

IntelGenx Technologies Corp.  
Form S-1/A  
September 04, 2009

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As filed with the Securities and Exchange Commission on August , 2009  
Registration No. 333-161305

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

**FORM S-1**  
**REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933**

**IntelGenx Technologies Corp.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**2834**

(Primary Standard Industrial  
Classification Code Number)

**870299034**

(I.R.S. Employer Identification Number)

**6425 Abrams, Ville St- Laurent, Quebec, H4S 1X9**

**(514) 331-7440**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Horst Zerbe**

**Chief Executive Officer**

**IntelGenx Technologies Corp, 6425 Abrams, Quebec, H4S 1X9**

**(514) 331-7440**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

**Richard Raymer**

**Hodgson Russ LLP**

**150 King Street West, Suite 2309, Toronto, Ontario M5H 1J9**

**Canada**

**Tel: (416) 595-5100**

**As soon as practicable after the effective date of this Registration Statement**

(Approximate date of commencement of proposed sale to the public)

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective

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registration statement for the same offering:

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a small reporting company:

Large accelerated filer

Non-accelerated filer

Accelerated filer

Smaller reporting company

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<b>Title of each class of securities to be registered</b>	<b>Amount to be registered</b>	<b>Proposed maximum offering price per share (4)</b>	<b>Proposed maximum aggregate offering price</b>	<b>Amount of registration fee (5)</b>
Common stock, par value \$.00001 per share (1)	12,083,120 shares	\$ 0.70	\$ 8,458,184	\$ 471.97
Common stock underlying warrants, par value \$.00001 per share (2)	10,826,000 shares	\$ 0.70	\$ 7,578,200	\$ 422.86
Common stock purchase warrants (3)	10,826,000 warrants	--	--	--
	22,909,120 shares	\$ 0.70	\$ 16,036,384	\$ 894.83
<b>Total</b>	10,826,000 warrants	\$ --	\$ --	\$ --

(1) Represents shares of common stock, par value \$.00001.

(2) Represents shares of common stock underlying warrants to purchase shares of common stock, par value \$.00001.

(3) Represents common stock purchase warrants exercisable at \$0.80 per share, subject to adjustment, expiring July 13, 2012, and 350,000 common stock purchase warrants exercisable at \$0.80 per share, subject to adjustment, expiring July 22, 2012.

(4) Estimated solely for purposes of calculating the registration fee in accordance with Rule 457(c) and Rule 457(g) under the Securities Act of 1933, as amended, based upon the average of the high and low prices of a share of common stock of IntelGenx Technologies Corp. as reported on the OTC Bulletin Board on August 7, 2009.

(5) Previously paid.

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE SECURITIES ACT OF 1933 OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(a), MAY DETERMINE.

**The information contained in this prospectus is not complete and may be changed. The selling security holders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.**

**SUBJECT TO COMPLETION, dated August \_\_, 2009**

**Prospectus**

**IntelGenx Technologies Corp.**

**22,909,120 Shares of Common Stock and 10,826,000 Warrants Offered by Selling Security Holders**

This prospectus relates to the sale by the selling security holders listed herein of up to 22,909,120 shares of common stock, par value \$.00001 per share, and 10,826,000 common stock purchase warrants of IntelGenx Technologies Corp. ("IntelGenx" or the "Company"). The securities being registered were purchased by the selling security holders in private placements completed on July 13, 2009 (the "Canadian Private Placement") and on July 22, 2009 (the "U.S. Private Placement"). For a complete description of the private placements please see the section entitled "Description of the July 2009 Private Placements", below).

The securities being registered include shares of outstanding common stock (the "Common Shares"), common stock purchase warrants exercisable at \$0.80 per share, subject to adjustment (the "Warrants"), and shares of common stock underlying the Warrants (the "Warrant Shares"). The securities being registered also include Common Shares and options issued to the placement agents in connection with the Canadian Private Placement (the "Placement Agent Options"). The Placement Agent Options permit the placement agents to purchase shares of common stock (the "Placement Agent Option Shares") at a price of \$0.80 per share, subject to adjustment.

Accordingly, the shares being registered include (i) 419,040 Common Shares issued to the placement agents under the Canadian Private Placement, (ii) 350,000 Common Shares issued under the U.S. Private Placement, (iii) 10,476,000 Common Shares to be issued upon exercise of Special Warrants issued under the Canadian Private Placement, (iv) 10,826,000 Warrants, (v) 10,826,000 Warrant Shares and (vi) 838,080 Placement Agent Option, Shares, issuable upon exercise of the Placement Agent Options.

