AKELA PHARMA INC.

ANNUAL INFORMATION FORM

YEAR ENDED DECEMBER 31, 2010

March 31, 2011

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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 P.O. Box 10424, Pacific Centre, Suite 1300, 777 Dunsmuir Street, Vancouver, B.C. V7Y and our principal place of business is located at Suite 130, 11501 Domain Drive, Austin, Texas 78758 USA.

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

(a) Formulation Technologies, LLC, a wholly-owned subsidiary of the Company incorporated as a limited liability company under the laws of the United States.

(b) Akela Pharma LLC, a wholly-owned subsidiary of the Company incorporated under the laws of the United States;

(c) Akela Pharma Oy, a wholly-owned subsidiary of the Company incorporated under the laws of Finland;

(d) Akela Pharma SRL, a wholly-owned subsidiary, owned 99% by the Company and 1% by Akela Pharma LLC, incorporated under the laws of Barbados;

(e) Akela Pharma USA, a wholly-owned subsidiary of the Company incorporated under the laws of the United States...

(f) Akela Clinical Research Services, Pvt, Ltd., a wholly-owned subsidiary of the Company incorporated under the laws of India;

(g) Akela Clinical Polska Sp. z o.o., a wholly-owned subsidiary of the Company incorporated under the laws of Poland;

(h) Blitz 07-676 GmbH, a wholly-owned subsidiary of the Company incorporated under the laws of Germany;

(i) 9172-2512 Quebec Inc., a wholly-owned subsidiary of the Company incorporated under the laws of Canada;

(j) 4349695 Canada, Inc., a wholly-owned subsidiary of the Company incorporated under the laws of Canada;

(k) Akela Subco Inc., a wholly-owned subsidiary of the Company incorporated under the laws of Canada;

(l) Nventa Biopharmaceuticals Corp. a wholly-owned subsidiary of the Company incorporated under the laws of Canada;

(m) Nventa Inc. a wholly-owned subsidiary of the Company incorporated under the laws of the United States;

(n) Stressgen Development Corp. a wholly-owned subsidiary of the Company incorporated under the laws of Barbados.

(o) Stressgen Holding Corp. a wholly-owned subsidiary of the Company incorporated under the laws of Canada;

(p) Stressgen Bioreagents Limited Partnership a wholly-owned subsidiary of the Company incorporated under the laws of the United States.

(q) Stressgen Gene Therapies Inc. a wholly-owned subsidiary of the Company incorporated under the laws of the United States,

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 57 people at its location in Austin, Texas.

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 “may”, “would”, “could”, “will”, “likely”, “intend”, “forecast”, “project”, “plans”, “trends”, “anticipates”, “should”, “estimates”, “expects”, “believes”, “indicates”, ‘targeting”, “suggests” 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. All forward looking statements and information made herein are based on our current expectations as of the date hereof and we disclaim any intention or obligation to revise or update such forward-looking statements and information to reflect subsequent 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

We started as LAB Gesellschaft für pharmakologische Untersuchungen GmbH, a contract research organization (“CRO”) established in 1979.

In 2002 we went public on the TSX by way of a reverse take-over transaction and changed our name 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 four years, we completed a number of private placements and acquisitions to grow our pipeline and CRO activities, until we ultimately evolved into a fully integrated drug development company with two separate, distinct business operations: a pharmaceutical development division ("Pharma") and a pre-clinical contract research organization ("LRI"). In 2006 LRI was spun off through an initial public offering, and we sold our entire CRO business for gross proceeds of $50,154. We retained our pharmaceutical development operations, and in June 2007 our name was changed to Akela Pharma Inc.

In January 2007, we completed the acquisition of all of the outstanding membership interests of Formulation Technologies, L.L.C. (doing business as "PharmaForm") a privately held company headquartered in Austin, Texas. The acquisition of PharmaForm added FDA and DEA approved specialized drug formulation and manufacturing capabilities. The results of PharmaForm are consolidated from the date of acquisition.

Business Acquisition

On May 21, 2009, we acquired all of the issued and outstanding securities of Nventa Biopharmaceuticals Corporation ("Nventa") by way of plan of arrangement (the "Arrangement") under the Business Corporations Act (British Columbia). The results of Nventa are consolidated from the date of acquisition.

Nventa, formerly listed on the TSX, was a biopharmaceutical company with a history of developing (i) innovative therapeutics incorporating its proprietary CoVal™ fusion technology for the treatment of viral infections and cancers, with a focus on diseases caused by the human papillomavirus (HPV) and (ii) a Toll-like Receptor 3 (TLR3) agonist for use as a vaccine adjuvant (a substance used to improve immune responses against target antigens) and as an immunotherapeutic for viral infections and cancer.

