

IntelGenx Technologies Corp.  
Form 10-K  
March 31, 2015

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

**FORM 10-K**

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

For the fiscal year ended December 31, 2014

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File Number: 000-31187

**IntelGenx Technologies Corp.**

*(Exact name of registrant as specified in its charter)*

**Delaware**

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

**87-0638336**

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

**6425 Abrams, Ville Saint Laurent, Quebec**

*(Address of principal executive offices)*

**H4S 1X9**

*(Zip Code)*

**(514) 331-7440**

*(Registrant's telephone number, including area code)*

Securities registered pursuant to Section 12(b) of the Act:

**None**

Securities registered pursuant to Section 12(g) of the Act:

**Common Stock, \$0.00001 par value per share**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes

No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

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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)

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

Yes [ ] No [X]

As of June 30, 2014, the aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates of the registrant was \$39,745,692 based on the closing price of the registrant's common shares of U.S. \$0.75, 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.

<b>Class</b>	<b>Outstanding at March 26, 2015</b>
Common Stock, \$.00001 par value	63,465,256 shares

**DOCUMENTS INCORPORATED BY REFERENCE:**

Portions of the Company's Proxy Statement for its 2015 Annual Meeting of Shareholders (the 2015 Proxy Statement ) are incorporated by reference into Part III

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

In this Form 10-K, unless otherwise specified, all monetary amounts are in United States dollars, all references to "\$", "U.S.\$", "U.S. dollars" and "dollars" mean U.S. dollars and all references to "C\$", "Canadian dollars" and "CAD" mean Canadian dollars. To the extent that such monetary amounts are derived from our consolidated financial statements included elsewhere in this Form 10-K, they have been translated into U.S. dollars in accordance with our accounting policies as described therein. Unless otherwise indicated, other Canadian dollar monetary amounts have been translated into United States dollars at the December 31, 2014 closing rate reported by the Bank of Canada, being U.S. \$1.00 = CAD\$1.1601.

## PART I

### Cautionary Statement Concerning Forward-Looking Statements

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

### ITEM 1. BUSINESS.

#### Corporate History

Our predecessor company, Big Flash Corp., was incorporated in Delaware on July 27, 1999. On April 28, 2006, Big Flash, through its Canadian holding corporation, completed the acquisition of IntelGenx Corp., a Canadian company incorporated on June 15, 2003. The Company did not have any operations prior to the acquisition of IntelGenx Corp. In connection with the acquisition, we changed our name from Big Flash Corp. to IntelGenx Technologies Corp. IntelGenx Corp. has continued operations as our operating subsidiary.

#### Overview

We are a drug delivery company focusing on the development of novel, orally administered drug delivery products based on our proprietary oral drug delivery technologies. We have positioned ourselves as a provider of product development services for the pharmaceutical industry, including the branded and generic pharmaceutical markets.

Drug delivery systems are an important tool in the hands of physicians for purposes of optimizing drug therapy. For the pharmaceutical industry, drug delivery systems represent an opportunity to extend the market exclusivity and product lifecycle of drugs whose patent protection is nearing expiration.

A significant portion of our current products under development focus on controlled release delivery systems. Controlled release delivery systems play an important role in the development of orally administered drug delivery

systems. Controlled release technology provides patients with the required amount of medication over a pre-determined, prolonged period of time. Because of the reduced fluctuation of the active drug in the blood and the avoidance of plasma spikes, controlled release products are deemed safer and more tolerable than conventional dosage forms, and have shown better patient compliance.

Our primary business strategy is to develop pharmaceutical products based upon our proprietary drug delivery technologies and license the commercial rights to companies in the pharmaceutical industry once the viability of a product has been demonstrated. In exchange for licensing rights to our products, we seek funding consisting of a combination of one or more of the following: advance down payments, milestone fees, reimbursement for development costs, and royalties on sales. In addition, we may receive a manufacturing royalty from our contract manufacturers for the exclusive right to manufacture our products. The companies we partner with are typically responsible for managing the regulatory approval process of the product with the United States Food and Drug Administration ( FDA ) and/or other regulatory bodies, as well as for the marketing and distribution of the products. On a case-by-case basis, we may be responsible for providing all or part of the documentation required for the regulatory submission. In addition to pursuing partnering arrangements that provide for the full funding of a drug development project, we may undertake development of selected product opportunities until the marketing and distribution stage. We would first assess the potential and associated costs for successful development of a product, and then determine at which stage it would be most prudent to seek a partner, balancing costs against the potential for higher returns later in the development process.

## Technology Platforms

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

The Oral Film 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<sup>®</sup> technology is designed to provide a rapid response compared to existing conventional tablets. The VersaFilm<sup>®</sup> technology is intended for indications requiring rapid onset of action, such as migraine, opioid dependence, 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 in 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 drugs are essentially copies of drugs that have already received FDA approval). Of the eleven projects currently in our product portfolio, three utilize our VersaTab<sup>®</sup> technology, five utilize our VersaFilm<sup>®</sup> technology, one utilizes our AdVersa<sup>®</sup> technology and the technology behind two of our projects remains, in accordance with our contractual obligations, confidential.

INT0001/2004: This is the most advanced generic product involving our multilayer tablet technology. Equivalency with the reference product Toprol XL<sup>®</sup> and its European equivalent Beloc-ZOK<sup>®</sup> has been demonstrated *in-vitro*. The product has been tested in phase I studies. We are working to progress pivotal development activities.

INT0004/2006: We developed a new, higher strength of the antidepressant Bupropion HCl, the active ingredient in Wellbutrin XL<sup>®</sup>, and, in November 2011, the FDA approved the drug for patients with Major Depressive Disorder. In February 2012, we entered into an agreement with Edgemont Pharmaceuticals LLC (Edgemont) for commercialization of the product in the United States. Under the terms of the agreement, Edgemont obtained certain

exclusive rights to market and sell the product in the U.S. In exchange we received a \$1.0 million upfront payment, will receive launch related milestones totaling up to \$4.0 million, and are eligible for additional milestones upon achieving certain sales and exclusivity targets of up to a further \$23.5 million. 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, 2014 we have received an upfront payment of \$1 million and a \$1 million milestone payment related to the launch. We commenced receiving royalty payments in the first quarter of 2013 and received total royalties of \$171 thousand in the year ended December 31, 2013. Royalty income increased by approximately 171% to \$463 thousand in 2014.

In August 2013 we announced receipt of a Paragraph IV Certification Letter from Wockhardt Bio AG, advising of the submission of an Abbreviated New Drug Application ("ANDA") to the FDA requesting authorization to manufacture and market generic versions of Forfivo XL® 450 mg 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: An oral film product based on our proprietary edible film technology is currently in the optimization stage. The product contains the active ingredient Tadalafil and is intended for the treatment of erectile dysfunction (ED). The results of a phase I pilot study that was conducted in the third quarter of 2010 indicate that the product is bioequivalent with the brand product, Cialis®. A second clinical trial comparing an alternative formulation with the reference listed drug was completed in the first quarter of 2013. The results of this study suggest the potential to develop a faster acting Tadalafil product using our VersaFilm™ technology. The formulation is currently being optimized and will be tested in a bioequivalency study upon finalization of the formulation optimization work.

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 manufactured by Merck & Co. The thin-film formulation of Rizatriptan was developed in accordance with the co-development and commercialization agreement with RedHill Biopharma Ltd. ( 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 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

regardless of the result of these compliance issues and have already identified and audited an alternative API supplier. However, changing suppliers is financially expensive and is a time-consuming process. As a result, we believe that FDA approval of this product for the US market will be delayed until 2016.

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 Mutual Recognition Procedure 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's potential feedback regarding the MAA is expected during the second half of 2015.

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

INT0024/2010: An oral tablet product based on our proprietary multilayer tablet technology is currently in the development stage. An interaction study was conducted in the third quarter of 2012 and yielded positive results. The product is intended for the treatment of idiopathic pulmonary fibrosis. The continuation of the project will depend upon further guidance from our development and commercialization partner, Pacific Therapeutics.

INT0027/2011: In accordance with a co-development and commercialization agreement with Par Pharmaceutical Companies, Inc. ( Par ), 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. The reference listed drug is Suboxone® Sublingual Film. 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.

INT0030/2011: An oral film product based on our proprietary edible film technology is currently in the development stage. The product is intended for the animal health market. An initial acceptability study of the placebo in dogs indicated that the product is well accepted.

INT0036/2013: An oral film product based on our proprietary edible film technology is currently in the early development stage. The product is intended for the treatment of schizophrenia-related disorders. Our first clinical study on this product, completed in Q4 2014, suggested improved bioavailability compared to the currently approved tablet.

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 is being developed in accordance with another development and commercialization agreement with Par Pharmaceutical, Inc. In accordance with confidentiality clauses contained in the agreement, the specifics of the product description, platform technology and financial terms remain confidential.

INT0039/2013: A product based on one of our proprietary technologies is currently in the early development stage. The product is being developed in accordance with another development and commercialization agreement with Par Pharmaceutical, Inc. In accordance with confidentiality clauses contained in the agreement, the specifics of the product description, platform technology and financial terms remain confidential.

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.

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

<b>Product</b>	<b>Indication</b>	<b>Status of Development</b>
INT0001/2004	CHF (Coronary Heart Failure), Hypertension	Pivotal development activities ongoing.
INT0004/2006	Antidepressant	FDA-approved November 2011. Commercially launched in USA as Forfivo XL® in October 2012.
INT0007/2006	Erectile Dysfunction	Product optimization ongoing.
INT0008/2007	Migraine	NDA filed with FDA in March 2013. Currently working to resolve API supply issues. Submitted MAA for Europe in October 2014.
INT0010/2006	Cancer pain	Formulation development ongoing.
INT0024/2010	Idiopathic pulmonary fibrosis	Interaction study completed. On hold pending instructions from partner.
INT0027/2011	Opioid dependence	ANDA submitted to FDA in July 2013. Awaiting FDA decision / approval
INT0030/2011	Animal health	Formulation development ongoing.
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.

### **Growth Strategy**

Our primary growth strategies include: (1) identifying lifecycle management opportunities for existing market leading pharmaceutical products, (2) developing generic drugs with high barriers to entry, (3) developing new drug delivery technologies, and (4) 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.