The common stock will be offered by the selling security holders at fixed prices, at the then-prevailing market prices at the time of sale, at varying prices, or in negotiated transactions (See "Plan of Distribution").

Our common stock is traded on the OTC Bulletin Board (the "OTCBB") under the symbol "IGXT" and on the TSX Venture Exchange (the "TSX") under the symbol "IGX". The closing price of our common stock on the OTCBB on August 26, 2009 was \$0.54, and the closing price of our common stock on the TSX on August 25, 2009 was CDN\$0.60.

Our executive office is located at 6425 Abrams, Ville Saint-Laurent, Quebec, H4S 1X9, Canada, and our telephone number is (514) 331-7440.

We will not receive any proceeds from the sale of the shares of common stock offered by the selling security holders to the public. However, we will receive proceeds from the exercise of the Warrants, as well as from the exercise of the Placement Agent Options. Any such proceeds will be used to support the Company's strategic development projects and for working capital. We have agreed to pay all of the costs of this offering, excluding commissions and discounts regarding the sale of the common stock by the selling security holders.

Brokers or dealers effecting transactions in the shares should confirm the registration of these securities under the securities laws of the states in which such transactions occur or the existence of an exemption from such registration.

Certain selling security holders and any participating broker-dealers may be deemed to be underwriters within the meaning of the Securities Act of 1933, as amended (the Securities Act), and any commissions or discounts given to any such broker-dealer may be regarded as underwriting commissions or discounts under the Securities Act. See Selling Security Holders and Plan of Distribution .

**Investing in our securities involves a high degree of risk. You should invest in the common stock only if you can afford to lose your entire investment. See Risk Factors beginning on page 4.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

The date of this prospectus is \_\_\_\_\_, 2009

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You should rely only on the information contained in this prospectus or any prospectus supplement. We have not and the selling security holders have not authorized anyone else to provide you with different information. If anyone provides you with different information, you should not rely on it. We are not and the selling security holders are not making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus or any prospectus supplement is accurate only as of the date on the front cover of the applicable document. Our business, financial condition, results of operations and

prospects may have changed since that date.

## 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, intend, plan, 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.

## PROSPECTUS SUMMARY

The following summary is qualified in its entirety by the more detailed information appearing elsewhere in this prospectus. In this prospectus, the words "Company," "IntelGenx" "we," "us," and "our," refer collectively to IntelGenx Technologies Corp. and IntelGenx Corp., our wholly-owned Canadian subsidiary.

### Our Business

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

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

Our executive offices are located at 6425 Abrams, Ville Saint-Laurent, Quebec, H4S 1X9, Canada and our telephone number is (514) 331-7440. Our web site address is <http://www.IntelGenx.com>. Information contained on our web site is not a part of this prospectus.





**THE OFFERING**

<b>The Offering</b>	
Shares of common stock offered by the selling security holders	Up to 22,909,120 shares of common stock and 10,826,000 Warrants, including (i) 419,040 Common Shares issued to the placement agents under the Canadian Private Placement, (ii) 350,000 Common Shares issued under the U.S. Private Placement, (iii) 10,476,000 Common Shares to be issued upon exercise of special warrants issued under the Canadian Private Placement, (iv) 10,826,000 Warrant Shares, and (v) 838,080 shares of Placement Agent Option Shares, issuable upon exercise of the Placement Agent Options... Assuming the full exercise of all the Warrants and the Placement Agent Options, the shares being registered would represent approximately 51% of our outstanding common stock. (1)
Common stock to be outstanding after the offering	Up to 44,840,194 shares of Common Stock, assuming the exercise of all of the Warrants and the Placement Agent Options.
Use of proceeds	IntelGenx will not receive any proceeds from the sale of the shares of common stock offered by the selling security holders to the public. However, IntelGenx will receive proceeds from any cash exercise of the Warrants, as well as from the exercise of the Placement Agent Options. Any such proceeds will be used to support the Company's strategic development projects and for working capital.
OTCBB Ticker Symbol	IGXT
TSX Venture Exchange Symbol	IGX

(1) The above information regarding common stock to be outstanding after the offering is based on 22,350,114 shares of common stock outstanding as of August 28, 2009.

