

AKELA PHARMA INC.

**ANNUAL INFORMATION FORM
YEAR ENDED DECEMBER 31, 2008**

MARCH 31, 2009

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CORPORATE STRUCTURE

Akela Pharma Inc. (the “Company”, “we” or “us”) resulted from the amalgamation on November 15, 1988 of T&H Resources Ltd. (“T&H”) and Coastoro Resources Ltd. On May 9, 2002 the Company was continued under the Canada Business Corporations Act. In connection with the continuance, the issued common shares were consolidated on a 1-for-20 basis and the name of the Company was changed to LAB International Inc. By articles of amendment dated July 5, 2007, our articles were amended (i) to change our name to “Akela Pharma Inc.”, and (ii) to change our authorized capital by deleting the existing Class A Shares and Class B Shares and creating a new class consisting of an unlimited number of Preference Shares issuable in series. By articles of amendment dated October 10, 2007, our articles were amended to consolidate our issued and outstanding common shares on a one-for-seven basis (as so consolidated, the “Common Shares”). Our registered office is located at 1 Place Ville Marie, 37th Floor, Montreal, Quebec H3B 3P4 and our principal place of business is located at Suite 4010, 11400 Burnet Road, Austin, Texas 78758.

The subsidiaries and other wholly-owned entities of the Company are as follows:

- (a) Akela Pharma Oy, a wholly-owned subsidiary of the Company incorporated under the laws of Finland;
- (b) Akela Pharma LLC, a wholly-owned subsidiary of the Company incorporated under the laws of Delaware;
- (c) Akela Pharma SRL, a wholly-owned subsidiary, owned 99% by the Company and 1% by Akela Pharma LLC, incorporated under the laws of Barbados;
- (d) Akela Pharma USA, a wholly-owned subsidiary of the Company incorporated under the laws of Delaware which acts as the employer of certain resident U.S. senior management;
- (e) Formulation Technologies, LLC, a Texas limited liability company which is wholly-owned by the Company;
- (f) Akela Clinical Research Services, Pvt, Ltd., a wholly-owned subsidiary of the Company incorporated under the laws of India; and
- (g) Akela Clinical Polska Sp. z o.o., a wholly-owned subsidiary of the Company incorporated under the laws of Poland.

As used herein, the terms “Company”, “we” and “us” mean Akela Pharma Inc. and its subsidiaries and wholly-owned entities, unless the context requires otherwise. All dollar amounts herein are in U.S. dollars unless expressly stated otherwise.

The Company employs more than 85 people at its locations in Austin, Texas, 3 in Poland and 4 in India.

FORWARD-LOOKING STATEMENTS

This annual information form (“AIF”) contains forward-looking statements within the meaning of the securities legislation of certain of the provinces of Canada and the *U.S. Private Securities Litigation Reform Act of 1995*. Forward-looking statements are necessarily made based on estimates and assumptions made by the Company in light of its experience and perception of historical trends, current conditions and expected future developments, as well as other factors it believes are appropriate in the circumstances. These estimates and assumption are inherently subject to significant business, economic and competitive uncertainties, many of which, with respect to future events, are subject to change. These uncertainties and contingencies can affect actual results and could cause actual results to differ materially from those expressed or implied in any forward-looking statements made by the Company, or on its behalf.

In making the forward-looking statements in this AIF, the Company has applied numerous material factors and assumptions, including, but not limited to:

- the assumption that the Company will have access to the amounts of additional capital that are necessary to fund the costs associated with researching, developing and marketing its pharmaceutical products and drug delivery technologies;
- the assumption that the results of the clinical trials on the pharmaceutical products and drug delivery technologies currently being developed will be sufficiently successful to support their continued development by the Company;
- the assumption that the Company will be successful in obtaining regulatory approvals to allow it to market its pharmaceutical products and drug delivery technologies; and
- the assumption that the pharmaceutical products and drug delivery technologies currently being developed by the Company can be successfully commercialized and will be competitive with the drug formulations and drug delivery systems being developed by its competitors .

The words “expect”, “anticipate”, “estimate”, “may”, “will”, “should”, “could”, “intend”, “believe”, “predict”, “potential”, “continue”, “plan”, “strategy” and similar expressions are intended to identify forward-looking statements in this AIF.

In light of the risks and uncertainties inherent in all forward-looking statements, the inclusion or incorporation by reference of forward-looking statements in this AIF should not be considered as a representation by the Company or any other person that its objectives or plans will be achieved. Numerous factors could cause the Company’s actual results to differ materially from those in the forward-looking statements, including the following, risks relating to the Company’s business, which are discussed in greater detail under the “Risk Factors” section herein:

- delays or unfavorable results from our current and planned clinical trials;
- our ability to establish and maintain intellectual property protection for our product candidates;
- our access to additional capital;
- our ability to enter into and maintain relationships with third parties, such as licensors, manufacturers, suppliers and those who conduct clinical trials for us;
- our ability to enroll patients for our clinical trials;
- our ability to implement and manage our sales and commercialization initiatives;
- the impact of competition and technological change;
- the timing of necessary regulatory clearances;
- general economic and business conditions, both nationally and in our markets;
- our ability to attract and retain key management and scientific personnel;
- existing and future regulations that affect our business; and
- other risk factors included under “Risk Factors” in this AIF.

The Company's actual results may also differ materially from those in the forward-looking statements because of risks related to its intellectual property and risks related to the Company's industry, both of which are discussed in detail under the "Risk Factors" section herein.

These factors should be considered carefully, and readers should not place undue reliance on the Company's forward-looking statements. The Company undertakes no obligation to release publicly the results of any future revisions it may make to forward-looking statements to reflect events or circumstances after the date of this AIF or to reflect the occurrence of unanticipated events, except as required by law.

GENERAL DEVELOPMENT OF THE BUSINESS

History and Development

In 1979, Dr. Halvor Jaeger established in Germany LAB Gesellschaft für pharmakologische Untersuchungen GmbH, a contract research organization ("CRO"). This entity opened its first North American operation in 1982 in New Jersey and its first Canadian operation in Vaudreuil (near Montréal), Québec in 1992. In 1996, the German operations were sold and its former subsidiary in Canada became the headquarters. The clinical CRO business was sold in 1999 and, from 1999 to 2002, the remaining entity focused on increasing preclinical CRO operations.

On May 9, 2002, the remaining entity, then known as LAB International Holdings Inc. ("LAB Holdings"), went public by way of a reverse take-over transaction and was listed on the Toronto Stock Exchange ("TSX"). The name of the listed company was changed to LAB International Inc. The objective of the reverse take-over was to facilitate the growth of our CRO activities as well as to enable us to start developing our own pipeline of therapeutic products. Over the next five years, we completed a number of private placements and acquisitions to grow our pipeline and CRO activities.

As a result of various acquisitions, we operated two distinct business units, which we referred to as Pharma and Contract Research. The Pharma business was developing and manufacturing novel inhalation therapeutic products and consisted of three separate wholly-owned subsidiaries in Finland, Barbados and Canada. The Contract Research business engaged in providing CRO services to the pharmaceutical and biotechnology industry. It consisted of four separate wholly-owned subsidiaries in Canada, Hungary, Denmark and California. This business model was unique in the pharmaceutical industry and was based upon using our ongoing access to the capital generated by Contract Research to fund the development by Pharma of novel therapeutics for the inhalation market.

On May 24, 2006, we incorporated LAB Research Inc. ("LRI"). Between June 30, 2006 and August 3, 2006, we effected a corporate reorganization to facilitate the transfer of the Contract Research business to LRI and the public offering of LRI. Between August and November 2006, we sold all of our holdings in LRI.

On January 25, 2007, we completed the acquisition of Formulation Technologies, L.L.C. ("PharmaForm"). On closing, we paid to the sellers of PharmaForm U.S.\$7.5 million in cash and issued 862,791 Common Shares (being the quotient of U.S.\$4,375,000 divided by an ascribed value of U.S.\$5.071 per share). The ascribed value per share was equal to Cdn. \$5.75477 (being the weighted average trading price of the Common Shares on the TSX for the 10 trading days ended October 24, 2006 which preceded the first public announcement of the transaction, converted into U.S. dollars based on the average exchange rate during the same period). Additional consideration is payable by us upon completion of certain milestones relating to PharmaForm's drug development programs.

In June 2007, we entered into an exclusive license and development agreement with Janssen Pharmaceutica N.V. ("Janssen") with respect to the continuing development and commercialization of Fentanyl TAIFUN®. On December 20, 2007, we entered into a supplemental license agreement with Janssen extending the geographic scope of the original agreement to include Canada.

Our Finnish subsidiary received certain low interest loans and subsidies from a Finnish governmental agency. In the summer of 2007, following our decision to down-size the Finnish operations, we were notified that this agency was reviewing loans and subsidies previously granted to us totaling €3,150,000 and €956,000, respectively. The agency has decided not to call the loans and we have not accepted its demand for repayment of the subsidies. Discussions

with the agency are ongoing and we cannot determine if such review will lead to repayment of all or a portion of the subsidies we received. However, the loans received from the Finnish governmental agency continue to be reflected as long-term debt in our financial statements in accordance with the original agreements.

We initially filed a Registration Statement on Form F-1 (the "Registration Statement") with the U.S. Securities and Exchange Commission ("SEC") on October 12, 2007 with the intention of effecting an initial public offering of Common Shares in the United States. Due to unfavorable market conditions, we determined that we were unable to proceed with the offering at that time. On January 17, 2008, we requested withdrawal of the Registration Statement, together with all exhibits thereto, from the SEC. The Registration Statement had not become effective when we requested its withdrawal from the SEC and we did not sell any securities by means of the preliminary prospectus that formed a part of the Registration Statement.

Recent Events

On February 4, 2008, we announced that we had received notice from the United States Food and Drug Administration ("FDA") that, due to Good Laboratory Practice ("GLP") deviations, the six month inhalation toxicology studies of Fentanyl TAIFUN® dry powder inhaler performed for us on dogs and rats by a CRO were deemed invalid. No toxicological reasons were cited. On March 10, 2009, we agreed to accept a payment of \$2,000 Cdn (\$1,562 US) and 500,000 warrants with an exercise price of \$0.50 Cdn (\$0.39 US) from LAB Research Inc. as full and final settlement of a lawsuit relating to this failed study. The toxicology studies are to be repeated in their entirety in the United States using a different CRO. The preparatory phase of these studies is complete but the program has been put on hold until additional sources of funding are secured.

On March 27, 2008 we issued 8,625,000 units, each unit consisting of one Common Share and one-half of one share purchase warrant, for gross proceeds of \$10,200 (Cdn \$10,350) pursuant to a short form prospectus dated March 15, 2008. Each whole share purchase warrant (a "Warrant") is exercisable to purchase one Common Share at a price of Cdn \$1.50 until March 28, 2011, subject to the right of the Company to accelerate the expiry date, on not less than 30 days prior written notice to the warrant holders, if the closing price of the Common Shares on the TSX is at least Cdn \$2.25 for any period of not less than 30 consecutive trading days. The offering was made partially on an underwritten and partially on a best efforts basis through Jennings Capital Inc. and Desjardins Securities Inc. (collectively the "Underwriters") pursuant to an underwriting agreement dated February 22, 2008 (the "Underwriting Agreement"). The Underwriters received a fee of \$714 (7% of the total proceeds) plus 603,750 compensation options, each compensation option being exercisable to purchase one Common Share at a price of Cdn \$1.20 until March 28, 2010.

On May 23, 2008, the licensing and development agreement with Janssen was amended in support of the development effort and to secure timely advancement of the Phase III clinical trials. Under the amended agreement, advanced milestone payments of \$3,500 (€2,500) were payable on the first local regulatory approval of the Phase III protocol and \$2,800 (€2,000) on the first clinical site readiness. An additional milestone of \$3,600 (€2,500) is due as of the inclusion of the 7th patient in the study. As part of the amended agreement, the Company also agreed to keep the advance milestones separate from other funds and apply the proceeds exclusively to Phase III clinical studies and other critical project expenses. As of December 31, 2008, the Company's commitment to fulfill this obligation is considered to have been met. The Company triggered the advance milestones in August and September 2008 and achieved the final milestone in December 2008.

On July 28, 2008, we signed a Facility Lease Agreement (the "Lease") with HEP-Davis Spring, L.P. Pursuant to the Lease, we plan on relocating our PharmaForm operation by the fourth quarter of 2010 from its current 50,000 square foot facility to approximately 69,872 square feet of space in a building located at 9825 Spectrum Drive, Austin, Texas for a term of 15 years, commencing on November 1, 2008. We estimate that the gross base rental obligation over the term of the Lease will be approximately \$15.8 million.

On November 6, 2008, we announced the resignation of Dr. Halvor Jaeger as Chief Executive Officer of the Company. Dr. Jaeger remains a member of the Board of Directors and will focus on financing and M&A opportunities. Dr. Taneli Jouhikainen, formerly our Senior Vice-President Corporate Development, replaced Dr. Jaeger as Acting Chief Executive Officer.

In December 2008, our multinational Fentanyl TAIFUN® Phase 3 clinical trial began enrolling patients. The Janssen licensing and development milestone payment of €2.5 million was triggered by the enrollment of the 7th patient just prior to the end of December 2008.

On February 9, 2009, we announced the implementation of a significant cost reduction program in order to preserve cash for our continuing operations. The reduction in costs is targeted primarily at our development programs. We will continue our Phase III clinical program under a more limited and focused scope.

On March 26, 2009, we entered into an agreement to combine Akela and Nventa Biopharmaceuticals Corporation ("Nventa") by way of a plan of arrangement under the Business Corporations Act (British Columbia). The board of directors of both companies unanimously approved the agreement. The transaction will be effected by an exchange of Akela common shares for the outstanding shares of Nventa on the basis of 0.0355 Akela shares for each Nventa share (or 1 Akela share for 28.169 Nventa shares), resulting in an approximate 70/30 ownership split between Akela and Nventa shareholders, respectively, in the combined entity. The public company will retain Akela's name, will operate under Akela's management, and will continue to be listed on the Toronto Stock Exchange under the ticker symbol AKL. Nventa will have the right to nominate two directors to the board of directors of Akela. The transaction is subject to a number of conditions including approval of the Toronto Stock Exchange for the listing of the common shares of the Company issuable to the shareholders of Nventa and to the favourable votes of not less than two-thirds of the votes cast in respect of the transaction by the shareholders of Nventa at a meeting of shareholders. In addition, both parties have the right to terminate their obligations under the agreement in certain events, including the entering into of a superior proposal, and upon payment, in the event of termination in certain circumstances, of a break fee of \$250,000. Subject to the satisfaction of certain customary closing conditions, including a minimum amount of \$1.5M of net cash in Nventa, the transaction is expected to close in May 2009.

BUSINESS OF THE COMPANY

Evolution of the Pharmaceutical Industry

The development of a new drug after discovery commences with pre-clinical testing in animals, is followed by three pre-approval phases (known in the pharmaceutical industry as Phases I, II and III) of clinical testing in humans and ends with regulatory approval and commercialization. The traditional role of a pharmaceutical company was to discover, develop, manufacture and market drugs. Pharmaceutical companies were vertically integrated and assumed all costs and risks of discovering a new drug and were entitled to all the benefits and rewards of commercializing a new drug product.

In the late 1960s, forced by increasing research and development ("R&D") budgets, pharmaceutical companies began to search for ways to convert the high fixed costs of their research departments into more manageable variable costs, while still maintaining control of the developmental process. As a further step in this evolutionary process, the risk of discovery, being the first stage in the creation of a new drug, was increasingly transferred to a new industry (known as the "biotech" industry), which also took over the management and risk of early drug development, usually up to Phase II. The principals of biotech companies usually came from academia and not from industry and were typically not experienced in the development process. This resulted in a high degree of failure that caused a temporary decline in the biotech industry.

The early disadvantages were remedied in the next step of the evolutionary process, known as product development organizations ("PDOs"). These companies were usually born out of CROs and offered greater potential for value creation through the ownership of products, which generally commands a much higher value than that for providing services. The intellectual property was now often licensed, rather than discovered.

Some PDOs further reduced risk by developing proprietary formulation platforms applicable to a number of patent-free and well-known drug substances, rather than new chemical entities ("NCEs"). These drug delivery organizations ("DDOs") reduced risk because they applied their platform over and over again with little additional development risk. They also increased income through a combination of service revenues and royalties. However, the upside was often reduced, since there may be similar technologies in the market creating a number of directly competing products.

To further reduce the risk and cost of the development process, the next logical step was that some PDOs migrated towards integration. They maintained or newly established the infrastructure and experience to develop and manufacture drugs in-house. By selling those abilities in the form of services to others, integrated PDOs ("IPDOs") create additional income.

To maximize profits some PDOs began to market their own products to the public, usually when those products addressed a limited market. These PDOs are known as “specialty pharmaceutical” companies.

In a parallel process, traditional pharmaceutical companies increased competition among themselves by developing similar products, resulting in dramatically increased marketing expenditures for the products. The first three years of marketing a new drug now usually costs more than its complete development. Companies had to grow by mergers and acquisitions to gain more critical mass for the marketing phase. With increasing size, they have lost even more flexibility necessary for drug development and focus more and more on late stage development and worldwide marketing of their drugs. This trend is leading to a polarization of the marketplace, with PDOs occupying one end of the spectrum, and traditional drug marketing and distribution companies occupying the other.