In accordance with the terms and conditions of the Arrangement, the Company issued 0.0355 Akela common shares (the "Ratio") in exchange for every one common share of Nventa. In addition, Akela common shares are issuable pursuant to share purchase warrants and stock options of Nventa, with the number of shares and exercise prices adjusted based on the Ratio. The aggregate purchase price amounted to $1,558 including $212 in transaction costs, 9,274,761 Akela common shares and the right to receive 533,565 Akela common shares on the exercise of Nventa stock options and 3,430,904 Akela common shares upon exercise of Nventa warrants valued at approximately, $1,198, $7 and $141, respectively.

Corporate Reorganization

Prior to 2007 Akela was a fully integrated drug development company with two separate, distinct business operations: a pharmaceutical development division ("Pharma") and a pre-clinical contract research organization ("LRI"). Akela's Pharma business focuses on pharmaceutical development for other companies as a contract service provider through PharmaForm and the development of its own product portfolio, principally Fentanyl TAIFUN®. Pharma's drug development activities were supported by the scientific expertise, infrastructure and cash flows derived from Akela's second business unit, LAB Research Inc. (''LRI''), a pre-clinical contract research services organization with operations in North America and Europe. During this time, the Company conducted business in Denmark, Canada, Germany, US and throughout Europe and Asia and derived a significant proportion of its revenues from Europe, Asia, Canada and the United States.

In 2006 LAB Research Inc. was spun off through an initial public offering. Akela sold its entire interest in LRI for gross proceeds of $50,154, and today, LAB Research is traded as an independent company on the Toronto Stock Exchange under the symbol LRI.

Following the dilution and disposition LRI, Akela now focuses strictly on Pharmaceutical Development as a developer of our own proprietary products, with Fentanyl TAIFUN® as our lead candidate, formulation development and manufacturing as a contract service provider through PharmaForm and as well as managing a portfolio of intellectual property which was expanded with the acquisition of Nventa Biopharmaceuticals Inc. in May 2009.

In 2009 we announced and undertook two corporate reorganizations. On February 9, 2009 we announced the implementation of measures to cut costs and preserve cash. The reduction in costs targeted the Pharmaceutical Development programs as well as, PharmaForm. The measures were taken to allow sufficient time for the completion of ongoing financing and M&A efforts. On September 3, 2009, we announced a comprehensive corporate restructuring designed to achieve several operational objectives. As part of its efforts to preserve its ability to execute on its development strategy for Fentanyl TAIFUN® and to optimize the infrastructure required to support its PharmaForm clients, the Company reduced its head count by 32 employees to a workforce of 65. Further, Akela announced the closure of its international operations and the centralization of the Company's operational headquarters in Austin, Texas. The restructuring also included the departure of Andrew Reiter as chief financial officer and Taneli Jouhikainen as acting chief executive officer.

On September 2, 2009, Akela announced a change in leadership with the appointment of Greg McKee to the position of President and Chief Executive Officer and Robert Rieder to the position of Chairman of the Board of Directors.

During the first quarter of 2010, we began negotiating the sale of our contract service operations, PharmaForm. After due consideration by the Company, the sale of PharmaForm did not occur in 2010. PharmaForm has benefited in 2010 performance from the corporate reorganizations of 2009 and is an integral portion of Akela's operations and revenues.

Recent Events

During the first quarter of 2010, The Canada Revenue Agency completed its audit of the Company's 2005 and 2006 tax returns. The net result of the audit and agreed settlement includes a $707 write back for losses previously recorded as a provisional liability in conjunction to the audit. The settlement causes a decrease in the Company's loss carry forward for tax purposes, but does not require a cash payment to the Canada Revenue Agency.

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 a drug development company with two principle areas of focus:

- The development of our own proprietary product for the treatment of breakthrough cancer pain, Fentanyl TAIFUN®.

- Contract pharmaceutical formulation development and manufacturing services through our wholly owned subsidiary, PharmaForm.

Fentanyl TAIFUN®, our lead product development candidate, has been demonstrated in phase 2 clinical trials to alleviate breakthrough pain significantly more rapidly than placebo in cancer patients. Based on these phase 2 trials and accompanying pharmacokinetic studies, we believe that Fentanyl TAIFUN® will act more rapidly than other non-injectable products, while also requiring a lower dose of fentanyl to be administered to patients.

In addition to Fentanyl TAIFUN® during 2010 we had ongoing research programs in the following areas:

- HspE7 for cervical dysplasia. HspE7 is an immunotherapy comprising components of the human papilloma virus intended to treat the underlying HPV infection.

- AKL 0721for chronic pain. AKL 0721 is an extended release formulation of a narcotic which has been designed to be resistant to overt physical abuse and alcohol dose dumping.

