IntelGenx Technologies Corp. Form 10-K March 30, 2010

# 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, 2009** 

[	] 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)

### 87-0638336

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

### 6425 Abrams, Ville Saint Laurent, Quebec

<u>H4S 1X9</u>

(Address of principal executive offices)

(Zip Code)

### (514) 331-7440

(Registrant s telephone number, including area code)

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

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

Common Stock, \$0.00001 par value

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the

Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant	was
required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X]	No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [X] No [ ]

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	Accelerated filer [ ]	Non-accelerated filer [ ]	Smaller reporting
[ ]			company [X]
		(Do not check if a smaller reporting	
		company)	
Indicate by check mark	whether the registrant is a sl	hell company (as defined in Rule 12b-2	2 of the Act). Yes [ ] No
		[X]	

As of June 30, 2009, the aggregate market value of the registrant s voting and non-voting common equity held by non-affiliates of the registrant was \$6,238,993 based on the closing price of the registrant s common shares of U.S. \$0.59, 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.

Class
Common Stock, \$.00001 par value

Outstanding at March 29, 2010 33,081,271 shares

Documents 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 Interchnologies 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, CDN\$ and 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, 2009 closing rate reported by the Bank of Canada, being U.S. \$1.00 = C\$1.0509.

### PART I

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

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

### Item 1. Business.

### **Corporate History**

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

### Overview

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

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

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

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

### **Technology Platforms**

Our product development efforts are based upon three delivery platform technologies: (1) a Multilayer Tablet technology (2) an Oral Film technology, and (3) a Mucoadhesive Tablet technology. Our Multilayer Tablet platform technology allows for the development of oral controlled-release products. It is designed to be versatile and to reduce manufacturing costs as compared to competing oral extended-release delivery technologies. The Oral Film technology allows for the instant delivery of pharmaceuticals to the oral cavity, while the Mucoadhesive Tablet allows for the controlled release of active substances to the oral mucosa.

The Multilayer Tablet (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 cover layers start to erode, their permeability for the active ingredient through the cover layers increases. Thus, the Multilayer Tablet can produce quasi-linear (zero-order) kinetics for releasing a chemical compound over a desired period of time. The erosion rate of the cover layers can be customized according to the physico-chemical properties of the active drug. In addition, our multilayer technology offers the opportunity to develop combination products in a regulatory-compliant format. Combination products are made up of two or more active ingredients that are combined into a single dosage form.

The Oral Film technology (VersaFilm) 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 ingredient 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 trilayer 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 a new strength antidepressant Bupropion HCl, the active ingredient in Wellbutrin XL® has been completed. A regulatory file for a 505(b)(2) NDA submission was filed in April, 2009. In a complete response letter received on February 4, 2010, the FDA commented on the food effect which was observed in the food effect study included in the NDA and on the lack of a commercial manufacturer. Both issues will be addressed in an amendment to the NDA which the Company intends to file in the second half of 2010.

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 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. The limited financial resources of our partner in this project have resulted in the project being put on hold.

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). A phase I pilot biostudy was completed.

INT0008/2007. An oral film product based on our proprietary edible film technology is currently in development. The product is intended for the treatment of migraine. The results of a phase I pilot study that was conducted in 2009 indicate that the product is bioequivalent with the reference listed drug.

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 but has temporarily been put on hold by our development partner.

INT0019/2009. 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 diarrhea.

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 [Coronary Heart Failure], Pivotal batches i Hypertension	
INT0003/2005	Smoking cessation	Pilot biostudy completed
INT0004/2006	Antidepressant	NDA filed April, 2009; complete response letter received Q1/2010

