

IntelGenx Technologies Corp.  
Form 10-K  
March 28, 2017

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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, 2016**

**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, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer    Accelerated filer                      Non-accelerated filer                      Smaller reporting company  
(Do not check if a smaller reporting company)

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

Yes      No

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As of June 30, 2016, the aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates of the registrant was \$26,564,328 based on the closing price of the registrant's common shares of U.S. \$0.50, 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 23, 2017</u> |
|----------------------------------|--------------------------------------|
| Common Stock, \$.00001 par value | 65,422,021 shares                    |

**DOCUMENTS INCORPORATED BY REFERENCE:**

Portions of the Company's Proxy Statement for its 2017 Annual Meeting of Shareholders (the 2017 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 December 31, 2016 closing rate reported by the Bank of Canada, being U.S. \$1.00 = CA\$1.3256.

## 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 are in the process of implementing 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, to license the commercial rights to partners in the pharmaceutical industry. In certain cases, we rely upon partners in the pharmaceutical industry to fund 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 of exclusivity 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 in swallowing: pediatric, geriatric, fear choking and/or 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 (USP) 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 onto 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 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<sup>th</sup>, 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 (CAD\$8 million). Forfivo XL<sup>®</sup> (Bupropion extended-release) is the first 450 mg bupropion HCl tablet indicated for Major Depressive Disorder, approved by the FDA. As per terms of the agreement, we received \$6 million from SKW at closing. In return for, (i) 100% of any and all royalties (as defined in the Edgemont Pharmaceuticals, LLC License Agreement) or similar royalty amounts received on or after April 1, 2016, (ii) 100% of the \$2 million milestone payment upon Edgemont reaching annual net sales of \$15 million, and (iii) 35% of all potential future milestone payments. Patent protection for Forfivo XL<sup>®</sup> in the United States expires in 2027 with an authorized generic entering the market in January 2018.

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.

**INT0007/2006:** We are developing an oral film product based on our VersaFilm™ technology containing the active ingredient Tadalafil. The product is intended for the treatment of erectile dysfunction (ED). The results of a phase I pilot study that was conducted in the second quarter of 2015 confirmed that the product is bioequivalent with the brand product, Cialis®. We are currently manufacturing submission batches that are intended to support a 505(b)(2) NDA filing with the FDA with a target submission date of about mid-2017 and a PDUFA date expected to be approximately mid-2018.

On November 21, 2016, we announced the signing of a binding term sheet for a license to Eli Lilly and Company's tadalafil dosing patent, United States Patent No. 6,943,166 (the '166 dosing patent). Any exclusivity associated with the tadalafil compound patent is not affected by this agreement.

Subject to FDA approval, this license allows us to commercialize a Tadalafil ED VersaFilm™ product in the U.S. prior to the expiration of the '166 dosing patent. This license terminates all our current tadalafil-related litigation activities.

We are currently actively seeking a partner for the commercialization of our Tadalafil ED VersaFilm™ product.

**INT0008/2007:** We developed this oral film product based on our VersaFilm™ technology. In March 2013 we submitted a 505(b)(2) new drug application ( NDA ) to the FDA for our novel oral thin-film formulation of Rizatriptan, the active drug in Maxalt-MLT® orally disintegrating tablets. Maxalt-MLT® is a leading branded anti-migraine product marketed by Merck & Co. The thin-film formulation of Rizatriptan was developed in accordance with a co-development and commercialization agreement with RedHill Biopharma Ltd. ( RedHill ). The product uses our proprietary immediate release VersaFilm™ 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®. 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 Cmax, AUC(0-t) and AUC(0-infinity) are well within the 80 - 125 acceptance range for bioequivalency.

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

In March 2014 we submitted our response to the FDA's CRL and in April, 2014 the FDA requested additional CMC data. We also reported that the supplier of the active pharmaceutical ingredient ( API ) of the product has been issued with an Import Alert by the FDA. The Import Alert bans the import into the USA of all raw materials from the supplier's manufacturing facility, which therefore prohibits the import of any products using these raw materials, and effectively prevents our VersaFilm™ product from being approved by the FDA. We have identified a new source of API which is currently used to manufacture new submission lots to support the re-submission of the NDA filing in mid 2017 with PDUFA date expected by early 2018.

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 (RMS), the Federal Institute for Drugs and Medical Devices of Germany (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 the Federal Institute for Drugs and Medical Devices of Germany (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 European Decentralized Procedure (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 2017. 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 Q4 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.

**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 metabolism of the drug. In the fourth quarter of 2010, we acquired from Cynapsus full control of, and interest in, this project going forward. We also obtained worldwide rights to U.S. Patent 7,592,328 and all corresponding foreign patents and patent applications to exclusively develop and further provide 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.

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 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 filing of the ANDA, we were named as a codefendant in a lawsuit pursuant to Paragraph IV litigation filed by Reckitt Benckiser Pharmaceuticals and Monosol RX in the U.S. District Court for the District of Delaware 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 U.S. District Court for the District of Delaware 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 of 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® 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 U.S. District Court for the District of Delaware 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 and Monosol Rx, LLC resulted in Par and the Company prevailing on the non-infringement of the U.S. Patent No. 8,017,150, which is set to expire in 2023, and on the invalidity (all claims) and non-infringement (certain claims) of the U.S. Patent No. 8,475,832, which is set to expire in 2030. The Court also ruled that Par's ANDA product would infringe the asserted claims of U.S. Patent No. 8,603,514, one of the Orange Book listed patents for Suboxone Film, and that the asserted claims of U.S. Patent No. 8,603,514 were not shown to be invalid.

Subsequent to year end, in late January 2017 we received a CRL from the FDA requesting more information on the API s and the finished product.

**INT0036/2013:** Loxapine is 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 in support of a marketing application to the FDA. The product was being developed in accordance with another development and commercialization agreement with Par Pharmaceutical, Inc. 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. Preparation of Scale-up activities for the product are currently ongoing.



**INT0039/2013:** A product based on one of our proprietary technologies has complete development and phase I clinical trial with positive data. The product was being developed in accordance with another development and commercialization agreement with Par Pharmaceutical, Inc. 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. 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 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. Preparation scale-up and submission activities 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 is currently in the development stage. In order to protect our competitive advantage, no further details of the product can be disclosed at this stage.

**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 are currently developing 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.

We commenced preparation for a phase II-a proof-of-concept ( POC ) study. The Company expects the results from the study to be available in Q4/2017. 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 1<sup>st</sup>, 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.

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             | Submission 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. CRL received and under review.   |
| INT0036/2012   | Schizophrenia        | Formulation development ongoing  |
| INT0037/2013   | Undisclosed          | Product developed. Preparing manufacture of submission batches.  |
| INT0039/2013   | Undisclosed          | Product developed. Preparing manufacture of submission batches   |
| INT0040/2013   | Undisclosed          | Formulation development ongoing  |
| INT0041/2015   | 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 include: (1) identifying lifecycle management opportunities for existing market leading pharmaceutical products, (2) develop oral film products that provide tangible patient benefits, (3) development of new drug delivery technologies, (4) repurposing existing drugs for new indications, (5) developing generic drugs where high technology barriers to entry exist in reproducing branded films, and (6) manufacturing our VersaFilm products for commercial sale. In addition, our service portfolio also includes contract manufacturing services as contract manufacturing presents an attractive short term revenue opportunity and increases the utilization of the manufacturing factory, thus further absorbing overhead costs.

### **Lifecycle Management Opportunities**

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

### **Product Opportunities that provide Tangible Patient Benefits**

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

### **Development of New Drug Delivery Technologies**

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

### **Repurposing Existing Drugs**

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

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

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

### **VersaFilm Manufacturing**

We are in the process of establishing a state-of-the-art manufacturing facility for the future manufacture of our VersaFilm products. Construction of the manufacturing and laboratories are now completed and equipment is being prepared to begin manufacturing in 2017. 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.

### **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 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.

### **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 (USP) components that are safe and approved by the FDA for use in food, pharmaceutical and cosmetic products. We completed construction of our manufacturing facility and expect it to be fully operational in 2017.

We are currently not a commercial manufacturer and we do not usually purchase large quantities of raw materials. Our manufacturing partners, however, may purchase significant quantities of raw materials, some of which may have long lead times. If raw materials cannot be supplied to our manufacturing partners in a timely and cost effective manner, our manufacturing partners may experience delays in production that may lead to reduced supplies of commercial products being available for sale or distribution. Such shortages could have a detrimental effect on sales of the products and a corresponding reduction on our royalty revenues earned.



## 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 8 patents and have an additional 18 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 the delays in the prosecution of the patent application that are not applicant delays.

| Patent No.   | Title  | Subject  | Date submitted / issued / expiration              |
|--------------|--|--|---|
| 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<br>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<br>Expires June 19, 2021  |
| US 7,132,113 | Flavored film  | Composition and manufacturing method of multi-layered films  | Issued November 7, 2006<br>Expires April 16, 2022 |
| US 8,691,272 | Multilayer tablet  | Formulation of multilayered tablets  | Issued April 8, 2014<br>Expires January 28, 2033  |
| US 8,703,191 | Controlled release pharmaceutical tablets                        | Formulation of tablets containing bupropion and mecamylamine   | Issued April 22, 2014<br>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<br>Expires July 25, 2027     |

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|              |  |  |  |
|--------------|--|--|--|
| US 8,735,374 | Oral mucoadhesive dosage form  | Direct compression formulation for buccal and sublingual dosage forms  | Issued May 27, 2014<br>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 05, 2016<br>Expires July 30, 2033 |

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|                             |   |  |                         |
|-----------------------------|---|--|-------------------------|
| US Appl. 13/079,348         | Solid oral dosage forms comprising tadalafil  | Formulation of oral films containing tadalafil                         | Filed April 4, 2011     |
| 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. 14/630,699         | Film dosage forms containing amorphous active agents                                | Film containing amorphous agent  | Filed February 25, 2015 |
| US Appl. 14/554,332         | Film dosage forms with extended release mucoadhesive particles                      | Film containing mucoadhesive particle                                  | Filed November 26, 2014 |
| US Appl. 13/748,241         | Oral film dosage forms and methods for making same                                  | Optimization of film strip technology                                  | Filed January 23, 2013  |
| US Appl. 15/216,903         | Film dosage forms containing amorphous active agents                                | Film containing amorphous agent  | Filed July 22, 2016     |
| PCT Appl. WO2016134454      | Film dosage forms containing amorphous active agents                                | Film containing amorphous agent  | Filed January 29, 2016  |
| PCT Appl. WO2016123696      | Oral dosage film exhibiting enhanced mucosal penetration                            | Formulation of oral films without conventional penetration enhancer    | Filed January 22, 2016  |
| US Appl. 14/612,433         | Oral dosage film exhibiting enhanced mucosal penetration                            | Formulation of oral films without conventional penetration enhancer    | Filed February 3, 2015  |
| 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. KR2016008935   | 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