- Poly ICR, a Toll-like Receptor 3 (TLR-3) agonist for use as an adjuvant in the prevention and treatment of infectious diseases or cancer.

Through, PharmaForm we operate a 50,000 sq. ft. facility located in Austin, Texas providing drug formulation solutions and product manufacturing to pharmaceutical and biotechnology companies. The specific types of service offered by PharmaForm include:

- Formulation and process development
- Analytical development
- GMP manufacturing and packaging
- QC testing and ICH stability storage
- Patent litigation support
- Consulting (IP validation and contestation)

PharmaForm markets its portfolio of technologies and expertise to enhance the bioavailability and development of poorly soluble compounds for new chemical entities (NCE), as well as Life Cycle Management (LCM) opportunities for currently marketed products. These technologies include hot melt extrusion, liquid filled hard gel and capsules, spray drying, fluid bed processing and various controlled release technologies.

During 2010 we expanded our client base with the addition of several large to mid-sized pharmaceutical and biotechnology companies.

The Company has incurred significant net losses and negative cash flows from operations in prior years. The Company has funded such losses with external debt, share issuances, exclusive licensing and development agreements, government grants and working capital. As of December 31, 2010, the Company has a cash balance of $474, net current liabilities of $8,173, a shareholders' deficit of $24,369 and no operating line of credit.

An acute shortage of investor capital available for pharmaceutical development has adversely impacted the ability of the Company to obtain financing as well as the financial stability of its customer base, the credit quality of its receivables and the certainty of its revenue projections. Moreover, Akela will continue to encounter difficulty in raising additional financing from either new or existing investors until the Company significantly reduces its outstanding debt. The Company could and may also receive claims from creditors, as a number of Akela's liability obligations are in default as at the audit report date (see notes 15, 18). As such, the realization of assets and discharge of liabilities in the ordinary course of business are subject to significant uncertainty.

Akela's ability to continue as a going concern is dependent upon, amongst other things, the successful development and marketing of its technologies, securing financing for its drug development program, the continued support and cooperation of shareholders, lenders, suppliers and the achievement of profitable operations. These endeavors are dependent on a number of circumstances outside the Company's control, especially as it relates to financing for small biotech and specialty pharmaceutical companies. Management's actions and plans with respect to addressing the going concern uncertainty include the following:

a) In 2009 the Company announced and undertook two corporate reorganizations to conserve cash. On February 9, 2009 the Company announced the implementation of measures to cut costs and preserve cash. The reduction in costs targeted the Pharmaceutical Development programs as well as, PharmaForm. On September 3, 2009, the Company announced a comprehensive corporate restructuring designed to achieve several operational objectives. As part of its efforts to preserve its ability to execute on its development strategy for Fentanyl TAIFUN® and to optimize the infrastructure required to support its PharmaForm clients, the Company reduced its head count by 32 employees to a workforce of 65. Further, the Company also announced the closure of the Company's

international operations and the centralization of the Company's operational headquarters in Austin, Texas.

b) As part of the Company's cost reduction effort, the Fentanyl TAIFUN® program operates with a focused scope limiting the size and the number of clinical trial sites. The Company's strategy therefore is to sustain the continuance of the Fentanyl TAIFUN® program and seek funding for the Company's proprietary compounds from the Company's current and new commercial partners. Until the Company succeeds in raising additional capital through partner funding, equity or debt financing the Company is not recruiting any further patients into clinical studies.

c) The Company is no longer funding the scientific development of GHRH, HspE7, AKL 0721 or Poly ICR. While the Company is actively seeking licensing arrangements as well as other external development strategies, the Company may not be able to obtain sufficient capital to continue to fund the maintenance and prosecution costs of the patents and intellectual property associated with these technologies. Because of the Company's significant liquidity issues, the Company may be forced to terminate these programs as the Company looks to strategically focus the Company's current remaining capital resources on Fentanyl TAIFUN®.

d) On April 16, 2010, the Company announced that the Company had reached agreement with HEP Davis Spring, L.P. to terminate its leased facility located at 9825 Spectrum Drive, Austin, Texas eliminating $14,481 in future lease payments to the Company. As part of the agreement, which took effect April 2, 2010, Akela released $938 of funds from associated cash secured letter-of-credit, undertook to issue 1,250,000 common shares and assumed an obligation to pay the landlord in monthly installments of $10 through March 2020.

e) On June 17, 2009, the Company announced that the Company had signed an amendment to the Company's Fentanyl TAIFUN® license and co-development agreement with Teikoku Seiyaku Co. Ltd. ("Teikoku"). According to the amendment to the original agreement announced in January 2006, milestone payments of up to $2.0 million would be advanced to be payable earlier than originally intended. The Company received $0.2 million upon signing of the amendment, and would receive $1.8 million subject to meeting a near term development milestone related to the pharmaceutical development of the Product. On February 11, 2010, Akela achieved a near term development milestone in the pharmaceutical development of the Fentanyl TAIFUN® inhaler (the "Product"). The remaining $1.8 million was received by Akela on August 6, 2010. All milestone funding is contractually committed to the ongoing development of Fentanyl TAIFUN®.