Company Overview

We are an integrated product development company primarily focused on therapeutics for pain utilizing our proprietary drug delivery technologies. Our lead product candidate is Fentanyl TAIFUN®, a fentanyl formulation specifically designed to be delivered with our TAIFUN® Multi-Dose Inhaler. We are developing Fentanyl TAIFUN® as a rapid-acting inhaled opioid analgesic for treatment of break-through cancer pain. We have entered into an exclusive license and development agreement with Janssen with respect to the continuing development and commercialization of Fentanyl TAIFUN®. We believe, based upon the results of our clinical trials to date, that our Fentanyl TAIFUN® product candidate, if approved by regulatory agencies, will deliver much faster onset of pain relief from break-through cancer pain at lower dosages than other non-injectable products currently indicated for break-through cancer pain.

Our Phase IIb clinical trial, completed in August 2007, showed the median time to significant pain relief for patients using our Fentanyl TAIFUN® was 5.2 minutes. This result was statistically significant versus placebo ($p=0.007$). We believe this offers significant clinical benefits for patients and physicians due to its rapid onset compared to other non-injectable therapies for break-through cancer pain. We have an open Investigational New Drug (“IND”) submission for Fentanyl TAIFUN®, which was submitted to the FDA in March 2006. On February 4, 2008, we announced that we had received notice from the United States Food and Drug Administration (“FDA”) that, due to Good Laboratory Practice (“GLP”) deviations, the six month inhalation toxicology studies of Fentanyl TAIFUN® dry powder inhaler performed for us on dogs and rats by a CRO were deemed invalid. No toxicological reasons were cited. On March 10, 2009, we agreed to accept a payment of \$2,000 Cdn (\$1,562 US) and 500,000 warrants with an exercise price of \$0.50 Cdn (\$0.39 US) from LAB Research Inc. as full and final settlement of a lawsuit relating to this failed study. The toxicology studies will be repeated in their entirety in the United States using a different CRO. The preparatory phase of these studies is complete but the program has been put on hold until additional sources of funding are secured.

In December 2008, our multinational Fentanyl TAIFUN® Phase III clinical trial began enrolling patients. The Janssen licensing and development milestone payment of €2.5 million was triggered by the enrollment of the 7th patient just prior to the end of December 2008.

On February 9, 2009, we announced the implementation of a significant cost reduction program in order to preserve cash for our continuing operations. The reduction in costs is targeted primarily at our development programs. We will continue our Phase III clinical program under a more limited and focused scope.

Break-through cancer-related pain has a severe impact on a patient’s quality of life and can occur even if the individual is taking chronic pain medication on a regular basis. Break-through pain is a common component of chronic pain and is characterized by its rapid onset, intensity and relatively short duration. These intermittent flare-ups of intense pain “break-through” the effect of chronic pain medication. We believe currently available therapeutics targeted at break-through cancer pain are inadequate because of their higher dosage of fentanyl and comparatively longer time to onset. The current leading products in this market segment are Cephalon’s Actiq® lozenge and Fentora® buccal tablet, both containing fentanyl as the active compound.

Abuse of opioid pain medications is a significant medical and social problem. Current dosage forms of prescription pain relievers are often abused by dissolving them in alcohol or crushing and inhaling the tablets. We have

developed a proprietary abuse-resistant delivery platform, which we call EDACS™, or Extruded Deterrence of Abusable Controlled Substances, to address opioid abuse. We intend to rely on a Section 505(b)(2) NDA approval process with the FDA, although no submissions have been made to date. For a description of the Section 505(b)(2) NDA approval process, see “Regulatory Matters – New Drug Applications and Biologics License Applications”. EDACS™ is manufactured by hot-melt extrusion of a homogeneously blended powder that can be formulated to provide a variety of dosing options including once-a-day extended pain release. Our product candidates do not contain opioid antagonists, such as naltrexone, which we believe may be vulnerable to unwanted leaking of the antagonist, thereby reducing the effect of the opioid. Our product candidates are intended to compete with the current market-leading oral controlled-release opioid products, including Oxycontin®, Avinza® and Opana®. The EDACS™ development program will be on hold until additional funding is secured.

In addition to our pain product candidates, our material non-pain product candidates and our platform technologies include:

- Growth Hormone Releasing Hormone (“GHRH”) — Our growth hormone releasing hormone is a synthetic analog of the natural human growth hormone releasing hormone and is considered an NCE. Our GHRH recently completed a small Phase IIa clinical trial outside the United States for the treatment of malnutrition associated with pre-dialysis stage chronic renal failure. The compound has been shown to have very high affinity for the pituitary GHRH receptor, and has a long circulating half life. The results of our GHRH clinical trial were reviewed by the FDA and we received positive and insightful regulatory planning and process feedback. Further development of this compound will depend on our ability to secure an out-licensing agreement or project specific financing.
- Calcitonin Gene Related Peptide (“CGRP”) — Our CGRP is a novel therapeutic that has been in development for the treatment of asthma. We have recently given notice of our intent to terminate our license agreement to this compound.
- To date, no submissions have been made to the FDA with respect to GHRH or CGRP.

Strategy

Our goal is to become a significant integrated product development company with a diversified product portfolio based on multiple drug delivery platforms. We intend to:

- *Focus on pain* — We believe the pain market represents a substantial near-term opportunity as many existing therapeutics, such as fentanyl, have the potential to be delivered by inhalation technology and lead to improved clinical benefit. In addition, given the prevalence of opioid abuse, deterrent products are likely to be in demand. We believe our drug delivery technologies and formulation expertise will allow us to develop products that will meet these unmet medical needs. All product development spending will be limited to the advancement of Fentanyl Taifun for the foreseeable future.
- *Maximize partnership opportunities* — We intend to enter into partnering arrangements with international pharmaceutical companies to market our product candidates worldwide. For our non-core product candidates, such as GHRH and EDACS, we intend to enter into partnership arrangements to advance clinical development prior to initiation of pivotal clinical trials.

Product Candidates

Fentanyl TAIFUN® – Break-through Cancer Pain

Overview

Fentanyl TAIFUN®, which completed Phase IIb clinical trials in 2007, is a rapid-acting inhaled opioid analgesic, that targets break-through cancer pain. Break-through cancer pain is experienced by large numbers of cancer patients. This cancer-related pain has a severe impact on a patient's quality of life and can occur even if the individual is taking pain medication on a regular basis. These intermittent flares of intense pain are called break-through pain because the pain breaks through the effect of the regular pain medication. The number of break-through pain episodes typically varies from one to eight per day. The duration of these break-through pain episodes varies from minutes to hours, with median and average duration typically reported as 30 and 60 minutes, respectively. Ideally, medication for break-through pain management should be easily administered, bring rapid pain relief and have minimal side effects.

We have developed a proprietary formulation of fentanyl to allow it to be used with our proprietary TAIFUN® inhalation delivery platform. We believe that inhalation is the fastest non-injection absorption route for fentanyl and may provide a faster analgesic effect than any other currently approved non-injection product. Our clinical studies to date have demonstrated that Fentanyl TAIFUN® provides significant pain relief with the lowest dose in the shortest amount of time compared to currently approved products.

Clinical Development

In two Phase I pharmacokinetic trials, our Fentanyl TAIFUN® dry power inhaler has shown an extremely rapid absorption. Peak concentration is reached within one minute, which correlates directly with the rapid onset of analgesic action. The absorption has been shown to be dose-dependent in a linear fashion across the dose range of 100 - 800 µg/dose; the highest dose representing four inhalations from the 200 µg/dose inhaler. After the rapid absorption, therapeutic concentrations of Fentanyl TAIFUN® are maintained over a period of several hours.

Our Phase IIb clinical trial, completed in August 2007, showed the median time to significant pain relief for patients using our Fentanyl TAIFUN® was 5.2 minutes. This result was statistically significant versus placebo (p=0.007). We believe this offers significant clinical benefits for patients and physicians due to its rapid onset compared to other non-injectable therapies for break-through cancer pain. We have an open Investigational New Drug ("IND") submission for Fentanyl TAIFUN®, which was submitted to the FDA in March 2006. We had an end-of-Phase II meeting with the FDA in August 2007 to present the data obtained.

On February 4, 2008, we announced that we had received notice from the United States Food and Drug Administration ("FDA") that, due to Good Laboratory Practice ("GLP") deviations, the six month inhalation toxicology studies of Fentanyl TAIFUN® dry powder inhaler performed for us on dogs and rats by a CRO were deemed invalid. No toxicological reasons were cited. On March 10, 2009, we agreed to accept a payment of \$2,000 Cdn (\$1,562 US) and 500,000 warrants with an exercise price of \$0.50 Cdn (\$0.39 US) from LAB Research Inc. as full and final settlement of a lawsuit relating to this failed study. The toxicology studies are to be repeated in their entirety in the United States using a different CRO. The preparatory phase of these studies is complete but the program has been put on hold until additional sources of funding are secured.

In December 2008, our multinational Fentanyl TAIFUN® Phase III clinical trial began enrolling patients. The Janssen licensing and development milestone payment of €2.5 million was triggered by the enrollment of the 7th patient just prior to the end of December 2008.

On February 9, 2009, we announced the implementation of a significant cost reduction program in order to preserve cash for our continuing operations. The reduction in costs is targeted primarily at our development programs. We will continue our Phase III clinical program under a more limited and focused scope.

GHRH or Growth Hormone Release Hormone – Chronic Renal Failure

Overview

Our GHRH is a patented synthetic analogue of the natural human growth hormone releasing hormone, and is classified as an NCE. Our GHRH, which has completed Phase II trials, is targeted for the treatment of malnutrition associated with pre-dialysis stage chronic renal failure. The compound has been shown to have very high affinity for the pituitary GHRH receptor, and a long circulating half life.

Growth hormone (“GH”), is a major element controlling multiple complex physiological processes, including growth and metabolism. GH stimulates the liver and other tissues to secrete insulin-like growth factor (“IGF-1”) to aid body and muscle growth. When growth hormone is not secreted in sufficient quantity, recombinant growth hormone has been used as a replacement. The significant cost of producing recombinant GH, the long-term safety concerns of GH therapy and the disruption of the endogenous GH releasing rhythm limit the hormone’s clinical uses. GHRH provides a method to increase GH secretion without disturbing the body’s own GH releasing pattern, and is being developed for several indications by different pharmaceutical companies.

Clinical Development

We completed a placebo-controlled Phase II trial in three centers in Europe, investigating the efficacy and safety of GHRH for the treatment of malnutrition in patients with late pre-dialysis chronic renal failure. The Phase II trial demonstrated that, within four weeks of treatment, our GHRH induced a highly significant stimulation of endogenous GH secretion and a marked increase of circulating IGF-1 as compared to placebo in patients with chronic kidney disease. These endocrine effects were associated with a significant increase in Fat Free Mass and concomitant reduction in Fat Mass when measured by DEXA scan. While stable isotope studies did not reveal significant changes in protein turnover within four weeks of treatment, a trend towards increased protein synthesis in our GHRH arm was observed.

The results of our GHRH clinical trial were reviewed by the FDA and we received positive and insightful regulatory planning and process feedback. Further development of this compound will depend on our ability to secure an out-licensing agreement or project specific financing.

EDACS™ – Opioid Abuse-Deterrent System

Overview

Non-medical abuse of opioids is a growing concern in the United States and in other countries. Our EDACS™ technology is being developed as an opioid abuse-deterrent system for application to opioids used for the treatment of chronic pain in multiple products and formulations. EDACS™ is manufactured by hot-melt extrusion of a homogeneously blended powder that can be formulated to provide a variety of dosing options including once-a-day extended pain release. We believe that our technology is superior to other approaches for abuse deterrence because products manufactured with EDACS™ are crush resistant and slow to dose-release in alcohol. In addition, our products do not contain opioid antagonists, such as maltrexone, which may increase costs and time to approval. Our products are intended to compete with the current market leading oral controlled release opioid products.

Recent approvals of opioid products in the United States have included risk-management plans to reduce abuse and diversion. New technologies that deter or prevent the abuse of opioids are expected to be of interest to the FDA and other drug regulatory agencies, as will the approval and adoption of products applying such technologies. Subject to such new product approvals, we anticipate that the majority of the opioid market will shift over time to abuse deterrent products.

Clinical Development

Our first indication applying EDACS™ to an existing opioid therapy for pain relief entered a Phase I clinical trial in 2008 but has been put on hold until additional funding is secured.. Our regulatory strategy for FDA approval of this product is expected to be based on the Section 505(b)(2) approval process.

Further development of this compound will depend on our ability to secure an out-licensing agreement or project specific financing.

CGRP or Calcitonin Gene Related Peptide – Asthma

Overview

Our CGRP is a novel therapeutic that has been in development for the treatment of asthma. We have recently given notice of our intent to terminate our license agreement to this compound.

Drug Delivery Technologies

We have developed the following proprietary drug delivery technologies:

- TAIFUN® dry powder multi-dose inhaler – Inhalation Technology;
- EDACS™ (Extruded Deterrence of Abusable Controlled Substances) – Abuse Deterrent System;

TAIFUN® Inhalation Technology

Due to the cost reduction emphasis of managed care organizations, many procedures once conducted on an inpatient basis requiring hospitalization are now performed in less expensive outpatient settings. The search for improved routes of administration and the desire for non-invasive delivery methods for self-medication of chronic conditions represent therapeutic application opportunities for developers of inhalation drug delivery based products.

Inhalation drug delivery is the fastest, non-invasive route of administration. This makes it a preferred route of administration when a fast onset of action is required. In addition, for products that are orally unstable or undergo significant first-pass-metabolism, inhalation is a preferred route of administration.

Factors influencing the demand for inhalation-based therapeutics include the following:

- the growth in the number of cases of upper respiratory disease;
- the expected increase in self-administration for the treatment of chronic conditions; and
- the pulmonary administration of systemically active drugs.

Important characteristics for systemic drug delivery via dry powder inhalers include the following:

- efficient delivery to the deep lungs for effective systemic or local delivery of the drug;
- dose-to-dose reproducibility;
- stable aerosol performance over life of inhaler; and
- reliable function in all environmental conditions, including high humidity.

Advantages of Our TAIFUN® Technology

We believe that our TAIFUN® technology provides a number of technical improvements and clinical benefits, compared to current leading inhaled drug delivery systems. In particular, TAIFUN® enables reliable and efficient delivery of active drugs into patients' lungs in a wide range of clinical and environmental conditions. We believe that the unique combination of strong technical performance, user friendliness, and distinctive style offers a competitive product platform for a variety of inhaled drugs.

In contrast to the competing inhaler technologies that are being used or developed for the pulmonary administration of systemically active drugs, the TAIFUN® inhaler is a simple, all mechanical, small device that is also inexpensive to manufacture. Despite its relative simplicity, the TAIFUN® is technically robust, and meets the regulatory requirements of modern dry powder inhalers. In particular, it can be adapted for a variety of small molecule drugs economically manufactured, and introduced into market segments where pricing is competitive.

The clinical and technical advantages of TAIFUN® technology are:

- advanced powder formulations with high physical and chemical stability;
- high lung deposition of active drug independent of inhalation flow rate;
- high resistance to humidity;
- dose uniformity and accurate dose metering complying with the tight FDA requirements;
- modern style and ease of use; and
- flexible dosing to accommodate patient variability.

The development advantages of TAIFUN® technology are:

- TAIFUN® Salbutamol inhaler, a generic asthma therapy incorporating our first generation of TAIFUN® technology, has been approved in ten European countries;
- robustness, simplicity of design and ease of use; and
- readily scalable for automated high volume manufacturing.

EDACS™ Opioid Abuse-Deterrent System

The reasons most often cited for prescription drug abuse include: prescription drugs are easier to acquire than illicit drugs (particularly in rural and suburban areas), the use/abuse of prescription drugs is more socially acceptable than illicit substances, and the purity and dosage is highly predictable and consequently safer to use.

Drug abusers typically prefer opioid formulations that provide rapid absorption of the drug in order to obtain the desired euphoric effect. Sustained release oral formulations are not ideally suited for abusers when used correctly, but abusers can bypass the sustained release features of current products by crushing and mixing them with alcoholic drinks or by crushing and snorting or dissolving and injecting the drug. As a result, there is an increasing need to introduce sustained release formulations that are resistant to these types of physical abuse.

There are two classes of abuse deterrent technologies in development with different principles of abuse deterrence. One class, which includes our EDACS™ technology, is based on formulations that are resistant to alcohol dissolution or physical tampering. The other class employs a combination of opioid analgesics and opioid antagonist/aversive agent.

One potential drawback with the use of a sustained release opioid antagonist preparation is that, if a tampered product is used by an opioid dependent person, even small doses of the antagonist can precipitate an abstinence syndrome, resulting in drug withdrawal. Opioid withdrawal symptoms can be severe, requiring hospitalization and reinstitution of the opioid agonist. Similarly, abuse deterrent pharmaceutical compositions containing sequestered aversive substances have the potential to cause harm if injected intravenously. Such formulations are also likely to release at least small amounts of the “sequestered” aversive agent under conditions of chronic normal use. Finally, abuse deterrent capsule formulations with sequestered opioid antagonists or aversive agents may be vulnerable to dose dumping, or rapid release, when co-ingested with alcohol.

Although abuse deterrent products provide no clinical benefit to the patients, we believe such products will likely be endorsed by the FDA and United States Drug Enforcement Administration (“DEA”) as a matter of public policy. As a result, it is our expectation that, if approved, abuse deterrent formulations will eventually be the technology of choice over current extended release opioid formulations on the market.

Advantages of Our EDACS™ Technology

Our EDACS™ technology is a solid oral dosage form designed to deter abuse of controlled substances or other drugs and to address the growing problem of prescription drug abuse. It has the following features:

- prevents alcohol-induced dose-dumping by maintaining its oral sustained release characteristics in 40% alcohol for more than three hours;
- is significantly harder than conventional oral dosage forms and, as a result, it is very difficult to crush or chew in an attempt to bypass the sustained release characteristics; and
- prevents dissolution and injection since it contains a polymer that forms a viscous gel not miscible in common solvents.