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|                                   |   |  |                         |
|-----------------------------------|---|--|-------------------------|
| Singapore Appl.<br>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.<br>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.<br>CA2,919,422     | 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. CA2797444          | Solid oral dosage forms comprising tadalafil  | Formulation of oral films containing tadalafil                         | Filed November 3, 2011  |
| EU Appl. EP1,968,562              | Multilayer tablet   | Formulation of multilayered tablets                                    | Filed November 22, 2007 |

### 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, or IND, 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, 2016 increased by \$733 thousand to \$1,766 thousand, compared with \$1,033 thousand for the year ended December 31, 2015. 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 25 full-time and four 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**

#### **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 \$17,737 thousand since our inception in 2003 through December 31, 2016. To date, these losses have been financed principally through sales of equity securities. Our revenues for the past five years ended December 31, 2016, December 31, 2015, December 31, 2014, December 31, 2013 and December 31, 2012 were \$5.2 million, \$5.1 million, \$1.7 million, \$948 thousand and \$1,198 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 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 current Good Manufacturing Practices (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 are in the process of establishing our own manufacturing facility for the future manufacture of VersaFilm products, which requires considerable financial investment and, if we are unsuccessful, 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 manufacture products for commercial use. In order to establish ourselves as a full-service partner for our thin film products, we invested approximately \$6.5 million to establish a state-of-the-art manufacturing facility for the commercial manufacture of products developed using our VersaFilm drug delivery technology. We anticipate the manufacturing facility to be qualified and ready for regulatory approval in the second half of 2017.

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 by various health authorities in addition to other product-related approvals. 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 Good Manufacturing Practices ( 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 8 patents and have an additional 18 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.

In the United States, our common stock is considered a penny stock. The SEC has adopted regulations which generally define a penny stock to be an equity security that has a market price of less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to specific exemptions. This designation requires any broker or dealer selling these securities to disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities. These rules may restrict the ability of brokers or dealers to sell our common stock and may affect the ability of investors to sell their shares.

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.

**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). 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/per year, 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.

We also finalised negotiations on April 29, 2015 for an agreement for the construction of manufacturing facilities, laboratories, and offices within the property located at 6420 Abrams, St-Laurent, Quebec, at an aggregate cost of CA\$2.9 million (approximately \$2.2 million). The construction agreement was awarded to BTL Construction Inc. (BTL) in Quebec following a tender process that was completed in December 2014. BTL specializes in the construction and renovation of facilities for the pharmaceutical industry, and has completed projects for various major pharmaceutical companies. We funded this project from cash on hand as well as a CA\$1 million loan from IQ.

**ITEM 3. LEGAL PROCEEDINGS**

Litigation related to Forfivo XL®

In August 2013, we announced receipt of a Paragraph IV Certification Letter from Wockhardt Bio AG, advising of the submission of an ANDA to the FDA requesting authorization to manufacture and market generic versions of Forfivo XL® 450 mg tablets in the 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 effective November 26, 2014, Wockhardt has been granted the rights, with effect from January 15, 2018, to be the exclusive marketer and distributor of an authorized generic of Forfivo XL® in the U.S.

Litigation related to Buprenorphine/Naloxone

In August 2013 we learned that, in response to the July 2013 filing of an ANDA by Par, for our generic formulation of buprenorphine and naloxone Sublingual Film, indicated for the treatment of opioid dependence, we were named as a codefendant in a lawsuit pursuant to Paragraph IV litigation filed by Reckitt Benckiser Pharmaceuticals and Monosol RX in the U.S. District Court for the District of Delaware alleging infringement of U.S. Patent Nos. 8,475,832 (the 832 patent), 8,603,514 (the 514 patent) and 8,017,150 (the 150 patent), each of which relate to Suboxone. In June 2016 we received a trial opinion from Judge Andrews in which the asserted claims of the 832 patent and 150 patent were found either invalid or not infringed, while at least one of the alleged claims of the 514 patent was found valid and infringed by the ANDA product. A post-judgment motion was filed to introduce additional evidence related to the definition of the term "dried" for the judge's consideration in support of our non-infringement position concerning the

ANDA product. The additional evidence was presented during the trial on the 497 patent in November 2016. We still believe the ANDA product does not infringe the 514 patent 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 were expecting Reckitt Benckiser and Monosol RX to launch suit, and the litigation timeline has been incorporated in our overall launch timeline.

In December 2014, Reckitt Benckiser Pharmaceuticals and Monosol RX filed a lawsuit for patent infringement in the U.S. District Court for the District of Delaware 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 of which relate to a process for making a uniform oral film ( the process patents ). The trial for the process patent was held in November 2016. We believe the ANDA product relating to Suboxone® 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.

## Litigation related to INT0007 Tadalafil VersaFilm™

On February 26, 2016, we filed a request for *inter partes* reviews (or IPR) in the United States Patent and Trademark Office (USPTO) of patent no. 6,943,166 owned by ICOS Corporation (wholly owned by Eli Lilly & Company), the 166 patent, to challenge its validity and remove any infringement liability concerning our tadalafil oral film. On September 1, 2016, the USPTO decided not to institute the *inter partes* review for the 166 Patent. The USPTO's decision was purely on statutory grounds and based on a technicality (in that the IPR was not addressing an essential element of the claim). On October 3, 2016, we filed a Request for Rehearing, requesting reconsideration of the USPTO's decision denying institution of the IPR. On November 16, 2016, we withdrew our Request for Rehearing and signed a binding term sheet with Eli Lilly & Company granting us a license for the commercialization of our tadalafil oral film upon FDA approval of the product and post expiration of the compound patent (US pat. No. 5,859,006).

There are no additional material pending legal proceedings to which we are a party or to which any of our property is subject and to the best of our knowledge, no such additional actions against us are contemplated or threatened.

**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 OTC Bulletin Board/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/OTCBB      |                 | TSX-V           |                |
|----------------|------------------|-----------------|-----------------|----------------|
|                | High<br>(U.S.\$) | Low<br>(U.S.\$) | High<br>(CAD\$) | Low<br>(CAD\$) |
| <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        |
| <b>2015</b>    |                  |                 |                 |                |
| Fourth Quarter | \$ 0.58          | \$ 0.46         | \$ 0.76         | \$ 0.59        |
| Third Quarter  | \$ 0.60          | \$ 0.40         | \$ 0.81         | \$ 0.66        |
| Second Quarter | \$ 0.73          | \$ 0.56         | \$ 0.98         | \$ 0.63        |
| First Quarter  | \$ 0.90          | \$ 0.52         | \$ 1.10         | \$ 0.61        |

**Number of Shareholders**

On March 23, 2017 there were approximately 46 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 2016, 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 2016, 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<br><br>(a) | Weighted-average exercise price of outstanding options, warrants and rights<br><br>(b) | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))<br><br>(c) |
|--|--|--|--|
| Equity Compensation Plans Approved by Security Holders     | 1,785,000 <sup>(1)</sup>   | \$0.54   | NIL <sup>(2)</sup>   |
| Equity Compensation Plans Not Approved by Security Holders | 1,175,000 <sup>(2)</sup>   | \$0.78   | 1,938,954 <sup>(3)</sup>   |
| Total  | 2,960,000  | \$0.63   | 1,938,954  |

(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, 2016.

## 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 are in the process of implementing 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, to license the commercial rights to partners in the pharmaceutical industry. In certain cases, we rely upon partners in the pharmaceutical industry to fund 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.

We have established a state-of-the-art manufacturing facility for the future manufacture of our VersaFilm products. Construction of the manufacturing and laboratories are completed and we are expecting to start commercial manufacturing in Q4 2017 / Q1 2018. 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.

As previously announced, we have financed the Manufacturing Establishment and Laboratory Expansion project from cash in hand and a government-backed bank financing of up to CA\$4 million with the Bank as well as a CA\$1 million loan from Investissement Québec (IQ).

We will continue to hire new personnel, primarily in the areas of research and development, manufacturing, and administration on an as-needed basis as we enter into partnership agreements, establish our VersaFilm manufacturing capability, and further increase our research and development activities and capabilities.

### **2016 Key Developments**

***Anti-depressant tablet, Forfivo XL<sup>®</sup>***

On August 5<sup>th</sup>, 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 (CAD\$8 million). Forfivo XL<sup>®</sup> (Bupropion extended-release) is the first 450 mg bupropion HCl tablet indicated for Major Depressive Disorder, approved by the FDA. As per terms of the agreement, we received \$6 million from SKW at closing. In return for, (i) 100% of any and all royalties (as defined in the Edgemont Pharmaceuticals, LLC License Agreement) or similar royalty amounts received on or after April 1, 2016, (ii) 100% of the \$2 million milestone payment upon Edgemont reaching annual net sales of \$15 million, and (iii) 35% of all potential future milestone payments. Patent protection for Forfivo XL<sup>®</sup> in the United States expires in 2027 with an authorized generic entering the market in January 2018.

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.

### ***Anti-migraine VersaFilm***

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 2017. 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 Q4 2017.

On December 14, 2016, we, together with our partner RedHill Biopharma, 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. IntelGenx will supply the commercial product to Pharmatronic. 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.

### ***Erectile Dysfunction VersaFilm***

On November 21, 2016, we announced the signing of a binding term sheet for a license to Eli Lilly and Company's tadalafil dosing patent, United States Patent No. 6,943,166 (the "166 dosing patent"). Any exclusivity associated with the tadalafil compound patent is not affected by this agreement.

Subject to FDA approval, this license allows us to commercialize a Tadalafil ED VersaFilm product in the U.S. prior to the expiration of the "166 dosing patent. This license terminates all our current tadalafil-related litigation activities.

### ***Opioid dependence VersaFilm***

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 Pharmaceutical, Inc. (Par) and the Company to the

United States Court of Appeals for the Federal Circuit from the final judgment issued by the U.S. District Court for the District of Delaware 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 and Monosol Rx, LLC resulted in Par and the Company prevailing on the non-infringement of the U.S. Patent No. 8,017,150, which is set to expire in 2023, and on the invalidity (all claims) and non-infringement (certain claims) of the U.S. Patent No. 8,475,832, which is set to expire in 2030. The Court also ruled that Par's ANDA product would infringe the asserted claims of U.S. Patent No. 8,603,514, one of the Orange Book listed patents for Suboxone Film, and that the asserted claims of U.S. Patent No. 8,603,514 were not shown to be invalid.