**Description of July 2009 Private Placements****Canadian Private Placement**

On July 13, 2009, we completed an offering to investors of 10,476,000 special warrants (the "Special Warrants") at a price of CDN\$0.40 per Special Warrant for gross proceeds of approximately CDN\$4,200,000 (the "Gross Proceeds") and net proceeds of approximately CDN\$3,780,050 ("the "Canadian Private Placement"). Each Special Warrant may be exercised at any time at the holder's option and will automatically exercise, in each case for no additional consideration, on the earliest to occur of (a) the fifth business day after the later of (i) the date a receipt is issued by the relevant securities regulatory authorities in Canada for the final prospectus qualifying the Common Shares and the Warrants to be issued upon the exercise of the Special Warrants, and (ii) the date this Registration Statement is declared effective by the U.S. Securities and Exchange Commission and (b) November 14, 2009. Each Special Warrant entitles its holder to receive, upon exercise or deemed exercise thereof, one Common Share and one Warrant, which together were referred to in the subscription agreements as a "Unit". Each Warrant will entitle the holder to purchase one Common Share (the "Warrant Shares") at a price of U.S.\$0.80 per share, subject to adjustment, until July 13, 2012. The exercise price of the Warrants is subject to adjustment for certain events, including dividends, distributions or split of the Company's common stock, subsequent equity sales or rights offerings by the Company, or in the event of the Company's consolidation, merger or reorganization.

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Paradigm Capital Inc. ("Paradigm"), Bolder Investment Partners Ltd. ("Bolder") and Union Securities Ltd. ("Union") (collectively, the "Placement Agents") acted as placement agents for the Canadian Private Placement on a best efforts basis. The Placement Agents' compensation consists of a cash commission equal to 8% of the Gross Proceeds, 419,040 Common Shares (the "Placement Agent Shares") and an option to acquire 838,080 Common Shares at U.S.\$0.80 per unit, subject to adjustment, until July 13, 2012 (the "Placement Agent Options"). (The shares of common stock issuable upon exercise of the Placement Agent Options shall be referred to as the "Placement Agent Option Shares".) The exercise price of the Placement Agent Options is subject to adjustment for certain events, including dividends, distributions or split of the Company's common stock, subsequent equity sales or rights offerings by the Company, or in the event of the Company's consolidation, merger or reorganization.

In connection with the Canadian Private Placement, the Company entered into a registration rights agreement (the "Registration Rights Agreement") providing for the filing of a registration statement (the "Registration Statement") with the U.S. Securities and Exchange Commission registering the Common Shares, the Warrants, the Warrant Shares, the Placement Agent Shares, the Placement Agent Options and the Placement Agent Option Shares. The Company is obligated to file the Registration Statement no later than 30 days from the date of closing and to use its commercially reasonable efforts to cause the Registration Statement to be declared effective no later than 120 days after the date of closing.

If, the fifth business day following the later of: (a) a receipt being issued by the relevant securities regulatory authorities in Canada for the final prospectus qualifying the Common Shares and the Warrants to be issued upon the exercise of the Special Warrants, or (b) this Registration Statement being declared effective by the U.S. Securities and Exchange Commission, has not occurred on or before November 10, 2009 (120 days following the closing date), then each unexercised Special Warrant will be deemed exercised for 1.1 Common Shares and 1.1 Warrants.

In connection with the Canadian Private Placement, each of the Company's officers and directors have entered into lock-up agreements in favor of the Placement Agents pursuant to which they have agreed not to sell or transfer their shares for a period of 90 days following the fifth business day after the later of (a) the date the Company receives a receipt for a prospectus qualifying the Common Shares and the Warrants issuable upon exercise of the Special Warrants, and (b) the date this Registration Statement is declared effective by the U.S. Securities and Exchange Commission, unless they first obtain the prior written consent of Paradigm or there occurs a take-over bid or similar transaction involving a change of control of the Company.

The issuances under the Canadian Private Placement were exempt from registration under Section 4(2) of the Securities Act and/or Regulation S, promulgated pursuant to the Securities Act. None of the purchasers under the Canadian Private Placement are U.S. persons, no sales efforts were conducted in the U.S., and the Common Shares, the Warrants, the Warrant Shares, the Placement Agent Shares, the Placement Agent Options and the Placement Agent Option Shares issued in connection with the Canadian Private Placement contain, or will contain upon issuance, a legend restricting the sale of such securities in accordance with Regulation S and pursuant to applicable Canadian securities laws.

