IntelGenx Technologies Corp. Form 10-K March 25, 2009

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 10-K

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

For the fiscal year ended December 31, 2008

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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.

(Name of small business issuer as specified in its charter)

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

6425 Abrams, Ville Saint Laurent, Quebec (Address of principal executive offices)

(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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes

o 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

**87-0638336** (I.R.S. Employer Identification No.)

> H4S 1X9 (Zip Code)

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

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.

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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 o Accelerated filer o Non-accelerated filer o Smaller reporting company x (Do not check if a smaller reporting company) Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o No x

As of June 30, 2008, the aggregate market value of the registrant s voting and non-voting common equity held by non-affiliates of the registrant was \$8,967,637 based on the closing price of the registrant s common shares of U.S. \$0.93, as reported on the OTC Bulletin Board 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.

ClassOutstanding at March 4, 2009Common Stock, \$.00001 par value20,850,002 sharesDocuments incorporated by reference: None.

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Terminology and references

In this Annual Report on Form 10-K, the words Company, IntelGenx, we, us, and our, refer collectively to Inter-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 CDN 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, 2008 closing rate reported by the Bank of Canada, being U.S. \$1.00 = C\$1.2180.

### PART I

#### **Cautionary Statement Concerning Forward-Looking Statements**

This Annual Report and the documents we incorporate by reference in this Annual Report contain forward-looking statements, within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. Any statement that is not a statement of historical fact may be deemed a forward-looking statement. For example, statements containing the words believes, anticipates, estimates, plar would and similar expressions may be forward-looking statements. W expects, intends, may, projects, will, actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. There are a number of important factors and risks that could cause our actual results to differ materially from those indicated by these forward-looking statements, including but not limited to those discussed in Item 1A Risk Factors. You should read these factors and the other cautionary statements made in this Form 10-K Annual Report and in the documents we incorporate by reference as being applicable to all related forward-looking statements wherever they appear in this Annual Report and in any documents incorporated by reference. We do not assume any obligation to update any forward-looking statements.

### Item 1. Business.

We are a drug delivery company headquartered in Montreal (Quebec) which focuses on the development of novel oral immediate release and controlled-release products for the branded and generic pharmaceutical market.

Our product development efforts are based upon three delivery platform technologies: (1) the VersaTab Multilayer Tablet technology (2) the VersaFilm Oral Film technology, and (3) the AdVersa Mucoadhesive Tablet technology. Our Multilayer platform technology allows for the development of oral controlled release products. It is versatile and is aimed at significantly reducing manufacturing costs as compared to competing 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.

Our executive offices are located at 6425 Abrams, Ville Saint-Laurent, Quebec, H4S 1X9, Canada. Our website is located at www.IntelGenx.com. The contents of our website are not otherwise incorporated into this filing.

### **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. 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.

According to a report by CMR International, a pharmaceutical industry research firm, products incorporating drug delivery systems represented 13% of the US \$337 billion global pharmaceutical market. In the United States, sales of drug delivery products totaled \$35 billion in 2006. Of this amount, the orally administered segment of the drug delivery market totaled \$21 billion in sales, according to CMR International. Controlled release (CR) dosage technologies play an important role in the development of orally administered drug delivery systems. Control release technology provides patients with the required amount of medication over a pre-determined, prolonged period of time, preferably over 24 hours. Because of the reduced fluctuation of the active drug in the blood, 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 & Drug Administration (the FDA ) and/or other regulatory bodies, as well as for the marketing and distribution of the products. On a case-by-case basis, IntelGenx 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 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) a Multilayer Tablet technology (2) an oral film technology, and (3) a Mucoadhesive Tablet technology. Our Multilayer 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 ( VersaTab ) 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 erodible layers start to disintegrate, the permeation of 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 oral film technology is made up of a thin (25-35 micron) polymeric film comprised of USP components that are approved by the FDA for use in food, pharmaceutical, and cosmetic products. Derived from the edible film technology used for breath strips and initially developed for the instant delivery of savory flavors to food substrates, the VersaFilm technology is designed to provide a rapid response relative to existing fast dissolving oral tablets. The VersaFilm technology is intended for indications requiring rapid onset of action, such as migraine, motion sickness, erectile dysfunction, and nausea.

The Mucoadhesive Tablet ( AdVersa ) 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 and greatly reduces the level of drug in the systemic circulation), (ii) it leads to a higher absorption rate 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).

INT0001/2004. This is the most advanced generic product involving our Multilayer technology. Equivalency with the reference product Toprol XL and its European equivalent Beloc-ZOK has been demonstrated *in-vitro*. The product has been tested in phase I studies.

INT0003/2005. We have entered into a partnership with Cary Pharmaceuticals for the development of a once-daily tablet product containing an antidepressant and a nicotine antagonist. The product is intended for smoking cessation.

INT0004/2006. The development of an antidepressant has been completed. A regulatory submission file for a 505(b)(2) NDA submission is in preparation.

INT0005/2005. We are developing a bilayer tablet containing a fixed-dose combination of a non-steroidal anti-inflammatory drug and a synthetic prostaglandin. Formulation development is completed and a pilot bio batch has been manufactured.

INT0006/2005. We have entered into a development and licensing agreement with Azur Pharma for the development and manufacture of a prenatal vitamin supplement. The product was developed using our proprietary technology. The product was launched in the United States during the fourth quarter of 2008 under the brand name Gesticare®.

INT0010/2006. We have entered into an agreement with Cannasat Therapeutics Inc. for the development of a buccal mucoadhesive tablet product containing a cannabinoid-based drug for the treatment of neuropathic pain and nausea in cancer patients undergoing chemotherapy.

INT0014/2008 Under a development agreement with Cannasat Therapeutics Inc., we are developing a controlled-release tablet containing Cannabidiol for the treatment of schizophrenia.

INT0007/2006. 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 erectile dysfunction (ED).

INT0008/2007. 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 migraine.

INT0015/2008. 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 panic attacks.

INT0018/2008. We have entered into a development and licensing agreement with Circ Pharma Ltd. to formulate, manufacture and supply a novel drug product, based upon our proprietary Versatab technology, for the treatment of hyperlipidemia. The product is currently in the early development stage.

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

Product	Application	Status of Development
INT0001/2004	CHF, Hypertension	Pivotal batches in preparation
INT0003/2005	Smoking cessation	Pilot biostudy completed
INT0004/2006	Antidepressant	Pivotal batches completed
INT0010/2006	Neuropathic pain	Pilot biostudy completed
INT0006/2005	Prenatal vitamin supplement	Product launched in USA Q4, 2008
INT0005/2005	Osteoarthritis	Pilot batch completed.
INT0007/2006	ED	Formulation development ongoing
INT0008/2007	Migraine	Formulation development ongoing
INT0014/2008	Schizophrenia	Formulation development ongoing
INT0015/2008	Panic Attack	Formulation development ongoing
INT0018/2008	Hyperlipidemia	Formulation development ongoing
Growth Strategy		

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

# Lifecycle Management Opportunities

We are seeking to position our delivery technologies as an opportunity for lifecycle management of products for which the 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 Food, Drug and Cosmetic Act. Such applications, known as a 505(b)(2) NDA s , 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. 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 these so-called 505(b)(2)

products represent a viable business opportunity for us.

### Generic Drugs with High Barriers to Entry

We will also plan to pursue the development generic drugs that have certain barriers to entry, such as where product development and manufacturing are 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. An example of such a product is our pro INT0005/2005, a fixed-dose combination medication requiring complex formulation and manufacturing technology.

#### Nutritional Supplement Products

We plan to develop additional products for the nutritional supplement market based upon our proprietary drug delivery technologies. The market for these supplements is large, with little differentiation between products. Our proprietary technology is aimed at increasing the absorption rate of active ingredients. We believe that supplements represent attractive short term revenue opportunities since they are not as regulated as pharmaceutical products and do not require FDA approval.

#### Development of New Drug Delivery Technologies

The rapidly disintegrating film technology contained in our Quick Release Wafer and our mucosal adhesive tablet are 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.