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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	Pilot biostudy completed
INT0014/2008	Schizophrenia	Project currently on hold
INT0015/2008	Panic Attack	Formulation development ongoing
INT0018/2008	Hyperlipidemia	Project on hold.
INT0019/2009	Diarrhea	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 U.S. Federal Food, Drug and Cosmetic Act. Such applications, known as a 505(b)(2) NDA, are permitted for new drug products that incorporate previously approved active ingredients, even if the proposed new drug incorporates an approved active ingredient in a novel formulation or for a new indication. A 505(b)(2) NDA may include information regarding safety and efficacy of a proposed drug that comes from studies not conducted by or for the applicant. The first formulation for a respective active ingredient filed with the FDA under a 505(b)(2) application may qualify for up to three years of market exclusivity upon approval. Based upon a review of past partnerships between third party drug delivery companies and pharmaceutical companies, management believes that drug delivery companies which possess innovative technologies to develop these special dosage formulations present an attractive opportunity to pharmaceutical companies. Accordingly, we believe 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 of generic drugs that have certain barriers to entry, e.g., 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 project 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 regulated as pharmaceutical products and do

not require FDA approval.

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

The rapidly disintegrating film technology contained in our VersaFilm and our AdVersa 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 we have. In addition, many of our competitors have significantly greater experience than we have in conducting clinical trials of pharmaceutical products, obtaining FDA and other regulatory approvals of products, and marketing and selling products that have been approved. We expect that we will be subject to competition from numerous other companies that currently operate or are planning to enter the markets in which we compete.

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

- The safety and efficacy of our products;
- The relative speed with which we can develop products;
- Generic competition for any product that we develop;
- Our ability to defend our existing intellectual property and to broaden our intellectual property and technology base;
- Our ability to differentiate our products;
- Our ability to manufacture our products in compliance with current Good Manufacturing Practices ( cGMP ) and any other regulatory requirements; and
- Our ability to obtain financing.

In order to establish ourselves as a viable industry partner, we plan to continue to invest in our research and development activities in order to strengthen further 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 / Strategy**

We manufacture products only for testing purposes in our own laboratories, and we do not manufacture products for clinical trials or for commercial use. We do not own manufacturing facilities for commercial production and we have no plans to acquire such facilities in the near future. Our strategy is to secure partnerships with specialist manufacturing companies that are able to offer reliable, high quality manufacturing services at cost effective pricing.

We formed a strategic alliance with LTS Lohmann Therapie-Systeme AG ("LTS") for the exclusive manufacturing of products developed by us using our VersaFilm drug delivery technology. LTS is regarded as a pioneer in the

development and production of transdermal and film form/wafer oral systems and has become one of the world's leading suppliers for the international pharmaceutical industry. VersaFilm is IntelGenx's immediate release wafer technology. It is comprised of a thin polymeric film using United States Pharmacopeia (USP) components that are safe and approved by the FDA for use in food, pharmaceutical and cosmetic products. VersaFilm provides a patent-protected method of re-formulating approved pharmaceuticals in a more convenient and discrete oral dosage form.

We are currently in negotiations to secure a manufacturing partnership for the productions of clinical test batches and commercial product for our VersaTab and AdVersa tablet products.

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

### **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) non-disclosure agreements, license agreements and appropriate contractual restrictions and controls on the distribution of information, and (iii) trade secrets, common law trademark rights and trademark registrations. We plan to file core technology patents covering the use of our platform technologies in any pharmaceutical products.

We have obtained four (4) patents and have an additional seven (7) pending patent applications, 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	The composition, manufacturing, and use of rapidly disintegrating flavored films for releasing flavors to certain substrates	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
	Multilayer Tablet		

US Appl. 2007/0190144

Formulation and Method of Preparation of Multilayered Tablets

Published August 16, 2007

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US Appl. 2007/0128272	Multi-Vitamin And Mineral Supplement	Formulation and Method of Preparation of Prenatal Multivitamin Supplement	Published June 7, 2007
PCT/CA2006/000336; 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	February 13, 2006
US Appl. 11/782,838 PCT/IB2007/03950	Controlled Release Pharmaceutical Tablets	Formulation and Method Of Making Tablets Containing Bupropion And Mecamylamine	July 2006
US Patent 7674479	Sustained-release Bupropion and Bupropion / Mecamylamine tablets	Formulation and Method Of Making Tablets Containing Bupropion And Mecamylamine	Issued March 9, 2010
US Provisional Appl. US 61/230504	Dosage forms of complexed cannabinoids	Formulation and Method of Preparation of gamma-cyclodextrin complexes containing cannabinoids	August 2009
US Provisional Appl. US 61/267626	Oral film dosage forms and methods for making same	Optimization of Film strip technology	December 2009

