

IntelGenx Technologies Corp.  
Form 10-K  
March 29, 2018

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 10-K**

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

**For the fiscal year ended December 31, 2017**

**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**

*(State or other jurisdiction of incorporation or  
organization)*

**87-0638336**

*(I.R.S. Employer Identification No.)*

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

*(Address of principal executive offices)*

**H4S 1Y2**

*(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

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

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Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes      No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes

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.

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

(Do not check if a smaller reporting company)

Smaller reporting company

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.

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Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes No

As of June 30, 2017, the aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates of the registrant was \$54,454,267 based on the closing price of the registrant's common shares of U.S. \$0.97, as reported on the OTCQX on that date. Shares of the registrant's common shares held by each officer and director and each person who owns 10% or more of the outstanding common shares 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.

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

<u>Class</u>	<u>Outstanding at March 29, 2018</u>
Common Stock, \$.00001 par value	67,731,467 shares

**DOCUMENTS INCORPORATED BY REFERENCE:**

Portions of the Company's Proxy Statement for its 2018 Annual Meeting of Shareholders (the 2018 Proxy Statement ) are incorporated by reference into Part III

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*Terminology and references*

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

In this Form 10-K, unless otherwise specified, all monetary amounts are in United States dollars, all references to "\$", "U.S.\$", "U.S. dollars" and "dollars" mean U.S. dollars and all references to "C\$", "Canadian dollars" and "CA\$" mean Canadian dollars. To the extent that such monetary amounts are derived from our consolidated financial statements included elsewhere in this Form 10-K, they have been translated into U.S. dollars in accordance with our accounting policies as described therein. Unless otherwise indicated, other Canadian dollar monetary amounts have been translated into United States dollars at the average annual exchange rate for 2017 as reported by the Bank of Canada, being U.S. \$1.00 = CA\$1.2979.

## 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, 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, 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:

- 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;
- 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 a 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 fourteen projects currently in our product portfolio, three utilize our VersaTab technology, ten utilize our VersaFilm technology, and one utilizes our AdVersa® technology.

**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 currently 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 \$1.0 million upfront payment, received launch related milestones totaling up to \$4.0 million, and are eligible for additional milestones of up to a further \$23.5 million upon achieving certain sales and exclusivity targets. We also receive tiered double-digit royalties on the net sales of the product. The agreement has no expiry date but may be terminated in the event of, without limitation (i) failure by either us or Edgemont to perform our respective obligations under the agreement; (ii) if either party files a petition for bankruptcy or insolvency or otherwise winds up, liquidates or dissolves its business, or (iii) otherwise by mutual consent of the parties. The agreement also contains customary confidentiality, indemnification and intellectual property protection provisions.

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. From that \$3 million milestone payment, \$1 million was received in Q3 2015. Of the remaining balance of \$2 million, \$1 million was received in Q4 2015 and \$1 million was received in Q1 2016. We commenced receiving royalty payments in the first quarter of 2013. We recorded \$433 thousand for the cost of royalty and license revenue in the twelve-month period ended December 31, 2015 compared with \$61 in the same period of 2014.

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<sup>®</sup> 450 mg tablets. In exchange, we received milestone payments of \$650 thousand in December 2014 and \$600 thousand in February 2015. All other financial obligations contained in the license agreement entered into by Edgemont and IntelGenx in February 2012, specifically launch-related and sales milestones, together with the contractual royalty rates on net sales of the product, remained in effect.

On August 5, 2016, we announced that we had sold our U.S. royalty on future sales of Forfivo XL<sup>®</sup> 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<sup>®</sup> in the United States expires in 2027.

SWK is a specialized finance company with a focus on the global healthcare sector. SWK partners with ethical product marketers and royalty holders to provide flexible financing solutions at an attractive cost of capital to create long-term value for both SWK's business partners and its investors.

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

**INT0007/2006:** We are developing an oral film product based on our VersaFilm<sup>™</sup> 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<sup>®</sup>. We are currently completing all required activities supporting the filing of a 505(b)(2) new drug application ( NDA ).

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<sup>™</sup> 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 currently actively seeking a partner for the commercialization of our Tadalafil ED VersaFilm<sup>™</sup> product.

**INT0008/2007:** We developed this oral film product based on our VersaFilm<sup>™</sup> technology. In March 2013 we submitted a 505(b)(2) NDA to the FDA for our novel oral thin-film formulation of Rizatriptan, the active drug in Maxalt-MLT<sup>®</sup> orally disintegrating tablets. Maxalt-MLT<sup>®</sup> 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 ). The product uses our proprietary immediate release VersaFilm<sup>™</sup> oral drug delivery technology. In December 2011, we received approval by Health Canada to conduct a pivotal bioequivalence study to determine if our product is safe and bioequivalent with the FDA approved reference product, Maxalt-MLT<sup>®</sup>. The trial was conducted in the second quarter of 2012 and was a randomized, two-period, two-way crossover study in healthy male and female subjects. The study results indicate that the product is safe, and that the 90% confidence intervals of the three relevant parameters C<sub>max</sub>, 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<sup>™</sup> 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<sup>™</sup> product from being approved by the FDA. We have identified a new source of API to manufacture new submission lots to support the re-submission of the NDA..

In October 2014 we announced the submission of 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. The submission is supported by several studies, including a comparative bioavailability study which successfully established the bioequivalence between RIZAPORT® and the European reference drug. BfArM validated the MAA and initiated the formal review process of the application on November 25, 2014. BfArM granted national marketing approval on November 9, 2015 for RIZAPORT® under the DCP.

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®. Marketing authorization in Luxemburg, the Concerned Member State, is expected to follow. IntelGenx and RedHill intend to continue to work together to obtain national phase approvals in other European DCP territories.

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 will receive upfront and milestone payments, together with a share of the net sales of RIZAPORT®. Commercial launch in Spain is estimated to take place in the second half of 2018. 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. Approval in Spain is currently expected for Q2 2017.

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. Commercial launch in South Korea is estimated to take place in the first quarter of 2019.

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 and recommended a telephone meeting between the Company and FDA to clarify which additional data need to be included in the re-submission. We are currently working on the required information and will request a meeting with the FDA to confirm its completeness.

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.

**INT0010/2006:** 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.

Subsequent to the 2016 fiscal year end, on February 9, 2017, we announced the signing of a binding term sheet with Tetra Bio-Pharma Inc. ( Tetra ) for the development and commercialization of a drug product containing dronabinol. Under the binding term sheet, Tetra will have exclusive rights to sell the product in North America with a right of first negotiation for outside the U.S. and Canada.

As per the Binding Term Sheet, we received a non-refundable exclusive negotiation payment from Tetra. We will also be entitled to receive an upfront payment along with set milestone payments based on the completion of an efficacy study, approvals from FDA and Health Canada and launching of the product.

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 follows 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 will make 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. IntelGenx will be responsible for the research and development of the Product, including clinical studies, and will develop the product as an oral mucoadhesive tablet based on its proprietary AdVersa® controlled-release technology. Tetra will be 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.

We will be 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 will develop the product as an oral mucoadhesive tablet based on our proprietary AdVersa® controlled-release technology. Tetra will be responsible for funding the product development, and will own and control all regulatory approvals, including the application and any other marketing authorizations. Tetra will also be responsible for all aspects of commercializing the drug product.

**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 ), 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, and will vigorously defend ourselves in this matter. In accordance with the terms of the co-development and commercialization agreement, Par is financially responsible for the costs of this defense. Since Paragraph IV litigation is a regular part of the ANDA process, we do not expect any unanticipated impact on our already planned 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 relate to a process for making a uniform oral film ( the process patents ). The trial for the process patents was held in November 2016. We believe the ANDA product relating to Suboxone<sup>®</sup> does not infringe those process patents or any other patents, and will vigorously defend ourselves in this matter. In accordance with the terms of the co-development and commercialization agreement, Par is financially responsible for the costs of this defense.

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<sup>®</sup> 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 of 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 are now under appeal before the U.S. Court of Appeals for the Federal Circuit.

There are currently several lawsuits for patent infringement in U.S. District Courts related to the Suboxone® ANDA product. These new ANDA lawsuits are based on patents submitted on the FDA Orange Book in 2017 and 2018. IntelGenx is not a party to any currently opened U.S. District Court instances related to the Suboxone® ANDA product.

In late January 2017, Par received a CRL from the FDA requesting more information on the APIs and the finished product. Since then, there were communications and follow up request from the FDA. The revision process is ongoing.

**INT0036/2013:** 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 currently optimizing the film to further improve time to reach peak plasma concentrations.

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.

**INT0037/2013:** A product based on one of our proprietary technologies has been developed and we are currently preparing submission batches and documentation in support of a marketing application to the FDA. 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. We continue to work closely with Par on the opioid dependence product and are pleased the relationship is on excellent terms.

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. Activities in preparation for filing are currently ongoing.

**INT0039/2013:** The product 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. We continue to work closely with Par on the opioid dependence product and are pleased the relationship is on excellent terms.

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.

Activities in preparation for filing are currently ongoing.

**INT0040/2014:** An oral film product based on our proprietary edible film technology is currently in the optimization development 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.

**INT0041/2015:** An oral film product based on our proprietary edible film technology in the development stage. In order to protect our competitive advantage, no further details of the product were disclosed. The project has been terminated in 2017.

**INT0042/2015:** An oral film product based on our proprietary edible film technology 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.