f) On October 29, 2010, the Company was awarded through the United States Qualifying Therapeutic Discovery Grant Program federal grants of $0.7 million to facilitate continued development of research programs.

g) During 2010 as a result of the measures to cut costs, reduce liabilities and increase cash which was begun in 2009, the Company has minimized costs related to the development strategy for Fentanyl TAIFUN®. The Company has effectively reduced operating costs and increased margins within the PharmaForm subsidiary.

h) In order to ensure the availability of current capital resources, the Company may attempt to issue new equity securities, issue new debt or pursue various other funding alternatives.

Management believes that the above actions, together with the continued support and cooperation of shareholders, lenders and suppliers, the securing of additional milestone payments and other financing will enable Akela to continue as a going concern. There can, however, be no assurance that the actions taken to date will result in sufficient funds being generated to enable the Company to continue as a going concern for the next twelve months. The financing environment within which the Company operates remains very challenging. Until such time as Akela's research and development efforts are commercialized or fully funded by third parties, for which no assurance can be given, the Company may continue to incur significant operating losses. Should the Company be unsuccessful in raising additional financing, it may have no choice but to seek protection from its creditors

Strategy

Our goal is to be the leader in management of break-through cancer pain. 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 Fentanyl TAIFUN® product in the United States and worldwide.

Product Candidate

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. Toxicology data was not reviewed by the FDA. 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 enrolment of the 7th patient just prior to the end of December 2008.

During 2009 we implemented 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. During 2010 we continued to operate in a fiscally minded and conservative approach to growing our contract pharmaceutical division. We will continue our Phase III clinical program under a more limited and focused scope.

Drug Delivery Technology

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.

Contract Services

Pharmaceutical Formulation Development and GMP Manufacturing

We provide contract pharmaceutical formulation development and manufacturing services under the name PharmaForm. PharmaForm operates a 50,000 sq. ft. facility located in Austin, Texas providing drug formulation solutions and product manufacturing to both small and large pharmaceutical and biotechnology companies. The specific types of service offered by PharmaForm include:

- Formulation development
- Process development/optimization

- GMP manufacturing
- Analytical methods development/validation
- QC testing / stability storage and testing
- Patent litigation support
- Consulting (IP validation and contestation)

PharmaForm strategically markets its portfolio of technologies and expertise to enhance the bioavailability and development of poorly soluble compounds for new chemical entities (NCE), as well as Life Cycle Management (LCM) opportunities for currently marketed products. These technologies include hot melt extrusion, liquid filled hard gel and capsules, spray drying, fluid bed processing and various controlled release technologies.

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.

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.

In December 20, 2007, we entered into a supplemental license agreement with Janssen extending the geographic scope of the original agreement to include Canada for a consideration of $1,100 which has been deferred and is being recognized ratably over the estimated development period.

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 terms of the amended agreement, advanced milestone payments of $3,700 (€ 2,500) were payable on the first local regulatory approval of the Phase III protocol and $2,900 (€ 2,000) on the first clinical site readiness. An additional milestone of $3,600 (€ 2,500) was due as of the inclusion of the 7th patient in the Phase III clinical study. The Company triggered the advance milestones in August, September and December of 2008. The resulting proceeds, $10,200, have been deferred and are being recognized ratably over the estimated development period. 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, 2009, the Company's commitment to fulfill this obligation is considered to have been met.

