IntelGenx Technologies Corp.
Form 10-K
March 22, 2019

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended **December 31, 2018**

[ ] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: **000-31187**

INTELGENX TECHNOLOGIES CORP.

(Exact name of registrant as specified in its charter)

Delaware	**87-0638336**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
6420 Abrams, Ville Saint-Laurent, Quebec	**H4S 1Y2**
(Address of principal executive offices)	*(Zip Code)*

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

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

Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $0.00001 par value per share

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

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

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 [X] 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 during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).
Yes [X] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or 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. (Check one):

Large accelerated filer [ ]	Accelerated filer [ ]
Non-accelerated filer [ ]	Smaller reporting company [X]
	Emerging growth 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 [X]

As of June 30, 2018, the aggregate market value of the registrant s voting and non-voting common equity held by non-affiliates of the registrant was $46,205,996 based on the closing price of the registrant s common stock of U.S. $0.77, 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.

Class	**Outstanding at March 22, 2019**
Common Stock, $.00001 par value	**93,527,474 shares**

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the Company s Proxy Statement for its 2019 Annual Meeting of Shareholders (the 2019 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 Inte 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 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 2018 as reported by the Bank of Canada, being U.S. $1.00 = CA$1.2957.

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 , p 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.

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 of novel oral immediate-release and controlled-release products for the pharmaceutical market. More recently, we have made the strategic decision to enter the oral film market and have implemented commercial oral film manufacturing capability. This enables us to offer our 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 develop pharmaceutical products based on our proprietary drug delivery technologies 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 partnering 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.

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.

Technology Platforms

Our product development efforts are based upon three delivery platform technologies: (1) VersaFilm , an Oral Film technology, (2) VersaTab , a Multilayer Tablet technology, and (3) AdVersa®, a Mucoadhesive Tablet technology.

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

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

Our VersaFilm technology consists of a thin (25-35 micron) polymeric film comprised of United States Pharmacopeia components that are approved by the FDA for use in food, pharmaceutical, and cosmetic products. Derived from the edible film technology used for breath strips and initially developed for the instant delivery of savory flavors to food substrates, the VersaFilm technology is designed to provide a rapid response 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 VersaTab platform technology allows for the development of oral controlled-release products. It is designed to be versatile and to reduce manufacturing costs as compared to competing oral extended-release delivery technologies. Our VersaFilm technology allows for the instant delivery of pharmaceuticals to the oral cavity, while our AdVersa® allows for the controlled release of active substances to the oral mucosa.

Our VersaTab technology represents a new generation of controlled release layered tablets designed to modulate the release of active compounds. The technology is based on a multilayer tablet with an active core layer and erodible cover layers. The release of the active drug from the core matrix initially occurs in a first-order fashion. As the cover

layers start to erode, their permeability for the active ingredient through the cover layers increases. Thus, the Multilayer Tablet can produce quasi-linear (zero-order) kinetics for releasing a chemical compound over a desired period of time. The erosion rate of the cover layers can be customized according to the physico-chemical properties of the active drug. In addition, our multilayer technology offers the opportunity to develop combination products in regulatory-compliant format. Combination products are made up of two or more active ingredients that are combined into a single dosage form.

Our Mucoadhesive Tablet is a drug delivery system capable of adhering to the oral mucosa and releasing the drug to the site of application at a controlled rate. The Mucoadhesive Tablet is designed to provide 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 designed to be 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.

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 thirteen projects currently in our product portfolio, ten utilize our VersaFilm technology, two utilize our VersaTab technology, and one utilizes our AdVersa® technology. Out of those thirteen projects, eight are actively progressing in research and development while the others have reached the regulatory or commercial stage.

Our most active projects:

INT0008/2008: We developed this 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 June 2013 the FDA assigned a Prescription Drug User Fee Act (PDUFA) action date of February 3, 2014 for the review of the NDA for marketing approval and in February 2014 we received a Complete Response Letter (CRL) from the FDA informing us that certain questions and deficiencies remain that preclude the approval of the application in its present form. The questions raised by the FDA in the CRL regarding the NDA for our anti-migraine VersaFilm product primarily relate to third party Chemistry, Manufacturing and Controls (CMC) and to the packaging and labeling of the product. No questions or deficiencies were raised relating to the product s safety and the FDA s CRL does not require additional clinical studies.

In March 2014 we submitted our response to the FDA s CRL and in April, 2014 the FDA requested additional CMC data. We also reported that the supplier of the active pharmaceutical ingredient (API) of the product has been issued with an Import Alert by the FDA. The Import Alert bans the import into the USA of all raw materials from the supplier s manufacturing facility, which therefore prohibits the import of any products using these raw materials, and effectively prevents our VersaFilm product from being approved by the FDA. We identified a new source of API to manufacture new submission lots to support the re-submission of the NDA.

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 brand name RIZAPORT® was also conditionally approved by the FDA as part of the NDA review process in the U.S. The MAA was submitted under the European Decentralized Procedure (DCP) with Germany as the reference member state.

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 October 31, 2017, we re-submitted the 505(b)(2)NDA in response to the CRL received in February, 2014 and the request from FDA for additional information received in April, 2014. The review of the submission by the FDA triggered an incomplete response letter. On December 1, 2017, the FDA notified the Company that additional data would be required before commencing the review of the application.

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 September 24, 2018 IntelGenx announced the successful completion of a clinical study comparing Rizaport®, oral soluble film, and Maxalt®, an orally disintegrating tablet. Following the study, on November 20, 2018, the FDA accepted the re-submitted 505(b) (2) NDA for review.

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. Approval of the manufacturing site change by the Spanish authorities is currently expected for the second half of 2019.

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. The FDA has assigned a Prescription Drug User Fee Act goal date of April 1, 2019, for completion of the review of the resubmitted NDA for RIZAPORT®. We do not expect the inspectional observations to impact the timeline for the FDA s decision on the approval of RIZAPORT®.

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 buprenorphine and naloxone Sublingual Film, 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 U.S. District Court for the District of Delaware (the Delaware Court) alleging infringement of U.S. Patent Nos. 8,475,832, 8,603,514 and 8,017,150, each of which relate to Suboxone®. We believe the ANDA product does not infringe those or any other patents. 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® 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 o 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 July 11, 2016, the Company announced the receipt of the notice of appeal for the buprenorphine/naloxone sublingual film product for the treatment of opiate addiction by Par and the Company to the United States Court of Appeals for the Federal Circuit from the final judgment issued by the Delaware Court on June 28, 2016.

The ruling in the U.S. District Court of Delaware in the ANDA litigation of Par and the Company against Indivior PLC (formerly Reckitt Benckiser Pharmaceuticals) and Monosol Rx, LLC resulted in Par and the Company prevailing on the non-infringement of the U.S. Patent No. 8,017,150, which is set to expire in 2023, and on the invalidity (all claims) and non-infringement (certain claims) of the U.S. Patent No. 8,475,832, which is set to expire in 2030. The Court also ruled that Par s ANDA product would infringe the asserted claims of U.S. Patent No. 8,603,514, one of the Orange Book listed patents for Suboxone® Film, and that the asserted claims of U.S. Patent No. 8,603,514 were not shown to be invalid.

On September 6, 2017, we announced that the Delaware Court, in a decision rendered August 31, 2017, determined that the process used to manufacture IntelGenx and Par s buprenorphine/naloxone sublingual film product for the treatment of opiate addiction does not infringe MonoSol Rx LLC (now Aquestive Therapeutics Inc.) 497 patent and that on August 31, 2017, the Delaware Court rendered a decision in a separate case, which previously resulted in a finding infringement of the MonoSol Rx LLC (now known as Aquestive Therapeutics Inc.) the 514 patent , denying IntelGenx and Par s motion to reopen the case. The Delaware Court decisions were under appeal before the U.S. Court of Appeals for the Federal CircuitThere were several lawsuits for patent infringement in U.S. District Courts related to the Suboxone® ANDA product. These new ANDA lawsuits were based on patents submitted on the FDA Orange Book in 2017 and 2018. IntelGenx was not a party to any of these U.S. District Court instances related to the Suboxone® ANDA product.

On May 14, 2018, we announced that all patent litigation between the Company, Par Pharmaceutical, Inc.`, Indivior, Inc., Indivior UK Limited, and Aquestive Therapeutics, Inc. (formerly MonoSol Rx, LLC) related to Suboxone® film had been settled. The settlement agreement permits Par to begin selling a generic version of Suboxone® film on January 1, 2023 or earlier under certain circumstances.

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 metabolization 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 U.S. 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 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 1 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 1 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 the last year. We are now actively working on advancing this project.

On February 10, 2016, we announced the submission of the patent application with the U.S. patent office for an oral film dosage form containing Loxapine for the treatment of anxiety and aggression in patients suffering from schizophrenia or bipolar 1 disorder. The application is currently under review.

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 U.S. market. Under the agreement, Endo has obtained certain exclusive rights to market and sell our product in the U.S. We received an upfront payment and will receive future milestone payments. Endo and IntelGenx will share the profits of commercialization.

INT0043/2015: We have developed an oral film containing montelukast as an active ingredient based on our proprietary edible film technology VersaFilm , which is in the early clinical trial phase. In pre-clinical studies, it was discovered that montelukast has the potential to rejuvenate the brain in aged rats.

We are collaborating with Dr. Ludwig Aigner, a neuroscientist who is 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 the pilot clinical study for our Montelukast VersaFilm that demonstrated a significantly improved pharmacokinetic profile against the reference product. The study data confirmed that buccal absorption of the drug from the Montelukast film product resulted in a significantly improved bioavailability of the drug compared to the commercial tablet. In addition, the study data confirmed that Montelukast crosses the blood brain barrier when administered using our Versafilm delivery technology.

In 2017 we announced receiving 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™ 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 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 week

INT0046/2018: Our first Cannabis project based on our VersaFilm technology is currently in the early development stage. 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, the 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.

INT0045/2018: A oral film product based on our proprietary VersaFilm technology. This is a new project we started in 2018 which is currently in the early development stage. In order to protect our competitive advantage, no further details of the product can be disclosed at this stage.

Regulatory Stage Projects:

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®. We are currently compiling data and reviewing the worldwide regulatory requirements.

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 U.S. 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.

We are in discussions with potential partners for the commercialization of our Tadalafil ED VersaFilm product.

INT0039/2013: The product based on one of our proprietary technologies 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 U.S. 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 U.S.

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.

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 our partner decision, activities in preparation for filing the marketing application for this product have been placed on hold.

Other projects:

INT0001/2004: This is the most advanced tablet generic product involving our multilayer tablet technology. Equivalency with the reference product Toprol XL® and its European equivalent Beloc-ZOK® 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 Group to advance the commercialization of our Versa Tab product. The manufacturing technology transfer to Chemo is still ongoing.

