Stock-based compensation of \$333 thousand and \$370 thousand was recorded during the year ended December 31, 2019 and 2018 respectively. An amount of \$286 thousand (2018 - \$356 thousand) expensed relates to stock options granted to employees and directors and an amount of \$47 thousand (2018- \$14 thousand) relates to stock options granted to consultants during the year ended December 31, 2018. As at December 31, 2019 the Company has \$157 thousand (2018 - \$453 thousand) of unrecognized stock-based compensation, of which \$36 thousand (2018 - \$83) relates to options granted to consultants.

#### Warrants

In the year ended December 31, 2018 a total of 4,044,606 warrants were exercised for 4,044,606 common shares having a par value of \$Nil in aggregate, for cash consideration of approximately \$2,295 thousand, resulting in an increase in additional paid-in capital of approximately \$2,295 thousand. No warrants were exercised in 2019.

### 15. 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.

# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2019 and 2018

(Expressed in U.S. Funds)

### 15. 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:

	2019	2018
Exercise price	0.69	0.74
Expected volatility	64%	5.9%
Expected life	5.63 years	5.63 years
Risk-free interest rate	2.18%	2.73%
Dividend yield	Nil	Nil

The weighted average fair value of the options granted to employees during the year ended December 31, 2019 is \$0.40 (2018 - \$0.40).

The weighted average fair value of the options granted to consultants during the year ended December 31, 2018 is \$0.19. No options were granted to consultants during the year ended December 31, 2019.

Information with respect to employees and directors stock option activity for 2018 and 2019 is as follows:

	Number of options	Weighted average exercise price \$
Outstanding - January 1, 2018	2,939,818	0.65
Granted	1,250,000	0.74
Forfeited	(175,000)	(0.69)
Expired	(100,000)	(0.52)
Exercised	(60,000)	(0.56)
Outstanding - December 31, 2018	3,854,818	0.68
Granted	100,000	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

# IntelGenx Technologies Corp.

Notes to Consolidated Financial Statements  
December 31, 2019 and 2018  
(Expressed in U.S. Funds)

## 15. Additional Paid-In Capital (Cont'd)

Information with respect to consultant's stock option activity for 2018 and 2019 is as follows:

	Number of options	Weighted average exercise price \$
Outstanding - January 1, 2018	50,000	0.73
Granted	500,000	0.72
Outstanding - December 31, 2018 and 2019	550,000	0.72

Details of stock options outstanding as at December 31, 2019 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 \$
0.41	275,000	0.07	0.03		275,000	0.03	
0.58	675,000	0.09	0.10		675,000	0.12	
0.62	150,000	0.01	0.02		150,000	0.03	
0.66	200,000	0.41	0.03		150,000	0.03	
0.69	100,000	0.23	0.02		25,000	0.01	
0.70	475,000	0.35	0.08		237,500	0.05	
0.73	525,000	0.82	0.10		525,000	0.11	
0.76	905,000	1.87	0.17		705,000	0.16	
0.77	359,818	0.69	0.07		359,818	0.08	
0.78	100,000	0.04	0.02		50,000	0.01	
0.89	250,000	0.44	0.06		250,000	0.07	
	4,014,818	5.02	0.70	16,500	3,402,318	0.70	16,500

# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2019 and 2018

(Expressed in U.S. Funds)

### 15. Additional Paid-In Capital (Cont'd)

Stock-based compensation expense recognized in 2019 with regards to the stock options was \$333 thousand (2018: \$345 thousand). As at December 31, 2019 the Company has \$157 thousand (2018 - \$453 thousand) of unrecognized stock-based compensation, of which \$36 thousand (2018 - \$83 thousand) relates to options granted to consultants. The amount of \$157 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 \$157 thousand being charged to stock-based compensation expense.

#### Warrants

In the year ended December 31, 2018 a total of 4,044,606 warrants were exercised for 4,044,606 common shares having a par value of \$Nil in aggregate, for cash consideration of approximately \$2,295 thousand, resulting in an increase in additional paid-in capital of approximately \$2,295 thousand. No warrants were exercised in 2019.