Other Agreements

Between 2001 and 2006, the Company's Finnish subsidiary 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 the Company in installments, with respect to inhalation and other technology development. Following the Company's decision to down-size its Finnish operations in the summer of 2007, the Company was notified that this agency was reviewing loans and subsidies previously granted totaling €3,150 and €956, respectively. The agency concluded that a portion of the loans would not be collected prematurely but made a demand for repayment of a portion of one loan and the issued grants, together with interest. In April 2009, the Company's appeal against the decision to repay the grants was rejected by the Administrative Court of Turku, which concluded that Tekes had the right, by virtue of its lawful discretion, to order repayment of financing received through the grants. As a result, during 2009 a charge of $1,544 was made for the US dollar equivalent of the grants received $1,269 (€956), together with interest from July 2007 through March 31, 2009. On June 30, 2009 Akela announced that it had reached an agreement with Tekes to settle their demand for immediate repayment of the grants. According to the terms of the agreement, Akela will pay back the grants received plus interest, in equal quarterly installments, during a period of four years, starting in September 2010 with the last payment to occur in September 2014. As a result of this settlement, in 2009 the Company's $1,544 provision associated with Tekes' claim was classified as long-term debt. In 2009, upon the advice of legal counsel, the Company's estimated obligation, $1,786 (€1,248), had been calculated as the principle amount of the original grants, €956, together with interest payable at rate of 11.5% from July 1, 2007 through December 31, 2008 and at a rate of 9.5% from January 1, 2009 thereafter. Prior to 2010 interest expense related to the loans issued to the Company by Tekes was not previously accrued. In March 2011, the Company was notified by Tekes of the actual interest rates applied. The Company no longer accrues interest on the Tekes' grants at a provisional rate of 9.5% as of December 31, 2010. Interest is calculated by Tekes under their amortization and payments schedule. As of December 31, 2010 the Company uses the actual rate of Tekes. The interest rates used by Tekes vary and are tied to the basic rate of interest of the Bank of Finland plus a potential 3% premium. The basic rate of interest of the Bank of Finland was 1% at December 31, 2010. As of December 31, 2010, the Company has not made two scheduled payments of principal and interest due on September 30, 2010 and December 31, 2010 representing (€159). In the fourth quarter of 2010, the Company recorded interest expense of $1,059 based upon the revised interest calculation utilizing the reported Tekes rates of interest for the government grants and loans received (see note 15 to the financial statements).

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.

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 FFDCA 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 paediatric 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 marking 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
Robert Rieder[(1) (2)(3) (4)] Vancouver, British Columbia	Executive Chairman, Cardiome Pharma Inc	June 2009
Gordon Busenbark[(1) (3) (4)] Irvine, California	SVP and Chief Financial Officer, Inspiration Biopharmaceuticals, Inc.	June 2009
Gregory McKee[(2) (3)] La Jolla, California	President and CEO of Akela Pharma Inc	June 2009
Beng Lai [(1) (3) (4)] Vancouver, British Columbia	President, Intrynsic Capital Corp.	December 2010

(1) Audit Committee (financially literate, independent member)
(2) Nominating Committee
(3) Member of Corporate Governance Committee
(4) Member of Compensation Committee
(5) Member of Scientific Committee
(6) Audit Committee (financial literate, non-independent member)

Each director holds office until the next annual meeting or until his successor is elected or appointed. During 2010, Robert Williams resigned from the Board. Robert Williams, who has served as director since January 2007, was also the President and Chief Financial Officer of PharmaForm prior to its acquisition by the Company.

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

Name and Municipality of Residence	Position(s) Held within the Company
Gregory McKee La Jolla, California	President and Chief Executive Officer
Rudy Emmelot Austin, Texas	Chief Financial Officer and Vice President Finance

The following are brief biographies of our directors and executive officers, including their principal occupation for the past five years:

Gregory M. McKee has served on our board and as our President and Chief Executive Officer since June 2009. Prior to joining Akela, Mr. McKee served President and Chief Executive Officer and director for Nventa Biopharmaceuticals Corporation, formerly Stressgen Biotechnologies Corporation, or Stressgen. Mr. McKee began working for Stressgen in June 2003 as Stressgen's Vice President, Corporate Development and Strategic Planning. He became Stressgen's Chief Financial Officer in January 2004, and then became Stressgen's President and Chief Executive Officer and a director in April 2005. His previous experience includes work as Senior Director, Corporate Development for Valentis, Inc., a San Francisco based gene therapy company, from July 2000 through June 2003. From June 1996 through December 1999, McKee served in several management positions at Genzyme Corporation, a biotechnology company. Mr. McKee also spent five years in investment banking. Mr. McKee graduated with a B.A. degree in Economics from the University of Washington, an M.A. in Interanational Studies from The Joseph H. Lauder Institute at the University of Pennsylvania and earned an MBA from the Wharton School.

Rudy J. Emmelot has served as our Chief Financial Officer and Vice President Finance since September 2009. Prior to joining Akela, Mr. Emmelot served as Senior Financial Consultant for Nventa Biopharmaceuticals Corporation (Nventa). During the acquisition of Nventa Inc and its transition to Akela Pharma Inc, Mr. Emmelot served as Executive Financial Consultant to Akela and PharmaForm. His previous experience includes work as Corporate Controller for Allergy Free, LLC, a San Diego based manufacturer and distributor of allergy preventative products from December 2004 to December 2005. In 2001 Mr. Emmelot founded Bodhi, LLC, a San Diego start-up in the health, fitness and wellness industry. From December 1998 until March 2001 Mr. Emmelot served as Vice President, Finance for Xencor, Inc., a biotech focused on the development of enhanced biotherapeutic design of antibodies and proteins. Prior to joining Xencor Mr. Emmelot served as Director of Operations at Clinical Micro Sensors, Inc. a biotech diagnostic company in the bio-electric DNA detection field. From 1991 through 1997 Mr. Emmelot served in several management positions with Stafford Trading (Ronin Capital) a privately held Market

Maker firm based at the Chicago Board of Options Exchange. Mr. Emmelot graduated with a B.S. degree in Finance from the University of Illinois.

