

IntelGenx Technologies Corp.  
Form 10-K/A  
September 21, 2011

---

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

**FORM 10-K/A**  
(Amendment No. 1)

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

For the fiscal year ended December 31, 2010

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 000-31187

**IntelGenx Technologies Corp.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or  
organization)

**87-0638336**

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

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

(Address of principal executive offices)

**H4S 1X9**

(Zip Code)

**(514) 331-7440**

(Registrant's telephone number, including area code)

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

**None**

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

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

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

Yes  No

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

Edgar Filing: IntelGenx Technologies Corp. - Form 10-K/A

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 (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.  
[X]

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

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

---

Edgar Filing: IntelGenx Technologies Corp. - Form 10-K/A

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

Yes [ ] No [X]

As of June 30, 2010, the aggregate market value of the registrant's voting and non-voting common equity held by non-affiliates of the registrant was \$11,302,636 based on the closing price of the registrant's common shares of U.S. \$0.50, 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.

| <b>Class</b>                     | <b>Outstanding at September 20, 2011</b> |
|----------------------------------|--|
| Common Stock, \$.00001 par value | 46,849,910 shares                        |

**Documents incorporated by reference: None.**

**EXPLANATORY NOTE**

IntelGenx Technologies Corp. (the Company ) is filing this Amendment No. 1 to its Annual Report on Form 10-K/A for the fiscal year ended December 31, 2010, which was originally filed with the Securities and Exchange Commission (the Commission ) on March 29, 2011 (the Original Form 10-K ), to incorporate the Company s revisions and responses to letters of comment from the staff of the Commission dated as of August 4, 2011, August 31, 2011 and September 14, 2011.

This Form 10-K/A includes new certifications as Exhibits 31.1, 31.2, 32.1 and 32.2 by the Company s principal executive officer and principal financial officer as required by Rules 12b-15 and 13a-14 promulgated under the Securities Exchange Act of 1934, as amended (the Exchange Act ). Except for the amended disclosures set forth below, the information in this Form 10-K/A has not been updated to reflect events that occurred after March 29, 2011, the filing date of the Original Form 10-K. Accordingly, this Form 10-K/A should be read in conjunction with the Original Form 10-K and the Company s filings made with the Commission subsequent to the filing of the Original Form 10-K, including any amendments to those filings. The following sections have been amended herein:

Part I, Item 1. Business; and

Part IV, Item 15. Exhibits, Financial Statements Schedules.

We have expanded upon the final column of the table on page 9 of the Original Form 10-K to disclose the exact expiration date of each of the Company s four issued patents. In addition, we have disclosed the material terms of the License and Development Agreement with Azur Pharma International II Ltd. on page 5 of the Original Form 10-K, which is filed as Exhibit 10.34 to this Form 10-K/A (confidential treatment has been requested for certain parts of this agreement, which are omitted and filed separately with the Commission).

This Form 10-K/A contains only the sections to the Original Form 10-K which are being amended, and those unaffected sections are not included herein. Except as set forth above, all other information in the Company s Original Form 10-K remains unchanged.

## PART I

### Cautionary Statement Concerning Forward-Looking Statements

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

### ITEM 1. BUSINESS.

#### Corporate History

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

#### Overview

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

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

Controlled release (CR) delivery systems play an important role in the development of orally administered drug delivery systems. Controlled release technology provides patients with the required amount of medication over a

pre-determined, prolonged period of time. Because of the reduced fluctuation of the active drug in the blood and the avoidance of plasma spikes, controlled release products are deemed safer and more tolerable than conventional dosage forms, and have shown better patient compliance.