#### 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 Biovail Corporation, Labopharm Inc., and Flamel Technologies S.A., have longer operating histories and greater financial, technical, marketing, legal and other resources than us. 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 in or are planning to enter the markets we compete in.

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

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 in order to further strengthen our technology base and to develop the ability to manufacture our products through our manufacturing partner at competitive costs.

# **Our Competitive Strengths**

We believe that our key competitive strengths include:

Our intellectual property;

The versatility of our drug delivery technology; and

The potential manufacturing cost savings associated with our technology.

#### **Manufacturing Partnership**

We have entered into a collaboration agreement with Keata Pharma Inc., a wholly owned subsidiary of PharmEng International Inc., based in Markham, Ontario. Under this agreement, Keata Pharma is our preferred supplier for the manufacturing of clinical test batches and commercial products. We also have a reciprocal relationship whereby we recommend Keata Pharma to our partners for pharmaceutical manufacturing services, and Keata Pharma promotes our product development services to pharmaceutical companies.

#### **Dependence on Major Customers**

We do not rely on any one or a few major customers for our end products. However, we depend upon a limited number of partners to develop our products, to provide funding for the development of our products, and to assist in obtaining regulatory approvals that are required in order to commercialize these 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) through non-disclosure agreements, license agreements and appropriate contractual restrictions and controls on the distribution of information, (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 three (3) patents and have an additional seven (7) pending patent applications pending, as described below. The patents expire 20 years after submission of the initial application.

Patent No.	Title	Subject	Date submitted / issued
US 6,231,957	Rapidly disintegrating flavor wafer for flavor enrichment		Issued May 15, 2001
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
US 7,132,113	Flavored film	Composition and manufacturing method of multi-layered films	Issued April 16, 2002
US Appl. 2007/0190144	Multilayer Tablet	Formulation and Method of Preparation of Multilayered Tablets	Published August 16, 2007
US Appl. 2007/0128272	Multi-Vitamin And Mineral Supplement	Formulation And Method of Preparation of Prenatal Multivitamin Supplement	Published June 7, 2007
PCT/CA2006/0003 36 ; US Appl. 11/403,262	Delayed Release Oral Dosage Form And Method Of Making Same	Formulation And Method Of Making Bilayer Tablets Containing Delayed-Release Diclofenac And Misoprostol	·
US Appl. 11/782,838 PCT/IB2007/03950	Controlled Release Pharmaceutical Tablets	Formulation And Method Of Making Tablets Containing Bupropion And	<sup>-</sup> July 2006

		Mecamylamine
US Appl. Make Special 11/828,287	Stabilized sustained- release Bupropion and Bupropion / Mecamylamine tablets	Formulation And Method Of August 2007 Making Tablets Containing Bupropion And Mecamylamine
US Provisional Appl. Attorney Docket INT34 P-311	Buccal And Sublingual Dosage Forms	Formulation And Method of July 2007 Preparation of mucoadhesive tablets containing THC
US Provisional Appl. Attorney Docket INT34 P-310	Cannabinoid Complexes	Formulation And Method of July 2007 Preparation of gamma- cyclodextrin complexes containing CBD 7

### **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, labelling, 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 New Drug Application, or NDA, or an Abbreviated New Drug Application, or 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 GMPs 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 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, 2008 were \$1,779,741 as compared to \$603,374 for the year ended December 31, 2007.

### **Environmental Regulatory Compliance**

We believe that we are in compliance with all material 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 9 full time employees.

#### Item 1A. Risk Factors.

The risks described below should be considered when evaluating our business and future prospects. Should any of the following risks actually occur, our business, financial condition and results of operations could be materially and adversely affected. In that event, the market price of our common stock could decline and investors could lose all or a portion of the value of their investment in our common stock.

#### **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 released 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 \$4,725,045 since our inception in 2003 through December 31, 2008. To date, these losses have been financed principally through sales of equity securities, long-term debt and debt from related parties. Our revenues for the years ended December 31, 2008, December 31, 2007, December 31, 2006, December 31, 2005 and December 31, 2004 were \$976,610, \$862,731, \$265,901, \$19,990 and \$257,374 respectively. Our revenues consisted primarily of development fee revenues from five clients and have 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 will likely require additional funding in order to sustain our operations in the near term.

### We may incur losses associated with foreign currency fluctuations.

The majority of our expenses are paid in Canadian dollars, while our revenues are primarily 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 will be required to raise additional funds in the future through private or public sales of equity securities or the incurrence of additional 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.

Our ability to raise capital will be severely hampered by adverse changes in general economic market conditions. The world economy is currently undergoing unprecedented turmoil amid stock market volatility, difficulties in the financial services sector, tightening of the credit markets, softness in the housing markets, concerns of inflation and deflation, reduced corporate profits and capital spending, reduced consumer spending, and continuing economic uncertainties. This turmoil and the uncertainty about future economic conditions could negatively impact our ability to obtain debt or equity financing of our operations. The cost and availability of credit has been and may continue to be adversely affected as concerns about the stability of the markets generally and the strength of counterparties specifically has led many lenders and institutional investors to reduce, and in some cases, cease, to provide funding to borrowers. If these market and economic conditions continue, they may limit our ability to access the capital markets to meet liquidity and capital expenditure requirements. We cannot predict the timing, strength or duration of the economic downturn.

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, particularly Horst G. Zerbe, our Chairman of the Board and Chief Executive Officer, 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 provided by 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 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. This would reduce our revenues received on the products.

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.

# 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 Biovail Corporation, Labopharm Inc., and Flamel Technologies S.A. 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 are dependent upon sales outside the United States, which are subject to a number of risks.

Our future results of operation could be harmed by risks inherent in doing business in international markets, including:

Unforeseen changes in regulatory requirements;

Weaker intellectual property rights protection in some countries;

New export license requirements, changes in tariffs or trade restrictions; and

Political and economic instability in our target markets.

#### We rely upon third-party manufacturers, which puts us at risk for supplier business interruptions.

We have entered into agreements with third party manufacturers to manufacture certain of our products once we complete development and after we receive regulatory approval. If our third-party manufacturers fail to perform, our ability to market products and to generate revenue would be adversely affected. Our failure to deliver products in a timely manner could lead to the dissatisfaction of our distribution partners and damage our reputation, causing our distribution partners to cancel existing agreements with us and to stop doing business with us.

The third-party manufacturers that we depend on to manufacture our products are required to adhere to FDA regulations regarding current Good Manufacturing Practices, 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 against them by regulatory agencies and jeopardize our ability to obtain products on a timely basis.

#### 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 collaborator'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 collaborators, 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 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 withdrawal 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 or criminal sanctions could be imposed for our failure to comply with regulatory standards or the occurrence of unforeseen problems following initial marketing.

The third party manufacturers that we depend on to manufacture our products are required to adhere to FDA regulations regarding cGMP and similar regulations in other countries, 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.

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 payors as clinically useful, cost-effective and safe. No product based on our technologies is marketed in the United States, so there can be no 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.

#### 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 and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. If we do not pay any dividends on our common stock, our stockholders will be able to profit from an investment only if the price of the stock appreciates before the stockholder sells it.

#### **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 3 U.S. patents and have applied for 7 US 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 collaborators.

# 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. 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 Abbreviated New Drug Applications or New Drug Applications (ANDAs or NDAs) for our controlled release products under development that are covered by one or more patents of the branded product. It is possible 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 the Company's stock price to decline. This could also make it more difficult to raise funds at acceptable levels via future securities offerings.

# We have a concentration of stock ownership and control, and a small number of stockholders have the ability to exert significant control in matters requiring stockholder vote and may have interests that conflict with ours.

Our common stock ownership is highly concentrated. See "Security Ownership of Certain Beneficial Owners and Management." As a result, a relatively small number of stockholders, acting together, have the ability to control all matters requiring stockholder approval, including the election of directors and approval of mergers and other significant corporate transactions. This concentration of ownership may have the effect of delaying, preventing or deterring a change in control of our company. It could also deprive our stockholders of an opportunity to receive a premium for their shares as part of a sale of our company and it may affect the market price of our common stock. In deciding how to vote on such matters, those stockholders' interests may conflict with yours.