Robert Rieder has served on our board since June 2009. Mr. Rieder is currently Chairman and Chief Executive Officer of Cardiome Pharma Corp., a publicly traded company. Mr. Rieder joined Cardiome in April of 1988 as President and Chief Executive Officer, and was appointed as Cardiome's Chairman of the Board of Directors in March 2007. Mr. Rieder also serves as a member of the Board of Directors of publicly traded Inovio Biomedical Corporation. Mr. Rieder has extensive experience in venture capital and in operational management. Prior to joining Cardoime, he was Vice President at MDS Ventures Pacific Inc., the Vancouver-based affiliate of MDS Capital Corp., and has serviced as a director for nine public and private technology companies. In his venture capital career, Mr. Rieder led several rounds of financing for Stressgen Boitechnologies Corporation and was a director of the Company from 1992 to 2000. Prior to joining MDS, Mr. Rieder was President and Chief Executive Officer of Synapse Technologies and Chief Operating Officer of DBA Telecom Inc. Mr. Rieder received his BASc (Chem. Eng.) from the University of British Columbia and his MBA from the University of Western Ontario.

Gordon Busenbark has served on our board since June 2009. Mr. Busenbark is currently Senior Vice President and Chief Financial Officer of Inspiration Biopharmaceuticals, Inc. Prior to joining Inspiration Biopharmaceuticals, he served as Chief Financial Officer of Xytis Pharmaceuticals, Inc., a biotechnology company, engaged in the development of central nervous system (CNS) drug candidates, from October 2007 through October 2009, and as Chief Financial Officer of Encysive Pharmaceuticals, a biopharmaceutical company engaged in the discovery, development, and commercialization of novel synthetic small molecule compounds for the treatment of various cardiovascular, vascular, and related inflammatory diseases, from October 2005 through July 2007. From 1981 through September 2004, Mr. Busenbark held a number of key management positions including Vice President Finance, Controller and Plasma Business President at Baxter International Inc., a global medical products and services company which develops, manufactures and markets products for the treatment of hemophilia, immune disorders, infectious diseases, kidney disease, trauma, and other chronic and acute medical conditions. Mr. Busenbark received his MBA from the University of Utah - David Eccles School of Business in 1979.

Beng Lai is the founder and President of Intrynsyc Capital Corporation, a registered Canadian securities dealer that provides investment banking services to growth companies and accredited investors. He was previously an investment banker at Jennings Capital Inc. with responsibility for the healthcare/biotechnology, technology and industrial sectors. His prior investment banking experience was with Barclays de Zoete Wedd Ltd. and N.M. Rothschild & Sons Ltd., both in the UK. He has also been the investment manager of a Canadian venture capital fund and has had board positions in public and private companies in Canada. Beng has a degree in Dental Surgery and a Masters in Business Administration.

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.

As at March 31, 2011 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 708,022 Common Shares, representing approximately 2.0% 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 31, 2011 no Preference Shares and 32,890,338 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.

	High ($)	Low ($)	Volume
2010			
January	0.18	0.14	34,000
February	0.17	0.12	37,200
March	0.17	0.12	17,200
April	0.14	0.12	23,300
May	0.13	0.09	28000
June	0.14	0.06	73,200
July	0.08	0.07	29,000
August	0.10	0.06	49,700
September	0.10	0.07	60,100
October	0.11	0.08	53,100
November	0.19	0.10	71,300
December	0.17	0.12	74,800
2011			
January	0.18	0.15	45,300
February	0.17	0.13	27,200
March	0.16	0.10	85,400

LEGAL PROCEEDINGS

In February 2010, Akela and its wholly owned subsidiary, PharmaForm, announced the outcomes of two legal cases involving former employees, Michael Crowley and Stephen Lermer. In Michael Crowley vs. Formulation Technologies, LLC doing business as ("d/b/a/") PharmaForm, the arbitrator found in favor of Mr. Crowley. As a result, Mr. Crowley has been awarded $325 for payment under Mr. Crowley's employment agreement, commissions and vacation accruals earned over his employment period, partial payment of Mr. Crowley's legal fees and Mr. Crowley's out-of-pocket expenses. In February 2010, Mr. Crowley filed suit against Formulation Technologies, LLC ("d/b/a") PharmaForm to confirm an arbitration award. On July, 2, 2010 the Court appointed receiver levied $442 from PharmaForm's financial accounts. On October 25, 2010 the Court agreed to discharge the receiver and released $92 plus interest as reimbursement to PharmaForm for the original levy.