### **VersaFilm Manufacturing**

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

### **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

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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 plan to establish a state-of-the-art manufacturing facility for the commercial manufacture of 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 re-formulating approved pharmaceuticals in a more convenient and discrete oral dosage form. We expect to establish our manufacturing facility by the third quarter of 2015.

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 (7) patents and have an additional three (3) pending patent applications, as described below. The patents expire 20 years after submission of the initial application.

<b>Patent No.</b>	<b>Title</b>	<b>Subject</b>	<b>Date submitted / issued / expiration</b>
US 6,231,957	Rapidly disintegrating flavor wafer for flavor enrichment	The composition, manufacturing, and use of rapidly disintegrating flavored films for releasing flavors to certain substrates	Issued May 15, 2001 Expires May 6, 2019
US 6,660,292	Rapidly disintegrating film for precooked foods	Composition and manufacturing of flavored films for releasing flavors to precooked food substrates	Issued December 9, 2003 Expires June 19, 2021
US 7,132,113	Flavored film	Composition and manufacturing method of multi-layered films	Issued November 7, 2006 Expires April 16, 2022
US 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 Appl. 12/963,132	Oral film dosage forms and methods for making same	Optimization of film strip technology	Filed December 8, 2010

US Appl. 13/079,348	Solid oral dosage forms comprising tadalafil	Formulation of oral films containing tadalafil	Filed April 04, 2011
US 14/447,071	Instantly wettable oral film dosage form without surfactant or polyalcohol	Formulation of oral films containing active pharmaceutical ingredients	Filed July 30, 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, 2014 increased by \$514 thousand to \$1,075 thousand, compared with \$561 thousand for the year ended December 31, 2013. The increase in R&D expenditure is explained in the section of this report entitled Management's Discussion and Analysis of Financial Condition and Results of Operations .

### **Environmental Regulatory Compliance**

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

### **Employees**

As of the date of this filing, we have 12 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**

### **We continue to sustain losses and our revenues are not sufficient to sustain our operations.**

Even though we ceased being a development stage company in April 2006, we are still subject to all of the risks associated with having a limited operating history and pursuing the development of new products. Our cash flows may be insufficient to meet expenses relating to our operations and the development of our business, and may be insufficient to allow us to develop new products. We currently conduct research and development using our proprietary platform technologies to develop oral controlled release and other delivery products. We do not know whether we will be successful in the development of such products. We have an accumulated deficit of approximately \$17,848 thousand since our inception in 2003 through December 31, 2014. To date, these losses have been financed principally through sales of equity securities. Our revenues for the past five years ended December 31, 2014, December 31, 2013, December 31, 2012, December 31, 2011 and December 31, 2010 were \$1.7 million, \$948 thousand, \$1,198 thousand, \$440 thousand, and \$1,337 thousand respectively. Our revenues in 2013 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 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 plan to establish 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 plan to invest approximately \$6 million during the course of the next 12 months to establish a state-of-the-art manufacturing facility for the commercial manufacture of products developed using our VersaFilm drug delivery technology.

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, or 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**

We currently occupy 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 the third quarter of 2015, we plan to occupy 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 thin film VersaFilm 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 do not expect any unanticipated impact on our already planned development schedule.

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\$)
<b>2014</b>				
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
<b>2013</b>				
Fourth Quarter	\$ 0.57	\$ 0.48	\$ 0.60	\$ 0.50
Third Quarter	\$ 0.72	\$ 0.49	\$ 0.74	\$ 0.51
Second Quarter	\$ 0.70	\$ 0.53	\$ 0.70	\$ 0.55
First Quarter	\$ 0.75	\$ 0.45	\$ 0.73	\$ 0.48

**Number of Shareholders**

On March 20, 2015 there were approximately 50 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 2014, 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 2014, 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.

## **ITEM 6. SELECTED FINANCIAL DATA**

Not applicable.

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

### **Introduction to Management's Discussion and Analysis**

The purpose of this section, Management's Discussion and Analysis of Financial Condition and Results of Operations, is to provide a narrative explanation of the financial statements that enables investors to better understand our business, to enhance our overall financial disclosure, to provide the context within which our financial information may be analyzed, and to provide information about the quality of, and potential variability of, our financial condition, results of operations and cash flows. Unless otherwise indicated, all financial and statistical information included herein relates to our continuing operations. Unless otherwise indicated or the context otherwise requires, the words,

IntelGenx, Company, we, us, and our refer to IntelGenx Technologies Corp. and its subsidiaries, including IntelGenx Technologies Corp. This information should be read in conjunction with the accompanying audited Consolidated Financial Statements and Notes thereto.

### **Company Background**

We are a drug delivery company established in 2003 and headquartered in Montreal, Quebec, Canada. Our focus is on the development of novel oral immediate-release and controlled-release products for the pharmaceutical market. Our business strategy is to develop pharmaceutical products based on our proprietary drug delivery technologies and, once the viability of a product has been demonstrated, to license the commercial rights to partners in the pharmaceutical industry. In certain cases, we rely upon partners in the pharmaceutical industry to fund development of the licensed products, complete the regulatory approval process with the FDA or other regulatory agencies relating to the licensed products, and assume responsibility for marketing and distributing such products.

In addition, we may choose to pursue the development of certain products until the project reaches the marketing and distribution stage. We will assess the potential for successful development of a product and associated costs, and then determine at which stage it is most prudent to seek a partner, balancing such costs against the potential for additional returns earned by partnering later in the development process.

We have 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 Section 505(b)(2) of the Food, Drug, and Cosmetics Act, the FDA may grant market exclusivity for a term of up to three years following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage, dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials, other than bioavailability studies, conducted by or for the sponsor.

We are currently continuing to develop the existing products in our pipeline and may also perform research and development on other potential products as opportunities arise.

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

We currently purchase and/or lease, on an as-needed basis, the equipment necessary for performing research and development activities related to our products.

We plan to hire new personnel 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 facility, and increase our research and development activities.

## Key Developments

There were a number of key events in the strategic development of our company throughout 2014, and subsequent to the end of the year, most notably:

### *Product-related*

#### *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 US, these patients can simplify their dosing regimen to a single Forfivo XL tablet, once-daily.

The commercialization of Forfivo XL® triggered launch-related milestone payments to us of up to \$4.0 million, of which \$1 million was received following commercial launch in October 2012. Based on current trends, Management expects that the remaining \$3 million will be earned in fiscal 2015. Additional 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®. We recorded total revenue for Forfivo XL® in 2014 of approximately \$1.1 million, compared with \$492 thousand in 2013.

The level of sales achieved for Forfivo XL® in 2014 improved significantly when compared to the previous year. According to Symphony Health Solutions, a recognized market research firm, gross sales of Forfivo XL® totaled \$8.9 million in the year ending December 31st, 2014 representing an increase of 230% compared with sales of \$2.7 million in the preceding year. The number of Forfivo XL® prescriptions filled increased by 123% from approximately 16,761 in 2013 to 30,378 in 2014. The average month-on-month growth rate of Forfivo XL® throughout 2014 exceeded 9%. Management anticipates this trend to continue throughout 2015 and expects significantly higher revenue from the sales of Forfivo XL® in 2015.

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 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 regardless of the result of these compliance issues and have already identified and audited an alternative API supplier. However, changing suppliers is financially expensive and is a time-consuming process. As a result, we believe that FDA approval of this product for the US market will be delayed until 2016.

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 Mutual Recognition Procedure 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's potential feedback regarding the MAA is expected during the second half of 2015.

It should be noted that BfArM is satisfied with the compliance status of the API and that therefore the Import Alert issued by the FDA has no effect upon the MAA submission in Europe.

#### ***Two new (undisclosed) projects***

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

Under the terms of the agreement, Par has obtained certain exclusive rights to market and sell our products in the USA. In exchange we will receive upfront and milestone payments, together with a share of the profits upon commercialization. In accordance with confidentiality clauses contained in the agreement, the specifics of the product descriptions, platform technologies and financial terms remain confidential.

#### ***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 (C<sub>max</sub>) 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 US, 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 order to maintain our competitive advantage, we are unable to disclose further details related to this project at this time.

### ***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***

Subsequent to the end of the fiscal year ended December 31, 2014, we finalised negotiations for an agreement to lease approximately 17,000 square feet in a property located at 6420 Abrams, St-Laurent, Quebec (the "Lease"), which we expect to execute in the coming weeks. The Lease has a 10 year and 6 month term commencing 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 \$95 thousand) per year, which will increase at a rate of CAD\$0.25 (\$0.22) per square foot 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 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), which we expect to execute in the coming weeks. The construction agreement will be awarded to BTL Construction Inc. ("BTL") in Quebec following a tender process that was completed in December 2014. BTL specializes in the renovation of existing buildings for pharmaceutical use and has completed projects for various major pharmaceutical companies. We plan to fund this project from cash on hand. Construction is anticipated to be completed in Q3, 2015.

On March 16, 2015 we received CAD\$500 thousand (approximately \$430 thousand) in cash as part of a credit facility of up to CAD\$3.5 million (approximately \$3.0 million) negotiated with BMO Bank of Montreal ( 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 CAD\$3.0 million (\$2.6 million) to follow after BMO has reviewed (in August 2015) our operating results for the first 6 months of 2015. 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 2 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 high end supplier 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), requires immediate 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 is expected to be delivered in Q3, 2015 and the commercial packaging machine is expected to be delivered in Q4, 2015. We intend to finance the acquisition of these 2 machines with the credit facility negotiated with BMO, as discussed above.

**Leadership succession**

In July 2014 we announced the resignation of Dr. Rajiv Khosla as President and Chief Executive Officer ( CEO ), and as a member of the Board, effective immediately.

Concurrently, our Board of Directors appointed Dr. Horst G. Zerbe, our Chairman of the Board, founder, and former President and CEO, to the positions of President and CEO.

**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, when comparing the currency rates used to prepare our financial statements for fiscal 2014 with the rates used to prepare the previous year, the strengthened US dollar resulted in an unrealized loss of approximately \$442 thousand on our cash position at December 31, 2014, but reduced our net loss from operations by approximately \$124 thousand for year ending December 31, 2014. The following management discussion and analysis takes this into consideration whenever material.