#### Our common stock is a high risk investment.

Our common stock has been quoted on the OTC Bulletin Board under the symbol IGXT.OB since January 2007 and has 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 price 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 rules that regulate broker-dealer practices in connection with transactions in penny stocks . These rules further restrict the trading activity and marketability of our common stock.

As a result of the foregoing, our common stock should be considered a high risk investment.

# 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. 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 since there are no broker-dealers who sold our stock in a public offering who would have an incentive to follow 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.

### Item 2. Properties.

We currently occupy 3,100 square feet of leased space at a rate of CAN\$8.64/square foot in an industrial zone in Ville St.-Laurent, Quebec, Canada, under a 5-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. In order to continue to support ongoing product development activities and allow the addition of further development programs, it may be necessary to seek alternative premises in the near future. Management has therefore entered into discussions with the current landlord to look for alternative facilities that would meet our need for additional space at affordable costs.

### Item 3. Legal Proceedings.

There are no 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 actions against us are contemplated or threatened.

#### Item 4. Submission of Matters to a Vote of Security Holders.

During the quarter ended December 31, 2008 no matters were submitted to a vote of security holders.

### PART II

# Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our common stock has been quoted on the OTC Bulletin Board under the symbol IGXT since January 2007. In addition, our common stock has 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 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.

		OTCBB				TSX	
	High (U.S.\$)		Low (U.S.\$)		High (CDN\$)		Low (CDN\$)
2008							
Fourth Quarter	\$ 0.95	\$	0.30	\$	0.90	\$	0.50
Third Quarter	\$ 0.98	\$	0.67	\$	1.04	\$	0.90
Second Quarter	\$ 1.01	\$	0.80	\$	1.00	\$	0.87
First Quarter	\$ 1.02	\$	0.60	\$	N/A	\$	N/A
2007							
Fourth Quarter	\$ 1.05	\$	0.45	\$	N/A	\$	N/A
Third Quarter	\$ 1.90	\$	0.88	\$	N/A	\$	N/A
Second Quarter	\$ 1.31	\$	0.60	\$	N/A	\$	N/A
First Quarter	\$ 1.20	\$	0.68	\$	N/A	\$	N/A
				14			

### Number of Shareholders

On March 4, 2009, there were approximately 75 holders of record of our common shares, 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.

#### **Equity Compensation Plan Information**

#### 2006 Stock Option Plan

A majority of our shareholders approved the 2006 Stock Option Plan at our Annual General Meeting of Stockholders held on August 10, 2006. Under the 2006 Stock Option Plan, up to 1,600,749 shares of common stock may be issued upon the exercise of options granted to directors, management, employees and consultants.

In May of 2008, the term of all options granted under the 2006 Stock Option Plan was amended to provide for a term not to exceed five years, in order to ensure compliance with applicable rules and regulation of the TSX Venture Exchange.

At the Annual General Meeting of Stockholders on September 8, 2008, our shareholders approved an amendment to the 2006 Stock Option Plan in order to increase the number of shares available under the plan by 473,251, to 2,074,000.

As of March 4, 2009, 2,002,676 options have been issued, 191,500 options have been exercised, 50,000 were forfeiture, 62,500 expired and 1,698,676 options remain outstanding under the 2006 Option Plan.

#### **Equity Compensation Plan Information**

Number of Securities to be issued upon	Weighted- Average Exercise Price	Number of securities remaining
exercise of	of outstanding	available for
outstanding	options,	future issuance
options,		under equity
		compensation
		plans
		(excluding
		securities
		reflected in the
		first Two

			columns
Equity Compensation Plans Approved by Security Holders	1,698,676	\$1.01	183,824
Equity Compensation Plans Not Approved by Security Holders	None	None	None
Total	1,698,676	\$1.01	183,824
15			

On September 26, 2006 we granted options to purchase 225,000 shares of common stock to three non-employee directors. These options have an exercise price of \$0.41, vest upon issuance and expire on September 26, 2016. The expire date was subsequently amended to September 26, 2011.

On October 1, 2006 we granted options to purchase up to 69,000 shares of common stock to a consultant. These options have an exercise price of \$0.41, vest upon issuance, and expire on October 1, 2016. The expire date was subsequently amended to September 26, 2011.

On November 9, 2006 we granted options to purchase up to 450,000 shares of common stock to the CFO and a management employee. These options have an exercise price of \$0.41, vest upon issuance, and expire on November 9, 2016. The expire date was subsequently amended to September 26, 2011.

On November 13, 2006 we granted options to purchase up to 250,000 shares of common stock to a consultant. These options have an exercise price of \$0.41, vest over two years at the rate of 25% every six months, and expire on November 13, 2016. The expire date was subsequently amended to September 26, 2011.

On November 16, 2006 we granted options to purchase up to 100,000 shares of common stock to employees and 25,000 options to a consultant. These options have an exercise price of \$0.41, vest over 2 years at the rate of 25% every six months, and expire on November 16, 2016. The expire date was subsequently amended to September 26, 2011.

On August 9, 2007 we granted options to purchase up to 107,500 shares of common stock to four non-employee directors. These options have an exercise price of \$1.15, vest upon issuance, and expire on August 9, 2017. The expire date was subsequently amended to August 9, 2012.

On August 9, 2007 we granted options to purchase up to 75,000 shares of common stock to our Vice President of Business Development. These options have an exercise price of \$1.15, vest over 2 years at the rate of 25% every six months, and expire on August 9, 2017 The expire date was subsequently amended to August 9, 2012.

On August 9, 2007 we granted options to purchase up to 75,000 shares of common stock to our chief financial officer. These options have an exercise price of \$1.15, vest over 2 years at the rate of 25% every six months, and expire on August 9, 2017 The expire date was subsequently amended to August 9, 2012. As the result of the termination of the employment agreement the 75,000 shares to purchase common stock expired un-exercised in November of 2008.

On May 22, 2008 we granted options to purchase up to 51,176 shares of common stock to two of our non-employee directors. These options have an exercise price of \$0.85, vest immediately and expire on May 22, 2013.

On May 29, 2008 we granted options to purchase up to 400,000 shares of common stock to Auctus Capital in consideration for investor relation services. The option grant was subject to shareholder approval to increase the number of shares to be issued under the 2006 Stock Option Plan. The shareholders approved to increase the number of shares by 473,251, to 2,074,000 at the Annual General Meeting on September 8, 2008. The options granted to Auctus Capital have an exercise price of \$1.00, and vest based on a combination of the achievement of certain performance conditions and the passage of time. The options expire on May 29, 2013. Approximately 150,000 options have vested to date.

On September 8, 2008 we granted options to purchase up to 75,000 shares of common stock to a non-employee director of the company. These options have an exercise price of \$0.85, vest immediately and expire on September 8, 2013.

On September 8, 2008 we granted options to purchase up to 100,000 shares of common stock to our chief financial officer. These options have an exercise price of \$0.85, vest over 2 years at the rate of 25% every six months, and

expire on September 8, 2013.

### Item 6. Selected Financial Data.

Not applicable.

#### Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operation.

#### 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 our financial statements that enables investors to better understand our business, to enhance our overall financial disclosures, 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 Intel Corp. This information should be read in conjunction with the accompanying Consolidated Financial Statements and Notes thereto.

### **Company Background**

We are a drug delivery company established in 2003 and headquartered in Montreal, Quebec, Canada, which focuses 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 our 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 product reaches the marketing and distribution stage. The Company 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.

The Company has also undertaken a strategy under which it will work with pharmaceutical companies in order to develop new dosage forms for pharmaceutical products for which patent protection is nearing expiration. Under (505)(b)(2) of the Food, Drug, and Cosmetics Act, the FDA may grant market exclusivity for a term of up to three years of exclusivity following approval of a listed drug that contains previously approved active ingredients but is approved in a new dosage, dosage form, route of administration or combination, 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. (See Government Regulation ).

The Company is currently continuing to develop the existing products in its pipeline and may also perform research and development on other potential products as opportunities arise.