INT0004/2006: We developed a new, higher strength of the antidepressant Bupropion HCl, the active ingredient in Wellbutrin XL®, and, in November 2011, the FDA approved the drug for patients with Major Depressive Disorder. In February 2012, we entered into an agreement with Edgemont Pharmaceuticals LLC (Edgemont) for commercialization of 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 U.S. 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 U.S. in October 2012 under the brand name Forfivo XL®. As of December 31, 2015 we had received an upfront payment of $1 million and a $1 million milestone payment related to the launch. The commercialization of Forfivo XL® 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® 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 Abbreviated New Drug Application (ANDA) to the FDA requesting authorization to manufacture and market generic versions of Forfivo XL® 450 mg tablets in the U.S. In November 2014 we announced that the Paragraph IV litigation with Wockhardt had been settled and that, under the terms of the settlement, Wockhardt has been granted the right, with effect from January 15, 2018, to be the exclusive marketer and distributor of an authorized generic of Forfivo XL® in the U.S.

In December 2014 we announced that Edgemont had exercised its right to extend the license for the exclusive marketing of Forfivo XL® 450 mg tablets. In exchange, we received milestone payments of $650 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 U.S. royalty on future sales of Forfivo XL® to SWK Holdings Corporation (SWK) for $6 million (CA$8 million). Forfivo XL® (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® in the United States expires in 2027.

In the first quarter of 2017, IntelGenx was informed that Edgemont Pharmaceuticals, LLC. assigned its product business, including Forfivo XL®, to Alvogen Group Holdings 3 LLC.

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

INT0044/2016: A product based on one of our VersaTab™ proprietary technologies.

On December 1st, 2016, we announced the signing of a term sheet for the co-development and commercialization of a generic tablet in the area of central nervous systems on a worldwide basis. As per the agreement, we received an upfront payment and would have been entitled to receive development costs of the product and future milestone payments. Chemo and IntelGenx would have also shared the profits of commercialization. The definitive agreement was signed on December 30, 2016. However, on May 23, 2018, Chemo and IntelGenx mutually agreed to terminate the agreement and Chemo assigned all rights, titles and interests in and to any product-related intellectual property and related data and regulatory dossiers to IntelGenx.

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**
INT0001/2004	Anti-hypertension	Technology transfer ongoing.
INT0004/2006	Antidepressant	FDA-approved November 2011. Commercially launched in USA as Forfivo XL® in October 2012. In 2016 we sold the royalty revenue to SWK.
INT0007/2006	Erectile dysfunction	Discussions with potential commercial partner.
INT0008/2008	Migraine	Additional data submitted, FDA accepted the re- submitted 505(b)(2) NDA for review. PDUFA date April 1st 2019. Submission from previous manufacturing site approved by Spanish authorities. Approval of the manufacturing site change by the

		Spanish authorities is currently expected for the second half of 2019.
INT0010/2006	Pain	Formulation optimization, scale-up preparation for clinical study evaluation.
INT0027/2011	Opioid dependence	ANDA submitted to FDA in July 2013. FDA review process ongoing.
INT0036/2013	Schizophrenia	Formulation development ongoing.
INT0037/2013	Undisclosed	Product developed. Preparation of documents for submission on hold.

INT0039/2013	Undisclosed	ANDA filed.
INT0040/2014	Undisclosed	Formulation development ongoing.
INT0043/2015	Alzheimer	Phase II clinical study activated, recruitment ongoing.
INT0045/2018	Undisclosed	Formulation development ongoing.
INT0046/2018	Adult use of Cannabis	Formulation development ongoing.

Growth Strategy

Our primary growth strategies are based on three pillars: (1) out licensing commercial rights of our existing pipeline products, (2) partnering on contract development and manufacturing projects leveraging our VersaFilm technology, (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,
- 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 VersaFilm technology

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

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

Lifecycle Management Opportunities

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

a viable business opportunity for us.

Product Opportunities that provide Tangible Patient Benefits

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

Development of New Drug Delivery Technologies

The rapidly disintegrating film technology contained in our VersaFilm , and our AdVersa® mucosal adhesive tablet, are two examples of our efforts to develop alternate technology platforms. As we work with various partners on different products, we seek opportunities to develop new proprietary technologies.

Repurposing Existing Drugs

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

Generic Drugs with High Barriers to Entry

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

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.

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Our Competitive Strengths

We believe that our key competitive strengths include:

- Our comprehensive full services;
- Our diversified pipeline;
- Our ability to swiftly develop products through to regulatory approval; and
- The versatility of our drug delivery technologies.
- Our highly qualified, dedicated professional team

Manufacturing Partnership

While we previously manufactured products only for testing purposes in our own laboratories, we have now started to manufacture products for pivotal clinical trials, and we are undertaking steps to manufacture products for commercial use. In order to establish ourselves as a full-service partner for our thin film products, we have completed the construction of a new, state-of-the-art oral film manufacturing facility and are in the process of preparing the equipment and finalizing plans to commercially manufacture our products using our VersaFilm drug delivery technology. VersaFilm is our proprietary immediate release polymeric film technology. It is comprised of a thin polymeric film using United States Pharmacopeia components that are safe and approved by the FDA for use in food, pharmaceutical and cosmetic products. We completed construction of our manufacturing facility in 2017 and successfully passed a quality audit by Health Canada in November, 2017 following which we received our Drug Establishment License. Since then, we are fully operational.

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 14 patents and have an additional 40 published pending patent applications, as described below. The patents expire 20 years after submission of the initial application. In the U.S. 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.

Patent No.	Title	Subject	Date issued / expiration
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
US 9,668,970	Film Dosage Form with Extended Release Mucoadhesive Particles	Film containing mucoadhesive particle	Issued June 6, 2017 Expires November 26, 2034
US 9,717,682	Solid Oral Film Dosage Forms and Methods for Making Same	Optimization of film strip technology	Issued August 1, 2017 Expires September 21, 2031
US 9,949,934	Device and method of treating conditions associated with neuroinflammation	Formulation of oral films containing montelukast	Issued April 24, 2018 Expires October 20, 2036
CA 2,998,223	Loxapine film oral dosage form	Formulation of oral films containing loxapine	Issued October 9, 2018 Expires January 24, 2037
EP 3,027,179	Instantly wettable oral film dosage form without surfactant or polyalcohol	Formulation of oral films containing active pharmaceutical ingredients	Issued October 17, 2018 Expires July 30, 2034
JP 6,482,552	Instantly wettable oral film dosage form without surfactant or polyalcohol	Formulation of oral films containing active pharmaceutical ingredients	Issued March 13, 2019 Expires July 30, 2034

Patent Application No.	Title	Subject	Date Filed
US Appl. 12/963,132	Oral film dosage forms and methods for making same	Optimization of film strip technology	Filed December 8, 2010
US Appl. 15/216,903	Film dosage forms containing amorphous active agents	Film containing amorphous agent	Filed July 22, 2016
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
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
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
Chinese Appl. CN108697656	Loxapine film oral dosage form	Formulation of oral films containing loxapine	Filed January 25, 2017
Chinese Appl. CN108778259	Montelukast the mucous membrane the membrane	Formulation of oral films containing montelukast	Filed March 1, 2017
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. MX 2016001399	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. 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
Israel Appl. 243651	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
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
Canadian Appl. CA2,797,444	Solid oral dosage forms comprising tadalafil	Formulation of oral films containing tadalafil	Filed November 3, 2011
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. CA3,017,264	Montelukast transmucosal film	Formulation of oral films containing montelukast	Filed March 1, 2017
Canadian Appl. CA3,015,555	Loxapine film oral dosage form	Formulation of oral films containing loxapine	Filed January 25, 2017
Australian Appl. AU2017231110	Montelukast transmucosal film	Formulation of oral films containing montelukast	Filed March 1, 2017
Australian Appl. AU2017214774	Loxapine film oral dosage form	Formulation of oral films containing loxapine	Filed January 25, 2017

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
US Appl. 15/067,309	Montelukast transmucosal film	Formulation of oral films containing montelukast	Filed March 11, 2016
US Appl. 15/588,897	Film dosage form with extended release mucoadhesive particles	Film containing mucoadhesive particle	Filed May 8, 2017
US Appl. 15/014,269	Loxapine film oral dosage form	Formulation of oral films containing loxapine	Filed February 3, 2016
US Appl. 14/630,699	Film dosage forms containing amorphous active agents	Film containing amorphous agent	Filed February 2, 2015
US Appl. 15/848,819	Film dosage form with multimodal and particle size distributions	Optimization of film strip technology	Filed December 20, 2017
US Appl. 15/822,734	Solid oral film dosage forms and methods for making same	Formulation of oral films containing tadalafil	Filed November 27, 2017
US Appl. 15/940,288	Method of treatment and device for the improved bioavailability of leukotriene receptor antagonists	Formulation of oral films containing montelukast	Filed March 29, 2018
US Appl. 16/110,737	Film dosage form with extended release mucoadhesive particles	Film containing mucoadhesive particle	Filed August 23, 2018
US Appl. 15/912,103	Device and method of treating conditions associated with neuroinflammation	Formulation of oral films containing montelukast	Filed March 5, 2018
US Appl. 16/053,383	Loxapine film oral dosage form	Formulation of oral films containing loxapine	Filed August 2, 2018
PCT Appln. WO 2018176149	Method of treatment and device for the improved bioavailability of leukotriene receptor antagonists	Formulation of oral films containing montelukast	Filed March 29, 2018
PCT Appln. WO 2018072015	Device and method of treating conditions associated with neuroinflammation	Formulation of oral films containing montelukast	Filed October 17, 2017

PCT Appln. WO 2018205017	Film dosage form with extended release mucoadhesive particles	Film containing mucoadhesive particle	Filed May 8, 2018

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 U.S. 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 GLPs;
- The submission to the FDA of an investigational new drug application, which must become effective before human clinical trials may begin;
- The completion of adequate and well-controlled clinical trials according to good clinical practice regulations, 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 a NDA, or an ANDA, for generic drugs. In certain cases, an application for marketing approval may include information regarding safety and efficacy of a proposed drug that comes from studies not conducted by or for the applicant. Such applications, known as a 505(b)(2) NDA, are permitted for new drug products that incorporate previously approved active ingredients, even if the proposed new drug incorporates an approved active ingredient in a novel formulation or for a new indication;
- Satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the product is to be produced, to assess compliance with cGMPs to assure that the facilities, methods and controls are adequate to preserve the drug s identity, strength, quality and purity; and
- FDA review and approval of the NDA or ANDA.

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

Cannabis in Canada

The signing of the Cannabis Act created a strict legal framework for controlling the production, distribution, sale and possession of cannabis across Canada. Cannabis edible products and concentrates will be legal for sale approximately one year after the Cannabis Act came into force on October 17th, 2018.

Our R&D expenses, net of R&D tax credits, for the year ended December 31, 2018 increased by $2,489 thousand to $5,104 thousand, compared with $2,615 thousand for the year ended December 31, 2017. The increase in R&D expenditure is explained in the section of this report entitled Management s Discussion and Analysis of Financial Condition and Results of Operations .

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 38 full-time and 4 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, 2018 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 $30,896 thousand since our inception in 2003 through December 31, 2018. To date, these losses have been financed principally through sales of equity securities. Our revenues for the past five years ended December 31, 2018, December 31, 2017, December 31, 2016, December 31, 2015 and December 31, 2014 were $1.8 million, $5.2 million, $5.2 million, $5.1 million and $1.7 million thousand, 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 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 manufacture, 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.

There is no assurance that the sale of cannabis edible products will be permitted in Canada.