**INT0043/2015:** We have developed an oral film containing montelukast as an active ingredient based on our proprietary edible film technology VersaFilm™. 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 initiation of a phase 1 clinical trial of montelukast, a unique drug repurposing opportunity for the treatment of degenerative diseases of the brain, such as: mild cognitive impairment and Alzheimer's disease, the most prominent form of dementia. The objectives of the trial were to demonstrate that our oral film product will provide therapeutically effective blood levels of montelukast, and that montelukast when delivered using our oral film crosses the blood brain barrier.

On August 22, 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 retaining the services of Cogstate and JSS Medical Research as the Contract Research Organizations to support the Montelukast VersaFilm™ study. Cogstate is currently preparing cognitive

testing materials and training for clinical staff and physicians to ensure proper administration of the cognitive testing. Once completed they will also proceed with data analysis. JSS will monitor clinical trial sites to ensure protocol adherence. Patient screening is expected to begin by the end of Q1 2018.

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.

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

On December 1st, 2016, we announced that we had strengthened our relationship with Chemo by signing a term sheet for the co-development and commercialization of a generic tablet in the area of CNS (central nervous system) on a worldwide basis. According to Global Data, worldwide sales in 2015 of the CNS related product exceeded \$4 billion.

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As per the agreement, we received an upfront payment and will be entitled to receive development costs of the product and future milestone payments. Chemo and IntelGenx will also share the profits of commercialization. The definitive agreement was signed on December 30, 2016.

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

<b>Product</b>	<b>Indication</b>	<b>Status of Development</b>
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	Submission preparation ongoing
INT0008/2008	Migraine	Response to an incomplete response preparation ongoing at IntelGenx. Submission currently under review by Spanish authorities.
INT0010/2006	Pain	Formulation optimization, scale-up preparation and clinical study evaluation
INT0027/2011	Opioid dependence	ANDA submitted to FDA in July 2013. FDA review process ongoing.
INT0036/2012	Schizophrenia	Formulation development ongoing
INT0037/2013	Undisclosed	Product developed. Preparing document for submission.
INT0039/2013	Undisclosed	Product developed. Preparing document for submission.
INT0040/2013	Undisclosed	Formulation development ongoing
INT0042/2015	Undisclosed	Formulation development ongoing
INT0043/2015	Alzheimer	Formulation development completed in preparation for clinical phase II proof of concept
INT0044/2016	Undisclosed	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<sup>®</sup> mucosal adhesive tablet, are two examples of our efforts to develop alternate technology platforms. As we work with various partners on different products, we seek opportunities to develop new proprietary technologies.

### **Repurposing Existing Drugs**

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

### **Generic Drugs with High Barriers to Entry**

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

### **Competition**

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



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

The regulatory requirements;

The safety and efficacy of our products;

The relative speed with which we can develop products;

Generic competition for any product that we develop;

Our ability to defend our existing intellectual property and to broaden our intellectual property and technology base;

Our ability to differentiate our products;

Our ability to develop products that can be manufactured on a cost effective basis;

Our ability to manufacture our products in compliance with current Good Manufacturing Practices ( cGMP ) and any other regulatory requirements; and

Our ability to obtain financing.

In order to establish ourselves as a viable industry partner, we plan to continue to invest in our research and development activities and in our manufacturing technology expertise, in order to further strengthen our technology base and to develop the ability to manufacture our VersaFilm products ourselves, and our VersaTab and AdVersa® products through our manufacturing partners, at competitive costs.

### **Our Competitive Strengths**

We believe that our key competitive strengths include:

Our comprehensive 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 10 patents and have an additional 25 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	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 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 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 8,735,374			

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	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 Inventors	Optimization of film strip technology	Issued August 1, 2017 Expires September 21, 2031

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<b>Patent Application No.</b>	<b>Title</b>	<b>Subject</b>	<b>Date Filed</b>
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
Japanese Appl. JP2016527262	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. 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
EU Appl. EP3,027,179	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. 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
Singapore Appl. SG11201600455X	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
Australian Appl. AU2014298130	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
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



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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
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
Columbian Appl. 16047053	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
Russian Appl. 2016106907	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
New Zealand Appl. 716574	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
Canadian Appl. CA2,797,444	Solid oral dosage forms comprising tadalafil	Formulation of oral films containing tadalafil	Filed November 3, 2011
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			Filed February 3, 2016

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	Loxapine film oral dosage form	Formulation of oral films containing loxapine	
US Appl. 14/630,699	Film dosage forms containing amorphous active agents	Film containing amorphous agent	Filed February 2, 2015
PCT Appln. WO 2017132752	Loxapine film oral dosage form	Formulation of oral films containing loxapine	Filed January 25, 2017
PCT Appln. WO 2017152272	Montelukast transmucosal film	Formulation of oral films containing montelukast	Filed March 1, 2017



## **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.

## **Research and Development Expense**

Our R&D expenses, net of R&D tax credits, for the year ended December 31, 2017 increased by \$849 thousand to \$2,615 thousand, compared with \$1,766 thousand for the year ended December 31, 2016. 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 32 full-time and 3 part-time employees. None of our employees are covered by collective bargaining agreements. We believe that our relations with our employees are very good.

### ITEM 1A. RISK FACTORS.

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

#### Risks Related to Our Business

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

Our financial statements have been prepared under the assumption that we will continue as a going concern. The opinion of our independent registered public accountants on our audited financial statements as of and for the year ended December 31, 2017 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 \$20,767 thousand since our inception in 2003 through December 31, 2017. To date, these losses have been financed principally through sales of equity securities. Our revenues for the past five years ended December 31, 2017, December 31, 2016, December 31, 2015, December 31, 2014 and December 31, 2013 were \$5.2 million, \$5.2 million, \$5.1 million, \$1.7 million and \$948 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 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.

**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. Since we recently received our cGMP-compliant rating from Health Canada for manufacturing and packaging activities, we anticipate the manufacturing of our products to commence on the second half of 2018.

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 10 patents and have an additional 25 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.



**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 ) would reduce a shareholder's percentage voting and ownership interest. The conversion, or potential conversion, of the Debentures 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 on the Debentures in shares of common stock.

**Our failure to avoid events of default as defined in the Debentures could require us to redeem such Debentures 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.

Our ability to avoid such Events of Default 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 elected to have us redeem their Debentures, 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. 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 \$59 thousand) per year, which will increase at a rate of CA\$0.25 (\$0.20) 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**

There are no legal proceedings other than in the ordinary course of business and described in the project update sections.

**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****Market Information**

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. The table below sets forth the high and low bid prices of our common stock as reported by the OTCQX and the TSX for the periods indicated. These prices represent inter-dealer quotations without retail markup, markdown, or commission and may not necessarily represent actual transactions.

	OTCQX		TSX-V	
	High (U.S.\$)	Low (U.S.\$)	High (CA\$)	Low (CA\$)
<b>2017</b>				
Fourth Quarter	\$ 0.83	\$ 0.60	\$ 1.05	\$ 0.78
Third Quarter	\$ 0.97	\$ 0.67	\$ 1.25	\$ 0.75
Second Quarter	\$ 1.09	\$ 0.65	\$ 1.39	\$ 0.88
First Quarter	\$ 0.90	\$ 0.62	\$ 1.20	\$ 0.87
<b>2016</b>				
Fourth Quarter	\$ 0.81	\$ 0.55	\$ 1.09	\$ 0.76
Third Quarter	\$ 1.00	\$ 0.45	\$ 1.35	\$ 0.61
Second Quarter	\$ 0.59	\$ 0.49	\$ 0.75	\$ 0.65
First Quarter	\$ 0.63	\$ 0.37	\$ 0.85	\$ 0.55

**Number of Shareholders**

On March 28, 2018, there were approximately 45 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 shares 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 2017, 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 2017, 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  (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	1,585,000 <sup>(1)</sup>	\$0.54	NIL <sup>(2)</sup>
Equity Compensation Plans Not Approved by Security Holders	1,404,818 <sup>(2)</sup>	\$0.78	1,824,136 <sup>(3)</sup>
Total	2,989,818	\$0.65	1,824,136

- (1) Includes shares of our common stock issuable pursuant to options granted under the 2006 Stock Option Plan.
- (2) 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.
- (3) Represents the maximum number of shares of our common stock available for grants under the 2016 Stock Option Plan as of December 31, 2017.

**2016 Stock Option Plan**

The 2016 Stock Option Plan was adopted by the Board of Director of the Company 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. 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.

**ITEM 6. SELECTED FINANCIAL DATA**

Not applicable.

**ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITIONS AND RESULTS OF OPERATIONS****Introduction to Management's Discussion and Analysis**

The purpose of this section, Management's Discussion and Analysis of Financial Condition and Results of Operations, is to provide a narrative explanation of the financial statements that enables investors to better understand our business, to enhance our overall financial disclosure, to provide the context within which our financial information may be analyzed, and to provide information about the quality of, and potential variability of, our financial condition, results of operations and cash flows. Unless otherwise indicated, all financial and statistical information included herein relates to our continuing operations. Unless otherwise indicated or the context otherwise requires, the words, IntelGenx, Company, we, us, and our refer to IntelGenx Technologies Corp. and its subsidiaries, including IntelGenx Technologies 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<sup>®</sup>, and our AdVersa<sup>®</sup> 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<sup>®</sup> 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 to 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*

#### Expansion to the existing Manufacturing Facility

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 \$59 thousand) per year, which will increase at a rate of CA\$0.25 (\$0.20) per square foot every two years. IntelGenx plans to use the newly leased space to expand its manufacture of oral film VersaFilm<sup>™</sup>.