#### U.S. Private Placement

On July 22, 2009, concurrently with the Canadian Private Placement, the Company completed an offering of 350,000 units to investors in the United States (the "U.S. Private Placement" and together with the Canadian Private Placement, the "July 2009 Private Placements"). No placement agent was used for the U.S. Private Placement and no commissions were paid in connection therewith. As in the Canadian Private Placement, each unit consists of one Common Share and one Warrant. Each Warrant entitles the holder thereof to purchase one Common Share at an initial exercise price of US\$0.80 per common share and expires on July 22, 2012. The exercise price of the Warrants is subject to adjustment for certain events, including without limitation, dividends, distributions or split of the Company's common stock, subsequent rights offerings by the Company, or in the event of the Company's consolidation, merger or reorganization.

The issuances under the U.S. Private Placement were exempt from registration under Section 4(2) of the Securities Act. The Common Shares, the Warrants and the Warrant Shares issued in connection with the U.S. Private Placement are subject to statutory resale restrictions under the Securities Act and contain, or will contain upon issuance, a legend restricting the sale of such securities in accordance with applicable exemptions from the registration requirements of the Securities Act.

## **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 \$4,725,045 since our inception in 2003 through December 31, 2008. To date, these losses have been financed principally through sales of equity securities, long-term debt and debt from related parties. Our revenues for the years ended December 31, 2008, December 31, 2007, December 31, 2006, December 31, 2005 and December 31, 2004 were \$976,610, \$862,731, \$265,901, \$19,990 and \$257,374 respectively. Our revenues consisted primarily of development fee revenues from five clients and have not been sufficient to sustain our operations. In order to achieve profitability, our revenue streams will have to increase and there is no assurance that revenues will increase to such a level.

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

The majority of our expenses are paid in Canadian dollars, while our revenues are primarily in U.S. dollars. Our financial results are subject to the impact of currency exchange rate fluctuations. Adverse movements in exchange rates could have a material adverse effect on our financial condition and results of operations. **We may need additional capital to fulfill our business strategies. We may also incur unforeseen costs. Failure to obtain such capital would adversely affect our business.**

We will need to expend significant capital in order to continue with our research and development by hiring additional research staff and acquiring additional equipment. If our cash flows from operations are insufficient to fund our expected capital needs, or our needs are greater than anticipated, we will be required to raise additional funds in the future through private or public sales of equity securities or the incurrence of additional indebtedness. Additional funding may not be available on favorable terms, or at all. If we borrow additional funds, we likely will be obligated to make periodic interest or other debt service payments and may be subject to additional restrictive covenants. If we fail to obtain sufficient additional capital in the future, we could be forced to curtail our growth strategy by reducing or delaying capital expenditures, selling assets or downsizing or restructuring our operations. If we raise additional funds through public or private sales of equity securities, the sales may be at prices below the market price of our stock and our shareholders may suffer significant dilution.

**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 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.

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

We compete with other companies within the drug delivery industry, many of which have more capital, more extensive research and development capabilities and greater human resources than we do. Some of these drug delivery competitors include Biovail Corporation, Labopharm Inc., and Flamel Technologies S.A. Our competitors may develop new or enhanced products or processes that may be more effective, less expensive, safer or more readily available than any products or processes that we develop, or they may develop proprietary positions that prevent us from being able to successfully commercialize new products or processes that we develop. As a result, our products or processes may not compete successfully, and research and development by others may render our products or processes obsolete or uneconomical. Competition may increase as technological advances are made and commercial applications broaden.

**We are dependent upon sales outside the United States, which are subject to a number of risks.**

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

- Unforeseen changes in regulatory requirements;
- Weaker intellectual property rights protection in some countries;
- New export license requirements, changes in tariffs or trade restrictions; and
- Political and economic instability in our target markets.

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

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

The third-party manufacturers that we depend on to manufacture our products are required to adhere to FDA regulations regarding current Good Manufacturing Practices ( 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. 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 payors as clinically useful, cost-effective and safe. No product based on our technologies is marketed in the United States, so there can be no assurance as to market acceptance.