EDACS™ products are manufactured by hot-melt extrusion of a homogeneously blended powder. The powder for extrusion can be formulated to yield targeted release characteristics much like other controlled release solid dose formulations. EDACS™ products can be formulated either with hydrophobic or hydrophilic drugs, in various sizes, shapes and colors with a wide range of sustained release profiles. We believe it is ideally suited to sustained release opioid formulations.

Competition

We are engaged in a business characterized by extensive research efforts, rapid technology developments and intense competition. Our competitors include large pharmaceutical, biotechnology and other companies, universities and research institutions. All of these competitors currently engage in, have engaged in or may engage in the future in the development, manufacturing, marketing and commercialization of new pharmaceuticals and existing pharmaceuticals, some of which may compete with our present or future product candidates. We expect that successful competition will depend, among other things, on product efficacy, safety, reliability, availability, timing and scope of regulatory approval and price.

A large part of our business is based upon the reformulation of existing drugs. As a result, our product candidates will face competition from generic and branded formulations of the existing drugs we reformulate. Our drug delivery technologies will compete with existing drug delivery technologies, as well as new drug delivery technologies that may be developed or commercialized in the future. Any of these drugs and drug delivery technologies may receive government approval or gain market acceptance more rapidly than our product candidates, may offer therapeutic or cost advantages over our product candidates or may cure our targeted diseases or their underlying causes completely. As a result, our product candidates may become non-competitive or obsolete.

We believe that our ability to successfully compete will depend on, among other things:

- the efficacy, safety and reliability of our product candidates;
- the timing and scope of regulatory approval;
- the speed at which we develop product candidates;
- our ability to manufacture and sell commercial quantities of a product to the market;
- product acceptance by physicians and other health care providers;
- the quality and breadth of our technology;
- the skills of our employees and our ability to recruit and retain skilled employees; and
- the protection of our intellectual property.

Break-through Cancer Pain

The current market leader for break-through cancer pain treatment is Cephalon Inc., the approved manufacturer of Fentora and Actiq. We understand that YM Biosciences Inc. and Aradigm Corporation have an inhaled formulation of fentanyl in clinical trials. We also understand that Biodelivery Sciences has a dissolvable formulation of fentanyl using a buccal tablet which is in pre-approval stage and that Nycomed and Archimedes are developing nasal formulations of fentanyl which are in early clinical trials.

Of the three known competing inhaled fentanyl projects, we believe our Fentanyl TAIFUN® product candidate is currently in a lead position and anticipate it will become the first approved inhaled fentanyl product. In addition to inhaled fentanyl, several new oral and intranasal products are in development. These products are expected to increase substantially the market for fentanyl in the treatment of break-through cancer pain. We believe that Fentanyl TAIFUN® will provide the fastest onset of pain relief.

We believe that the clinical performance of Fentanyl TAIFUN® will enable us to capture a significant share of the overall break-through cancer pain market. In particular, the excellent dosage success and very fast onset of action obtained with Fentanyl TAIFUN® compare favorably with data published from trials on transmucosal fentanyl preparations. In these transmucosal trials, higher doses have been required to achieve the desired results. Even with such higher doses of medication, the proportion of patients that were successfully titrated was lower, and onset of efficacy much slower. This apparent opioid sparing effect of Fentanyl TAIFUN®, with a narrow range of titration, is most likely due to its unique pharmacokinetic profile, which combines an essentially immediate absorption of the drug with a prolonged and relatively steady concentration for the duration of a typical break-through pain attack.

Abuse Deterrence

It is our understanding that several companies are currently developing abuse deterrent systems using the combination of opioid and opioid antagonist/irritant, including Alpharma Inc., Acura Pharmaceuticals Inc., Purdue Pharma L.P. and Elite Pharmaceuticals Inc.

We also understand that companies such as Egalet A/S, Pain Therapeutics Inc./Durect Corporation, TheraQuest Biosciences, LLC and Collegium Pharmaceutical Inc. are developing products using non-crushable/chemical resistant technologies.

Asthma

We understand that many established companies' products currently command large market shares in the mild to moderate asthma market, including Merck & Co., Inc.'s Singulair®, GlaxoSmithKline plc's Advair® and inhaled corticosteroid products. These therapies are also used in combination with, or as add-on therapies to, oral and injectable steroid treatments in the severe asthma market. One product, Xolair®, developed jointly by Novartis AG, Genentech, Inc. and Tanox, Inc. was approved in 2004 for severe allergic asthma. We may also face competition from pharmaceutical companies seeking to develop new drugs for the asthma market.

Growth Hormone

Based upon information publicly available to us, we understand that Theratechnologies Inc. is currently in clinical trials with TH9507 (natural 44 amino-acid sequence of human GRF with a hexenoyl moiety) in HIV-associated lipodystrophy. It is administered via intravenous injection and increases endogenous secretion of growth hormone from the pituitary gland in a pulsatile fashion. We anticipate that the effective therapeutic dose of our GHRH agonists will have a lower duration of action than TH9507. This should result in improved convenience and greater cost-effectiveness of our GHRH candidate.

We understand that other companies have growth hormone compounds in development, including Conjuchem Inc., Aeterna Zentaris Inc., Sapphire Therapeutics Inc. and QLT Inc.

Inhalation Technology

Our most significant competitors as technology providers are pulmonary drug delivery companies. Skyepharma Plc and Vectura Group Plc are both developing multiple dose dry-powder inhalers. In addition, Ventaira Pharmaceuticals, Inc. is emerging into the field with a liquid based inhaler using an electrical aerosolization system.

In the United States, the key competitors are Aradigm Corporation and Alkermes Inc.

Aradigm Corporation has a sophisticated liquid based multiple unit dose inhaler, which was being developed for the administration of insulin via the lungs. Alkermes is using its AIR® technology to develop inhaled insulin.

Licensing and Development

Agreement with Janssen

On June 20, 2007, we entered into an Exclusive License, Development and Supply Agreement with Janssen with respect to the continuing development and commercialization of Fentanyl TAIFUN®. Janssen and its affiliates are the originators of a fentanyl product that was successfully marketed worldwide as DUROGESIC®, the fentanyl transdermal patch.

Under the agreement, Janssen has been granted an exclusive license in the field of pulmonary administration to humans of fentanyl and related compounds to certain of our patents, know-how and trademarks to develop, make, use, market, sell, promote and distribute the Fentanyl TAIFUN® metered dose dry-powder inhaler (the "Device") containing 30 doses of powder formulation of fentanyl citrate in two separate strengths of 100 and 200 micrograms per dose and any improvements relating thereto (collectively defined in the agreement as the "Product") in countries in the European Union, Eastern Europe, Russia and the former Soviet republics, the Middle East, Africa, Sri Lanka and Pakistan (collectively defined in the agreement as the "Territory"). Janssen may market the Product either directly, through its affiliates, or through sublicensees. For a period of two years after the month following the first commercial sale of the Product within the Territory, Janssen has the right of first negotiation to extend the exclusive license to other territories. Janssen has been granted additional rights with respect to the ability to extend the scope of its license under the agreement.

We have specifically not reserved any right, beyond our obligations under the agreement, to develop, make, use, market, sell, promote or distribute the Product ourselves, directly or indirectly, in the Territory. However, the agreement does not preclude us from developing and manufacturing (i) the Device in the Territory for use by us or third parties in or outside the Territory and (ii) the Product in the Territory for use by us or third parties outside the Territory.

Under the agreement, ownership of any improvements resulting from the development of the Product will be owned by the party that developed the improvement. In general, an improvement is any change or modification of the characteristics and features of the Product. In the case of improvements made by us or jointly with Janssen, we have agreed to grant Janssen an exclusive, royalty-free and sub-licensable license in the field within the Territory. With respect to improvements made solely by Janssen or jointly with us, Janssen has agreed, if such improvements cannot be used separately from the Product, to grant us a royalty-free, non-exclusive license in the field outside the Territory, as well as for manufacturing and development purposes in the Territory. To the extent that improvements can be used separately from the Product, Janssen has agreed to grant us a royalty-free, non-exclusive license in and outside the field on a worldwide basis, subject to certain limitations.

We have agreed to collaborate exclusively with Janssen to develop the Product for the initial indication of managing break-through cancer pain; Janssen is responsible for developing any additional indications. We are responsible exclusively for manufacturing and supplying the Product to Janssen or its designees for all territories. The agreement also provides for other development projects relating to Fentanyl TAIFUN®.

We are responsible for enforcing applicable patent rights relating to the Product within the Territory. In the event the Product is alleged to infringe or constitutes an infringement of intellectual property rights of third parties, subject to certain limitations, in the Territory, we will work with Janssen to develop a strategy that will enable Janssen to continue marketing the Product in the Territory.

Under the terms of the agreement, we received an initial fee of \$10.8 million (€8.0 million) and are entitled to receive

- payments aggregating up to \$33.6 million (€25.0 million) upon achievement of specified development and regulatory milestones;
- payments upon achievement of specified commercial sales milestones; and
- payments of royalty revenues and revenues from the sale of product to Janssen.

The agreement is for a term expiring upon the last to occur of: (i) 10 years from the date of the first commercial sale of the Product in the Territory, (ii) the expiration of the longest lasting patent owned by us relating to the Product, or (iii) the expiration of the longest lasting regulatory exclusivity period for the Product in the Territory. The term may be extended by Janssen for subsequent two-year periods on the same terms and conditions upon 12 months written notice prior to the expiration of the term.

The agreement is subject to termination upon the occurrence of standard events, including, but not limited to, bankruptcy, winding-up or an uncured material breach. Under the agreement, each party has provided certain standard representations, warranties and indemnities to the other.

On December 20, 2007, we entered into a supplemental license agreement with Janssen extending the geographic scope of the original agreement to include Canada.

On May 23, 2008, the licensing and development agreement with Janssen was amended in support of the development effort and to secure timely advancement of the Phase III clinical trials. Under the amended agreement, advanced milestone payments of \$3,500,000 (€2,500,000) were paid on the first local regulatory approval of the Phase III protocol which occurred in August 2008 and \$2,800,000 (€2,000,000) on the first clinical site readiness which was triggered in October 2008. An additional milestone of \$3,600,000 (€2,500,000) was triggered in December 2008 with the inclusion of the 7th patient in the study. As part of the amended agreement, the Company

also agreed to keep the advance milestones separate from other funds and apply the proceeds exclusively to Phase III clinical studies and other critical project expenses. As of December 31, 2008, the Company's commitment to fulfill this obligation is considered to have been met.

Other Agreements

In 2004 and 2005, we entered into certain funding arrangements with Tekes, the Finnish Funding Agency for Technology and Innovation. These arrangements provided for funding grants and loans, payable to us in instalments, with respect to inhalation technology development. Tekes provided approximately \$1.6 million (€1.1 million) in loans and grants during 2006 and \$0.6 million (€0.4 million) in January 2007. No additional funding is anticipated under either of these arrangements. The financing was provided to us on a loan-weighted basis whereby 30% of the funds were provided by way of grants and 70% by way of long-term loans with favorable repayment terms. Each loan bears an interest rate of 1% below the prime rate, but not less than 3%, over a term of eight years and repayments under the loans are payable only at such time as the costs of the underlying development project have been recouped and profits are available. Following our decision to down-size the Finnish operations, we were notified that this agency was reviewing loans and subsidies previously granted to us totalling €3,150,000 and €956,000, respectively. The agency has decided not to call the loans and we have not accepted its demand for repayment of the subsidies. Discussions with the agency are ongoing and we cannot determine if such review will lead to repayment of all or a portion of the subsidies we received. However, the loans received from the Finnish governmental agency continue to be reflected as long-term debt in our financial statements in accordance with the original agreements.

We have entered into licensing and development agreements with SK Chemicals Co. Ltd. in Korea in 2004 and Teikoku Seiyaku Co. Ltd. in Japan in 2005 for the development and registration of Fentanyl TAIFUN® in the South Korean/Chinese (excluding Taiwan and Hong Kong) and Japanese markets, respectively. Under these agreements, we received a signing fee and are entitled to development milestone payments and reimbursements for our development activities. In addition, the licensees will pay us royalties on sales and manufacturing revenues, if any, for supplying the finished product. We will enter into additional licensing and development agreements in other markets for our product candidates as suitable opportunities arise. At the academic level, we maintain strong ties with our licensors including:

- In relation to our GHRH analog technology, L'Universite de Montreal and Centre Hospitalier de L'Universite de Montreal, Quebec, where the product candidate was initially discovered and developed and in-licensed in 2000. We are obligated to pay licensing fees on milestones achieved and royalties, if products subject to this licensing arrangement are commercialized.

Fentanyl TAIFUN® Manufacturing Plan

The Phase III clinical trial supplies for Fentanyl TAIFUN® are being manufactured at our facility in Austin, Texas.

A continuous series of three successful 600g batches will be utilized as the NDA registration batches. Our plan is to optimize our processes and scale up to commercial manufacturing at our new facility in Austin, Texas.

Clinical Operations

Our Clinical Operations Group supports our product development activities by facilitating timely access in a cost-effective manner to highly competitive clinical patient populations. The worldwide competition for suitable patients, especially in pain trials, requires us to seek greater control over costs and quality in our clinical trials. We have established clinical operations sites in lower-cost countries such as Poland and India to promote rapid and efficient drug development.

REGULATORY MATTERS

The pharmaceutical industry is regulated by the FDA in the United States and by corresponding regulatory authorities in foreign jurisdictions. Regulation by governmental authorities in the United States and other countries

will be a significant factor in the development, production, and marketing of our product candidates and our ongoing R&D activities. All of our product candidates require rigorous preclinical and clinical testing and regulatory approval by government agencies prior to commercialization and are subject to pervasive and continuing regulation upon approval. The lengthy process of seeking approval and the subsequent compliance with applicable statutes and regulations, if approval is obtained, is very costly and requires the expenditure of substantial resources.

These agencies and other federal, state and local entities regulate research and development activities and the testing, approval, manufacture, quality control, safety, effectiveness, packaging, labelling, storage, recordkeeping, distributing, advertising and promotion of our product candidates. Failure to comply with applicable FDA or other requirements may result in civil or criminal penalties, recall or seizure of products, partial or total suspension of production or withdrawal of a product from the market, or other enforcement actions.

In the United States, the FDA regulates therapeutic drug products under the Federal Food, Drug, and Cosmetic Act (“FFDCA”), and the Public Health Service Act, as amended, and the regulations promulgated thereunder. The process required by the FDA before our drug and biologic product candidates may be marketed in the United States generally involves the following steps:

- completion of extensive preclinical laboratory tests, preclinical animal studies and formulation studies primarily performed in accordance with FDA's current GLP, regulations to ensure the quality and integrity of the safety data;
- submission to the FDA's Center for Drug Evaluation and Research (“CDER”), or the Center for Biologics Evaluation and Research (“CBER”), of an investigational new drug application, or IND, which must become effective before human clinical trials may begin. The IND contains the plan for the clinical trials. FDA specialists carefully review the IND application to determine whether there are any flaws in the initial studies and whether the overall development plan is feasible;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication, as approved by an institutional review board, or IRB, that assesses human subject protections;
- submission to the FDA of an NDA or a Biologics License Application (“BLA”);
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facilities at which the product is produced to assess compliance with current Good Manufacturing Practices (“GMP”) regulations; and
- FDA review and approval of the NDA or BLA prior to any commercial marketing, sale or shipment of the drug or biologic.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all.

Preclinical tests include laboratory evaluation of product chemistry, formulation and stability, as well as animal studies (to evaluate potential safety and efficacy). Violations of the regulations related to these activities can, in some cases, lead to invalidation of the studies, requiring them to be replicated as well as other regulatory actions against us, our employees and the study investigator(s).

The results of preclinical tests, together with manufacturing information and analytical data, are submitted as part of an IND to the FDA. Typically an IND requires a three-phase human-clinical testing program which itself is subject to numerous laws and regulatory requirements, including adequate monitoring, reporting, recordkeeping, and informed consent. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trials, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor

and the FDA must resolve any outstanding concerns before the clinical trials can begin. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development.

Also, an Institutional Review Board (“IRB”) for each medical center or clinical study site proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that center or site and it conducts additional reviews of the clinical trial until completed. An IRB is a separate board of scientists, physicians, and nurses (or other pharmaceutical industry stakeholders) who are not associated with the clinical trial. Once approved by the board, the clinical trial's human subject protections procedures and safety-related information are given a formal review each year, or other interval, depending on the length of the clinical trial.

The FDA, the IRB, or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy extensive Good Clinical Practices (“GCP”) regulations, including regulations for informed consent.

Clinical Trials

The human clinical trials that are conducted pursuant to an IND and included in the NDA or BLA are typically done in four sequential phases, which may overlap:

- Phase I Clinical Trials. Trials are initially conducted in a limited population to test the product candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients, such as cancer patients.
- Phase II Clinical Trials. Trials are generally conducted in the intended patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product candidate for the specific targeted indications and to determine dose tolerance and optimal dosage.
- Phase III Clinical Trials. These are commonly referred to as pivotal or registration trials, when designed to provide the principal basis for approval. When Phase II clinical trials demonstrate that a dose range of the product candidate is effective and has an acceptable safety profile, Phase III clinical trials are undertaken in large patient populations to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically dispersed clinical trial sites.
- Phase IV Clinical Trials. In some cases, the FDA may condition approval of an NDA or a BLA for a product candidate on the sponsor's agreement to conduct additional clinical trials to further assess the drug's safety and effectiveness after NDA or BLA approval. Such post-approval trials are typically referred to as Phase IV clinical trials.