The Company has 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. 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, 2017 an amount of Euro646 thousand has been paid.

On June 29, 2017, the Company announced that it had filed a final short form prospectus in connection with an offering of a minimum of CA\$5,000,000 and a maximum of CA\$10,000,000 aggregate principal amount of 8% convertible unsecured subordinated debentures due June 30, 2020. The Corporation had also filed an amended registration statement on Form S-1 with the United States Securities and Exchange Commission to register the Debentures and the shares of common stock underlying the Debentures. On April 4, 2017, the Company had filed a preliminary short form prospectus with respect to the offering as well as a registration statement on Form S-1 with the United States Securities and Exchange Commission.

On July 12, 2017, the Company announced that it had closed its previously announced prospectus offering of convertible unsecured subordinated debentures of the Corporation for gross aggregate proceeds of CA\$6,838,000. Pursuant to the Offering, the Corporation issued an aggregate principal amount of CA\$6,838,000 of Debentures at a price of CA\$1,000 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

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 CA\$1.35 per common share of the Corporation, being a conversion rate of approximately 740 Shares per CA\$1,000 principal amount of Debentures, subject to adjustment in certain events.

On August 8, 2017, the Company announced that it had 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, 2017, pursuant to which it had raised additional gross proceeds of CA\$762,000.

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

The Offering was conducted on a commercially reasonable best efforts basis by a syndicate of agents led by Desjardins Capital Markets and including Laurentian Bank Securities Inc. and Echelon Wealth Partners Inc. The net proceeds from the Offering will be used for investments in leasehold improvements and equipment, clinical studies, product development and general working capital requirements.

*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, 2017 report an accumulated other comprehensive loss due mainly to foreign currency translation adjustments of \$637 due to the fluctuations in the rates used to prepare our financial statements, \$311 of which positively impacted our comprehensive income for the fiscal year ended December 31, 2017. The following Management Discussion and Analysis takes this into consideration whenever material.

### **Reconciliation of Comprehensive (Loss) Income 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) income, 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,		Twelve-month period ended December 31,	
	2017	2016	2017	2016
	\$	\$	\$	\$
Comprehensive (loss) income	(1,065)	(22)	(2,649)	(1,473)
<b>Add (deduct):</b>				
Depreciation and amortization	210	150	735	511
Finance costs	240	57	569	203
Finance income	(3)	(2)	(11)	(4)
Share-based compensation	48	54	315	195
Other comprehensive (income) loss	(26)	398	(382)	293
<b>Adjusted EBITDA</b>	<b>(596)</b>	<b>635</b>	<b>(1,423)</b>	<b>(275)</b>

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

Adjusted EBITDA decreased by \$1,231 for the three-month period ended December 31, 2017 to (\$596) compared to \$635 for the three-month period ended December 31, 2016. Adjusted EBITDA decreased by \$1,168 for the twelve-month period ended December 31, 2017 to (\$1,443) compared to (\$275) for the twelve-month period ended December 31, 2016. The decrease in Adjusted EBITDA of \$1,231 for the three month period ended December 31, 2017 is mainly attributable to a decrease in revenues of \$449, an increase in R&D expenses of \$263 before consideration of stock-based compensation and an increase in SG&A expenses of \$515 before consideration of stock-based compensation. The decrease in Adjusted EBITDA of \$1,168 for the twelve-month period ended December 31, 2017 is mainly attributable to an increase in R&D expenses of \$828 before consideration of stock-based compensation and an increase in SG&A expenses of \$261 before consideration of stock-based compensation.

**Results of operations for the three month and twelve month periods ended December 31, 2017 compared with the three month and twelve month periods ended December 31, 2016.**

In U.S.\$ thousands	Three-month period ended December 31,		Twelve-month period ended December 31,	
	2017	2016	2017	2016
Revenue	\$ 1,462	\$ 1,911	\$ 5,195	\$ 5,220
Cost of Royalty and License Revenue	95	91	373	319
Research and Development Expenses	739	471	2,615	1,766
Selling, General and Administrative Expenses	1,272	768	3,965	3,605
Depreciation of tangible assets	210	150	735	511
<b>Operating (Loss) Income</b>	<b>(854)</b>	431	<b>(2,493)</b>	(981)
<b>Net (Loss) Income</b>	<b>(1,091)</b>	376	<b>(3,051)</b>	(1,180)
<b>Comprehensive Loss</b>	<b>(1,065)</b>	(22)	<b>(2,669)</b>	(1,473)

Total revenues for the three-month period ended December 31, 2017 amounted to \$1,462, representing a decrease of \$449 or 23% compared to \$1,911 for the three-month period ended December 31, 2016. Total revenues for the twelve-month period ended December 31, 2017 amounted to \$5,195 representing a decrease of \$25 or 0.5% compared to \$5,220 for the twelve-month period ended December 31, 2016. The decrease for the three-month period ended December 31, 2017 compared to the last year's corresponding period is mainly attributable to upfront payments received in Q4 2016 for \$662 partially offset by an increase in R&D revenues of \$161. The decrease for the twelve-month period ended December 31, 2017 compared to the last year's corresponding period is mainly attributable to a decrease in royalties of \$1,041 following the monetization of Forfivo, up-fronts of \$1,131 from multiple agreements signed in 2016 and sales milestones of \$358. This decrease was partially offset by an increase in deferred revenues of \$1,919 (deferred revenues following the monetization of Forfivo were recorded for the entire year in 2017 vs two quarters in 2016) and R&D revenues of \$585.

### **Cost of royalty and license revenue**

We recorded \$95 for the cost of royalty and license revenue in the three-month period ended December 31, 2017 compared with \$91 in the same period of 2016. We recorded \$373 for the cost of royalty and license revenue in the twelve-month period ended December 31, 2017 compared with \$319 in the same period of 2016. 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<sup>®</sup>, our novel, high strength formulation of Bupropion hydrochloride, the active ingredient in Wellbutrin XL<sup>®</sup>. Pursuant to the Project Transfer Agreement, and following commercial launch of Forfivo XL<sup>®</sup> 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<sup>®</sup> (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, 2017 amounted to \$739, representing an increase of \$268 or 57%, compared to \$471 for the three-month period ended December 31, 2016. R&D expenses for the twelve-month period ended December 31, 2017 amounted to \$2,615, representing an increase of \$849 or 48%, compared to \$1,766 recorded in the same period of 2016.

The increase in R&D expenses for the three-month period ended December 31, 2017 is mainly attributable to an increase in study costs of \$348, R&D salaries of \$98 related to new hires and analytical costs of \$78 partially offset by an increase in R&D credits of \$131, a decrease in laboratory supplies of \$78 and a decrease in patent expenses of \$64. The increase in R&D expenses for the twelve-month period ended December 31, 2017 is mainly attributable to an increase in study costs of \$593, R&D salaries of \$425 related to new hires, analytical costs of \$193 and lab supplies of \$131, offset by an increase in R&D credits of \$155 and a decrease in patent expenses of \$413.

In the twelve-month period ended December 31, 2017 we recorded estimated Research and Development Tax Credits of \$303, compared with \$148 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, 2017 amounted to \$1,272, representing an increase of \$504 or 66%, compared to \$768 for the three-month period ended December 31, 2016. SG&A expenses for the twelve-month period ended December 31, 2017 amounted to \$3,965, representing an increase of \$360 or 9%, compared to \$3,605 recorded in the same period of 2016.

The increase in SG&A expenses for the three-month period ended December 31, 2017 is mainly attributable to an increase in manufacturing expenses of \$124, business development expenses of \$108, professional fees of \$86, leasehold expenses of \$31 as well as a variation of the foreign exchange expense of \$86 due to the appreciation of the CA dollar vs the US currency. The increase in SG&A expenses for the twelve-month period ended December 31, 2017 is mainly attributable to an increase in manufacturing expenses of \$239, leasehold expenses of \$46 as well as a variation of the foreign exchange expense of \$138 due to the appreciation of the CA dollar vs the US currency, offset by a decrease in professional fees of \$106.

### **Depreciation of tangible assets**

In the three-month period ended December 31, 2017 we recorded an expense of \$210 for the depreciation of tangible assets, compared with an expense of \$150 thousand for the same period of the previous year. In the twelve-month period ended December 31, 2017 we recorded an expense of \$735 for the depreciation of tangible assets, compared with an expense of \$511 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, 2017 amounted to \$48 compared to \$54 for the three-month period ended December 31, 2016. Share-based compensation warrants and share-based payments expense for the twelve-month period ended December 31, 2017 amounted to \$315 compared to \$195 for the twelve-month period ended December 31, 2016.

We expensed approximately \$178 in the twelve-month period ended December 31, 2017 for options granted to our employees in 2015, 2016 and 2017 under the 2006 and 2016 Stock Option Plans, approximately \$131 for options granted to non-employee directors in 2015, 2016 and 2017, and \$6 for options granted to a consultant in 2016. compared with \$141, \$52 and \$2 respectively that was expensed in the same period of the previous year.