Although the Government of Canada has approved the Cannabis Act which is expected to allow for regulated and restricted access to cannabis for recreational use in Canada as of October 17, 2018, cannabis edible products are not currently on the list of products permitted for legal sale in Canada under the Cannabis Act and there is no assurance that they will be in the future.

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.

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.

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 and will depend on a number of factors, including future earnings, capital requirements, financial conditions and future prospect and other factors that the Board of Directors 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 the Company s warrants, 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 warrants. As a result, a market may not develop for the Company s warrants and holders may not be able to sell the Company s warrants. Future trading prices of the Company s warrants will depend on many factors, including prevailing interest rates, 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 their maturity. We do not intend to apply for listing or quotation of the Company s warrants on any securities exchange or automated quotation system.

Risks related to our outstanding unsecured convertible debentures.

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.

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$110 thousand (approximately $84 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 IntelGenx executed an agreement to lease approximately an additional 11,000 square feet in a property located at 6410 Abrams, St-Laurent, Quebec (the Lease). The Lease has an 8 year and 5-month term commencing on October 1, 2017 and IntelGenx has retained two options to extend the Lease, with each option being for an additional five years. Under the terms of the Lease IntelGenx will be required to pay base rent of approximately CA$74 thousand (approximately $54 thousand) per year, which will increase at a rate of CA$0.25 ($0.18) per square foot, every two years. IntelGenx plans to use the newly leased space to expand its manufacture of oral film VersaFilm TM.

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, “Defendants”) from BioDelivery Sciences International, Inc., and Arius Two, Inc., (collectively, “Plaintiffs”) asserting that the Defendants infringe BioDelivery Sciences International, Inc. Orange Book listed patents for BELBUCA, including U.S. Patent Nos. 8,147,866 and 9,655,843, both expiring in July of 2027, and U.S. Patent No. 9,901,539 expiring December of 2032. This complaint follows the receipt by BioDelivery Sciences International, Inc. of a Notice Letter by Chemo Research S.L. on January 31, 2019, stating that it has 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. Because 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 30 months or a decision in the case that each of the patents is not infringed or invalid. The same complaint for patent infringement was also filed in the United States District Court for the District of New Jersey on March 15, 2019.
We believe that we will be able to prevail in this lawsuit.

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 22, 2019, there were approximately 49 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, or 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 of Directors and will depend on a number of factors, including future earnings, capital requirements, financial conditions and future prospect and other factors that the board of directors may deem relevant.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

During the fourth quarter of 2018, 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 2018, we did not sell equity securities without registration under the Securities Act of 1933, as amended, except as disclosed on a Current Report on Form 8-K.

Equity Compensation Plan Information

	Number of Securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights[2] (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity Compensation Plans Approved by Security Holders	1,253,846[1]	$0.54	946,154[3]
Equity Compensation Plans Not Approved by Security Holders	3,004,818[3]	$0.75	3,485,358[4]
Total	4,204,818	$0.69	4,431,512[4]

(1) Includes shares of our Common Stock issuable pursuant to options granted under the 2006 Stock Option Plan and RSUs awarded under our PRSU Plan.
(2) The weighted average exercise price excludes RSU awards, which have no exercise price.
(3) 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 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, 2018.

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 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.

The PRSU Plan permits the Board to grant RSU awards to employees, consultants or directors of the Company and 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 of the Company, 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 going 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 Inte Corp. This information should be read in conjunction with the accompanying audited Consolidated Financial Statements and Notes thereto.

Company Background

We are a drug delivery company established in 2003 and headquartered in Montreal, Quebec, Canada. Our focus is on the development of novel oral immediate-release and controlled-release products for the pharmaceutical market.

More recently, we have made the strategic decision to enter the oral film market and have implemented commercial oral film manufacturing capability. This enables us to offer our 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 develop pharmaceutical products based on our proprietary drug delivery technologies 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 partnering later in the development process.

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

- identifying lifecycle management opportunities for existing market leading pharmaceutical products,
- develop oral film products that provide tangible patient benefits,
- development of new drug delivery technologies,
- 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 VersaFilm technology

We have established a state-of-the-art manufacturing facility for the future manufacture of our VersaFilm 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. 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.

Lifecycle Management Opportunities

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

Product Opportunities that provide Tangible Patient Benefits

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

Development of New Drug Delivery Technologies

The rapidly disintegrating film technology contained in our VersaFilm , and our AdVersa® mucosal adhesive tablet, are two examples of our efforts to develop alternate technology platforms. As we work with various partners on different products, we seek opportunities to develop new proprietary technologies.

Repurposing Existing Drugs

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

Generic Drugs with High Barriers to Entry

We plan to pursue the development of generic drugs that have certain barriers to entry, e.g., where product development and manufacturing is complex and can limit the number of potential entrants into the generic market. We

plan to pursue such projects only if the number of potential competitors is deemed relatively insignificant.

Corporate

On October 18, 2018, IntelGenx announced the pricing of an agency offering of 17,144,314 units for gross proceeds of approximately US$12,000,000 million at a price of US$0.70 (Offering Price) per unit (a Unit) (the Offering). Each Unit consists of one share of Common Stock and one half of one warrant (a Warrant), each whole Warrant to purchase one share of Common Stock at an exercise price of US$1.00 per share. The Warrants were exercisable immediately and expire on the third anniversary of the date of their issuance.

The Offering was made on a best efforts basis in the United States and the Canadian provinces of British Columbia, Alberta, Manitoba, Ontario and Québec. H.C. Wainwright & Co. acted as the exclusive agent for the Units offered in the United States. Echelon Wealth Partners Inc. (Echelon) acted as the exclusive placement agent for the Units offered in Canada.

The intended use of the net proceeds of the Offering was expected to be for its 2a Montelukast study, Tadalafil 505(b)(2) submission to the FDA, and working capital.

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, 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.

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 million.

All amounts are expressed in thousands of U.S. dollars unless otherwise stated.

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, 2018 report an accumulated other comprehensive loss due mainly to foreign currency translation adjustments of $1,166 due to the fluctuations in the rates used to prepare our financial statements, $532 of which negatively impacted our comprehensive loss for the fiscal year ended December 31, 2018. 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

In U.S.$ thousands	Three-month period ended December 31, **2018**	2017	Twelve-month period ended December 31, **2018**	2017
	$	$	$	$
Comprehensive loss	(2,938)	(1,065)	(10,637)	(2,669)
Add (deduct):				
Depreciation	179	210	719	735
Finance costs	300	240	1,121	569
Finance income	(11)	(3)	(11)	(11)
Share-based compensation	59	48	370	315
Other comprehensive loss (income)	763	(26)	853	(382)
Adjusted EBITDA	**(1,972)**	(596)	**(7,909)**	(1,443)

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

Adjusted EBITDA decreased by $1,376 for the three-month period ended December 31, 2018 to ($1,972) compared to ($596) for the three-month period ended December 31, 2017. Adjusted EBITDA decreased by $6,466 for the twelve-month period ended December 31, 2018 to ($7,909) compared to ($1,443) for the twelve-month period ended December 31, 2017. The decrease in Adjusted EBITDA of $1,376 for the three[ ]month period ended December 31, 2018 is mainly attributable to a decrease in revenues of $811, an increase in R&D expenses of $1,256 before consideration of stock-based compensation offset by a decrease in SG&A expenses of $596 before consideration of stock-based compensation. The decrease in Adjusted EBITDA of $6,466 for the twelve-month period ended December 31, 2018 is mainly attributable to a decrease in revenues of $3,371, an increase in R&D expenses of $2,465 before consideration of stock-based compensation and an increase in SG&A expenses of $1,003 before consideration of stock-based compensation.

Results of operations for the three month and twelve month periods ended December 31, 2018 compared with the three month and twelve month periods ended December 31, 2017.

Revenue

In U.S.$ thousands	Three-month period ended December 31, **2018**	2017	Twelve-month period ended December 31, **2018**	2017
Revenue	$ 651	$ 1,462	$ 1,824	$ 5,195
Cost of Royalty and License Revenue	-	95	-	373
Research and Development Expenses	1,998	739	5,104	2,615
Selling, General and Administrative Expenses	684	1,272	4,999	3,965
Depreciation of tangible assets	179	210	719	735
Operating Loss	**(2,210)**	(854)	**(8,998)**	(2,493)
Net Loss	**(2,499)**	(1,091)	**(10,108)**	(3,051)

Comprehensive Loss	**(2,938)**	(1,065)	**(10,637)**	(2,669)

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Revenue

Total revenues for the three-month period ended December 31, 2018 amounted to $651, representing a decrease of $811 or 55% compared to $1,462 for the three-month period ended December 31, 2017. Total revenues for the twelve-month period ended December 31, 2018 amounted to $1,824 representing a decrease of $3,371 or 65% compared to $5,195 for the twelve-month period ended December 31, 2017. The decrease for the three-month period ended December 31, 2018 compared to the last year s corresponding period is mainly attributable to a decrease in deferred revenues of $940 following the monetization of Forfivo partially offset by an increase in R&D revenues of $129. The decrease for the twelve-month period ended December 31, 2018 compared to the last year s corresponding period is mainly attributable to a decrease in deferred revenues of $3,760 following the monetization of Forfivo and a decrease in up-fronts of $416. This decrease was partially offset by an increase in R&D revenues of $805.

Cost of royalty and license revenue

We recorded $Nil for the cost of royalty and license revenue in the three-month period ended December 31, 2018 compared with $95 in the same period of 2017. We recorded $Nil for the cost of royalty and license revenue in the twelve-month period ended December 31, 2018 compared with $373 in the same period of 2017. These expenses relate to a Project Transfer Agreement that was executed in May 2010 with one of our former development partners whereby we acquired full rights to, and ownership of, Forfivo XL®, our novel, high strength formulation of Bupropion hydrochloride, the active ingredient in Wellbutrin XL®. Pursuant to the Project Transfer Agreement, and following commercial launch of Forfivo XL® in October 2012, we are required, after recovering an aggregate $200 for management fees previously paid, to pay our former development partner 10% of net product sales received from the sale of Forfivo XL® (including the deferred revenues resulting from the Forfivo monetization). We recovered the final portion of the management fees in December 2014, thereby invoking payments to our former development partner.

Research and development (R&D) expenses

R&D expenses for the three-month period ended December 31, 2018 amounted to $1,998, representing an increase of $1,259 or 170%, compared to $739 for the three-month period ended December 31, 2017. R&D expenses for the twelve-month period ended December 31, 2018 amounted to $5,104, representing an increase of $2,489 or 95%, compared to $2,615 recorded in the same period of 2017.

The increase in R&D expenses for the three-month period ended December 31, 2018 is mainly attributable to an increase in lab supplies of $912 and analytical costs of $266. The increase in R&D expenses for the twelve-month period ended December 31, 2018 is mainly attributable to an increase in study costs of $907, lab supplies of $813, analytical costs of $613 and R&D salaries of $273 related to new hires, offset by an increase in R&D credits of $134.

In the twelve-month period ended December 31, 2018 we recorded estimated Research and Development Tax Credits of $438, compared with $303 that was recorded in the same period of the previous year.