**Results of Operations Year ended December 31, 2014 compared to the Year ended December 31, 2013.**

In U.S.\$ thousands	2014	2013	Increase/ (Decrease)	Percentage Increase/ (Decrease)
Revenue	\$ 1,659	\$ 948	\$ 711	75%
Research and Development Expenses	1,075	561	514	92%
Selling, General and Administrative Expenses	2,290	1,954	336	17%
Depreciation of tangible assets	35	34	1	3%
Amortization of intangible assets	39	38	1	3%
Interest and other income	34	-	34	N/A
Net Loss	(1,746)	(1,639)	107	7%

**Revenue and Other Income**

Total revenue in the year ended December 31, 2014 increased by 75% to \$1,659 thousand from \$948 thousand in the year ended December 31, 2013.

Revenue recorded in the year ended December 31, 2014 includes \$1,097 thousand (2013 - \$492 thousand) related to Forfivo XL®, our first FDA approved product, which was launched in October 2012 under a licensing partnership with Edgemont Pharmaceuticals LLP ( Edgemont ). Upon entering into the licensing agreement, Edgemont paid us an upfront fee of \$1 million, which we recognized as deferred license revenue. The deferred license revenue is amortized in income over the 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, we invoiced \$1.25 million to Edgemont and recognized the full amount as deferred revenue, to be amortized in income from October 2014 through September 2015. As a result of this policy, we recognized \$621 thousand (2013 - \$308 thousand) in income during the year ended December 31, 2014. As at December 31, 2014, we have a deferred revenue balance of \$1,245 thousand (December 31, 2013: \$616 thousand) that has not been recognized as revenue. In addition, we recognized approximately \$463 thousand (2013 - \$171 thousand) of royalty income earned from the sale of Forfivo XL®, and a further \$13 thousand (2013 - \$13 thousand) of manufacturing royalty income related to a license to manufacture Forfivo XL® that was granted by us to a contract manufacturing organization. Forfivo XL® is indicated for the treatment of MDD and is the only extended-release bupropion HCl product to provide a once-daily, 450mg dose in a single tablet.



The level of sales achieved for Forfivo XL® in 2014 improved significantly when compared to the previous year. According to Symphony Health Solutions, gross sales of Forfivo XL® totaled \$8.9 million in the year ending December 31st, 2014, an increase of 230% compared with sales of \$2.7 million in the preceding year. The number of Forfivo XL® prescriptions filled increased by 123% from approximately 16,761 in 2013 to 30,378 in 2014. The average month-on-month growth rate of Forfivo XL® throughout 2014 exceeded 9%. We anticipate significantly higher revenue from the sales of Forfivo XL® in 2015.

Revenue for the year ended December 31, 2014 also includes an aggregate \$550 thousand (2013: \$450 thousand) in payments received for successfully achieving certain R&D development milestones for certain R&D development projects currently under development. We anticipate the receipt of further milestone payments as and when we successfully achieve further development milestones in accordance with contractual terms.

### **Research and Development ( R&D ) Expenses**

R&D expenses totaled \$1,075 thousand in the year ended December 31, 2014 compared with \$561 thousand the previous year, representing an increase of \$711 thousand, or 92%.

The increase in R&D expenses is primarily attributable to approximately \$401 thousand of expenses incurred in the development of our second Par project, which is progressing according to plan. In addition, we incurred approximately \$96 thousand of R&D costs for 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 tadalafil product, and approximately \$100 thousand for the development and successful completion of a pilot clinical study for our VersaFilm product, indicated for the treatment of schizophrenia, that demonstrated a significantly improved pharmacokinetic profile against the reference product. We also recorded estimated Research and Development Tax Credits and refunds of \$94 thousand in the year ended December 31, 2014, representing a decrease of \$72 thousand compared with \$166 thousand that was recorded in the previous year.

Included within R&D expenses for 2014 are R&D Salaries of \$478 thousand, of which approximately \$8 thousand represents non-cash compensation. This compares to R&D salaries of \$604 thousand in 2013, of which approximately \$17 thousand represented non-cash compensation. The decrease in R&D salaries is primarily attributable to the fact that we ceased, with effect from December 31, 2013, to apportion 50% of the remuneration of our CEO to the R&D department, and to lower salaries as a result of paternity leave of two employees during period of 2014.

### **Selling, General and Administrative ( SG&A ) Expenses**

SG&A expenses increased by 17% from \$1,954 thousand in the year ended December 31, 2013 to \$2,290 thousand in the year ended December 31, 2014. Approximately \$125 thousand of the increase is attributable to the fact that we ceased, with effect from December 31, 2013, to apportion 50% of the remuneration of our CEO to the R&D department, and approximately \$110 thousand relates to an increase in directors fees. In addition, legal expenses increased by approximately \$56 thousand, primarily related to our Paragraph IV litigation with Wockhardt that was settled in November 2014. Furthermore, fees for investor relations services increased by approximately \$80 thousand due to the appointment of the Cockrell Group in August 2014. The increases were partly offset by a profit of approximately \$126 thousand (2013: \$77 thousand) realized on currency exchange, primarily from the conversion of US\$ to CAD\$.

Included in SG&A expenses are approximately \$76 thousand (2013: \$70 thousand) in non-cash compensation from options granted to management employees in 2012, 2013 and 2014, \$17 thousand (2013: \$10 thousand) in non-cash compensation from options granted to non-employee directors in 2013 and 2014, and \$Nil (2013: \$17 thousand) in non-cash compensation from options granted to consultants.





**Depreciation of tangible assets**

In the year ended December 31, 2014 we recorded an expense of \$35 thousand for the depreciation of tangible assets, compared with \$34 thousand for the previous year.

**Amortization of intangible assets**

In the year ended December 31, 2014 we recorded an amortization of intangible assets expense of \$39 thousand, compared with \$38 thousand for the previous year.

**Share-Based Compensation Expense, Warrants and Stock Based Payments**

Share-based compensation expense, warrants and share-based payments totaled \$101 thousand for the year ended December 31, 2014 compared with \$114 thousand for the year ended December 31, 2013.

We expensed approximately \$84 thousand in the year ended December 31, 2014 for options granted to our employees in 2012, 2013 and 2014 under the 2006 Stock Option Plan, and approximately \$17 thousand for options granted to non-employee directors in 2013 and 2014 compared with \$87 thousand and \$10 respectively that was expensed in the same period of the previous year.

We also expensed \$17 thousand in the year ended December 31, 2013 for options granted to consultants, compared with \$Nil in the year ended December 31, 2014.

As at December 31, 2014 there remains approximately \$74 thousand in stock based compensation to be expensed in fiscal 2015 through 2016, all of which relates to the issuance of options to employees and directors of the Company during 2013 and 2014. 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	2014	2013	Increase/ (Decrease)	Percentage Increase/ (Decrease)
Current Assets	\$ 5,255	\$ 5,550	\$ (295)	(5%)
Leasehold Improvements and Equipment	983	588	395	67%
Intangible Assets	46	79	(33)	(42%)
Accounts Payable and Accrued Liabilities	466	593	(127)	(21%)
Deferred License Revenue	1,245	616	629	102%
Capital Stock	1	1	0	N/A
Additional Paid-in-Capital	22,654	20,934	1,720	8%

**Current Assets**

Current assets totaled \$5,255 thousand at December 31, 2014 compared with \$5,550 thousand at December 31, 2013. The decrease of \$295 thousand is attributable to a decrease in cash of \$606 thousand, a decrease in prepaid expenses of \$37 thousand, and a decrease in investment tax credits receivable of \$160 thousand, partly offset by an increase in accounts receivable of \$508 thousand.

**Cash and cash equivalents**

Cash and cash equivalents totaled \$4,399 thousand as at December 31, 2014 representing a decrease of \$606 thousand compared to the balance of \$5,005 thousand as at December 31, 2013. The decrease in cash on hand relates to net cash

used in operating activities of \$1,379 thousand, net cash used in investing activities of \$403 thousand, and an unrealized foreign exchange loss of \$443 thousand, partly offset by net cash provided by financing activities of \$1,619 thousand.

In the year ended December 31, 2014 a total of 2,480,988 warrants were exercised for 2,480,988 common shares for cash consideration of approximately \$1,619 thousand.

### **Accounts receivable**

Accounts receivable totaled \$652 thousand (2013: \$144 thousand) as at December 31, 2014, of which approximately \$600 thousand is part of the \$1.25 million that was invoiced to Edgemont Pharmaceuticals in the fourth quarter of 2014. We received payment against this amount in February 2015.

### **Prepaid Expenses**

As of December 31, 2014, prepaid expenses totaled \$96 thousand compared with \$133 thousand as of December 31, 2013. Prepaid expenses at December 31, 2013 included a deposit paid for a biostudy planned to be completed in the first quarter of 2014 and a deposit paid on R&D machinery to be supplied and installed in the second half of 2014.

### **Investment tax credits receivable**

R&D investment tax credits receivable totaled approximately \$108 thousand as at December 31, 2014 compared with \$268 thousand as at December 31, 2013. The balance receivable as at December 31, 2014 related to credits accrued throughout fiscal 2014, whereas the balance receivable as at December 31, 2013 related to credits accrued throughout fiscal 2013, and to a balance outstanding from 2012 of \$106 thousand.

### **Leasehold Improvements and Equipment**

As at December 31, 2014, the net book value of property and equipment amounted to \$983 thousand, compared to \$588 thousand at December 31, 2013. In the year ended December 31, 2014 additions to assets totaled \$403 thousand and comprised \$54 thousand for manufacturing equipment for our VersaFilm products, \$144 thousand for laboratory equipment, \$8 thousand for computer equipment and \$197 thousand for leasehold improvements to a new facility that we plan to occupy in the third quarter of 2015. Depreciation on Leasehold Improvements and equipment in the year ended December 31, 2014 amounted to \$35 thousand and a foreign exchange gain of \$27 thousand was recorded.