## Undisclosed projects

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 U.S. Preparation of Scale-up activities for the product are currently ongoing.

On December 1<sup>st</sup>, 2016, we announced that we had strengthened our relationship with Chemo Group 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. 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

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.

## Corporate

### *New Manufacturing Facility with increased R&D and Administration space*

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). 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 are paying 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 /per year, every two years.

We also finalised negotiations on April 29, 2015 for an agreement for the construction of manufacturing facilities, laboratories, and offices within the property located at 6420 Abrams, St-Laurent, Quebec, at an aggregate cost of CA\$2.9 million (approximately \$2.2 million). The construction agreement was awarded to BTL Construction Inc. ( BTL ) in Quebec following a tender process that was completed in December 2014. BTL specializes in the construction and renovation of facilities for the pharmaceutical industry, and has completed projects for various major pharmaceutical companies. We funded this project from cash on hand as well as a CA\$1 million loan from IQ.

Construction was successfully completed in Q1, 2016. As of December 31, 2016, we had received CA\$4 million in cash as part of a credit facility (approximately \$3.2 million) negotiated with the Bank. The credit facility is supported by a 50% guarantee under the Export Guarantee Program from Export Development Canada, Canada's export credit agency.

*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, 2016 report an accumulated other comprehensive loss due to foreign currency translation adjustments of \$1,019 due to the fluctuations in the rates used to prepare our financial

statements, \$293 of which negatively impacted our comprehensive income for the fiscal year ended December 31, 2016. 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<br>ended December 31, |            | Twelve-month period<br>ended December 31, |              |
|--|--|------------|---|--------------|
|  | 2016                                     | 2015       | 2016                                      | 2015         |
|  | \$                                       | \$         | \$  | \$           |
| Comprehensive (loss) income  | (22)                                     | 233        | (1,473)                                   | 799          |
| <b>Add (deduct):</b>   |  |            |   |              |
| Depreciation and amortization  | 150                                      | 123        | 511                                       | 171          |
| Finance costs  | 57                                       | 22         | 203                                       | 123          |
| Finance income   | (2)                                      | (8)        | (4)                                       | (28)         |
| Share-based compensation   | 54                                       | 25         | 195                                       | 130          |
| Foreign currency translation<br>adjustment   | 398                                      | 34         | 293                                       | 492          |
| <b>Adjusted EBITDA</b>   | <b>635</b>                               | <b>429</b> | <b>(275)</b>                              | <b>1,687</b> |
| <b>Adjusted Earnings before Interest, Taxes, Depreciation and Amortization (Adjusted EBITDA)</b> |  |            |   |              |

Adjusted EBITDA increased by \$206 for the three-month period ended December 31, 2016 to \$635 compared to \$429 for the three-month period ended December 31, 2015. Adjusted EBITDA decreased by \$1,962 for the twelve-month period ended December 31, 2016 to negative \$275 compared to \$1,687 for the twelve-month period ended December 31, 2015. The increase in Adjusted EBITDA of \$206 for the three month period ended December 31, 2016 is mainly attributable to an increase in revenues of \$409 partially offset by an increase in R&D expenses of \$77 and an increase in SG&A expenses of \$176. The decrease in Adjusted EBITDA of \$1,962 for the twelve-month period ended December 31, 2016 is mainly attributable to an increase in R&D expenses of \$733 and an increase in SG&A expenses of \$1,533 partially offset by an increase in revenues of \$125.

**Results of operations for the three month and twelve month periods ended December 31, 2016 compared with the three month and twelve month periods ended December 31, 2015.**

| In U.S.\$ thousands                             | Three-month period<br>ended December 31, |            | Twelve-month period<br>ended December 31, |              |
|---|--|------------|---|--------------|
|   | 2016                                     | 2015       | 2016                                      | 2015         |
| Revenue   | \$ 1,911                                 | \$ 1,502   | \$ 5,220                                  | \$ 5,095     |
| Cost of Royalty and License<br>Revenue          | 91                                       | 141        | 319                                       | 433          |
| Research and Development<br>Expenses            | 471                                      | 390        | 1,766                                     | 1,033        |
| Selling, General and Administrative<br>Expenses | 768                                      | 567        | 3,605                                     | 2,072        |
| Depreciation of tangible assets                 | 150                                      | 106        | 511                                       | 125          |
| Amortization of intangible assets               | -  | 17         | -   | 46           |
| <b>Operating Income (Loss)</b>                  | <b>431</b>                               | <b>281</b> | <b>(981)</b>                              | <b>1,386</b> |
| <b>Net Income (Loss)</b>                        | <b>376</b>                               | <b>267</b> | <b>(1,180)</b>                            | <b>1,291</b> |
| <b>Comprehensive Income (Loss)</b>              | <b>(22)</b>                              | <b>233</b> | <b>(1,473)</b>                            | <b>799</b>   |

**Revenue**

Total revenues for the three-month period ended December 31, 2016 amounted to \$1,911, representing an increase of \$409 or 27% compared to \$1,502 for the three-month period ended December 31, 2015. Total revenues for the twelve-month period ended December 31, 2016 amounted to \$5,220 representing an increase of \$125 or 2% compared to \$5,095 for the twelve-month period ended December 31, 2015. The increase for the three-month period ended December 31, 2016 compared to the last year's corresponding period is mainly attributable to upfront payments received in Q4 2016. The increase for the twelve-month period ended December 31, 2016 compared to the last year's corresponding period is also mainly attributable to upfront payments received during 2016. The main differences between the three-month and twelve-month periods of 2016 vs 2015 is mainly the source of revenues that went from royalties and milestones in 2015 to deferred revenues from monetization of Forfivo and upfront payments from multiple agreements signed in 2016.

**Cost of royalty and license revenue**

We recorded \$91 for the cost of royalty and license revenue in the three-month period ended December 31, 2016 compared with \$141 in the same period of 2015. We recorded \$319 for the cost of royalty and license revenue in the twelve-month period ended December 31, 2016 compared with \$433 in the same period of 2015. 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>. 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, 2016 amounted to \$471, representing an increase of \$81 or 21%, compared to \$390 for the three-month period ended December 31, 2015. R&D expenses for the twelve-month period ended December 31, 2016 amounted to \$1,766, representing an increase of \$733 or 71%, compared to \$1,033 recorded in the same period of 2015.

The increase in R&D expenses for the three-month period ended December 31, 2016 is mainly attributable to an increase in R&D salaries of \$96 and laboratory supplies of \$79 partially offset by a decrease in patent expenses of \$59. The increase in R&D expenses for the twelve-month period ended December 31, 2016 is mainly attributable to an increase in patent expenses of \$290, an increase in R&D salaries of \$206 for new hires, laboratory supplies of \$99, analytical costs of \$78 as well as an increase in study costs of \$48.

In the twelve-month period ended December 31, 2016 we recorded estimated Research and Development Tax Credits of \$148, compared with \$105 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, 2016 amounted to \$768, representing an increase of \$201 or 35%, compared to \$567 for the three-month period ended December 31, 2015. SG&A expenses for the twelve-month period ended December 31, 2016 amounted to \$3,605, representing an increase of \$1,533 or 74%, compared to \$2,072 recorded in the same period of 2015.

The increase in SG&A expenses for the three-month period ended December 31, 2016 is mainly attributable to an increase in administration salaries of \$119 as well as an increase in business development salaries of \$49. The increase in SG&A expenses for the twelve-month period ended December 31, 2016 is mainly attributable to an increase in administration salaries of \$585, business development salaries of \$205 and business development expenses of \$188 as well as an increase in professional fees of \$163, rent and utilities of \$115 and finally an increase in office and general expenses of \$95.

### **Depreciation of tangible assets**

In the three-month period ended December 31, 2016 we recorded an expense of \$150 for the depreciation of tangible assets, compared with an expense of \$106 thousand for the same period of the previous year. In the twelve-month period ended December 31, 2016 we recorded an expense of \$511 for the depreciation of tangible assets, compared with an expense of \$125 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, 2016 amounted to \$54 compared to \$25 for the three-month period ended December 31, 2015. Share-based compensation warrants and share-based payments expense for the twelve-month period ended December 31, 2016 amounted to \$195 compared to \$130 for the twelve-month period ended December 31, 2015.

We expensed approximately \$141 in the twelve-month period ended December 31, 2016 for options granted to our employees in 2014, 2015 and 2016 under the 2006 and 2016 Stock Option Plans, and approximately \$52 for options granted to non-employee directors in 2014, 2015 and 2016, compared with \$60 and \$70 respectively that was expensed in the same period of the previous year.

There remains approximately \$320 in stock based compensation to be expensed in fiscal 2016 and 2017, \$309 of which relates to the issuance of options to our employees and directors during 2014 to 2016 and \$11 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<br>31, 2016 | December<br>31, 2015 | Increase/<br>(Decrease) | Percentage<br>Increase/<br>(Decrease) |
|--------------------------------------|----------------------|----------------------|-------------------------|---------------------------------------|
| Current Assets                       | \$ 6,352             | \$ 4,172             | \$ 2,180                | 52%                                   |
| Leasehold improvements and Equipment | 5,730                | 4,238                | 1,492                   | 35%                                   |
| Security Deposits                    | 708                  | 506                  | 202                     | 40%                                   |
| Current Liabilities                  | 5,235                | 1,779                | 3,456                   | 194%                                  |
| Deferred lease obligations           | 45                   | 27                   | 18                      | 67%                                   |
| Long-term debt                       | 2,565                | 1,546                | 1,019                   | 66%                                   |
| Capital Stock                        | 1                    | 1                    | 0                       | 0%                                    |
| Additional Paid-in-Capital           | 23,700               | 22,846               | 854                     | 4%                                    |

**Current assets**

Current assets totaled \$6,352 at December 31, 2016 compared with \$4,172 at December 31, 2015. The increase of \$2,180 is mainly attributable to an increase in short term financial investments of \$3,884 as well as an increase in prepaid expenses of \$496 partially offset by a decrease in cash and cash equivalents of \$2,253.