The time and expense required to perform clinical testing can vary and is substantial. We cannot be certain that we will successfully complete Phase I, Phase II or Phase III testing of our product candidates within any specific time period, if at all. Additionally, clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Negative or inconclusive results or adverse medical events during a clinical trial could cause a clinical trial to be delayed; repeated, suspended, or terminated (e.g., if side effects become too severe, the clinical trial may be cancelled). In addition, clinical results may be affected by third-party actions that are outside of our control, including patients, investigators, CROs, IRBs, Data Safety Monitoring Boards (“DSMBs”), and government regulators.

New Drug Applications and Biologics License Applications

The results of product development, preclinical studies and clinical trials are submitted to the FDA as part of an NDA or BLA, depending upon whether the therapeutic product is regulated as a drug or biologic, for marketing and commercial shipment approval. Section 505 of the FFDCA describes three types of new drug applications: (i) an application that contains full reports of investigations of safety and effectiveness (section 505(b)(1)); (ii) an application that contains full reports of investigations of safety and effectiveness but where at least some of the

information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference (section 505(b)(2)); and (iii) an application that contains information to show that the proposed product is identical in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics, and intended use, among other things, to a previously approved product (section 505(j)). We expect to seek FDA approval of our product candidates via the 505(b)(2) NDA route, although the FDA could in certain circumstances require that we file a 505(b)(1) NDA. We do not expect to seek product candidate approval via the 505(j) route for abbreviated new drug applications for generic drugs.

Although the 505(b)(1) and 505(b)(2) NDAs must meet the same standards for approval, they differ in the source of information that supports the product candidate's safety and effectiveness, the patent certification requirements, bioavailability or bioequivalence evidence, marketing exclusivity bars, and processing within the FDA. A 505(b)(2) NDA is one for which one or more of the investigations relied upon by the applicant for approval "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted" (21 U.S.C. 355(b)(2)). In other words, Section 505(b)(2) of the FDCA permits reliance for new drug approvals on published literature or on an FDA finding of safety and effectiveness for a previously approved drug product. This statutory provision expressly permits the FDA to rely, for approval of an NDA, on data not developed by the applicant. Because the 505(b)(2) NDA applicant is not required to develop all of its own data, the product research and development process may be shorter and less expensive as compared to the 505(b)(1) NDA. For example, for a well-known chemical compound, the 505(b)(2) NDA applicant may not be required to develop preclinical animal data or extensive clinical safety data in humans. However, it is within the FDA's scientific discretion to require an animal study program or extensive human clinical study program even for a 505(b)(2) NDA. In addition, a 505(b)(2) NDA must include an identification of those portions of the application that rely on information the applicant does not own or to which the applicant does not have a right of reference, an identification of any and all listed drugs that will be referenced in the application, a bioavailability and bioequivalence study comparing the proposed product to the listed drug, and any other studies necessary to support the proposed product's change or modification from the listed drug.

Unlike a 505(b)(1) NDA for which the sponsor has conducted or obtained a right of reference to all the data essential to approval, the filing or approval of a 505(b)(2) NDA may be delayed due to patent or exclusivity protections covering an approved product. Section 505(b)(2) applications must include patent certifications on any patents listed with the FDA that pertain to the listed drug and must provide notice of certain patent certifications to the NDA holder and patent owner.

A 505(b)(2) application may itself be granted three years of marketing exclusivity if one or more of the clinical investigations, other than bioavailability and bioequivalence studies, was essential to approval of the application and was conducted or sponsored by the applicant. A 505(b)(2) application may also be granted five years of marketing exclusivity if it is for a new chemical entity, and may be eligible for orphan drug exclusivity or pediatric exclusivity. A 505(b)(2) application must contain information on any patents claiming the drug or its method of use. NDA and BLA applications must also contain extensive manufacturing information. We anticipate that our applications will require payment of a use fee. Once the application has been accepted for filing, the FDA targets 10 months to review the application and respond to the applicant. This 10-month review time from the date of the receipt of the application is in accordance with the performance goals related to the Prescription Drug User Fee Act. However, the review process is often significantly extended by FDA requests for additional information or clarification. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. There is no statutory limit to the time for which the FDA may continue to extend the review process.

The FDA may deny approval of an NDA if the applicable regulatory criteria are not satisfied, or it may require additional clinical data. Even if such data is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and the FDA may interpret data differently than we or our collaborators interpret data. Once issued, the FDA may withdraw product approval if ongoing regulatory requirements are not met or if safety problems occur after the end product reaches the market. In addition, the FDA may require testing, including Phase IV clinical trials, and surveillance programs to monitor the safety effects of approved products which have been commercialized, and the FDA can try to prevent or limit further marketing of a product based on the results of these post-marketing programs or other information.

We cannot be certain that the FDA or other regulatory agencies will approve any of our product candidates on a timely basis, if at all. Success in preclinical or early stage clinical trials does not assure success in later stage clinical trials. We cannot take any action to market a new drug or biologic product in the United States until our marketing application has been approved. Even if a product receives regulatory approval, the approval may be significantly limited to specific indications or uses. Delays in obtaining, or failures to obtain regulatory approvals would have a materially adverse effect on our business. We will also be required to obtain separate approval for the use of any products for indications other than those initially approved, which may require the conduct of additional preclinical studies or clinical trials. In addition, side effects or adverse events that are reported during clinical trials can delay, impede, or prevent marketing approval. Similarly, adverse events that are reported after marketing approval can result in additional limitations being placed on the product's use and, potentially, withdrawal of the product from the market. Any adverse event, either before or after marketing approval, can result in product liability claims against us.

In addition to regulating human clinical trials and the marketing of drugs and biologics, the FDA regulates and inspects equipment, facilities, laboratories, and processes used in the manufacturing and testing of such products prior to providing approval to market a product. If after receiving FDA approval we make a material change in manufacturing equipment, location or process, additional regulatory review and approval may be required.

Fast-Track

Fast-track products are those products intended for the treatment of a serious or life-threatening condition and which demonstrate the potential to address unmet medical needs for such conditions. If fast-track designation is obtained, the FDA may initiate review of sections of an NDA before the application is complete. This "rolling review" is available if the applicant provides and the FDA approves a schedule for the remaining information. Fast-track designation also makes a product eligible for accelerated approval under FDA regulations. That is, the product may be approved on the basis of either a clinical objective or a surrogate objective that is reasonably likely to predict clinical benefit. Approvals of this kind typically include requirements for appropriate post-approval Phase IV clinical trials to validate the surrogate objective or otherwise confirm the effect of the clinical objective. Our product candidates may be eligible for "priority review," if we can demonstrate that they offer major advances in treatment, or provide treatment where no adequate therapy exists. Priority review can apply both to drugs that are used to treat serious diseases, and to drugs for less serious illnesses. FDA's goal for completing a priority review is six months. Because we are studying our product candidates for the treatment of serious and life-threatening conditions, we regularly assess the potential for using these programs. However, there can be no assurance that any of our product candidates in development will receive fast-track designation, be eligible for accelerated approval, or qualify for priority review and thereby will be reviewed or approved more expeditiously than would otherwise have been the case.

Special Protocol Assessment and Agreement

In the United States, certain clinical trial protocols can be submitted to the FDA for Special Protocol Assessment ("SPA"). Under an SPA, we can reach an agreement with the FDA on the design and size of a clinical trial. This agreement is in writing and cannot be changed after the clinical trial begins except: (i) with written agreement between us and the FDA, or (ii) if the director of the FDA reviewing division determines that "a substantial scientific issue essential to determining the safety or effectiveness of the drug" was identified after testing began. This SPA agreement, however, will not apply to approvals outside the United States. We may submit one or more of our protocols to the FDA for SPA in the future.

Other Regulatory Requirements

Any products manufactured or distributed by us or our collaborators pursuant to FDA approvals are subject to pervasive and continuing regulation and inspection by the FDA, including requirements related to recordkeeping and reporting sampling and distribution, manufacturing or labeling changes, and promotion and advertising. Adverse experiences with the product that are known by us must be reported to the FDA in a timely fashion and pharmacovigilance programs to proactively look for these adverse events may be mandated by the FDA. Manufacturers of drugs and biologics, and their subcontractors, are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state

agencies for compliance with ongoing regulatory requirements, including cGMPs, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, recalls, suspension of manufacturing, import or export restrictions, revocation of marketing licenses, seizure of product, injunctive action or possible civil or criminal sanctions.

The FDA closely regulates the labelling, post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, comparisons to competing products off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the Internet. Drugs and biologics may be marketed only for the approved indications and in accordance with the provisions of the approved label. Further, if there are any modifications to the drug, including changes in indications, labelling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA or BLA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. Physicians may prescribe legally available drugs for uses that are not described in the product's labelling and that differ from those tested by us and approved by the FDA. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding off-label use.

In addition to the FDA, our products may be strictly regulated by the DEA. The DEA closely regulates those drugs that are defined as controlled substances or listed chemicals by the Controlled Substances Act or its amendments and implementing regulations. Under U.S. federal law, a person, including an individual or corporation, who manufactures, distributes, dispenses, imports, or exports any controlled substance, or who proposes to engage in these activities, must register with the DEA, unless exempt. In addition, manufacturers are subject to DEA-established procurement, production, and manufacturing quotas. Registrants must comply with a series of regulatory requirements, and have detailed procedures in place, relating to drug labelling, packaging, security, shipment and disposal; customer, clinical investigator, or other recipient licensure; employee limitations and controls; transaction reporting; records accountability; inventory maintenance; and diversion control procedures. Although we have taken steps to ensure compliance with DEA requirements, including DEA registration and licensure, we cannot guarantee that DEA will determine that our activities comply with current or future DEA regulations. The DEA has the authority to enter and inspect our facilities at any time.

We and our product candidates are subject to a variety of other federal and state laws and regulations which may hinder our ability to market our product candidates or products. Some examples include those relating to safe working conditions, manufacturing practices, environmental protection, import and export controls, fire hazard control, and disposal of hazardous or potentially hazardous substances. We may incur significant costs to comply with these laws and regulations.

International and Canadian Regulation

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our product candidates. Whether or not we obtain FDA approval for a product candidate, we must obtain approval for product candidates by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product candidate in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. We may incur significant costs to comply with these laws and regulations now or in the future.

Under European Union regulatory systems, marketing authorizations may be submitted either under a centralized or a mutual recognition or a decentralized procedure. The centralized procedure provides for the grant of a single marketing authorization that is valid for all European Union Member States. Use of the centralized procedure is mandatory for drugs developed by means of certain biotechnological processes; drugs containing a new active substance, if the substance has not been authorized in the Community before November 20, 2005 and the therapeutic indication is AIDS, cancer, neurodegenerative disorder, diabetes and orphan drugs. It is optional for new active substances or products that constitute a significant therapeutic, scientific, or technical innovation, or if the granting of a single authorization is in the interest of patients; and for generic or similar biological products.

The mutual recognition procedure provides for recognition by the European Union Member States of an approval granted by one Member State, the reference Member State. Under this procedure, the holder of a national marketing authorization may submit an application to the remaining Member States, and the reference Member State provides the assessment report together with the approved summary of product characteristics, labelling, and package leaflet to the other Member States. Within 90 days of receiving the applications and assessment report, each Member State must decide whether to recognize approval. The decentralized procedure is used in order to obtain marketing authorizations in several Member States where the product in question has not yet received a marketing authorization in any Member State. The applicant must submit an application to each Member State where a marketing authorization is sought, and one Member State will act as the reference Member State and prepare a draft assessment report on the product. The concerned Member States have 90 days to approve the draft assessment report, labeling and package leaflet.

In Canada, applications for marketing authorizations are submitted to Health Canada, which is a centralized regulatory body overseeing prescription drug approvals for all of Canada. At present, Health Canada targets 355 days for application review and approvals. Once approved, the sponsor has the right to sell the drug in Canada; however, placement on the reimbursement formularies to qualify for reimbursement under provincial public drug plans in the various Canadian provinces may take an unspecified amount of time and, in any event, may be denied by the provincial authority.

In addition to regulations in the United States, Europe and Canada, we will be subject to a variety of foreign regulations governing clinical trials, product approval, manufacturing, labeling, reporting, recordkeeping and commercial distribution of our future product candidates. Failure to substantially comply with these ongoing requirements could lead to government action against us, the product, and our representatives.

DIRECTORS AND OFFICERS

The following table sets forth, for each director of the Company, his name, municipality of residence, principal occupation and the period during which he has served as director of the Company.

Name and Municipality of Residence	Principal Occupation	Director Since
John Dempsey ^{(1) (2) (4)} Kirkland, Quebec	Managing Director of COFICO Inc., a financial consulting firm	July 2008
Yves Glaude ^{(1) (2) (4)} Beaconsfield, Quebec	Independent financial services consultant	June 2007
Dr. Halvor Jaeger ⁽⁵⁾ St. Philip, Barbados	Special envoy to the Board on financing and M&A activities	May 2005
Dr. Günter Knorr ⁽³⁾ Munich, Germany	Partner, Knorr Rechtsanwälte AG, law firm	May 2002
Raj Maheshwari ⁽²⁾ New York, New York	Managing Director, Charlestown Capital Advisors, LLC, private investment management company	June 2008
Rolf Reininghaus ^{(1) (2) (4)} Toronto, Ontario	Business Development Consultant	June 2006
Robert O. Williams III, Ph.D. ^{(3) (5)} Austin, Texas	Professor of Pharmacology, University of Texas at Austin	January 2007

(1) Member of Audit Committee

- (2) Nominating Committee
- (3) Member of Corporate Governance Committee
- (4) Member of Compensation Committee
- (5) Member of Scientific Committee

Dr. Maurice St.-Jacques and Dr. Hans Rainer Hoffman resigned from the Board on July 15, 2008 and February 12, 2009, respectively.

Each of the foregoing individuals has held the principal occupation set forth beside his name for the past five years except for: Mr Dempsey who, prior to 2008, was Vice President, Finance and Chief Financial Officer of Atrium Innovations Inc. which manufactures and markets nutritional products; Yves Glaude who, prior to 2008, was Chief Financial Officer of SolVision, Inc., an automated visual inspection equipment manufacturer; Mr. Reininghaus who, prior to June 2005, was Senior Vice President and a director of Biovail Corporation, a pharmaceutical company; and Mr. Williams who, prior to its acquisition by the Company, was also the President and Chief Financial Officer of PharmaForm.

Each director holds office until the next annual meeting or until his successor is elected or appointed.

The following table sets forth, for each executive officer of the Company, his name, municipality of residence and position(s) held within the Company.

<u>Name and Municipality of Residence</u>	<u>Position(s) Held within the Company</u>
Dr. Taneli Jouhikainen Austin, Texas	Acting Chief Executive Officer
Andrew Reiter CA Austin, Texas	Chief Financial Officer and Chief Operating Officer

Each of the foregoing individuals has held the position(s) set forth beside his name for the past five years except for Andrew Reiter who, prior to November 2004, was Chief Financial Officer of Silonex Inc., a specialty manufacturer of optical sensors.

Except as set out below, no director or executive director of the Company:

- (a) is, as at the date hereof, or has been, within 10 years before the date hereof, a director, chief executive officer or chief financial officer of any company that:
 - (i) was subject to an order that was issued while the director or executive officer was acting in the capacity as director, chief executive officer or chief financial officer, or
 - (ii) was subject to an order that was issued after the director or executive officer ceased to be a director, chief executive officer or chief financial officer and which resulted from an event that occurred while that person was acting in the capacity as director, chief executive officer or chief financial officer; or
- (b) is, as at the date hereof, or has been, within 10 years before the date hereof, a director or executive officer of any company that, while that person was acting in that capacity, or within a year of that person ceasing to act in that capacity, became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted any proceedings, arrangement, or compromise with creditors or had a receiver, receiver-manager or trustee appointed to hold its assets; or

- (c) has, within 10 years before the date hereof, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or become subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver-manager or trustee appointed to hold the assets of the director or executive officer; or
 - (d) has been subject to:
 - (i) any penalties or sanctions imposed by a court relating to securities legislation or by a securities regulatory authority or has entered into a settlement agreement with a securities regulatory authority, or
 - (ii) any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable investor in making an investment decision.
1. Yves Glaude was Chief Financial Officer of SolVision Inc. on January 25, 2008 when the court assigned an interim receiver to its assets and undertakings. On February 28, 2008 these assets were acquired by a US publicly listed company.
 2. Mr. Jouhikainen was Chairman of the Board of Directors of Spectrum Medical Services Oy when it filed for bankruptcy in 2002.
 3. Mr. Reiter was Chief Financial Officer of Silonex Inc. when it filed for protection from its creditors on March 9, 2004 and until it was released from creditor protection status on September 3, 2004.

As at March 1, 2009, the directors and executive officers of the Company, as a group, beneficially owned, directly or indirectly, or exercised control or direction over, an aggregate of 2,228,416 Common Shares, representing approximately 10% of the total number outstanding on such date.

CAPITAL STRUCTURE

The authorized capital of the Company consists of an unlimited number of Preference Shares issuable in series and an unlimited number of Common Shares, of which, as at March 1, 2009 no Preference Shares and 21,615,577 Common Shares were issued and outstanding

The following is a description of the material characteristics of the Preference Shares and Common Shares.

Preference Shares

The Preference Shares may be issued in one or more series, each series to consist of such number of shares as may, before the issue thereof, be fixed by resolution of the Board of Directors of the Company. The directors of the Company shall determine before the issue thereof the designations, rights, privileges, restrictions and conditions attaching to the Preference Shares of each series including, the rate or amount of dividends or the method of calculating dividends, the dates of payment thereof, the redemption and/or purchase prices and terms and conditions of redemption and/or purchase, any voting rights, any conversion rights and any sinking fund or other provisions.

