IntelGenx Technologies Corp.
Form 10-K
March 30, 2016

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

FORM 10-K

[X] **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2015

[ ] **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____to _____

Commission File Number: 000-31187

IntelGenx Technologies Corp.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was

required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes [X] No [ ]

Indicate by check mark whether the registrant has submitted electronically 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 [X] No [ ]

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 [X]
		(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 [X]

As of June 30, 2015, the aggregate market value of the registrant s voting and non-voting common equity held by non-affiliates of the registrant was $35,540,543 based on the closing price of the registrant s common shares of U.S. $0.56, 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.

Class	**Outstanding at March 25, 2016**
Common Stock, $.00001 par value	63,615,256 shares

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the Company s Proxy Statement for its 2016 Annual Meeting of Shareholders (the 2016 Proxy Statement) are incorporated by reference into Part III

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Terminology and references

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

In this Form 10-K, unless otherwise specified, all monetary amounts are in United States dollars, all references to $, U.S.$, U.S. dollars and dollars mean U.S. dollars and all references to C$, Canadian dollars and CAD 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, 2015 closing rate reported by the Bank of Canada, being U.S. $1.00 = CAD$1.3841.

PART I

Cautionary Statement Concerning Forward-Looking Statements

Certain statements included or incorporated by reference in this report constitute forward-looking statements within the meaning of applicable securities laws. All statements contained in this report that are not clearly historical in nature are forward-looking, and the words anticipate , believe , continue , expect , estimate , intend , may , p and other similar expressions are generally intended to identify forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. All forward-looking statements are based on our beliefs and assumptions based on information available at the time the assumption was made. These forward-looking statements are not based on historical facts but on management s expectations regarding future growth, results of operations, performance, future capital and other expenditures (including the amount, nature and sources of funding thereof), competitive advantages, business prospects and opportunities. Forward-looking statements involve significant known and unknown risks, uncertainties, assumptions and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from those implied by forward-looking statements. These factors should be considered carefully and prospective investors should not place undue reliance on the forward-looking statements. Although the forward-looking statements contained in this report or incorporated by reference herein are based upon what management believes to be reasonable assumptions, there is no assurance that actual results will be consistent with these forward-looking statements. These forward-looking statements are made as of the date of this report or as of the date specified in the documents incorporated by reference herein, as the case may be. **We undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date on which such statements were made or to reflect the occurrence of unanticipated events, except as may be required by applicable securities laws.** The factors set forth in Item 1A., "Risk Factors", as well as any cautionary language in this report, provide examples of risks, uncertainties and events that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. Before you invest in the common stock, 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. 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.

We have also undertaken a strategy under which we will work with pharmaceutical companies in order to develop new dosage forms for pharmaceutical products for which patent protection is nearing expiration. 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 are in the process of establishing a state-of-the-art manufacturing facility for the future manufacture of our VersaFilm products 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

The 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. The 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 Multilayer Tablet 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. The Oral Film technology allows for the instant delivery of pharmaceuticals to the oral cavity, while the Mucoadhesive Tablet allows for the controlled release of active substances to the oral mucosa.

The Multilayer Tablet platform 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.

The 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. The Mucoadhesive Tablet technology is designed to be versatile in order to permit the site of application, residence time, and rate of release of the drug to be modulated to achieve the desired results.

Product Portfolio

Our product portfolio includes a blend of generic and branded products based on our proprietary delivery technology (generic products are essentially copies of products that have already received FDA approval). Of the thirteen projects currently in our product portfolio, two 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. The project is currently on hold.

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 have 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.

The level of sales achieved for Forfivo XL® continues to improve significantly. According to Edgemont Pharmaceuticals, net sales of Forfivo XL® totaled $3 million in the fourth quarter ending December 31, 2015 compared to $2.4 million in the third quarter ending September 30, 2015, representing an increase of 24% according to the actual Edgemont Pharmaceutical sales report. For the past twelve months, net sales of Forfivo XL® totaled $9.3 million ($17.4 million gross), an increase of 102% compared to the comparative period of 2014 with net sales of $4.6 million ($7.7 million gross). Management expects the sales trend to continue in fiscal 2016.

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 capsules in the United States. In November 2014 we announced that the Paragraph IV litigation with Wockhardt had been settled and that, under the terms of the settlement, Wockhardt has been granted the right, with effect from January 15, 2018, to be the exclusive marketer and distributor of an authorized generic of Forfivo XL® in the U.S.

In December 2014 we announced that Edgemont had exercised its right to extend the license for the exclusive marketing of Forfivo XL® 450 mg tablets. In exchange, we received milestone payments of $650 thousand in December 2014 and $600 thousand in February 2015. All other financial obligations contained in the license

agreement entered into by Edgemont and IntelGenx in February 2012, specifically launch-related and sales milestones, together with the contractual royalty rates on net sales of the product, remain in effect.

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 submission later this year.

INT0008/2007: 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 at this time. We continue to work together with RedHill, our development partner, on a variety of options to ensure continued supply of the raw material. We plan to file a re-submission of the NDA in Q4, 2016 and expect to receive a new PDUFA date later in Q4, 2016. The PDUFA date for FDA approval is expected to be set by Q2 2017.

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.

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. A clinical biostudy undertaken in 2009 on the muco-adhesive tablet developed by us and based on our proprietary AdVersa technology indicated improved bioavailability and reduced first-pass metabolization of the drug. In the fourth quarter of 2010, we acquired from Cynapsus full control of, and interest in, this project going forward. We also obtained worldwide rights to U.S. Patent 7,592,328 and all corresponding foreign patents and patent applications to exclusively develop and further provide intellectual property protection for this project.

INT0027/2011: 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 maintenance 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 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.

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. A second pilot clinical study confirming the improved bioavailability compared to the current tablet was completed late 2015. Further formulation optimization work is ongoing.

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. IntelGenx is now actively looking for a commercialization partner to conclude an agreement with to finalize the development of this product. Scale-up activities for the product commenced in 2015.

INT0039/2013: A product based on one of our proprietary technologies is currently in the early development stage. 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. IntelGenx is now actively looking for a commercialization partner to conclude an agreement with to finalize the development of this product.

INT0040/2014: 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.

INT0041/2015: 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.

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: 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.

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

Product	Indication	Status of Development
INT0004/2006	Antidepressant	FDA-approved November 2011. Commercially launched in USA as Forfivo XL® in October 2012.
INT0007/2006	Erectile dysfunction	Scale-up preparation ongoing
INT0008/2007	Migraine	NDA filed with FDA in March 2013. Currently working to resolve API supply issues. BfArM granted national marketing approval in November 2015.
INT0010/2006	Cancer pain	Formulation development ongoing
INT0027/2011	Opioid dependence	ANDA submitted to FDA in July 2013. Awaiting FDA decision / approval.
INT0036/2012	Schizophrenia	Formulation development ongoing
INT0037/2013	Undisclosed	Product developed. Preparing manufacture of submission batches.
INT0039/2013	Undisclosed	Formulation development ongoing
INT0040/2013	Undisclosed	Formulation development ongoing
INT0041/2015	Undisclosed	Formulation development ongoing
INT0042/2015	Undisclosed	Formulation development ongoing
INT0043/2015	Undisclosed	Formulation development ongoing

Growth Strategy

Our primary growth strategies include: (1) identifying lifecycle management opportunities for existing market leading pharmaceutical products, (2) developing generic drugs where high technology barriers to entry exist in reproducing branded films, (3) development of new drug delivery technologies, (4) repurposing existing drugs for new indications, and (5) manufacturing our VersaFilm products for commercial sale.

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.

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.

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.

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.

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 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 diversified pipeline;

Our ability to swiftly develop products through to regulatory approval; and

The versatility of our drug delivery technology.

Manufacturing Partnership

We currently manufacture products only for testing purposes in our own laboratories, and we do not manufacture products for pivotal clinical trials or for commercial use. In order to establish ourselves as a full-service partner for our thin film products, we have completed the construction of our new state-of-the-art facility and are in the process of preparing the equipment and finalizing plans to commercially manufacture 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. VersaFilm provides a patent-protected method of reformulating approved pharmaceuticals in a more convenient and discrete oral dosage form. We completed construction of our manufacturing facility and expect it to be fully operational in 2017.

We formed a strategic alliance with LTS Lohmann Therapie-Systeme AG ("LTS") for the manufacturing of certain products developed by us using our VersaFilm technology. LTS is regarded as a pioneer in the development and production of transdermal and film form oral systems and has become one of the world's leading suppliers for the international pharmaceutical industry.

We formed a strategic manufacturing partnership with Pillar5 Pharma Inc. (Pillar5). This manufacturing partnership secures the production of clinical test batches and commercial products for our VersaTab and AdVersa tablet products.

We are not currently a 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 seven (8) patents and have an additional three (5) pending patent applications, as described below. The patents expire 20 years after submission of the initial application.