**Cash and cash equivalents**

Cash and cash equivalents totaled \$612 as at December 31, 2016 representing a decrease of \$2,253 compared with the balance of \$2,865 as at December 31, 2015. The decrease in cash on hand relates to net cash used in investing activities of (\$5,910) as well an unrealized foreign exchange loss of \$4, partially offset by net cash provided by operating activities of \$1,729 as well as net cash provided by financing activities of \$1,924.

The cash provided by financing activities derives from a loan negotiated with 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.

**Accounts receivable**

Accounts receivable totaled \$1,044 as at December 31, 2016 representing a decrease of \$96 compared with the balance of \$1,140 as at December 31, 2015. The main component of this year's accounts receivable is composed of upfront payments on agreements signed in Q4 2016 received in Q1 2017.

**Prepaid expenses**

As at December 31, 2016 prepaid expenses totaled \$566 compared with \$70 as of December 31, 2015. The increase in prepaid expenses is mainly attributable to the 10% prepayment to Cary Pharmaceuticals following the monetization of Forfivo to SWK Holding.

**Investment tax credits receivable**

R&D investment tax credits receivable totaled approximately \$246 as at December 31, 2016 compared with \$97 as at December 31, 2015. The increase relates to the accrual estimated and recorded for the twelve-month period ended December 31, 2016.

### **Leasehold improvements and equipment**

As at December 31, 2016, the net book value of leasehold improvements and equipment amounted to \$5,730, compared to \$4,238 at December 31, 2015. In the twelve-month period ended December 31, 2016 additions to assets totaled \$2,326 and mainly comprised of \$1,651 for manufacturing and packaging equipment for our new, state-of-the-art, VersaFilm manufacturing facility, and \$483 for leasehold improvements related to our new manufacturing facility at 6420 Abrams, St-Laurent, Quebec, Canada, \$176 for laboratory and office equipment and \$16 for computer equipment.

### **Security deposit**

A security deposit in the amount of CA\$300 (\$223) 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, 2016 and 2015. Security deposits in the amount of CA\$650 (\$484) and CA\$400 (\$289) for the term loans were also recorded as at December 31, 2016 and 2015, respectively.

### **Accounts payable and accrued liabilities**

Accounts payable and accrued liabilities totaled \$897 as at December 31, 2016 (December 31, 2015 - \$1,595) and is mainly attributable to accounts payable and accrued payroll.

### **Long-term debt**

Long-term debt totaled \$3,269 as at December 31, 2016 (December 31, 2015 - \$1,730). An amount of \$2,636 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 \$633 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.

### **Shareholders equity**

As at December 31, 2016 we had accumulated a deficit of \$17,737 compared with an accumulated deficit of \$16,557 as at December 31, 2015. Total assets amounted to \$12,790 and shareholders equity totaled \$4,945 as at December 31, 2016, compared with total assets and shareholders equity of \$8,916 and \$5,564 respectively, as at December 31, 2015.

### **Capital stock**

As at December 31, 2016 capital stock amounted to \$0.648 (December 31, 2015: \$0.636) . 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 \$23,700 as at December 31, 2016, as compared to \$22,846 at December 31, 2015. Additional paid in capital increased by \$596 for warrants exercised, increased by \$63 for options exercised, and increased by \$195 for stock based compensation attributable to the expensing of stock options granted to employees and directors.

### **Taxation**

As at December 31, 2016, the date of our latest annual tax return, we had Canadian and provincial net operating losses of approximately \$7,585 (December 31, 2015: \$6,462) and \$7,763 (December 31, 2015: \$6,725) 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 2036. A portion of the net operating losses may expire before they can be utilized.

As at December 31, 2016, we had non-refundable tax credits of \$1,190 thousand (2015: \$1,022 thousand) of which \$8 thousand is expiring in 2026, \$10 thousand is expiring in 2027, \$168 thousand is expiring in 2028, \$147 thousand is expiring in 2029, \$126 thousand is expiring in 2030, \$133 thousand is expiring in 2031, \$167 thousand is expiring in 2032 and \$111 thousand is expiring in 2033, \$84 thousand expiring in 2034 and \$99 thousand is expiring in 2035 and \$137 thousand expiring in 2036. We also had undeducted research and development expenses of \$5,438 thousand (2015: \$4,563 thousand) with no expiration date.

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



**Key items from the statement of cash flows**

| In U.S.\$ thousands                     | December<br>31, 2016 | December<br>31, 2015 | Increase/<br>(Decrease) | Percentage<br>Increase/<br>(Decrease) |
|---|----------------------|----------------------|-------------------------|---------------------------------------|
| Operating Activities                    | \$ 1,729             | \$ 546               | \$ 1,183                | 217%                                  |
| Financing Activities                    | 1,924                | 1,792                | 132                     | 7%                                    |
| Investing Activities                    | (5,910)              | (3,380)              | (2,530)                 | 75%                                   |
| Cash and cash equivalents end of period | 612                  | 2,865                | (2,253)                 | (79%)                                 |

**Statement of cash flows**

Net cash provided by operating activities was \$1,729 for the twelve-month period ended December 31, 2016, compared to \$546 for the twelve-month period ended December 31, 2015. For the twelve-month period ended December 31, 2016, net cash used by operating activities consisted of a net loss of (\$1,180) (2015: \$1,291) and an increase in non-cash operating elements of working capital of \$2,203 compared with a decrease of (\$1,046) for the twelve-month period ended December 31, 2015.

The net cash provided by financing activities was \$1,924 for the twelve-month period ended December 31, 2016, compared to \$1,792 provided in the same period of the previous year. An amount of \$1,940 derives from several disbursements of a term loan negotiated with the bank partially offset by loan repayment of (\$675). Finally, proceeds from exercise of warrants and options generated an inflow of \$659.

Net cash used in investing activities amounted to (\$5,910) for the twelve-month period ended December 31, 2016 compared to (\$3,380) in the same period of 2015. The net cash used in investing activities for the twelve-month period ended December 31, 2016 relates to the purchase of fixed assets for (\$2,326) as well as net acquisitions of short-term investments of (\$3,584).

The balance of cash and cash equivalents as at December 31, 2016 amounted to \$612, compared to \$2,865 at December 31, 2015.

**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 \$82 thousand) per year, which will increase at a rate of CA\$0.25 (\$0.19) per square foot / year every two years.

The aggregate minimum rentals, exclusive of other occupancy charges, for property leases expiring in 2026, are approximately \$824 thousand, as follows:

|            |       |
|------------|-------|
| 2017       | \$ 83 |
| 2018       | 85    |
| 2019       | 87    |
| 2020       | 89    |
| 2021       | 90    |
| Thereafter | 390   |

**Subsequent events**

Subsequent to the end of the year, 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 \$55 thousand) per year, which will increase at a rate of CA\$0.25 (\$0.19) per square foot every two years. IntelGenx plans to use the newly leased space to expand its manufacture of oral film VersaFilm TM.

### **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**

#### **9. 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, 2016 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, 2016. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission

(COSO) in Internal Control Integrated Framework (2013). Based on our processes and assessment, as described above, management has concluded that, as of December 31, 2016 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 2017 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 2017 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 2017 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 2017 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 2017 Proxy Statement.

### **PART IV**

#### **ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

##### **(a) Financial Statements and Schedules**

##### **1. Financial Statements**

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

- A. Report of Independent Registered Public Accounting Firm.
- B. Consolidated Balance Sheets as of December 31, 2016 and 2015.

- C. Consolidated Statements of Shareholders' Equity for the years ended of December 31, 2016 and 2015.
- D. Consolidated Statements of Comprehensive Loss for the years ended of December 31, 2016 and 2015.
- E. Consolidated Statements of Cash Flows for the years ended December 31, 2016 and 2015.
- 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.**

| <b>Exhibit No.</b> | <b>Description</b>   |
|--------------------|--|
| 2.1                | Share exchange agreement dated April 10, 2006 (incorporated by reference to the Form 8-K/A filed on May 5, 2006)   |
| 3.1                | Certificate of Incorporation (incorporated by reference to the Form SB-2 (File No. 333-90149) filed on November 16, 1999)  |
| 3.2                | Amendment to the Certificate of Incorporation (incorporated by reference to amendment No. 2 to Form SB-2 (File No. 333-135591) filed on August 28, 2006)                   |
| 3.3                | Amendment to the Certificate of Incorporation (incorporated by reference to the Form DEF 14C filed on April 20, 2007)  |
| 3.4                | By-Laws (incorporated by reference to the Form SB-2 (File No. 333-91049) filed on November 16, 1999)   |
| 3.5                | Amended and Restated By-Laws (incorporated by reference to the Form 8-K filed on March 31, 2011)   |
| 3.6                | Amended and Restated By-Laws (incorporated by reference to the Form 8-K filed on March 21, 2012)   |
| 9.1                | Voting Trust agreement (incorporated by reference to the Form 8-K/A filed on May 5, 2006)  |
| 9.2                | Amended and Restated Unanimous Shareholders Agreement, May 26, 2011  |
| 10.1 +             | Horst Zerbe employment agreement dated October 1, 2014 (incorporated by reference to the Form 10-Q filed on November 12, 2014)   |
| 10.2               | Registration rights agreement (incorporated by reference to the Form SB-2 (File No. 333-135591) filed on July 3, 2006)   |
| 10.3               | Principal's registration rights agreement (incorporated by reference to the Form SB-2 (File No. 333-135591) filed on July 3, 2006)   |
| 10.4 +             | 2006 Stock Option Plan (incorporated by reference to the Form S-8 filed on November 21, 2006)  |
| 10.5 +             | Amended and Restated 2006 Stock Option Plan, May 29, 2008 (incorporated by reference to the Form 10-K filed on March 25, 2009)   |
| 10.6               | Co-Development and Commercialization Agreement with RedHill Biopharma Ltd. (incorporated by reference to the Form 10-Q filed on November 9, 2010)                          |
| 10.7 +             | Amended and Restated 2006 Stock Option Plan (incorporated by reference to the Form S-8 filed on November 15, 2010)   |
| 10.8               | Project Transfer Agreement (incorporated by reference to the Form 10-Q filed on May 14, 2010)  |
| 10.9               | Co-development and Licensing Agreement (incorporated by reference to the Form 10-Q filed on May 14, 2010)  |
| 10.10              | License and Asset Transfer Agreement with Edgemont Pharmaceuticals (incorporated by reference to the Form 10Q filed on May 15, 2012)                                       |
| 10.11+             | 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 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 16, 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 31, 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 11, 2016)
- 10.23 Amended Principal s Registration Rights Agreement, November 8, 2016 (incorporated by reference to Form 10Q filed on November 10, 2016)
- 21.1 Subsidiaries of the small business issuer (incorporated by reference to the Form SB-2 (File No. 333-135591) filed on June 1, 2006)
- 23.1\* Consents of Richter LLP
- 31.1\* Certification of Horst G. Zerbe, President and Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002\*
- 31.2\* Certification of Andre Godin, Executive Vice President and Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002\*
- 32.1\* Certification of Horst G. Zerbe, President and Chief Executive Officer, pursuant to 18 U.S.C. Section 1350\*
- 32.2\* Certification of Andre Godin, Executive Vice President and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350\*

\* Filed herewith.