Information with respect to warrant activity for 2018 and 2019 is as follows:

	Number of warrants (All Exercisable)	Weighted average exercise price \$
Outstanding - January 1, 2018	4,070,902	0.5646
Granted	12,954,397	0.9464
Exercised	(4,044,606)	(0.5675)
Expired	(76,296)	(0.5646)
Outstanding - December 31, 2018 and 2019	12,904,397	0.9470

# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2019 and 2018

(Expressed in U.S. Funds)

### 15. Additional Paid-In Capital (Cont'd)

#### 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 (287,355 on May 16, 2018) have been granted under the DSU Plan, accordingly, an amount of \$128 thousand (\$160 thousand in 2018) has been recognized in general and administrative expenses.

#### 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, 2018, 53,846 rewards have been issued under the PRSU Plan, accordingly an amount of \$25 thousand has been recognized as stock-based compensation in general and administrative expenses in 2018. No rewards were granted under the PRSU Plan in 2019.

### 16. Income Taxes

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

	2019	2018
Statutory income taxes	\$ (2,398)	\$ (2,421)
Net operating losses for which no tax benefits have been recorded	1,189	1,185
Deficiency of depreciation over capital cost allowance	(178)	(236)
Non-deductible expenses	667	422
Undeducted research and development expenses	820	1,167
Investment tax credit	(100)	(117)
	\$ -	\$ -

# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2019 and 2018

(Expressed in U.S. Funds)

### 16. Income Taxes (Cont'd)

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

	2019		2018
Leasehold improvements and equipment	\$ 440	\$	418
Net operating losses carryforward	6,396		4,170
Undeducted research and development expenses	2,903		2,774
Non-refundable tax credits carryforward	2,082		1,982
	11,821		9,344
Valuation allowance	(11,821)		(9,344)
	\$ -	\$	-

As at December 31, 2019, 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 \$23,101 thousand (2018: \$14,934 thousand) and \$25,264 thousand (2018: \$16,498 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 2039. A portion of the net operating losses may expire before they can be utilized.

As at December 31, 2019, the Company had non-refundable tax credits of \$2,486 thousand (2018: \$1,981 thousand) of which \$8 thousand is expiring in 2026, \$10 thousand is expiring in 2027, \$174 thousand is expiring in 2028, \$152 thousand is expiring in 2029, \$130 thousand is expiring in 2030, \$138 thousand is expiring in 2031, \$173 thousand is expiring in 2032, \$115 thousand is expiring in 2033, \$87 thousand expiring in 2034, \$102 thousand is expiring in 2035, \$141 thousand expiring in 2036, \$270 thousand is expiring in 2037, \$582 thousand expiring in 2038 and \$404 thousand expiring in 2039 and undeducted research and development expenses of \$14,282 thousand (2018: \$10,663 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.

# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2019 and 2018

(Expressed in U.S. Funds)

### 16. 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, 2019:

<b>Tax Jurisdictions</b>	<b>Tax Years</b>
Federal - Canada	2015 and onward
Provincial - Quebec	2015 and onward
Federal - USA	2015 onward

### 17. Revenues

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

	<b>December 31, 2019</b>	<b>December 31, 2018</b>
Research and development agreements	\$ 742	\$ 1,824

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

	<b>December 31, 2019</b>	<b>December 31, 2018</b>
Product and services transferred at point in time	\$ 372	\$ -
Products and services transferred over time	370	1,824
	\$ 742	\$ 1,824

# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2019 and 2018

(Expressed in U.S. Funds)

### 17. Revenues (Cont'd)

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

	December 31, 2019	December 31, 2018
Europe	\$ 534	1,715
Canada	208	109
	\$ 742	\$ 1,824

#### Remaining performance obligations

As at December 31, 2019, the aggregate amount of the transaction price allocated to the remaining performance obligation is \$1,084 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 \$4,169 in research and development milestone payments, approximately 60% of which is expected to be recognized in the next three years, with the remaining 40% expected in the two years following; up to \$28,376 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.

### 18. Statement of Cash Flows Information

In US\$ thousands	2019	2018
<b>Additional Cash Flow Information:</b>		
Interest paid	\$ 465	\$ 476



# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2019 and 2018

(Expressed in U.S. Funds)

### 19. 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, 2019 included in general and administrative expenses is \$152 thousand. The cash outflows from operating leases for the year ended December 31, 2019 was \$144 thousand.