There remains approximately \$196 in stock-based compensation to be expensed in fiscal 2018 and 2019, \$191 of which relates to the issuance of options to our employees and directors during 2016 and 2017 and \$5 relates to the issuance of options to a consultant. 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, 2017	December 31, 2016	Increase/ (Decrease)	Percentage Increase/ (Decrease)
Current Assets	\$ 6,044	\$ 6,352	\$ (308)	(5%)
Leasehold improvements and Equipment	6,346	5,730	616	11%
Security Deposits	757	708	49	7%
Current Liabilities	2,077	5,235	(3,158)	(60%)
Deferred lease obligations	50	45	5	11%
Long-term debt	1,992	2,565	(573)	(22%)
Convertible debentures	5,199	-	5,199	100%
Capital Stock	1	1	-	0%
Additional Paid-in- Capital	25,253	23,700	1,553	7%

### Going Concern

The Company has financed its operations to date primarily through public offerings of its common stock, bank loans, royalty, up-front and milestone payments, license fees, proceeds from exercise of warrants and options, research and development revenues and the sale of U.S. royalty on future sales of Forfivo XL<sup>®</sup>. The Company has devoted substantially all of its resources to its drug development efforts, conducting clinical trials to further advance the product pipeline, the expansion of its facilities, protecting its intellectual property and general and administrative functions relating to these operations. The future success of the Company is dependent on its ability to develop its product pipeline and ultimately upon its ability to attain profitable operations. As of December 31, 2017, the Company had cash and short-term investments totaling approximately \$4,904. 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 \$6,044 at December 31, 2017 compared with \$6,352 at December 31, 2016. The increase of \$287 is mainly attributable to a decrease in short term investments of \$571, a decrease in accounts receivable of \$421 as well as a decrease in prepaid expenses of \$363 partially offset by increases in cash of \$979 and investment tax credits receivable of \$68.

### **Cash**

Cash totaled \$1,591 as at December 31, 2017 representing an increase of \$979 compared with the balance of \$612 as at December 31, 2016. The increase in cash on hand relates to net cash provided by financing activities of \$5,508, partially offset by net cash used in investing activities of \$207 and by net cash used by operating activities of \$4,383.

### **Accounts receivable**

Accounts receivable totaled \$632 as at December 31, 2017 representing a decrease of \$421 compared with the balance of \$1,044 as at December 31, 2016. The decrease in accounts receivable is attributable to the collection in 2017 of upfront payments accounted for as at December 31, 2016.

### **Prepaid expenses**

As at December 31, 2017 prepaid expenses totaled \$203 compared with \$566 as of December 31, 2016. The decrease in prepaid expenses is mainly attributable to the 10% prepayment to Carry Pharmaceuticals following the monetization of Forfivo to SWK Holding which was fully expensed in 2017.

### **Investment tax credits receivable**

R&D investment tax credits receivable totaled approximately \$314 as at December 31, 2017 compared with \$246 as at December 31, 2016. The increase relates to the accrual estimated and recorded for the twelve-month period ended December 31, 2017 offset by the collection of the 2015 and 2016 tax credits.

### **Leasehold improvements and equipment**

As at December 31, 2017, the net book value of leasehold improvements and equipment amounted to \$6,346, compared to \$5,730 at December 31, 2016. In the twelve-month period ended December 31, 2017 additions to assets totaled \$973 and mainly comprised of \$795 for manufacturing and packaging equipment for our new, state-of-the-art, VersaFilm manufacturing facility, and \$272 for leasehold improvements, \$72 for laboratory and office equipment and \$31 for computer equipment, offset by \$197 for tax credits received for the portion of the capital cost of qualified investments.

### **Security deposit**

A security deposit in the amount of CA\$300 (\$239) 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, 2017. Security deposits in the amount of CA\$650 (\$518) for the term loans were also recorded as at December 31, 2017.

The difference between the amount at December 31, 2017 and the amount at December 31, 2016 is related to the US currency fluctuation.

**Accounts payable and accrued liabilities**

Accounts payable and accrued liabilities totaled \$1,305 as at December 31, 2017 (December 31, 2016 - \$897). The increase is mainly attributable to accounts payables for study costs incurred.

### **Long-term debt**

Long-term debt totaled \$2,764 as at December 31, 2017 (December 31, 2016 - \$3,269). The current portion of long-term debt totaled \$772 as at December 31, 2017 (December 31, 2016 - \$704). An amount of \$2,233 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 \$531 is attributable to a second loan secured by a second ranking on all present and future property of the Company reimbursable in monthly principal payments starting January 2017 to March 2021.

### **Convertible debentures**

Convertible debentures totaled \$5,199 as at December 31, 2017 resulting in the issuance by the Corporation of a total aggregate principal amount of CA\$7,600,000 of debentures at a price of CA\$1,000 per debenture in July 2017 and August 2017. The convertible debentures have been recorded as a liability. Total transactions costs in the amount of CA\$1,237,000 were recorded against the liability. The accretion expense for the year ended December 31, 2017 amounts to CA\$160,000. The accrued interest on the convertible debentures as December 31, 2017 amounts to CA\$286,000 and was paid on December 29, 2017 is recorded in Financing and interest expense.

### **Shareholders equity**

As at December 31, 2017 we had accumulated a deficit of \$20,788 compared with an accumulated deficit of \$17,737 as at December 31, 2016. Total assets amounted to \$13,147 and shareholders equity totaled \$3,829 as at December 31, 2017, compared with total assets and shareholders equity of \$12,790 and \$4,945 respectively, as at December 31, 2016.

### **Capital stock**

As at December 31, 2017 capital stock amounted to \$0.670 (December 31, 2016: \$0.648) . 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 \$25,253 as at December 31, 2017, as compared to \$23,700 at December 31, 2016. Additional paid in capital increased by \$1,176 for warrants exercised, increased by \$62 for options exercised, and increased by \$315 for stock based compensation attributable to the expensing of stock options granted to employees and directors.

### **Taxation**

As at December 31, 2017, the date of our latest annual tax return, we had Canadian and provincial net operating losses of approximately \$9,560 (December 31, 2016: \$7,585) and \$10,052 (December 31, 2016: \$7,763) 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 2027 and 2037. A portion of the net operating losses may expire before they can be utilized.

As at December 31, 2017, we had non-refundable tax credits of \$1,553 thousand (2016: \$1,190 thousand) of which \$8 thousand is expiring in 2026, \$10 thousand is expiring in 2027, \$180 thousand is expiring in 2028, \$158 thousand is expiring in 2029, \$134 thousand is expiring in 2030, \$143 thousand is expiring in 2031, \$179 thousand is expiring in 2032 and \$119 thousand is expiring in 2033, \$90 thousand expiring in 2034, \$106 thousand is expiring in 2035, \$146

thousand expiring in 2036 and \$280 thousand expiring in 2037. We also had undeducted research and development expenses of \$7,532 thousand (2016: \$5,438 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**

<b>In U.S.\$ thousands</b>	<b>December 31, 2017</b>	<b>December 31, 2016</b>	<b>Increase/ (Decrease)</b>	<b>Percentage Increase/ (Decrease)</b>
Operating Activities	\$ (4,383)	\$ 1,729	\$ (6,112)	(353%)
Financing Activities	5,508	1,924	3,584	186%
Investing Activities	(207)	(5,910)	(5,703)	(96%)
Cash - end of Period	1591	612	979	160%

**Statement of cash flows**

Net cash used in operating activities was \$4,383 for the twelve-month period ended December 31, 2017, compared to net cash provided by operating activities of \$1,729 for the twelve-month period ended December 31, 2016. For the twelve-month period ended December 31, 2017, net cash used by operating activities consisted of a net loss of (\$3,051) (2016: \$1,180) before depreciation, stock-based compensation and accretion expense in the amount of \$1,173 (2016: \$ 706) and a decrease in non-cash operating elements of working capital of \$2,505 compared with an increase of \$2,203 for the twelve-month period ended December 31, 2016.

The net cash provided by financing activities was \$5,508 for the twelve-month period ended December 31, 2017, compared to \$1,924 provided in the same period of the previous year. An amount of \$4,978 (\$Nil in 2016) derives from the net proceeds from issuance of convertible debentures and an amount of \$1,238 (2016: \$659) derives from the proceeds from exercise of warrants and stock options, partially offset by repayment of long-term debt in the amount of \$708 (2016: \$675) and the issuance of long term debt of \$1,940 in 2016 (\$Nil in 2017).

Net cash used in investing activities amounted to \$207 for the twelve-month period ended December 31, 2017 compared to \$5,910 in the same period of 2016. The net cash used in investing activities for the twelve-month period ended December 31, 2017 relates to the redemptions of short-term investments of \$4,718 (2016: \$1,652) offset by the purchase of fixed assets for \$973 (2016: \$2,326) as well as acquisitions of short-term investments of \$3,952 (2016: \$5,236).

The balance of cash as at December 31, 2017 amounted to \$1,591, compared to \$612 at December 31, 2016.

**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 \$88 thousand) per year, which will increase at a rate of CA\$0.25 (\$0.20) 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 \$59 thousand) per year, which will increase at a rate of CA\$0.25 (\$0.20) per square foot every two years. IntelGenx plans to use the newly leased space to expand its manufacture of oral film VersaFilm TM.

The aggregate minimum rentals, exclusive of other occupancy charges, for property leases expiring in 2026, are approximately \$1,301 thousand, as follows:

2018	\$	150
2019		152
2020		156
2021		158
2022		161
Thereafter		524

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, 2017 an amount of Euro646 thousand has been paid with respect to these agreements.

### **Subsequent events**

On January 16, 2018, the Company granted 100,000 options to purchase common stock to an employee. The stock options are exercisable at \$0.79 per share and vest over 2 years at 25% every six months. Subsequent to the end of the year, total of 700,000 warrants were exercised for 700,000 common shares having a par value of \$Nil in aggregate, for cash consideration of approximately \$395 thousand.

### **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, 2015 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, 2017 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, 2017. 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, 2017 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 2018 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 2018 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 2018 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 2018 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 2018 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.