Included in the net book value of property and equipment as at December 31, 2014 are amounts of approximately \$520 thousand (2013: \$466 thousand) for manufacturing equipment that is being prepared for use in our new facility later in 2015, and \$207 thousand (2013: \$10 thousand) for leasehold improvements for our new facility. In accordance with US generally accepted accounting principles, these assets are not being depreciated as they are not yet in use.

### **Intangible Assets**

As at December 31, 2014 NDA acquisition costs of \$46 thousand (December 31, 2013 - \$79 thousand) were recorded as intangible assets on our balance sheet and are related to the acquisition of 100% ownership of Forfivo XL®. The asset is being amortized over its expected useful life and amortization commenced upon commercial launch of Forfivo XL® in the fourth quarter of 2012.

### **Accounts Payable and Accrued Liabilities**

Current liabilities totaled \$466 thousand as at December 31, 2014 (December 31, 2013 - \$593 thousand) and include approximately \$21 thousand related to research and development activities, approximately \$63 thousand related to professional fees, approximately \$59 thousand related to royalties payable to a former development partner, and approximately \$280 thousand related to accrued payroll liabilities.

### **Deferred License Revenue**

Pursuant to the execution of a licensing agreement for Forfivo XL®, we received an upfront fee from Edgemont Pharmaceuticals in the first quarter of 2012, which we recognized as deferred license revenue. The deferred license revenue is being amortized in income over the 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, to be amortized in income from October 2014 through September 2015.

As a result of this policy, we have a deferred revenue balance of \$1,245 thousand at December 31, 2014 (December 31, 2013: \$616 thousand) that has not been recognized as revenue.

### **Shareholders Equity**

As at December 31, 2014 we had accumulated a deficit of \$17,848 thousand compared with an accumulated deficit of \$16,102 thousand as at December 31, 2013. Total assets amounted to \$6,284 thousand and shareholders equity totaled \$4,573 thousand as at December 31, 2014, compared with total assets and shareholders equity of \$6,217 thousand and \$5,008 thousand respectively, as at December 31, 2013.

### **Contractual Obligations and Commitments**

The Company currently operates out of a 3,500 square feet leasehold facility consisting of laboratories and office space at 6425 Abrams, Saint-Laurent, Quebec. The monthly rent for this property is approximately \$2 thousand. The original lease agreement expired in August 2009, and has since been extended for varying periods. The most recent extension is defined as the day immediately preceding the fulfillment of certain conditions relating to the occupation of new leased premises at 6420 Abrams.

Subsequent to the end of the 2014 fiscal year we finalized negotiations for an agreement to lease approximately 17,000 square feet in a new facility at 6420 Abrams. The Lease has a 10 year and 6 month term commencing on 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 will be required to pay base rent of approximately CAD\$110 thousand per year, which will increase at a rate of CAD\$0.25 per square foot every two years. IntelGenx plans to use the newly leased space for manufacturing of its oral film VersaFilm™ products, enlarging research and development capabilities, and administration.

On October 1, 2009, the Company signed an agreement with Little Gem Life Science Partners for investor relation services in the USA. Under the terms of the agreement, the Company was required to pay \$4.5 thousand per month to Little Gem Life Science Partners. The Company renegotiated the agreement in May 2012 and reduced payments to \$2.5 thousand per month. The agreement automatically renews unless specifically terminated.

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.

### **Capital Stock**

As at December 31, 2014 capital stock amounted to \$635 compared to \$610 at December 31, 2013. The increase reflects the issuance of 2,480,988 shares related to the exercise of warrants with all shares issued at par value of \$0.00001. 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 \$22,654 thousand at December 31, 2014, as compared to \$20,934 thousand at December 31, 2013. Additional paid in capital increased by \$1,619 thousand for warrants exercised and increased by \$101 thousand for stock based compensation of which \$101 thousand is attributable to the amortization of stock

options granted to employees and directors.

**Taxation**

As at December 31, 2014 we had Canadian and provincial net operating losses of approximately \$9,530 thousand (2013 - \$8,874 thousand) and \$9,683 thousand (2013 - \$9,040 thousand) 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 2034. A portion of the net operating losses may expire before they can be utilized.

As at December 31, 2014, we had non-refundable tax credits of \$1,100 thousand (2013 - \$1,098 thousand) of which \$20 thousand is expiring in 2017, \$194 thousand is expiring in 2018, \$170 thousand is expiring in 2019, \$145 thousand is expiring in 2020, \$154 thousand is expiring in 2021, \$193 thousand is expiring in 2022 and \$129 thousand is expiring in 2023 and \$95 thousand is expiring in 2024. We also had undeducted research and development expenses of \$4,805 thousand (2013 - \$4,354 thousand) with no expiration date.

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

### Key items from the Statement of Cash Flows

In U.S.\$ thousands	2014	2013	Increase/ (Decrease)	Percentage Increase/ (Decrease)
Operating Activities	\$ (1,379)	\$ (1,173)	\$ 206	18%
Financing Activities	1,619	4,479	(2,860)	(64%)
Investing Activities	(403)	(266)	137	52%
Cash and cash equivalents end of period	4,399	5,005	(606)	(12%)

### Statement of cash flows

Net cash used by operating activities was \$1,379 thousand in the year ended December 31, 2014, compared to \$1,173 thousand for the year ended December 31, 2013. In fiscal 2014, net cash used by operating activities consisted of an operating loss of \$1,571 thousand (2013 - \$1,453 thousand) and an increase in non-cash operating elements of working capital of \$192 thousand compared with an increase of \$280 thousand in 2013.

Operating activities will continue to consume our available funds until we are able to generate increased revenues.

The net cash provided by financing activities was \$1,619 thousand in fiscal 2014, compared to \$4,479 thousand provided in the previous year. The net cash provided in 2014 resulted from the exercise of warrants, whereas the net cash provided in 2013 resulted from gross proceeds of \$3,500 thousand from our public offering completed in December 2013, \$1,465 thousand from the exercise of warrants and a further \$31 thousand from the exercise of options, less transaction costs for the public offering of \$517 thousand.

Net cash used in investing activities amounted to \$403 thousand in the year ended December 31, 2014 compared to \$266 thousand in the year ended December 31, 2013. The net cash used in investing activities in 2014 relates exclusively to the purchase of fixed assets and comprised \$54 thousand for manufacturing equipment for our VersaFilm products, \$144 thousand for laboratory equipment, \$8 thousand for computer equipment and \$197 thousand for leasehold improvements to a new facility that we plan to occupy in the third quarter of 2015.

The balance of cash and cash equivalents as at December 31, 2014 amounted to \$4,399 thousand, compared to \$5,005 thousand at December 31, 2013.

### Off-Balance Sheet Arrangements

We have no off-balance sheet arrangements as contemplated by SK 229 303 (A) (4) (ii).

### 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, 2014 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, 2014 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, 2014. 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 (1992). Based on our processes and assessment, as described above, management has concluded that, as of December 31, 2014 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 that permit the Company to provide only management's report in this Annual Report.

**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 2015 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 2015 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 2015 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 2015 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 2015 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, 2014 and 2013.
- C. Consolidated Statements of Shareholders' Equity for the years ended of December 31, 2014 and 2013.
- D. Consolidated Statements of Comprehensive Loss for the years ended of December 31, 2014 and 2013.
- E. Consolidated Statements of Cash Flows for the years ended December 31, 2014 and 2013.
- 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**

<b>Exhibit No.</b>	<b>Description</b>
2.1	Share exchange agreement dated April 10, 2006 (incorporated by reference to the Form 8-K/A filed on May 5, 2006)
3.1	Certificate of Incorporation (incorporated by reference to the Form SB-2 (File No. 333-90149) filed on November 16, 1999)
3.2	Amendment to the Certificate of Incorporation (incorporated by reference to amendment No. 2 to Form SB-2 (File No. 333-135591) filed on August 28, 2006)
3.3	Amendment to the Certificate of Incorporation (incorporated by reference to the Form DEF 14C filed on April 20, 2007)
3.4	By-Laws (incorporated by reference to the Form SB-2 (File No. 333-91049) filed on November 16, 1999)
3.5	Amended and Restated By-Laws (incorporated by reference to the Form 8-K filed on March 31, 2011)
3.6	Amended and Restated By-Laws (incorporated by reference to the Form 8-K filed on March 21, 2012)
9.1	Voting Trust agreement (incorporated by reference to the Form 8-K/A filed on May 5, 2006)
10.1 +	

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- Horst Zerbe employment agreement dated October 1, 2014 (incorporated by reference to the Form 10-Q filed on November 12, 2014)
- 10.2 + Ingrid Zerbe employment agreement (incorporated by reference to the Form SB-2 (File No. 333-135591) filed on July 3, 2006)
- 10.3 Registration rights agreement (incorporated by reference to the Form SB-2 (File No. 333-135591) filed on July 3, 2006)
- 10.4 Principal's registration rights agreement (incorporated by reference to the Form SB-2 (File No. 333-135591) filed on July 3, 2006)
- 10.5 + 2006 Stock Option Plan (incorporated by reference to the Form S-8 filed on November 21, 2006)
- 10.6 + Employment Contract Paul A. Simmons (incorporated by reference to the Form 8-K filed on September 5, 2008)
- 10.7 + Amended and Restated 2006 Stock Option Plan, May 29, 2008 (incorporated by reference to the Form 10-K filed on March 25, 2009)