In the separate matter of Lermer vs. Akela Pharma Inc. and Formulation Technologies, LLC d/b/a/ PharmaForm, a jury sided with Mr. Lermer and awarded him $189 in severance pay and approximately $47 in vacation pay earned during the period which he was employed by the company in addition to out of pocket legal expenses. The judgment was solely against Akela Pharma. After reviewing the evidence and hearing the arguments of counsel, the District Court of Travis County, Texas denied the jury's award of severance in the Lermer suit, and on May 11, 2010, the court issued a final verdict awarding Mr. Lermer unused vacation pay and out of pocket legal expenses. Akela's provision for this unpaid liability at December 31, 2010 was $118.

The Company and certain board members were named as defendants in actions filed in the District Court of Travis County, Texas by two former employees; Andrew Reiter and Robert Clayborough. The company has reached settlement agreements with both Mr. Reiter and Mr. Clayborough with neither agreement having a material adverse effect on the Company's consolidated financial statements. Both legal matters before the Court have been dismissed.

In 2010 the Company was notified of potential claims related to previous employees. Although no formal litigation has been entered into, the Company has entered a provisional accrual of $450 related to these matters.

On December 31, 2010, the Company did not meet its obligation to pay Tekes, the Finnish Funding Agency for Technology and Innovation, an initial quarterly installment of approximately $0.1 million as part of a litigation settlement arrangement between Tekes and Akela's Finnish subsidiary (see notes 5 and 8 to the financial statements). While the Company intends to resolve Tekes' grievances as part of an action plan to address all outstanding claims associated with Akela's Finish subsidiary, which represent approximately $6.2 million of the Company's consolidated long-term debt as of December 31, 2010, it is not possible to estimate the amount of additional losses or range of possible losses, if any, that might result from an adverse resolution of this matter.

The Company also faces claims from creditors for unpaid services and supplies, as a number of Akela's liability obligations are in default (see notes 1 and 8 to the financial statements). While the outcome of these claims cannot be predicted with certainty the Company does not anticipate that these pending legal matters will have a material adverse effect on the Company's financial condition. The amounts payable under such claims have been recorded in accounts payable and accrued liabilities as of December 31, 2010.

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 2010, 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 totalling €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 HEP Davis Spring, L.P. (HEP Davis Spring).

11. An Agreement dated June 17, 2009 with Tekes to settle their demand for immediate repayment of €955,664 in previously granted subsidies. According to the terms of the agreement, Akela will pay back the grants received plus interest, in equal quarterly instalments, during a period of four years, starting in September 2010 with the last payment to occur in September 2014. Described under "Other Agreements."

12. A lease termination agreement dated April 2, 2010 with landlord HEP Davis Spring to terminate a lease in Austin, Texas, which had been planned for a new laboratory facility. Described under "Recent Events."

13. A development and commercialization agreement, as amended, with Teikoku Seiyaku Co. Ltd. dated June 10, 2009 for Fentanyl TAIFUN®. Described under "Other Agreements."

14. A line of credit agreement dated January 26, 2010 between Ingalls & Snyder Value Partners LP, and MacBay Partners LP a ("Lender"), and Formulation Technologies LLC, a Texas limited liability company, d/b/a PharmaForm ("PharmaForm"). This agreement terminated by all parties on September 24, 2010.

15. A line of credit agreement dated September 15, 2010, between MacBay Partners LP a ("Lender"), and Formulation Technologies LLC, a Texas limited liability company, d/b/a PharmaForm ("PharmaForm"). This agreement terminated by December 31, 2010.

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.

The Company has incurred significant net losses and negative cash flows from operations in prior years. The Company has funded such losses with external debt, share issuances, exclusive licensing and development agreements, government grants and working capital. As of December 31, 2010, the Company has a cash balance of $474, net current liabilities of $8,173, a shareholders' deficit of $24,369 and no operating line of credit.

An acute shortage of investor capital available for pharmaceutical development has adversely impacted the ability of the Company to obtain financing as well as the financial stability of its customer base, the credit quality of its receivables and the certainty of its revenue projections. Moreover, Akela will continue to encounter difficulty in raising additional financing from either new or existing investors until the Company significantly reduces its

outstanding debt. The Company could and may also receive claims from creditors, as a number of Akela's liability obligations are in default as at the audit report date (see notes 15, 18). As such, the realization of assets and discharge of liabilities in the ordinary course of business are subject to significant uncertainty.