+ Indicates management contract or employee compensation plan.

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

#### **ITEM 16. FORM 10K SUMMARY.**

None.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned on March 28, 2017, 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><br><br>Horst G. Zerbe    | Chairman of the Board, President and<br>Chief Executive Officer | March 28, 2017 |
| By: <i>/s/Andre Godin</i><br><br>Andre Godin           | Executive Vice President and Chief<br>Financial Officer         | March 28, 2017 |
| By: <i>/s/ Bernard Boudreau</i><br>J. Bernard Boudreau | Director, Vice Chairman of the Board                            | March 28, 2017 |
| By: <i>/s/Ian Troup</i><br>John (Ian) Troup            | Director  | March 28, 2017 |
| By: <i>/s/Bernd Melchers</i><br>Bernd J. Melchers      | Director  | March 28, 2017 |
| By: <i>/s/John Marinucci</i><br>John Marinucci         | Director  | March 28, 2017 |
| By: <i>/s/Clemens Mayr</i><br>Clemens Mayr             | Director  | March 28, 2017 |
| By: <i>/s/Mark Nawacki</i>                             | Director  | March 28, 2017 |

**IntelGenx Technologies Corp**

**Consolidated Financial Statements**

**December 31, 2016 and 2015**

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

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**IntelGenx Technologies Corp**

**Consolidated Financial Statements**  
**December 31, 2016 and 2015**  
**(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.**

We have audited the accompanying consolidated balance sheets of IntelGenx Technologies Corp. as at December 31, 2016 and 2015 and the related consolidated statements of comprehensive loss, shareholders' equity and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform an audit to obtain reasonable assurance whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, these consolidated financial statements present fairly in all material respects, the financial position of the Company as at December 31, 2016 and 2015 and the results of its operations and its cash flows for the years then ended in accordance with U.S. generally accepted accounting principles.

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

Montréal, Québec  
March 28, 2017

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

**514.934.3400**  
**mtlinfo@richter.ca**

**Richter LLP**  
**1981 McGill**  
**College**  
**Mtl (Qc) H3A 0G6**  
**www.richter.ca**

**Montréal,**  
**Toronto**

**IntelGenx Technologies Corp.****Consolidated Balance Sheets****As at December 31, 2016 and 2015****(Expressed in Thousands of U.S. Dollars (\$ 000) Except Share and Per Share Data)**

|   | 2016             | 2015            |
|---|------------------|-----------------|
| <b>Assets</b>   |                  |                 |
| <b>Current</b>  |                  |                 |
| Cash and cash equivalents   | \$ 612           | \$ 2,865        |
| Short-term investments (note 5)   | 3,884            | -               |
| Accounts receivable   | 1,044            | 1,140           |
| Prepaid expenses  | 566              | 70              |
| Investment tax credits receivable   | 246              | 97              |
| <b>Total Current Assets</b>   | <b>6,352</b>     | <b>4,172</b>    |
| <b>Leasehold Improvements and Equipment, net</b> (note 6)   | <b>5,730</b>     | <b>4,238</b>    |
| <b>Security Deposits</b>  | <b>708</b>       | <b>506</b>      |
| <b>Total Assets</b>   | <b>\$ 12,790</b> | <b>\$ 8,916</b> |
| <b>Liabilities</b>  |                  |                 |
| <b>Current</b>  |                  |                 |
| Accounts payable and accrued liabilities  | 897              | 1,595           |
| Current portion of long-term debt (note 9)  | 704              | 184             |
| Deferred revenue (note 8)   | 3,634            | -               |
| <b>Total Current Liabilities</b>  | <b>5,235</b>     | <b>1,779</b>    |
| <b>Deferred lease obligations</b>   | <b>45</b>        | <b>27</b>       |
| <b>Long-term debt</b> (note 9)  | <b>2,565</b>     | <b>1,546</b>    |
| <b>Total Liabilities</b>  | <b>7,845</b>     | <b>3,352</b>    |
| <b>Commitments (note 10)</b>  |                  |                 |
| <b>Subsequent event (note 17)</b>   |                  |                 |
| <b>Shareholders' Equity</b>   |                  |                 |
| Capital Stock, common shares, \$0.00001 par value; 100,000,000 shares authorized;<br>64,812,020 shares issued and outstanding (2015: 63,615,255 common shares)<br>(note 11) | <b>1</b>         | <b>1</b>        |

|                                      |                  |                 |
|--------------------------------------|------------------|-----------------|
| Additional Paid-in-Capital (note 12) | <b>23,700</b>    | 22,846          |
| Accumulated Deficit                  | <b>(17,737)</b>  | (16,557)        |
| Accumulated Other Comprehensive Loss | <b>(1,019)</b>   | (726)           |
| <b>Total Shareholders Equity</b>     | <b>4,945</b>     | 5,564           |
|                                      | <b>\$ 12,790</b> | <b>\$ 8,916</b> |

See accompanying notes

**Approved on Behalf of the Board:**

*/s/ Bernd J. Melchers*

Director

*/s/ Horst G. Zerbe*

Director

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**IntelGenx Technologies Corp.****Consolidated Statement of Shareholders' Equity****For the Year Ended December 31, 2015****(Expressed in Thousands of U.S. Dollars (\$ 000) Except Share and Per Share Data)**

|  | <u>Capital Stock</u> |             | Additional       | Accumulated        | Accumulated     | <b>Total</b>         |
|--|----------------------|-------------|------------------|--------------------|-----------------|----------------------|
|  | Number               | Amount      | Paid-In          | Deficit            | Other           | <b>Shareholders'</b> |
|  |                      |             | Capital          |                    | Comprehensive   | <b>Equity</b>        |
|  |                      |             |                  |                    | Loss            |                      |
| <b>Balance -<br/>December 31,<br/>2014</b>       | 63,465,255           | \$ 1        | \$ 22,654        | \$ (17,848)        | \$ (234)        | <b>4,573</b>         |
| Foreign<br>currency<br>translation<br>adjustment | -                    | -           | -                | -                  | (492)           | <b>(492)</b>         |
| Options<br>exercised<br>(note 12)                | 150,000              | -           | 62               | -                  | -               | <b>62</b>            |
| Stock-based<br>compensation<br>(note 12)         | -                    | -           | 130              | -                  | -               | <b>130</b>           |
| Net income<br>for the year                       | -                    | -           | -                | 1,291              | -               | <b>1,291</b>         |
| <b>Balance<br/>December 31,<br/>2015</b>         | <b>63,615,255</b>    | <b>\$ 1</b> | <b>\$ 22,846</b> | <b>\$ (16,557)</b> | <b>\$ (726)</b> | <b>5,564</b>         |

See accompanying notes



**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)**

|  | <u>Capital Stock</u> |             | Additional       | Accumulated        | Accumulated       | <b>Total</b>         |
|--|----------------------|-------------|------------------|--------------------|-------------------|----------------------|
|  | Number               | Amount      | Paid-In          | Deficit            | Other             | <b>Shareholders'</b> |
|  |                      |             | Capital          |                    | Comprehensive     | <b>Equity</b>        |
|  |                      |             |                  |                    | Loss              |                      |
| <b>Balance -<br/>December 31,<br/>2015</b>       | 63,615,255           | \$ 1        | \$ 22,846        | \$ (16,557)        | \$ (726)          | <b>5,564</b>         |
| Foreign<br>currency<br>translation<br>adjustment | -                    | -           | -                | -                  | (293)             | <b>(293)</b>         |
| Warrants<br>exercised<br>(note 12)               | 1,056,765            | -           | 596              | -                  | -                 | <b>596</b>           |
| Options<br>exercised<br>(note 12)                | 140,000              | -           | 63               | -                  | -                 | <b>63</b>            |
| Stock-based<br>compensation<br>(note 12)         | -                    | -           | 195              | -                  | -                 | <b>195</b>           |
| Net loss for<br>the year                         | -                    | -           | -                | (1,180)            | -                 | <b>(1,180)</b>       |
| <b>Balance<br/>December 31,<br/>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 Statements of Comprehensive Loss****For the Years Ended December 31, 2016 and 2015****(Expressed in Thousands of U.S. Dollars (\$ 000) Except Share and Per Share Data)**

|  | 2016              | 2015              |
|--|-------------------|-------------------|
| <b>Revenues</b>                                      |                   |                   |
| Royalties  | \$ 1,041          | \$ 981            |
| License and other revenue                            | 4,179             | 4,114             |
| <b>Total Revenues</b>                                | <b>5,220</b>      | <b>5,095</b>      |
| <b>Expenses</b>                                      |                   |                   |
| Cost of royalty, license and other revenue           | 319               | 433               |
| Research and development expense                     | 1,766             | 1,033             |
| Selling, general and administrative expense          | 3,605             | 2,072             |
| Depreciation of tangible assets                      | 511               | 125               |
| Amortization of intangible assets                    | -                 | 46                |
| <b>Total Expenses</b>                                | <b>6,201</b>      | <b>3,709</b>      |
| <b>Operating (Loss) Income</b>                       | <b>(981)</b>      | <b>1,386</b>      |
| <b>Interest Income</b>                               | <b>4</b>          | <b>28</b>         |
| <b>Financing and Interest expense</b>                | <b>(203)</b>      | <b>(123)</b>      |
|  | <b>(199)</b>      | <b>(95)</b>       |
| <b>(Loss) Income Before Income Taxes</b>             | <b>(1,180)</b>    | <b>1,291</b>      |
| Income taxes (note 13)                               | -                 | -                 |
| <b>Net (Loss) Income</b>                             | <b>(1,180)</b>    | <b>1,291</b>      |
| <b>Other Comprehensive Income (Loss)</b>             |                   |                   |
| Foreign currency translation adjustment              | (293)             | (492)             |
| <b>Comprehensive (Loss) Income</b>                   | <b>\$ (1,473)</b> | <b>\$ 799</b>     |
| <b>Basic:</b>  |                   |                   |
| <b>Weighted Average Number of Shares Outstanding</b> | <b>63,956,543</b> | <b>63,524,023</b> |
| Basic (Loss) Earnings Per Common Share (note 16)     | \$ (0.02)         | \$ 0.01           |
| <b>Diluted:</b>                                      |                   |                   |
| <b>Weighted Average Number of Shares Outstanding</b> | <b>63,956,543</b> | <b>70,855,146</b> |
| Diluted (Loss) Earnings Per Common Share (note 16)   | \$ (0.02)         | \$ 0.01           |