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- 10.8 Co-Development and Commercialization Agreement with RedHill Biopharma Ltd. (incorporated by reference to the Form 10-Q filed on November 9, 2010)
- 10.9 + Amended and Restated 2006 Stock Option Plan (incorporated by reference to the Form S-8 filed on November 15, 2010)
- 10.10 Agency Agreement, dated as of August 27, 2010, between the Company and Bolder Investment Partners, Ltd. (incorporated by reference to the Form 8-K filed on August 30, 2010)
- 10.11 Registration Rights Agreement, dated as of August 27, 2010, by and among the Company and the purchasers pursuant to the offering (incorporated by reference to the Form 8-K filed on August 30, 2010)
- 10.12 Form of Subscription Agreement (incorporated by reference to the Form 8-K filed on August 30, 2010)
- 10.13 Form of Warrant (incorporated by reference to the Form 8-K filed on August 30, 2010)
- 10.14 Form of Compensation Option (incorporated by reference to the Form 8-K filed on August 30, 2010)
- 10.15 Project Transfer Agreement (incorporated by reference to the Form 10-Q filed on May 14, 2010)
- 10.16 Co-development and Licensing Agreement (incorporated by reference to the Form 10-Q filed on May 14, 2010)
- 10.17 License and Asset Transfer Agreement with Edgemont Pharmaceuticals (incorporated by reference to the Form 10Q filed on May 15, 2012)
- 10.18 Securities Purchase Agreement (incorporated by reference to the Form 8-K filed on June 3, 2011)
- 10.19 Registration Rights Agreement (incorporated by reference to the Form 8-K filed on June 3, 2011)
- 10.20 Form of Warrant (incorporated by reference to the Form 8-K filed on June 3, 2011)
- 10.21+ Amended and Restated 2006 Stock Option Plan, (incorporated by reference to the Form 8-K filed on May 9, 2013)
- 10.22+ Employment Agreement Rajiv Khosla (incorporated by reference to the Form 10-Q filed on May 14, 2013)
- 10.23 Engagement Letter Wainwright dated October 10, 2013, amended December 3, 2013 (incorporated by reference to the Form S-1/A Registration Statement filed December 16, 2013)
- 10.24 Amended Form of Securities Purchase Agreement (incorporated by reference to the Form S-1/A Registration Statement filed on December 16, 2013)
- 10.25 Form of Warrant (incorporated by reference to the Form S-1 Registration Statement filed on October 25, 2013)
- 10.26 Form of Placement Agent Warrant (incorporated by reference to the Form S-1/A Registration Statement filed on December 16, 2013)
- 10.27 ++ Development Services and Commercialization Agreement with PAR Pharmaceuticals, dated December 19, 2011 (incorporated by reference to the Form 10-K filed on March 11, 2014)
- 10.28 ++ Development Services and Commercialization Agreement with PAR Pharmaceuticals, dated January 8, 2014 (incorporated by reference to the Form 10-K filed on March 11, 2014)
- 10.29+\* Employment-Agreement John Durham, January 2015
- 21.1 Subsidiaries of the small business issuer (incorporated by reference to the Form SB-2 (File No. 333-135591) filed on July 3, 2006)
- 23.1\* Consents of Richter LLP
- 31.1\* Certification of Horst G. Zerbe, President and Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.\*

31.2\* Certification of Paul A. Simmons, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.\*

32.1\* Certification of Horst G. Zerbe, President and Chief Executive Officer, pursuant to 18 U.S.C. Section 1350.\*

32.2\* Certification of Paul A. Simmons, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350.\*

\* Filed herewith.

+ Indicates management contract or employee compensation plan

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



**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, 2015, thereunto duly authorized.

**INTELGEX TECHNOLOGIES CORP.**

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

By: */s/Paul A. Simmons*  
 Paul A. Simmons  
 Chief Financial Officer  
 (Principal Financial and Accounting Officer)

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

<b>Signature</b>	<b>Position</b>	<b>Date</b>
By: <i>/s/ Horst G. Zerbe</i> Horst G. Zerbe	Chairman of the Board, President and Chief Executive Officer	March 30, 2015
By: <i>/s/Paul A. Simmons</i> Paul A. Simmons	Chief Financial Officer	March 30, 2015
By: <i>/s/ Bernard Boudreau</i> J. Bernard Boudreau	Director	March 30, 2015
By: <i>/s/Ian Troup</i> John (Ian) Troup	Director	March 30, 2015
By: <i>/s/Bernd Melchers</i> Bernd J. Melchers	Director	March 30, 2015
By: <i>/s/John Marinucci</i> John Marinucci	Director	March 30, 2015

# **IntelGenx Technologies Corp**

**Consolidated Financial Statements**

**December 31, 2014 and 2013**

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

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# IntelGenx Technologies Corp

**Consolidated Financial Statements**  
**December 31, 2014 and 2013**  
**(Expressed in U.S. Funds)**

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**Report of Independent Registered Public Accounting Firm**

To the Shareholders and Board of Directors of  
**IntelGenx Technologies Corp.**

We have audited the accompanying consolidated balance sheets of IntelGenx Technologies Corp. as at December 31, 2014 and 2013 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, 2014 and 2013 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, 2015

1CPA auditor, CA, public accountancy permit No.  
A110982

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**Montréal, Toronto**



# IntelGenx Technologies Corp.

## Consolidated Balance Sheets

As at December 31, 2014 and 2013

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

	2014	2013
<b>Assets</b>		
<b>Current</b>		
Cash and cash equivalents	\$ 4,399	\$ 5,005
Accounts receivable	652	144
Prepaid expenses	96	133
Investment tax credits receivable	108	268
<b>Total Current Assets</b>	<b>5,255</b>	<b>5,550</b>
<b>Leasehold Improvements and Equipment</b> (note 5)	<b>983</b>	<b>588</b>
<b>Intangible Assets</b> (note 6)	<b>46</b>	<b>79</b>
<b>Total Assets</b>	<b>\$ 6,284</b>	<b>\$ 6,217</b>
<b>Liabilities</b>		
<b>Current</b>		
Accounts payable and accrued liabilities	466	593
Deferred license revenue (note 7)	1,245	308
<b>Total Current Liabilities</b>	<b>1,711</b>	<b>901</b>
<b>Deferred License Revenue, non-current portion</b> (note 7)	<b>-</b>	<b>308</b>
<b>Total Liabilities</b>	<b>1,711</b>	<b>1,209</b>
<b>Commitments</b> (note 8)		
<b>Shareholders' Equity</b>		
Capital Stock (note 9)	1	1
Additional Paid-in-Capital (note 10)	22,654	20,934
Accumulated Deficit	(17,848)	(16,102)
Accumulated Other Comprehensive Income (Loss)	(234)	175
<b>Total Shareholders' Equity</b>	<b>4,573</b>	<b>5,008</b>
	<b>\$ 6,284</b>	<b>\$ 6,217</b>

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, 2013

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

	Capital Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income/(Loss)	Total Shareholders' Equity
	Number	Amount				
<b>Balance - December 31, 2012</b>	49,890,421	\$ 0	\$ 16,342	\$ (14,463)	\$ 299	\$ 2,178
Foreign currency translation adjustment	-	-	-	-	(124)	(124)
Issue of common stock, net of transaction costs of \$387 (note 9)	7,920,346	-	1,808	-	-	1,808
Warrants issued, net of transaction costs of \$230 (note 10)	-	-	1,075	-	-	1,075
Agents warrants (note 10)	-	-	100	-	-	100
Warrants exercised (note 10)	3,098,500	1	1,464	-	-	1,465
Options exercised (note 10)	75,000	-	31	-	-	31
Stock-based compensation (note 10)	-	-	114	-	-	114
Net loss for the period	-	-	-	(1,639)	-	(1,639)
<b>Balance December 31, 2013</b>	<b>60,984,267</b>	<b>\$ 1</b>	<b>\$ 20,934</b>	<b>\$ (16,102)</b>	<b>\$ 175</b>	<b>\$ 5,008</b>
See accompanying notes						

## 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)

	<u>Capital Stock</u>		Additional	Accumulated	Accumulated	Other	<b>Total</b>
	Number	Amount	Paid-In	Deficit	Income?(Loss)	Comprehensive	<b>Shareholders'</b>
			Capital				<b>Equity</b>
<b>Balance -</b>							
<b>December 31,</b>							
<b>2013</b>	60,984,267	\$ 1	\$ 20,934	\$ (16,102)	\$ 175	\$	<b>5,008</b>
Foreign currency translation adjustment	-	-	-	-	(409)		<b>(409)</b>
Warrants exercised (note 10)	2,480,988	-	1,619	-	-		<b>1,619</b>
Stock-based compensation (note 10)	-	-	101	-	-		<b>101</b>
Net loss for the period	-	-	-	(1,746)	-		<b>(1,746)</b>
<b>Balance</b>							
<b>December 31,</b>							
<b>2014</b>	<b>63,465,255</b>	<b>\$ 1</b>	<b>\$ 22,654</b>	<b>\$ (17,848)</b>	<b>\$ (234)</b>	<b>\$</b>	<b>4,573</b>
See accompanying notes							



## IntelGenx Technologies Corp.

### Consolidated Statements of Comprehensive Loss

For the Years Ended December 31, 2014 and 2013

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

	2014	2013
<b>Revenues</b>		
Royalties	\$ 476	\$ 188
License and other revenue	1,183	760
<b>Total Revenues</b>	<b>1,659</b>	<b>948</b>
<b>Expenses</b>		
Research and development expense	1,075	561
Selling, general and administrative expense	2,290	1,954
Depreciation of tangible assets	35	34
Amortization of intangible assets	39	38
<b>Total Costs and Expenses</b>	<b>3,439</b>	<b>2,587</b>
<b>Loss from Operations</b>	<b>(1,780)</b>	<b>(1,639)</b>
<b>Other Income</b>		
Interest and other income	34	-
<b>Total Other Income</b>	<b>34</b>	<b>-</b>
<b>Loss Before Income Taxes</b>	<b>(1,746)</b>	<b>(1,639)</b>
Income taxes (note 11)	-	-
<b>Net Loss</b>	<b>(1,746)</b>	<b>(1,639)</b>
<b>Other Comprehensive Loss</b>		
Foreign currency translation adjustment	(409)	(124)
<b>Comprehensive Loss</b>	<b>\$ (2,155)</b>	<b>\$ (1,763)</b>
<b>Basic and Diluted Weighted Average Number of Shares Outstanding</b>	<b>63,182,224</b>	<b>54,023,739</b>
Basic and Diluted Loss Per Common Share (note 14)	\$ (0.03)	\$ (0.03)