Patent No.	Title	Subject	Date submitted / issued / expiration
US 6,231,957	Rapidly disintegrating flavor wafer for flavor enrichment	The composition, manufacturing, and use of rapidly disintegrating flavored films for releasing flavors to certain substrates	Issued May 15, 2001 Expires May 6, 2019
US 6,660,292	Rapidly disintegrating film for precooked foods	Composition and manufacturing of flavored films for releasing flavors to precooked food substrates	Issued December 9, 2003 Expires June 19, 2021
US 7,132,113	Flavored film	Composition and manufacturing method of multi-layered films	Issued November 7, 2006 Expires April 16, 2022
US 8,691,272	Multilayer tablet	Formulation of multilayered tablets	Issued April 8, 2014 Expires January 28, 2033
US 8,703,191	Controlled release pharmaceutical tablets	Formulation of tablets containing bupropion and mecamylamine	Issued April 22, 2014 Expires January 10, 2032
US 7,674,479	Sustained-release bupropion and bupropion / mecamylamine tablets	Formulation and method of making tablets containing bupropion and mecamylamine	Issued March 9, 2010 Expires July 25, 2027
US 8,735,374	Oral mucoadhesive dosage form	Direct compression formulation for buccal and sublingual dosage forms	Issued May 27, 2014 Expires April 15, 2032
US 9,301,948	Instantly wettable oral film dosage form without surfactant or polyalcohol	Formulation of oral films containing active pharmaceutical ingredients	Issued April 05, 2016 Expires July 30, 2033
US Appl. 13/079,348	Solid oral dosage forms	Formulation of oral films	

	comprising tadalafil	containing tadalafil	Filed April 04, 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

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 inspection of the manufacturing facility or facilities at which the product is 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, 2015 decreased by $42 thousand to $1,033 thousand, compared with $1,075 thousand for the year ended December 31, 2014. The decrease 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 facility located in Ville Saint Laurent, Quebec.

Employees

As of the date of this filing, we have 21 full-time and no part-time employees. None of our employees are covered by collective bargaining agreements. We believe that our relations with our employees are 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

While we had positive earnings in the fiscal year ended December 31, 2015, 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. While we had positive earnings in the fiscal year ended December 31, 2015, 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 $16,557 thousand since our inception in 2003 through December 31, 2015. To date, these losses have been financed principally through sales of equity securities. Our revenues for the past five years ended December 31, 2015, December 31, 2014, December 31, 2013, December 31, 2012 and December 31, 2011 were $5.1 million, $1.7 million, $948 thousand, $1,198 thousand and $440 thousand respectively. Our revenues in 2015 consisted primarily of royalty income and the amortization of deferred revenue related to the commercialization of Forfivo XL®, our first FDA-approved product, which was commercialized in October 2012, and milestone payments related to the development of our VersaFilm products. 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 controlled release 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 or adversely affect perception of us in the business and financial communities;

- 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 many 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.

We have entered 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.

The 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 testing purposes in our own laboratories 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 are in the process of investing $6 million to establish a state-of-the-art manufacturing facility for the commercial manufacture of products developed using our VersaFilm drug delivery technology. Approximately 75% of these funds were spent during the fiscal year ended December 31 2015 and accordingly the manufacturing facility is approximately 75% completed. The remaining approximately 25% will be spent in 2016. We anticipate the manufacturing facility to be qualified and ready for regulatory approval by Q1 2017.

We have limited expertise in establishing 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 FDA inspection of our manufacturing facilities, processes and quality systems in addition to other product-related approvals. Further, pharmaceutical manufacturing facilities are continuously subject to inspection by the FDA, 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. In recent years, health authorities have intensified their scrutiny of manufacturers' compliance with such requirements, and are increasingly challenging practices that were previously considered acceptable. 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. 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 covering 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 could 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.

We may have 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 seven U.S. patents and have applied for three U.S. patents, 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.

In 1995, the U.S. Patent and Trademark Office adopted changes to the U.S. patent law that made the term of issued patents 20 years from the date of filing rather than 17 years from the date of issuance, subject to specified transition periods. Beginning in June 1995, the patent term became 20 years from the earliest effective filing date of the underlying patent application. These changes may reduce the effective term of protection for patents that are pending for more than three years. While we cannot predict the effect that these changes will have on our business, they could have a material adverse effect on our ability to protect our proprietary information. Furthermore, the possibility of extensive delays in the patent issuance process could effectively reduce the term during which a marketed product is protected by patents.

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. In addition, we may not be able to attract the attention of major brokerage firms or institutional buyers.

Additional risks may exist because we became public through a "reverse merger" with a shell corporation. Although the shell did not have recent or past 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. Security analysts of major brokerage firms and securities institutions may not cover us or recommend the purchase of our common stock. No assurance can be given that established brokerage firms will want to conduct any financings for us in the future.

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

Until September 30, 2015, we occupied 3,500 square feet of leased space at a rate of CAD$8.88/square foot in an industrial zone at 6425 Abrams, St.-Laurent, Quebec, Canada under a five year renewable lease agreement signed in 2004. We expanded our laboratory and office space at this facility to its maximum during the second quarter of 2006. We extended the term of the lease agreement to, most recently, the day immediately preceding the fulfillment of certain conditions relating to the occupation of new leased premises at 6420 Abrams. Commencing in October of 2015, we began occupation of approximately 17,000 square feet of leased space at a base rent of approximately CAD$110 thousand annually for the first two years of a ten year and 6 months renewable lease agreement. The base rent increases at CAD$0.25 per square foot every two years. We plan to utilize approximately 9,500 square feet of the new facility 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.

ITEM 3. LEGAL PROCEEDINGS

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 capsules in the United States. In November 2014 we announced that the Paragraph IV litigation with Wockhardt had been settled and that, under the terms of the settlement 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.

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 maintenance 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 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 were expecting Reckitt Benckiser and Monosol to launch suit, and the litigation timeline has been incorporated in our overall launch timeline.

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 (U.S.$)	Low (U.S.$)	High (CAD$)	Low (CAD$)
2015				
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
2014				
Fourth Quarter	$ 0.69	$ 0.36	$ 0.75	$ 0.39
Third Quarter	$ 0.75	$ 0.46	$ 0.80	$ 0.50
Second Quarter	$ 1.06	$ 0.68	$ 1.12	$ 0.73
First Quarter	$ 1.05	$ 0.54	$ 1.16	$ 0.57

Number of Shareholders

On March 25, 2016 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 2015, 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 2015, 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 warrants and rights	Weighted-Average Exercise Price of options, warrants and rights	Number of securities remaining available for future issuance compensation plans (excluding securities reflected in the first column)
Equity Compensation Plans Approved by Security Holders	2,942,571(1)	$ 0.56	2,087,721(2)
Equity Compensation Plans Not Approved by Security Holders	None	None	None
Total	2,942,571	$ 0.56	2,087,721

(1) Includes shares of our common stock issuable pursuant to options granted under the 2006 Stock Option Plan.

(2) Represents the maximum number of shares of our common stock available for grants under the 2006 Stock Option Plan as of December 31, 2015.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITIONS AND RESULTS OF OPERATIONS

Introduction to Management s Discussion and Analysis

The purpose of this section, Management s Discussion and Analysis of Financial Condition and Results of Operations, is to provide a narrative explanation of the financial statements that enables investors to better understand our business, to enhance our overall financial disclosure, to provide the context within which our financial information may be analyzed, and to provide information about the quality of, and potential variability of, our financial condition, results of operations and cash flows. Unless otherwise indicated, all financial and statistical information included herein relates to our continuing operations. Unless otherwise indicated or the context otherwise requires, the words, IntelGenx , Company , we , us , and our refer to IntelGenx Technologies Corp. and its subsidiaries, including Inte Corp. This information should be read in conjunction with the accompanying audited Consolidated Financial Statements and Notes thereto.

Company Background

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

We have also undertaken a strategy under which we will work with pharmaceutical companies in order to develop new dosage forms for pharmaceutical products for which patent protection is nearing expiration. 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 are in the process of establishing a state-of-the-art manufacturing facility for the future manufacture of our VersaFilm products 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.

As previously announced, we plan to finance the project from cash in hand and a government-backed bank financing of up to CAD$3.5 million with BMO Bank of Montreal (BMO) as well as a CAD$1 million loan from Investissement Québec (IQ).

We plan 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 increase our research and development activities.

Key developments

Anti-depressant tablet, Forfivo XL®

Forfivo XL®, our first FDA approved product, was launched in October 2012 and is being marketed in the United States under the terms of a license agreement between us and Edgemont Pharmaceuticals. Forfivo XL® is indicated for the treatment of Major Depressive Disorder (MDD) and is the only extended-release bupropion HCl product to provide a once-daily, 450mg dose in a single tablet. The active ingredient in Forfivo XL® is bupropion, the same active ingredient used in the well-known antidepressant product Wellbutrin XL®. Prior to the launch of Forfivo XL®, most patients in the US requiring a 450mg dose of bupropion had been taking multiple tablets to achieve their 450mg dose requirement. With Forfivo XL® now available in the U.S., these patients can simplify their dosing regimen to a single Forfivo XL® tablet, once-daily.

The commercialization of Forfivo XL® triggered a performance-related milestone payment of $3 million from IntelGenx licensing partner Edgemont triggered by 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. From the $2 million remaining balance, $1 million was received in Q4 2015 and $1 million will be received in Q1 2016.

The level of sales achieved for Forfivo XL® continues to improve significantly. According to Edgemont Pharmaceuticals, net sales of Forfivo XL® totaled $3 million in the fourth quarter ending December 31, 2015 compared to $2.4 million in the third quarter ending September 30, 2015, representing an increase of 24% according to the official Edgemont Pharmaceutical sales report. For the past twelve months, net sales of Forfivo XL® totaled $9.3 million ($17.4 million gross), an increase in net sales of 102% compared to the comparative period of 2014. Management expects the sales trend to continue in fiscal 2016.

We expect sales of Forfivo XL® to continue this growth trend for the foreseeable future given that the settlement of the Paragraph IV litigation with Wockhardt Bio AG in November 2014 should prevent the entry of generic competition into the marketplace until early 2018.

Additional potential milestones of up to a further $23.5 million are due upon achieving certain sales and exclusivity targets. We also receive tiered, double-digit, royalties on net sales of 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 capsules in the United States. In November 2014 we announced that the Paragraph IV litigation with Wockhardt had been settled and that, under the terms of the settlement, Wockhardt has been granted the 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.

In December 2014 we announced that Edgemont had exercised its right to extend the license for the exclusive marketing of Forfivo XL® 450 mg tablets. In exchange, we received milestone payments of $650 thousand in December 2014 and $600 thousand in February 2015. All other financial obligations contained in the license agreement entered into by Edgemont and IntelGenx in February 2012, specifically launch-related and sales milestones, together with the contractual royalty rates on net sales of the product, remain in effect.