### **Government Regulation**

The pharmaceutical industry is highly regulated. The products we participate in developing require certain regulatory approvals. In the United States, drugs are subject to rigorous regulation by the FDA. The U.S. Federal Food, Drug, and Cosmetic Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, record keeping, packaging, labeling, adverse event reporting, advertising, promotion, marketing, distribution, and import and export of pharmaceutical products. Failure to comply with applicable regulatory requirements may subject a company to a variety of administrative or judicially-imposed sanctions and/or the inability to obtain or maintain required approvals or to market drugs. The steps ordinarily required before a new pharmaceutical product may be marketed in the United States include:

- preclinical laboratory tests, animal studies and formulation studies under FDA s good laboratory practices regulations, or GLPs;
- the submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin;
- the completion of adequate and well-controlled clinical trials according to good clinical practice regulations, or GCPs, to establish the safety and efficacy of the product for each indication for which approval is sought;

• After successful completion of the required clinical testing, submission to the FDA of a 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.

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- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMPs to assure that the facilities, methods and controls are adequate to preserve the drug s identity, strength, quality and purity; and
- FDA review and approval of the NDA or ANDA.

The cost of complying with the foregoing requirements, including preparing and submitting an NDA or ANDA, may be substantial.

Accordingly, we typically rely upon our partners in the pharmaceutical industry to spearhead and bear the costs of the FDA approval process. We also seek to mitigate regulatory costs by focusing on 505(b)(2) NDA opportunities. By applying our drug delivery technology to existing drugs, we seek to develop products with lower Research & Development (R&D) expenses and shorter time-to-market timelines as compared to regular NDA products.

### **Research and Development Expense**

Our R&D expenses, net of R&D tax credits, for the year ended December 31, 2009 decreased significantly to \$1,237.1 thousand as compared to \$1,779.7 thousand for the year ended December 31, 2008.

### **Environmental Regulatory Compliance**

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

### **Employees**

As of the date of this filing, we have 9 full time employees.

#### Item 1A. Risk Factors.

An investment in our common stock involves significant risks. You should carefully consider the following risks and all other information set forth in this prospectus before deciding to invest in shares of our common stock. If any of the events or developments described below occurs, our business, financial condition and results of operations may suffer. In that case, the value of our common stock may decline and you could lose all or part of your investment.

#### Risks Related to Our Business

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

Even though we ceased being a development stage company in April 2006, we are still subject to all of the risks associated with having a limited operating history and pursuing the development of new products. Our cash flows may be insufficient to meet expenses relating to our operations and the development of our business, and may be insufficient to allow us to develop new products. We currently conduct research and development using our proprietary platform technologies to develop oral controlled release and other delivery products. We do not know whether we will be successful in the development of such products. We have an accumulated deficit of approximately \$6,665.4 thousand since our inception in 2003 through December 31, 2009. 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, 2009, December 31, 2008, December 31, 2007, December 31, 2006, December 31, 2005 and December 31, 2004 were \$1,278.7 thousand, \$976.6 thousand, \$862.7 thousand, \$265.9 thousand, \$20.0 thousand and \$257.4 thousand respectively. Our revenues in 2009 consisted primarily of development fee revenues from four clients, and royalty income earned from commercialization of the first product fully-developed by the Company, a prenatal multivitamin supplement marketed as Gesticare® in the USA, which was commercialized in November 2008.

Revenue generated to date has not been sufficient to sustain our operations. In order to achieve profitability, our revenue streams will have to increase and there is no assurance that revenues will increase to such a level.

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

The majority of our expenses are paid in Canadian dollars, while a significant portion of our revenues are in U.S. dollars. Our financial results are subject to the impact of currency exchange rate fluctuations. Adverse movements in exchange rates could have a material adverse effect on our financial condition and results of operations.

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# 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.