The weighted average remaining lease term and the weighted average discount rate for operating leases at December 31, 2019 were 6.2 years and 10%, respectively.

The following table reconciles the undiscounted cash flows for the operating leases as of December 31, 2019 to the operating lease liabilities recorded on the balance sheet:

	<b>Operating Leases</b>
2020	\$ 150
2021	152
2022	156
2023	158
2024	161
Thereafter	188
Total undiscounted lease payments	965
Less: Interest	273
Present value of lease liabilities	\$ 692

  

Current portion of operating lease liability	\$ 137
Operating lease liability	\$ 555

# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2019 and 2018

(Expressed in U.S. Funds)

### 20. Related party transactions

Included in management salaries are \$67 thousand (2018 - \$75 thousand) for options and PRSUs granted to the Chief Executive Officer, \$50 thousand (2018 - \$46 thousand) for options and PRSUs granted to the President and Chief Financial Officer, \$29 thousand (2018 - \$24) for options granted to the Vice-President, Research and Development, \$29 thousand (2018 - \$54) for options granted to the Vice-President, Business and Corporate Development, and \$36 thousand (2018 - \$12) for options granted to the Vice-President, Operations under the 2016 Stock Option Plans and \$Nil (2018 - \$11 thousand) for options granted to non-employee directors.

Included in general and administrative expenses are director fees of \$231 thousand (2018: \$250 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.

### 21. 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.

### 22. Subsequent events

On February 11, 2020, the Company announced that it has closed its offering (the "Offering") of 16,317,000 units (the "Units") at a price of CAD\$0.50 per Unit (the "Offering Price") for gross proceeds of CAD\$8,158,500.

Each Unit consists of one share of common stock (the "Offered Shares") and one warrant (a "Warrant") entitling the holder to purchase one share of common stock of the Company at an exercise price of CAD\$0.75 per share (a "Warrant Share"). The Warrants are exercisable immediately and 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 the Company in connection with the Offering and have been 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 "Registration Statement"). The Offering was conducted, on a best efforts basis, by Echelon Wealth Partners Inc. (the "Agent"). In consideration for the services rendered by the Agent, the Company has paid the Agent an agency fee equal to 7% of the gross proceeds of the Offering and has issued the Agent a number of warrants (the "Agent 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 of the Company at an exercise price of CAD\$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, the Company expects the net proceeds from the Offering to be approximately CAD\$7.4 million.

# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2019 and 2018

(Expressed in U.S. Funds)

### 22. Subsequent events (Cont'd)

The TSX Venture Exchange (the "TSXV") has approved the listing of the Warrants and the common stock that will be issued by the Company in the Offering, including the shares of common stock issuable upon the exercise of the Warrants and the Agent Warrants.

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

On March 11, 2020, the World Health Organization declared the outbreak of a novel coronavirus ("COVID-19") as a global pandemic, which continues to spread throughout Canada and around the world. On March 23, 2020, the government of Quebec ordered the closure of all non-essential businesses effective March 25, 2020, through April 13, 2020. Because of the nature of its operations, the Company is only partially affected by this order. As of March 26, 2020, 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. This partial disruption, even temporary, may impact our operations and overall business by delaying the progress of our research and development programs and production activities. 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.

**DESCRIPTION OF THE REGISTRANT'S SECURITIES  
REGISTERED PURSUANT TO SECTION 12 OF THE  
SECURITIES EXCHANGE ACT OF 1934**

As of the date of the Annual Report on Form 10-K of which this Exhibit 4.3 is a part, IntelGenx Technologies Corp. (the "**Company**", "**we**", "**us**" or "**our**") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: the Company's common stock (the "**Common Stock**").

**Description of Common Stock**

*The following description of our Common Stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our Certificate of Incorporation, as amended, and our Bylaws, as amended, each of which are incorporated by reference as an exhibit to the Annual Report on Form 10-K of which this Exhibit 4.3 is a part.*

The Company has 110,259,653 shares of Common Stock outstanding.