Anti-migraine VersaFilm

In March 2013 we submitted a 505(b)(2) NDA to the FDA for our novel oral thin-film formulation of Rizatriptan, the active drug in Maxalt-MLT® orally disintegrating tablets. Maxalt-MLT® is a leading branded anti-migraine product manufactured by Merck & Co. The thin-film formulation of Rizatriptan was developed in accordance with the co-development and commercialization agreement with RedHill using 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 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 API of the product had 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 at this time. We continue to work together with RedHill, our development partner, on a variety of options to ensure continued supply of the raw material. We plan to file a re-submission of the NDA in Q4, 2016 and expect to receive a new PDUFA date later in Q4, 2016. The PDUFA date for FDA approval is expected to be set by Q2 2017.

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.

Opioid dependence VersaFilm

In accordance with a co-development and commercialization agreement with Par Pharmaceutical Companies, Inc., we developed an oral controlled-release film product based on our proprietary VersaFilm technology. The product is a generic formulation of buprenorphine and naloxone Sublingual Film, indicated for maintenance 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 learned 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 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.

Two (undisclosed) projects

In January 2014 we announced the signing of another development and commercialization agreement with Par Pharmaceutical, Inc. (Par) for two new undisclosed products.

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 products have been returned back to the Company with 100% ownership and do not require 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 as we look to other possibilities to partner in the future.

IntelGenx is now actively looking for partners to conclude agreements with to continue commercialization of these two products.

Erectile Dysfunction VersaFilm

In February 2014 we announced the completion of a pilot biostudy with our proprietary VersaFilm tadalafil product for erectile dysfunction that indicated bioequivalence with the leading brand reference listed drug (RLD) tadalafil product.

This was a randomized, two-period, two-way crossover study in healthy male subjects. The study was designed to determine whether VersaFilm tadalafil was bioequivalent as measured by industry standard pharmacokinetic measures of peak plasma concentration (Cmax) and area under the curve (AUC). The study results demonstrated that VersaFilm tadalafil was within an acceptable range of bioequivalency with the RLD on both of these measures.

Schizophrenia VersaFilm

In April 2014 we announced financial support from the National Research Council of Canada Industrial Research Assistance Program (NRC-IRAP). In addition to advisory services and technological expertise, the funding provided by NRC-IRAP will support further development of a product for the treatment of central nervous system (CNS) diseases and disorders, based upon our proprietary, oral thin film, VersaFilm , technology.

In November 2014 we announced the successful completion of a pilot clinical study for our INT0036 VersaFilm product, which is intended for the treatment of schizophrenia-related disorders. INT0036 showed a significantly improved pharmacokinetic profile against the reference product. The study data confirm that buccal absorption of the drug from our VersaFilm product results in a significantly higher bioavailability of the drug compared to oral tablets. Therapeutically relevant plasma concentrations are reached significantly faster with our VersaFilm product compared to conventional tablets and confirm the suitability of the film product for the intended indication.

According to a Datamonitor Healthcare schizophrenia forecast published July 13, 2012, sales of schizophrenia drugs across the seven major markets (the U.S., Japan, France, Germany, Italy, Spain, and the UK) were estimated at $5.2 billion in 2012 and by 2021, the market is forecast to grow to $6.9 billion at a compound annual growth rate (CAGR) of 3.3% . The introduction of additional atypical antipsychotic depot injections, price increases in the US, and the use of pipeline drugs targeted against negative and cognitive symptoms alongside current antipsychotic treatments, are some of the catalysts for this growth. US sales were approximately $3.7 billion in 2012 and are forecast to grow at a CAGR of 4.7% until 2021.

In February 2016, the Company announced it had submitted a 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.

Proprietary Technology

In February 2014 we announced receipt of a Notice of Allowance ("NOA") from the United States Patent and Trademark Office (USPTO) for U.S. Patent Application Serial No. 11/647,033 entitled "Multilayer tablet" which covers the technology used in our hypertension product currently under development. We also announced that a second NOA has been received for U.S. Patent Application Serial No. 11/782,838 entitled "Controlled-release pharmaceutical tablets" which is related to the drug delivery technology used in Forfivo XL®, our first FDA-approved product currently commercialized in the U.S.

In April 2014 we announced receipt of a third NOA from the USPTO for U.S. Patent Application Serial No. 12/836,810 entitled "Oral mucoadhesive dosage form" which covers our proprietary AdVersa mucoadhesive drug delivery technology.

These three NOA's conclude the examination of each U.S. patent application and resulted in the issuance of three U.S. patents that significantly strengthen our patent portfolio and provide further protection for our proprietary technologies.

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 will be required to pay base rent of approximately CAD$110 thousand (approximately $83 thousand) per year, which will increase at a rate of CAD$0.25 ($0.19) per square foot /per year, every two years. We plan to use the newly leased space to manufacture our oral film VersaFilm products, to enlarge our research and development capabilities, and for administration purposes.

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 CAD$2.9 million (approximately $2.5 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 CAD$1 million loan from IQ. Construction was completed in Q1, 2016.

As of December 31, 2015, we had received CAD$1.644 million in cash as part of a credit facility of up to CAD$3.5 million (approximately $3.0 million) negotiated with BMO. The credit facility is supported by a 50% guarantee under the Export Guarantee Program from Export Development Canada, Canada s export credit agency. Management expects disbursement of the remaining balance to be disbursed in the first half of 2016. The credit facility may be drawn down in multiple disbursements over 12 months and, after a 6 month moratorium on the capital, has a repayment term of up to 60 months. The financial covenants of the credit facility require us to maintain a Minimum Debt Service Coverage ratio of 1.25:1, and a Maximum Total Debt to Tangible Net Worth ratio of 2.5:1. Based upon Management s business forecasts and projections, Management believes that we will be able to fully comply with these financial covenants. As part of securing the credit facility, we will maintain our operating bank account with BMO and we will conduct all future banking transactions related to our business operations through BMO. We intend to use the funds for the purchase and installation of new equipment for our new, state-of the-art, manufacturing facility.

On March 16, 2015 we placed an order for two packaging machines to be manufactured by Harro Höfliger Verpackungsmaschinen GmbH (Harro Höfliger) and installed in our new, state-of the-art, manufacturing facility. Harro Hofliger is widely recognized as a technological leader in the supply of production and packaging equipment, primarily to the pharmaceutical and medical device industries, and is noted for providing innovative, custom equipment to meet the needs of customers. Our purchase order consists of one commercial grade packaging machine for the commercial packaging of our VersaFilm products, and one smaller machine for our R&D laboratories to be used for clinical trials, submission batches and manufacturing scale up. The purchase order, in the aggregate amount of approximately €1.5 million (approximately $1.6 million), required a payment of a 20% deposit with a further 70% to be paid upon delivery of each machine and the balance of 10% to be paid upon satisfactory completion of a Site Acceptance Test of each machine. The laboratory packaging machine was delivered in Q4, 2015 and the commercial packaging machine is expected to be delivered in Q2, 2016. We intend to finance the acquisition of these two machines with the credit facility negotiated with BMO, as discussed above.

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, 2015 report an accumulated other comprehensive loss due to foreign currency translation adjustments of $726 due to the fluctuations in the rates used to prepare our financial statements, $492 of which negatively impacted our comprehensive income for the fiscal year ended December 31, 2015. The following Management Discussion and Analysis takes this into consideration whenever material.

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

Adjusted EBITDA is a non-US GAAP financial measure. A reconciliation of the Adjusted EBITDA is presented in the table below. The Company uses adjusted financial measures to assess its operating performance. Securities regulations require that companies caution readers that earnings and other measures adjusted to a basis other than US-GAAP do not have standardized meanings and are unlikely to be comparable to similar measures used by other companies. Accordingly, they should not be considered in isolation. The Company uses Adjusted EBITDA to measure its performance from one period to the next without the variation caused by certain adjustments that could potentially distort the analysis of trends in our operating performance, and because the Company believes it provides meaningful information on the Company s financial condition and operating results.

IntelGenx obtains its Adjusted EBITDA measurement by adding to comprehensive income (loss), finance income and costs, depreciation and amortization, income taxes and foreign currency translation adjustment incurred during the period. IntelGenx also excludes the effects of certain non-monetary transactions recorded, such as share-based compensation, for its Adjusted EBITDA calculation. The Company believes it is useful to exclude these items as they are either non-cash expenses, items that cannot be influenced by management in the short term, or items that do not impact core operating performance. Excluding these items does not imply they are necessarily nonrecurring. Share-based compensation costs are a component of employee and consultant s remuneration and can vary significantly with changes in the market price of the Company s shares. Foreign currency translation adjustments are a component of other comprehensive income and can vary significantly with currency fluctuations from one period to another. In addition, other items that do not impact core operating performance of the Company may vary significantly from one period to another. As such, Adjusted EBITDA provides improved continuity with respect to the comparison of the Company s operating results over a period of time. Our method for calculating Adjusted EBITDA may differ from that used by other corporations.