Our primary business strategy is to develop pharmaceutical products based upon our proprietary drug delivery technologies and license the commercial rights to companies in the pharmaceutical industry once the viability of a product has been demonstrated. In exchange for licensing rights to our products, we seek funding consisting of a combination of one or more of the following: advance down payments, milestone fees, reimbursement for development costs, and royalties on sales. In addition, we may receive a manufacturing royalty from our contract manufacturers for the exclusive right to manufacture our products. The companies we partner with are typically responsible for managing the regulatory approval process of the product with the United States Food and Drug Administration (FDA) and/or other regulatory bodies, as well as for the marketing and distribution of the products. On a case-by-case basis, 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 United States Pharmacopeia (USP) components that are approved by the FDA for use in food, pharmaceutical, and cosmetic products. Derived from the edible film technology used for breath strips and initially developed for the instant delivery of savory flavors to food substrates, the VersaFilm technology is designed to provide a rapid response compared to existing conventional tablets. The VersaFilm technology is intended for indications requiring rapid onset of action, such as migraine, 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 in the oral cavity as compared to the conventional oral route, and (iii) it achieves a rapid onset of action for the drug. The Mucoadhesive Tablet technology is designed to be versatile in order to permit the site of application, residence time, and rate of release of the drug to be modulated to achieve the desired results.

## Product Portfolio

Our product portfolio includes a blend of generic and branded products based on our proprietary delivery technology ( generic drugs are essentially copies of drugs that have already received FDA approval).

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

INT0004/2006. The development of a new, higher strength of the antidepressant Bupropion HCl, the active ingredient in Wellbutrin XL®, has been completed. A regulatory file for a 505(b)(2) New Drug Application (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 have been resolved with new pivotal batches being manufactured by Pillar5 Pharma and, using product from these pivotal batches, a new clinical study is being undertaken to address the food effect. A response to the complete response letter is expected to be filed in the second quarter of 2011.

INT0006/2005. On December 10, 2007, we entered into a license and development agreement with Azur Pharma for the development and manufacture of a prenatal vitamin supplement using product specific intellectual property that we developed. Under the terms of the agreement, Azur Pharma has obtained certain exclusive rights to market and sell the product using our proprietary, controlled-release delivery technology in the United States. In exchange for granting Azur Pharma such rights, we will receive an annual single digit percentage royalty of all net sales. The term of the agreement is 15 years from the effective date of May 1, 2007, unless otherwise terminated in the event of, without limitation (i) failure by either us or Azur Pharma to perform our respective obligations under the agreement; (ii) if either party files a petition for bankruptcy or insolvency or otherwise winds up, liquidates or dissolves its business, or (iii) otherwise by mutual consent of the parties. The agreement also contains customary confidentiality, indemnification and intellectual property protection provisions.



The product was launched in the United States during the fourth quarter of 2008 under the brand name Gesticare®. As of December 31, 2010, we have received upfront, milestone and development fees totaling approximately \$1.4 million and royalty income totaling approximately \$0.5 million. We do not anticipate receiving additional milestone payments under the agreement.

INT0010/2006. We initially entered into an agreement with Cynapsus Therapeutics Inc. (formerly Cannasat Therapeutics Inc., Cynapsus ) 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. A clinical biostudy undertaken in 2009 on the mucoadhesive tablet developed by IntelGenx indicated improved bioavailability and reduced first-pass metabolization of the drug. In the 4<sup>th</sup> quarter of 2010, we acquired from Cynapsus full control of, and interest in, this project going forward. We also obtained worldwide rights to US Patent 7,592,328 and all corresponding foreign patents and patent applications to exclusively develop and further provide intellectual property protection for this project. We are preparing pivotal activities, including manufacturing scale-up and a clinical efficacy study.

INT0007/2006. An oral film product based on our proprietary edible film technology is currently in the optimization stage. The product is intended for the treatment of erectile dysfunction (ED). The results of a phase I pilot study that was conducted in the third quarter of 2010 indicate that the product is bioequivalent with the reference listed drug.

INT0008/2007. An oral film product based on our proprietary edible film technology is currently in the pivotal stage of development, with pivotal batch manufacturing expected to be completed in the third quarter of 2011. 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. In the third quarter of 2010, we entered into an agreement with RedHill Biopharma Ltd. for the co-development and commercialization of this product.

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.