See accompanying notes



## IntelGenx Technologies Corp.

## Consolidated Statements of Cash Flows

For the Year Ended December 31, 2016 and 2015

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

|  | 2016           | 2015            |
|--|----------------|-----------------|
| <b>Funds Provided (Used) -</b>                                 |                |                 |
| <b>Operating Activities</b>                                    |                |                 |
| Net (Loss) Income  | \$ (1,180)     | \$ 1,291        |
| Amortization and depreciation                                  | 511            | 171             |
| Stock-based compensation                                       | 195            | 130             |
|  | (474)          | 1,592           |
| Changes in assets and liabilities                              |                |                 |
| Accounts receivable  | 96             | (488)           |
| Prepaid expenses   | (496)          | 26              |
| Investment tax credits receivable                              | (149)          | 11              |
| Security deposits  | (202)          | (506)           |
| Accounts payable and accrued liabilities                       | (698)          | 1,129           |
| Deferred revenue   | 3,634          | (1,245)         |
| Deferred lease obligations                                     | 18             | 27              |
| <b>Net change in assets and liabilities</b>                    | <b>2,203</b>   | <b>(1,046)</b>  |
| <b>Net cash provided by operating activities</b>               | <b>1,729</b>   | <b>546</b>      |
| <b>Financing Activities</b>                                    |                |                 |
| Issuance of term loans   | 1,940          | 1,752           |
| Repayment of term loans  | (675)          | (22)            |
| Proceeds from exercise of warrants and stock options           | 659            | 62              |
| <b>Net cash provided by financing activities</b>               | <b>1,924</b>   | <b>1,792</b>    |
| <b>Investing Activities</b>                                    |                |                 |
| Additions to leasehold improvements and equipment              | (2,326)        | (3,380)         |
| Acquisitions of short-term investments                         | (5,236)        | -               |
| Redemptions of short-term investments                          | 1,652          | -               |
| <b>Net cash used in investing activities</b>                   | <b>(5,910)</b> | <b>(3,380)</b>  |
| <b>Decrease in Cash and Cash Equivalents</b>                   | <b>(2,257)</b> | <b>(1,042)</b>  |
| <b>Effect of Foreign Exchange on Cash and Cash Equivalents</b> | <b>4</b>       | <b>(492)</b>    |
| <b>Cash and Cash Equivalents</b>                               |                |                 |
| <b>Beginning of Year</b>                                       | <b>2,865</b>   | <b>4,399</b>    |
| <b>End of Year</b>   | <b>\$ 612</b>  | <b>\$ 2,865</b> |

See accompanying notes

**IntelGenx Technologies Corp.**

**Notes to Consolidated Financial Statements**

**December 31, 2016 and 2015**

**(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. 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 14 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, 10 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, 2016 and 2015**

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

**3. Adoption of New Accounting Standards**

The FASB issued Update 2015-16, Business Combinations, which requires that an acquirer recognize adjustments to provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. The amendments in this Update require that the acquirer record, in the same period's financial statements, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the change to the provisional amounts, calculated as if the accounting had been completed at the acquisition date. The amendments in this Update require an entity to present separately on the face of the income statement or disclose in the notes the portion of the amount recorded in current-period earnings by line item that would have been recorded in previous reporting periods if the adjustment to the provisional amounts had been recognized as of the acquisition date. The amendments in this Update apply to all entities that have reported provisional amounts for items in a business combination for which the accounting is incomplete by the end of the reporting period in which the combination occurs and during the measurement period have an adjustment to provisional amounts recognized. For public business entities, the amendments in this Update are effective for fiscal years beginning after December 15, 2015, including interim periods within those fiscal years. The amendments in this Update should be applied prospectively to adjustments to provisional amounts that occur after the effective date of this Update with earlier application permitted for financial statements that have not yet been issued. The adoption of this Statement did not have a material effect on the Company's financial position or results of operations.

The FASB issued amendments to ASU 2015-03, Interest - Imputation of Interest, which are intended to simplify the presentation of debt issuance costs. These amendments require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the amendments in this ASU. The amendments are effective for public business entities for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. The adoption of this Statement did not have a material effect on the Company's financial position or results of operations.

The FASB issued amendments to ASU 2015-01, Income Statement - Extraordinary and Unusual Items, eliminating from U.S. GAAP the concept of extraordinary items. Subtopic 225-20, Income Statement - Extraordinary and Unusual Items, required that an entity separately classify, present and disclose extraordinary events and transactions. This ASU will also align more closely U.S. GAAP income statement presentation guidance with IAS 1, *Presentation of Financial Statements*, which prohibits the presentation and disclosure of extraordinary items. The amendments are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. The adoption of this Statement did not have a material effect on the Company's financial position or results of operations.

**IntelGenx Technologies Corp.**

**Notes to Consolidated Financial Statements**

**December 31, 2016 and 2015**

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

**3. Adoption of New Accounting Standards (cont d)**

The FASB issued ASU No. 2014-12, Compensation – Stock Compensation, which requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. A reporting entity should apply existing guidance in Topic 718, *Compensation – Stock Compensation*, as it relates to awards with performance conditions that affect vesting to account for such awards. The performance target should not be reflected in estimating the grant-date fair value of the award. Compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved. The amendments in this ASU are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. The adoption of this Statement did not have a material effect on the Company's financial position or results of operations.

The FASB issued ASU 2014-15, Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, which is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures. This ASU provides guidance to an organization's management, with principles and definitions that are intended to reduce diversity in the timing and content of disclosures that are commonly provided by organizations today in the financial statement footnotes. For public business entities, the amendments in this ASU are effective for fiscal years ending December 31, 2016, including interim periods within fiscal years beginning after December 15, 2016. The adoption of this Statement did not have a material effect on the Company's financial position or results of operations.

**4. Summary of Significant Accounting Policies**

**Revenue Recognition**

The Company recognizes revenue from research and development contracts as the contracted services are performed or when milestones are achieved, recorded as other revenue, 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.

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, 2016, the Company recognized royalty revenue earned under a licensing agreement totaling \$1,041 thousand compared to \$981 thousand in 2015.

For the year ended December 31, 2016, the Company recognized revenues as a result of sales milestones achieved under a licensing agreement totaling \$358 thousand compared to \$2,808 thousand in 2015.

**IntelGenx Technologies Corp.**

**Notes to Consolidated Financial Statements**

**December 31, 2016 and 2015**

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

**4. Summary of Significant Accounting Policies (cont d)**

**Use of Estimates**

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

**Cash and Cash Equivalents**

Cash and cash equivalents is comprised of cash on hand and term deposits with original maturity dates of less than three months that are stated at cost, which approximates fair value.

**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, 2016 accounts receivable (2015: \$Nil).

**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, 2016 totaled \$Nil (2015: \$108 thousand).



**IntelGenx Technologies Corp.****Notes to Consolidated Financial Statements****December 31, 2016 and 2015****(Expressed in U.S. Funds)****4. Summary of Significant Accounting Policies (Cont d)****Leasehold Improvements and Equipment**

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

On the declining balance method -

|                                 |     |
|---------------------------------|-----|
| Laboratory and office equipment | 20% |
| Computer equipment              | 30% |

On the straight-line method -

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

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

**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.

**Impairment of Long-lived Assets**

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

**Deferred Lease Obligations**

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

**IntelGenx Technologies Corp.**

**Notes to Consolidated Financial Statements**

**December 31, 2016 and 2015**

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

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

**Deferred Lease Obligations (Cont d)**

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, 2016 and 2015**

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

**4. 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) Earnings Per Share**

Basic (loss) earnings 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) earnings 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, 2016 and 2015**

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

**4. 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 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 2016-15 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 2016-06 - Derivatives and Hedging (Topic 815) Contingent Put and Call Options in Debt Instruments**

The amendments in this Update clarify 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. An entity performing the assessment under the amendments in this Update is required 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 financial statements issued for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years and should be applied on a retrospective basis.



**IntelGenx Technologies Corp.**

**Notes to Consolidated Financial Statements**

**December 31, 2016 and 2015**

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

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

**ASU 2016-09 - Compensation Stock Compensation (Topic 718) Improvements to Employee Share-Based Payment Accounting**

FASB issued this Update as part of its Simplification Initiative. The areas for simplification in this Update involve several aspects of the accounting for share-based payment transactions, including the 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 annual periods beginning after December 15, 2016, and interim periods within those annual periods. Early adoption is permitted for any entity 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 2016-01 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 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.

**IntelGenx Technologies Corp.**

**Notes to Consolidated Financial Statements**

**December 31, 2016 and 2015**

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

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

**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.

**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.

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) which was issued to add clarification to the implementation guidance on principle versus agent considerations. 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.
2. ASU 2016-10: Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing which was issued to clarifying the following two aspects of topic 606; identifying performance obligations and the licensing implementation guidance. 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.





**IntelGenx Technologies Corp.**

**Notes to Consolidated Financial Statements**

**December 31, 2016 and 2015**

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

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

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. With this amendment, the SEC Staff is rescinding the following SEC Staff Observer comments that are codified in Topic 605, Revenue Recognition, and Topic 932, Extractive Activities Oil and Gas, effective upon adoption of Topic 606. This amendment is effective immediately.

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.

This ASU is to be applied retrospectively, with certain practical expedients allowed. The Company is currently evaluating the impact of this Statement on its consolidated financial statements.

**ASU 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory**

The amendments in this Update more closely align the measurement of inventory in GAAP with the measurement of inventory in International Financial Reporting Standards (IFRS). 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. Subsequent measurement is unchanged for inventory measured using LIFO or the retail inventory method.

The Board has amended some of the other guidance in Topic 330 to more clearly articulate the requirements for the measurement and disclosure of inventory. However, the Board does not intend for those clarifications to result in any changes in practice. Other than the change in the subsequent measurement guidance from the lower of cost or market to the lower of cost and net realizable value for inventory within the scope of this Update, there are no other substantive changes to the guidance on measurement of inventory.