Reconciliation of Non-U.S.-GAAP Financial Information

	Three-month period ended December 31,		Twelve-month period ended December 31,	
In U.S.$ thousands	**2015**	2014	**2015**	2014
	$	$	$	$
Comprehensive income (Loss)	233	(339)	799	(2,155)
Add (deduct):				
Depreciation and amortization	123	23	171	74
Finance costs	22	-	123	-
Finance income	(8)	(11)	(28)	(34)
Share-based compensation	25	19	130	101
Foreign currency translation adjustment	34	83	492	409
Adjusted EBITDA	**429**	(225)	**1,687**	(1,605)

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

Adjusted EBITDA increased by $654 for the three-month period ended December 31, 2015 to $429 compared to negative ($225) for the three-month period ended December 31, 2014. Adjusted EBITDA increased by $3,292 for the twelve-month period ended December 31, 2015 to $1,687 compared to negative ($1,605) for the twelve-month period ended December 31, 2014. The increase in Adjusted EBITDA of $654 for the three month period ended December 31, 2015 is mainly attributable to an increase in comprehensive income of $572 as well as an increase in Depreciation and amortization of $100 partially offset by a decrease of the foreign currency translation adjustment of $49. The increase in Adjusted EBITDA of $3,292 for the twelve-month period ended December 31, 2015 is mainly attributable to an increase in comprehensive income of $2,954 as well as an increase in depreciation and amortization of $97, an

increase in finance costs of $123 and finally, an increase of the foreign currency translation adjustment of $83.

Results of operations for the three month and twelve month periods ended December 31, 2015 compared with the three month and twelve month periods ended December 31, 2014.

	Three-month period ended December 31,		Twelve-month period ended December 31,	
In U.S.$ thousands	**2015**	2014	**2015**	2014
Revenue	$ 1,502	$ 825	$ 5,095	$ 1,659
Cost of Royalty and License Revenue	141	61	433	61
Research and Development Expenses	390	303	1,033	1,075
Selling, General and Administrative Expenses	567	705	2,072	2,229
Depreciation of tangible assets	106	10	125	35
Amortization of intangible assets	17	13	46	39
Operating Income (Loss)	**281**	(267)	**1,386**	(1,780)
Net Income (Loss)	**267**	(256)	**1,291**	(1,746)
Comprehensive Income (Loss)	**233**	(339)	**799**	(2,155)

Revenue

Total revenues for the three-month period ended December 31, 2015 amounted to $1,502, representing an increase of $677 or 82% compared to $825 for the three-month period ended December 31, 2014. Total revenues for the twelve-month period ended December 31, 2015 amounted to $5,095 representing an increase of $3,436 or 207% compared to $1,659 for the twelve-month period ended December 31, 2014. The increases for the three-month and twelve-month periods ended December 31, 2015 compared to the last year s corresponding periods are mainly attributable to the attainment of milestones, totaling $2,667 from IntelGenx licensing partner Edgemont triggered by Edgemont reaching in July 2015, $7,000 of cumulative net trade sales of Forfivo XL® over the preceding 12 months. From the $2,667 milestones, $1,000 was received in the third quarter. From the remaining balance, $1,000 was received in Q4 2015 and $1,000 will be received in Q1 2016, with revenue to be recognized in Q1 2016 of $333. Nevertheless, 3/6 of the $2,000 was recognized as revenue in the fourth quarter and 5/6 of the $2,000 was recognized as revenue in the twelve-month period ended December 31, 2015.

The level of sales achieved for Forfivo XL® continues to improve significantly. According to the official Edgemont Pharmaceuticals sales report, net sales of Forfivo XL® totaled $3,000 in the fourth quarter ending December 31, 2015 compared to $2,400 in the third quarter ending September 30, 2015, representing an increase of 24%. For the past twelve months, net sales of Forfivo XL® totaled $9,300 ($17,400 gross), an increase in net sales of 102% compared to the comparative period of 2014. Management expects the sales trend to continue in fiscal 2016.

We expect sales of Forfivo XL® to continue this growth trend for the foreseeable future given that the settlement of the Paragraph IV litigation with Wockhardt Bio AG in November 2014 should prevent the entry of generic competition into the marketplace until early 2018.

Cost of royalty and license revenue

We recorded $141 for the cost of royalty and license revenue in the three-month period ended December 31, 2015 compared with $61 in the same period of 2014. We recorded $433 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. These expenses relate to a Project Transfer Agreement that was executed in May 2010 with one of our former development partners whereby we acquired full rights to, and ownership of, Forfivo XL®, our novel, high strength formulation of Bupropion hydrochloride, the active ingredient in Wellbutrin XL®. Pursuant to the Project Transfer Agreement, and following commercial launch of Forfivo XL® in October 2012, we are required, after recovering an aggregate $200 for management fees previously paid, to pay our former development partner 10% of net product sales received from the sale of Forfivo XL®. 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, 2015 amounted to $390, representing an increase of $87 or 29%, compared to $303 for the three-month period ended December 31, 2014. R&D expenses for the twelve-month period ended December 31, 2015 amounted to $1,033, representing a decrease of $42 or 4%, compared to $1,075 recorded in the same period of 2014.

The increase in R&D expenses for the three-month period ended December 31, 2015 is mainly attributable to an increase in patent costs of $155 partially offset by a decrease in manufacturing batch/scale-up of $88. The decrease in R&D expenses for the twelvemonth period ended December 31, 2015 is mainly attributable to a decrease in manufacturing batch/scale-up of $216 and a decrease in clinical study of $152 partially offset by an increase in patent costs of $210 and an increase in laboratory supplies of $135.

In the twelve-month period ended December 31, 2015 we recorded estimated Research and Development Tax Credits and refunds of $105, compared with $94 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, 2015 amounted to $567, representing a decrease of $137 or 19%, compared to $704 for the three-month period ended December 31, 2014. SG&A expenses for the twelve-month period ended December 31, 2015 amounted to $2,072, representing a decrease of $138 or 20%, compared to $705 recorded in the same period of 2014.

The decrease in SG&A expenses for the three-month period ended December 31, 2015 is mainly attributable to a decrease in professional fees of $142 partially offset by an increase in manufacturing salaries of $71. The decrease in SG&A expenses for the twelve-month period ended December 31, 2015 is mainly attributable to a decrease in administration salaries $242 partially offset by an increase in manufacturing salaries of $116.

Depreciation of tangible assets

In the three-month period ended December 31, 2015 we recorded an expense of $106 for the depreciation of tangible assets, compared with an expense of $10 thousand for the same period of the previous year. In the twelve-month period ended December 31, 2015 we recorded an expense of $125 for the depreciation of tangible assets, compared with an expense of $35 for the same period of the previous year

Amortization of intangible assets

The amortization of intangible assets expense for the three-month period ended December 31, 2015 amounted to $17, compared to $13 in the same period of last year. The amortization of intangible assets expense for the twelve-month period ended December 31, 2015 amounted to $46, compared to $39 in the same period of last year. This expense relates to the amortization of NDA acquisition costs in respect of the final progress payment to acquire 100% ownership of Forfivo XL®. Commercialization of Forfivo XL® in October 2012 triggered amortization of the asset over its estimated useful life of 39 months.

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, 2015 amounted to $25 compared to $19 for the three-month period ended December 31, 2014. Share-based compensation warrants and share-based payments expense for the twelve-month period ended December 31, 2015 amounted to $130 compared to $101 for the twelve-month period ended December 31, 2014.

We expensed approximately $65 in the twelve-month period ended December 31, 2015 for options granted to our employees in 2013, 2014 and 2015 under the 2006 Stock Option Plan, and approximately $65 for options granted to non-employee directors in 2013, 2014 and 2015, compared with $80 and $21 respectively that was expensed in the same period of the previous year.

There remains approximately $158 in stock based compensation to be expensed in fiscal 2016 and 2017, all of which relates to the issuance of options to our employees and directors during 2013 to 2015. We anticipate the issuance of additional options and warrants in the future, which will continue to result in stock-based compensation expense.

Key items from the balance sheet

In U.S.$ thousands	December 31, 2015	December 31, 2014	Increase/ (Decrease)	Percentage Increase/ (Decrease)
Current Assets	$ 4,172	$ 5,255	$ -1,083	-21%
Leasehold improvements and Equipment	4,238	983	3,255	331%
Intangible Assets	-	46	-46	N/A
Security Deposit	506	-	506	N/A
Current Liabilities	1,779	466	1,313	282%
Deferred License Revenue	-	1,245	-1,245	N/A
Long-term debt	1,546	-	1,546	N/A
Capital Stock	1	1	0	0%
Additional Paid-in- Capital	22,846	22,654	192	1%

Current assets

Current assets totaled $4,172 at December 31, 2015 compared with $5,255 at December 31, 2014. The decrease of $1,083 is mainly attributable to a decrease in cash and cash equivalents of approximately $1,534, partially counterbalanced by an increase in accounts receivable of $488.

Cash and cash equivalents

Cash and cash equivalents totaled $2,865 as at December 31, 2015 representing a decrease of $1,534 compared with the balance of $4,399 as at December 31, 2014. The decrease in cash on hand relates to net cash used in investing activities of ($3,380) as well an unrealized foreign exchange loss of $492, partially offset by net cash provided by operating activities of $546 as well as net cash provided by financing activities of $1,792.

The cash provided by financing activities derives from two loans. The first loan is in the amount of $1,210 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. Further disbursements will be received in the first half of the 2016 fiscal year. There is a moratorium on capital repayments for the first 6 months of each drawdown, at which point the term loan will be repayable in monthly installments over 60 months.

An amount of $542 was received from 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 December 2021.

Accounts receivable

Accounts receivable totaled $1,140 as at December 31, 2015 representing an increase of $488 compared with the balance of $652 as at December 31, 2014. The main reason for the increase is related to the remaining balance of $1,000 to be received in Q1 2016 from Edgemont s $2,000 milestone payment.

Prepaid expenses

As at December 31, 2015 prepaid expenses totaled $70 compared with $96 as of December 31, 2014. The decrease in prepaid expenses is attributable to the advance payment in December 2014 of certain expenses that related to services provided for the twelvemonth period ended December 31, 2015.

Investment tax credits receivable

R&D investment tax credits receivable totaled approximately $97 as at December 31, 2015 compared with $108 as at December 31, 2014. The decrease relates to the accrual estimated and recorded for the twelve-month period ended December 31, 2015.