Selling, general and administrative (SG&A) expenses

SG&A expenses for the three-month period ended December 31, 2018 amounted to $684, representing a decrease of $588 or 46%, compared to $1,272 for the three-month period ended December 31, 2017. SG&A expenses for the twelve-month period ended December 31, 2018 amounted to $4,999, representing an increase of $1,034 or 26%, compared to $3,965 recorded in the same period of 2017.

The decrease in SG&A expenses for the three-month period ended December 31, 2018 is mainly attributable to decreases in manufacturing expenses of $280, salaries and compensation expenses of $204, a variation of the foreign exchange expense due to the depreciation of the CA dollar vs the US currency of $187, and general expenses of $46, partially offset by an increase in professional fees of $168. The increase in SG&A expenses for the twelve-month

period ended December 31, 2018 is mainly attributable to increases in professional fees of $522, salaries and compensation expenses of $342, office and general expenses of $145, manufacturing expenses of $132, rent and utilities expenses of $130, investor relations expenses of $86, and business development expense of $60, partially offset by variation of the foreign exchange expense due to the depreciation of the CA dollar vs the US currency of $356. The increase in professional fees were mainly related to costs attributable to the aborted capital raise as well as the Laboval acquisition which is currently on hold. These expenses are deemed to be non-recurring in nature.

Depreciation of tangible assets

In the three-month period ended December 31, 2018 we recorded an expense of $179 for the depreciation of tangible assets, compared with an expense of $210 thousand for the same period of the previous year. In the twelve-month period ended December 31, 2018 we recorded an expense of $719 for the depreciation of tangible assets, compared with an expense of $735 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, 2018 amounted to $59 compared to $48 for the three-month period ended December 31, 2017. Share-based compensation warrants and share-based payments expense for the twelve-month period ended December 31, 2018 amounted to $370 compared to $315 for the twelve-month period ended December 31, 2017.

We expensed approximately $320 in the twelve-month period ended December 31, 2018 for options granted to our employees in 2016, 2017 and 2018 under the 2016 Stock Option Plans, $11 for options granted to non-employee directors in 2016, 2017 and 2018, and $14 for options granted to consultants in 2016 and 2018 compared with $178, , $131 and $6 respectively that was expensed in the same period of the previous year. Approximately $25 were expensed for RSU s granted to the CEO and CFO under the PRSU Plan, $Nil in the same period for the previous years.

There remains approximately $453 in stock-based compensation to be expensed in fiscal 2019 and 2020, $370 of which relates to the issuance of options to our employees during 2017 and 2018 and $83 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

In U.S.$ thousands	December 31, 2018	December 31, 2017	Increase/ (Decrease)	Percentage Increase/ (Decrease)
Current Assets	$ 13,063	$ 6,044	$ 7,019	116%
Leasehold improvements and Equipment	6,248	6,346	(98)	(2%)
Security Deposits	707	757	(50)	(7%)
Current Liabilities	2,722	2,077	645	31%
Deferred lease obligations	49	50	(1)	(2%)
Long-term debt	1,140	1,992	(852)	(43%)
Convertible debentures	5,047	5,199	(152)	(3%)
Convertible notes	1,073	-	1,073	100%
Capital Stock	1	1	-	0%
Additional Paid-in- Capital	42,048	25,253	16,795	67%

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 U.S. royalty on future sales of Forfivo XL®. The Company has devoted substantially all of its resources to its drug development efforts, conducting clinical trials to further advance the product pipeline, the expansion of its facilities, protecting its intellectual property and general and administrative functions relating to these operations. The future success of the Company is dependent on its ability to develop its product pipeline and ultimately upon its ability to attain profitable operations. As of December 31, 2018, the Company had cash and short-term investments totaling approximately $10,995. 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.

If the Company is unable to 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 $13,063 at December 31, 2018 compared with $6,044 at December 31, 2017. The increase of $7,019 is mainly attributable to increases in cash of $5,224, short term investments of $867, inventories of $375, prepaid expenses of $259, accounts receivable of $192 as well as an increase in investment tax credits receivable of $102.

Cash

Cash totaled $6,815 as at December 31, 2018 representing an increase of $5,224 compared with the balance of $1,591 as at December 31, 2017. The increase in cash on hand relates to net cash provided by financing activities of $16,401, partially offset by net cash used in operating activities of $8,531 and net cash used in investing activities of $2,177.

Short term investments

Short term investments totaled $4,180 as at December 31, 2018, representing an increase of $867 compared with the balance of $3,313 as at December 31, 2017. The increase in short term investments is attributable to additional investment in term deposits following the October 2018 public offering.

Accounts receivable

Accounts receivable totaled $815 as at December 31, 2018 representing an increase of $192 compared with the balance of $623 as at December 31, 2017. The increase in accounts receivable is attributable to the R&D revenues accounted for as at December 31, 2018.

Prepaid expenses

As at December 31, 2018, prepaid expenses totaled $462 compared with $203 as of December 31, 2017. The increase in prepaid expenses is mainly attributable to a payment of CAD$275 with respect to the Laboval acquisition (from which CAD$200 is refundable if the acquisition does not take place).

Investment tax credits receivable

R&D investment tax credits receivable totaled approximately $416 as at December 31, 2018 compared with $314 as at December 31, 2017. The increase relates to the accrual estimated and recorded for the twelve-month period ended December 31, 2018 offset by the collection of the 2017 tax credits.

Inventory

As at December 31, 2018, inventories totaled $375 compared to a balance of $Nil as at December 31, 2017. The increase is attributable to the purchase of raw materials.

Leasehold improvements and equipment

As at December 31, 2018, the net book value of leasehold improvements and equipment amounted to $6,248, compared to $6,346 at December 31, 2017. In the year ended December 31, 2018 additions to assets totaled $1,096 and mainly comprised of $1,032 for manufacturing equipment, $47 for leasehold improvements, $12 for computer equipment and $5 for laboratory and office equipment, offset by depreciation expense of $719 and variation of foreign exchange fluctuation.

Security deposit

A security deposit in the amount of CA$300 ($220) 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, 2018. Security deposits in the amount of CA$650 ($476) for the term loans were also recorded as at December 31, 2018. The difference between the amount at December 31, 2018 and the amount at December 31, 2017 is related to the US currency fluctuation.

Accounts payable and accrued liabilities

Accounts payable and accrued liabilities totaled $2,030 as at December 31, 2018 (December 31, 2017 - $1,305). The increase is mainly attributable to payables related to R&D expenses in the amount of $553, payables related to professional fees incurred in the amount of $154, and the accrual for DSUs to independent board of Director members in the amount of $152.

Long-term debt

Long-term debt totaled $1,832 as at December 31, 2018 (December 31, 2017 - $2,764). The current portion of long-term debt totaled $692 as at December 31, 2018 (December 31, 2017 - $772). An amount of $1,502 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 $330 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 $5,047 as at December 31, 2018 as compared to $5,199 as at December 31, 2017. The Corporation issued a total aggregate principal amount of CAD$7,600,000 ($5,571,030) of debentures at a price of CAD$1,000 ($733)per debenture in July 2017 and August 2017. The convertible debentures have been recorded as a liability. Total transactions costs in the amount of CAD$1,237,000 ($907) were recorded against the liability. The accretion expense for the year ended December 31, 2018 amounts to CAD$383,000 ($296,000) (CAD$160,000, $123,000 in 2017). The interest on the convertible debentures as at December 31, 2018 amounts to CAD$607,000 ($468,000) (CAD$286,000, $221,000 in 2017) and is recorded in Financing and interest expense.

Convertible notes

Convertible notes totaled $1,073 as at December 31, 2018 as compared to $Nil as at December 31, 2017. 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 of the Corporation. 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, 2018 was $98 thousand. The interest on the convertible notes as at December 31, 2018 was $63 thousand ($Nil in 2017) and was recorded as a financing and interest expense.

Shareholders equity

As at December 31, 2018 we had accumulated a deficit of $30,896 compared with an accumulated deficit of $20,788 as at December 31, 2017. Total assets amounted to $20,018 and shareholders equity totaled $9,987 as at December 31, 2018, compared with total assets and shareholders equity of $13,147 and $3,829 respectively, as at December 31, 2017.

Capital stock

As at December 31, 2018 capital stock amounted to $0.935 (December 31, 2017: $0.670) . 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 $42,048 as at December 31, 2018, as compared to $25,253 at December 31, 2017. Additional paid in capital increased by $16,795 from which $1,460 was the value of the common stock issued in the May 2018 private placement offering, $2,328 came from proceeds from exercise of warrants and stock options, $437 was the value of the warrants issued in the May 2018 private placement, $370 from stock based compensation attributable to the amortization of stock options granted to employees and directors, $231 was the value of the interest paid by issuance of Common Stock, $50 was the value attributed to the Agents warrants in the May 2018 private placement transaction, $9,187 was the value of the common stock issued in the October 2018 public offering, $1,436 was the value of the warrants issued in the October 2018 public offering, $280 was the value attributed to the agents warrants in the October 2018 public offering transaction, $1,000 was the value of common stock issued in the November 2018 private placement and $16 was the value of the converted debentures .

Taxation

As at December 31, 2018, the date of our latest annual tax return, we had Canadian and provincial net operating losses of approximately $14,934 (December 31, 2017: $9,560) and $10,052 (December 31, 2017: $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 2028 and 2038. A portion of the net operating losses may expire before they can be utilized.

As at December 31, 2018, we had non-refundable tax credits of $1,981 thousand (2017: $1,553 thousand) of which $8 thousand is expiring in 2026, $9 thousand is expiring in 2027, $165 thousand is expiring in 2028, $145 thousand is expiring in 2029, $124 thousand is expiring in 2030, $131 thousand is expiring in 2031, $164 thousand is expiring in 2032 and $109 thousand is expiring in 2033, $83 thousand expiring in 2034, $97 thousand is expiring in 2035, $135 thousand expiring in 2036 and $257 thousand expiring in 2037 and $554 thousand expiring in 2038. We also had undeducted research and development expenses of $10,663 thousand (2017: $7,532 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, 2018	December 31, 2017	Increase/ (Decrease)	Percentage Increase/ (Decrease)
Operating Activities	$ (8,530)	$ (4,383)	$ (4,147)	(95%)
Financing Activities	16,404	5,508	10,896	198%
Investing Activities	(2,177)	(207)	(1,970)	(952)%
Cash - end of period	6,815	1,591	5,224	328%

Statement of cash flows

Net cash used in operating activities was $8,530 for the twelve-month period ended December 31, 2018, compared to net cash used by operating activities of $4,383 for the twelve-month period ended December 31, 2017. For the twelve-month period ended December 31, 2018, net cash used by operating activities consisted of a net loss of ($10,108) (2017: $3,051) before depreciation, stock-based compensation, accretion expense, DSU expense, interest paid by issuance of Common Stock and conversion of convertible debentures in the amount of $1,860 (2017: $1,173) and a decrease in non-cash operating elements of working capital of $282 compared with a decrease of $2,505 for the twelve-month period ended December 31, 2017.