### 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 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 U.S. Food and Drug Administration (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 incur financial and cash-flow difficulties that force them to limit or reduce their participation in our joint projects.

- Our partners may be pursuing alternative technologies or developing alternative products that are competitive to our product, either on their own or in partnership with others;
- Our partners may reduce marketing or sales efforts, or discontinue marketing or sales of our products. 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; and
- 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.

- Our partners may incur financial and cash-flow difficulties that force them to limit or reduce their participation in our development projects
- Our partners may become the target of litigation for purported patent or intellectual property infringement, which could delay or prohibit commercialization of our products and which would reduce our revenue from such products.

# We face competition in our industry, and many of our competitors have substantially greater experience and resources than we do.

We compete with other companies within the drug delivery industry, many of which have more capital, more extensive research and development capabilities and greater human resources than we do. Some of these drug delivery competitors include 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 cGMP, which include testing, control and documentation requirements. Ongoing compliance with cGMP and other regulatory requirements is monitored by periodic inspection by the FDA and comparable agencies in other countries. Failure by our third-party manufacturers to comply with cGMP and other regulatory requirements could result in actions against them by regulatory agencies and jeopardize our ability to obtain products on a timely basis.

We are 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.

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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 products, and our product candidates. Failure to comply with regulatory requirements could have a material adverse impact on our business.

Regulations regarding the manufacture and sale of our future products are subject to change. We cannot predict what impact, if any, such changes may have on our business, financial condition or results of operations. Failure to comply with applicable regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

Additionally, the time required for obtaining regulatory approval is uncertain. We may encounter delays or product rejections based upon changes in FDA policies, including cGMP, during periods of product development. We may encounter similar delays in countries outside of the United States. We may not be able to obtain these regulatory acceptances on a timely basis, or at all.

The failure to obtain timely regulatory acceptance of our products, any product marketing limitations, or any product 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 payers as clinically useful, cost-effective and safe. To date, only one product based upon our technologies has been marketed in the United States, which limits our ability to provide guidance or assurance as to market acceptance.

Factors that we believe could materially affect market acceptance of these products include:

- the timing of the receipt of marketing approvals and the countries in which such approvals are obtained;
- the safety and efficacy of the product as compared to competitive products;
- the relative convenience and ease of administration as compared to competitive products;
- the strength of marketing distribution support; and
- the cost-effectiveness of the product and the ability to receive third party reimbursement.

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# 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. We currently intend to retain future earnings, if any, to support operations and to finance the growth and development of our business. Therefore, we do not expect to pay cash dividends in the foreseeable future. Any future determination relating to our dividend policy will be made at the discretion of our Board of Directors and will depend on a number of factors, including future earnings, capital requirements, financial conditions and future prospect and other factors that the board of directors may deem relevant. If we do not pay any dividends on our common stock, our stockholders will be able to profit from an investment only if the price of the stock appreciates before the stockholder sells it. Investors seeking cash dividends should not purchase our common stock.

### **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 four U.S. patents and have applied for seven U.S. patents, we will need to pursue additional protection for our intellectual property as we develop new products and enhance existing products. We may not be able to obtain appropriate protection for our intellectual property in a timely manner, or at all. Our inability to obtain appropriate protections for our intellectual property may allow competitors to enter our markets and produce or sell the same or similar products.

If we are forced to resort to legal proceedings to enforce our intellectual property rights, the proceedings could be burdensome and expensive. In addition, our proprietary rights could be at risk if we are unsuccessful in, or cannot afford to pursue, those proceedings.

We also rely on trade secrets and contract law to protect some of our proprietary technology. We have entered into confidentiality and invention agreements with our employees and consultants. Nevertheless, these agreements may not be honored and they may not effectively protect our right to our un-patented trade secrets and know-how. Moreover, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets and know-how.