The Company does not currently plan to acquire a manufacturing facility. The Company currently purchases and/or leases, on an as-needed basis, the equipment necessary for performing research and development activities related to its products.

The Company plans to hire new personnel, primarily in the area of research and development, on an as-needed basis as the Company enters into partnership agreements and increases its research and development activities.

### **Key Developments**

The Company achieved a number of milestones in 2008, including the following:

**Private Placement -** In March 2008, the Company completed a private placement of its securities for gross proceeds of US\$2.8 million. The Company issued 4,001,000 Units (Units) at a price of US \$0.70 per unit. Each Unit consists of one share of common stock and one common share purchase warrant. The warrants have an exercise price of US\$1.02 and a term of 24 months.

 $TSX-V \ Listing$  - In May 2008 the Company received approval from the TSX Venture Exchange (the TSX-V) for the listing of its common stock under the trading symbol IGX. The common stock commenced trading on TSX-V at the opening on May 23, 2008. IntelGenx s common stock also continues to be quoted on the OTC Bulletin Board under the symbol IGXT.

**Development and Commercialization of Prenatal Vitamins Supplements -** In January 2008 the Company signed a strategic agreement with Azur Pharma to develop and commercialize prenatal vitamin supplements using the Company s proprietary oral delivery technology. Under the terms of the agreement IntelGenx is responsible for completing the development of the product and is entitled to receive royalties based on Azur s net U.S. revenues from

the product. Azur will be responsible for commercialization and marketing activities in the U.S.

The product was launched in the United States under the brand name Gesticare® in November 2008 and the Company commenced receiving royalty revenue payments in February 2009.

*Strategic Alliance to Develop Cardiovascular Product* - In April 2008 the Company formed a strategic alliance with DAVA Pharmaceuticals Inc (DAVA) to develop and commercialize a generic equivalent to a major cardiovascular product using the Company s proprietary Versatab delivery technology.

Under the terms of the alliance, IntelGenx will be entitled to fees for the development of the product, as well as recurring revenue through a share of DAVA s U.S. gross profit from the product. DAVA will be responsible for commercialization and marketing activities in the U.S.

*Development and Commercialization of Anti-Depressant CPI-300* - In April 2008 the Company ratified a definitive agreement with Cary Pharmaceuticals ( Cary ), originally signed on November 5, 2007, to jointly develop and commercialize the antidepressant product CPI-300.

In accordance with the terms of this Collaborative Agreement, IntelGenx was required to provide funding of \$2 million for completion of the product development. The funding was secured through the closing of a private placement worth \$2.8 million on March 27, 2008. IntelGenx will be entitled to profit sharing upon commercialization of the product.

In July 2008, the Company attended an End-of-Phase II meeting with the FDA with respect to the CPI-300 antidepressant. During this meeting the FDA indicated that it would accept a recently completed pivotal food effect study as sufficient to support a 505(b)(2) NDA ( New Drug Application ) submission. After reviewing the study results, the FDA confirmed that it will accept a labeling that the product may be taken without regard to food. With respect to the remaining clinical program, the FDA confirmed that it will require a single-dose, fasting, two-way crossover study vs. the Reference Listed Drug (RLD) to support the 505(b)(2) NDA submission.

In October 2008 the Company and Cary announced positive results from a clinical trial on its antidepressant CPI-300. The results from the bioequivalence study undertaken in September 2008 confirm that CPI-300 is bioequivalent to the reference product. IntelGenx and Cary anticipate filing a (505(b)(2) NDA in the first quarter of 2009 based on the results of this and the food effect study.

#### **Currency rate fluctuations**

The Company s operating currency is Canadian dollars, while its reporting currency is U.S. dollars. Accordingly, the Company s results of operations and balance sheet position have been affected by currency rate fluctuations. The following management discussion and analysis takes this into consideration whenever material.

			Increase/	Percentage
	2008	2007	(Decrease)	Change
Revenue	\$ 976,610	\$ 862,731	\$ 113,879	13%
Research and Development Expenses	2,085,433	777,773	1,307,660	168%
Research and Development Tax Credit	(305,692)	(174,399)	(131,293)	75%
Management Salaries	551,771	328,513	223,258	68%
General and Administrative Expenses	212,915	166,249	46,666	28%
Professional Fees	695,158	424,817	270,341	64%
Interest and Financing Fees	766,136	349,093	417,043	120%
Foreign Exchange	(122,915)	113,552	(236,467)	N/A
Income taxes	(151,581)	(64,077)	(87,504)	137%
Net Income (Loss)	(2,806,387)	(1,100,793)	(1,705,594)	155%

# Results of Operations - Year ended December 31, 2008 compared to Year ended December 31, 2007.

## Revenue

Total revenue increased \$113,879, or 13%, to \$976,610 for the year ended December 31, 2008 from \$862,731 for the year ended December 31, 2007.

The increase in revenue is primarily attributable to revenues invoiced pursuant to our research and development agreements with our pharmaceutical partners for development milestones achieved, which amounted to \$945,760 in 2008 compared with \$835,376 in the previous year.

Also included within revenue is interest income of \$30,864 earned on the cash proceeds from the sale of our securities in May 2007 and in March 2008. This compares to interest income of \$27,355 in 2007.

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

R&D expenses, net of R&D tax credits, for the year ended December 31, 2008 were \$1,779,741 and represent an increase of \$1,176,367 compared to the year ended December 31, 2007.

Gross R&D expenses for the year ended December 31, 2008 were \$2,085,433, as compared to \$777,773 for the previous year.

Included within R&D expenses for 2008 are approximately \$915,444 of costs related to the development of the CPI-300 pursuant to the collaboration agreement with Cary Pharmaceuticals. These expenses, while significant, are in line with both the project plan and with management s expectations. These expenses include approximately \$500,122 related to clinical trials for the Food Effect Study and the Bioequivalence Study undertaken in recent months.

The remainder of the increase is primarily attributable to the increased drug development activities of our other projects.

Also included within R&D expenses for 2008 are R&D Salaries of \$422,930, approximately \$13,404 of which represents non-cash compensation. This compares to R&D salaries of \$301,935 in 2007, including \$18,187 in non-cash compensation.

For the year ended December 31, 2008, we have recorded estimated Research and Development Tax Credits and refunds of \$305,692, as compared to \$174,399 for 2007.

### Management Salaries and General and Administrative ( G&A ) Expenses

Management salaries increased \$223,258, or 68% in 2008, to \$551,771 from \$328,513 in 2007. General and administrative expenses increased 28%, to \$212,915 in 2008 from \$166,249 in 2007.

The following items are included in management salaries: (i) approximately \$40,572 in non-recurring cash compensation to non employee directors of the Company (no such costs were incurred in 2007) (ii) approximately \$51,727 in non cash compensation in the form of options granted to non-employee directors, as compared to \$76,734 in 2007, and (iii) approximately \$45,483 in non cash compensation resulting from options granted to management employees in 2007 and 2008, as compared to \$21,218 in 2007. The remaining increase in management salaries is attributable to the hiring of a full time Chief Financial Officer and a Vice-President Business Development.

The increase in G&A expenses is primarily attributable to the increase in corporate operations.

### **Professional Fees**

Professional fees for the year ended December 31, 2008 increased by \$270,341, or 64%, to \$695,158 from \$424,817 in 2007.

The increase in professional fees is primarily attributable to: (i) management fees of approximately \$222,236 paid to Cary Pharmaceuticals related to the CPI 300 antidepressant (no such costs were incurred in 2007), and (ii) expenses of approximately \$108,714 related to the Company s listing on the TSX Venture Exchange, as compared to \$22,418 in 2007.

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

Share-based compensation expense, warrants and share based payments totaled \$365,225 for the year ended December 31, 2008, as compared to \$202,607 for the year ended December 31, 2007.

We expensed \$111,619 in connection with the amendment of the anti-dilution terms of convertible notes issued in May 2007. As consideration for entering into this amendment, the Company agreed to issue to the note holders an aggregate of 159,456 fully paid common shares. At the same time, the exercise price of outstanding warrants held by the note holders was adjusted from \$1.02 to \$0.80, resulting in an increase in the fair value of the warrant and an additional compensation charge of \$92,571.