The net cash provided by financing activities was $16,404 for the twelve-month period ended December 31, 2018, compared to $5,508 provided in the same period of the previous year. An amount of $11,405 derives from proceeds from the public offering (2017:$nil), $4,004 derives from the proceeds of a private placement (2017: $nil) and an amount of $2,328 derives from proceeds from exercise of warrants and stock options (2017: $1,238) offset by repayment of term loans for an amount of $749 (2017: $708), the transaction costs related to the private placement of $82 (2017: $nil) and the transaction costs related to the public offering of $502 (2017:$nil).

Net cash used in investing activities amounted to $2,177 for the twelve-month period ended December 31, 2018 compared to $207 in the same period of 2017. The net cash used in investing activities for the twelve-month period ended December 31, 2018 relates to the redemptions of short-term investments of $3,192 (2017: $4,718) offset by the purchase of fixed assets for $1,096 (2017: $973) as well as acquisitions of short-term investments of $4,273 (2017: $3,952).

The balance of cash as at December 31, 2018 amounted to $6,815, compared to $1,591 at December 31, 2017.

Commitments

On April 24, 2015 the Company entered into an agreement to lease approximately 17,000 square feet in a property located at 6420 Abrams, St-Laurent, Québec. The lease has a 10 year and 6-month term commencing September 1, 2015. IntelGenx has retained two options to extend the lease, with each option being for an additional five years. Under the terms of the lease IntelGenx is required to pay base rent of approximately CA$110 thousand (approximately $81 thousand) per year, which will increase at a rate of CA$0.25 ($0.18) per square foot, every two years.

On March 6, 2017 IntelGenx executed an agreement to lease approximately an additional 11,000 square feet in a property located at 6410 Abrams, St-Laurent, Quebec. The Lease has an 8 year and 5-month term commencing on October 1, 2017 and IntelGenx has retained two options to extend the Lease, with each option being for an additional five years. Under the terms of the Lease IntelGenx will be required to pay base rent of approximately CA$74 thousand (approximately $54 thousand) per year, which will increase at a rate of CA$0.25 ($0.18) per square foot every two years.

The aggregate minimum rentals, exclusive of other occupancy charges, for property leases expiring in 2026, are approximately $1,058 thousand, as follows:

2019	$140
2020	143
2021	145
2022	148
2023	150
Thereafter	332

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, 2018 an amount of Euro1,395 thousand has been paid with respect to these agreements.

Subsequent events

Subsequent to the end of the year, total of 50,000 stock options were exercised for 50,000 common shares having a par value of $Nil in aggregate, for cash consideration of approximately $21thousand.

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, 2018 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, 2018 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 of Directors 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, 2018. 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, 2018 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 2019 Proxy Statement.

We have adopted a Code of Business Conduct and Ethics that applies to our directors and officers, including our principal executive officer, and our principal financial officer and principal accounting officer. The Code of Business Conduct and Ethics is posted on our website at http://www.intelgenx.com. We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of our Code of Business Conduct and Ethics by posting such information on our website at the web address specified above.

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 2019 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 2019 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 2019 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 2019 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, 2018 and 2017.

C. Consolidated Statements of Shareholders Equity for the years ended of December 31, 2018 and 2017.

D. Consolidated Statements of Comprehensive Loss for the years ended of December 31, 2018 and 2017.

E. Consolidated Statements of Cash Flows for the years ended December 31, 2018 and 2017.

F. Notes to Consolidated Financial Statements.

2. Financial Statement Schedules

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

(b) Exhibits.

EXHIBIT INDEX

Exhibit No.	Description
2.1	Share exchange agreement dated April 10, 2006 (incorporated by reference to the Form 8-K/A filed on May 5, 2006)
3.1	Certificate of Incorporation (incorporated by reference to the Form SB-2 (File No. 333-90149) filed on November 16, 1999)
3.2	Amendment to the Certificate of Incorporation (incorporated by reference to amendment No. 2 to Form SB-2 (File No. 333-135591) filed on August 28, 2006)
3.3	Amendment to the Certificate of Incorporation (incorporated by reference to the Form DEF 14C filed on April 20, 2007)
3.4	Amendment to the Certificate of Incorporation (incorporated by reference to the Form S-1/A filed on May 12, 2017)
3.5	By-Laws (incorporated by reference to the Form SB-2 (File No. 333-91049) filed on November 16, 1999
3.6	Amended and Restated By-Laws (incorporated by reference to the Form 8-K filed on March 31, 2011)
3.7	Amended and Restated By-Laws (incorporated by reference to the Form 8-K filed on March 21, 2012)
4.1	Trust Indenture with TSX Trust Company, dated July 12, 2017 (incorporated by reference to the Form 8-K filed on July 12, 2017)
9.1	Voting Trust agreement (incorporated by reference to the Form 8-K/A filed on May 5, 2006)
10.1 +	Horst Zerbe employment agreement dated October 1, 2014 (incorporated by reference to the Form 10-Q filed on November 12, 2014)
10.2	Registration rights agreement (incorporated by reference to the Form SB-2 (File No. 333-135591) filed on July 3, 2006)
10.3	Principal s registration rights agreement (incorporated by reference to the Form SB-2 (File No. 333-135591) filed on July 3, 2006)
10.4 +	2006 Stock Option Plan (incorporated by reference to the Form S-8 filed on November 21, 2006)
10.5 +	Amended and Restated 2006 Stock Option Plan, May 29, 2008 (incorporated by reference to the Form 10-K filed on March 25, 2009)
10.6	Co-Development and Commercialization Agreement with RedHill Biopharma Ltd. (incorporated by reference to the Form 10-Q filed on November 9, 2010)
10.7 +	

	Amended and Restated 2006 Stock Option Plan (incorporated by reference to the Form S-8 filed on November 15, 2010)
10.8	Project Transfer Agreement (incorporated by reference to the Form 10-Q filed on May 14, 2010)
10.9	Co-development and Licensing Agreement (incorporated by reference to the Form 10-Q filed on May 14, 2010)
10.10	License and Asset Transfer Agreement with Edgemont Pharmaceuticals (incorporated by reference to the Form 10Q filed on May 15, 2012)
10.11	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)
10.12	Development Services and Commercialization Agreement with PAR Pharmaceuticals, dated January 8, 2014 (incorporated by reference to the Form 10-K filed on March 11, 2014)
10.13+	Employment Agreement Andre Godin, July 2015 (incorporated by reference to the Form 8-K filed on July 20, 2015)
10.14+	Employment Agreement Nadine Paiement, January 2016 (incorporated by reference to the Form 10-K filed on March 30, 2016)
10.15+	Employment Agreement Dana Matzen, March 2016 (incorporated by reference to the Form 10-K filed on March 30, 2016)

10.16+	2016 Stock Option Plan May, 11 2016 (incorporated by reference to the Form S-8 Registration Statement filed on August 3, 2016)
10.17	Amended Principal s Registration Rights Agreement, November 8, 2016 (incorporated by reference to Form 10-Q filed on November 10, 2016)
10.18	Agency Agreement dated June 28, 2017 (incorporated by reference from the Company s Form 8-K filed on July 5, 2017)
10.19+	Deferred Share Unit Plan for non-employee directors (incorporated by reference to the Form 10K filed on March 29, 2018)
10.20	Placement Agent Agreement dated May 8, 2018 (incorporated by reference to the Form 8-K filed on May 10, 2018)
10.21	Form of Warrant dated May 8, 2018 (incorporated by reference to the Form 8-K filed on May 10, 2018)
10.22	Form of Securities Purchase Agreement dated May 8, 2018 (incorporated by reference to the Form 8-K filed on May 10, 2018)
10.23	Form of Registration Rights Agreement dated May 8, 2018 (incorporated by reference to the Form 8-K filed on May 10, 2018)
10.24	Form of Note dated May 8, 2018 (incorporated by reference to the Form 8-K filed on May 10, 2018)
10.25	Placement Agent Agreement between the Company and H.C. Wainwright & Co., LLC dated October 18, 2018 (incorporated by reference to the Form 8-K filed on October 22, 2018)
10.26	Placement Agent Agreement between the Company and Echelon Wealth Partners Inc. dated October 18, 2018 (incorporated by reference to the Form 8-K filed on October 22, 2018)
10.27	Form of Warrant (incorporated by reference to the Form 8-K on October 22, 2018)
10.28	Form of Securities Purchase Agreement (incorporated by reference to the Form 8-K on October 22, 2018)
21.1	Subsidiaries of the small business issuer (incorporated by reference to the Form SB-2 (File No. 333-135591) filed on July 3, 2006)
23.1*	Consents of Richter LLP
31.1*	Certification of Horst G. Zerbe, President and Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*
31.2*	Certification of Andre Godin, Executive Vice President and Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*
32.1*	Certification of Horst G. Zerbe, President and Chief Executive Officer, pursuant to 18 U.S.C. Section 1350*
32.2*	

Certification of Andre Godin, Executive Vice President and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350.*

* 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 22, 2019, thereunto duly authorized.

INTELGENX TECHNOLOGIES CORP.

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

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

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

Signature	**Position**	**Date**
By: /s/ *Horst G. Zerbe* Horst G. Zerbe	Chairman of the Board, President and Chief Executive Officer	March 22, 2019
By*: /s/Andre Godin* Andre Godin	Executive Vice President and Chief Financial Officer	March 22, 2019
By: /s/ *Bernard Boudreau* J. Bernard Boudreau	Director, Vice Chairman of the Board	March 22, 2019
By: /s/*Bernd Melchers* Bernd J. Melchers	Director	March 22, 2019
By: /s/*John Marinucci* John Marinucci	Director	March 22, 2019
By: /s/*Clemens Mayr* Clemens Mayr	Director	March 22, 2019
By: /s/*Mark Nawacki* Mark Nawacki	Director	March 22, 2019

IntelGenx Technologies Corp.

Consolidated Financial Statements
December 31, 2018 and 2017
(Expressed in U.S. Funds)

IntelGenx Technologies Corp.

Consolidated Financial Statements
December 31, 2018 and 2017
(Expressed in U.S. Funds)

Contents

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, 2018 and 2017, the related consolidated statements of comprehensive loss, shareholders' equity and cash flows for each of the two years in the period ended December 31, 2018, 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, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, 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.

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.

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.

Richter LLP (Signed) [1]

Montréal, Quebec
March 22, 2019

[1]CPA auditor, CA, public accountancy permit No. A112505

IntelGenx Technologies Corp.