INT0020/2010. An oral film product based on our proprietary edible film technology is currently being tested for bioequivalence against the reference listed drug. Results are expected in the first half of 2011. The product is intended for the treatment of insomnia.

INT0022/2010. An oral film product based on our proprietary edible film technology is currently in the final stages of optimization. The results of a phase I pilot study that was conducted in 2010 indicate that the product is bioequivalent with the reference listed drug. The product is intended for the treatment of bipolar disorder.

INT0024/2010. An oral tablet product based on our proprietary multilayer tablet technology is currently in the early development stage. The product is intended for the treatment of idiopathic pulmonary fibrosis.

INT0025/2010. An oral controlled release film product based on our proprietary edible film technology is currently in the early development stage. The product is intended for the treatment of benign prostatic hyperplasia.

INT0026/2011. 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 benign prostatic hyperplasia.

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

| <b>Product</b> | <b>Application</b>                            | <b>Status of Development</b>    |
|----------------|---|---------------------------------|
| INT0001/2004   | CHF (Coronary Heart Failure),<br>Hypertension | Pivotal batches in preparation. |

Edgar Filing: IntelGenx Technologies Corp. - Form 10-K/A

|              |                             |   |
|--------------|-----------------------------|---|
| INT0004/2006 | Antidepressant              | NDA filed April, 2009; complete response letter received Q1/2010. Pivotal batches completed at new manufacturing facility. Pivotal Phase I clinical study completed and ongoing stability study to support filing of response to complete response letter Q2, 2011. |
| INT0006/2005 | Prenatal vitamin supplement | Product launched in USA Q4, 2008.   |
| INT0010/2006 | Neuropathic pain            | Pilot biostudy completed. Pivotal activities in preparation.  |

|              |                               |  |
|--------------|-------------------------------|--|
| INT0007/2006 | Erectile Dysfunction          | Pilot biostudy completed indicating bioequivalence with Reference Listed Drug (RLD).     |
| INT0008/2007 | Migraine                      | Pilot biostudy completed indicating bioequivalence with RLD. Pivotal activities ongoing. |
| INT0019/2009 | Diarrhea                      | Formulation development ongoing.   |
| INT0020/2010 | Insomnia                      | Formulation development completed. Proof of concept clinical study ongoing.              |
| INT0022/2008 | Bipolar Disorder              | Pilot biostudy completed indicating bioequivalence with RLD.                             |
| INT0024/2010 | Idiopathic pulmonary fibrosis | Formulation development ongoing.   |
| INT0025/2010 | Benign prostatic hyperplasia  | Formulation development ongoing.   |
| INT0026/2011 | Benign prostatic hyperplasia  | 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 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.

### **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 two examples of our efforts to develop alternate technology platforms. As we work with various partners on different products, we seek opportunities to develop new proprietary technologies.

## 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 Valeant Pharmaceuticals International, Inc. (formerly Biovail Corporation), Labopharm Inc., Monosol Rx, Labtec GmbH and Skye Pharma PLC, 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 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 manufacture products only for testing purposes in our own laboratories, and we do not manufacture products for clinical trials or for commercial use.

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' 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 formed a strategic manufacturing partnership with, and took an ownership position in, Pillar5 Pharma Inc. ( Pillar5 ). We have undertaken to use our best efforts to ensure that distributors of our oral solid dose pharmaceutical products that are developed for commercial production, be directed to Pillar5 for the purpose of negotiating a manufacturing agreement requiring Pillar5 to manufacture such products. As consideration for this undertaking, Pillar5 issued to us common shares representing 10% of the issued and outstanding shares of Pillar5. This manufacturing partnership secures the production of clinical test batches and commercial products 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, may purchase significant quantities of raw materials, some of which may have long lead times. If raw materials cannot be supplied to our manufacturing partners in a timely and cost effective manner, our manufacturing partners may experience delays in production that may lead to reduced supplies of commercial products being available for sale or distribution. Such shortages could have a detrimental effect on sales of the products and a corresponding reduction on our royalty revenues earned.