See accompanying notes

## IntelGenx Technologies Corp.

### Consolidated Statements of Cash Flows

For the Year Ended December 31, 2014 and 2013

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

	2014	2013
<b>Funds Provided (Used) -</b>		
<b>Operating Activities</b>		
Net loss	\$ (1,746)	\$ (1,639)
Amortization and depreciation	74	72
Stock-based compensation	101	114
	<b>(1,571)</b>	<b>(1,453)</b>
Changes in assets and liabilities		
Accounts receivable	(508)	1,138
Prepaid expenses	37	(31)
Investment tax credits receivable	160	(55)
Accounts payable and accrued liabilities	(127)	(465)
Deferred license revenue	629	(307)
<b>Net change in assets and liabilities</b>	<b>191</b>	<b>280</b>
<b>Net cash used by operating activities</b>	<b>(1,380)</b>	<b>(1,173)</b>
<b>Financing Activities</b>		
Issuance of common stock and warrants	-	3,500
Proceeds from exercise of warrants, agents' warrants and stock options	1,619	1,496
Transaction costs	-	(517)
<b>Net cash provided by financing activities</b>	<b>1,619</b>	<b>4,479</b>
<b>Investing Activities</b>		
Additions to leasehold improvements and equipment	(403)	(266)
<b>Net Cash used in investing activities</b>	<b>(403)</b>	<b>(266)</b>
<b>Increase (Decrease) in Cash and Cash Equivalents</b>	<b>(164)</b>	<b>3,040</b>
<b>Effect of Foreign Exchange on Cash and Cash Equivalents</b>	<b>(442)</b>	<b>(94)</b>
<b>Cash and Cash Equivalents</b>		
<b>Beginning of Year</b>	<b>5,005</b>	<b>2,059</b>
<b>End of Year</b>	<b>\$ 4,399</b>	<b>\$ 5,005</b>

See accompanying notes

# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2014 and 2013

(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* . The Company has an aggressive product development initiative that primarily focuses on addressing unmet market needs and focuses on utilization of the U.S. Food and Drug Administration's ( FDA ) 505(b)(2) approval process to obtain more timely and efficient approval of new formulations of previously approved products.

The Company's product pipeline currently consists of 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, 2014 and 2013

(Expressed in U.S. Funds)

#### 3. Adoption of New Accounting Standards

The FASB issued Update No. 2013-05, Foreign Currency Matters (Topic 830) Parent's Accounting for the Cumulative Translation Adjustment upon Derecognition of Certain Subsidiaries or Groups of Assets within a Foreign Entity or of an Investment in a Foreign Entity. The amendments in this Update resolve the diversity in practice about whether Subtopic 810-10, Consolidation Overall, or Subtopic 830-30, Foreign Currency Matters Translation of Financial Statements, applies to the release of the cumulative translation adjustment into net income when a parent either sells a part or all of its investment in a foreign entity or no longer holds a controlling financial interest in a subsidiary or group of assets that is a nonprofit activity or a business (other than a sale of in substance real estate or conveyance of oil and gas mineral rights) within a foreign entity. In addition, the amendments in this Update resolve the diversity in practice for the treatment of business combinations achieved in stages (sometimes also referred to as step acquisitions) involving a foreign entity. For public entities, the amendments in this ASU were effective prospectively for fiscal years, and interim reporting periods within those years, beginning after December 15, 2013. The adoption of this Statement did not have a material effect on the Company's financial position or results of operations.

The FASB issued Update No. 2013-07, Presentation of Financial Statements Liquidation Basis of Accounting. The objective of this Update is to clarify when an entity should apply the liquidation basis of accounting and to provide principles for the measurement of assets and liabilities under the liquidation basis of accounting, as well as any required disclosures. These amendments were effective for entities that determine liquidation is imminent during annual reporting periods beginning after December 15, 2013, and interim reporting periods therein. Entities should apply the requirements prospectively from the day that liquidation becomes imminent. The adoption of this Statement did not have a material effect on the Company's financial position or results of operations.

The FASB issued Update No. 2013-11, Income Taxes (Topic 740) Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists. The amendments in this ASU provide guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, similar tax loss, or tax credit carryforward exists. The amendments were effective for fiscal years, and interim periods within those years, beginning after December 15, 2013 and should be applied prospectively to all unrecognized tax benefits that exist at the effective date. The adoption of this Statement did not have a material effect on the Company's financial position or results of operations.

## **IntelGenx Technologies Corp.**

### **Notes to Consolidated Financial Statements**

**December 31, 2014 and 2013**

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

#### **3. Adoption of New Accounting Standards (Cont d)**

The FASB has issued ASU No. 2014-17 which provides an acquired entity with an option to apply pushdown accounting in its separate financial statements upon occurrence of an event in which an acquirer obtains control of the acquired entity. The amendments were effective on November 18, 2014. After the effective date, an acquired entity can make an election to apply the guidance to future change-in-control events or to its most recent change-in-control event. However, if the financial statements for the period in which the most recent change-in-control event occurred have already been issued or made available to be issued, the application of this guidance would be a change in accounting principle.

#### **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.

In August 2010, the Company entered into a joint development and commercialization agreement with RedHill Biopharma ( RedHill ), an Israeli company, for an anti-migraine product based upon the Company's VersaFilm technology. In accordance with the terms of the agreement, RedHill made up-front and milestone payments in the aggregate amount of \$800 thousand, of which \$200 thousand was received by the Company in 2013 upon the filing of an NDA and acceptance of the filing by the U.S. Food and Drug Administration. RedHill is required to make additional milestone payments of \$500 thousand upon receipt of FDA marketing approval for the product, together with royalties and / or a share of profits upon commercialization.

## IntelGenx Technologies Corp.

### Notes to Consolidated Financial Statements

December 31, 2014 and 2013

(Expressed in U.S. Funds)

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

In December 2011, the Company entered into a co-development and commercialization agreement with Par Pharmaceutical, Inc. ("Par"), a US company, for a generic formulation of buprenorphine and naloxone Sublingual Film, utilizing the Company's VersaFilm technology. The reference listed drug is Suboxone® (buprenorphine and naloxone) Sublingual Film and is indicated for the maintenance treatment of opioid dependence. In accordance with the terms of the agreement, IntelGenx has received upfront and milestone payments in the aggregate amount of \$750 thousand, of which \$250 thousand was received by the Company in 2014 following acceptance by the FDA of the ANDA submission. The agreement provides for additional, undisclosed, milestone payments, together with a share of profits upon commercialization.

In February 2012, the Company entered into a license agreement with Edgemont Pharmaceuticals LLC (Edgemont), a US company, for the commercialization Forfivo XL® in the United States. In accordance with the terms of the agreement, IntelGenx has received upfront and milestone payments in the aggregate amount of \$3.25 million to date, and will be eligible for additional milestones upon achieving certain sales and exclusivity targets of up to a further \$26.5 million.

In January 2014, the Company entered into another development and commercialization agreement with Par for two new products utilizing the Company's VersaFilm technology. Under the terms of the agreement, Par has obtained certain exclusive rights to market and sell IntelGenx' products in the USA. In exchange IntelGenx received an undisclosed upfront payment and has received certain undisclosed development milestones and will receive additional milestone payments, together with a share of the profits, upon commercialization. In accordance with confidentiality clauses contained in the agreement, the specifics of the product descriptions and financial terms of the transaction remain confidential.

#### Product Sales:

The Company launched Forfivo XL® in the USA in October 2012 under a licensing partnership with Edgemont. Under the terms of the license agreement, the commercial launch of Forfivo XL® triggered launch-related milestone payments for IntelGenx of up to \$4.0 million, of which \$1 million was invoiced by the Company and recognized as revenue in the fourth quarter of 2012. Additional milestones of up to a further \$23.5 million are payable upon achieving certain sales and exclusivity targets and the Company commenced receiving royalties from sales of the product in the first quarter of 2013. Royalty income from sales of Forfivo XL® totaled \$463 thousand in 2014 compared with \$171 thousand in 2013.

In the fourth quarter of 2014, Edgemont exercised its right to extend the license for the exclusive marketing of Forfivo XL®, for which the Company invoiced \$1.25 million to Edgemont and recognized as deferred revenue, to be amortized in income from October 2014 through September 2015. In addition, upon entering into the licensing partnership, Edgemont paid the Company an upfront fee of \$1 million, which the Company recognized as deferred license revenue. The deferred license revenue is being amortized in income over the period where sales of Forfivo XL® are expected to be exclusive. As a result of this policy, the Company recognized revenue in the aggregate amount of \$621 thousand in 2014 and has a deferred revenue balance of \$1.2 million at December 31, 2014 that has not been recognized as revenue.



## **IntelGenx Technologies Corp.**

### **Notes to Consolidated Financial Statements December 31, 2014 and 2013 (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, 2014 accounts receivable (2013: \$Nil).



## IntelGenx Technologies Corp.

### Notes to Consolidated Financial Statements

December 31, 2014 and 2013

(Expressed in U.S. Funds)

Summary of Significant Accounting Policies (Cont d)

#### Investment Tax Credits

Investment tax credits relating to qualifying expenditures are recognized in the accounts at the time at which the related expenditures are incurred and there is reasonable assurance of their realization. Management has made estimates and assumptions in determining the expenditures eligible for investment tax credits claimed.

#### 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.

#### Impairment of Long-lived Assets

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

## IntelGenx Technologies Corp.

### Notes to Consolidated Financial Statements

December 31, 2014 and 2013

(Expressed in U.S. Funds)

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

##### 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, 2014 and 2013**

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

#### **4. Summary of Significant Accounting Policies (Cont d) Share-Based Payments**

The Company accounts for share-based payments to employees in accordance with the provisions of FASB ASC 718 "Compensation - Stock Compensation" and accordingly recognizes in its financial statements share-based payments at their fair value. In addition, the Company will recognize in the financial statements an expense based on the grant date fair value of stock options granted to employees. The expense will be recognized on a straight-line basis over the vesting period and the offsetting credit will be recorded in additional paid-in capital. Upon exercise of options, the consideration paid together with the amount previously recorded as additional paid-in capital will be recognized as capital stock. The Company estimates its forfeiture rate in order to determine its compensation expense arising from stock-based awards. The Company uses the Black-Scholes option pricing model to determine the fair value of the options.

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

#### **Loss Per Share**

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

## **IntelGenx Technologies Corp.**

### **Notes to Consolidated Financial Statements**

**December 31, 2014 and 2013**

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

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

##### **Fair Value Measurements**

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

Level 1: Quoted market prices in active markets for identical assets or liabilities.

Level 2: Observable market based inputs or unobservable inputs that are corroborated by market data.