We also expensed approximately \$58,887 during 2008 for options granted to Company employees in 2006, 2007 and 2008 under the 2006 Stock Option Plan, \$51,727 for options granted to non-employee directors, and \$50,421 for options granted to Auctus Capital for investor relations services.

There remains approximately \$47,162 in stock based compensation to be expensed in fiscal 2009 and 2010 related to the issuance of options during 2007 and 2008. We anticipate that we will issue additional options and warrants in the future, which will continue to result in stock-based compensation expense.

# **Financing Cost**

We incurred interest and financing fee expense of \$766,136 for the year ended December 31, 2008, as compared to \$349,093 in 2007. Approximately \$670,108 of the expense incurred in 2008 relates to non-cash items.

The costs in 2008 relate primarily to a non-cash accretion expense of \$465,918 (2007 - \$195,317) and cash interest payments of \$79,215 (2007 - \$66,180) on the convertible notes issued in May 2007.

In addition, we expensed a non-cash amount of \$111,619 in connection with the amendment of the anti-dilution terms of convertible notes issued in May 2007. As consideration for entering into this amendment, the Company agreed to issue to the note holders an aggregate of 159,456 fully paid common shares. At the same time, the exercise price of outstanding warrants held by the note holders was adjusted from \$1.02 to \$0.80, resulting in an increase in the fair value of the warrant and an additional compensation charge of \$92,571.

The remainder of \$16,813 in financing cost relates to interest paid on the outstanding shareholder loan, bank fees, and interest.

Based on the outstanding principal amount of the convertible notes issued in May 2007, and assuming no additional conversions of these notes into common stock, we expect to incur interest expense of approximately \$71,627 and approximately \$515,739 of accreted interest in 2009.

# **Foreign Exchange**

A foreign exchange gain of \$122,915 was recorded in 2008, as compared to a foreign exchange loss of \$113,552 in 2007. The foreign exchange gain in 2008 and the foreign exchange loss in 2007 relate primarily to currency fluctuations between the Canadian dollar and the U.S. dollar.

# Net Loss

The net loss for the year ended December 31, 2008 was \$2,806,387, an increase of \$1,705,594, or 155%, as compared to a net loss of \$1,100,793 in 2007. The increase in net loss is attributable to the following:

- a) R&D expenses of approximately \$915,444 and Management Fees of approximately \$222,236 relating to the collaboration agreement with Cary Pharmaceuticals to develop the antidepressant CP-300,
- b) Professional fees of approximately \$108,714 related to the Company s listing on the TSX Venture Exchange,
- c) Financing costs of approximately \$749,323 incurred in relation to the convertible notes issued in May 2007, of which approximately \$545,133 relates to interest paid and accreted, and \$204,190 relates to amendments to the terms and conditions of the convertible notes.

Non-cash related expenses totaling approximately \$882,915 are included within the net loss for 2008, as follows:

a) \$465,918 in respect of accretion expense on the convertible notes issued in May 2007.

- b) \$111,619 related to the amendment of the anti-dilution terms of the convertible notes whereby, as consideration for entering into this amendment, the Company agreed to issue to the holders of the convertible notes an aggregate of 159,456 fully paid common shares.
- c) \$92,571 additional compensation charge relating to the amendment of the exercise price of the outstanding warrants to the note holders from \$1.02 to \$0.80 resulting in an increase in the fair value of the warrant.
- d) \$58,887 for options granted to Company employees.
- e) \$51,772 in respect of the amortization of fixed assets.
- f) \$51,727 for options granted to non-employee directors.
- g) \$50,421 for options granted to Auctus Capital as per the investor relations agreement.

#### Key items from the Balance Sheet

				Increase/	Percentage
	2008	2007	(	(Decrease)	Change
Current Assets	\$ 1,464,374	\$ 1,035,920	\$	428,454	41%
Property and Equipment	157,156	235,244		(78,088)	33%
Current Liabilities	525,661	261,485		264,176	101%
Loan Payable, Shareholder	82,357	101,193		(18,836)	19%
Convertible notes	714,502	417,634		296,868	71%
Deferred Income Tax Liability	127,408	278,988		(151,580)	54%
Capital Stock	209	162		47	29%
Additional Paid-in-Capital	5,080,780	2,071,818		3,008,962	145%

#### **Current Assets**

Current assets totaled \$1,464,374 at December 31, 2008, as compared to \$1,035,920 at December 31, 2007. The increase of \$428,454 is primarily attributable to an increase in cash resulting from the completion of our private placement on March 27, 2008, and also includes a cash balance of \$277,220 which is restricted in accordance with the Collaborative Agreement with Cary Pharmaceuticals to jointly develop and commercialize an oral antidepressant using IntelGenx s proprietary oral delivery technology.

#### **Prepaid Expenses**

As of December 31, 2008, prepaid expenses totaled \$44,936, as compared to \$23,443 at December 31, 2007. The increase of \$21,493 is attributable to the payment of a security deposit of \$22,681 in connection with a lease agreement for new premises that the Company plans to relocate to in 2009.

#### **Contractual Obligations and Commitments**

Excluding trade accounts payable and accrued liabilities, the Company is committed to the following contractual obligations and commitments.

	2009	2010	
Operating Lease Obligations	\$ 8,119	\$	0
Investor relation	\$ 24,630	\$	0
Interest on Convertible Notes	\$ 71,627	\$	0
Total	\$ 104,376	\$	0
Liquidity and Capital Resources			

Our cash and cash equivalents totaled \$833,219 as of December 31, 2008, an increase of \$502,252 as compared to \$330,967 as of December 31, 2007. The increase is primarily attributable to proceeds received from a the private placement completed on March 27, 2008. Our cash and cash equivalents balance includes a restricted cash amount of \$277,220. This amount represents the remaining balance of the \$2,000,000 in cash that was set aside under the terms of the Collaborative Agreement ratified on April 7, 2008 with Cary Pharmaceuticals to jointly develop and commercialize an oral antidepressant using IntelGenx s proprietary oral delivery technology.

As at December 31, 2008, we had an accumulated deficit of \$4,725,045, as compared to an accumulated deficit of \$1,918,658 as of December 31, 2007. Total assets amounted to \$1,621,530 and shareholders equity amounted to \$171,602 as of December 31, 2008, as compared with total assets and shareholders equity of \$1,271,164 and \$211,864, respectively, as of December 31, 2007.

As of December 31, 2008, accounts receivable totaled \$317,063 (2007 - \$427,476), of which \$122,095 is a sales tax refund which we expect to receive during the first quarter of 2009. In addition, we had R&D investment tax credits receivable of \$269,156, as compared to \$243,006 as at December 31, 2007. We expect to receive the R&D investment tax credits during the third quarter of 2009.

Accounts payable and accrued liabilities as of December 31, 2008 amounted to \$525,661 (2007 - \$261,485), of which approximately \$435,100 relates to research and development activities, approximately \$12,706 relates to professional fees, and \$17,857 relates to a retainer to a non-employee director of the Company. Included within other accruals is approximately \$13,390 due to a shareholder.

Our consolidated financial statements as of December 31, 2008 have been prepared under the assumption that we will continue as a going concern for the twelve months ending December 31, 2009. The report of our independent registered public accounting firm which accompanies our financial statements includes an explanatory paragraph raising substantial doubt about our ability to continue as a going concern due to our operating losses our need to obtain significant additional capital in order to finance our operations and repay our indebtedness. Accordingly, our ability to continue as a going concern is dependent upon our ability to obtain additional capital from equity and/or debt financing, or by generating increased revenues or other sources of income.

We presently do not have any available credit, bank financing or other external sources of liquidity. Due to our brief operating history, our operations have not been a consistent source of liquidity. We have financed our operating and capital expenditures principally through the sale of debt and equity securities to accredited and institutional investors. In May 2007, we issued convertible notes in an aggregate principal amount of \$1.5 million, of which \$1,230,241 remained outstanding as of December 31, 2008. In March 2008, we completed a private placement of common stock and warrants for net proceeds of \$2,349,119. Management believes that the Company s existing cash resources will be sufficient to meet our operating requirements for the first six months of 2009. We are seeking additional funding through additional equity and/or debt financings. However, there can be no assurance that that any additional financing will become available to us, and if available, on terms acceptable to us. Any financing, if available, may involve restrictive covenants that impact our ability to conduct our business and raise additional funds. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates.