### Dependence on Major Customers

We 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 / expiration             |
|--------------------------|---|--|--|
| US 6,231,957             | Rapidly disintegrating flavor wafer for flavor enrichment | The composition, manufacturing, and use of rapidly disintegrating flavored films for releasing flavors to certain substrates | Issued May 15, 2001<br>Expires May 6, 2019       |
| US 6,660,292             | Rapidly disintegrating film for precooked foods           | Composition and manufacturing of flavored films for releasing flavors to precooked food substrates                           | Issued December 9, 2003<br>Expires June 19, 2021 |
| US 7,132,113             | Flavored film   | Composition and manufacturing method of multi-layered films  | Issued April 16, 2002<br>Expires April 16, 2022  |
| US Appl.<br>2007/0190144 | Multilayer Tablet   | Formulation and Method of Preparation of Multilayered Tablets  | Published August 16, 2007                        |
| US Appl.<br>2007/0128272 | Multi-Vitamin And Mineral Supplement                      | Formulation and Method of Preparation of Prenatal  | Published June 7, 2007                           |

Edgar Filing: IntelGenx Technologies Corp. - Form 10-K/A

| Multivitamin Supplement                    |  |  |   |
|--|--|--|---|
| US Appl.<br>2006/0127478                   | Oral dosage formulation  | Multilayer oral dosage forms   | Published June 15, 2006                       |
| US Appl.<br>11/782,838<br>PCT/IB2007/03950 | Controlled Release<br>Pharmaceutical Tablets                           | Formulation and Method Of<br>Making Tablets Containing<br>Bupropion And Mecamylamine | July 25, 2006                                 |
| US Patent 7674479                          | Sustained-release Bupropion<br>and Bupropion / Mecamylamine<br>tablets | Formulation and Method Of<br>Making Tablets Containing<br>Bupropion And Mecamylamine | Issued March 9, 2010<br>Expires July 25, 2027 |



|                                      |  |   |                  |
|--------------------------------------|--|---|------------------|
| US Appl.<br>12/836810                | Oral Mucoadhesive dosage form  | Direct compression formulation for buccal and sublingual dosage forms | July 15, 2010    |
| US Appl.<br>US 12/936.132            | Oral film dosage forms and methods for making same                       | Optimization of Film strip technology                                 | December 8, 2010 |
| US Provisional Appl.<br>US 61/327969 | Methods for making improved solid oral dosage forms comprising Tadalafil | Oral films containing Tadalafil                                       | April 26, 2010   |

### 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;
- 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, 2010 increased to \$1,565 thousand as compared to \$1,237 thousand for the year ended December 31, 2009. The increase in R&D expenditure is explained in the section of this report entitled Management's Discussion and Analysis of Financial Condition and Results of

Operations .

**Environmental Regulatory Compliance**

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

**Employees**

As of the date of this filing, we have 10 full-time and no part-time employees. None of our employees are covered by collective bargaining agreements. We believe that our relations with our employees are good.

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES (a) Financial Statements and Schedules 1. Financial Statements**

The following financial statements are filed as part of the Original Form 10-K under Item 8 of Part II Financial Statements and Supplementary Data:

- A. Report of Independent Registered Public Accounting Firm.
- B. Consolidated Balance Sheets as of December 31, 2010 and 2009.
- C. Consolidated Statements of Operations for the years ended of December 31, 2010 and 2009.
- D. Consolidated Statements of Changes in Shareholders' Equity for the years ended of December 31, 2010 and 2009.
- E. Consolidated Statements of Cash Flows as of December 31, 2010 and 2009.
- F. Notes to Consolidated Financial Statements.