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

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

**We are subject to environmental regulations and any failure to comply may result in substantial fines and sanctions.**

Our operations are subject to Canadian and international environmental laws and regulations governing, among other things, emissions to air, discharges to waters and the generation, handling, storage, transportation, treatment and disposal of raw materials, waste and other materials. Many of these laws and regulations provide for substantial fines and criminal sanctions for violations. We believe that we are and have been operating our business and facility in a manner that complies in all material respects with environmental, health and safety laws and regulations; however, we may incur material costs or liabilities if we fail to operate in full compliance. We do not maintain environmental damage insurance coverage with respect to the products which we manufacture.

We may have to make significant expenditures in the future to comply with evolving environmental, health and safety requirements, including new requirements that may be adopted or imposed in the future. To meet changing licensing and regulatory standards, we may have to make significant additional site or operational modifications that could involve substantial expenditures or reduction or suspension of some of our operations. We cannot be certain that we have identified all environmental and health and safety matters affecting our activities and in the future our environmental, health and safety problems, and the costs to remediate them, may be materially greater than we expect.

**Our limited cash resources restrict our ability to pay cash dividends.**

Since our inception, we have not paid any cash dividends on our common stock. 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 three 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. Third-party infringement claims, regardless of their outcome, would not only consume significant financial resources, but would also divert our management's time and attention. Such claims could also cause our customers or potential customers to purchase competitors' products or defer or limit their purchase or use of our affected products until resolution of the claim. If any of our products are found to violate third-party intellectual property rights, we may have to re-engineer one or more of our products, or we may have to obtain licenses from third parties to continue offering our products without substantial re-engineering. Our efforts to re-engineer or obtain licenses could require significant expenditures and may not be successful.

**Our controlled release products that are generic versions of branded controlled release products that are covered by one or more patents may be subject to litigation, which could delay FDA approval and commercial launch of our products**

We expect to file or have our 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 ours.**

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

### **Lack of Independent Directors**

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 thereof. 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 price in response to various factors which are beyond our control. The price of our common stock is not necessarily indicative of our operating performance or long term business prospects. In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our common stock.

In the United States, our common stock is considered a penny stock . The 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. 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.

## **DESCRIPTION OF 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.

According to a report by CMR International, a pharmaceutical industry research firm, products incorporating drug delivery systems represented 13% of the \$337 billion global pharmaceutical market. In the United States, sales of drug delivery products totaled \$35 billion in 2006. Of this amount, the orally administered segment of the drug delivery market totaled \$21 billion in sales, according to CMR International. Controlled release (CR) dosage technologies play an important role in the development of orally administered drug delivery systems. Control release technology provides patients with the required amount of medication over a pre-determined, prolonged period of time, preferably over 24 hours. Because of the reduced fluctuation of the active drug in the blood, controlled release products are deemed safer and more tolerable than conventional dosage forms, and have shown better patient compliance.

Our primary business strategy is to develop pharmaceutical products based upon our proprietary drug delivery technologies and license the commercial rights to companies in the pharmaceutical industry once the viability of a product has been demonstrated. In exchange for licensing rights to our products, we seek funding consisting of a combination of one or more of the following: advance down payments, milestone fees, reimbursement for development costs, and royalties on sales. In addition, we may receive a manufacturing royalty from our contract manufacturers for the exclusive right to manufacture our products. The companies we partner with are typically responsible for managing the regulatory approval process of the product with the 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 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 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 an antidepressant has been completed. A regulatory file for a 505(b)(2) NDA submission was filed and has been accepted by the FDA for standard review .

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.

INT0007/2006. An oral film product based on our proprietary edible film technology is currently in the early development stage. The product is intended for the treatment of erectile dysfunction (ED).

INT0008/2007. An oral film product based on our proprietary edible film technology is currently in the early development stage. The product is intended for the treatment of migraine.

INT0015/2008. An oral film product based on our proprietary edible film technology is currently in the early development stage. The product is intended for the treatment of panic attacks.