The Preference Shares of each series will, with respect to payment of dividends and the distribution of assets in the event of liquidation, dissolution or winding up of the Company, rank on a parity with the Preference Shares of every other series and be entitled to preference over the Common Shares and over any other shares of the Company ranking junior to the Preference Shares. The Preference Shares of any series may also be given such other preferences over the Common Shares and over any other shares of the Company ranking junior to the Preference Shares as may be fixed by the directors.

Common Shares

The holders of Common Shares are entitled (a) to vote at all meetings of shareholders, on the basis of one vote for each Common Share, except meetings at which only holders of a specified class of shares are entitled to vote; (b) to receive dividends as and when declared by the Board of Directors of the Company out of moneys of the Company properly applicable thereto subject to the rights of the holders of the Preference Shares; and (c) to receive the remaining property of the Company upon dissolution of the Company, subject to the rights of the holders of the Preference Shares.

DIVIDENDS

The Company has not paid any dividends to date. There are no restrictions that prevent the Company from paying dividends. However, the Company currently intends to retain future earnings, if any, for use in its business, and does not anticipate paying dividends on the Common Shares. Any determination to pay dividends in the future will remain at the discretion of the Board of Directors and will be made taking into account its financial condition and other factors deemed relevant by the Board of Directors.

MARKET FOR COMMON SHARES

The Common Shares are listed for trading under the symbol “AKL” on the TSX. The following table sets forth the high and low prices at which a board lot of Common Shares were traded and the trading volumes of the Common Shares for the periods indicated on the TSX.

	<u>High (\$)</u>	<u>Low (\$)</u>	<u>Volume</u>
<u>2008</u>			
January	3.99	2.52	343,363
February	2.68	.99	446,611
March	1.34	1.05	217,400
April	1.40	1.17	815,000
May	1.50	1.15	410,700
June	1.69	1.25	58,500
July	1.70	1.22	74,800
August	1.57	0.95	101,600
September	1.05	0.90	262,800
October	0.94	0.55	168,300
November	0.70	0.25	108,400
December	0.29	0.09	0
<u>2009</u>			
January	0.25	0.10	428,000
February	0.23	0.13	399,000
March (to March 16 th)	0.24	0.16	259,000

LEGAL PROCEEDINGS

We are the defendant in an action brought against us in the District Court of Travis County, Texas by Stephen Lermer, our former Senior Vice President, Manufacturing. The action claims actual and compensatory damages in

an unspecified amount, costs and other relief in connection with the termination of Mr. Lermer's employment in October 2007.

On March 10, 2009, we agreed to accept a payment of \$2,000 Cdn (\$1,562 US) and 500,000 warrants with an exercise price of \$0.50 Cdn (\$0.39 US) from LAB Research Inc. as full and final settlement of our lawsuit relating to a failed Fentanyl TAIFUN® toxicology study.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not currently a party to any legal proceedings the outcome of which, if determined adversely to us, would individually or in the aggregate have a material adverse effect on our business, operating results, financial condition or cash flows. See "Risk Factors".

INTERESTS OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

No director or executive officer of the Company, person or company that is the direct or indirect beneficial owner of, or who exercises control or direction over, more than 10% of the outstanding Common Shares or associate or affiliate of any of the foregoing has any material interest, direct or indirect, in any transaction since January 1, 2006 that has materially affected or will materially affect the Company, except as follows:

In November 2006, Halvor Jaeger and Andrew Reiter received a bonus of \$1,395,000 and \$155,000, respectively, upon the completion of the public offering of LRI. The bonus was equal to 5% of the net proceeds received by the Company from the secondary public offering of LRI common shares (including the exercise by the underwriters of their over-allotment option). Messrs. Jaeger and Reiter were also entitled to a bonus of 5%, payable in LRI common shares, of the LRI common shares retained by the Company following the completion of the public offering. In November 2006, this bonus was paid in cash as to \$1,095,194 to Halvor Jaeger and as to \$121,687 to Andrew Reiter based on the number of common shares of LRI underlying the special warrants sold by the Company to which each of them was entitled.

MATERIAL CONTRACTS

The following is a list of the contracts (other than contracts in the ordinary course of business) that are material to the Company and which were entered into (i) during 2008, or (ii) since January 1, 2002 and are still in effect.

1. A funding agreement with Tekes dated February 8, 2005, whereby a maximum of €5,892,330 of approved project expenses relating to the development of Fentanyl TAIFUN were funded by a €883,845 euro grant and a €2,062,315 loan. This project was completed in 2006 and both capital and interest thereon are subordinated to all other debts. The capital and interest need only be refunded when the net deficit of our Finnish subsidiary has been recovered and there are consistent distributable profits. The term of the loan is eight years and the interest rate is 1% below the Finnish national base rate but cannot be less than 3%. Following our decision to down-size the Finnish operations, we were notified that this agency was reviewing loans and subsidies previously granted to us totaling €2,062,315 and €955,664, respectively. The agency has decided not to call the loans and we have not accepted its demand for repayment of the subsidies. Discussions with the agency are ongoing and we cannot determine if such review will lead to repayment of all or a portion of the subsidies we received. However, the loans received from the Finnish governmental agency continue to be reflected as long-term debt in our financial statements in accordance with the original agreements.
2. A funding agreement with Tekes dated October 10, 2005, whereby a maximum of €3,109,610 of approved project expenses relating to the development of Combination TAIFUN and CGRP will be funded by a €466,000 grant and a €1,088,000 loan. Both capital and interest thereon are subordinated to all other debts. The capital and interest need only be refunded when the net deficit of our Finnish subsidiary has been recovered and there are consistent distributable profits. The term of the loan is eight years and the interest rate is 1%. Tekes is also reviewing the status of these loans and grants as highlighted in (1) above.

3. An agreement dated November 23, 2004 with SK Chemicals Co. Ltd. described under “Licensing and Development”.
4. An agreement dated December 19, 2005 with Teikoku Seiyaku Co. Ltd. described under “Licensing and Development”.
5. A preferred supplier agreement dated August 3, 2006 between the Company and LRI pursuant to which the Company undertook, for a period of 60 months following the closing, to use LRI’s services with respect to all pre-clinical research services required by the Company in the field of toxicology and toxico-kinetics at a price to be calculated on the basis of all direct and indirect costs plus a profit margin to vary in accordance with the annual volume of services performed by LRI during any given year.
6. A non-competition and non-solicitation agreement dated August 3, 2006 between the Company and LRI pursuant to which the Company undertook not to, directly or indirectly, for a period of 60 months following the closing, carry on, own, operate or be engaged in any business in Canada, the U.S. or any member state of the European Union which provides pre-clinical CRO services on non-human subjects in the field of toxicology and toxico-kinetics or solicit or hire any of LRI’s employees for the same period of time. The non-competition obligations under this agreement will automatically terminate upon termination of the Preferred Supplier Agreement by the Company as a result of a breach of the Preferred Supplier Agreement by LRI.
7. The PharmaForm Acquisition Agreement dated as of January 10, 2007 by and between the Company and Daniel J. Bates, John J. Koleng Jr., Feng Zhang, Michael M. Crowley, James W. McGinity and Robert O. Williams, III described under “History and Development”.
8. The Exclusive licence, Development and Supply Agreement, as amended, with Janssen for Fentanyl TAIFUN® described under “Licensing and Development.”
9. A warrant indenture dated March 27, 2008 between the Company and Equity Transfer and Trust Company pursuant to which the Warrants were issued and are governed.
10. A facility lease agreement executed July 28, 2008 with HEP-Davis Spring LP described under “Recent Events”.

RISK FACTORS

Risks Related to Financing Our Business

We have incurred operating losses and anticipate that we will continue to incur losses for the foreseeable future. We have never had any products available for commercial sale and we may never achieve or sustain profitability.

We are an integrated product development company and our proposed products are currently in research and development. We are not profitable and have incurred operating losses. We have never had any products available for commercial sale and we have not generated any revenue from product sales. We do not anticipate that we will generate revenues from the sale of products for the foreseeable future, but we continue to incur expenses related to our operations. Our consolidated net loss for the years ended December 31, 2006, 2007 and 2008 was \$0.2 million, \$32.7 million and \$26.0 million, respectively. For the year ended December 31, 2006, results include a gain on the disposal of LRI; our net loss excluding the gain was \$34.4 million. As of December 31, 2008, we had an accumulated deficit of \$86.8 million. We expect to continue to incur losses for the foreseeable future, and we expect these losses to persist as we continue our research activities and conduct development of, and seek regulatory approvals for, our product candidates, and prepare for and begin to commercialize any approved products. We may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability. Any failure to successfully develop and obtain regulatory approval for product candidates that are currently under development would have a material adverse effect on our business, financial condition and results of operations.

We will have additional future capital needs and there are uncertainties as to our ability to raise additional funding. If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our product candidates or continue our clinical trials and other research and development programs.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to:

- initiate and complete the clinical development of our other product candidates;
- develop, license or acquire additional product candidates;
- launch and commercialize any product candidates for which we receive regulatory approval; and
- continue our research and development programs.

Based upon our existing capital resources and funds received from co-development and licensing agreements, substantial additional funds will be required over the next five years to develop our current product and platform portfolio to the point where these products and platforms can be either commercialized or out-licensed. These costs will be financed using our current working capital, by funds received through co-development and licensing arrangements and through the issuance of shares and/or debt as required. In addition, our future cash requirements may vary materially from those now expected. For example, our future capital requirements may increase if we:

- experience scientific progress sooner than expected in our discovery, research and development projects, if we expand the magnitude and scope of these activities, or if we modify our focus as a result of our discoveries;
- experience setbacks in our progress with preclinical studies and clinical trials are delayed;
- experience delays or unexpected increased costs in connection with obtaining regulatory approvals;
- experience unexpected or increased costs relating to preparing, filing, prosecuting, maintaining, defending and enforcing patent claims; or
- elect to develop, acquire or license new technologies and products.

If sufficient capital is not available, we may be required to delay, reduce the scope of or eliminate one or more of our clinical trials and/or research and/or development projects, any of which could have a material adverse effect on our business, financial condition, prospects or results of operations. We may also seek collaborators for our product candidates at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available. We may be required to relinquish or license on unfavorable terms our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves.

A Finnish governmental agency is reviewing the loans and subsidies previously granted to our Finnish subsidiary and may attempt to change the terms of the original agreement or demand repayment of all or a portion of the amounts received.

Our Finnish subsidiary received certain low interest loans and subsidies from a Finnish governmental agency. In the summer of 2007, following our decision to down-size the Finnish operations, we were notified that this agency was reviewing loans and subsidies previously granted to us totalling €3,150,000 and €956,000, respectively. The agency has decided not to call the loans and we have not accepted its demand for repayment of the subsidies. Discussions with the agency are ongoing and we cannot determine if such review will lead to repayment of all or a portion of the subsidies we received. We have made no provision in our financial statements for the repayment of such amounts and, if any such payment were required, additional funding would be necessary. There is no assurance that any such

additional funding would be available on terms that we consider reasonable or at all. In the absence of such financing, we would likely have to scale back the development of our product candidates.

If we raise additional financing, the terms of such transactions will cause dilution to existing shareholders and/or may contain terms that are not favorable to us or existing shareholders.

We may seek to raise additional financing through private placements or public offerings of our equity or debt securities. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional funds by issuing equity securities, our shareholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants, such as limitations on our ability to incur additional indebtedness, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business.

Risks Related to Clinical Trials and Regulatory Approval

We have been highly dependent on the success of our lead product candidate, Fentanyl TAIFUN®, and we cannot give any assurance that it or any of our other product candidates will receive regulatory approval or be successfully commercialized.

We have invested a significant portion of our financial resources in the development of our lead product candidate, Fentanyl TAIFUN®. Although we have several other products under development, they are at an earlier stage of development.

We completed our Fentanyl TAIFUN® Phase IIb clinical trials in 2007. In order to market Fentanyl TAIFUN®, we will have to conduct additional clinical trials, including a Phase III clinical trial, to demonstrate safety and efficacy. The FDA recently deemed invalid the inhalation toxicology studies on Fentanyl TAIFUN® dry powder inhaler performed for us on dogs and rats by a CRO due to GLP deviations. These studies will have to be repeated. On March 10, 2009, we agreed to accept a payment of \$2,000 Cdn (\$1,562 US) and 500,000 warrants with an exercise price of \$0.50 Cdn (\$0.39 US) from LAB Research Inc. as full and final settlement of a lawsuit relating to this failed study. The toxicology studies will be repeated in their entirety in the United States using a different CRO. The preparatory phase of these studies is complete but the program has been put on hold until additional sources of funding are secured.

Our other product candidates focusing on pain that utilize our abuse-deterrent EDACS™ technology are currently in preclinical development. Our other non-pain product candidates, a GHRH analog and a calcitonin composition, are also in Phase II clinical trials and are subject to the risk that Phase III clinical trials may be delayed, altered or not initiated, that regulatory approval may never be achieved and that these products, if commercialized, may not be successful. Our clinical development programs for each of these three product candidates may fail to receive regulatory approval if we are not able to demonstrate that the relevant product candidate is safe and effective in clinical trials, and consequently we may fail to obtain necessary approvals from the FDA, European Agency for the Evaluation of Medicinal Products (“EMA”) or similar regulatory agencies in Canada and elsewhere.

The results of preclinical studies and previous clinical trials are not necessarily predictive of future results, and our current product candidates may not have favourable results in later testing or trials.

Preclinical tests and Phase I and Phase II clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of products at various doses and schedules. Success in preclinical or animal studies and early clinical trials does not ensure that later large-scale efficacy trials will be successful and is not necessarily predictive of final results. Favourable results in early trials may not be repeated in later trials and positive interim results do not ensure success in final results.

The results of preclinical tests and clinical trials are frequently susceptible to:

- varying interpretations of results that may delay, limit or prevent regulatory approvals;

- negative or inconclusive results or adverse medical events that may cause the clinical trial to be delayed, repeated or terminated; or
- third-party actions that are outside of our control, including patients, investigators, CROs, IRBs or ethics committees, DSMBs and government regulators.

Even after the completion of Phase III clinical trials, the FDA, EMEA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data, and may require us to conduct additional clinical trials to demonstrate the efficacy of our product candidates.

Share prices for life sciences companies have declined significantly in instances where clinical results were not favorable, were perceived negatively or otherwise did not meet expectations. Unfavorable results or negative perceptions regarding the results of clinical trials for any of our product candidates could cause our share price to decline significantly and could lead to shareholder lawsuits, securities regulatory inquiries and government investigations.

Clinical trials for our product candidates are expensive and time-consuming, and their outcome is uncertain.

Before we can obtain regulatory approval for the commercial sale of any product candidate, we are required to complete extensive clinical trials to demonstrate the product's safety and efficacy. Clinical trials are very expensive and difficult to design and implement. Notwithstanding any estimates we may make as to the timing of the commencement, continuation and completion of any of our clinical trials, there can be no guarantee that such trials will not be subject to significant delays relating to various causes, including:

- our inability to manufacture or obtain sufficient quantities of materials for use in clinical trials;
- delays arising from collaborative arrangements;
- delays in obtaining regulatory approvals to commence a study, or government intervention to suspend or terminate a study;
- delays, suspension, or termination of the clinical trials due to the independent ethics board responsible for overseeing the study to protect research subjects at a particular study site;
- delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;
- difficulty recruiting and enrolling sufficient numbers of patients, which is affected by design of the protocol, the size of the patient population, eligibility criteria for the study in question, perceived risks and benefits of the drug under study, availability of competing therapies, efforts to facilitate timely enrollment in clinical trials, public reputation of the investigator(s) or study site(s), patient referral practices of physicians, and availability of clinical trial sites.
- uncertain dosing issues;
- inability or unwillingness of medical investigators to follow clinical protocols or drug control procedures;
- variability in the number and types of subjects available for each study and resulting difficulties in identifying and enrolling subjects who meet trial eligibility criteria;
- scheduling conflicts with participating clinicians and clinical institutions;
- difficulty in maintaining contact with subjects after treatment, resulting in incomplete data;

- unforeseen safety issues or side effects;
- lack of efficacy during the clinical trials;
- reliance on CROs to conduct clinical trials, which may not conduct those trials with good clinical or laboratory practices; and
- other regulatory delays.

For example, in February 2008 the FDA deemed invalid the inhalation toxicology studies on Fentanyl TAIFUN® dry powder inhaler performed for us on dogs and rats by a CRO due to GLP deviations.

Our clinical trials may be suspended or terminated at any time by the FDA, EMEA or other regulatory authorities, the IRB or ethics committee overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site or us. Any failure or significant delay in completing clinical trials for our product candidates could materially harm our financial results and the commercial prospects for our product candidates.

Our product candidates may cause undesirable and potentially serious side effects during clinical trials that could delay or prevent their regulatory approval or commercialization.

Undesirable side effects caused by any of our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA, EMEA or other non-U.S. regulatory authorities for any or all targeted indications. This, in turn, could prevent us from commercializing our product candidates and generating revenues from their sale.

Any one or a combination of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the product, which in turn could delay or prevent us from generating significant revenues from the sale of the product.

Fentanyl TAIFUN® is a potent opioid analgesic that may cause potentially life-threatening respiratory depression if administered in high doses. This risk may be increased with a product that produces a very rapid and high concentration of fentanyl, such as Fentanyl TAIFUN®. For this reason, all patients that receive Fentanyl TAIFUN® treatment must be tolerant to opioids, and the administration is started from low doses and increased to higher doses only if the patient requires a higher dose to achieve analgesia and has no undesirable effects, such as respiratory depression. With adherence to these precautions, no respiratory depression has been observed in patients receiving Fentanyl TAIFUN®.