# **Property and Equipment**

As at December 31, 2008, the net book value of our property and equipment amounted to \$157,156, as compared to \$235,244 at December 31, 2007. In the year ended December 31, 2008 additions to assets totaled \$11,274 and comprised \$2,812 for computer equipment, \$6,579 for laboratory equipment, and \$1,883 for office equipment, fixtures and fittings. Total depreciation in the year ended December 31, 2008 amounted to \$51,772 and a foreign exchange loss of \$37,590 was recorded.

# Loan Payable, Shareholder

As of December 31, 2008, we had a loan payable to a shareholder with an outstanding principal amount of \$82,357, as compared to an outstanding principal amount of \$101,193 at December 31, 2007. \$18,836 of the decrease in the outstanding principal amount is attributable to currency exchange rate fluctuation.

# **Capital Stock**

As at December 31, 2008, capital stock amounted to \$209 compared to \$162 at December 31, 2007. The increase reflects the issue of 4,692,856 shares at par value of \$0.00001, the majority of which relates to the private placement completed on March 27, 2008. Capital stock is disclosed at its par value with the excess of proceeds shown in Additional Paid-in-Capital.

# Private Placement of Convertible Notes and Warrants - May 2007

On May 22, 2007 the Company entered into convertible note agreements with certain institutional and accredited investors for amounts totaling \$1,500,000. The convertible notes bear interest at the rate of 8% per annum and are

repayable on September 22, 2009. Interest is payable quarterly and payments commenced on July 1, 2007. The notes are convertible into common shares of the Company, at the option of the holders, at a conversion price of \$0.70 per share. The Company also issued to the holders 2,142,857 stock purchase warrants exercisable at \$1.02 per share before May 22, 2012. The exercise price of the warrants was subsequently amended to \$0.80 per share in the second quarter of 2008.

The Company may, at its option, elect to pay the interest by the issuance of common shares. The number of shares is to be determined by dividing the amount of the interest payment by the number which is 85% of the average market price of the Company s common shares for the 20 trading days immediately prior to the interest payment date assuming that the average market price is equal or greater than \$0.70 as adjusted for reverse and forward share splits, recapitalizations and the like that occur after the date of the Securities Purchase Agreements.

On May 22, 2007 the Company paid approximately \$229,323 in cash consideration and issued warrants with a fair value of \$82,993 in consideration for transaction costs. These transaction costs were allocated between the convertible debt and the warrants based on their relative fair value.

In the second quarter of 2008 the Company issued 159,456 shares of common stock at \$0.70 per share for a total of \$111,619 to convertible note holders. The compensation was for acceptance of the amendment of the anti-dilution terms of the convertible notes required in connection with the Company s TSX listing. At the same time the exercise price of the warrants was amended from \$1.02 to \$0.80 per share.

As at December 31, 2008 we had convertible notes of \$714,502 (2007 - \$417,634) outstanding, which represents \$1,230,241 in convertible note financing less unamortized discount and deferred charges of \$515,739. In 2008 a total of 235,714 notes were converted into common shares resulting in an increase of \$165,000 in additional paid in capital.

#### Private Placement of Common Stock and Warrants - March 2008

On March 27, 2008, we completed a private placement of common stock and warrants for gross proceeds of \$2,800,700. We sold 4,001,000 units, with each unit consisting of one share of common stock and one common share purchase warrant. Each warrant entitles the holder to purchase one share of common stock at an exercise price of \$1.02 per common share and expires 24 months after the date of issuance.

In connection with this private placement, we paid a placement agent a cash commission in the amount of \$196,000, which is equal to 7% of the gross proceeds of the offering. We also issued to the placement agent an option entitling the placement agent to acquire 320,080 units at \$0.70 per unit, which expires 24 months after the date of issuance.

The cash consideration paid to the placement agent and the fair value of the placement agent s option is reflected as a reduction to additional paid-in capital.

Pursuant to the terms of the private placement, we were obligated to use our best efforts to: (i) have our common stock listed on the TSX Venture Exchange, and (ii) file a resale registration statement with the U.S. Securities and Exchange Commission that registers for resale the common stock and the common stock issuable upon exercise of the warrants and the placement agent option. We fulfilled these obligations within the required time limits.

# **Additional Paid-in-Capital**

Additional paid-in capital totaled \$5,080,780 at December 31, 2008, as compared to \$2,071,818 at December 31, 2007. The increase is attributable to increases of \$2,127,920, \$672,740, and \$95,000 for the private placement completed in March 2008 in relation to common stock issued, warrants and placement agent compensation respectively as well as a decrease of \$546,581 for transaction costs. Additional paid in capital also increased by \$365,223 for stock based compensation. Of this amount, \$111,617 relates to compensation to convertible note holders for their acceptance of an amendment of the anti-dilution terms of their convertible notes required in connection with the Company s TSX listing; \$92,571 relates to the adjustment of the exercise price of the warrants held by the convertible note holders; and \$161,035 relates to the amortization of stock options granted to employees, directors, and to our investor relations consultant, Auctus Capital. Additional paid in capital increased further by \$164,998 for converted notes, by \$88,663 for options exercised, and by \$40,999 for warrants exercised.

#### Key items from the Statement of Cash Flows

			Increase/	Percentage
	2008	2007	(Decrease)	Change
Operating Activities	\$ (1,737,032)	\$ (968,659)	\$ (768,373)	79%
Financing Activities	2,478,784	1,162,806	1,315,978	113%

Statement of cash flows				
Cash and cash equivalents - end of period	555,999	330,967	225,032	68%
Investing Activities	(284,277)	(82,961)	(201,316)	243%

Net cash used by operating activities was \$1,737,032 in the year ended December 31, 2008, as compared to \$968,659 for the same period in 2007. In 2008, net cash used by operating activities consisted of an operating loss of \$2,806,387 and an increase in non-cash operating elements of working capital of \$337,974.

Non-cash items included in operating activities totaled approximately \$731,334, as follows:

- a) \$465,918 in respect of accretion expense on the convertible notes issued in May 2007.
- b) \$111,619 related to the amendment of the anti-dilution terms of the convertible notes whereby, as consideration for entering into this amendment, the Company agreed to issue to the holders of the convertible notes an aggregate of 159,456 fully paid common shares.
- c) \$92,571 additional compensation charge relating to the amendment of the exercise price of the outstanding warrants to the note holders from \$1.02 to \$0.80 resulting in an increase in the fair value of the warrant.
- d) \$58,887 for options granted to Company employees.
- e) \$51,772 in respect of the amortization of fixed assets.
- f) \$51,727 for options granted to non-employee directors.
- g) \$50,421 for options granted to Auctus Capital as per the investor relation agreement.
- h) (\$151,581) in respect of deferred income tax related to the convertible debt.
- Our operating activities will continue to consume our available funds until we can generate increased revenues.

Net cash provided by financing activities was \$2,478,784 for the year ended December 31, 2008, as compared to \$1,162,806 provided in 2007. Of the net cash provided by financing activities in 2008, \$2,800,700 came from a private placement financing completed on March 27, 2008, less \$451,581 used to pay related transaction costs, and \$129,665 was generated from the issue of capital stock in the second and third quarters.

Net cash used in investing activities was \$284,277 for the year ended December 31, 2008 compared to a use of funds of \$82,961 in 2007. Net cash used in investing activities in 2008 includes \$277,220 of cash restricted for the CPI-300 project under the collaborative agreement with Cary Pharmaceuticals. In accordance with the collaborative agreement dated April 7, 2008 the Company agreed to restrict \$2,000,000 of its cash reserves in development support activities for an oral antidepressant using the Company s proprietary oral delivery technology. As at December 31, 2008, in line with project planning and management s expectations, the Company had expensed approximately \$1,832,470 on the project of which \$1,722,780 had been disbursed, resulting in a restricted cash balance of \$277,220 and amounts payable of \$109,690. Included within these disbursements is approximately \$222,236 paid to Cary Pharmaceuticals in respect of management fees.