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- B. Consolidated Balance Sheets as of December 31, 2017 and 2016.
- C. Consolidated Statements of Shareholders' Equity for the years ended of December 31, 2017 and 2016.
- D. Consolidated Statements of Comprehensive Loss for the years ended of December 31, 2017 and 2016.
- E. Consolidated Statements of Cash Flows for the years ended December 31, 2017 and 2016.
- 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
<u>2.1</u>	<u>Share exchange agreement dated April 10, 2006 (incorporated by reference to the Form 8-K/A filed on May 5, 2006)</u>
<u>3.1</u>	<u>Certificate of Incorporation (incorporated by reference to the Form SB-2 (File No. 333-90149) filed on November 16, 1999)</u>
<u>3.2</u>	<u>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)</u>
<u>3.3</u>	<u>Amendment to the Certificate of Incorporation (incorporated by reference to the Form DEF 14C filed on April 20, 2007)</u>
<u>3.4</u>	<u>Amendment to the Certificate of Incorporation (incorporated by reference to the Form S-1/A filed on May 12, 2017)</u>
<u>3.5</u>	<u>By-Laws (incorporated by reference to the Form SB-2 (File No. 333-91049) filed on November 16, 1999)</u>
<u>3.6</u>	<u>Amended and Restated By-Laws (incorporated by reference to the Form 8-K filed on March 31, 2011)</u>
<u>3.7</u>	<u>Amended and Restated By-Laws (incorporated by reference to the Form 8-K filed on March 21, 2012)</u>
<u>4.1</u>	<u>Trust Indenture with TSX Trust Company, dated July 12, 2017 (incorporated by reference to the Form 8-K filed on July 12, 2017)</u>
<u>9.1</u>	<u>Voting Trust agreement (incorporated by reference to the Form 8-K/A filed on May 5, 2006)</u>
<u>10.1 +</u>	<u>Horst Zerbe employment agreement dated October 1, 2014 (incorporated by reference to the Form 10-Q filed on November 12, 2014)</u>
<u>10.2</u>	<u>Registration rights agreement (incorporated by reference to the Form SB-2 (File No. 333-135591) filed on July 3, 2006)</u>
<u>10.3</u>	<u>Principal's registration rights agreement (incorporated by reference to the Form SB-2 (File No. 333-135591) filed on July 3, 2006)</u>
<u>10.4 +</u>	<u>2006 Stock Option Plan (incorporated by reference to the Form S-8 filed on November 21, 2006)</u>
<u>10.5 +</u>	<u>Amended and Restated 2006 Stock Option Plan, May 29, 2008 (incorporated by reference to the Form 10-K filed on March 25, 2009)</u>
<u>10.6</u>	<u>Co-Development and Commercialization Agreement with RedHill Biopharma Ltd. (incorporated by reference to the Form 10-Q filed on November 9, 2010)</u>
<u>10.7 +</u>	<u>Amended and Restated 2006 Stock Option Plan (incorporated by reference to the Form S-8 filed on November 15, 2010)</u>
<u>10.8</u>	<u>Project Transfer Agreement (incorporated by reference to the Form 10-Q filed on May 14, 2010)</u>

10.9 Co-development and Licensing Agreement (incorporated by reference to the Form 10-Q filed on May 14, 2010)

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- 10.10 License and Asset Transfer Agreement with Edgemont Pharmaceuticals (incorporated by reference to the Form 10Q filed on May 15, 2012)
- 10.11+ Amended and Restated 2006 Stock Option Plan, (incorporated by reference to the Form 8-K filed on May 9, 2013)
- 10.12 Engagement Letter Wainwright dated October 10, 2013, amended December 3, 2013 (incorporated by reference to the Form S-1/A Registration Statement filed December 16, 2013)
- 10.13 Amended Form of Securities Purchase Agreement (incorporated by reference to the Form S-1/A Registration Statement filed on December 16, 2013)
- 10.14 Form of Warrant (incorporated by reference to the Form S-1/A Registration Statement filed on October 25, 2013)
- 10.15 Form of Placement Agent Warrant (incorporated by reference to the Form S-1/A Registration Statement filed on December 4, 2013)
- 10.16 ++ 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)
- 10.17 ++ 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)
- 10.18+ Employment Agreement John Durham, January 2015 (incorporated by reference to the Form 10-K filed on March 31, 2015)
- 10.19+ Employment Agreement Andre Godin, July 2015 (incorporated by reference to the Form 8-K filed on July 20, 2015)
- 10.20+ Employment Agreement Nadine Paiement, January 2016 (incorporated by reference to the Form 10-K filed on March 30, 2016)
- 10.21+ Employment Agreement Dana Matzen, March 2016 (incorporated by reference to the Form 10-K filed on March 30, 2016)
- 10.22+ 2016 Stock Option Plan May, 11 2016 (incorporated by reference to the Form S-8 Registration Statement filed on August 3, 2016)
- 10.23 Amended Principal s Registration Rights Agreement, November 8, 2016 (incorporated by reference to Form 10-Q filed on November 10, 2016)
- 10.24 Agency Agreement dated June 28, 2017 (incorporated by reference from the Company s Form 8-K filed on July 5, 2017)
- 10.25+\* Deferred Share Unit Plan for non-employee directors
- 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 Certification of Horst G. Zerbe, President and Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley
- 31.1\* Act of 2002\* Certification of Andre Godin, Executive Vice President and Chief Financial Officer, pursuant to Section 302 of the
- 31.2\* 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 29, 2018, thereunto duly authorized.

**INTELGEX 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.

<b>Signature</b>	<b>Position</b>	<b>Date</b>
By: <i>/s/ Horst G. Zerbe</i> Horst G. Zerbe	Chairman of the Board, President and Chief Executive Officer	March 29, 2018
By: <i>/s/Andre Godin</i> Andre Godin	Executive Vice President and Chief Financial Officer	March 29, 2018
By: <i>/s/ Bernard Boudreau</i> J. Bernard Boudreau	Director, Vice Chairman of the Board	March 29, 2018
By: <i>/s/Bernd Melchers</i> Bernd J. Melchers	Director	March 29, 2018
By: <i>/s/John Marinucci</i> John Marinucci	Director	March 29, 2018
By: <i>/s/Clemens Mayr</i> Clemens Mayr	Director	March 29, 2018
By: <i>/s/Mark Nawacki</i> Mark Nawacki	Director	March 29, 2018

**IntelGenx Technologies Corp**

**Consolidated Financial Statements**

**December 31, 2017 and 2016**

**(Expressed in U.S. Funds)**

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**IntelGenx Technologies Corp**

**Consolidated Financial Statements**

**December 31, 2017 and 2016**

**(Expressed in U.S. Funds)**

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## 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, 2017 and 2016, the related consolidated statements of comprehensive loss, shareholders' equity and cash flows for each of the two years in the period ended December 31, 2017, 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, 2017 and 2016, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017, 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.

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

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

Montréal, Québec  
March 29, 2018

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

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**IntelGenx Technologies Corp.****Consolidated Balance Sheets**

As at December 31, 2017 and 2016

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

	2017	2016
<b>Assets</b>		
<b>Current</b>		
Cash	\$ 1,591	\$ 612
Short-term investments (note 6)	3,313	3,884
Accounts receivable	623	1,044
Prepaid expenses	203	566
Investment tax credits receivable	314	246
<b>Total current assets</b>	<b>6,044</b>	<b>6,352</b>
<b>Leasehold improvements and equipment, net</b> (note 7)	<b>6,346</b>	<b>5,730</b>
<b>Security deposits</b>	<b>757</b>	<b>708</b>
<b>Total assets</b>	<b>\$ 13,147</b>	<b>\$ 12,790</b>
<b>Liabilities</b>		
<b>Current</b>		
Accounts payable and accrued liabilities	1,305	897
Current portion of long-term debt (note 10)	772	704
Deferred revenue (note 9)	-	3,634
<b>Total current liabilities</b>	<b>2,077</b>	<b>5,235</b>
<b>Deferred lease obligations</b>	<b>50</b>	<b>45</b>
<b>Long-term debt</b> (note 10)	<b>1,992</b>	<b>2,565</b>
<b>Convertible debentures</b> (note 11)	<b>5,199</b>	<b>-</b>
<b>Total liabilities</b>	<b>9,318</b>	<b>7,845</b>
<b>Commitments</b> (note 12)		
<b>Subsequent event</b> (note 19)		
<b>Shareholders' equity</b>		
Capital stock, common shares, \$0.00001 par value; 100,000,000 shares authorized; 67,031,467 shares issued and outstanding (2016: 64,812,020 common shares) (note 13)	1	1
Additional paid-in capital (note 14)	25,253	23,700
Accumulated deficit	(20,788)	(17,737)
Accumulated other comprehensive loss	(637)	(1,019)
<b>Total shareholders equity</b>	<b>3,829</b>	<b>4,945</b>
	<b>\$ 13,147</b>	<b>\$ 12,790</b>

See accompanying notes

**Approved on Behalf of the Board:**

/s/ Bernd J. Melchers Director

/s/ Horst G. Zerbe Director

**IntelGenx Technologies Corp.****Consolidated Statement of Shareholders' Equity****For the Year Ended December 31, 2016****(Expressed in Thousands of U.S. Dollars (\$ 000) Except Share and Per Share Data)**