The FDA has indicated to us that we will need to submit a risk minimization action plan (“**RiskMAP**”) to address certain identified risks associated with the use of Fentanyl TAIFUN®. Generally speaking, a RiskMAP is a strategic safety program designed to achieve specific safety-related health outcomes or goals in minimizing known risks of a product, while preserving its benefits. We expect that our RiskMAP will fully address the risks identified by the FDA and our risk minimization program.

If new therapies become broadly used, we may need to conduct clinical trials of our product candidates in combination with these new therapies to demonstrate the safety and efficacy of the combination. Additional trials will delay the development of our product candidates and increase our costs. The failure of our product candidates to work in combination with these new therapies would have an adverse effect on our business.

We will need to assess new therapies as they are developed to determine whether to conduct clinical trials of our product candidates in combination with them to demonstrate safety and efficacy of the combination. If we determine to conduct additional clinical trials of our product candidates in combination with these new therapies, the development of our product candidates will be delayed and our costs increased. If these clinical trials generate safety concerns or lack of efficacy, our business would be adversely affected.

If our product candidates become approved in combination with a specific therapy that is broadly used and that therapy becomes displaced by another product, the market for our product candidate may decrease.

We rely, in part, on third parties to conduct clinical trials and other studies for our product candidates and plan to rely on third parties to conduct future clinical trials and other studies. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval for or commercialize our product candidates.

To implement our product development strategies, we rely, in part, on third parties, such as CROs, medical institutions, clinical investigators and contract laboratories, to conduct the clinical trials of our product candidates. One CRO, Allied Research International, conducted our CGRP Phase IIa clinical trial; Encorium Oy, a Finnish CRO, conducted our GHRH pilot Phase II clinical trial; and two CROs, Hyperphar N.V. and Pharos GmbH, conducted our Fentanyl TAIFUN® Phase II clinical trial. In addition, we relied on LRI to conduct inhalation toxicology studies on Fentanyl TAIFUN®. The types of services provided by these CROs include the preparation of case report forms, site management and monitoring, bio-statistics, data management and final report preparation and can be replaced with a minimum of operational disruption. Although the services our CROs currently perform are commodity services that can be easily relocated, we may rely more substantially on third parties in the future.

Despite our utilization of third-party services to conduct our clinical trials, we are responsible for ensuring that each of our clinical trials is conducted in accordance with our investigational plan and protocol, and regulations and standards for conducting, monitoring, recording and reporting the results of clinical trials. Such regulations and standards, commonly referred to as Good Clinical Practices (“GCPs”) have been designed to ensure that the data and results of clinical trials are scientifically credible and accurate and that the clinical trial subjects are adequately informed of the potential risks of participating in clinical trials.

If the third parties conducting our clinical trials do not perform their contractual duties or obligations, do not meet expected deadlines or need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to GCPs or for any other reason, we may need to enter into new arrangements with alternative third parties and our clinical trials may be extended, delayed or terminated. For example, in February 2008 the FDA deemed invalid the inhalation toxicology studies on Fentanyl TAIFUN® dry powder inhaler performed for us on dogs and rats by LRI due to GLP deviations. In addition, a failure by such third parties to perform their obligations in compliance with GCPs may cause our clinical trials to fail to meet regulatory requirements, which may require us to repeat our clinical trials, and may lead to investigations or enforcement actions by applicable government regulators against us or the third parties.

In the future, we may conduct our own clinical trials in certain countries through either targeted acquisitions of certain existing clinical operations or the establishment of new operations. There can be no assurance that we will pursue this strategy or that such strategy would mitigate against this risk.

Our drug development and formulation services business is regulated by numerous federal, state, and local governmental authorities in the United States and elsewhere subjecting us to compliance costs and risks of non-compliance.

Our operations in Austin, Texas provide pharmaceutical development and formulation services and pre-commercial manufacturing on a fee-for-service basis to third parties for their products. We expect that these capabilities, together with the intellectual property acquired by us in the PharmaForm acquisition, will assist us in our product development strategy, potentially broaden our drug platform pipeline and provide for the eventual manufacture of our products within the United States. However, the manufacturing, distribution, processing, formulation, packaging, storage, and disposal functions in Austin are subject to numerous and complicated federal, state, and local governmental regulations in the United States including, but not limited to, GLPs, GCPs, and GMPs. We must maintain our facility’s DEA and FDA registrations. Failure to do so would require new testing and compliance inspections. Compliance with all federal, state, and local requirements in the United States is difficult and expensive. Manufacturers and their facilities are subject to continual review and periodic inspections. Failure to comply could result in penalties; suspension of manufacturing, and/or testing; costly changes to achieve compliance; loss of permits or licenses; or facility closure. Each of the foregoing occurrences could have a material and adverse effect on our business, financial condition, and current operation, and could negatively affect our ability to service our

third-party customers or meet contractual commitments, as well as significantly delay or prevent us from developing and commercializing our own product candidates.

If our third-party customers file complaints about our services or our facilities, we could be subject to lawsuits and the DEA or FDA may impose restrictions or limitations on our activities or potentially close the facility. We are subject to ongoing periodic unannounced inspection by the FDA, DEA and non-U.S. regulatory authorities to ensure strict compliance with GLP, GCP and cGMP and other applicable government regulations and corresponding standards. There can be no assurance that the FDA, DEA or other regulatory agencies will find our contract research and development activities to be in compliance with GLP, GCP and cGMP requirements or other applicable requirements. If we fail to achieve and maintain high laboratory testing standards, clinical research standards, or manufacturing standards in compliance with GLP, GCP and cGMP regulations, we may experience testing, research or manufacturing errors or results leading to problems that could seriously harm our business, financial condition and reputation and could result in significant legal liability. In the future, PharmaForm may conduct commercial manufacturing activities for our products or for our third-party customers that would increase our risks and potential liabilities. In addition, significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve.

FDA review of our product candidates and, consequently, approval of our product candidates in the United States, may be subject to delay given the locations of our clinical studies.

The FDA will generally accept an application for marketing approval based solely on non-U.S. clinical data meeting U.S. criteria if:

- the non-U.S. data is applicable to the U.S. population and U.S. medical practice;
- the studies have been performed by clinical investigators of recognized competence; and
- the data may be considered valid without the need for an on-site inspection by the FDA, or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

We have primarily conducted clinical trials for our lead product candidate, Fentanyl TAIFUN®, and our other product candidates outside the United States at study sites in Canada, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Moldova, Poland, Romania, Serbia, the Netherlands, Ukraine, and the United Kingdom. To the extent the FDA deems it necessary to conduct an on-site inspection as described above, our applications for marketing approval may be delayed longer than similarly situated companies that have conducted trials in the United States. In addition, though we believe that our non-U.S. data is applicable to the U.S. population and U.S. medical practice, the FDA has not yet concluded so and if the FDA were to question our non-U.S. data, our applications for marketing approval might be delayed longer than similarly situated companies that have conducted trials in the United States or may not be approved at all.

Should the FDA, contrary to our expectations, not consider our non-U.S. data applicable to the U.S. population, we would need to increase the number of U.S. study sites in the Phase III program, or conduct the Phase III program entirely in the United States, which consequences could result in a higher cost, a delay of the clinical program, or both.

FDA approval for our product candidates in the United States could be delayed if our competitors obtain FDA approval for a competitive product before we do.

As an alternate path to FDA approval for new indications or improved formulations of previously approved products, a company may submit a Section 505(b)(2) NDA, instead of a “stand-alone” or “full” NDA filing under Section 505(b)(1). Section 505(b)(2) of the FDCA, was enacted as part of the *Drug Price Competition and Patent Term Restoration Act of 1984* (United States), otherwise known as the Hatch-Waxman Amendments. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of

reference. This provision allows the FDA to rely for approval of the NDA on data not developed by the applicant, such as published literature or the agency's finding of safety and effectiveness of a previously approved drug.

Under the Hatch-Waxman Amendments, in the United States newly approved drugs and indications benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Amendments prohibit the submission of an ANDA, or a Section 505(b)(2) NDA for a drug product that references the newly approved drug for a five-year period, except that the ANDA or 505(b)(2) application may be submitted after four years if it contains a Paragraph IV certification of patent invalidity or non-infringement. A Section 505(b)(2) application may itself be granted five years of exclusivity if it is for a new chemical entity. Protection under the Hatch-Waxman Amendments will not prevent the submission or approval of another "full" or "stand-alone" NDA; however, the applicant would be required to conduct its own non-clinical and adequate and well-controlled clinical trials to demonstrate safety and effectiveness. The Hatch-Waxman Amendments also provide three years of marketing exclusivity for the approval of new and supplemental NDAs, including Section 505(b)(2) NDAs, for, among other things, new indications, dosages, or strengths of an existing drug, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are essential to the approval of the application containing those changes. The Hatch-Waxman Amendments prohibit the FDA's approval of an ANDA or a 505(b)(2) NDA for a drug product that references the newly approved drug for a three-year period. A 505(b)(2) NDA may itself be granted three years of exclusivity if it contains new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant and that are essential to the approval of the application. The five-year and three-year periods may be extended by up to two periods of six-month exclusivity for the submission of pediatric studies.

If the FDA approves another company's version of our product candidates, such as GHRH, before it approves our product candidate, and awards that company five-year marketing exclusivity for a new chemical entity, then we could not submit a 505(b)(2) application for that product candidate for at least four years. However, since our GHRH has a unique amino acid sequence and is considered a new chemical entity different from other GHRH compounds, we will need to submit a full 505(b)(1) NDA. Therefore, data protection relating to other companies' GHRH compounds should not extend to our GHRH. In addition, if the FDA approves another company's version of our product candidates, such as a dry-powder form of inhaled fentanyl, before it approves our product candidate, such as Fentanyl TAIFUN®, and awards that company three-year marketing exclusivity for a new clinical study, then we could not receive FDA approval of our 505(b)(2) application for that product candidate for at least three years.

The regulatory approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates.

The research, testing, manufacturing, packaging, labeling, approval, storage, selling, marketing and distribution of drug products are subject to extensive regulation in the United States by the FDA, in Canada by the Therapeutics Products Directorate ("TPD") and by similar regulatory authorities in the European Union, Japan and elsewhere, and regulations and requirements differ from country to country. We are not permitted to market our product candidates in the United States until we receive approval of an NDA, or BLA from the FDA. We have not submitted an application for or received marketing approval for any of our product candidates. Obtaining approval can be a lengthy, expensive and uncertain process.

The FDA has substantial discretion in the drug approval process. Despite the time and expense exerted by us, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to address, and the regulations applicable to any particular drug candidate. The FDA can delay, limit or deny approval of a drug candidate for many reasons, including:

- a drug candidate may not be deemed safe or effective;
- the FDA may not find the data from preclinical studies and clinical trials sufficient;
- the FDA may not approve our third-party manufacturer's processes or facilities;

- the FDA may change its approval policies or adopt new regulations; or
- third-party products may enter the market and change approval requirements.

Our operations and facilities are subject to ongoing governmental review. Development, manufacturing, labeling, and promotional activities are continually regulated by the FDA, DEA and certain non-U.S. regulatory bodies, and we must also report certain adverse events involving our products and those we service to these agencies. Previously unidentified adverse events or an increased frequency of adverse events at our facility could result in costly and time-consuming alterations, including temporary shutdown of our operations. In addition, approvals may be withdrawn if compliance with regulatory standards is not maintained. The restriction, suspension, or revocation of regulatory approvals or any other failure to comply with regulatory requirements could have a material adverse effect on our business, financial condition, and results of operations.

We are required to follow cGMP requirements and are subject to routine unannounced periodic inspections by the FDA, DEA and certain U.S. state and non-U.S. regulatory agencies for compliance with cGMP requirements and other applicable regulations. There can be no assurance that the FDA, DEA or other regulatory agencies will find our CRO or manufacturing process or facilities or other operations to be in compliance with cGMP requirements and other regulations. Our failure to maintain satisfactory compliance with cGMP could have a material adverse effect on our ability to continue to develop, produce, market and distribute our product candidates and, in the most serious cases, could result in the issuance of warning letters, seizure or recall of products, civil penalties or closure of our development and manufacturing facilities until such cGMP compliance is achieved.

Failure to comply with regulatory authorities or applicable regulatory requirements may, either before or after product approval, if any, subject us to administrative or judicially imposed sanctions.

Failure to comply with FDA, EMEA or other applicable U.S. and non-U.S. regulatory requirements may, either before or after product approval, if any, subject us to administrative or judicially imposed sanctions, including restrictions on the products, manufacturers or manufacturing process; warning letters or untitled letters; civil and criminal penalties; injunctions; suspension or withdrawal of regulatory approvals; suspension of or holds on clinical trials; product seizures, detentions or import bans; product recalls and publicity requirements; total or partial suspension of production; imposition of restrictions on operations, including costly new manufacturing requirements, via consent decrees or other administrative action; and refusal to approve pending NDAs or BLAs or supplements to approved NDAs or BLAs.

Regulatory approval of an NDA, NDA supplement, BLA or BLA supplement is not guaranteed, and the approval process is very expensive and may take several years, if it occurs at all.

Failure to maintain DEA registration and licensing or compliance with DEA requirements could prevent us from marketing our product candidates in the United States.

Our product candidates may be strictly regulated by the DEA. The DEA closely regulates those drugs that are defined as controlled substances or listed chemicals by the *Controlled Substances Act* (United States) and its amendments and implementing regulations. Under U.S. federal law, a person, including an individual or corporation, who manufactures, distributes, dispenses, imports, or exports any controlled substance, or who proposes to engage in these activities, must register with the DEA, unless exempt. In addition, manufacturers are subject to DEA-established procurement, production, and manufacturing quotas. Registrants must comply with a series of regulatory requirements, and have detailed procedures in place, relating to drug labeling, packaging, security, shipment and disposal; customer, clinical investigator, or other shipper licensure; employee limitations and controls; transaction reporting; records accountability; inventory maintenance; and diversion control procedures. Although we have taken steps to ensure compliance with DEA requirements, including DEA registration and licensure, we cannot guarantee that DEA will determine that our activities comply with current or future DEA regulations. The DEA has the authority to enter and inspect our facilities at any time. There may be similar regulatory issues in other non-U.S. jurisdictions.

Failure to obtain regulatory approval outside the United States would prevent us from marketing our product candidates in such jurisdictions.

We intend to market certain of our product candidates in non-U.S. markets. In order to market our product candidates in the European Union and many other jurisdictions, we must obtain separate regulatory approvals. The approval procedures vary among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the regulatory authorities in one country does not ensure approval by regulatory authorities in other countries. The non-U.S. regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain regulatory approvals on a timely basis, if at all. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our product candidates in any market. Once we obtain regulatory approvals in any jurisdiction, we will be subject to post-approval requirements and non-compliance with these requirements could result in enforcement actions against us.

Even if we obtain regulatory approvals for our product candidates, the terms of approvals and ongoing regulation of our product candidates may limit how we manufacture, distribute and market our product candidates, which could materially impair our ability to generate revenue.

Even if we or our collaborators obtain regulatory approval for a drug candidate, we will be subject to post-marketing regulatory obligations, including requirements to maintain records regarding product safety and report to regulatory authorities adverse events. The occurrence of unanticipated serious adverse events or other safety problems could cause the regulatory authorities to impose significant restrictions on the indicated uses for which the product may be marketed, impose other restrictions on the distribution or sale of the product, require labeling changes that affect the risk-benefit ratio of the drug or require potentially costly post-approval studies.

In addition, post-market discovery of any previously unknown safety problem could result in withdrawal of the product from the market and product recalls. Compliance with extensive post-marketing recordkeeping and reporting requirements requires a significant commitment of time and funds, which may limit our ability to commercialize approved product candidates.

In addition, manufacturing of approved drug products must comply with extensive regulations governing cGMP. Manufacturers and their facilities are subject to continual review and periodic inspections. Failure to comply with cGMP requirements could result in a suspension of manufacturing, product recalls or even withdrawals from the market. As we will be dependent on third parties for manufacturing, we will have limited ability to ensure that any entity manufacturing products on our behalf is doing so in compliance with applicable cGMP requirements. Failure or delay by any manufacturer of our products to comply with cGMP regulations or to satisfy regulatory inspections could have a material adverse effect on us, including potentially preventing us from being able to supply products for clinical trials or commercial sales. In addition, manufacturers may need to obtain approval from regulatory authorities for product, manufacturing, or labeling changes, which requires time and money to obtain and can cause delays in product availability.

There are extensive post-approval requirements related to the sale and marketing of pharmaceutical products in many jurisdictions, including laws governing approved labeling, comparisons to competing products' off-label promotion, scientific/educational grants, gifts, and adverse event monitoring and post-marketing reporting.

Compliance with extensive regulatory requirements requires training and monitoring of the sales force, which would impose a substantial cost on us and our collaborators. To the extent our products, when and if we have any, are marketed by our collaborators, the ability to ensure their compliance with applicable regulations will be limited. Failure to comply with applicable legal and regulatory requirements may result in issuance of warning or untitled letters by regulatory authorities, or both; fines and other civil penalties; criminal prosecutions and penalties; injunctions, suspensions or revocations of marketing licenses or approvals; suspension of any ongoing clinical trials; suspension of manufacturing; delays in commercialization; refusal by regulatory authorities to approve pending applications or supplements to approved applications filed by us or our collaborators; refusals to permit products to be imported or exported to or from the United States or Canada; detention or destruction of the imported product; restrictions on operations, including costly new manufacturing requirements; and product recalls or seizures.