Cash of \$7,057 was used to purchase capital assets in 2008, as compared to \$82,961 in 2007.

The balance of cash as of December 31, 2008 amounted to \$555,999, as compared to \$330,967 at December 31, 2007. This amount excludes the restricted cash amount of \$277,220 for the CPI-300 project. The increase in cash is primarily the result of proceeds from the private placement completed in March 2008. The increase in cash was partially offset by an increase in R&D expenses, the full year effect of management salaries, and costs associated with the Company s listing on the TSX Venture Exchange.

# **Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements.

# Item 8. Financial Statements and Supplementary Data.

The financial statements for the fiscal years ending December 31, 2008 and 2007, required by Item 8 are set forth on pages F-1 through F-30.

# Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

# 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, 2008 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 Securities and Exchange Commission 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, 2008 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). The Company s internal control system was designed to provide reasonable assurance to the Company s management and 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.

The Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2008. In making this assessment, the Company's management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control Integrated Framework. Based on this assessment, management believes that, as of December 31, 2008, the Company's internal control over financial reporting was effective based on those criteria.

This Annual Report does not include an attestation report of the Company's 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 temporary rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this Annual Report.

# Item 9B. Other Information.

We do not have any information required to be disclosed in a report on Form 8-K during the fourth quarter of 2008 that was not reported.

# PART III

#### Item 10. Directors, Executive Officers and Corporate Governance.

Name	Age	Position	Position since
Horst G. Zerbe	62	Chairman of the Board, President and Chief	April 2006
		Executive Officer	
Paul A. Simmons	47	Chief Financial Officer	September 2008
Joel Cohen <sup>(1)</sup>	37	Director	April 2006
J. Bernard Boudreau <sup>(1)</sup> (2)	62	Director	June 2006
David Coffin-Beach <sup>(2)</sup> (3)	60	Director	June 2006
Ian Troup <sup><math>(1)</math></sup> (2)	66	Director	May 2008
Ingrid Zerbe	54	Secretary, Director Finance and Administration	April 2006

# (2) Compensation Committee member

(3) Subsequently Mr. David Coffin-Beach resigned from the board of directors effective March 17, 2009.

All directors hold office until the next annual meeting of stockholders and until their successors have been duly elected and qualified. There are no agreements with respect to the election of directors. Officers are appointed annually by the board and each executive officer serves at the discretion of the board.

# Horst G. Zerbe, Ph.D.

Dr. Zerbe has more than 20 years experience in the pharmaceutical industry. He has been the President, Chief Executive Officer, and Chairman of IntelGenx Technologies Corp. since April 2006. In addition, Dr. Zerbe has served as the President, Chief Executive Officer and Director of IntelGenx Corp., our Canadian Subsidiary, since 2005. From 1998 to 2005, he served as the president of Smartrix Technologies Inc. in Montreal; prior thereto, from 1994 to 1998, he was Vice President of R&D at LTS Lohmann Therapy Systems in West Caldwell, NJ. He has published numerous scientific papers in recognized journals and holds over 30 patents.

# Paul A. Simmons

Mr. Simmons was appointed as our Chief Financial Officer in September 2008. From 2003-2008, Mr. Simmons was employed by the CLAAS Group, a leading manufacturer of agricultural harvesting machinery. Mr. Simmons was initially based at Group HQ in Germany as Head of Corporate Controlling. In August 2005, he was transferred to the Baler Manufacturing subsidiary (Usines CLAAS France). In September 2006, Paul was transferred to French subsidiary Renault Agriculture to restructure and integrate the newly acquired Tractor Manufacturing Division into the CLAAS Group.

Mr. Simmons international finance credentials include an Association of Financial Controllers and Administrators (AFCA) certification, and a designation with the Association of Accounting Technicians (MAAT). He has expertise in both U.S. Generally Accepted Accounting Principles (GAAP) and International Financial Reporting Standards (IFRS).

# J. Bernard Boudreau

Mr. Boudreau has been a director of IntelGenx since June 2006. Since 2005, Mr. Boudreau has served as the Vice-president of Pharmeng International Inc., a company listed on the Toronto Stock Exchange. From 2001 to July 2005, he was President and CEO of Radcliffe Consulting and Investment Limited, a private consulting firm located in Halifax, N.S.. Mr. Boudreau has also served on the Board of Directors of a number of public and private companies, including Export Development Canada.

Mr. Boudreau has worked as a lawyer and as a public official in Canada. His litigation experience includes appearances at every level of the judicial system in Nova Scotia. He was appointed as Queen's Counsel in 1985. Mr. Boudreau was first elected to the provincial legislature of Nova Scotia in 1988. He served as Chair of the Public Accounts Committee and opposition critic for Finance and Economic Development. In 1993 he was re-elected as a member of government and held responsibilities as Minister of Finance, Minister of Health, Chair of the Cabinet Priorities and Planning Committee. Mr. Boudreau served as Government Leader in the Senate of Canada and Member of the federal Cabinet between 1999 and 2001.

# David Coffin-Beach, Ph.D.

Dr. Coffin-Beach has been a director of IntelGenx since June, 2006. From April 2007 to 2008 he held a position as President and COO at Synovics Pharmaceuticals in Fort Lauderdale, Florida. From 2004 to 2007, Dr. Coffin-Beach served as President of ATP Solutions, a privately held consulting firm in Toronto which specializes in delivering strategic, technical, marketing and management services to pharmaceutical manufacturers and investors. Dr. Coffin-Beach was the founder, President and director of TorPharm from 1994 to 2004, the U.S. division of Apotex Inc. Prior to that assignment, Dr. Coffin-Beach held various positions at Schering-Plough Corporation ending with the position of Associate Director. Dr. Coffin-Beach has also held the following positions: Director of Research at Superpharm Corporation, a Division of Goldline Laboratories, where he was in charge of research and development of generic products; Senior Scientist and Group Leader at DuPont Pharmaceuticals, where he participated in the design and qualification of a new pharmaceutical research facility in Wilmington, Delaware, and was the co-inventor on two

U.S. patents assigned to DuPont.

Dr. Coffin-Beach received his BS in Pharmacy from Union University, Albany College of Pharmacy, Schenectady, N.Y., and practiced both community and clinical pharmacy before returning for graduate studies at the University of Maryland in Baltimore to finish graduate school with a PhD in Pharmaceutics.

Subsequently Mr. David Coffin-Beach resigned from the board of directors effective March 17, 2009.

#### Ian Troup

Mr. Troup has been a director of IntelGenx Technologies Corp. since May 2008. Since April 2008 Mr. Troup has been a Director of Vital Medix, an early stage drug development company. In July 2007 he was appointed to the Board of Medisyn Technologies Inc., a privately held "in silica" drug discovery and development company. From September 1995 until December 2003, Mr. Troup was President and COO of Upsher-Smith Laboratories, a privately held generic company.

Born and educated in Scotland, Mr. Troup has worked in the pharmaceutical industry for over 35 years. Originally an industrial chemist, he has served in roles in the sales and marketing area for several leading companies. As President, he led the UK wing of Schwarz Pharma for 7 years before serving as President in Schwarz's subsidiary in the USA for an additional 9 years. Following this he served as President/COO of Upsher-Smith Laboratories. His experience includes new product development and launch, M&A work and strategic planning.

# Joel Cohen, CFA

Mr. Cohen has been a director of IntelGenx Technologies Corp. since April, 2006. Mr. Cohen also served as the Chief Financial Officer of IntelGenx from April, 2006 until May 23, 2007. Mr. Cohen has experience in biotechnology and high tech financings and in financial analysis. From 2002 until 2007, Mr. Cohen was the consulting Chief Financial Officer for Osta Biotechnologies, a publicly traded company on the TSX venture exchange. Mr. Cohen continues to act as a consultant for various companies and is a director of ICP Solar Technologies Inc., a publicly traded company quoted on the OTC Bulletin Board that operates in the solar energy industry. From 1999 to 2002, Mr. Cohen was an investment banker at Canaccord Capital Corporation, where he specialized in biotechnology financings. He has worked on private and public offerings for various companies including Neurochem, Adherex, Bioniche, Diagnocure, Qbiogene and Aeterna. Mr. Cohen holds a Bachelor of Commerce degree in Finance from Concordia University and is a Chartered Financial Analyst.