The holders of Common Stock are entitled to one vote per share on all matters voted on by stockholders, including the election of directors. Except as otherwise required by law, the holders of Common Stock exclusively possess all voting power. The holders of Common Stock are entitled to dividends as may be declared from time to time by our board of directors from funds available for distribution to holders. No holder of Common Stock has any pre-emptive right to subscribe to any securities of ours of any kind or class or any cumulative voting rights.

***Rights Upon Dissolution or Winding Up***

The Delaware General Corporation Law provides that upon dissolution, liquidation or winding-up of the Company, holders of Common Stock have the lowest priority in the distribution of assets and will only receive a distribution if all senior obligations have been paid. If all senior obligations have been paid, the holders of shares of Common Stock will be entitled to receive our assets available for distribution proportionate to their pro rata ownership of the outstanding shares of Common Stock.

***Anti-Takeover Effects of Various Provisions of Delaware Law and Our Certificate of Incorporation and By-laws***

The Delaware General Corporation Law, our certificate of incorporation and our by-laws contain provisions that may have some anti-takeover effects and may delay, defer or prevent a tender offer or takeover attempt that a stockholder might consider in his, her or its best interest, including those attempts that might result in a premium over the market price for the shares held by stockholders.

***Delaware Anti-Takeover Statute***

We are subject to Section 203 of the Delaware General Corporation Law ("Section 203"). Subject to specific exceptions, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the time the stockholder becomes an interested stockholder, unless:

- the business combination, or the transaction in which the stockholder became an interested stockholder, is approved by our board of directors prior to the time the interested stockholder attained that status;
  - upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of our voting stock outstanding at the time the transaction commenced, excluding those shares owned by persons who are directors and also officers and employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
-

- at or after the time a stockholder became an interested stockholder, the business combination is approved by our board of directors and authorized at an annual or special meeting of stockholders by the affirmative vote of at least two-thirds of our outstanding voting stock that is not owned by the interested stockholder.

"Business combinations" include mergers, asset sales and other transactions resulting in a financial benefit to the interested stockholder. Subject to various exceptions, in general, an "interested stockholder" is a stockholder who, together with his, her or its affiliates and associates, owns, or within three years did own, 15% or more of the shares of our outstanding voting stock. These restrictions could prohibit or delay the accomplishment of mergers or other takeover or change of control attempts with respect to us and, therefore, may discourage attempts to acquire us.

***Listing***

The Common Stock is quoted on the OTCQX under the symbol "IGXT" and are listed on the TSX Venture Exchange under the symbol "IGX."

**Consent of Independent Registered Public Accounting Firm**

We hereby consent to the incorporation by reference of our report dated March 26, 2020 relating to our audits of financial statements of IntelGenx Technologies Corp. as of and for the years ended December 31, 2019 and 2018 appearing in this Annual Report on Form 10-K of IntelGenx Technologies Corp. for the year ended December 31, 2019.

*Richter LLP (Signed)*<sup>1</sup>

Montréal, Québec,  
Canada  
March 26, 2020

<sup>1</sup>CPA auditor, CA, public accountancy permit No. A112505

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**CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Horst G. Zerbe, certify that:

1. I have reviewed this Annual Report on Form 10-K of IntelGenx Technologies Corp. for the year ended December 31, 2019;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d - 15f) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 26, 2020

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

**CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Andre Godin, certify that:

1. I have reviewed this Annual Report on Form 10-K of IntelGenx Technologies Corp. for the year ended December 31, 2019;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d - 15f) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's certifying other officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

March 26, 2020

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





**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of IntelGenx Technologies Corp. (the "Company") on Form 10-K for the year ended December 31, 2019 as filed with the Securities and Exchange Commission (the "Report"), I, Horst G. Zerbe, Principal Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

March 26, 2020

By: /s/Horst G. Zerbe

Horst G. Zerbe  
Chief Executive Officer  
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO  
18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of IntelGenx Technologies Corp. (the "Company") on Form 10-K for the year ended December 31, 2019 as filed with the Securities and Exchange Commission (the "Report"), I, Andre Godin, Principal Financial and Accounting Officer of the Company, certify, pursuant to 18 U.S.C. §. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

March 26, 2020

By: /s/Andre Godin

Andre Godin  
President and Chief Financial Officer  
(Principal Financial and Accounting Officer)

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