	Capital Stock Number	Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Shareholders' Equity
<b>Balance - December 31, 2015</b>	63,615,255	\$ 1	\$ 22,846	\$ (16,557)	\$ (726)	<b>5,564</b>
Other comprehensive loss	-	-	-	-	(293)	<b>(293)</b>
Warrants exercised (note 14)	1,056,765	-	596	-	-	<b>596</b>
Options exercised (note 14)	140,000	-	63	-	-	<b>63</b>
Stock-based compensation (note 14)	-	-	195	-	-	<b>195</b>
Net loss for the year	-	-	-	(1,180)	-	<b>(1,180)</b>
<b>Balance December 31, 2016</b>	<b>64,812,020</b>	<b>\$ 1</b>	<b>\$ 23,700</b>	<b>\$ (17,737)</b>	<b>\$ (1,019)</b>	<b>4,945</b>

See accompanying notes

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

**IntelGenx Technologies Corp.****Consolidated Statements of Comprehensive Loss****For the Years Ended December 31, 2017 and 2016****(Expressed in Thousands of U.S. Dollars (\$ 000) Except Share and Per Share Data)**

	2017	2016
<b>Revenues</b>		
License and other revenue	\$ 5,195	\$ 4,179
Royalties	-	1,041
<b>Total revenues</b>	<b>5,195</b>	<b>5,220</b>
<b>Expenses</b>		
Cost of royalty, license and other revenue	373	319
Research and development expense	2,615	1,766
Selling, general and administrative expense	3,965	3,605
Depreciation of tangible assets	735	511
<b>Total expenses</b>	<b>7,688</b>	<b>6,201</b>
<b>Operating loss</b>	<b>(2,493)</b>	<b>(981)</b>
<b>Interest income</b>	<b>11</b>	<b>4</b>
<b>Financing and interest expense</b>	<b>(569)</b>	<b>(203)</b>
<b>Net financing and interest expense</b>	<b>(558)</b>	<b>(199)</b>
<b>Loss before income taxes</b>	<b>(3,051)</b>	<b>(1,180)</b>
Income taxes (note 15)	-	-
<b>Net loss</b>	<b>(3,051)</b>	<b>(1,180)</b>
<b>Other comprehensive income (loss)</b>		
Change in fair value	71	-
Foreign currency translation adjustment	311	(293)
	382	(293)
<b>Comprehensive loss</b>	<b>\$ (2,669)</b>	<b>\$ (1,473)</b>
<b>Basic and diluted:</b>		
<b>Weighted average number of shares outstanding</b>	<b>66,152,830</b>	<b>63,956,543</b>
Basic and diluted loss per common share (note 18)	\$ (0.04)	\$ (0.02)

See accompanying notes

## IntelGenx Technologies Corp.

## Consolidated Statements of Cash Flows

For the Year Ended December 31, 2017 and 2016

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

	2017	2016
<b>Funds (used) provided -</b>		
<b>Operating activities</b>		
Net loss	\$ (3,051)	\$ (1,180)
Depreciation of tangible assets	735	511
Stock-based compensation	315	195
Accretion expense	123	-
	<b>(1,878)</b>	<b>(474)</b>
Changes in non-cash items related to operations:		
Accounts receivable	421	96
Prepaid expenses	363	(496)
Investment tax credits receivable	(68)	(149)
Security deposits	-	(202)
Accounts payable and accrued liabilities	408	(698)
Deferred revenue	(3,634)	3,634
Deferred lease obligations	5	18
<b>Net change in non-cash items related to operations</b>	<b>(2,505)</b>	<b>2,203</b>
<b>Net cash (used in) provided by operating activities</b>	<b>(4,383)</b>	<b>1,729</b>
<b>Financing activities</b>		
Issuance of long-term debt	-	1,940
Repayment of long-term debt	(708)	(675)
Proceeds from exercise of warrants and stock options	1,238	659
Net proceeds from issuance of convertible debentures	5,469	-
Convertible debentures issuance costs	(491)	-
<b>Net cash provided by financing activities</b>	<b>5,508</b>	<b>1,924</b>
<b>Investing activities</b>		
Additions to leasehold improvements and equipment	(973)	(2,326)
Acquisitions of short-term investments	(3,952)	(5,236)
Redemptions of short-term investments	4,718	1,652
<b>Net cash used in investing activities</b>	<b>(207)</b>	<b>(5,910)</b>
<b>Increase (decrease) in cash</b>	<b>918</b>	<b>(2,257)</b>
<b>Effect of foreign exchange on cash</b>	<b>61</b>	<b>4</b>
<b>Cash</b>		
<b>Beginning of year</b>	<b>612</b>	<b>2,865</b>
<b>End of year</b>	<b>\$ 1,591</b>	<b>\$ 612</b>

See accompanying notes



**IntelGenx Technologies Corp.**

**Notes to Consolidated Financial Statements**

**December 31, 2017 and 2016**

**(Expressed in U.S. Funds)**

**1. Basis of Presentation**

IntelGenx Technologies Corp. ( IntelGenx or the Company ) prepares its 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, 2017, the Company had cash and short-term investments totaling approximately \$4,904. 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.

**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 13 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, 3 utilize the *VersaTab* technology, and one utilizes the *AdVersa* technology.

**IntelGenx Technologies Corp.**

**Notes to Consolidated Financial Statements**

**December 31, 2017 and 2016**

**(Expressed in U.S. Funds)**

**4. Adoption of New Accounting Standards**

The FASB issued Update 2016-06, Derivatives and Hedging Contingent Put and Call Options in Debt Instruments, clarifying the requirements for assessing whether contingent call (put) options that can accelerate the payment of principal on debt instruments are clearly and closely related to their debt hosts. The amendments in this Update require an entity performing the assessment to assess the embedded call (put) options solely in accordance with the four-step decision sequence. For public business entities, the amendments in this Update are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. The adoption of this Update did not have a material effect on the Company's financial position or results.

The FASB issued Update 2016-09, Compensation—Stock Compensation Improvements to Employee Share-Based Payment Accounting, simplifying several aspects of the accounting for share-based payment transactions, including income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. For public business entities, the amendments in this Update are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. The adoption of this Update did not have a material effect on the Company's financial position or results.

The FASB issued Update 2015-11, Inventory: Simplifying the Measurement of Inventory, aligning the measurement of inventory in GAAP with the measurement of inventory in International Financial Reporting Standards (IFRS). The amendments in this Update state that an entity should measure inventory within the scope of this update at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. For public business entities, the amendments in this Update are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. The adoption of this Update did not have a material effect on the Company's financial position or results.

The FASB issued 2015-017, Income Taxes: Balance Sheet Classification of Deferred Taxes, which requires that deferred tax liabilities be classified as noncurrent in a classified statement of financial position. For public business entities, the amendments in this Update are effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years. The adoption of this Update did not have a material effect on the Company's financial position or results.

**5. Summary of Significant Accounting Policies**

**Revenue Recognition**

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, 2017 and 2016**

**(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 compared to \$1,546 thousand in 2016.

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 compared to \$434 thousand in 2016.

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 compared to \$358 thousand in 2016.

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 compared to \$1,041 thousand in 2016.

**Use of Estimates**

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

**Accounts Receivable**

The Company accounts for trade receivables at original invoice amount less an estimate made for doubtful receivables based on a review of all outstanding amounts on a quarterly basis. Management determines the allowance for doubtful accounts by regularly evaluating individual customer receivables and considering a customer's financial condition, credit history and current economic conditions. The Company writes off trade receivables when they are deemed uncollectible and records recoveries of trade receivables previously written off when they receive them. Management has determined that no allowance for doubtful accounts is necessary in order to adequately cover exposure to loss in

its December 31, 2017 accounts receivable (2016: \$Nil). A bad debt expense in the amount of \$29 (2016: \$Nil) is recorded in the year ended December 31, 2017.

**IntelGenx Technologies Corp.****Notes to Consolidated Financial Statements****December 31, 2017 and 2016****(Expressed in U.S. Funds)****5. Summary of Significant Accounting Policies (Cont d)****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, 2017 totaled \$255 thousand (2016: \$Nil).

**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.

**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.

**IntelGenx Technologies Corp.**

**Notes to Consolidated Financial Statements**

**December 31, 2017 and 2016**

**(Expressed in U.S. Funds)**

**5. Summary of Significant Accounting Policies (Cont d)**

**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.

**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.



**IntelGenx Technologies Corp.**

**Notes to Consolidated Financial Statements**

**December 31, 2017 and 2016**

**(Expressed in U.S. Funds)**

**5. Summary of Significant Accounting Policies (Cont d)**

**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 estimates its forfeiture rate in order to determine its compensation expense arising from stock-based awards. 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.

**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.

**IntelGenx Technologies Corp.**

**Notes to Consolidated Financial Statements**

**December 31, 2017 and 2016**

**(Expressed in U.S. Funds)**

**5. Summary of Significant Accounting Policies (Cont d)**

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 as 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 2017-09 Stock Compensation (Topic 718) Scope of Modification Accounting**

In May 2016, the FASB issued ASU 2017-09 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. Early adoption is permitted in any interim or annual period for which financial statements have not yet been issued. 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 2017-01 - Business Combinations (Topic 805) - Clarifying the Definition of a Business**

The FASB issued ASU 2017-01 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. Early adoption is permitted under certain circumstances and should be applied on a prospective basis. The Company is currently evaluating the impact of this Statement on its consolidated financial statements.