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

We may need to obtain licenses to patents or other proprietary rights from third parties. We may not be able to obtain the licenses required under any patents or proprietary rights or they may not be available on acceptable terms. If we do not obtain required licenses, we may encounter delays in product development or find that the development, manufacture or sale of products requiring licenses could be foreclosed. We may, from time to time, support and collaborate in research conducted by universities and governmental research organizations. We may not be able to acquire exclusive rights to the inventions or technical information derived from these collaborations, and disputes may arise over rights in derivative or related research programs conducted by us or our 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. Such litigation costs could be as a result of direct litigation against us, or as a result of litigation against one or more of our partners to whom we have contractually agreed to indemnify in the event that our intellectual property is the cause of a successful litigious action against our partner. Third-party infringement claims, regardless of their outcome, would not only consume significant financial resources, but would also divert our management s time and attention. Such claims could also cause our customers or potential customers to purchase competitors products or defer or limit their purchase or use of our affected products until resolution of the claim. If any of our products are found to violate third-party intellectual property rights, we may have to re-engineer one or more of our products, or we may have to obtain licenses from third parties to continue offering our products without substantial re-engineering. Our efforts to re-engineer or obtain licenses could require significant expenditures and may not be successful.

# We may not be successful in defending the lawsuit filed by Biovail Laboratories SLR against us and may have to reimburse certain legal expenses and damages awarded.

While we believe that the lawsuit filed by Biovail Laboratories SLR (Biovail), which holds the patent for Wellbutrin XL®, against our development partner Cary Pharmaceuticals Inc. (Cary Pharma), in the U.S. District Court for the District of Delaware for patent infringement under the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984, is without foundation or merit, if Biovail is successful in its action against Cary Pharma, we may have to reimburse Cary Pharma s legal expense and/or any damages awarded.

# 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 collaborators 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 likely that the owners of the patents covering the brand name product or the sponsors of the NDA with respect to the branded product will sue or undertake regulatory initiatives to preserve marketing exclusivity. Any significant delay in obtaining FDA approval to market our products as a result of litigation, as well as the expense of such litigation, whether or not we or our collaborators 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 yours.

Directors and others hold 34% of our common stock. See Security Ownership of Certain Beneficial Owners and Management. As a result, such stockholders, acting together, may have the ability to control 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 may also deprive our stockholders of an opportunity to receive a premium for their shares as part of a sale of our company and may affect the market price of our common stock. In deciding how to vote on such matters, those stockholders interests may conflict with yours.

### **Directors Independence**

Currently, we have a majority of independent directors, but in the future we cannot guarantee that our Board of Directors will always have a majority of independent directors. In the absence of a majority of independent directors, our chief executive officer, who is also a principal stockholder and director, could establish policies and enter into transactions without independent review and approval. This could present the potential for a conflict of interest between the Company and its stockholders generally and the controlling officers, stockholders or directors.

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

Our common stock has been quoted on the OTC Bulletin Board under the symbol IGXT 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 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 U.S. Securities and Exchange Commission 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 with which we merged. In addition, we may not be able to attract the attention of major brokerage firms or institutional buyers.

Additional risks may exist because we became public through a "reverse merger" with a shell corporation. Although the shell did not have recent or past operations or assets and we performed a due diligence review of the public company, there can be no assurance that we will not be exposed to undisclosed liabilities resulting from the prior operations of our company.

Security analysts of major brokerage firms and securities institutions may not cover us 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 CDN\$8.64/square foot in an industrial zone in Ville St.-Laurent, Quebec, Canada under a five year renewable lease agreement signed in 2004. We extended the term of the lease agreement to August 31, 2010 under similar financial conditions, with the option to terminate at any time after February 28, 2010, provided we give four months—notice. 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 we might be required to seek a different location in 2010. Management has started the search for alternative, or additional, facilities that would meet our short to medium requirements at affordable rates.