In addition, the FDA, EMEA and non-U.S. regulatory authorities may change their policies and additional regulations may be enacted that could prevent or delay regulatory approval or impact the commercialization of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States, Canada or abroad. If we are not able to maintain regulatory compliance, we would likely not be permitted to market our product candidates and we may not achieve or sustain profitability.

Risks Related to Marketability and Commercialization

Our development strategy focuses on reformulations of off-patent drugs and others may develop similar reformulations of those same drugs.

Our product development strategy involves the reformulation of existing drugs with active ingredients that are off-patent. Our products, when and if we have any, are likely to face competition from other generic versions of such drugs. Regulatory approval for generic drugs may be obtained without investing in costly and time-consuming clinical trials. Because of substantially reduced development costs, manufacturers of generic drugs are often able to charge much lower prices for their products than the original developer of a product. If we face competition from manufacturers of generic drugs on products we may commercialize, the prices at which such products are sold and the revenues we receive may be reduced. Although the process of manufacturing the fentanyl drug powder used in our TAIFUN® inhalation device is patented, the composition of the powder is not, so our proprietary rights may not be sufficient to prevent others from commercializing an inhaled version of fentanyl for break-through cancer pain. We will, as a general principle, attempt to reduce the risk of generic competition by means of including proprietary drug delivery technology into all of our products and product candidates. However, our competitors may be able to use their own proprietary technologies to achieve similar results as our products and launch similar products which do not infringe our patents.

Even if we receive regulatory approval to market our product candidates, the market may not be receptive to our products.

Even if our product candidates obtain regulatory approval, resulting products may not gain market acceptance among physicians, patients, health care payors or the medical community. We believe that the degree of market acceptance will depend on a number of factors, including timing of market introduction of competitive products; perceived extent of safety and efficacy of our product candidates; prevalence and severity of any side effects; potential advantages or disadvantages over alternative treatments; strength of supply, marketing and distribution support; price of our product candidates, both in absolute terms and relative to alternative treatments; physician and patient willingness to participate in any post-market surveillance program that is a prerequisite to prescribing or receiving the product candidate; and availability of coverage and reimbursement from government and other third-party payors.

In addition, by the time our products, if any, are ready to be commercialized there is risk that, any such product:

- will not be economical to produce or market at prices that will allow us to achieve profitability;
- will not be successfully marketed or achieve market acceptance;
- will not be preferable to existing or newly developed products marketed by third parties;
- will no longer be protected by patent terms; or
- will infringe proprietary rights held by third parties now or in the future that would preclude us from marketing any such product.

The failure to successfully introduce and market our products that are under development would have a material adverse effect on our business, financial condition, and results of operations.

We do not currently have our own marketing, sales and distribution capability needed to commercialize our product candidates and may not be able to develop it in the future.

We do not currently have a sales force or the resources to market, sell and distribute any of our product candidates. We intend, where possible and consistent with our strategy, to partner with local companies to market, sell and distribute our products. If we fail to successfully find marketing partners or fail to develop a sales force, the sales of our products and, therefore, our revenues, results of operations and losses could be materially adversely affected.

If our competitors develop and market products that are more effective, safer or less expensive than our product candidates, our clinical trials and commercial opportunities will be negatively impacted.

The life sciences industry is highly competitive, and we face significant competition from many pharmaceutical, biopharmaceutical and biotechnology companies that are researching and marketing products designed to address the indications for which we are currently developing products or for which we may develop products in the future. We are aware of several other companies, including BioDelivery Sciences International, Nektar, Aradigm and Alexza, that are developing multiple dose inhalers, and others, such as Cephalon Inc. and YM Biosciences Inc. that have developed, or are developing, products for break-through cancer pain. Any products we may develop in the future are also likely to face competition from other drugs and therapies. Many of our competitors have significantly greater financial, manufacturing, marketing and drug development resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing and in obtaining regulatory approvals for drugs. These companies also have significantly greater research and marketing capabilities than we do. In addition, many universities and private and public research institutes are, or may become, active in inhalation therapy and pain research, the products of which may be in direct competition with us. If our competitors market products that are more effective, safer or less expensive than our product candidates, if any, or that reach the market sooner than our product candidates, if any, or achieve better market acceptance, we may not achieve commercial success.

Risks Associated with the Administration of Our Business

We may not be able to attract and retain key personnel to achieve our scientific and business objectives.

Intellectual input from key management and our other scientists is critical to achieve our scientific and business objectives. Consequently, our ability to retain these individuals and attract other qualified individuals is critical to our success. The loss of the services of key individuals might significantly delay or prevent achievement of our scientific or business objectives. In addition, because of a relative scarcity of individuals with the high degree of education and scientific achievement required for our business, competition among life sciences companies for qualified employees is intense. As a result, even though we have not to date experienced problems attracting or retaining key management or scientists, in the future we may not be able to attract and retain such individuals on acceptable terms, or at all. Our employment arrangements with our key executives are terminable at will by us or the executive.

We also have relationships with scientific collaborators at academic and other institutions, some of whom conduct research at our request or assist us in formulating our research and development strategies. These scientific collaborators are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, these collaborators may have arrangements with other companies to assist such other companies in developing technologies that may prove competitive to us.

We expect that our potential expansion into areas and activities requiring additional expertise, such as further clinical trials, governmental approvals, sales and marketing, will place additional requirements on our management, operational and financial resources. We expect these demands will require an increase in the number of management and scientific personnel and the development of additional expertise by existing management personnel. The failure to attract and retain such personnel, or to develop such expertise, could materially adversely affect prospects for our success.

Our current personnel may be inadequate and we may fail to assimilate and train new employees. Highly skilled employees with the education and training that we require, especially employees with significant experience and

expertise in drug delivery systems, are in high demand. Once trained, our employees may be hired by our competitors.

We may encounter difficulties in managing our expected growth and in expanding our operations successfully.

As we advance our product candidates through development and clinical trials, we will need to develop or expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for us. Maintaining additional relationships and managing our future growth will impose significant added responsibilities on our management. We must be able to manage our development efforts effectively; manage our clinical trials effectively; hire, train and integrate additional management, development, manufacturing, administrative and sales and marketing personnel; improve our managerial, development, operational and finance systems; and expand our facilities. Each of these responsibilities may impose a strain on our administrative and operational infrastructure. When we manufacture our own clinical supplies and/or product candidates, we expose ourselves to numerous operational and regulatory risks, which may delay our commencement of clinical trials or the commercialization of our products.

We may acquire additional businesses, products or product candidates that complement or augment our existing business. Integrating any newly acquired business, product or product candidate could be expensive and time-consuming. We may not be able to integrate any acquired business, product or product candidate successfully or operate any acquired business profitably. Our future financial performance will depend, in part, on our ability to manage any future growth effectively and our ability to integrate any acquired businesses. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing our company.

Our reliance on third parties to develop and distribute our products exposes us to a number of risks.

We may rely on collaboration, distribution or other partnering agreements because we do not have our own capabilities. We intend to secure agreements relating to the marketing and distribution of our products for which we may receive regulatory approval. If we are unable to reach agreements with suitable partners, we may fail to meet our business objectives for the affected product or program. We face, and will continue to face, significant competition in seeking appropriate partners. Moreover, collaboration, distribution and other partnering arrangements are complex and time-consuming to negotiate, document and implement. We may not be successful in our efforts to establish and implement such partnering arrangements upon satisfactory terms or at all.

We may rely on third parties to manufacture and supply our product candidates.

If, in the future, one of our product candidates is approved for commercial sale, we will need to manufacture that product candidate in commercial quantities and we do not expect to have the capability to do so on our own in the near term. We cannot assure you that the third-party manufacturers with which we contract will have sufficient capacity to satisfy our future manufacturing needs, or that we will be able to negotiate additional purchases of active pharmaceutical ingredient or drug product from manufacturers on terms favorable to us, or at all. Our contract manufacturers will have to employ precise, high-quality manufacturing processes and will be subject to ongoing periodic unannounced inspection by the FDA and non-U.S. regulatory authorities to ensure strict compliance with cGMP and other applicable government regulations and corresponding standards. Significant scale-up of manufacturing may require additional validation studies, which the FDA must review and approve. If we are unable to successfully increase the manufacturing capacity for a product candidate in conformity with cGMPs, the regulatory approval or commercial launch of any related products may be delayed or there may be a shortage in supply.

We may not be able to successfully acquire and integrate complementary technologies or businesses needed for the development of our business and any acquisitions we make could disrupt our business and harm our financial condition.

We may pursue product, technology or business acquisitions that could complement or expand our business. However, we may not be able to identify appropriate acquisition candidates. If an acquisition candidate is identified, we may not be able to successfully negotiate the terms of any such acquisition or finance such acquisition. For example, in January 2007 we completed the acquisition of PharmaForm. We acquired our EDACS™ technology through this acquisition. The integration of PharmaForm and any similar acquisition could result in unanticipated costs or liabilities, diversion of management's attention from our core business, the expenditure of resources and the potential loss of key employees, particularly those of the acquired organizations. In addition, we may not be able to successfully integrate any businesses, products, technologies or personnel that we might acquire, which may harm our business.

Risks Associated with the Multinational Character of Our Business

We generate revenues and expenses in currencies other than the US dollar and face exposure to adverse movements in foreign currency exchange rates.

We intend to generate revenue and expenses internationally which are likely to be denominated in euros and other foreign currencies. Effective as of January 1, 2007, we determined that our functional currency is the U.S. dollar. Previously, our functional currency was the Canadian dollar. Our intended international business will be subject to risks typical of an international business including, but not limited to, differing tax structures, a myriad of regulations and restrictions, and general foreign exchange rate volatility. A decrease in the value of such foreign currencies relative to our functional and reporting currency, the U.S. dollar, could result in losses from currency exchange rate fluctuations. To date, we have not generated sufficient revenues to warrant the necessity of hedging against risks associated with foreign exchange rate exposure. Although we may do so in the future, we cannot be sure that any hedging techniques we may implement will be successful or that our business, results of operations, financial condition and cash flows will not be materially adversely affected by exchange rate fluctuations.

We may not achieve our projected development goals in the time frames we announce and expect.

We have and will set goals for and make public statements regarding our expected timing for meeting the objectives material to our success, such as the commencement and completion of clinical trials, anticipated regulatory approval and product launch dates. The actual timing of these forward-looking events can vary dramatically due to factors such as delays or failures in our clinical trials, the need to develop additional data required by regulators as a condition of approval, the uncertainties inherent in the regulatory approval process and delays in achieving manufacturing or marketing arrangements necessary to commercialize our product candidates.

Risks Related to Our Intellectual Property

Rapid technological change could make our products or drug delivery technologies obsolete.

Pharmaceutical technologies are subject to rapid and significant technological change. We expect our competitors will develop new technologies and products that may render our products and drug delivery technologies uncompetitive or obsolete. The products and drug delivery technologies of our competitors may be more effective than the products and drug delivery technologies developed by us. As a result, our products may become obsolete before we recover expenses incurred in connection with their development or realize revenues from any product.

Our proprietary rights may not adequately protect our technologies and product candidates.

Our commercial success will depend, in part, on our ability and the abilities of our licensors to obtain patents and/or regulatory exclusivity and maintain adequate protection for our technologies and product candidates in Canada, the United States, the European Union and other countries. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies and product candidates are covered by valid and enforceable patents or are effectively maintained as unpatented proprietary technology. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability.

We and our licensors apply for patents and regulatory exclusivity covering our technologies and product candidates, as we deem appropriate. However, we may fail to apply for patents or regulatory exclusivity on important technologies or product candidates in a timely fashion, or at all. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products and technologies. In addition, we do not control the patent prosecution of subject matter that we license from others. Accordingly, we are sometimes unable to exercise the same degree of control over this intellectual property as we would over our own. Moreover, the patent positions of life sciences companies are highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. As a result, the validity and enforceability of our patents cannot be predicted with certainty.

We also rely on trade secrets to protect some of our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to maintain. While we use reasonable efforts to protect our trade secrets, our or our collaboration partners' employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time-consuming and uncertain. In addition, non-Canadian or U.S. courts are sometimes less willing than Canadian and U.S. courts to protect trade secrets. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secrets against them and our business could be harmed.

Certain existing patents may adversely impact our ability to commercialize our EDACS™ technology.

We are aware of certain issued U.S. patents and related foreign counterparts that contain claims that might be infringed by product candidates which embody our EDACS™ technology. We could modify our EDACS™ technology to circumvent these patents; but, such modifications may be time-consuming and costly or may not be successful. If an EDACS™ product candidate infringes, or is alleged to infringe, a valid claim of a third-party patent, including these patents, we may choose or may be required to obtain a license or licenses under such patents. We cannot guarantee that we would be able to secure such license(s) on favorable terms or at all. Alternatively, we can seek a court judgment that such patent claims are invalid. Claims of issued patents are presumed to be valid, and any finding of invalidity would come, if at all, only following litigation that could prove lengthy and costly and/or unsuccessful. These patents could materially affect our ability to develop product candidates or commercialize any product candidates based on our EDACS™ technology.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents and trademarks on all of our product candidates, products and product names, when and if we have any, in every jurisdiction would be prohibitively expensive. Competitors may use our technologies and our trademarks in jurisdictions where we, our subsidiaries or our licensors have not obtained patent and trademark protection. These products may compete with our products, when and if we have any, and may not be covered by any of our or our licensors' patent claims or other intellectual property rights.

The laws of some countries do not protect intellectual property rights to the same extent as the laws of Canada and the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trademarks and other intellectual property protection, particularly those protections relating to biotechnology and pharmaceuticals, which could make it difficult for us to stop the infringement of our patents. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

We have assigned certain intellectual property to our Barbados subsidiary. There is no assurance these arrangements will be respected by the applicable authorities or that the relevant regulations will not be changed.

We have assigned certain intellectual property to our Barbados subsidiary and organized our foreign operations in part based on assumptions about the application of various tax laws, foreign currency exchange and capital repatriation laws and other relevant laws of a number of jurisdictions. While we believe that such assumptions are

reasonable, there can be no assurance that taxing or other authorities will reach the same conclusion. In addition, if such jurisdictions were to change or modify such laws, we could also suffer adverse tax and financial consequences.

The patent protection for our product candidates or products may expire before we are able to maximize their commercial value which may subject us to increased competition and reduce or eliminate our opportunity to generate revenue.

The patents in our worldwide patent estate corresponding to our product candidates have U.S. expiration dates ranging from 2011 to 2020 and, when these patents expire, we may be subject to increased competition and we may not be able to recover our development costs. In some of the larger economic territories, such as the United States and Europe, patent term extension or restoration may be available to compensate for time taken during aspects of the product candidate's regulatory review. However, we cannot be certain that an extension will be granted or, if granted, what the applicable time period or the scope of patent protection afforded during any extended period will be. In addition, even though some regulatory agencies may provide some other exclusivity for a product candidate under its own laws and regulations, we may not be able to qualify the product candidate or obtain the exclusive time period.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use of, our technology.

We are primarily responsible for the maintenance of our patents and enforcement of our rights with respect thereto, even where such patents are licensed from third parties. If we choose to go to court to stop someone else from using the inventions claimed in our patents or our licensed patents, that individual or company has the right to ask the court to rule that these patents are invalid and should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are invalid or unenforceable and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that its activities do not infringe our rights. In some cases, these lawsuits would involve the government's application of patent-related rules to our situation and, therefore, the lawsuits could include government entities such as the FDA.

If we wish to use the technology or compound claimed in issued and unexpired patents owned by others, we will need to obtain a license from the owner, enter into litigation to challenge the validity or enforceability of the patents or incur the risk of litigation in the event that the owner asserts that we infringed its patents. The failure to obtain a license to technology or the failure to challenge an issued patent that we may require to discover, develop or commercialize our product candidates may have a material adverse impact on us.

If a third party asserts that we infringed its patents or other proprietary rights, we could face a number of risks that could seriously harm our results of operations, financial condition and competitive position, including:

- patent infringement and other intellectual property claims, which would be costly and time-consuming to defend, whether or not the claims have merit, and which could delay the regulatory approval process and divert management's attention from our business;
- substantial damages for past infringement, which we may have to pay if a court determines that our product candidates or technologies infringe a competitor's patent or other proprietary rights;
- a court prohibiting us from selling or licensing our product candidates or methods of use unless the third party licenses its patents or other proprietary rights to us on commercially reasonable terms, which it is not required to do; and
- if a license is available from a third party, we may have to pay substantial royalties or lump-sum payments or grant cross licenses to our patents or other proprietary rights to obtain that license.

The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use, and which patents must be listed with the FDA. We cannot be certain that others have not filed patent applications that cover technology similar to ours, or that we or our licensors were the first to invent the technology covered by our or our licensors' issued patents or pending applications. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our product candidates or methods of use either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

We may be subject to damages resulting from claims that we, or our employees or consultants, have wrongfully used or disclosed intellectual property rights of third parties.

Many of our employees were previously employed, and certain of our consultants are currently employed, at universities or biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we have not received any claim to date, we may be subject to claims that these employees or consultants or employees of our partners or licensors of technology licensed by us have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of these current or former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel.

If we fail to protect our trademark rights, competitors may be able to take advantage of our goodwill, which would weaken our competitive position, reduce our revenues and increase our costs.

We believe that the protection of our trademark rights is an important factor in product recognition. We may expend substantial cost and effort in an attempt to register, maintain and enforce our trademark rights. If we do not adequately protect our rights in our trademarks from infringement, any goodwill that we have developed in those trademarks could be lost or impaired.