Leasehold improvements and equipment

As at December 31, 2015, the net book value of leasehold improvements and equipment amounted to $4,238, compared to $983 at December 31, 2014. In the twelve-month period ended December 31, 2015 additions to assets totaled $3,380 and mainly comprised of $530 for manufacturing and packaging equipment required for our new, state-of-the-art, VersaFilm manufacturing facility, and $2,220 for leasehold improvements related to our new manufacturing facility at 6420 Abrams, St-Laurent, Quebec, Canada, and $545 for laboratory equipment.

Security deposit

A security deposit in the amount of CAD$300 ($217) 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, 2015. Security deposits in the amount of CAD$400 ($289) for the term loans were also recorded as at December 31, 2015.

Accounts payable and accrued liabilities

Accounts payable and accrued liabilities totaled $1,595 as at December 31, 2015 (December 31, 2014 - $466) and is mainly attributable to the outstanding amount due to the construction Company related to our new facility located at 6420 Abrams, St-Laurent, Quebec.

Long-term debt

Long-term debt totaled $1,730 as at December 31, 2015 (December 31, 2014 - Nil). An amount of $1,188 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. Further disbursements will be received in the first half of the 2016 fiscal year. There is a moratorium on capital repayments for the first 6 months of each drawdown, at which point the term loan will be repayable in monthly installments over 60 months.

An amount of $542 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 December 2021.

Shareholders equity

As at December 31, 2015 we had accumulated a deficit of $16,557 compared with an accumulated deficit of $17,848 as at December 31, 2014. Total assets amounted to $8,916 and shareholders equity totaled $5,564 as at December 31, 2015, compared with total assets and shareholders equity of $6,284 and $4,573 respectively, as at December 31, 2014.

Capital stock

As at December 31, 2015 capital stock amounted to $0.636 (December 31, 2014: $0.635) . 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 $22,846 as at December 31, 2015, as compared to $22,654 at December 31, 2014. Additional paid in capital increased by $62 for options exercised and increased by $130 for stock based compensation attributable to the amortization of stock options granted to employees and directors.

Taxation

As at December 31, 2015, the date of our latest annual tax return, we had Canadian and provincial net operating losses of approximately $6,462 (December 31, 2014: $9,530) and $6,725 (December 31, 2014: $9,683) 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 2035. A portion of the net operating losses may expire before they can be utilized.

As at December 31, 2015, we had non-refundable tax credits of $1,022 (December 31, 2014: $1,100) of which $8 is expiring in 2026, $9 is expiring in 2027, $163 is expiring in 2028, $143 is expiring in 2029, $122 is expiring in 2030, $129 is expiring in 2031, $162 is expiring in 2032, $108 is expiring in 2033, $82 expiring in 2034 and $96 is expiring in 2035. We also had undeducted research and development expenses of $6,315 (December 31, 2014: $4,805) with no expiration date.

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

Key items from the statement of cash flows

In U.S.$ thousands	December 31, 2015	December 31, 2014	Increase/ (Decrease)	Percentage Increase/ (Decrease)
Operating Activities	$ 546	$ (1,380)	$ 1,926	140%
Financing Activities	1,792	1,619	173	11%
Investing Activities	(3,380)	(403)	(2,977)	(739%)
Cash and cash equivalents - end of period	2,865	4,399	(1,534)	(35%)

Statement of cash flows

Net cash provided by operating activities was $546 for the twelve-month period ended December 31, 2015, compared to ($1,380) for the twelve-month period ended December 31, 2014. For the twelve-month period ended December 31, 2015, net cash used by operating activities consisted of a net income of $1,291 (2014: ($1,746)) and a decrease in non-cash operating elements of working capital of ($1,046) compared with an increase of $191 for the twelve-month period ended December 31, 2014.

The net cash provided by financing activities was $1,792 for the twelve-month period ended December 31, 2015, compared to $1,619 provided in the same period of the previous year. An amount of $1,210 derives from several disbursements of a term loan negotiated with BMO Bank and $542 derives from a loan from IQ, whereas the net cash provided in the twelve-month period ended December 31, 2014 resulted from the exercise of warrants and stock options.

Net cash used in investing activities amounted to ($3,380) for the twelve-month period ended December 31, 2015 compared to ($403) in the same period of 2014. The net cash used in investing activities for the twelve-month period ended December 31, 2015 relates exclusively to the purchase of fixed assets and mainly comprised of $530 for manufacturing and packaging equipment required for our new, state-of-the-art, VersaFilm manufacturing facility, and $2,220 for leasehold improvements related to our new manufacturing facility at 6420 Abrams, St-Laurent, Quebec, and $545 for laboratory equipment.

The balance of cash and cash equivalents as at December 31, 2015 amounted to $2,865, compared to $4,399 at December 31, 2014.

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 $80 thousand) per year, which will increase at a rate of CAD$0.25 ($0.19) per square foot / month every two years. IntelGenx is using the newly leased space for manufacturing its oral film VersaFilm products, enlarging research and development capabilities, and for administration.

The aggregate minimum rentals, exclusive of other occupancy charges, for property leases expiring in 2026, are approximately $866 thousand, as follows:

(In U.S. $ thousands)	
2016	$ 66
2017	81
2018	83
2019	84
2020	86
Thereafter	466

On March 3, 2015, the Company signed an agreement in the amount of €1,490 thousand with a supplier with respect to the fabrication of customized manufacturing equipment. As at December 31, 2015, an amount of €298 thousand had been paid.

On May 7, 2010, the Company executed a Project Transfer Agreement with one of its former development partners whereby the Company acquired full rights to, and ownership of, Forfivo XL®, a novel, high strength formulation of Bupropion hydrochloride, the active ingredient in Wellbutrin XL®. In accordance with the Project Transfer Agreement, and following commercial launch of Forfivo XL® in October 2012, the Company is required, after recovering an aggregate $200 thousand for management fees previously paid, to pay its former development partner 10% of net income received from the sale of Forfivo XL®. In December 2014 the Company fully recovered said management fees and owed approximately $58 thousand to its former development partner that was remitted in February 2015. During fiscal year 2015 the amount paid was $433.

Off-balance sheet arrangements

We have no off-balance sheet arrangements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The consolidated financial statements and supplementary data of the Company required in this item are set forth beginning on page F-1 of this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

a. Evaluation of Disclosure Controls and Procedures

Based on an evaluation under the supervision and with the participation of our management, our Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act) were effective as of December 31, 2015 to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC rules and forms and (ii) accumulated and communicated to the Company's management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

b. Changes in Internal Controls over Financial Reporting

Our Chief Executive Officer and Chief Financial Officer have concluded that there were no changes in the Company s internal controls over financial reporting during the quarter ended December 31, 2015 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, 2015. 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, 2015 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 2016 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 2016 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 2016 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 2016 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 2016 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, 2015 and 2014.

C. Consolidated Statements of Shareholders Equity for the years ended of December 31, 2015 and 2014.

D. Consolidated Statements of Comprehensive Loss for the years ended of December 31, 2015 and 2014.

E. Consolidated Statements of Cash Flows for the years ended December 31, 2015 and 2014.

F. Notes to Consolidated Financial Statements.

2. Financial Statement Schedules

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

(b) Exhibits.

EXHIBIT INDEX

Exhibit No.	**Description**
2.1	Share exchange agreement dated April 10, 2006 (incorporated by reference to the Form 8-K/A filed on May 5, 2006)
3.1	Certificate of Incorporation (incorporated by reference to the Form SB-2 (File No. 333-90149) filed on November 16, 1999)
3.2	Amendment to the Certificate of Incorporation (incorporated by reference to amendment No. 2 to Form SB-2 (File No. 333-135591) filed on August 28, 2006)
3.3	Amendment to the Certificate of Incorporation (incorporated by reference to the Form DEF 14C filed on April 20, 2007)
3.4	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)
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, 201
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 f 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+	Employment Agreement Rajiv Khosla (incorporated by reference to the Form 10-Q filed on May 14, 2013)
10.13	Engagement Letter Wainwright dated October 10, 2013, amended December 3, 2013 (incorporated by reference to the S-1/A Registration Statement filed December 16, 2013)
10.14	Amended Form of Securities Purchase Agreement (incorporated by reference to the Form S-1/A Registration Statemer on December 16, 2013)
10.15	Form of Warrant (incorporated by reference to the Form S-1 Registration Statement filed on October 25, 2013)
10.16	Form of Placement Agent Warrant (incorporated by reference to the Form S-1/A Registration Statement filed on Dec 16, 2013)
10.17 ++	Development Services and Commercialization Agreement with PAR Pharmaceuticals, dated December 19 (incorporated by reference to the Form 10-K filed on March 11, 2014)
10.18 ++	Development Services and Commercialization Agreement with PAR Pharmaceuticals, dated January 8, 2014 (incorp by reference to the Form 10-K filed on March 11, 2014)
10.19+*	Employment Agreement John Durham, January 2015 (incorporated by reference to the Form 10-K filed on March 31,
10.20+*	Employment Agreement Andre Godin, July 2015 (incorporated by reference to the Form 8-K filed on July 20, 2015)
10.21+*	Employment Agreement Nadine Paiement, January 2016*
10.22+*	Employment Agreement Robert Bechard, January 2016*
10.23+*	Employment Agreement Dana Matzen, March 2016*
21.1	Subsidiaries of the small business issuer (incorporated by reference to the Form SB-2 (File No. 333-135591) filed on 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 2002*
31.2*	Certification of Andre Godin, Executive Vice President and Chief Financial Officer, pursuant to Section 302 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 135

* 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 o portions of these exhibits have been submitted separately with the SEC.

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 30, 2016, thereunto duly authorized.

INTELGENX TECHNOLOGIES CORP.