**2. Financial Statement Schedules**

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

**(b) Exhibits.**

**EXHIBIT INDEX**

**Exhibit**

| <b>No.</b> | <b>Description</b>  |
|------------|---|
| 2.1        | Share Exchange Agreement dated April 10, 2006 (incorporated by reference to the Form 8-K/A filed on April 28, 2006).                                    |
| 3.1        | Articles of Incorporation (incorporated by reference to the Form SB-2 (File No. 333-90149) filed on November 16, 1999).                                 |
| 3.2        | By-Laws (incorporated by reference to the Form SB-2 (File No. 333-91049) filed on November 16, 1999).   |
| 3.3        | Amendment to the Articles of Incorporation (incorporated by reference to amendment No. 2 to Form SB-2 (File No. 333- 135591) filed on August 28, 2006). |
| 3.4        | Amended and Restated By-Laws (incorporated by reference to the Form 8-K filed on March 31, 2010).   |
| 9.1        | Voting Trust Agreement (incorporated by reference to the Form 8-K/A filed on April 28, 2006).   |
| 10.1       | Horst Zerbe Employment Agreement (incorporated by reference to the Form SB-2 (File No. 333-135591) filed on July 3, 2006).                              |
| 10.2       | Ingrid Zerbe Employment Agreement (incorporated by reference to the Form SB-2 (File No. 333-135591) filed on July 3, 2006).                             |
| 10.3       | Registration Rights Agreement (incorporated by reference to the Form SB-2 (File No. 333-135591) filed on July 3, 2006).                                 |
| 10.4       | Principal's Registration Rights Agreement (incorporated by reference to the Form SB-2 (File No. 333-135591) filed on July 3, 2006).                     |
| 10.5       | Investor Relations Consulting Agreement (incorporated by reference to the Form SB-2 (File No. 333-135591) filed on July 3, 2006).                       |
| 10.6       | 2006 Stock Option Plan (incorporated by reference to the Form S-8 filed on November 21, 2006).  |

Edgar Filing: IntelGenx Technologies Corp. - Form 10-K/A

|       |  |
|-------|--|
| 10.7  | Form of Securities Purchase Agreement (incorporated by reference to the Form 8-K filed on May 23, 2007).   |
| 10.8  | Form of Registration Rights Agreement (incorporated by reference to the Form 8-K filed on May 23, 2007).   |
| 10.9  | Form of Warrant (incorporated by reference to the Form 8-K filed on May 23, 2007).                         |
| 10.10 | Form of Registration Rights Agreement (incorporated by reference to the Form 8-K filed on March 28, 2008). |
| 10.11 | Form of Warrant (incorporated by reference to the Form 8-K filed on March 28, 2008).                       |
| 10.12 | Form of Lock up Agreement (incorporated by reference to the Form 8-K filed on March 28, 2008).             |
| 10.13 | Form of Amended and Restated Warrant (incorporated by reference to the Form 8-K filed on August 4, 2008).  |