**IntelGenx Technologies Corp.**

**Notes to Consolidated Financial Statements**

**December 31, 2017 and 2016**

**(Expressed in U.S. Funds)**

**5. Summary of Significant Accounting Policies (Cont d)**

**ASU 2016-18 Statement of Cash Flows (Topic 230) Restricted Cash**

In November 2016, the FASB issued ASU 2016-18 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. 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 2016-16 Income Taxes (Topic 740) Intra-Entity Transfers of Assets Other Than Inventory**

The FASB issued ASU 2016-16 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 amendments should be applied on a modified retrospective basis through a cumulative-effect adjustment directly to retained earnings as of the beginning of the period of adoption. The Company is currently evaluating the impact of this Statement on its consolidated financial statements.

**ASU 2016-15 Statement of Cash Flows (Topic 230) Classification of Certain Cash Receipts and Cash Payments**

In August 2016, the FASB issued ASU 2016-15 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. Early adoption is permitted in any interim or annual period, with any adjustments reflected as of the beginning of the fiscal year of adoption. 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.

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.

**IntelGenx Technologies Corp.**

**Notes to Consolidated Financial Statements**

**December 31, 2017 and 2016**

**(Expressed in U.S. Funds)**

**5. Summary of Significant Accounting Policies (Cont d)**

**ASU 2016-01 Financial Instruments Overall (Subtopic 825-10) Recognition and Measurement of Financial Assets and Financial Liabilities**

In January 2016, the FASB issued ASU 2016-01, which will significantly change practice for all entities. The targeted amendments to existing guidance are expected to 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 Company is currently evaluating the impact of this Statement on its consolidated financial statements.

**Revenue from Contracts with Customers (Topic 606)**

The FASB and IASB (the Boards) have issued converged standards on revenue recognition. ASU No. 2014-09 which affects any entity using U.S. GAAP that either enters into contracts with customers to transfer goods or services or enters into contracts for the transfer of nonfinancial assets unless those contracts are within the scope of other standards. This ASU will supersede the revenue recognition requirements in Topic 605, Revenue Recognition and most industry-specific guidance. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To achieve that core principle, an entity should apply the following steps:

- Step 1: Identify the contract(s) with a customer.
- Step 2: Identify the performance obligations in the contract.
- Step 3: Determine the transaction price.
- Step 4: Allocate the transaction price to the performance obligations in the contract.
- Step 5: Recognize revenue when (or as) the entity satisfies a performance obligation.

**IntelGenx Technologies Corp.**

**Notes to Consolidated Financial Statements**

**December 31, 2017 and 2016**

**(Expressed in U.S. Funds)**

**5. Summary of Significant Accounting Policies (Cont d)**

In the year ended December 31, 2016, the FASB issued three new amendments related to Topic 606:

1. ASU 2016-08: Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations (Reporting Revenue Gross versus Net).
2. ASU 2016-10: Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing.
3. ASU 2016-11 Revenue Recognition (Topic 605) and Derivatives and Hedging (Topic 815): Rescission of SEC Guidance Because of Accounting Standards Updates 2014-09 and 2014-16 Pursuant to Staff Announcements at the March 3, 2016 EITF Meeting.

In the year ended December 31, 2017, the FASB issued a new amendment related to Topic 606:

1. ASU 2017-14: Revenue from Contracts with Customers (Topic 606). This amendment does not provide any changes to the previously issued ASU No. 2014-09 and is effective for the same reporting period which was deferred by one year in ASU 2015-14: Revenue From Contracts with Customers (Topic 606), Deferral of the Effective Date.

Public business entities, certain not-for-profit entities, and certain employee benefit plans should apply the guidance in Update 2014-09 to annual reporting periods beginning after December 15, 2017, including interim reporting periods within that reporting period. Earlier application is permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period.

The new standards are required to be adopted using either a full-retrospective or a modified-retrospective approach. The Company will adopt these standards using the modified-retrospective approach beginning in 2018. The Company is in the process of completing the impact assessment on accounting policies and total revenues in the Consolidated Statements of Comprehensive Income (Loss) and disclosures.

**6. Short-term investments**

As at December 31, 2017, short-term investments consisting of mutual funds (CAD\$3,589 million) and term deposits (\$450 thousand) are with a Canadian financial institution having a high credit rating. The term deposits have a maturity date of August 17, 2018, bear interest at 0.40% and are cashable at any time.

**IntelGenx Technologies Corp.****Notes to Consolidated Financial Statements****December 31, 2017 and 2016****(Expressed in U.S. Funds)****7. Leasehold improvements and Equipment**

	Cost	Accumulated Depreciation	2017 Net Carrying Amount	2016 Net Carrying Amount
Manufacturing equipment	\$ 3,328	\$ 375	\$ 2,953	\$ 2,429
Laboratory and office equipment	1,380	621	759	807
Computer equipment	102	58	44	23
Leasehold improvements	3,253	663	2,590	2,471
	\$ 8,063	\$ 1,717	\$ 6,346	\$ 5,730

From the balance of manufacturing equipment, an amount of \$822 thousand (2016: \$125 thousand) represents assets which are not yet in service as at December 31, 2017.

**8. Bank Indebtedness**

The Company's credit facility is subject to review annually and consists of an operating demand line of credit of up to CAD\$250 thousand, corporate credits cards of up to CAD\$75 and \$60 thousand, and foreign exchange contracts limited to CAD\$425 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 present and future movable property of the Company for an amount of CAD\$4,250,000 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, 2017, 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.

**9. Deferred Revenue**

On August 5, 2016, the Company sold its U.S. royalty on future sales of Forfivo XL<sup>®</sup> to SWK Holdings Corporation for \$6 million. Under the terms of the agreement, SWK paid IntelGenx \$6 million at closing. In return for, (i) 100% of any and all royalties 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.

The payment received for the royalty on future sales in the amount of \$6 million less the Q2-2016 royalties recognized in the second quarter in the amount of \$352 thousand was recognized in other revenue on a straight-line basis until December 31, 2017.

10% of the proceeds were paid to our former development partner, Cary Pharmaceuticals Inc. This amount was included in prepaid expenses less the portion expensed during the six-month period ended December 31, 2016. This expense was recognized as cost of royalty, license and other revenue on a straight-line basis until December 31, 2017.

**IntelGenx Technologies Corp.****Notes to Consolidated Financial Statements****December 31, 2017 and 2016****(Expressed in U.S. Funds)****10. Long-term debt**

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

	<b>December 31, 2017</b>	<b>December 31, 2016</b>
	\$	\$
Term loan facility	2,233	2,636
Secured loan	531	633
Total debt	2,764	3,269
Less: current portion	772	704
Total long-term debt	1,992	2,565

The Company's term loan facility consists of a total of CAD\$4 million bearing interest at the Bank's prime lending rate plus 2.50%, with monthly principal repayments of CAD\$62 thousand. The term loan is subject to the same security and financial covenants as the bank indebtedness (see note 8).

The secured loan has a principal balance authorized of CAD\$1 million bearing interest at prime plus 7.3%, reimbursable in monthly principal payments of CAD\$17 thousand from January 2017 to March 2021. 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, 2017, 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 four years are as follows:

2018	772 (CAD 969)
2019	753 (CAD 945)
2020	753 (CAD 945)
2021	486 (CAD 610)

**IntelGenx Technologies Corp.****Notes to Consolidated Financial Statements****December 31, 2017 and 2016****(Expressed in U.S. Funds)****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. Pursuant to the Offering, the Corporation issued an aggregate principal amount of CAD\$6,838,000 of Debentures at a price of CAD\$1,000 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 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 (the Conversion Price) per common share of the Corporation (Share), being a conversion rate of approximately 740 Shares per CAD\$1,000 principal amount of Debentures, subject to adjustment in certain events.

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

Together with the principal amount of CAD\$6,838,000 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 per Debenture.

The convertible debentures have been recorded as a liability. Total transactions costs in the amount of CAD\$1,237,000 were recorded against the liability. The accretion expense for the period ended December 31, 2017 amounts to CAD\$160,000.

The components of the convertible debentures as at December 31, 2017 are as follows:

	<b>December 31, 2017</b>	
	<b>\$</b>	
<b>(in U.S. \$ thousands)</b>		
Face value of convertible debentures	\$	6,058
Transaction costs		(986)
Accretion		127
Convertible debentures	\$	5,199

Interest accrued as at December 31, 2017 on the convertible debentures in the amount of CAD\$287 thousand was paid on December 29, 2017 and is recorded in financing and interest expense.



**IntelGenx Technologies Corp.****Notes to Consolidated Financial Statements****December 31, 2017 and 2016****(Expressed in U.S. Funds)****12. 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 \$88 thousand) per year, which will increase at a rate of CAD\$0.25 (\$0.20) 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 \$59 thousand) per year, which will increase at a rate of CAD\$0.25 (\$0.20) 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 \$1,301 thousand, as follows:

2018	150
2019	152
2020	156
2021	158
2022	161
Thereafter	524

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, 2017 an amount of Euro646 thousand has been paid with respect to these agreements.

**IntelGenx Technologies Corp.****Notes to Consolidated Financial Statements****December 31, 2017 and 2016****(Expressed in U.S. Funds)****13. Capital Stock**

	2017	2016
Authorized -		
100,000,000 common shares of \$0.00001 par value		
20,000,000 preferred shares of \$0.00001 par value		
Issued -		
67,031,467 (December 31, 2016: 64,812,020) common shares	\$ 1	\$ 1

**Stock options**

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.

During the year ended December 31, 2016 a total of 140,000 stock options were exercised for 140,000 common shares having a par value of \$0 thousand in aggregate, for cash consideration of \$63 thousand, resulting in an increase in additional paid-in capital of \$63 thousand.