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

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

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

Signature	**Position**	**Date**
By: /s/ *Horst G. Zerbe* Horst G. Zerbe	Chairman of the Board, President and Chief Executive Officer	March 30, 2016
By*: /s/Andre Godin* Andre Godin	Executive Vice President and Chief Financial Officer	March 30, 2016
By:/s/ *Bernard Boudreau* J. Bernard Boudreau	Director	March 30, 2016
By: /s/*Ian Troup* John (Ian) Troup	Director	March 30, 2016
By:/s/*Bernd Melchers* Bernd J. Melchers	Director	March 30, 2016
By:/s/*John Marinucci* John Marinucci	Director	March 30, 2016
By:/s/*Clemens Mayr* Clemens Mayr	Director	March 30, 2016

IntelGenx Technologies Corp

Consolidated Financial Statements
December 31, 2015 and 2014
(Expressed in U.S. Funds)

IntelGenx Technologies Corp

Consolidated Financial Statements
December 31, 2015 and 2014
(Expressed in U.S. Funds)

Contents

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, 2015 and 2014 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, 2015 and 2014 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)

Montréal, Québec
March 30, 2016

IntelGenx Technologies Corp.

Consolidated Balance Sheets
As at December 31, 2015 and 2014
(Expressed in Thousands of U.S. Dollars ($ 000) Except Share and Per Share Data)

		2015		2014
Assets				
Current				
Cash and cash equivalents	**$**	**2,865**	$	4,399
Accounts receivable		**1,140**		652
Prepaid expenses		**70**		96
Investment tax credits receivable		**97**		108
Total Current Assets		**4,172**		5,255
Leasehold Improvements and Equipment, net (note 5)		**4,238**		983
Intangible Assets (note 6)		**-**		46
Security Deposits		**506**		-
Total Assets	**$**	**8,916**	$	6,284
Liabilities				
Current				
Accounts payable and accrued liabilities		**1,595**		466
Current portion of long-term debt (note 9)		**184**		-
Deferred license revenue (note 7)		-		1,245
Total Current Liabilities		**1,779**		1,711
Deferred lease obligations		**27**		-
Long-term debt (note 9)		**1,546**		-
Total Liabilities		**3,352**		1,711
Commitments (note 10)				
Shareholders' Equity				
Capital Stock, common shares, $0.00001 par value; 100,000,000 shares authorized; 63,615,255 shares issued and outstanding (December 31, 2014; 63,465,255 common shares) (note 11)		**1**		1

Additional Paid-in-Capital (note 12)	**22,846**	22,654
Accumulated Deficit	**(16,557)**	(17,848)
Accumulated Other Comprehensive Loss	**(726)**	(234)
Total Shareholders Equity	**5,564**	4,573
	$ 8,916	$ 6,284

See accompanying notes

Approved on Behalf of the Board:

/s/ Bernd Melchers Director
/s/Horst G. Zerbe Director

IntelGenx Technologies Corp.

Consolidated Statement of Shareholders' Equity
For the Year Ended December 31, 2014
(Expressed in Thousands of U.S. Dollars ($ 000) Except Share and Per Share Data)

	Capital Stock		Additional		Accumulated Other	
	Number	Amount	Paid-In Capital	Accumulated Deficit	Comprehensive Income (Loss)	**Total Shareholders' Equity**
Balance - December 31, 2013	60,984,267	$ 1	$ 20,934	$ (16,102)	$ 175	**$ 5,008**
Foreign currency translation adjustment	-	-	-	-	(409)	**(409)**
Warrants exercised (note 12)	2,480,988	-	1,619	-	-	**1,619**
Stock-based compensation (note 12)	-	-	101	-	-	**101**
Net loss for the year	-	-	-	(1,746)	-	**(1,746)**
Balance December 31, 2014	**63,465,255**	**$ 1**	**$ 22,654**	**$ (17,848)**	**$ (234)**	**$ 4,573**

See accompanying notes

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)

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

See accompanying notes

IntelGenx Technologies Corp.

Consolidated Statements of Comprehensive Income
For the Years Ended December 31, 2015 and 2014
(Expressed in Thousands of U.S. Dollars ($ 000) Except Share and Per Share Data)

		2015		2014
Revenues				
Royalties	**$**	**981**	$	476
License and other revenue		**4,114**		1,183
Total Revenues		**5,095**		1,659
Expenses				
Cost of royalty and license revenue		**433**		61
Research and development expense		**1,033**		1,075
Selling, general and administrative expense		**2,072**		2,229
Depreciation of tangible assets		**125**		35
Amortization of intangible assets		**46**		39
Total Expenses		**3,709**		3,439
Operating Income (Loss)		**1,386**		(1,780)
Interest Income		**28**		34
Financing and Interest expense		**(123)**		-
		(95)		34
Income (Loss) Before Income Taxes		**1,291**		(1,746)
Income taxes (note 13)		**-**		-
Net Income (Loss)		**1,291**		(1,746)
Other Comprehensive Income (Loss)				
Foreign currency translation adjustment		**(492)**		(409)
Comprehensive Income (Loss)	**$**	**799**	$	(2,155)
Basic:				
Weighted Average Number of Shares Outstanding		**63,524,023**		63,182,224
Basic Earnings (Loss) Per Common Share (note 16)	**$**	**0.01**	$	(0.03)
Diluted:				
Weighted Average Number of Shares Outstanding		**70,855,146**		63,182,224
Diluted Earnings (Loss) Per Common Share (note 16)	**$**	**0.01**	$	(0.03)

See accompanying notes

IntelGenx Technologies Corp.

Consolidated Statements of Cash Flows
For the Year Ended December 31, 2015 and 2014
(Expressed in Thousands of U.S. Dollars ($ 000) Except Share and Per Share Data)

		2015		2014
Funds Provided (Used) -				
Operating Activities				
Net Income (Loss)	**$**	**1,291**	$	(1,746)
Amortization and depreciation		**171**		74
Stock-based compensation		**130**		101
		1,592		(1,571)
Changes in assets and liabilities				
Accounts receivable		**(488)**		(508)
Prepaid expenses		**26**		37
Investment tax credits receivable		**11**		160
Security deposits		**(506)**		-
Accounts payable and accrued liabilities		**1,129**		(127)
Deferred revenue		**(1,245)**		629
Deferred lease obligations		**27**		-
Net change in assets and liabilities		**(1,046)**		191
Net cash provided (used) by operating activities		**546**		(1,380)
Financing Activities				
Issuance of term loans		**1,752**		-
Repayment of term loans		**(22)**		
Proceeds from exercise of warrants and stock options		**62**		1,619
Net cash provided by financing activities		**1,792**		1,619
Investing Activities				
Additions to leasehold improvements and equipment		**(3,380)**		(403)
Net cash used in investing activities		**(3,380)**		(403)
Decrease in Cash and Cash Equivalents		**(1,042)**		(164)
Effect of Foreign Exchange on Cash and Cash Equivalents		**(492)**		(442)
Cash and Cash Equivalents				
Beginning of Year		**4,399**		5,005
End of Year	**$**	**2,865**	$	4,399

See accompanying notes

IntelGenx Technologies Corp.

Notes to Consolidated Financial Statements
December 31, 2015 and 2014
(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 research, development, and commercialization of pharmaceutical products based upon three proprietary delivery platforms, including an immediate release oral film VersaFilm , a mucoadhesive tablet AdVersa , and a multilayer controlled release tablet VersaTab 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 10 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, 6 utilize the *VersaFilm* technology, 2 utilize the *VersaTab* technology, and one utilizes the *AdVersa* technology. In accordance with contractual commitments and for reasons of confidentiality, the Company is unable to disclose either the indicated treatment behind two of the products under development.

The Company s first FDA-approved product, Forfivo XL®, was launched in the USA in October 2012 under a licensing partnership with Edgemont Pharmaceuticals LLP. Forfivo XL® is indicated for the treatment of Major Depressive Disorder (MDD) and is the only extended-release bupropion HCl product to provide a once-daily, 450mg dose in a single tablet. The active ingredient in Forfivo XL® is bupropion, the same active ingredient used in Wellbutrin XL®.

IntelGenx Technologies Corp.

Notes to Consolidated Financial Statements
December 31, 2015 and 2014
(Expressed in U.S. Funds)

3. Adoption of New Accounting Standards

The FASB issued ASU No. 2014-08 which enhances convergence between U.S. GAAP and International Financial Reporting Standards (IFRS). The amendments in the ASU change the criteria for reporting discontinued operations while enhancing disclosures in this area. It also addresses sources of confusion and inconsistent application related to financial reporting of discontinued operations guidance in U.S. GAAP. Under the new guidance, only disposals representing a strategic shift in operations should be presented as discontinued operations. Those strategic shifts should have a major effect on the organization s operations and financial results. Examples include a disposal of a major geographic area, a major line of business, or a major equity method investment. In addition, the new guidance requires expands disclosures about discontinued operations that will provide financial statement users with more information about the assets, liabilities, income, and expenses of discontinued operations. The amendments in the ASU were effective in the first quarter of 2015 for public organizations with calendar year ends. 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. Licensees usually report sales and royalty information in the 45 days after the end of the quarter in which the activity takes place and typically do not provide forward estimates or current-quarter information. Because the Company is not able to reasonably estimate the amount of royalties earned during the period in which these licensees actually ship products, royalty revenue is not recognized until the royalties are reported to the Company and the collection of these royalties is reasonably assured.

For the year ended December 31, 2015, the Company recognized royalty revenue earned under a licensing agreement totaling $946 thousand compared to $463 thousand in 2014.

For the year ended December 31, 2015, the Company recognized revenues as a result of sales milestones achieved under a licensing agreement totaling $2,808 thousand (2014: $Nil).

For the year ended December 31, 2015, the Company recognized revenues as a result of sales milestones achieved under a development and commercialization agreement in the amount of $Nil (2014: $552).

IntelGenx Technologies Corp.