Third parties may claim that the sale or promotion of our products, when and if we have any, may infringe on the trademark rights of others. Trademark infringement problems occur frequently in connection with the sale and marketing of pharmaceutical products. If we become involved in any dispute regarding our trademark rights, regardless of whether we prevail, we could be required to engage in costly, distracting and time-consuming litigation that could harm our business. If the trademarks we use are found to infringe upon the trademark of another company, we could be liable for damages and be forced to stop using those trademarks, and as result, we could lose all the goodwill that has been developed in those trademarks.

Risks Related to Our Industry

Legislative actions, potential new accounting pronouncements, and higher insurance costs are likely to impact our future financial position or results of operations.

Future changes in financial accounting standards may cause adverse, unexpected revenue fluctuations and affect our financial position or results of operations. New pronouncements and varying interpretations of pronouncements have occurred with greater frequency and are expected to occur in the future, and we may make or be required to make changes in our accounting policies in the future. Compliance with changing regulations of corporate governance and public disclosure may result in additional expenses. Changing laws, regulations, and standards relating to corporate governance and public disclosure are creating uncertainty for companies such as us, and insurance costs are increasing as a result of this uncertainty.

If product liability lawsuits are successfully brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability lawsuits related to the products manufactured for third parties by PharmaForm and the testing of our product candidates. We will face an even greater risk if our product candidates are introduced commercially. An individual may bring a liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury. Because we conduct clinical trials in humans, we face the risk that the use of our product candidates will result in adverse side effects. We cannot predict the possible harms or side effects that may result from our clinical trials. Although we have liability insurance in customary amounts with respect to each of our clinical trials, our insurance may be insufficient to cover any such events. We do not know whether we will be able to continue to obtain clinical trial coverage on acceptable terms, or at all. We may not have sufficient resources to pay for any liabilities resulting from a claim excluded from, or beyond the limit of, our insurance coverage.

If we cannot successfully defend ourselves against a product liability claim, we may incur substantial liabilities. Such liabilities, including expenses of litigation or settlements, or both, and the amount of any award imposed on us in excess of existing insurance coverage, if any, may have a material adverse impact on us and on the price of our common shares and could have a material adverse effect on our financial condition, business and results of operations. We have not currently obtained product liability insurance. Because of increasing cost and difficult underwriting standards, such insurance may not be available at all, may not be available on commercial terms or, if obtained, may be insufficient to satisfy asserted claims.

Litigation may result in financial losses or harm our reputation and may divert management resources.

Public companies, like ours, may be the subject of certain claims, including those asserting violations of securities laws and derivative actions. We cannot predict with certainty the eventual outcome of any future litigation or third-party inquiry. We may not be successful in defending ourselves or asserting our rights in new lawsuits, investigations or claims that may be brought against us, and, as a result, our business could be materially harmed. These lawsuits, investigations or claims may result in large judgments or settlements against us, any of which could have a negative effect on our financial performance and business. Additionally, lawsuits and investigations can be expensive to defend, whether or not the lawsuit or investigation has merit, and the defense of these actions may divert the attention of our management and other resources that would otherwise be engaged in running our business.

We are subject to the risks associated with the use of hazardous materials in our research and development.

Our research and development activities at our Austin, Texas facility involve the use of hazardous materials and chemicals. We are subject to U.S. federal, state and local laws and regulations and non-U.S. laws and regulations governing the use, manufacture, storage, handling and disposal of such materials and certain waste products. Although we believe that our safety procedures for handling and disposing of such materials will comply with the standards prescribed by U.S. federal, state and local regulations and non-U.S. regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. In the event of such an accident, we could be held liable for any damages that result and any such liability could exceed our resources and available insurance coverage. Currently, PharmaForm maintains general liability coverage in the amount of \$1,000,000 per occurrence. If we are required to institute additional safety procedures because we are found not to be in compliance or if more stringent or additional regulations are adopted, we may be required to incur significant costs to comply with environmental laws and regulations, which might have a material adverse effect on our business, financial condition and results of operations.

REGISTRAR AND TRANSFER AGENT

The registrar and transfer agent for the Common Shares of the Company is Equity Transfer and Trust Company, Suite 420, 120 Adelaide Street, Toronto, Ontario M5H 4C3.

EXPERTS

Deloitte & Touche are the auditors of the Company and signed the auditors' report for the audited financial statements of the Company for the year ended December 31, 2008. Our auditors, Deloitte & Touche, are independent in accordance with the Code of Ethics of l'Ordre des comptables agrees du Quebec.

ADDITIONAL INFORMATION

Additional information relating to the Company may be found on SEDAR at www.sedar.com.

Additional information, including director's and officer's remuneration and indebtedness, principal holders of the Company's securities and options to purchase securities, is contained in the Company's Management Information Circular dated May 29, 2008.

Additional financial information is provided in the Company's audited financial statements and the MD&A for the year ended December 31, 2008.

AUDIT COMMITTEE INFORMATION

Audit Committee Charter

Responsibilities and Duties

The Audit Committee (the "Committee") of the board of directors (the "Board") of AKELA Pharma Inc. (the "Corporation") is responsible for performing the duties set out in this Charter to enable the Board to fulfil its oversight responsibilities in relation to:

- the integrity of the Corporation's financial reporting;
- the Corporation's internal and disclosure controls; and
- the qualifications, independence and performance of the Corporation's independent auditor.

The Committee shall perform such other duties as may be delegated to the Committee by the Board from time to time. The Committee shall only have decision-making authority when expressly granted to the Committee by the Board. The Committee shall otherwise make recommendations to the Board in accordance with this Charter and at the Board's request.

Members

The Committee shall consist of at least three directors as determined by the Board. Each member of the Committee shall be:

- a director who is not an officer or employee of the Corporation or an affiliate of the Corporation; and
- an independent director as defined in Multilateral Instrument 52-110 – Audit Committees, NASDAQ Rule 4200(a)(15) and Rule 10A-3 under the United States Securities Exchange Act of 1934, as amended.

Each member of the Committee shall be financially literate and at least one member of the Committee shall be considered a financial expert.

Members of the Committee shall not serve on more than three public company audit committees without the approval of the Board.

The Board shall appoint the members of the Committee and the Chair of the Committee annually at the first meeting of the Board after the meeting of the shareholders at which directors are elected each year. Each successor to the Chair of the Committee shall be designated by the Board. Any member of the Committee may be removed or replaced at any time by the Board.

Meetings

The Committee shall meet at least once each quarter. Meetings are called by the Chair of the Committee. He must call a meeting when requested to do so by a member of the Committee, the independent auditor, the Chairman of the Board, the Chief Executive Officer or the Chief Financial Officer. Notice of the time and place of each meeting of the Committee must be given to each member of the Committee and the independent auditor, not less than 48 hours before the time of the meeting. A quorum of the Committee shall be a majority of its members. The powers of the Committee may be exercised at a meeting at which a quorum of the Committee is present in person or by telephone or other electronic means. Each member is entitled to one vote in Committee proceedings.

The Chair shall preside at all meetings of the Committee at which he or she is present and shall, with input from the Chief Financial Officer and independent auditor, develop the agenda for each committee meeting. The agenda for each meeting of the Committee shall be delivered to each member of the Committee at least 48 hours prior to any meeting of the Committee, together with such other materials as the Chair determines necessary.

The Chair shall designate from time to time a person who may, but need not be, a member of the Committee, to be Secretary of Committee. Minutes shall be kept of all meetings of the Committee and shall be maintained by the Secretary of the Committee.

The procedures to be followed at meetings shall be determined by the Committee unless otherwise determined by the by-laws of the Corporation, by a resolution of the Board or by this Charter.

The Committee shall meet at least quarterly in separate private sessions with management. After such sessions, the Committee shall also meet with only members of the Committee present.

The Committee may invite any director, officer or employee of the Corporation or the Corporation's counsel or independent auditor or any other person to attend meetings of the Committee to assist in the discussion and examination of the matters under consideration by the Committee. The independent auditor shall, at the expense of the Corporation, be entitled to attend and be heard at any meeting of the Committee.

Reports

The Committee shall report the proceedings of each meeting and all recommendations made by the Committee at such meeting to the Board at the Board's next meeting.

The Committee shall also review and approve the report of the Committee to be included in the Corporation's annual information form and such other reports relating to the activities of the Committee as may be required by the Corporation or the Board from time to time.

Financial Reporting

Generally, the Committee is responsible for:

- (overseeing the accounting and financial reporting processes of the Corporation and the audits of the financial statements of the Corporation;

- reviewing the Corporation's financial statements, MD&A and annual and interim earnings press releases before the Corporation publicly discloses this information; and
- satisfying itself that adequate procedures are in place for the review of the Corporation's public disclosure of financial information extracted or derived from the Corporation's financial statements, other than the public disclosure referred to in (b), and periodically assessing the adequacy of those procedures.

The Committee shall review at least once a year with management and the independent auditor:

- the appropriateness of the Corporation's accounting and financial reporting;
- any changes to the Corporation's accounting and financial reporting as such changes are recommended by management or the independent auditor;
- the accounting treatment of significant risks and uncertainties;
- key estimates and judgements of management that may be material to the Corporation's financial reporting; and
- significant auditing and financial reporting issues discussed during the fiscal period and the method of resolution.

The Committee shall:

- review the annual audited financial statements and discuss with management and the independent auditor related significant issues regarding accounting principles, practices, and judgments to satisfy itself that these annual audited financial statements are presented in accordance with applicable generally accepted accounting principles, report thereon to the Board and recommend to the Board whether or not same should be approved, prior to their being filed with the appropriate regulatory authorities;
- satisfy itself that the information contained in the annual audited financial statements is not significantly erroneous, misleading or incomplete and that the audit function has been effectively carried out;
- review the quarterly unaudited financial statements; and
- review management's discussion and analysis relating to the annual audited financial statements and the quarterly unaudited financial statements, and any other public disclosure documents, including interim earnings press releases, that are required to be reviewed by the Committee under any applicable laws, prior to their being publicly disclosed.

The Committee's review of any financial statement or other public disclosure document shall include a review with management of the presentation and impact of significant risks and uncertainties and as well as key estimates and judgements of management that may be material to the statements of disclosure. Before recommending any financial statements to the Board for approval, the Committee shall seek confirmation from management that such financial statements, together with the other financial information included in the Corporation's annual and interim filings, fairly present in all material respects the financial condition, results of operations and cash flows of the Corporation as of the relevant date and for the relevant periods.

The Committee shall review disclosures made to the Committee by the Chief Executive Officer and Chief Financial Officer during their certification process for applicable securities regulatory filings about any significant deficiencies and material weaknesses in the design or operation of the Corporation's internal control over financial reporting which are reasonably likely to adversely affect the Corporation's ability to record, process, summarize and report financial information, and any fraud involving management or other employees who have a significant role in the Corporation's internal controls. In addition, the Committee shall review management's recommendations for rectifying such deficiencies and weaknesses and review, as appropriate, the implementation of such recommendations.

Internal Controls

The Committee shall:

- require management to design, implement and maintain appropriate internal control procedures;
- review, evaluate and approve the Corporation's internal control policies and procedures including any reports of the independent auditor thereon;
- meet with management to discuss the effectiveness of the Corporation's internal control procedures; and
- conduct an appropriate review of all related party transactions for potential conflict of interest situations on an ongoing basis and approve (or recommend to the Board for approval) all such transactions.

The Committee shall also establish procedures for:

- the receipt, retention and treatment of complaints received by the Corporation regarding accounting, internal accounting controls, or auditing matters; and
- the confidential, anonymous submission by employees of the Corporation of concerns regarding questionable accounting or auditing matters.

Responsibilities to External Auditor

The independent auditor shall report directly to the Committee and the Board, as representatives of the shareholders. The Committee shall have the authority to communicate directly with the independent auditor (and the internal auditor, if any). The Committee shall evaluate and be responsible for the Corporation's relationship with the independent auditor, including direct responsibility for overseeing:

- the work of the independent auditor engaged for the purpose of preparing or issuing an auditor's report or performing other audit, review or attest services for the Corporation;
- the resolution of disagreements between management and the independent auditor regarding financial reporting; and
- the independence of the independent auditor.

Specifically, the Committee shall:

- make recommendations to the Board regarding the independent auditor to be nominated for the purpose of preparing or issuing an auditor's report or performing other audit, review or attest services for the Corporation;
- review the terms of the independent auditor's engagement, the annual audit plan and the appropriateness and reasonableness of the proposed compensation of the independent auditor (including audit fees) and make recommendations to the Board thereon;
- require the independent auditor to confirm in its engagement letter each year that it reports to the Board and the Committee, as representatives of the shareholders;
- require the independent auditor to provide a formal written statement delineating all relationships between the independent auditor and the Corporation and actively engage in a dialogue with the independent auditor with respect to any disclosure of relationships or services that may impact on the objectivity or independence of the independent auditor;
- satisfy itself that the audit plan is risk based and covers all relevant activities over a measurable cycle;
- review the scope and results of the audit conducted by the independent auditor with the independent auditor and management, including:
 - (i) the independent auditor's evaluation of the Corporation's internal accounting controls that the independent auditor tested and relied on and any recommendations related thereto;
 - (ii) the degree of cooperation the independent auditor received from management and any problems experienced by the independent auditor in conducting the audit, including any restrictions imposed by management or significant accounting issues on which there was a disagreement with management;
 - (iii) the existence of problems or potential problems related to accounting and/or auditing matters and any accounting errors;
 - (iv) the independent auditor's management letter, management's response and subsequent follow-up of any identified weaknesses;
 - (v) the appropriateness and quality of all critical accounting policies and practices used by the Corporation and the selection of new policies and practices; and
 - (vi) any alternative treatments of financial information that have been discussed with management, the ramifications of their use and the independent auditor's preferred treatment, as well as any other material communications with management;

and the Committee shall advise the Board of the Corporation's performance in these areas;

- meet, should the need arise, but at least once a year with the independent auditor without management present and ask the independent auditor to report on any significant disagreements, unresolved issues and consultations with management as well as any other matters the independent auditor believes the Committee should be aware of to exercise its responsibilities;
- oversee the resolution of any disagreements between the independent auditor and management related to audit findings;

- review all material correspondence between the independent auditor and management related to audit findings; and
- evaluate the independent auditor's audit performance, taking into account management's evaluation of such performance.

The Committee shall pre-approve all audit services and permitted non-audit services (including the fees and terms thereof) to be provided to the Corporation or its subsidiaries by the independent auditor. The Committee may delegate to one or more independent Committee members the authority to pre-approve audit and permitted non-audit services to be provided to the Corporation by the independent auditor, provided that any such pre-approvals shall be presented to the full Committee at its first scheduled meeting following such pre-approval.

The Committee shall review and approve the Corporation's hiring policies regarding partners, employees and former partners and employees of the present and former independent auditors of the Corporation.

Risk Management

The Committee shall review and consider the Corporation's policies and procedures with respect to risk assessment and risk management and make recommendations thereon to the Board.

Access to Management and Outside Advisors

The Committee shall have full, free and unrestricted access to management and employees and to the independent auditor. The Committee shall have the authority to delegate to individual members or subcommittees of the Committee. The Committee has the authority to retain and compensate legal counsel, consultants and other outside advisors, with respect to any issue or to assist it in fulfilling its responsibilities without consulting or obtaining the approval of any officer of the Corporation and the Corporation shall provide appropriate funding, as determined by the Committee, for the independent auditor and for any such other advisors.

Annual Review and Assessment

The Committee shall conduct an annual review and assessment of its performance, including a review of its compliance with this Charter, in accordance with the process developed by the Corporate Governance Committee and approved by the Board. The Committee shall conduct such review and assessment in such manner as it deems appropriate and report the results to the Corporate Governance Committee.

The Committee shall also review and assess the adequacy of this Charter on an annual basis taking into account all legislative and regulatory requirements applicable to the Committee as well as any best practice guidelines recommended by stock exchanges on which the Corporation is listed and, if appropriate, shall recommend changes to the Charter to the Corporate Governance Committee.

Composition and Relevant Education and Experience of the Audit Committee

Yves Glaude, Director. Mr. Glaude received the designation of Chartered Accountant from the University of Montreal in 1982. Over the last 12 years, Mr. Glaude has served in various senior management positions in the pharmaceutical development, contract research and high-technology industries. Mr. Glaude is currently an independent financial consultant and prior to 2008, Mr. Glaude was the Chief Financial Officer of SolVision, Inc., a designer and manufacturer of high-performance automated visual inspection equipment for the microelectronics industry. Mr. Glaude served as Vice President Finance for MDS Pharma Services in Montreal from 2001 to 2005.

John Dempsey. Mr. Dempsey is the Managing Director of COFICO Inc., a financial consulting firm since 2008 and was previously the Vice President, Finance and CFO of Atrium Innovations Inc. He has also held senior financial positions worked for corporations such as BCE Inc., Bell Canada, Quebecor World Inc. and UAP Inc. Mr. Dempsey holds a Bachelor's degree in electrical engineering and an MBA degree from McGill University, Montreal, Quebec. He is also a member of the Quebec Certified General Accountants professional corporation and of the Québec Order of Engineers.

Rolf Reininghaus. Mr. Reininghaus is independent and financially literate. He has played a key role in various successful start ups including as a founding member of Biovail Corporation where he served as a Senior Vice President and a Director.

External Audit Service Fees

The following amounts were paid or payable to the Company's auditors for professional services rendered during the last two fiscal years:

	2008	2007
Audit fees	\$205,761	\$240,000
Audit-related fees ⁽¹⁾	\$0	\$1,116,000
Tax fees ⁽²⁾	\$9,974	\$8,000
	\$215,735	\$1,364,000

(1) These fees relate primarily to our failed attempt to list our shares in the U.S.

(2) These fees were incurred primarily for statutory tax compliance and tax planning services.

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