Consolidated Balance Sheets
As at December 31, 2018 and 2017
(Expressed in Thousands of U.S. Dollars ($ 000) Except Share and Per Share Data)

	2018	2017
Assets		
Current		
Cash	**$ 6,815**	$ 1,591
Short-term investments (note 6)	**4,180**	3,313
Accounts receivable	**815**	623
Prepaid expenses	**462**	203
Investment tax credits receivable	**416**	314
Inventory (note 7)	**375**	-
Total current assets	**13,063**	6,044
Leasehold improvements and equipment, net (note 8)	**6,248**	6,346
Security deposits	**707**	757
Total assets	**$ 20,018**	$ 13,147
Liabilities		
Current		
Accounts payable and accrued liabilities	**2,030**	1,305
Current portion of long-term debt (note 10)	**692**	772
Total current liabilities	**2,722**	2,077
Deferred lease obligations	**49**	50
Long-term debt (note 10)	**1,140**	1,992
Convertible debentures (note 11)	**5,047**	5,199
Convertible notes (note 12)	**1,073**	-
Total liabilities	**10,031**	9,318
Commitments (note 13)		
Subsequent event (note 21)		
Shareholders' equity		

Capital stock, common shares, $0.00001 par value; 200,000,000 shares authorized; 93,477,473 shares issued and outstanding (2017: 67,031,467 common shares) (note 14)	**1**	1
Additional paid-in capital (note 15)	**42,048**	25,253
Accumulated deficit	**(30,896)**	(20,788)
Accumulated other comprehensive loss	**(1,166)**	(637)
Total shareholders equity	**9,987**	3,829
	$ 20,018	$ 13,147

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, 2017
(Expressed in Thousands of U.S. Dollars ($ 000) Except Share and Per Share Data)

	Capital Stock		Additional		Accumulated Other	
	Number	Amount	Paid-In Capital	Accumulated Deficit	Comprehensive Loss	**Total Shareholders' Equity**
Balance - December 31, 2016	64,812,020	$ 1	$ 23,700	$ (17,737)	$ (1,019)	**$ 4,945**
Other comprehensive income	-	-	-	-	382	**382**
Warrants exercised (note 14)	2,084,447	-	1,176	-	-	**1,176**
Options exercised (note 14)	135,000	-	62	-	-	**62**
Stock-based compensation (note 14)	-	-	315	-	-	**315**
Net loss for the year	-	-	-	(3,051)	-	**(3,051)**
Balance December 31, 2017	**67,031,467**	**$ 1**	**$ 25,253**	**$ (20,788)**	**$ (637)**	**$ 3,829**

See accompanying notes

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		Accumulated Other	**Total**
	Number	Amount	Paid-In Capital	Accumulated Deficit	Comprehensive Loss	**Shareholders' Equity**
Balance - December 31, 2017	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)**
Balance December 31, 2018	**93,477,473**	**$ 1**	**$ 42,048**	**$ (30,896)**	**$ (1,166)**	**$ 9,987**

See accompanying notes

IntelGenx Technologies Corp.

Consolidated Statements of Comprehensive Loss
For the Years Ended December 31, 2018 and 2017
(Expressed in Thousands of U.S. Dollars ($ 000) Except Share and Per Share Data)

		2018		2017
Revenues (note 17)	**$**	**1,824**	$	5,195
Total revenues		**1,824**		5,195
Expenses				
Cost of royalty, license and other revenue		**-**		373
Research and development expense		**5,104**		2,615
Selling, general and administrative expense		**4,999**		3,965
Depreciation of tangible assets		**719**		735
Total expenses		**10,822**		7,688
Operating loss		**(8,998)**		(2,493)
Interest income		**11**		11
Financing and interest expense		**(1,121)**		(569)
Net financing and interest expense		**(1,110)**		(558)
Loss before income taxes		**(10,108)**		(3,051)
Income taxes (note 16)		**-**		-
Net loss		**(10,108)**		(3,051)
Other comprehensive income (loss)				
Change in fair value		3		71
Foreign currency translation adjustment		(532)		311
		(529)		382
Comprehensive loss	**$**	**(10,637)**	$	(2,669)
Basic and diluted:				
Weighted average number of shares outstanding		**74,121,922**		66,152,830
Basic and diluted loss per common share (note 20)	**$**	**(0.14)**	$	(0.04)

See accompanying notes

IntelGenx Technologies Corp.

Consolidated Statements of Cash Flows
For the Year Ended December 31, 2018 and 2017
(Expressed in Thousands of U.S. Dollars ($ 000) Except Share and Per Share Data)

	2018	2017
Funds (used) provided -		
Operating activities		
Net loss	**$ (10,108)**	$ (3,051)
Depreciation of tangible assets	**719**	735
Stock-based compensation	**370**	315
Accretion expense	**396**	123
DSU expense	**160**	-
Interest paid by issuance of common shares	**231**	-
Conversion of convertible debentures	**(16)**	-
	(8,248)	(1,878)
Changes in non-cash items related to operations:		
Accounts receivable	**(192)**	421
Prepaid expenses	**(259)**	363
Investment tax credits receivable	**(102)**	(68)
Inventory	**(375)**	-
Security deposits	**(11)**	-
Accounts payable and accrued liabilities	**658**	408
Deferred revenue	**-**	(3,634)
Deferred lease obligations	**(1)**	5
Net change in non-cash items related to operations	**(282)**	(2,505)
Net cash used in operating activities	**(8,530)**	(4,383)
Financing activities		
Repayment of long-term debt	**(749)**	(708)
Proceeds from exercise of warrants and stock options	**2,328**	1,238
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)**	-
Net proceeds from issuance of convertible debentures	**-**	5,469
Convertible debentures issuance costs	**-**	(491)
Net cash provided by financing activities	**16,404**	5,508
Investing activities		
Additions to leasehold improvements and equipment	**(1,096)**	(973)
Acquisitions of short-term investments	**(4,273)**	(3,952)
Redemptions of short-term investments	**3,192**	4,718
Net cash used in investing activities	**(2,177)**	(207)
Increase in cash	**5,697**	918
Effect of foreign exchange on cash	**(473)**	61
Cash		

Beginning of year		**1,591**		612
End of year	**$**	**6,815**	$	1,591

See accompanying notes

IntelGenx Technologies Corp.

Notes to Consolidated Financial Statements
December 31, 2018 and 2017
(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®. 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, 2018, the Company had cash and short-term investments totaling approximately $10,995. 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.

If the Company is unable to 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 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
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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.

IntelGenx is a pharmaceutical company focused on the development of novel oral immediate-release and controlled-release products for the pharmaceutical market. More recently, the Company has made the strategic decision to enter the oral film market and is in the process of implementing commercial oral film manufacturing capability. The Company s product development efforts are based upon three proprietary delivery platforms, including an immediate release oral film VersaFilm , a mucoadhesive tablet AdVersa , and a multilayer controlled release tablet VersaTab . The Company has an aggressive product development initiative that primarily focuses on addressing unmet market needs and focuses on utilization of 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 product pipeline currently consists of 11 products in various stages of development from inception through commercialization, including products for the treatment of major depressive disorder, opioid dependence, hypertension, erectile dysfunction, migraine, schizophrenia, idiopathic pulmonary fibrosis, and pain management. Of the products currently under development, 9 utilize the *VersaFilm* technology, one utilizes the *VersaTab* technology, and one utilizes the *AdVersa* technology.

4. Adoption of New Accounting Standards

The Company adopted Topic 606 Revenue from Contracts with Customers with a date of the initial application of January 1, 2018 using the modified retrospective method. As a result, the Company has changed its accounting policy for revenue recognition as detailed below.

This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those good or services. To determine revenue recognition for arrangements subject to the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract and identifies performance obligations that are distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to each performance obligation when (or as) the performance obligation is satisfied.

IntelGenx Technologies Corp.

Notes to Consolidated Financial Statements
December 31, 2018 and 2017
(Expressed in U.S. Funds)

4. Adoption of New Accounting Standards (Cont d)

ASC 606 uses the terms contract asset and contract liability to describe what might more commonly be known as accrued revenue and deferred revenue . The Company has adopted the terminology used in ASC 606 to describe such balances.

The Company s accounting policies for its revenue streams are disclosed in Note 5 below. Apart from providing more extensive disclosures on the Company s revenue transactions, the application of ASC 606 has not had a significant impact on the financial position and/or financial performance of the Company.

The FASB issued ASU 2017-09, Stock compensation, which provides guidance on determining which changes to the terms and conditions of share-based payment awards require an entity to apply modification accounting under Topic 718. The statement is effective for annual periods beginning after December 15, 2017. The Company has made an accounting policy choice to recognize the effect of awards for which the requisite service is not rendered when the award is forfeited (that is, recognize the effect of forfeitures in compensation cost when they occur). Previously recognized compensation cost for an award shall be reversed in the period that the award is forfeited. The adoption of this statement did not have a material effect on the Company s financial position or results.

The FASB issued ASU 2017-01, Business Combinations, which clarifies the definition of a business and is intended to help companies evaluate whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. These amendments are effective for a public business entity for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The adoption of this statement did not have a material effect on the Company s financial position or results.

The FASB issued ASU 2016-18, Statement of Cash Flows, which requires that the statement of cash flows explain the change during the period in the total cash, cash equivalents, and amounts generally described as restricted or restricted cash equivalents. The statement is effective for annual periods beginning after December 15, 2017, and interim periods within those annual periods. The adoption of this statement did not have a material effect on the Company s financial position or results.

The FASB issued ASU 2016-16, Income taxes, and requires an entity to recognize the income tax consequences of an intra-entity transfer of an asset other than inventory when the transfer occurs. These amendments are effective for a public business entity for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The adoption of this statement did not have a material effect on the Company s financial position or results.

The FASB issued ASU 2016-15, Statement of Cash Flows, which clarifies how certain cash receipts and payments are to be presented in the Statement of cash flows. The statement is effective for annual periods beginning after December 15, 2017, and interim periods within those annual periods. The adoption of this statement did not have a material effect on the Company s financial position or results.

IntelGenx Technologies Corp.

Notes to Consolidated Financial Statements
December 31, 2018 and 2017
(Expressed in U.S. Funds)

4. Adoption of New Accounting Standards (Cont d)

The FASB issued ASU 2016-01, Financial Instruments. The targeted amendments to existing guidance include:

1. Equity investments that do not result in consolidation and are not accounted for under the equity method would be measured at fair value through net income, unless they qualify for the proposed practicability exception for investments that do not have readily determinable fair values.

2. Changes in instrument-specific credit risk for financial liabilities that are measured under the fair value option would be recognized in other comprehensive income.

3. Entities would make the assessment of the realizability of a deferred tax asset (DTA) related to an available- for-sale (AFS) debt security in combination with the entity s other DTAs. The guidance would eliminate one method that is currently acceptable for assessing the realizability of DTAs related to AFS debt securities. That is, an entity would no longer be able to consider its intent and ability to hold debt securities with unrealized losses until recovery.

4. Disclosure of the fair value of financial instruments measured at amortized cost would no longer be required for entities that are not public business entities.

For public business entities, the amendments in this Update are effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. The adoption of this statement did not have a material effect on the Company s financial position or 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.

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.

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)

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.

For the year ended December 31, 2017, the Company s revenue recognition policy is as follows:

The Company enters into product development agreements with collaborators for the research and development and manufacturing of novel oral immediate-release and controlled-release products. The terms of these agreements may include non-refundable exclusivity, signing and licensing fees, funding for research, development and manufacturing, milestone payments and royalties on any product sales derived from collaborations. The Company typically receives non-refundable, up-front payments when licensing its intellectual property and know- how, which often occurs in conjunction with a research and development agreement. The Company analyses its multiple-element arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting.

IntelGenx Technologies Corp.

Notes to Consolidated Financial Statements
December 31, 2018 and 2017
(Expressed in U.S. Funds)

5. Summary of Significant Accounting Policies (Cont d)

The Company recognizes up-front license payments as revenue upon delivery of the license only if the license has stand-alone value and qualifies for treatment as a separate unit of accounting under multiple-element arrangement guidance. License fees with ongoing involvement or performance obligations that do not have standalone value are recorded as deferred revenue. For the year ended December 31, 2017, the Company recognized up-front licensing fees totaling $416 thousand.