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

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:

<b>Product</b>	<b>Application</b>	<b>Status of Development</b>
INT0001/2004	CHF, Hypertension	Pivotal batches in preparation
INT0003/2005	Smoking cessation	Pilot biostudy completed
INT0004/2006	Antidepressant	NDA filed Q1, 2009
INT0010/2006	Neuropathic pain	Pilot biostudy completed
INT0006/2005	Prenatal vitamin supplement	Product launched in USA Q4, 2008
INT0005/2005	Osteoarthritis	Pilot batch completed
INT0007/2006	ED	Formulation development ongoing
INT0008/2007	Migraine	Formulation development ongoing
INT0014/2008	Schizophrenia	Formulation development ongoing
INT0015/2008	Panic Attack	Formulation development ongoing
INT0018/2008	Hyperlipidemia	Formulation development ongoing
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 us. In addition, many of our competitors have significantly greater experience than we have in conducting clinical trials of pharmaceutical products, obtaining FDA and other regulatory approvals of products, and marketing and selling products that have been approved. We expect that we will be subject to competition from numerous other companies that currently operate 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 "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 have entered into a collaboration agreement with Keata Pharma Inc. ("Keata Pharma"), a wholly owned subsidiary of PharmEng International Inc., based in Markham, Ontario. Under this agreement, Keata Pharma is our preferred supplier for the manufacturing of clinical test batches and commercial products. We also have a reciprocal relationship whereby we recommend Keata Pharma to our partners for pharmaceutical manufacturing services and Keata Pharma promotes our product development services to pharmaceutical companies.

### Dependence on Major Customers

We do not rely on any one or a few major customers for our end products. However, we depend upon a limited number of partners to develop our products, to provide funding for the development of our products, and to assist in obtaining regulatory approvals that are required in order to commercialize these products.

### Intellectual Property and Patent Protection

We protect our intellectual property and technology by using the following methods: (i) applying for patent protection in the United States and in the appropriate foreign markets, (ii) non-disclosure agreements, license agreements and appropriate contractual restrictions and controls on the distribution of information, (iii) trade secrets, common law trademark rights and trademark registrations. We plan to file core technology patents covering the use of our platform technologies in any pharmaceutical products.

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

Patent No.	Title	Subject	Date submitted / issued
US 6,231,957	Rapidly disintegrating flavor wafer for flavor enrichment	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
US Appl. 2007/0190144	Multilayer Tablet	Formulation and Method of Preparation of Multilayered Tablets	Published August 16, 2007

US Appl. 2007/0128272	Multi-Vitamin And Mineral Supplement	Formulation And Method of Preparation of Prenatal Multivitamin Supplement	Published June 7, 2007
PCT/CA2006/000336; US Appl. 11/403,262	Delayed Release Oral Dosage Form And Method Of Making Same	Formulation And Method Of Making Bilayer Tablets C o n t a i n i n g D e l a y e d - R e l e a s e D i c l o f e n a c A n d 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 Appl. Make Special 11/828,287	Stabilized sustained-release Bupropion and Bupropion / Mecamylamine tablets	Formulation And Method Of Making Tablets Containing Bupropion And Mecamylamine	August 2007
US Provisional Appl. Attorney Docket INT34 P-311	Buccal And Sublingual Dosage Forms	Formulation And Method of Preparation of mucoadhesive tablets containing THC	July 2007
US Provisional Appl. Attorney Docket INT34 P-310	Cannabinoid Complexes	Formulation And Method of Preparation of gamma-cyclodextrin complexes containing CBD	July 2007

### 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 R&D expenses and shorter time-to-market timelines as compared to regular NDA products.

### Research and Development Expense

Our Research & Development ( R&D ) expenses, net of R&D tax credits, for the year ended December 31, 2008 were \$1,779,741 as compared to \$603,374 for the year ended December 31, 2007.

### Environmental Regulatory Compliance

We believe that we are in compliance with 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 nine full time employees.

## DESCRIPTION OF PROPERTY

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 2009. Management has therefore entered into discussions with the current landlord to look for alternative facilities that would meet our need for additional space at affordable costs.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

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



## **Revenues**

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

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

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

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

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

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

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

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

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

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

## **Management Salaries and General and Administrative Expenses**

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

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

The increase in general and administrative expenses is primarily attributable to the increase in corporate operations.

## **Professional Fees**

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

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

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

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

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

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

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

### **Financing Cost**

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

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

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

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

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

### **Foreign Exchange**

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

### **Net Loss**

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

- a) R&D expenses of approximately \$915,444 and Management Fees of approximately \$222,236 relating to the collaboration agreement with Cary Pharmaceuticals to develop the antidepressant CP-300;
- b) Professional fees of approximately \$108,714 related to the Company's listing on the TSX Venture Exchange; and

- c) Financing costs of approximately \$749,323 incurred in relation to the convertible notes issued in May 2007, of which approximately \$545,133 relates to interest paid and accreted, and \$204,190 relates to amendments to the terms and conditions of the convertible notes.

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

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