The amendments in this Update do not apply to inventory that is measured using last-in, first-out (LIFO) or the retail inventory method. The amendments apply to all other inventory, which includes inventory that is measured using first-in, first-out (FIFO) or average cost.

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 amendments in this Update should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The adoption of this Statement is not expected to have a material effect on the Company's financial position or results of operations.

**IntelGenx Technologies Corp.****Notes to Consolidated Financial Statements****December 31, 2016 and 2015****(Expressed in U.S. Funds)****4. Summary of Significant Accounting Policies (Cont d)****ASU 2015-17 Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes ( ASU 2015-17 )**

In November 2015, the FASB issued ASU 2015-17, which require that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position.

The amendments apply to all entities that present a classified statement of financial position. The current requirement that deferred tax liabilities and assets of a tax-paying component of an entity be offset and presented as a single amount is not affected by the amendments.

For public business entities, the amendments are effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. The Company is currently evaluating the impact of this Statement on its consolidated financial statements.

**5. Short-term investments**

As at December 31, 2016, short-term investments consisting of mutual funds (CAD\$3 million) and term deposits (\$1,650 million) are with a Canadian financial institution having a high credit rating. The term deposits have a maturity date of August 17, 2017, bear interest at 0.40% and are cashable at any time.

**6. Leasehold improvements and Equipment**

|                                 | Cost     | Accumulated<br>Depreciation | 2016<br>Net Carrying<br>Amount | 2015<br>Net Carrying<br>Amount |
|---------------------------------|----------|-----------------------------|--------------------------------|--------------------------------|
| Manufacturing equipment         | \$ 2,550 | \$ 121                      | \$ 2,429                       | \$ 1,050                       |
| Laboratory and office equipment | 1,222    | 415                         | 807                            | 821                            |
| Computer equipment              | 66       | 43                          | 23                             | 17                             |
| Leasehold improvements          | 2,786    | 315                         | 2,471                          | 2,350                          |
|                                 | \$ 6,624 | \$ 894                      | \$ 5,730                       | \$ 4,238                       |

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

**IntelGenx Technologies Corp.**

**Notes to Consolidated Financial Statements**

**December 31, 2016 and 2015**

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

**7. 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 and corporate credits cards of up to CAD\$75 thousand. Borrowings under the operating demand line of credit bear interest at the Bank's prime lending rate plus 2%. The credit facility and term loan (see note 9) are secured by a first ranking movable hypothec on all present and future movable property of the Company 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, 2016, 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.

**8. 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 deferred revenue represents the payment received for the royalty on future sales in the amount of \$6 million less the Q2 royalties recognized in the second quarter in the amount of \$352 thousand, less the amount recognized in other revenue during the six-month period ended December 31, 2016. The deferred revenue will be recognized as 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 is included in prepaid expenses less the portion expensed during the six-month period ended December 31, 2016. This expense will be 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, 2016 and 2015****(Expressed in U.S. Funds)****9. Long-term debt**

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

|                             | <b>December 31, 2016</b> | <b>December 31, 2015</b> |
|-----------------------------|--------------------------|--------------------------|
|                             | \$                       | \$                       |
| Term loan facility          | 2,636                    | 1,188                    |
| Secured loan                | 633                      | 542                      |
| <b>Total debt</b>           | <b>3,269</b>             | <b>1,730</b>             |
| Less: current portion       | 704                      | 184                      |
| <b>Total long-term debt</b> | <b>2,565</b>             | <b>1,546</b>             |

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%. The term loan is subject to the same security and financial covenants as the bank indebtedness (see note 7).

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, 2016, 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 five years are as follows:

|      |                 |
|------|-----------------|
| 2017 | \$704 (CAD 945) |
| 2018 | 704 (CAD 945)   |
| 2019 | 704 (CAD 945)   |
| 2020 | 704 (CAD 945)   |
| 2021 | 453 (CAD 610)   |

**10. 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 \$82 thousand) per year, which will increase at a rate of CAD\$0.25 (\$0.19) per square foot every two years.



**IntelGenx Technologies Corp.****Notes to Consolidated Financial Statements****December 31, 2016 and 2015****(Expressed in U.S. Funds)****10. Commitments (Cont d)**

The aggregate minimum rentals, exclusive of other occupancy charges, for property leases expiring in 2026, are approximately \$824 thousand, as follows:

|            |       |
|------------|-------|
| 2017       | \$ 83 |
| 2018       | 85    |
| 2019       | 87    |
| 2020       | 89    |
| 2021       | 90    |
| Thereafter | 390   |

**11. Capital Stock**

|  | 2016 | 2015 |
|--|------|------|
| Authorized -   |      |      |
| 100,000,000 common shares of \$0.00001 par value         |      |      |
| 20,000,000 preferred shares of \$0.00001 par value       |      |      |
| Issued -   |      |      |
| 64,812,020 (December 31, 2015: 63,615,255) common shares | \$ 1 | \$ 1 |

**Stock options**

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.

During the year ended December 31, 2015 a total of 150,000 stock options were exercised for 150,000 common shares having a par value of \$0 thousand in aggregate, for cash consideration of \$62 thousand, resulting in an increase in additional paid-in capital of \$62 thousand.

Stock-based compensation of \$195 thousand and \$130 thousand was recorded during the year ended December 31, 2016 and 2015 respectively. An amount of \$193 thousand expensed in 2016 relates to stock options granted to employees and directors and an amount of \$2 thousand relates to stock options granted to a consultant. The entire amounts expensed in 2015 relate to stock options granted to employees and directors. As at December 31, 2016 the Company has \$320 thousand (2015 - \$158 thousand) of unrecognized stock-based compensation, of which \$11 thousand (2015 - \$nil) relates to options granted to a consultant.

**IntelGenx Technologies Corp.****Notes to Consolidated Financial Statements****December 31, 2016 and 2015****(Expressed in U.S. Funds)****11. Capital Stock (Cont d)****Warrants**

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. No warrants were exercised during the year ended December 31, 2015.

**12. 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.

On April 2, 2015 the Company granted 200,000 options to purchase common stock to four non-employee directors. The stock options are exercisable at \$0.62, and vested immediately. The stock options were accounted for at their fair value, as determined by the Black-Scholes valuation model, of approximately \$45 thousand, using the following assumptions:

|                         |           |
|-------------------------|-----------|
| Expected volatility     | 66%       |
| Expected life           | 2.5 years |
| Risk-free interest rate | 0.87%     |
| Dividend yield          | Nil       |
|                         | F - 22    |



**IntelGenx Technologies Corp.****Notes to Consolidated Financial Statements****December 31, 2016 and 2015****(Expressed in U.S. Funds)****12. Additional Paid-In Capital (Cont d)**

On April 2, 2015 the Company granted 100,000 options to purchase common stock to an officer. The stock options are exercisable at \$0.62 per share and vest over 2 years at 25% every six months. The stock options were accounted for at their fair value, as determined by the Black-Scholes valuation model, of approximately \$24 thousand, using the following assumptions:

|                         |            |
|-------------------------|------------|
| Expected volatility     | 62%        |
| Expected life           | 3.13 years |
| Risk-free interest rate | 0.87%      |
| Dividend yield          | Nil        |

On July 20, 2015 the Company granted 600,000 options to purchase common stock to an employee. The stock options are exercisable at \$0.58 per share and vest over 2 years at 25% every six months. The stock options were accounted for at their fair value, as determined by the Black-Scholes valuation model, of approximately \$120 thousand, using the following assumptions:

|                         |            |
|-------------------------|------------|
| Expected volatility     | 63%        |
| Expected life           | 3.13 years |
| Risk-free interest rate | 1.09%      |
| Dividend yield          | Nil        |

On August 13, 2015 the Company granted 75,000 options to purchase common stock to a non-employee director. The stock options are exercisable at \$0.58 per share and vest over 2 years at 25% every six months. The stock options were accounted for at their fair value, as determined by the Black-Scholes valuation model, of approximately \$15 thousand, using the following assumptions:

|                         |            |
|-------------------------|------------|
| Expected volatility     | 62%        |
| Expected life           | 3.13 years |
| Risk-free interest rate | 1.06%      |
| Dividend yield          | Nil        |

On December 14, 2015 the Company granted 150,000 options to purchase common stock to an employee. The stock options are exercisable at \$0.48 per share and vest over 2 years at 25% every six months. The stock options were accounted for at their fair value, as determined by the Black-Scholes valuation model, of approximately \$25 thousand, using the following assumptions:

|                         |            |
|-------------------------|------------|
| Expected volatility     | 63%        |
| Expected life           | 3.13 years |
| Risk-free interest rate | 1.25%      |
| Dividend yield          | Nil        |

**IntelGenx Technologies Corp.****Notes to Consolidated Financial Statements****December 31, 2016 and 2015****(Expressed in U.S. Funds)****12. Additional Paid-In Capital (Cont d)**

On January 19, 2016 the Company granted 225,000 options to purchase common stock to two officers. The stock options are exercisable at \$0.41 per share and vest over 2 years at 25% every six months. The stock options were accounted for at their fair value, as determined by the Black-Scholes valuation model, of approximately \$32 thousand, using the following assumptions:

|                         |            |
|-------------------------|------------|
| Expected volatility     | 63%        |
| Expected life           | 3.13 years |
| Risk-free interest rate | 1.11%      |
| Dividend yield          | Nil        |

On January 19, 2016 the Company granted 250,000 options to purchase common stock to five non-employee directors. The stock options are exercisable at \$0.41 per share and vested immediately. The stock options were accounted for at their fair value, as determined by the Black-Scholes valuation model, of approximately \$33 thousand, using the following assumptions:

|                         |           |
|-------------------------|-----------|
| Expected volatility     | 66%       |
| Expected life           | 2.5 years |
| Risk-free interest rate | 1.11%     |
| Dividend yield          | Nil       |

On September 15, 2016 the Company granted 200,000 options to purchase common stock to an officer, 325,000 options to purchase common stock to 7 employees and 75,000 options to purchase common stock to a non-employee director. The stock options are exercisable at \$0.73 per share and vest over 2 years at 25% every six months. The stock options were accounted for at their fair value, as determined by the Black-Scholes valuation model, of approximately \$202 thousand, using the following assumptions:

|                         |            |
|-------------------------|------------|
| Expected volatility     | 65%        |
| Expected life           | 5.63 years |
| Risk-free interest rate | 1.30%      |
| Dividend yield          | Nil        |