Edgar Filing: IntelGenx Technologies Corp. - Form 10-K/A

- 10.14 Employment Contract Paul A. Simmons (incorporated by reference to the Form 8-K filed on September 5, 2008).
- 10.15 Broker's Warrant (incorporated by reference to the Form S-1 filed on March 24, 2009).
- 10.16 Code of Ethics (incorporated by reference to the Form S-1 filed on March 24, 2009).
- 10.17 Amended and Restated 2006 Stock Option Plan, May 29, 2008 (incorporated by reference to the Form 10-K filed on March 25, 2009).
- 10.18 Agency Agreement, dated as of July 13, 2009, by and among the Company, Bolder Investment Partners Ltd., Union Securities Ltd. and Paradigm Capital Inc. (incorporated by reference to the Form 8-K filed on July 14, 2009).
- 10.19 Registration Rights Agreement, dated as of July 13, 2009, by and among the Company, Paradigm Capital Inc., Bolder Investment Partners Ltd. and Union Securities Ltd. (incorporated by reference to the Form 8-K filed on July 14, 2009).
- 10.20 Form of Warrant (incorporated by reference to the Form 8-K filed on July 14, 2009).
- 10.21 Form of Compensation Option (incorporated by reference to the Form 8-K filed on July 14, 2009).
- 10.22 Project Transfer Agreement (incorporated by reference to the Form 10-Q filed on May 14, 2010).
- 10.23 Co-development and Licensing Agreement (incorporated by reference to the Form 10-Q filed on May 14, 2010).
- 10.24 Form of Amended and Restated Warrant (incorporated by reference to the Form 8-K filed on July 29, 2010).
- 10.25 Agency Agreement, dated as of August 27, 2010, between the Company and Bolder Investment Partners, Ltd. (incorporated by reference to the Form 8-K filed on August 30, 2010).
- 10.26 Registration Rights Agreement, dated as of August 27, 2010, by and among the Company and the purchasers pursuant to the offering (incorporated by reference to the Form 8-K filed on August 30, 2010).
- 10.27 Form of Warrant (incorporated by reference to the Form 8-K filed on August 30, 2010).
- 10.28 Form of Compensation Option (incorporated by reference to the Form 8-K filed on August 30, 2010).
- 10.29 Co-Development and Commercialization Agreement with RedHill Biopharma Ltd. (incorporated by reference to the Form 10-Q filed on November 9, 2010).
- 10.30 Amended and Restated 2006 Stock Option Plan (incorporated by reference to the Form S-8 filed on November 15, 2010).
- 10.31 Form of Securities Purchase Agreement (incorporated by reference to the Form 8-K filed on June 3, 2011).
- 10.32 Form of Warrant (incorporated by reference to the Form 8-K filed on June 3, 2011).
- 10.33 Form of Registration Rights Agreement (incorporated by reference to the Form 8-K filed on June 3, 2011).
- 10.34\* License and Development Agreement between the Company and Azur Pharma International II Ltd.\*
- 14 Code of Ethics (incorporated by reference to the Form S-1 filed on March 24, 2009)
- 16.1 Letter on change in certifying accountant (incorporated by reference to the Form SB-2 (File No. 333-135591) filed on July 3, 2006).
- 21.1 Subsidiaries of the small business issuer (incorporated by reference to the Form SB-2 (File No. 333-135591) filed on July 3, 2006).
- 23.1 Consent of RSM Richter Chamberland, LLP (incorporated by reference with original 10K filing on March 29, 2011
- 31.1\*\* Certification of Horst G. Zerbe, President and Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.\*\*
- 31.2\*\* Certification of Paul A. Simmons, Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.\*\*
- 32.1\*\* Certification of Horst G. Zerbe, President and Chief Executive Officer, pursuant to 18 U.S.C. Section 1350.\*\*
- 32.2\*\* Certification of Paul A. Simmons, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350.\*\*

\* Filed herewith. Confidential treatment has been requested for certain parts of this document, which are omitted and filed separately with the SEC.

\*\* Filed herewith.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Exchange Act, the registrant has duly caused this Form 10-K/A Annual Report to be signed on its behalf by the undersigned on September 20, 2011, thereunto duly authorized.

**INTELGENX TECHNOLOGIES  
CORP.**

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

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

In accordance with the requirements of the Securities Exchange Act of 1934, this Form 10-K/A Annual Report has been signed by the following persons in the capacities and on the dates indicated.

| <b>Signature</b>   | <b>Position</b>                                 | <b>Date</b>        |
|--|---|--------------------|
| By: <i>/s/ Horst G. Zerbe</i><br>Horst G. Zerbe            | President, Chief Executive Officer and Director | September 20, 2011 |
| By: <i>/s/ Paul Simmons</i><br>Paul Simmons                | Chief Financial Officer                         | September 20, 2011 |
| By: <i>/s/ Bernard<br/>Boudreau</i><br>J. Bernard Boudreau | Director  | September 20, 2011 |
| By: <i>/s/ Ian Troup</i><br>John (Ian) Troup               | Director  | September 20, 2011 |
| By: <i>/s/ Bernd Melchers</i><br>Bernd J. Melchers         | Director  | September 20, 2011 |
| By: <i>/s/ John Marinucci</i><br>John Marinucci            | Director  | September 20, 2011 |
| By: <i>/s/ Dr. Rajiv<br/>Khosla</i><br>Dr. Rajiv Khosla    | Director  | September 20, 2011 |