# **Ingrid Zerbe**

Mrs. Zerbe is our Director of Finance and Administration, Corporate Secretary and is a full time employee of IntelGenx . Mrs. Zerbe is the founder of IntelGenx Corp., our Canadian Subsidiary. She served as the president of IntelGenx Corp, since its incorporation in June 2003 until December, 2005. She has been a Director of the subsidiary since its incorporation in June, 2003 and a Director of the parent company from April 2006 until August 2006. Prior to founding IntelGenx, she worked in the travel industry. She holds a bachelor degree in economics from the business school in Bottrop, Germany, and a bachelor degree in social sciences from the University of Dortmund, Germany.

# **Key Personnel and Consultants**

# James Wittenberg, R.Ph, MS

Mr. Wittenberg serves as IntelGenx's Vice President Business Development since August, 2007. He has accumulated over 20 years of experience in the pharmaceutical industry in market research and most recently as Director of Business Development at Schwarz Pharma.

# Nadine Paiement, MSc

Ms. Paiement serves as our Director of Research & Development. She joined IntelGenx in 2006. Ms. Paiement holds a M.Sc. degree in Polymer Chemistry from Sherbrooke University, and is co-inventor of IntelGenx's Tri-Layer technology. Prior to joining IntelGenx, she worked for five years as a formulation scientist at Smartrix Technologies, Inc.

# **The Board of Directors**

#### Meetings of the Board of Directors

The Company's Board of Directors held four meetings during our 2008 Fiscal Year.

#### **Compensation of the Board of Directors**

Directors are reimbursed for their out-of-pocket expenses incurred in attending meetings of the Board of Directors. As described below in "Director Compensation", during our 2008 Fiscal Year, our non-employee directors were granted options to purchase an aggregate number of 126,176 shares of our common stock. Since November of 2008 our directors receive cash compensation of CDN \$500 for attending board meeting in person and CDN\$100 for participating in board meetings via teleconference.

# **Committees of the Board of Directors**

The Board of Directors has two standing committees: the Audit Committee and the Compensation Committee.

<u>Audit Committee</u>. The Audit Committee is composed of J. Bernard Boudreau, Joel Cohen and Ian Troup. The audit committee held four meetings during our 2008 Fiscal Year.

Our audit committee assists our board of directors in fulfilling its responsibilities for oversight and supervision of financial and accounting matters. The chairman of the audit committee is J. Bernard Boudreau. Our audit committee s responsibilities include, among others (i) recommending to the board of directors the engagement of the external auditor and the terms of the external auditor s engagement; (ii) overseeing the work of the external auditor, including dispute resolution between management and the external auditor, if required; (iii) pre- approving all non-audit service to be provided to us by our external auditor; (iv) reviewing our financial statements, management s discussion and analysis and annual and interim earnings press releases before this information is publicly disclosed; (v) assessing the adequacy of procedures for our public disclosure of financial information; (vi) establishing procedures to deal with complaints received by us relating to our accounting and auditing matters; and (vii) reviewing our hiring policies regarding employees of our external auditor or former auditor. We have adopted, along with our audit committee, a written charter of the audit committee setting out the mandate and responsibilities of the audit committee which provides that the audit committee convene no less than four times per year.

Accordingly, the Audit Committee discusses with RSM Richter, LLP, our auditors, our audited financial statements, including, among other things the quality of our accounting principles, the methodologies and accounting principles applied to significant transactions, the underlying processes and estimates used by our management in our financial statements and the basis for the auditor's conclusions regarding the reasonableness of those estimates, in addition to the auditor's independence.

<u>Audit Committee Financial Expert.</u> Joel Cohen serves as our audit committee financial expert. Mr. Cohen is not an independent director , as defined in the Nasdaq Stock Market, Inc. Marketplace Rules.

<u>Compensation Committee.</u> The Compensation Committee of the Board of Directors consists of David Coffin-Beach, J. Bernard Boudreau and Ian Troup. The Compensation Committee held its formal annual meeting in September 2008 during the 2008 Fiscal Year.

Our compensation committee reviews and makes recommendations to our board of directors concerning the compensation of our executive officers and key employees which include the review of our executive compensation and other human resource policies, the review and administration of any bonuses and stock options and major changes to our benefit plans and the review of and recommendations regarding the performance of the Chief Executive Officer and the Chief Financial Officer of the Company. Our compensation committee is comprised of non-management members of our board of directors and is required to convene at least annually. The chairman of our compensation committee is David Coffin-Beach.

<u>Compensation Committee Interlocks and Insider Participation.</u> As stated above, the Compensation Committee consists of David Coffin-Beach, J. Bernard Boudreau and Ian Troup. There are no interlocking relationships, as described by the Securities and Exchange Commission, between the Compensation Committee members.

# Executive Compensation

The key objectives of the Company's executive compensation policies are to attract and retain key executives who are important to the long-term success of the Company and to provide incentives for these executives to achieve high levels of job performance and enhancement of shareholder value. The Company seeks to achieve these objectives by paying its executives a competitive level of base compensation for companies of similar size and industry and by providing its executives an opportunity for further reward for outstanding performance in both the short term and the long term.

<u>Executive Officer Compensation.</u> The Company's executive officer compensation program is comprised of three elements: base salary, annual cash bonus and long-term incentive compensation in the form of stock option grants.

<u>Salary</u>. The Compensation Committee and the Board of Directors will review base salaries for the Company's executive officers, taking into account individual experience, job responsibility and individual performance during the prior year. These factors are not assigned a specific weight in establishing individual base salaries. The Committee will also consider the Company's executive officers' salaries relative to salary information for executives in similar industries and similarly sized companies.

<u>Cash Bonuses</u>. The purpose of the cash bonus component of the compensation program is to provide a direct financial incentive in the form of cash bonuses to executives.

<u>Stock Options</u>. Stock options are the primary vehicle for rewarding long-term achievement of Company goals. The objectives of the program are to align employee and shareholder long-term interests by creating a strong and direct link between compensation and increases in share value. Under the Company's Stock Option Plan, the Board of Directors or the Compensation Committee may authorize the grant options to purchase Common Stock of the Company to key employees of the Company. The options generally vest in increments over a period of years established at the time of grant except for the options granted to the non-employees directors which vest immediately.

# **Involvement in Certain Legal Proceedings.**

None of our officers or directors have, during the last five years: (i) been convicted in or is currently subject to a pending a criminal proceeding; (ii) been a party to a civil proceeding of a judicial or administrative body of competent jurisdiction and as a result of such proceeding was or is subject to a judgment, decree or final order enjoining future violations of, or prohibiting or mandating activities subject to any federal or state securities or banking laws including, without limitation, in any way limiting involvement in any business activity, or finding any violation with respect to such law, nor (iii) has any bankruptcy petition been filed by or against the business of which such person was an executive officer or a general partner, whether at the time of the bankruptcy of for the two years prior thereto.

#### Compliance with Section 16(a) of the Exchange Act

Section 16(a) of the Exchange Act requires directors, officers and persons who own more than 10% of a registered class of our equity securities to file reports of ownership and change in ownership with the Securities and Exchange Commission. Directors, officers and greater than 10% shareholders are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file.

Based solely upon our review of the copies of such forms that we received during the fiscal year ended December 31, 2008, we believe that each person who at any time during the fiscal year was a director, officer, or beneficial owner of more than ten percent of our common stock complied with all Section 16(a) filing requirements during such fiscal year, except as follows: The Form 4 s filed by the following directors were not filed timely: Bernard Boudreau and David Coffin-Beach. The Form 3 filed by our director Ian Troup was not filed timely.

#### **Code of Ethics**