Level 3: Unobservable inputs that are not corroborated by market data.

In determining the appropriate levels, the Company performs a detailed analysis of the assets and liabilities that are subject to ASC 820. At each reporting period, all assets and liabilities for which the fair value measurement is based on significant unobservable inputs are classified as Level 3. There are no assets or liabilities measured at fair value as at December 31, 2014.

##### **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 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 update on its consolidated financial statements.

## IntelGenx Technologies Corp.

### Notes to Consolidated Financial Statements

December 31, 2014 and 2013

(Expressed in U.S. Funds)

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

ASU 2014-13, Consolidation (Topic 810): Measuring the Financial Assets and the Financial Liabilities of a Consolidated Collateralized Financing Entity

The FASB has issued ASU No. 2014-13 which will apply to a reporting entity that is required to consolidate a collateralized financing entity under the Variable Interest Entities guidance. The fair value of the financial assets of a collateralized financing entity, as determined under GAAP, may differ from the fair value of its financial liabilities even when the financial liabilities have recourse only to the financial assets. Before this ASU, there was no specific guidance in GAAP on how a reporting entity should account for that difference. The amendments in this ASU provide an alternative to Topic 820, Fair Value Measurement, for measuring the financial assets and the financial liabilities of a consolidated collateralized financing entity to eliminate that difference. The amendments in this ASU are effective for public business entities for annual periods, and interim periods within those annual periods, beginning after December 15, 2015. Early adoption is permitted as of the beginning of an annual period. The adoption of ASU 2014-13 is not expected to have a material effect on the Company's financial position or results of operations.

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 ASU-2014-12 is not expected to have material effect on the Company's financial position or results of operations.

ASU No. 2014-09, Revenues from Contracts with Customers (Topic 606)

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.



## IntelGenx Technologies Corp.

### Notes to Consolidated Financial Statements

December 31, 2014 and 2013

(Expressed in U.S. Funds)

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

For a public entity, the amendments in this ASU are effective for annual reporting periods beginning after December 15, 2016, including interim periods within that reporting period. This ASU is to be applied retrospectively, with certain practical expedients allowed. Early application is not permitted. The Company is currently evaluating the impact of this update on its consolidated financial statements.

ASU No. 2014-08, Presentation of Financial Statements (Topic 205) and Property, Plant, and Equipment (Topic 360): Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity

The FASB has issued ASU No. 2014-08 which enhance 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 expanded 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 are effective in the first quarter of 2015 for public organizations with calendar year ends. Early adoption is permitted. The adoption of ASU-2014-08 is not expected to have material effect on the Company's financial position or results of operations.

## IntelGenx Technologies Corp.

### Notes to Consolidated Financial Statements December 31, 2014 and 2013 (Expressed in U.S. Funds)

#### 5. Leasehold Improvements and Equipment

In US\$ thousands	Cost	Accumulated Depreciation	2014 Net Carrying Amount	2013 Net Carrying Amount
Manufacturing equipment	\$ 520	\$ 0	\$ 520	\$ 446
Laboratory and office equipment	570	329	241	121
Computer equipment	57	42	15	11
Leasehold improvements - current premises	63	63	0	0
Leasehold improvements - future premises	207	0	207	10
	\$ 1,417	\$ 434	\$ 983	\$ 588

As of December 31, 2014 no depreciation has been recorded on manufacturing equipment as this equipment is being acquired for the Company's new manufacturing facility and is therefore not currently in use.

Leasehold improvements carried out on our current premises have been fully depreciated. IntelGenx has invested approximately \$207 thousand related to leasehold improvement activities for new premises that the Company plans to occupy in the third quarter of 2015. Depreciation of this asset will commence upon occupation of the premises by the Company.

#### 6. Intangible Assets

As of December 31, 2014 NDA acquisition costs of \$46 thousand (December 31, 2013: \$79 thousand) were recorded as intangible assets on the Company's balance sheet and represent the net book value of the final progress payment related to the acquisition of 100% ownership of Forfivo XL®. The asset is being amortized over its estimated useful life of 39 months and the Company commenced amortization upon commercial launch of the product in October 2012.

#### 7. Deferred License Revenue

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

Upon entering into the licensing agreement with Edgemont Pharmaceuticals the Company received an upfront fee of \$1 million, which the Company recognized as deferred license revenue. This amount is being amortized in income over a period of 39 months, commencing October 2012, which is the minimum period where sales of Forfivo XL® are expected to be exclusive.



## **IntelGenx Technologies Corp.**

### **Notes to Consolidated Financial Statements**

**December 31, 2014 and 2013**

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

#### **7. Deferred License Revenue (Cont d)**

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, to be amortized in income from October 2014 through September 2015.

As at December 31, 2014, the Company has a deferred revenue balance of \$1,245 thousand (December 31, 2013: \$616 thousand) that has not been recognized as revenue.

#### **8. Commitments**

The Company currently operates out of a 3,500 square feet leasehold facility consisting of laboratories and office space at 6425 Abrams, Saint-Laurent, Quebec. The monthly rent for this property is approximately \$2 thousand. The original lease agreement expired in August 2009, since when it has been extended for varying periods. The most recent extension is defined as the day immediately preceding the fulfillment of certain conditions relating to the occupation of new leased premises at 6420 Abrams.

On October 1, 2009, the Company signed an agreement with Little Gem Life Science Partners for investor relation services in the USA. Under the terms of the agreement, the Company was required to pay \$4.5 thousand per month to Little Gem Life Science Partners. The Company renegotiated the agreement in May 2012 and reduced payments to \$2.5 thousand per month. The agreement automatically renews unless specifically terminated.

## IntelGenx Technologies Corp.

### Notes to Consolidated Financial Statements

December 31, 2014 and 2013

(Expressed in U.S. Funds)

#### 8. Commitments (Cont d)

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.

#### 9. Capital Stock

	2014	2013
Authorized -		
100,000,000 common shares of \$0.00001 par value		
20,000,000 preferred shares of \$0.00001 par value		
Issued -		
63,465,255 (December 31, 2013: 60,984,267) common shares	\$ 635	\$ 610

On December 16, 2013, as part of a registered public offering, the Company issued approximately 7.9 million shares of common stock at \$0.4419 per share, and five-year warrants to purchase up to approximately 7.9 million shares of common stock, for aggregate gross proceeds of approximately US\$3.5 million. Each warrant entitles the holder to purchase one common share at an exercise price of \$0.5646 per common share and expires 60 months after the date of issuance. Proceeds were allocated between the common shares and the warrants based on their relative fair value. The common shares were recorded at a value of \$1,808 thousand. (See note 10 for the portion allocated to the warrants).

The Company paid an agent cash commissions in the amount of approximately \$210 thousand, representing 6% of the aggregate gross proceeds received by the Company, plus expenses in the amount of approximately \$35 thousand, and issued warrants to the agent to purchase 475,221 shares of common stock, representing 6% of the amount of shares sold in the public offering. Each warrant entitles the holder to purchase one common share at an exercise price of \$0.5646 per common share and expires 48 months after the date of issuance.

In addition, the Company paid approximately \$272 thousand in cash consideration for other transaction costs, which have been reflected as a reduction of the common shares and the warrants based on their relative fair values.

No stock options were exercised in the year ended December 31, 2014. In the year ended December 31, 2013 a total of 75,000 stock options were exercised for 75,000 common shares having a par value of \$0 thousand in aggregate, for cash consideration of \$31 thousand, resulting in an increase in additional paid-in capital of \$31 thousand.

## IntelGenx Technologies Corp.

### Notes to Consolidated Financial Statements

December 31, 2014 and 2013

(Expressed in U.S. Funds)

#### 9. Capital Stock (cont'd)

In the year ended December 31, 2014 a total of 2,480,988 (2013: 3,098,500) warrants were exercised for 2,480,988 (2013: 3,098,500) common shares having a par value of \$Nil (2013: \$1 thousand) in aggregate, for cash consideration of approximately \$1,619 thousand (2013: \$1,465 thousand), resulting in an increase in additional paid-in capital of approximately \$1,619 thousand (2013: \$1,464 thousand).

#### 10. 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.

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.

## IntelGenx Technologies Corp.

### Notes to Consolidated Financial Statements

December 31, 2014 and 2013

(Expressed in U.S. Funds)

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

On April 24, 2013 the Company granted 480,000 stock options to an officer to purchase common shares. The stock options are exercisable at \$0.65 per share and vest on December 31, 2015. The stock options were accounted for at their fair value, as determined by the Black-Scholes valuation model, of approximately \$157 thousand, using the following assumptions:

Expected volatility	78%
Expected life	3.83 years
Risk-free interest rate	0.34%
Dividend yield	Nil

On April 24, 2013 the Company granted 200,000 stock options to an officer to purchase common shares. The stock options are exercisable at \$0.65 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 \$59 thousand, using the following assumptions:

Expected volatility	77%
Expected life	3.13 years
Risk-free interest rate	0.34%
Dividend yield	Nil

On August 6, 2013 the Company granted 35,000 stock options to a non-employee director to purchase common shares. The stock options are exercisable at \$0.65 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 \$9 thousand, using the following assumptions:

Expected volatility	75%
Expected life	3.13 years
Risk-free interest rate	0.62%
Dividend yield	Nil

On December 3, 2013 the Company granted 75,000 stock options to a non-employee director to purchase common shares. The stock options are exercisable at \$0.52 per share and vest over 2 years at 25% every six months. The stock options were accounted for at their fair value, as determined by the Black-Scholes valuation model, of approximately \$16 thousand, using the following assumptions:

Expected volatility	67%
Expected life	3.13 years
Risk-free interest rate	0.58%
Dividend yield	Nil

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## IntelGenx Technologies Corp.