### Item 3. Legal Proceedings.

In June of 2009 we announced that our New Drug Application filing for our antidepressant CPI-300 had been accepted by the FDA for standard review. We entered into a collaborative agreement with Cary Pharma in November 2007 to jointly develop and commercialize CPI-300 using our proprietary oral delivery technology. CPI-300 is a novel, high strength dosage of Bupropion HCl, the active ingredient in Wellbutrin XL® for which Biovail Laboratories SLR (Biovail) holds the patent. As required in connection with the filing of the NDA, our development partner Cary Pharma, which serves as the NDA applicant, provided notice of the NDA filing to Biovail asserting that CPI-300 would not infringe Biovail's patents. On August 18, 2009, we learned that Cary Pharma was named in a lawsuit filed by Biovail in the U.S. District Court for the District of Delaware for patent infringement under the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 with respect to Biovail's U.S. Patent No. 6,096,341 for Wellbutrin XL®. The filing of the patent infringement lawsuit instituted an automatic stay of any FDA approval of the NDA until the earlier of a judgment or January 3, 2012. Although we are not a party to the action, a negative decision may have an effect on our potential revenues relating to CPI-300. Further, in accordance with the collaborative agreement, if Biovail is successful in their lawsuit, we may have to indemnify Cary Pharma for any litigation costs incurred, or damages awarded. Cary Pharma and IntelGenx believe that CPI-300 does not infringe Biovail's patent and will vigorously assert their rights.

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

During the quarter ended December 31, 2009 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		TS	SX
	High	Low	High	Low
	(U.S.\$)	(U.S.\$)	(CDN\$)	(CDN\$)
2009				
Fourth Quarter	\$ 0.71	\$ 0.52	\$ 0.70	\$ 0.57
Third Quarter	\$ 0.70	\$ 0.50	\$ 0.74	\$ 0.51
Second Quarter	\$ 0.60	\$ 0.28	\$ 0.62	\$ 0.37
First Quarter	\$ 0.60	\$ 0.25	\$ 0.75	\$ 0.40
2008				
Fourth Quarter	\$ 0.95	\$ 0.30	\$ 0.90	\$ 0.50
Third Quarter	\$ 0.98	\$ 0.67	\$ 1.09	\$ 0.85
Second Quarter	\$ 1.01	\$ 0.80	\$ 1.00	\$ 0.80
First Quarter	\$ 1.02	\$ 0.51	\$ N/A	\$ N/A
2007				
Fourth Quarter	\$ 1.05	\$ 0.45	\$ N/A	\$ N/A
Third Quarter	\$ 1.90	\$ 0.87	\$ N/A	\$ N/A

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Second Quarter	\$ 1.31	\$ 0.60	\$ N/A	\$ N/A
First Quarter	\$ 1.20	\$ 0.67	\$ N/A	\$ N/A
			10	

### **Number of Shareholders**

On March 29, 2010 there were approximately 66 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 December 31, 2009, 2,202,676 options have been issued, 222,571 options have been exercised, 250,000 were forfeiture, 382,017 expired and 1,348,088 options remain outstanding under the 2006 Option Plan.

### Equity Compensation Plan Information as of December 31, 2009

	Number of Securities to be issued upon exercise of outstanding options,	Weighted- Average Exercise Price of outstanding options,	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in the first column)
Equity Compensation Plans Approved by Security Holders	1,348,088	\$0.56	503,341
	· · ·		·

Equity Compensation Plans Not			
Approved by Security Holders	None	None	None
Total	1,348,088	\$0.56	503,341
	19	·	,

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 CEO 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 options 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. As the result of the termination of the agreement all options to purchase common stock expired un-exercised in May of 2009

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.

On March 11, 2009 we granted options to purchase up to 25,000 shares of common stock to an employee of the company. The options have an exercise price of \$0.31, vest over 2 years at the rate of 25% every six months, and expire on March 11, 2014.

On October 3, 2009 we granted options to purchase up to 50,000 shares of common stock to Little Gem Life Science Partners in consideration for investor relation services. The options have an exercise price of \$0.55, vest 50% on the first, and 50% on the second anniversary of the agreement and expire on October 3, 2012.

On November 24, 2009 we granted options to purchase up to 125,000 shares of common stock each to three of our non-employee directors, the chief financial officer and the chief executive officer. The options have an exercise price of \$0.61, The options for the non-employee directors vest immediately, the options for the executive employees vest over 2 years at the rate of 25% every six months. All options expire on November 24, 2014.