On September 15, 2016 the Company granted 50,000 options to purchase common stock to a consultant. The stock options are exercisable at \$0.73 per share and vest over 2 years at 25% every six months. The stock options were accounted for at their fair value, as determined by the Black-Scholes valuation model, of approximately \$16 thousand, using the following assumptions:

|                         |            |
|-------------------------|------------|
| Expected volatility     | 64%        |
| Expected life           | 3.13 years |
| Risk-free interest rate | 0.87%      |
| Dividend yield          | Nil        |

**IntelGenx Technologies Corp.****Notes to Consolidated Financial Statements****December 31, 2016 and 2015****(Expressed in U.S. Funds)****12. Additional Paid-In Capital (Cont d)**

On December 27, 2016 the Company granted 225,000 options to purchase common stock to 6 employees. The stock options are exercisable at \$0.76 per share and vest over 2 years at 25% every six months. The stock options were accounted for at their fair value, as determined by the Black-Scholes valuation model, of approximately \$79 thousand, using the following assumptions:

|                         |            |
|-------------------------|------------|
| Expected volatility     | 63%        |
| Expected life           | 5.63 years |
| Risk-free interest rate | 2.20%      |
| Dividend yield          | Nil        |

Information with respect to employees and directors stock option activity for 2015 and 2016 is as follows:

|             |                   | <b>Number of options</b> | <b>Weighted average<br/>exercise price<br/>\$</b> |
|-------------|-------------------|--------------------------|---|
| Outstanding | January 1, 2015   | 1,130,000                | 0.54  |
| Granted     |                   | 1,125,000                | 0.58  |
| Forfeited   |                   | (410,000)                | (0.59)  |
| Expired     |                   | (25,000)                 | (0.45)  |
| Exercised   |                   | (150,000)                | (0.41)  |
| Outstanding | December 31, 2015 | 1,670,000                | 0.56  |
| Granted     |                   | 1,300,000                | 0.62  |
| Forfeited   |                   | (50,000)                 | (0.53)  |
| Expired     |                   | (120,000)                | (0.53)  |
| Exercised   |                   | (140,000)                | (0.45)  |
| Outstanding | December 31, 2016 | 2,660,000                | 0.60  |

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## IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2016 and 2015

(Expressed in U.S. Funds)

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

Information with respect to consultant's stock option activity for 2015 and 2016 is as follows:

|             |                   | Number of options | Weighted average<br>exercise price<br>\$ |
|-------------|-------------------|-------------------|--|
| Outstanding | January 1, 2015   | 100,000           | 0.59                                     |
| Expired     |                   | (100,000)         | 0.59                                     |
| Outstanding | December 31, 2015 | -                 | -  |
| Granted     |                   | 50,000            | 0.73                                     |
| Outstanding | December 31, 2016 | 50,000            | 0.73                                     |

Details of stock options outstanding as at December 31, 2016 are as follows:

| Outstanding options   |                      |  |  | Exercisable options                   |                      |  |                                       |
|-----------------------|----------------------|--|--|---------------------------------------|----------------------|--|---------------------------------------|
| Exercise prices<br>\$ | Number of<br>options | Weighted average<br>remaining<br>contractual life<br>(years) | Weighted<br>average<br>exercise<br>price<br>\$ | Aggregate<br>intrinsic<br>value<br>\$ | Number of<br>options | Weighted<br>average<br>exercise<br>price<br>\$ | Aggregate<br>intrinsic<br>value<br>\$ |
| 0.41                  | 375,000              | 0.57   | 0.06   |                                       | 281,250              | 0.09   |                                       |
| 0.48                  | 150,000              | 0.22   | 0.03   |                                       | 75,000               | 0.03   |                                       |
| 0.51                  | 20,000               | 0.00   | 0.00   |                                       | 20,000               | 0.01   |                                       |
| 0.52                  | 25,000               | 0.00   | 0.00   |                                       | 25,000               | 0.01   |                                       |
| 0.52                  | 100,000              | 0.07   | 0.02   |                                       | 100,000              | 0.04   |                                       |
| 0.53                  | 125,000              | 0.14   | 0.02   |                                       | 125,000              | 0.05   |                                       |
| 0.58                  | 35,000               | 0.02   | 0.01   |                                       | 35,000               | 0.02   |                                       |
| 0.58                  | 600,000              | 0.79   | 0.13   |                                       | 300,000              | 0.13   |                                       |
| 0.58                  | 75,000               | 0.10   | 0.02   |                                       | 37,500               | 0.02   |                                       |
| 0.60                  | 30,000               | 0.01   | 0.01   |                                       | 30,000               | 0.01   |                                       |
| 0.62                  | 300,000              | 0.36   | 0.07   |                                       | 275,000              | 0.13   |                                       |
| 0.73                  | 600,000              | 2.16   | 0.16   |                                       | -                    | -  |                                       |
| 0.73                  | 50,000               | 0.09   | 0.01   |                                       | -                    | -  |                                       |
| 0.76                  | 225,000              | 0.83   | 0.06   |                                       | -                    | -  |                                       |
|                       | 2,710,000            | 5.36   | 0.60   | 485,000                               | 1,303,750            | 0.53   | 320,000                               |

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**IntelGenx Technologies Corp.****Notes to Consolidated Financial Statements****December 31, 2016 and 2015****(Expressed in U.S. Funds)****12. Additional Paid-In Capital (Cont d)**

Stock-based compensation expense recognized in 2016 with regards to the stock options was \$195 thousand (2015: \$130 thousand). As at December 31, 2016 the Company has \$320 thousand (2015 - \$158 thousand) of unrecognized stock-based compensation, of which \$11 thousand (2015 - \$nil) relates to options granted to a consultant. The amount of \$195 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 \$195 thousand being charged to stock based compensation expense.

**Warrants**

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. No warrants were exercised during the year ended December 31, 2015.

Information with respect to warrant activity for 2015 and 2016 is as follows:

|                                      | <b>Number of<br/>warrants<br/>(All Exercisable)</b> | <b>Weighted average<br/>exercise price<br/>\$</b> |
|--------------------------------------|---|---|
| Outstanding January 1, 2015 and 2016 | 7,231,123   | 0.5646  |
| Exercised                            | (1,056,765)   | (0.5646)  |
| Outstanding - December 31, 2016      | 6,174,358   | 0.5646  |

**13. Income Taxes**

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

|  |                 |             |
|--|-----------------|-------------|
| Statutory income taxes   | <b>2016</b>     | <b>2015</b> |
|  | <b>\$ (305)</b> | <b>\$ 3</b> |
| Net operating losses for which no tax benefits have been recorded    | <b>201</b>      | <b>201</b>  |
| Net operating losses used for which no tax benefit had been recorded | <b>-</b>        | <b>(4)</b>  |
| Deficiency of depreciation over capital cost allowance               | <b>(206)</b>    | <b>(6)</b>  |
| Non-deductible expenses  | <b>105</b>      | <b>105</b>  |
| Undeducted research and development expenses                         | <b>245</b>      | <b>1</b>    |
| Investment tax credit  | <b>(40)</b>     | <b>(40)</b> |
|  | <b>\$ -</b>     | <b>\$ -</b> |



**IntelGenx Technologies Corp.****Notes to Consolidated Financial Statements****December 31, 2016 and 2015****(Expressed in U.S. Funds)****13. Income Taxes (Cont d)**

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

|  | <b>2016</b>    | 2015    |
|--|----------------|---------|
| Leasehold improvements and equipment         | \$ 201         | \$ 117  |
| Net operating losses carryforward            | <b>2,062</b>   | 1,770   |
| Undeducted research and development expenses | <b>1,501</b>   | 1,274   |
| Non-refundable tax credits carryforward      | <b>1,190</b>   | 1,022   |
|  | <b>4,954</b>   | 4,183   |
| Valuation allowance                          | <b>(4,954)</b> | (4,183) |
|  | \$ -           | \$ -    |

As at December 31, 2016, 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 2017, 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 \$7,585 thousand (2015: \$6,462 thousand) and \$7,763 thousand (2015: \$6,725 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 2036. A portion of the net operating losses may expire before they can be utilized.

As at December 31, 2016, the Company had non-refundable tax credits of \$1,190 thousand (2015: \$1,022 thousand) of which \$8 thousand is expiring in 2026, \$10 thousand is expiring in 2027, \$168 thousand is expiring in 2028, \$147 thousand is expiring in 2029, \$126 thousand is expiring in 2030, \$133 thousand is expiring in 2031, \$167 thousand is expiring in 2032 and \$111 thousand is expiring in 2033, \$84 thousand expiring in 2034 and \$99 thousand is expiring in 2035 and \$137 thousand expiring in 2036 and undeducted research and development expenses of \$5,438 thousand (2015: \$4,563 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, 2016 and 2015****(Expressed in U.S. Funds)****13. 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, 2016:

| <b>Tax Jurisdictions</b> | <b>Tax Years</b> |
|--------------------------|------------------|
| Federal - Canada         | 2013 and onward  |
| Provincial - Quebec      | 2013 and onward  |
| Federal - USA            | 2013 onward      |

**14. Statement of Cash Flows Information**

| <b>In US\$ thousands</b> | <b>2016</b> | <b>2015</b> |
|--------------------------|-------------|-------------|
|--------------------------|-------------|-------------|

**Additional Cash Flow Information:**

|               |        |       |
|---------------|--------|-------|
| Interest paid | \$ 176 | \$ 23 |
|---------------|--------|-------|

**15. Related party transactions**

Included in management salaries are \$2 thousand (2015 - \$3 thousand) for options granted to the Chief Executive Officer, \$60 thousand (2015 - \$39 thousand) for options granted to the Chief Financial Officer, \$12 thousand (2015-\$9 thousand) for options granted to the Vice President, Operations, \$5 thousand (2015 - \$nil) for options granted to the Vice-President, Research and Development, \$21 thousand (2015 - \$nil) for options granted to the former Vice President, Corporate Development, and \$8 thousand for options granted to Vice-President, Business and Corporate Development (2015 - \$nil) under the 2006 or 2016 Stock Option Plans and \$52 thousand (2015 - \$70 thousand) for options granted to non-employee directors.

Included in general and administrative expenses are director fees of \$184 thousand (2015: \$179 thousand). During the year a non-employee director rendered consulting services amounting to \$14 thousand (2015 - \$nil).

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, 2016 and 2015**

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

**16. Basic and Diluted Earnings (Loss) Per Common Share**

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

**17. Subsequent event**

Subsequent to the end of the year, 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 \$55 thousand) per year, which will increase at a rate of CAD\$0.25 (\$0.19) per square foot every two years. IntelGenx plans to use the newly leased space to expand its manufacture of oral film VersaFilm™.

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