Revenues related to the research and development with corporate collaborators are recognized as other revenue as research and development services are performed. Under these agreements, the Company is required to perform research and development activities as specified in the agreement. For the year ended December 31, 2017, the Company recognized research and development revenues totaling $1,019 thousand.

The Company recognizes revenue from milestones when milestones are achieved, in accordance with the terms of the specific agreements and when collection of the payment is reasonably assured. In addition, the performance criteria for the achievement of milestones are met if substantive effort was required to achieve the milestone and the amount of the milestone payment appears reasonably commensurate with the effort expended. Amounts received in advance of the recognition criteria being met, if any, are included in deferred income. For the year ended December 31, 2017, the Company recognized revenues as a result of sales milestones achieved under a licensing agreement totaling $Nil.

IntelGenx has license agreements that specify that certain royalties are earned by the Company on sales of licensed products in the licensed territories. Royalty revenue is recognized on an accrual basis in accordance with the relevant license agreement. For the year ended December 31, 2017, the Company recognized royalty revenue earned under a licensing agreement totaling $Nil.

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.

IntelGenx Technologies Corp.

Notes to Consolidated Financial Statements
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5. Summary of Significant Accounting Policies (Cont d)

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, 2018 accounts receivable (2017: $Nil). A bad debt expense in the amount of $Nil (2017: $29) is recorded in the year ended December 31, 2018.

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, 2018 totaled $289 thousand (2017: $255).

Inventory

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

Leasehold Improvements and Equipment

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

On the declining balance method -

Laboratory and office equipment	20%
Computer equipment	30%

On the straight-line method -

Leasehold improvements	over the lease term
Manufacturing equipment	5 10 years

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

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)

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.

Deferred Lease Obligations

Rent under operating leases is charged to expense on a straight-line basis over the lease term. Any difference between the rent expense and the rent payable is reflected as deferred lease obligations on the balance sheet.

Deferred lease obligations are amortized on a straight-line basis over the term of the related leases. Lease term includes free rent periods as well as the construction period prior to the commencement of the lease.

Foreign Currency Translation

The Company's reporting currency is the U.S. dollar. The Canadian dollar is the functional currency of the Company's Canadian operations, which is translated to the United States dollar using the current rate method. Under this method, accounts are translated as follows:
Assets and liabilities - at exchange rates in effect at the balance sheet date;

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

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

Income Taxes

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

deferred tax assets will be realized. Deferred tax assets and liabilities are adjusted for the effects of changes in tax laws and rates on the date of enactment.

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)

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 505-50, Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services". The fair value of the option issued is used to measure the transaction, as this is more reliable than the fair value of the services received. The fair value is measured at the value of the Company s common stock on the date that the commitment for performance by the counterparty has been reached or the counterparty s performance is complete. The fair value of the equity instrument is charged directly to compensation expense and additional paid-in capital. For common stock issuances to non-employees that are fully vested and are for future periods, the Company classifies these issuances as prepaid expenses and expenses the prepaid expenses over the service period. At no time has the Company issued common stock for a period that exceeds one year.

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.

IntelGenx Technologies Corp.

Notes to Consolidated Financial Statements
December 31, 2018 and 2017
(Expressed in U.S. Funds)

5. Summary of Significant Accounting Policies (Cont d)

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 2018-20 Leases (Topic 842): Narrow-Scope Improvements for Lessors

The FASB issued ASU 2018-20 which addresses the following issues facing lessors when applying the leases standard:

- Sales taxes and other similar taxes collected from lessees. The amendments in the ASU permit lessors, as an accounting policy election, to not evaluate whether certain sales taxes and other similar taxes are lessor costs or lessee costs. Instead, those lessors will account for those costs as if they are lessee costs and exclude the costs from being reported as lease revenue with an associated expense.

- Certain lessor costs paid directly by lessees. The amendments in the ASU related to certain lessor costs require lessors to exclude from variable payments, and therefore revenue, lessor costs paid by lessees directly to third parties. The amendments also require lessors to account for costs excluded from the consideration of a contract that are paid by the lessor and reimbursed by the lessee as variable payments. A lessor will record those

reimbursed costs as revenue.

IntelGenx Technologies Corp.

Notes to Consolidated Financial Statements
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5. Summary of Significant Accounting Policies (Cont d)

- Recognition of variable payments for contracts with lease and nonlease components. The amendments in the ASU related to recognizing variable payments for contracts with lease and nonlease components require lessors to allocate (rather than recognize as currently required in the new leases standard) certain variable payments to the lease and nonlease components when the changes in facts and circumstances on which the variable payment is based occur. After the allocation, the amount of variable payments allocated to the lease components will be recognized as income in profit or loss in accordance with the new leasing guidance, while the amount of variable payments allocated to nonlease components will be recognized in accordance with other accounting guidance, such as revenue from contracts with customers.

These amendments are effective when the entity first applies Topic 842.

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.

IntelGenx Technologies Corp.

Notes to Consolidated Financial Statements
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5. Summary of Significant Accounting Policies (Cont d)

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.

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.

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5. Summary of Significant Accounting Policies (Cont d)

ASU 2018-07 Compensation Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting

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 nonemployees. 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 Company is currently evaluating the impact of this Statement on its consolidated financial statements.

ASU 2018-02 Income Statement Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income

The FASB issued ASU 2018-02 which provides financial statement preparers with an option to reclassify stranded tax effects within AOCI to retained earnings in each period in which the effect of the change in the U.S. federal corporate income tax rate in the Tax Cuts and Jobs Act (or portion thereof) is recorded. These amendments are effective for fiscal years beginning after December 15, 2018. The Company is currently evaluating the impact of the Statement on its consolidated financial statements.

ASU 2017-11 Earnings Per Share (Topic 260); Distinguishing Liabilities from Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments with Down Round Features

The FASB issued ASU 2017-11 which requires companies to disregard the down round feature when assessing whether the instrument is indexed to its own stock, for purposes of determining liability or equity classification. Companies that provide earnings per share (EPS) data will adjust their basic EPS calculation for the effect of the feature when triggered (i.e., when the exercise price of the related equity-linked financial instrument is adjusted downward because of the down round feature) and will also recognize the effect of the trigger within equity. These amendments are effective for fiscal years beginning after December 15, 2018. The Company is currently evaluating the impact of this Statement on its consolidated financial statements.

ASU 2017-04 Intangibles Goodwill and Other (Topic 350) Simplifying the Test for Goodwill Impairment

The FASB issued ASU 2017-04 which eliminates Step 2 from the goodwill impairment test and eliminates the requirements for any reporting unit with a zero or negative carrying amount to perform a qualitative assessment. These amendments are effective for a public business entity for fiscal years beginning after December 15, 2019. Early adoption is permitted in any interim or annual period and should be applied on a retrospective basis. The Company is currently evaluating the impact of this Statement on its consolidated financial statements.

ASU 2016-02: Leases (Topic 842) Section A

The FASB issued ASU 2016-02 to increase the transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing

arrangements.

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5. Summary of Significant Accounting Policies (Cont d)

The FASB issued ASU 2018-11 which provides entities with an additional (and optional) transition method to adopt the new leases standard. Under this new transition method, an entity initially applies the new leases standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Consequently, an entity s reporting for the comparative periods presented in the financial statements in which it adopts the new leases standard will continue to be in accordance with current GAAP (Topic 840, Leases).

The FASB issued ASU 2018-10 which amends the narrow aspects of the guidance issued in the amendments in ASU 2016-02 including those regarding residual value guarantees, rate implicit in the lease, lessee reassessment of lease classification, lessor reassessment of lease term and purchase option, variable lease payments that depend on an index or a rate, investment tax credits, lease term and purchase option, transition guidance for amounts previously recognized in business combinations, certain transition adjustments, transition guidance for leases previously classified as capital leases under Topic 840, transition guidance for modifications to leases previously classified as direct financing or sales-type leases under Topic 840, transition guidance for sale and leaseback transactions, impairment of net investment in the lease, unguaranteed residual asset, effect of initial direct costs on rate implicit in the lease, and failed sale and leaseback transactions.

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 Company has begun the process of evaluating the impact of this Statement on its consolidated financial statements and has identified all outstanding leases.

6. Short-term investments

As at December 31, 2018, short-term investments consisting of mutual funds (CAD$5,703 million) are with a Canadian financial institution having a high credit rating. As at December 31, 2017, short-term investments consisted of mutual funds (CAD$3,589 million) and term deposits ($450 thousand).

7. Inventory

Inventory as at December 31, 2018 consisted of raw materials in the amount of $375 (2017: $Nil).

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8. Leasehold improvements and Equipment

	Cost	Accumulated Depreciation	**2018 Net Carrying Amount**	2017 Net Carrying Amount
Manufacturing equipment	$ 4,092	$ 580	**$ 3,512**	$ 2,953
Laboratory and office equipment	1,273	711	**562**	759
Computer equipment	106	67	**39**	44
Leasehold improvements	3,039	904	**2,135**	2,590
	$ 8,510	$ 2,262	**$ 6,248**	$ 6,346

From the balance of manufacturing equipment, an amount of $1,703 thousand (2017: $822 thousand) represents assets which are still under construction as at December 31, 2018 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 ($183 thousand) and corporate credits cards of up to CAD$75 thousand ($55 thousand), and foreign exchange contracts limited to CAD$425 thousand ($312 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 ($3,115,000) 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, 2018, 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.

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10. Long-term debt

The components of the Company s debt are as follows:

	December 31, 2018	December 31, 2017
	$	$
Term loan facility	1,502	2,233
Secured loan	330	531
Total debt	1,832	2,764
Less: current portion	692	772
Total long-term debt	1,140	1,992

The Company s term loan facility consists of a total of CAD$4 million ($2.93 million) bearing interest at the Bank s prime lending rate plus 2.50%, with monthly principal repayments of CAD$62 thousand ($45 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 ($733 thousand) bearing interest at prime plus 7.3%, reimbursable in monthly principal payments of CAD$17 thousand ($12 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, 2018, 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 three years are as follows:

2019 692 (CAD 945)
2020 692 (CAD 945)
2021 448 (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 ($5,012,000). Pursuant to the Offering, the Corporation issued an aggregate principal amount of CAD$6,838,000 ($5,012,000) of Debentures at a price of CAD$1,000 ($733) 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 ($0.99) (the Conversion Price) per common share of the Corporation (Share), being a conversion rate of approximately 740 Shares per CAD$1,000 ($733) principal amount of Debentures, subject to adjustment in certain events.

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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 ($559,000).

Together with the principal amount of CAD$6,838,000 ($5,012,000) 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 ($733) per Debenture.

The convertible debentures have been recorded as a liability. Total transactions costs in the amount of CAD$1,237,000 ($907,000) were recorded against the liability. The accretion expense for the period ended December 31, 2018 amounts to CAD$383,000 ($296,000) compared to CAD$160,000 ($123,000) for the year ended December 31, 2017.