On January 22, 2010 we granted options to purchase up to 50,000 common stock to Sector Speak in consideration for investor relation services. The options have an exercise price of \$0.47, vest 50% on the first, and 50% on the second anniversary of the agreement and expire on January 22, 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. 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  $\S(505)(b)(2)$  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 anticipates significant returns from successfully obtaining market exclusivity in this manner.

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**

Since the end of fiscal 2008 the Company improved its cash reserves, freed its balance sheet from debt, and made significant progress in a number of its research and development projects, the most notable of which are the following:

### Financial:

Raised approximately \$3.9 million in the third quarter through private placements:

On July 13, 2009 the Company closed a private placement offering of approximately 10.5 million special warrants for gross proceeds of approximately \$3.6 million. Each special warrant entitles its holder to receive, upon exercise or deemed exercise thereof, one common share of the Company and one common share purchase warrant. Each warrant entitles the holder thereof to purchase one common share of the Company at a price of \$0.80 until July 13, 2012.

On July 22, 2009, as part of a private placement, the Company issued 350,000 units to investors in the United States for gross proceeds of approximately \$127.5 thousand. Each unit consists of one common share of the Company and one common share purchase warrant. Each warrant entitles the holder to purchase one common share at an exercise price of \$0.80 per common share and expires 36 months after the date of issuance.

On September 3, 2009, as part of a private placement, the Company issued 250,000 units to investors for gross proceeds of approximately \$92.9 thousand. Each unit consists of one common share of the Company and one common share purchase warrant. Each warrant entitles the holder to purchase one common share at an exercise price of \$0.80 per common share and expires 36 months after the date of issuance.

#### Debt-free balance sheet:

Repaid convertible notes outstanding:

On September 22, 2009, the Company repaid the balance of the convertible notes outstanding of \$976.3 thousand. The Company had entered into convertible note agreements with certain institutional and accredited investors on May 22, 2007 for amounts totaling \$1,500,000. The convertible notes bore interest at the rate of 8% per annum, payable quarterly. The assets of the Company, which had been pledged as security of the convertible notes, were released upon repayment of the convertible notes.

Repaid loan payable, shareholder:

On December 4, 2009, pursuant to a board of directors resolution dated November 5, 2009, the Company repaid the loan payable, shareholder, in the amount of \$88.2 thousand. The loan payable, shareholder, who is also an officer of the Company, was unsecured and bore interest at 6% per annum.

### Research and Development Projects:

#### Antidepressant Tablet:

On April 6, 2009 IntelGenx submitted an NDA to theFDA for CPI-300. CPI-300 is a higher strength of the antidepressant bupropion HCl, the active ingredient in Wellbutrin XL®. The NDA was accepted for standard review by the FDA in June 2009. As required under NDA filings, IntelGenx's development partner Cary Pharmaceuticals (Cary), the NDA applicant, notified Biovail Laboratories SLR (Biovail), holder of the Wellbutrin XL patent of the filing contending non-infringement of the Wellbutrin XL patent.

On August 18, 2009, Cary was sued by Biovail in the U.S. District Court of Delaware for patent infringement, under provisions of the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), with respect to Biovail's U.S. Patent No. 6,096,341. Pursuant to the Hatch-Waxman Act, the filing of the patent infringement lawsuit by Biovail instituted an automatic stay of FDA approval of the NDA until the earlier of a judgment or January 3, 2012. Any decision could have an effect on IntelGenx's potential revenues relating to CPI-300. IntelGenx believes CPI-300 does not infringe Biovail's patent and is vigorously defending its position.

On January 11, 2010 IntelGenx announced a manufacturing site change for CPI-300. The original manufacturer, PharmPro of Aurora, IL ("PharmPro") was sold to URL Pharma of Philadelphia, PA. As a result of this acquisition, URL advised IntelGenx they would no longer manufacture CPI-300. IntelGenx has identified and engaged Pillar5 Pharma, Arnprior, ON, as the new manufacturing facility for the product. Arnprior is a state-of-the-art GMP facility with a long-standing record of manufacturing quality product for the pharmaceutical industry. As a result of the manufacturing site change, IntelGenx and Cary are preparing an amendment to the NDA. IntelGenx expects that the changes will not materially affect the existing timeline for commercialization of CPI-300.