Notes to Consolidated Financial Statements
December 31, 2015 and 2014
(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, the investment tax credits receivable, the determination of the fair value of warrants issued as part of fundraising activities, and the resulting impact on the allocation of the proceeds between the common shares and the warrants.

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, 2015 accounts receivable (2014: $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, 2015 totaled $108 thousand (2014: $268 thousand).

IntelGenx Technologies Corp.

Notes to Consolidated Financial Statements
December 31, 2015 and 2014
(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.

Intangible Assets

Payments made to third parties subsequent to regulatory approval are capitalized and amortized over the remaining useful life of the related product. Amounts capitalized for such payments are included in other intangibles, net of accumulated amortization.

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, 2015 and 2014
(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;

Fixed assets - at historical rates

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, 2015 and 2014
(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.

Earnings (Loss) Per Share

Basic earnings (loss) per share is calculated based on the weighted average number of shares outstanding during the year. Any antidilutive instruments are excluded from the calculation of diluted earnings (loss) per share.

Fair Value Measurements

ASC 820 applies to all assets and liabilities that are being measured and reported on a fair value basis. ASC 820 requires disclosure that establishes a framework for measuring fair value in US GAAP, and expands disclosure about fair value measurements. This statement enables the reader of the financial statements to assess the inputs used to develop those measurements by establishing a hierarchy for ranking the quality and reliability of the information used to determine fair values. The statement requires that assets and liabilities carried at fair value be classified and disclosed in one of the following three categories:

Level 1: Quoted market prices in active markets for identical assets or liabilities.
Level 2: Observable market based inputs or unobservable inputs that are corroborated by market data.
Level 3: Unobservable inputs that are not corroborated by market data.

IntelGenx Technologies Corp.

Notes to Consolidated Financial Statements
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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. There are no assets or liabilities measured at fair value as at December 31, 2015.

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 2015-16, Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments

The FASB issued this Update 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.

For all other entities, the amendments in this Update are effective for fiscal years beginning after December 15, 2016, and interim periods within fiscal years beginning after December 15, 2017. The adoption of this Statement is not expected to have a material effect on the Company`s financial position or results of operations.

ASU 2015-14, Revenue From Contracts With Customers (Topic 606), Deferral of the Effective Date
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IntelGenx Technologies Corp.

Notes to Consolidated Financial Statements
December 31, 2015 and 2014
(Expressed in U.S. Funds)

4. Summary of Significant Accounting Policies (Cont d)

The FASB and IASB (the Boards) have issued converged standards on revenue recognition. ASU No. 2014-09 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.

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.

All other entities should apply the guidance in Update 2014-09 to annual reporting periods beginning after December 15, 2018, and interim reporting periods within annual reporting periods beginning after December 15, 2019. All other entities may apply the guidance in Update 2014-09 earlier as of an annual reporting period beginning after December 15, 2016, including interim reporting periods within that reporting period. All other entities also may apply the guidance in Update 2014-09 earlier as of an annual reporting period beginning after December 15, 2016, and interim reporting periods within annual reporting periods beginning one year after the annual reporting period in which the entity first applies the guidance in Update 2014-09.

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

IntelGenx Technologies Corp.

Notes to Consolidated Financial Statements
December 31, 2015 and 2014
(Expressed in U.S. Funds)

4. Summary of Significant Accounting Policies (Cont d)

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. For all other entities, the amendments in this Update are effective for fiscal years beginning after December 15, 2016, and interim periods within fiscal years beginning after December 15, 2017. 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.

ASU 2015-03, Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs

The amendments in ASU 2015-03 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. Early adoption is permitted for financial statements that have not been previously issued. The adoption of this Statement is not expected to have a material effect on the Company`s financial position or results of operations.

ASU 2015-01, Income Statement - Extraordinary and Unusual Items (Subtopic 225-20): Simplifying Income Statement Presentation by Eliminating the Concept of Extraordinary Items

The amendments in ASU 2015-01 eliminate 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. The FASB heard from stakeholders that the concept of extraordinary items causes uncertainty because it is unclear when an item should be considered both unusual and infrequent. Additionally, some stakeholders said that although users find information about unusual or infrequent events and transactions useful, they do not find the extraordinary item classification and presentation necessary to identify those events and transactions. Other stakeholders noted that it is extremely rare in current practice for a

4. Summary of Significant Accounting Policies (Cont d)

transaction or event to meet the requirements to be presented as an extraordinary item. 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. A reporting entity may apply the amendments prospectively. A reporting entity also may apply the amendments retrospectively to all prior periods presented in the financial statements. Early adoption is permitted provided that the guidance is applied from the beginning of the fiscal year of adoption. The adoption of this Statement is not expected to have a material effect on the Company s financial position or results of operations.

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

The FASB has issued ASU No. 2014-15 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. The amendments are effective for annual periods ending after December 15, 2016, and interim periods within annual periods beginning after December 15, 2016. Early application is permitted for annual or interim reporting periods for which the financial statements have not previously been issued. The Company is currently evaluating the impact of this Statement on its consolidated financial statements.

ASU 2014-12, Compensation Stock Compensation (Topic 718): Accounting for shared-based payments when the terms of an award provide that a performance target could be achieved after the requisite service period.

The FASB has issued ASU No. 2014-12 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. Earlier adoption is permitted. The adoption of this Statement is not expected to have a material effect on the Company s financial position or results of operations.

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:

IntelGenx Technologies Corp.

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

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. For all other entities, the amendments in this Update are effective for fiscal years beginning after December 15, 2018, and interim periods within fiscal years beginning after December 15, 2019.

Entities would be able to early adopt a provision that would allow them to recognize the fair value change from own credit in other comprehensive income for financial liabilities measured under the fair value option, and entities that are not public business entities would be able to adopt a provision to eliminate the fair value disclosures for financial instruments not recognized at fair value. Non-public business entities would be able to early adopt the guidance as of the effective date for public business entities. The Company is currently evaluating the impact of this Statement on its consolidated financial statements.

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 all other entities, the amendments are effective for financial statements issued for annual periods beginning after December 15, 2017, and interim periods within annual periods beginning after December 15, 2018.

The Company is currently evaluating the impact of its pending adoption of ASU 2015-17 on its financial statements.

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5. Leasehold improvements and Equipment

In U.S.$ thousands	Cost	Accumulated Depreciation	**2015 Net Carrying Amount**	2014 Net Carrying Amount
Manufacturing equipment	$ 1,050	$ 0	**$ 1,050**	$ 520
Laboratory and office equipment	1,193	372	**821**	241
Computer equipment	64	47	**17**	15
Leasehold improvements	2,427	77	**2,350**	207
	$ 4,734	$ 496	**$ 4,238**	$ 983

As of December 31, 2015 no depreciation has been recorded on manufacturing equipment as this equipment is not yet in use.

As of December 31, 2015 no depreciation has been recorded on laboratory equipment in the amount of $471 as the equipment is not yet in use.

6. Intangible Assets

As of December 31, 2015 NDA acquisition costs representing the net book value of the final progress payment related to the acquisition of 100% ownership of Forfivo XL® were fully amortized.

7. Deferred License Revenue

Deferred license revenue represents upfront payments received for the granting of licenses to the Company s patents, intellectual property, and proprietary technology, for commercialization. Deferred license revenue is recognized in income over the period where sales of the licensed products will occur.

Pursuant to the execution of a licensing agreement for Forfivo XL®, IntelGenx received an upfront fee from Edgemont Pharmaceuticals (Edgemont) in the first quarter of 2012, which IntelGenx recognized as deferred license revenue. The deferred license revenue was amortized in income over a period of 39 months, which was the minimum period where sales of Forfivo XL® are expected to be exclusive.

In the fourth quarter of 2014, Edgemont exercised its right to extend the license for the exclusive marketing of Forfivo XL®. In accordance with the terms for exercising such right, IntelGenx invoiced $1.25 million to Edgemont and recognized the full amount as deferred revenue, which was recognized as revenue from October 2014 through September 2015.

As of December 31, 2015, the entire deferred revenue balance has been recognized as revenue (December 31, 2014 - $1.24 million that had not been recognized as revenue).

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8. Bank Indebtedness

The Company's credit facility is subject to review annually and consists of an operating demand line of credit of up to CAD$250 thousand and corporate credits cards of up to CAD$55 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, 2015, the Company was in compliance with its financial covenants and has not drawn on its credit facility.

9. Long-term debt

The components of the Company s debt are as follows:

In U.S.$ thousands	December 31, 2015 $	December 31, 2014 $
Term loan facility	1,188	-
Secured loan	542	-
Total debt	1,730	-
Less: current portion	184	-
Total long-term debt	1,546	-

The Company s term loan facility consists of a total of CAD$3.5 million, consisting of CAD$1.6 million bearing interest at the Bank s prime lending rate plus 2.50%, and CAD$1.8 million bearing interest at a fixed rate to be determined at drawdown. The term loan is subject to the same security and financial covenants as the bank indebtedness (see note 8).

The CAD$1.8 million tranche of the term loan will be disbursed subsequent to meeting certain conditions. There is a moratorium on capital repayments for the first 6 months of each drawdown, at which point the term loan will be repayable in monthly instalments over 60 months.

The secured loan has a principal balance authorized of CAD$1 million of which CAD$0.75 million was disbursed as at December 2015, bearing interest at prime plus 7.3%, reimbursable in monthly principal payments of CAD$12,5 thousand from January 2017 to December 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, 2015, the Company was in compliance with its financial covenants.

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9. Long-term debt (Cont d)

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

In U.S.$ thousands	
2016	$184
2017	344
2018	344
2019	344
2020	344
Thereafter	170

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 $80 thousand) per year, which will increase at a rate of CAD$0.25 ($0.18) per square foot every two years. IntelGenx is using the newly leased space for manufacturing its oral film VersaFilm products, enlarging research and development capabilities, and for administration.