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, 2018		**December 31, 2017**
Face value of the convertible debentures	**$**	**5,556**	$	6,058
Transaction costs		**(907)**		(986)
Accretion		**398**		127
Convertible debentures	**$**	**5,047**	$	5,199

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. Interest accrued as at December 31, 2017 on the convertible debentures amounts to CAD$287 thousand ($221 thousand) and was paid on December 29, 2017. The interest expense on the convertible debentures is recorded in financing and interest expense.

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

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12. Convertible Notes (Cont d)

due on September 1, 2018), matures on June 1, 2021 and is convertible into Common Shares at a conversion price of $0.80 per Common Share. Each Warrant entitles its holder to purchase one Common Share at a price of $0.80 per Common Share until June 1, 2021.

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

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

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

The convertible notes have been recorded as a liability. Total transactions costs in the amount of $111 thousand were recorded against the liability. The accretion expense for the year ended December 31, 2018 amounts to $98,000. The warrants have been recorded as equity.

The components of the convertible notes are as follows:

	December 31, 2018
Attributed value of net proceeds to convertible notes	$ 975
Accretion	98
Convertible notes	$ 1,073

The interest on the convertible notes for the year ended December 31, 2018 amounts to $63 thousand 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.

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13. Commitments

On April 24, 2015 the Company entered into an agreement to lease approximately 17,000 square feet in a property located at 6420 Abrams, St-Laurent, Québec. The Lease has a 10 year and 6-month term commencing September 1, 2015. IntelGenx has retained two options to extend the lease, with each option being for an additional five years. Under the terms of the lease IntelGenx is required to pay base rent of approximately CAD$110 thousand (approximately $81 thousand) per year, which will increase at a rate of CAD$0.25 ($0.18) per square foot every two years.

On March 6, 2017 IntelGenx executed an agreement to lease approximately an additional 11,000 square feet in a property located at 6410 Abrams, St-Laurent, Quebec (the Lease). The lease has an 8 year and 5-month term commencing on October 1, 2017 and IntelGenx has retained two options to extend the Lease, with each option being for an additional five years. Under the terms of the Lease IntelGenx will be required to pay base rent of approximately CAD$74 thousand (approximately $54 thousand) per year, which will increase at a rate of CAD$0.25 ($0.18) per square foot every two years. IntelGenx plans to use the newly leased space to expand its manufacture of oral film VersaFilm ™.

The aggregate minimum rentals, exclusive of other occupancy charges, for property leases expiring in 2026, are approximately $1,058 thousand, as follows:

2019	140
2020	143
2021	145
2022	148
2023	150
Thereafter	332

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, 2018 an amount of Euro1,395 thousand has been paid with respect to these agreements (note 8).

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14. Capital Stock

		2018		2017
Authorized -				
200,000,000 common shares of $0.00001 par value				
20,000,000 preferred shares of $0.00001 par value				
Issued -				
93,477,473 (December 31, 2017: 67,031,467) common shares	**$**	**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.

Private Placement Financing

On November 13, 2018, the Company announced the closing of Tilray Inc. s strategic investment in IntelGenx by was 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.

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14. Capital Stock (Cont d)

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

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14. Capital Stock (Cont d)

Stock options

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.

During the year ended December 31, 2017 a total of 135,000 stock options were exercised for 135,000 common shares having a par value of $0 thousand in aggregate, for cash consideration of $62 thousand, resulting in an increase in additional paid-in capital of $62 thousand.

Stock-based compensation of $370 thousand and $315 thousand was recorded during the year ended December 31, 2018 and 2017 respectively. An amount of $356 thousand (2017 - $309 thousand) expensed relates to stock options granted to employees and directors and an amount of $14 thousand (2017- $6 thousand) relates to stock options granted to consultants during the year ended December 31, 2018 and 2017. As at December 31, 2018 the Company has $453 thousand (2017 - $196 thousand) of unrecognized stock-based compensation, of which $83 thousand (2017 $5) 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.

In the year ended December 31, 2017 a total of 2,084,447 warrants were exercised for 2,084,447 common shares having a par value of $Nil in aggregate, for cash consideration of approximately $1,176 thousand, resulting in an increase in additional paid-in capital of approximately $1,176 thousand.

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.

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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:

	2018	2017
Exercise price	0.74	0.82
Expected volatility	59%	60%
Expected life	5.63 years	5.34 years
Risk-free interest rate	2.73%	1.85%
Dividend yield	Nil	Nil

The weighted average fair value of the options granted to employees and directors during the year ended December 31, 2018 is $0.40 (2017 - $0.44) .

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, 2017.

Information with respect to employees and directors stock option activity for 2017 and 2018 is as follows:

		Number of options	Weighted average exercise price $
Outstanding	January 1, 2017	2,660,000	0.60
Granted		659,818	0.82
Forfeited		(170,000)	(0.63)
Expired		(75,000)	(0.65)
Exercised		(135,000)	(0.46)
Outstanding	December 31, 2017	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

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15. Additional Paid-In Capital (Cont d)

Information with respect to consultant s stock option activity for 2017 and 2018 is as follows:

	Number of options	Weighted average exercise price $
Outstanding January 1, 2017 and December 31, 2017	50,000	0.73
Granted	500,000	0.72
Outstanding December 31, 2018	550,000	0.72

Details of stock options outstanding as at December 31, 2018 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	325,000	0.15	0.03		325,000	0.05	
0.53	125,000	0.03	0.02		125,000	0.02	
0.58	675,000	0.24	0.09		675,000	0.14	
0.62	200,000	0.06	0.03		200,000	0.04	
0.66	275,000	0.58	0.04		68,750	0.02	
0.70	475,000	0.43	0.08		-	-	
0.73	600,000	0.99	0.10		600,000	0.15	
0.76	945,000	1.98	0.16		345,000	0.09	
0.77	359,818	0.71	0.06		179,909	0.05	
0.78	100,000	0.06	0.02		-	-	
0.79	25,000	0.05	0.00		25,000	0.01	
0.89	300,000	0.55	0.06		300,000	0.09	
	4,404,818	5.83	0.69	43,500	2,843,659	0.66	43,500

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15. Additional Paid-In Capital (Cont d)

Stock-based compensation expense recognized in 2018 with regards to the stock options was $345 thousand (2017: $315 thousand). As at December 31, 2018 the Company has $453 thousand (2017 - $196 thousand) of unrecognized stock-based compensation, of which $83 thousand (2017 $5 thousand) relates to options granted to consultants. The amount of $453 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 $453 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.

In the year ended December 31, 2017 a total of 2,084,447 warrants were exercised for 2,084,447 common shares having a par value of $Nil in aggregate, for cash consideration of approximately $1,176 thousand, resulting in an increase in additional paid-in capital of approximately $1,176 thousand.

Information with respect to warrant activity for 2017 and 2018 is as follows:

	Number of warrants (All Exercisable)	Weighted average exercise price $
Outstanding January 1, 2017	6,174,358	0.5646
Exercised	(2,084,447)	(0.5646)
Expired	(19,009)	(0.5646)
Outstanding - December 31, 2017	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	12,904,397	0.9470

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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 May 16, 2018, 287,355 DSUs have been granted under the DSU Plan as of the date of this filing, accordingly, an amount of $160 thousand 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.

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:

	2018	2017
Statutory income taxes	**$ (2,421)**	$ (794)
Net operating losses for which no tax benefits have been recorded	**1,185**	346
Deficiency of depreciation over capital cost allowance	**(236)**	(235)
Non-deductible expenses	**422**	239
Undeducted research and development expenses	**1,167**	525
Investment tax credit	**(117)**	(81)
	$ -	$ -

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16. Income Taxes (Cont d)

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

	2018	2017
Leasehold improvements and equipment	**$ 418**	$ 252
Net operating losses carryforward	**4,170**	2,620
Undeducted research and development expenses	**2,774**	2,054
Non-refundable tax credits carryforward	**1,982**	1,553
	9,344	6,479
Valuation allowance	**(9,344)**	(6,479)
	$ -	$ -

As at December 31, 2018, 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. Although management believes that certain of the net operating losses will be applied against earnings in 2019, 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 $14,934 thousand (2017: $9,560 thousand) and $16,498 thousand (2017: $10,052 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 2027 and 2038. A portion of the net operating losses may expire before they can be utilized.

As at December 31, 2018, the Company had non-refundable tax credits of $1,981 thousand (2017: $1,553 thousand) of which $8 thousand is expiring in 2026, $9 thousand is expiring in 2027, $165 thousand is expiring in 2028, $145 thousand is expiring in 2029, $124 thousand is expiring in 2030, $131 thousand is expiring in 2031, $164 thousand is expiring in 2032, $109 thousand is expiring in 2033, $83 thousand expiring in 2034, $97 thousand is expiring in 2035, $135 thousand expiring in 2036, $257 thousand is expiring in 2037 and $554 thousand expiring in 2038 and undeducted research and development expenses of $10,663 thousand (2017: $7,532 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.

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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, 2018:

Tax Jurisdictions	Tax Years
Federal - Canada	2014 and onward
Provincial - Quebec	2014 and onward
Federal - USA	2014 onward

17. Revenues

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

	December 31, 2018	December 31, 2017
Research and development agreements	**$ 1,824**	$ 1,019
Licensing agreements	**-**	416
Deferred revenue (sale of future royalties)	**-**	3,760
	$ 1,824	$ 5,195

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

	December 31, 2018	December 31, 2017
Product and services transferred at point in time	**$ -**	$ 416
Products and services transferred over time	**1,824**	4,779
	$ 1,824	$ 5,195

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17. Revenues (Cont d)

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

	December 31, 2018	December 31, 2017
Europe	**$ 1,715**	$ 1,005
Canada	**109**	399
U.S.	**-**	3,760
Other foreign countries	**-**	31
	$ 1,824	$ 5,195

Remaining performance obligations

As at December 31, 2018, the aggregate amount of the transaction price allocated to the remaining performance obligation is $1,509 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 $4,854 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 $28,751 in commercial sales milestone payments, the majority of which is expected to be recognized in the next five years, but is 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.

The Company applies the transition practical expedient in paragraph 606-10-65-1(f)(3) and does not disclose the amount of the transaction price allocated to the remaining performance obligations and an explanation of when the Company expects to recognize that amount as revenue for the year ended December 31, 2018.

18. Statement of Cash Flows Information

In US$ thousands	**2018**	2017
Additional Cash Flow Information:		
Interest paid	**$ 476**	$ 408

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19. Related party transactions

Included in management salaries are $75 thousand (2017 - $10 thousand) for options and PRSUs granted to the Chief Executive Officer, $46 thousand (2017 - $37 thousand) for options and PRSUs granted to the Chief Financial Officer, $Nil thousand (2017 - $3 thousand) for options granted to the former Vice President, Operations, $24 thousand (2017 - $9) for options granted to the Vice-President, Research and $54 thousand for options granted to Vice-President, Business and Corporate Development (2017 $34) under the 2016 Stock Option Plans and $11 thousand (2017 - $131 thousand) for options granted to non-employee directors.

Included in general and administrative expenses are director fees of $250 thousand (2017: $256 thousand).

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

20. Basic and Diluted Loss Per Common Share

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

21. Subsequent events

Subsequent to the end of the year, a total of 50,000 options were exercised for 50,000 common shares having a par value of $Nil in aggregate, for cash consideration of approximately $21 thousand.