### Notes to Consolidated Financial Statements

December 31, 2014 and 2013

(Expressed in U.S. Funds)

#### 10. Additional Paid In Capital (Cont d)

On December 3, 2013 the Company granted 100,000 stock options to an officer to purchase common shares. The stock options are exercisable at \$0.52 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 \$21 thousand, using the following assumptions:

Expected volatility	67%
Expected life	3.13 years
Risk-free interest rate	0.58%
Dividend yield	Nil

On December 6, 2013 the Company granted an aggregate of 100,000 stock options to four employees to purchase common shares. The stock options are exercisable at \$0.52 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 \$21 thousand, using the following assumptions:

Expected volatility	67%
Expected life	3.13 years
Risk-free interest rate	0.64%
Dividend yield	Nil

On December 8, 2014 the Company granted an aggregate of 175,000 stock options to three non-employee directors, two officers, and two employees to purchase common shares. 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

During the year ended December 31, 2013 a total of 75,000 stock options were exercised for 75,000 common shares having a par value of \$0 thousand in aggregate, for cash consideration of \$31 thousand, resulting in an increase in additional paid-in capital of \$31 thousand. The intrinsic value of the stock options exercised, as at the dates of exercise, totaled \$20 thousand. No stock options were exercised in the year ended December 31, 2014.

## IntelGenx Technologies Corp.

### Notes to Consolidated Financial Statements December 31, 2014 and 2013 (Expressed in U.S. Funds)

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

Information with respect to employees and directors stock option activity for 2013 and 2014 is as follows:

		Number of options	Weighted average exercise price \$
Outstanding	January 1, 2013	915,588	0.59
Granted		990,000	0.61
Forfeited		(45,000)	(0.48)
Expired		(238,088)	(0.80)
Exercised		(25,000)	(0.31)
Outstanding	December 31, 2013	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

Information with respect to consultant s stock option activity for 2013 and 2014 is as follows:

		Number of options	Weighted average exercise price \$
Outstanding	January 1, 2013	150,000	0.55
Granted		-	-
Forfeited		-	-
Expired		-	-
Exercised		(50,000)	(0.47)
Outstanding	December 31, 2013	100,000	0.59
Granted		-	-
Forfeited		-	-
Expired		-	-
Exercised		-	-
Outstanding	December 31, 2014	100,000	0.59



## IntelGenx Technologies Corp.

### Notes to Consolidated Financial Statements

December 31, 2014 and 2013

(Expressed in U.S. Funds)

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

Details of stock options outstanding as at December 31, 2014 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 \$
0.37	75,000	0.04	0.02		75,000	0.03	
0.45	100,000	0.03	0.04		100,000	0.05	
0.51	20,000	0.04	0.01		20,000	0.01	
0.52	50,000	0.06	0.02		50,000	0.03	
0.52	275,000	0.89	0.12		137,500	0.08	
0.53	175,000	0.71	0.08		-	-	
0.54	145,000	0.23	0.06		145,000	0.09	
0.55	50,000	0.02	0.02		50,000	0.03	
0.58	35,000	0.10	0.02		17,500	0.01	
0.60	55,000	0.13	0.03		55,000	0.04	
0.62	50,000	0.04	0.03		50,000	0.04	
0.65	200,000	0.54	0.11		150,000	0.11	
	1,230,000	2.85	0.54	17,865	850,000	0.54	17,865

Stock-based compensation expense recognized in 2014 with regards to the stock options was \$101 thousand (2013: \$114 thousand). As of December 31, 2014, total unrecognized compensation expense related to unvested stock options was \$74 thousand (2013: \$228 thousand), all of which relates to options granted to employees and directors. The amount of \$74 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 \$74 thousand being charged to stock based compensation expense.



## IntelGenx Technologies Corp.

### Notes to Consolidated Financial Statements December 31, 2014 and 2013 (Expressed in U.S. Funds)

#### 10. Additional Paid-In Capital (Cont d) Warrants

On December 16, 2013 the Company issued approximately 7.9 million stock purchase warrants exercisable into approximately 7.9 million common shares at \$0.5646 per share which expire on December 16, 2018. The stock purchase warrants were issued in connection with the December 16, 2013 registered public offering described in note 9. The stock purchase warrants were valued at \$1,305 thousand based on their relative fair value, as determined by the Black-Scholes valuation model using the assumptions below:

Expected volatility	80%
Expected life	5 years
Risk-free interest rate	1.55%
Dividend yield	Nil

On December 16, 2013 the Company issued approximately 0.5 million agents stock purchase warrants exercisable into approximately 0.5 million common shares at \$0.5646 per share which expire on December 11, 2017. The stock purchase warrants were issued in connection with the December 16, 2013 registered public offering described in note 9. The stock purchase options were valued at \$100 thousand based on their relative fair value, as determined by the Black-Scholes valuation model using the assumptions below:

Expected volatility	72%
Expected life	4 years
Risk-free interest rate	1.12%
Dividend yield	Nil

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. In the year ended December 31, 2013 a total of 3,098,500 warrants were exercised for 3,098,500 common shares having a par value of \$1 thousand in aggregate, for cash consideration of approximately \$1,465 thousand, resulting in an increase in additional paid-in capital of approximately \$1,464 thousand.

## IntelGenx Technologies Corp.

### Notes to Consolidated Financial Statements December 31, 2014 and 2013 (Expressed in U.S. Funds)

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

Information with respect to warrant activity for 2012 and 2013 is as follows:

	Number of warrants (All Exercisable) \$	Weighted average exercise price
Outstanding January 1, 2013	6,104,165	0.5938
Warrants attached to registered public offering	7,920,346	0.5646
Agents warrants attached to registered public offering	475,221	0.5646
Exercised	(3,098,500)	(0.4741)
Agents warrants expired	(257,500)	(0.4741)
Outstanding - December 31, 2013	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

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## IntelGenx Technologies Corp.

### Notes to Consolidated Financial Statements

December 31, 2014 and 2013

(Expressed in U.S. Funds)

#### 11. Income Taxes

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

	2014	2013
Statutory income taxes	\$ (429)	\$ (442)
Net operating losses for which no tax benefits have been recorded	238	278
Excess of depreciation over capital cost allowance	9	11
Non-deductible expenses	26	56
Undeducted research and development expenses	181	142
Investment tax credit	(25)	(45)
	\$ -	\$ -

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

	2014	2013
Leasehold improvements and equipment	\$ 9	\$ 14
Net operating losses carryforward	2,582	2,407
Undeducted research and development expenses	1,355	1,283
Non-refundable tax credits carryforward	1,102	1,098
	5,048	4,802
Valuation allowance	(5,048)	(4,802)
	\$ -	\$ -

The valuation allowance at December 31, 2013 was \$4,802 thousand. The net change in the valuation allowance during the period ended December 31, 2014, was an increase of \$246 thousand. In assessing the realizability of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred income tax assets will not be realized. The ultimate realization of deferred income tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of deferred income tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. Based on consideration of these items, management has determined that enough uncertainty exists relative to the realization of the deferred income tax asset balances to warrant the application of a full valuation allowance as of December 31, 2014.

# IntelGenx Technologies Corp.

## Notes to Consolidated Financial Statements

December 31, 2014 and 2013

(Expressed in U.S. Funds)

### 11. Income Taxes (Cont d)

There were Canadian and provincial net operating losses of approximately \$9,530 thousand (2013: \$8,874 thousand) and \$9,683 thousand (2013: \$9,040 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 2034. A portion of the net operating losses may expire before they can be utilized.

As at December 31, 2014, the Company had non-refundable tax credits of \$1,100 thousand (2013: \$1,098 thousand) of which \$20 thousand is expiring in 2017, \$194 thousand is expiring in 2018, \$170 thousand is expiring in 2019, \$145 thousand is expiring in 2020, \$154 thousand is expiring in 2021, \$193 thousand is expiring in 2022, \$129 thousand is expiring in 2023 and \$95 thousand is expiring in 2024 and undeducted research and development expenses of \$4,805 thousand (2013: \$4,354 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.

### 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, 2014:

<b>Tax Jurisdictions</b>	<b>Tax Years</b>
Federal - Canada	2011 and onward
Provincial - Quebec	2011 and onward
Federal - USA	2011 and onward

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## IntelGenx Technologies Corp.

### Notes to Consolidated Financial Statements December 31, 2014 and 2013 (Expressed in U.S. Funds)

#### 12. Statement of Cash Flows Information

In US\$ thousands	2014	2013
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#### Additional Cash Flow Information:

Interest paid	\$ 5	\$ 5
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#### 13. Related Party Transactions

Included in management salaries are \$29 thousand (2013: \$10 thousand) for options granted to the Chief Executive Officer, \$Nil (2013: \$39 thousand) for options granted to the Chief Operating Officer, and \$43 thousand (2013: \$29 thousand) for options granted to the Chief Financial Officer under the 2006 Stock Option Plan and \$17 thousand (2013: \$10 thousand) for options granted to non-employee directors.

Included in general and administrative expenses are director fees of \$187 thousand (2013: \$80 thousand) comprising an annual stipend and for payments for attendance at board meetings and audit committee meetings.

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.

#### 14. Basic and Diluted Loss Per Common Share

Basic and diluted loss per common share is calculated based on the weighted average number of shares outstanding during the period. The warrants and stock options have been excluded from the calculation of diluted loss per share since they are anti-dilutive.

#### 15. Subsequent Events

Subsequent to the end of the year, on March 16, 2015 the Company received CAD\$500 thousand (approximately \$430 thousand) in cash as part of a credit facility of up to CAD\$3.5 million (approximately \$3.0 million) negotiated with BMO Bank of Montreal. The credit facility is supported by a 50% guarantee under the Export Guarantee Program from Export Development Canada. Disbursement of the remaining CAD\$3.0 million (\$2.6 million) is subject to review in August 2015 of the Company's operating results for the first 6 months of 2015. 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 Company will use the funds for the purchase and installation of new equipment for its new, state-of-the-art, manufacturing facility.

## **IntelGenx Technologies Corp.**

### **Notes to Consolidated Financial Statements**

**December 31, 2014 and 2013**

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

#### **15. Subsequent Events (Cont d)**

On March 16, 2015 the Company placed an order for 2 packaging machines to be manufactured and installed in the Company's new, state-of-the-art, manufacturing facility. The purchase order, in the aggregate amount of Euros 1.5 million (approximately \$1.6 million), requires immediate payment of a 20% deposit with the balance to be paid upon completion of each machine. The laboratory packaging machine is expected to be delivered in Q3, 2015 and the commercial packaging machine is expected to be delivered in Q4, 2015.

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