Stock-based compensation of \$315 thousand and \$195 thousand was recorded during the year ended December 31, 2017 and 2016 respectively. An amount of \$309 thousand (2016 - \$193 thousand) expensed relates to stock options granted to employees and directors and an amount of \$6 thousand (2016- \$2 thousand) relates to stock options granted to a consultant during the year ended December 31, 2017. As at December 31, 2017 the Company has \$196 thousand (2016 - \$320 thousand) of unrecognized stock-based compensation, of which \$5 thousand (2016 \$11) relates to options granted to a consultant.

**Warrants**

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.

In the year ended December 31, 2016 a total of 1,056,765 warrants were exercised for 1,056,765 common shares having a par value of \$Nil in aggregate, for cash consideration of approximately \$596 thousand, resulting in an increase in additional paid-in capital of approximately \$596 thousand.

**IntelGenx Technologies Corp.****Notes to Consolidated Financial Statements****December 31, 2017 and 2016****(Expressed in U.S. Funds)****14. Additional Paid-In Capital  
Stock Options**

On May 9, 2016, the Board of Directors of the Company adopted the 2016 Stock Option Plan which amended and restated the 2006 Stock Option. As a result of the adoption of the 2016 Stock Option Plan, no additional options will be granted under the 2006 Stock Option Plan and all previously granted options will be governed by the 2016 Stock Option Plan. The 2016 Stock Option Plan permits the granting of options to officers, employees, directors and eligible consultants of the Company. A total of 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. Options may be granted under the 2016 Stock Option Plan on terms and at prices as determined by the Board except that the options cannot be granted at less than the market closing price of the common stock on the TSX-V, on the date prior to the grant. Each option will be exercisable after the period or periods specified in the option agreement, but no option may be exercised after the expiration of 10 years from the date of grant. The 2016 Stock Option Plan provides the Board with more flexibility when setting the vesting schedule for options which was otherwise fixed in the 2006 Stock Option Plan.

The 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:

	2017	2016
Exercise price	0.82	0.62
Expected volatility	60%	65%
Expected life	5.34 years	4.60 years
Risk-free interest rate	1.85%	1.39%
Dividend yield	Nil	Nil

The weighted average fair value of the options granted to employees and directors during the year ended December 31, 2017 is \$0.44 (2016 - \$0.33) .

No options were granted to consultants during the year ended December 31, 2017. The weighted average fair value of the options granted to consultants during the year ended December 31, 2016 is \$0.32.

Information with respect to employees and directors stock option activity for 2016 and 2017 is as follows:

**IntelGenx Technologies Corp.****Notes to Consolidated Financial Statements****December 31, 2017 and 2016****(Expressed in U.S. Funds)****14. Additional Paid-In Capital (Cont d)**

		Number of options	Weighted average exercise price \$
Outstanding	January 1, 2016	1,670,000	0.56
Granted		1,300,000	0.62
Forfeited		(50,000)	(0.53)
Expired		(120,000)	(0.43)
Exercised		(140,000)	(0.45)
Outstanding	December 31, 2016	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

Information with respect to consultant's stock option activity for 2016 and 2017 is as follows:

		Number of options	Weighted average exercise price \$
Outstanding	January 1, 2016	-	-
Granted		50,000	0.73
Outstanding	December 31, 2016 and 2017	50,000	0.73

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## IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2017 and 2016

(Expressed in U.S. Funds)

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

Details of stock options outstanding as at December 31, 2017 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	0.33	0.04		306,250	0.06	
0.52	125,000	0.04	0.02		125,000	0.03	
0.53	125,000	0.08	0.02		125,000	0.03	
0.58	710,000	0.58	0.14		710,000	0.18	
0.62	300,000	0.23	0.06		300,000	0.08	
0.73	600,000	1.66	0.15		300,000	0.10	
0.76	145,000	0.44	0.04		72,500	0.02	
0.77	359,818	1.16	0.09		-	-	
0.89	300,000	0.91	0.09		300,000	0.12	
	2,989,818	5.43	0.65	437,396	2,238,750	0.62	402,900

Stock-based compensation expense recognized in 2017 with regards to the stock options was \$315 thousand (2016: \$195 thousand). As at December 31, 2017 the Company has \$196 thousand (2016 - \$320 thousand) of unrecognized stock-based compensation, of which \$5 thousand (2016 - \$11 thousand) relates to options granted to a consultant. The amount of \$196 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 \$196 thousand being charged to stock-based compensation expense.

## Warrants

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.

In the year ended December 31, 2016 a total of 1,056,765 warrants were exercised for 1,056,765 common shares having a par value of \$Nil in aggregate, for cash consideration of approximately \$596 thousand, resulting in an increase in additional paid-in capital of approximately \$596 thousand.

**IntelGenx Technologies Corp.****Notes to Consolidated Financial Statements****December 31, 2017 and 2016****(Expressed in U.S. Funds)****14. Additional Paid-In Capital (Cont d)**

Information with respect to warrant activity for 2016 and 2017 is as follows:

	<b>Number of warrants (All Exercisable)</b>	<b>Weighted average exercise price \$</b>
Outstanding - January 1, 2016	7,231,123	0.5646
Exercised	(1,056,765)	(0.5646)
Outstanding - December 31, 2016	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

**15. Income Taxes**

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

	<b>2017</b>	<b>2016</b>
Statutory income taxes	\$ (794)	\$ (305)
Net operating losses for which no tax benefits have been recorded	346	201
Deficiency of depreciation over capital cost allowance	(235)	(206)
Non-deductible expenses	239	105
Undeducted research and development expenses	525	245
Investment tax credit	(81)	(40)
	\$ -	\$ -

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**IntelGenx Technologies Corp.****Notes to Consolidated Financial Statements****December 31, 2017 and 2016****(Expressed in U.S. Funds)****15. Income Taxes (Cont d)**

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

	2017	2016
Leasehold improvements and equipment	\$ 252	\$ 201
Net operating losses carryforward	2,620	2,062
Undeducted research and development expenses	2,054	1,501
Non-refundable tax credits carryforward	1,553	1,190
	6,479	4,954
Valuation allowance	(6,479)	(4,954)
	\$ -	\$ -

As at December 31, 2017, 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 2018, 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 \$9,560 thousand (2016: \$7,585 thousand) and \$10,052 thousand (2016: \$7,763 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 2037. A portion of the net operating losses may expire before they can be utilized.

As at December 31, 2017, the Company had non-refundable tax credits of \$1,553 thousand (2016: \$1,190 thousand) of which \$8 thousand is expiring in 2026, \$10 thousand is expiring in 2027, \$180 thousand is expiring in 2028, \$158 thousand is expiring in 2029, \$134 thousand is expiring in 2030, \$143 thousand is expiring in 2031, \$179 thousand is expiring in 2032, \$119 thousand is expiring in 2033, \$90 thousand expiring in 2034, \$106 thousand is expiring in 2035, \$146 thousand expiring in 2036 and \$280 thousand is expiring in 2037 and undeducted research and development expenses of \$7,532 thousand (2016: \$5,438 thousand) with no expiration date.

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

**Unrecognized Tax Benefits**

The Company does not have any unrecognized tax benefits.

**IntelGenx Technologies Corp.****Notes to Consolidated Financial Statements****December 31, 2017 and 2016****(Expressed in U.S. Funds)****15. Income Taxes (Cont d)****Tax Years and Examination**

The Company files tax returns in each jurisdiction in which it is registered to do business. For each jurisdiction a statute of limitations period exists. After a statute of limitations period expires, the respective tax authorities may no longer assess additional income tax for the expired period. Similarly, the Company is no longer eligible to file claims for refund for any tax that it may have overpaid. The following table summarizes the Company's major tax jurisdictions and the tax years that remain subject to examination by these jurisdictions as of December 31, 2017:

<b>Tax Jurisdictions</b>	<b>Tax Years</b>
Federal - Canada	2014 and onward
Provincial - Quebec	2014 and onward
Federal - USA	2014 onward

**16. Statement of Cash Flows Information**

<b>In US\$ thousands</b>	<b>2017</b>	<b>2016</b>
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**Additional Cash Flow Information:**

Interest paid	\$ 408	\$ 176
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**17. Related party transactions**

Included in management salaries are \$10 thousand (2016 - \$2 thousand) for options granted to the Chief Executive Officer, \$37 thousand (2016 - \$60 thousand) for options granted to the Chief Financial Officer, \$3 thousand (2016 - \$12 thousand) for options granted to the former Vice President, Operations, \$9 thousand (2016 - \$5) for options granted to the Vice-President, Research and Development, \$Nil (2016 - \$21) for options granted to the former Vice President, Corporate Development, and \$37 thousand for options granted to Vice-President, Business and Corporate Development (2016 - \$8) under the 2006 or 2016 Stock Option Plans and \$131 thousand (2016 - \$52 thousand) for options granted to non-employee directors.

Included in general and administrative expenses are director fees of \$256 thousand (2016: \$184 thousand). During the year a non-employee director rendered consulting services amounting to \$Nil (2016 - \$14 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.



**IntelGenx Technologies Corp.**

**Notes to Consolidated Financial Statements**

**December 31, 2017 and 2016**

**(Expressed in U.S. Funds)**

**18. 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.

**19. Subsequent events**

On January 16, 2018, the Company granted 100,000 options to purchase common stock to an employee. The stock options are exercisable at \$0.79 per share and vest over 2 years at 25% every six months.

Subsequent to the end of the year, total of 700,000 warrants were exercised for 700,000 common shares having a par value of \$Nil in aggregate, for cash consideration of approximately \$395 thousand.