On January 21, 2010 IntelGenx announced the U.S. Patent and Trademark Office ("USPTO") issued a formal Notice of Allowance for the patent application protecting CPI-300. The patent was issued on March 9, 2010 under the number US 7,674,479. It will be listed in the FDA s Orange Book and will provide broad protection for CPI-300 against generic copies.

On February 8, 2010 IntelGenx received a Complete Response Letter (CRL) from the FDA regarding CPI-300. The CRL lists two main issues which need to be addressed before obtaining final approval: 1) qualification of Pillar5 as the commercial manufacturing site and 2) an observed food effect seen with CPI-300 and the reference product. The FDA found no other notable deficiencies in the NDA. As noted in the January 11, 2010 press release, the FDA was notified about Pillar5. IntelGenx believes the food effect issue can be addressed through a label adjustment and post-approval education. In addition, the Company plans to conduct a pilot food effect study with CPI-300 tablets having a modified enteric coating. In the coming weeks IntelGenx will request a meeting with FDA to clarify the steps necessary to obtain approval. IntelGenx is confident the activities required to support the NDA amendment can be completed in time for a submission in the second half of 2010.

### Neuropathic Pain Tablet:

On April 14, 2009 IntelGenx and its development partner, Cannasat Therapeutics Inc. (Cannasat), announced positive Phase 1b results for Relivar, a buccal formulation of dronabinol. The randomized, single dose, double blind crossover study compared Cannasat s Relivar with Marinol 2.5 mg in healthy volunteers. Relivar delivered twice the amount of dronabinol into the bloodstream as the brand with no increase in side effects due to a corresponding reduction in the metabolite responsible for the CNS adverse effects of dronabinol. Relivar was developed using IntelGenx s proprietary AdVersa buccal delivery technology.

On March 4, 2010 IntelGenx and Cannasat announced the signing of a Letter of Intent for a definitive license agreement under which IntelGenx would acquire a fifty percent ownership stake from Cannasat and an exclusive worldwide license to develop and commercialize Relivar. Upon completion of the transaction, IntelGenx would assume sole product development and commercialization rights for Relivar and would forgive approximately CAD\$231 thousand of debt owed by Cannasat.

### Antihypertensive Tablet:

On April 20, 2009 IntelGenx announced results of a pilot study showing development of a product bioequivalent to a leading antihypertensive. The product was developed using IntelGenx s proprietary VersaTab delivery technology. Scale-up activities are ongoing at the contract manufacturer. The product is being developed under a strategic alliance between IntelGenx and DAVA Pharmaceuticals Inc. (DAVA). Under terms of the alliance, IntelGenx will complete the development. DAVA has commercialization rights in the U.S. IntelGenx will receive development milestones and a share of DAVA s revenues.

### Anti-migraine Film:

On November 17, 2009 IntelGenx announced results of a pilot study showing successful development of a product bioequivalent to a leading anti-migraine therapy. The product was developed using IntelGenx's proprietary VersaFilm drug delivery technology. It is anticipated the pivotal bioequivalence study will be conducted in 2010 and the NDA filed shortly thereafter.

### VersaFilm Manufacturing:

On January 25, 2010 IntelGenx announced a strategic alliance with LTS Lohmann Therapie-Systeme AG (LTS) for the exclusive manufacturing of pharmaceutical products developed by IntelGenx using its VersaFilm drug delivery technology. VersaFilm is comprised of a thin polymeric film using components that are safe and approved by the

FDA. VersaFilm provides a patent-protected method of re-formulating approved pharmaceuticals in a more convenient and discrete oral dosage form. It is particularly intended for indications requiring a rapid onset of action. IntelGenx currently has three products in development using the VersaFilm technology.

# **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.

Results of Operations - Year ended December 31, 2009 compared to Year ended December 31, 2008.

In US\$ thousands	2009	2008	Increase/ (Decrease)	Percentage Change
Revenue	\$ 1,278.7	\$ 976.6	\$ 302.1	31%