The aggregate minimum rentals, exclusive of other occupancy charges, for property leases expiring in 2026, are approximately $866 thousand, as follows:

In U.S.$ thousands	
2016	$66
2017	81
2018	83
2019	84
2020	86
Thereafter	466

On March 3, 2015, the Company signed an agreement in the amount of Euro1,490 thousand with a supplier with respect to the fabrication of customized manufacturing equipment. As at December 31, 2015, an amount of Euro298 thousand had been paid.

On May 7, 2010, the Company executed a Project Transfer Agreement with one of its former development partners whereby the Company acquired full rights to, and ownership of, Forfivo XL®, a novel, high strength formulation of Bupropion hydrochloride, the active ingredient in Wellbutrin XL®. In accordance with the Project Transfer Agreement, and following commercial launch of Forfivo XL® in October 2012, the Company is required, after recovering an aggregate $200 thousand for management fees previously paid, to pay its former development partner 10% of net income received from the sale of Forfivo XL®. In December 2014 the Company fully recovered said

management fees and owed approximately $58 thousand to its former development partner that was remitted in February 2015. During fiscal year 2015 the amount due was $433.

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11. Capital Stock

		2015		2014
Authorized -				
100,000,000 common shares of $0.00001 par value				
20,000,000 preferred shares of $0.00001 par value				
Issued -				
63,615,255 (December 31, 2014: 63,465,255) common shares	**$**	**636**	$	635

Stock options

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. No stock options were exercised in the year ended December 31, 2014.

Stock-based compensation of $130 thousand and $101 thousand was recorded during the year ended December 31, 2015 and 2014 respectively. The entire amounts expensed in 2015 and 2014 relate to stock options granted to employees and directors. As at December 31, 2015 the Company has $158 thousand (2014 - $74 thousand) of unrecognized stock-based compensation.

Warrants

No warrants were exercised during the year ended December 31, 2015. In the year ended December 31, 2014 a total of 2,480,988 warrants were exercised for 2,480,988 common shares having a par value of $Nil in aggregate, for cash consideration of approximately $1,619 thousand, resulting in an increase in additional paid-in capital of approximately $1,619 thousand.

12. Additional Paid-In Capital

Stock Options

In November 2006, the Company adopted the 2006 Stock Incentive Plan (the "Plan") for the purpose of issuing both Incentive Options and Nonqualified Options to officers, employees, directors and eligible consultants of the Company. A total of 1,600,749 shares of common stock were reserved for issuance under this plan. Options may be granted under the Plan on terms and at prices as determined by the Board of Directors except that the options cannot be granted at less than 100%, of the fair market value of the common stock on the date of 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. All options granted to individuals other than non- employee directors will have a total vesting period of 24 months from the date of grant, with one quarter of the total options granted vesting and becoming exercisable every six months. Options granted to non-employees may vest and become 100% fully exercisable immediately upon grant.

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12. Additional Paid-In Capital (Cont d)

In the second quarter of 2008, the life of the options was reduced from 10 years to 5 years to comply with the regulations of the Toronto Stock Exchange. Accordingly, because the grant-date fair value of the modified options was less than the fair value of the original options measured immediately before the modification, no incremental share-based compensation expense resulted from the modification.

At the Annual General Meeting (AGM) on September 8, 2008 the shareholders of the Company approved an amendment to increase the number of shares available for issuance under the Plan from 1,600,749 to 2,074,000, or 10% of the Company s issued and outstanding common shares as of July 28, 2008. Subsequent amendments were approved by the shareholders at the AGM s held on June 3, 2010 and on May 7, 2013 to increase the number of shares available for issuance to 3,308,127 and 5,030,292 respectively.

On December 8, 2014 the Company granted an aggregate of 175,000 options purchase common stock to three non-employee directors, two officers, and two employees. The stock options are exercisable at $0.53 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 $36 thousand, using the following assumptions:

Expected volatility	63%
Expected life	3.13 years
Risk-free interest rate	1.10%
Dividend yield	Nil

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

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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

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12. Additional Paid-In Capital (Cont d)

During the year ended December 31, 2015 a total of 150,000 options were exercised for 150,000 common stock 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. The intrinsic value of the stock options exercised, as at the dates of exercise, totaled $31 thousand. No stock options were exercised in the year ended December 31, 2014.

Information with respect to employees and directors stock option activity for 2014 and 2015 is as follows:

		Number of options	Weighted average exercise price $
Outstanding	January 1, 2014	1,597,500	0.58
Granted		175,000	0.53
Forfeited		(517,500)	(0.64)
Expired		(125,000)	(0.61)
Exercised		-	-
Outstanding	December 31, 2014	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

Information with respect to consultant s stock option activity for 2014 and 2015 is as follows:

		Number of options	Weighted average exercise price $
Outstanding	January 1, 2014 and 2015	100,000	0.59
Expired		(100,000)	0.59
Outstanding	December 31, 2015	-	-

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12. Additional Paid-In Capital (Cont d)

Details of stock options outstanding as at December 31, 2015 are as follows:

	Outstanding options				Exercisable options		
Exercise prices $	Number of options	Weighted average remaining contractual life (years)	Weighted average exercise price $	Aggregate intrinsic value $	Number of options	Weighted average exercise price $	Aggregate intrinsic value $
0.48	150,000	0.45	0.04		-	-	
0.51	20,000	0.02	0.01		20,000	0.01	
0.52	50,000	0.01	0.02		50,000	0.04	
0.52	150,000	0.27	0.05		150,000	0.11	
0.53	150,000	0.36	0.05		75,000	0.06	
0.54	110,000	0.06	0.04		110,000	0.09	
0.58	35,000	0.06	0.01		35,000	0.03	
0.58	600,000	1.65	0.21		-	-	
0.58	75,000	0.21	0.03		-	-	
0.60	30,000	0.04	0.01		30,000	0.03	
0.62	300,000	0.76	0.11		225,000	0.20	
	1,670,000	3.88	0.56	6,200	695,000	0.56	200

Stock-based compensation expense recognized in 2015 with regards to the stock options was $130 thousand (2014: $101 thousand). As of December 31, 2015, total unrecognized compensation expense related to unvested stock options was $158 thousand (2014: $74 thousand), all of which relates to options granted to employees and directors. The amount of $158 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 $158 thousand being charged to stock based compensation expense.

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12. Additional Paid-In Capital (Cont d)

Warrants

No warrants were exercised in the year ended December 31, 2015. In the year ended December 31, 2014 a total of 2,480,988 warrants were exercised for 2,480,988 common shares having a par value of $Nil in aggregate, for cash consideration of approximately $1,619 thousand, resulting in an increase in additional paid-in capital of approximately $1,619 thousand.

Information with respect to warrant activity for 2014 and 2015 is as follows:

	Number of warrants (All Exercisable)	Weighted average exercise price $
Outstanding January 1, 2014	11,143,732	0.6079
Exercised	(2,480,988)	(0.6524)
Expired	(1,431,621)	(0.7400)
Outstanding - December 31, 2014	7,231,123	0.5646
Exercised	-	-
Expired	-	-
Outstanding - December 31, 2015	7,231,123	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:

In U.S.$ thousands	2015	2014
Statutory income taxes	**$ 387**	$ (429)
Net operating losses for which no tax benefits have been recorded	**-**	238
Net operating losses used for which no tax benefit had been recorded	**(484)**	-
Excess (deficiency) of depreciation over capital cost allowance	**(98)**	9
Non-deductible expenses	**44**	26
Undeducted research and development expenses	**178**	181
Investment tax credit	**(27)**	(25)
	$ -	$ -

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13. Income Taxes (Cont d)

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

In U.S.$ thousands	**2015**	2014
Leasehold improvements and equipment	**$ 117**	$ 9
Net operating losses carryforward	**1,770**	2,582
Undeducted research and development expenses	**1,274**	1,355
Non-refundable tax credits carryforward	**1,022**	1,102
	4,183	5,048
Valuation allowance	**(4,183)**	(5,048)
	$ -	$ -

As at December 31, 2015, 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 2016, 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 $6,462 thousand (2014: $9,530 thousand) and $6,725 thousand (2014: $9,683 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 2035. A portion of the net operating losses may expire before they can be utilized.

As at December 31, 2015, the Company had non-refundable tax credits of $1,022 thousand (2014: $1,102 thousand) of which $8 thousand is expiring in 2026, $9 thousand is expiring in 2027, $163 thousand is expiring in 2028, $143 thousand is expiring in 2029, $122 thousand is expiring in 2030, $129 thousand is expiring in 2031, $162 thousand is expiring in 2032 and $108 thousand is expiring in 2033, $82 thousand expiring in 2034 and $96 thousand is expiring in 2035 and undeducted research and development expenses of $6,315 thousand (2014: $4,805 thousand) with no expiration date.

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

Unrecognized Tax Benefits

The Company does not have any unrecognized tax benefits.

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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, 2015:

Tax Jurisdictions	Tax Years
Federal - Canada	2012 and onward
Provincial - Quebec	2012and onward
Federal - USA	2012 onward

14. Statement of Cash Flows Information

In US$ thousands	2015	2014
Additional Cash Flow Information:		
Interest paid	**$ 23**	$ 5

15. Related party transactions

Included in management salaries are $3 thousand (2014: $29 thousand) for options granted to the Chief Executive Officer, $9 thousand (2014: $Nil) for options granted to the Vice President, Operations, and $39 thousand (2014: $43 thousand) for options granted to two Chief Financial Officers under the 2006 Stock Option Plan and $70 thousand (2014: $17 thousand) for options granted to non-employee directors.

Included in general and administrative expenses are director fees of $250 thousand (2014: $187 thousand) comprising an annual stipend.

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.

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

Basic and diluted earnings (loss) 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.