Akela's ability to continue as a going concern is dependent upon, amongst other things, the successful development and marketing of its technologies, securing financing for its drug development program, the continued support and cooperation of shareholders, lenders, suppliers and the achievement of profitable operations. These endeavors are dependent on a number of circumstances outside the Company's control, especially as it relates to financing for small biotech and specialty pharmaceutical companies. Management's actions and plans with respect to addressing the going concern uncertainty include the following:

i) In 2009 the Company announced and undertook two corporate reorganizations to conserve cash. On February 9, 2009 the Company announced the implementation of measures to cut costs and preserve cash. The reduction in costs targeted the Pharmaceutical Development programs as well as, PharmaForm. On September 3, 2009, the Company announced a comprehensive corporate restructuring designed to achieve several operational objectives. As part of its efforts to preserve its ability to execute on its development strategy for Fentanyl TAIFUN® and to optimize the infrastructure required to support its PharmaForm clients, the Company reduced its head count by 32 employees to a workforce of 65. Further, the Company also announced the closure of the Company's international operations and the centralization of the Company's operational headquarters in Austin, Texas.

j) As part of the Company's cost reduction effort, the Fentanyl TAIFUN® program operates with a focused scope limiting the size and the number of clinical trial sites. The Company's strategy therefore is to sustain the continuance of the Fentanyl TAIFUN® program and seek funding for the Company's proprietary compounds from the Company's current and new commercial partners. Until the Company succeeds in raising additional capital through partner funding, equity or debt financing the Company is not recruiting any further patients into clinical studies.

k) The Company is no longer funding the scientific development of GHRH, HspE7, AKL 0721 or Poly ICR. While the Company is actively seeking licensing arrangements as well as other external development strategies, the Company may not be able to obtain sufficient capital to continue to fund the maintenance and prosecution costs of the patents and intellectual property associated with these technologies. Because of the Company's significant liquidity issues, the Company may be forced to terminate these programs as the Company looks to strategically focus the Company's current remaining capital resources on Fentanyl TAIFUN®.

l) On April 16, 2010, the Company announced that the Company had reached agreement with HEP Davis Spring, L.P. to terminate its leased facility located at 9825 Spectrum Drive, Austin, Texas eliminating $14,481 in future lease payments to the Company. As part of the agreement, which took effect April 2, 2010, Akela released $938 of funds from associated cash secured letter-of-credit, undertook to issue 1,250,000 common shares and assumed an obligation to pay the landlord in monthly installments of $10 through March 2020.

m) On June 17, 2009, the Company announced that the Company had signed an amendment to the Company's Fentanyl TAIFUN® license and co-development agreement with Teikoku Seiyaku Co. Ltd. ("Teikoku"). According to the amendment to the original agreement announced in January 2006, milestone payments of up to $2.0 million would be advanced to be payable earlier than originally intended. The Company received $0.2 million upon signing of the amendment, and would receive $1.8 million subject to meeting a near term development milestone related to the pharmaceutical development of the Product. On February 11, 2010, Akela achieved a near term development milestone in the pharmaceutical development of the Fentanyl TAIFUN® inhaler (the "Product"). The

remaining $1.8 million was received by Akela on August 6, 2010. All milestone funding is contractually committed to the ongoing development of Fentanyl TAIFUN®.

n) On October 29, 2010, the Company was awarded through the United States Qualifying Therapeutic Discovery Grant Program federal grants of $0.7 million to facilitate continued development of research programs.

o) During 2010 as a result of the measures to cut costs, reduce liabilities and increase cash which was begun in 2009, the Company has minimized costs related to the development strategy for Fentanyl TAIFUN®. The Company has effectively reduced operating costs and increased margins within the PharmaForm subsidiary.

p) In order to ensure the availability of current capital resources, the Company may attempt to issue new equity securities, issue new debt or pursue various other funding alternatives.

Management believes that the above actions, together with the continued support and cooperation of shareholders, lenders and suppliers, the securing of additional milestone payments and other financing will enable Akela to continue as a going concern. There can, however, be no assurance that the actions taken to date will result in sufficient funds being generated to enable the Company to continue as a going concern for the next twelve months. The financing environment within which the Company operates remains very challenging. Until such time as Akela's research and development efforts are commercialized or fully funded by third parties, for which no assurance can be given, the Company may continue to incur significant operating losses. Should the Company be unsuccessful in raising additional financing, it may have no choice but to seek protection from its creditors

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:

- the clinical development of our product candidates;
- develop, license or acquire additional product candidates;
- launch and commercialize 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 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.

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 other products under development, they are at an earlier stage of development.

In 2007 we completed our Fentanyl TAIFUN® Phase IIb clinical trials. In order to market Fentanyl TAIFUN®, we will have to conduct additional clinical trials, including Phase III clinical trials, to demonstrate safety and efficacy. 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. Thus toxicology results of this study were not reviewed by the FDA. 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 ($0.39US) 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 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 enrolment 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 enrolment in our Phase III clinical program is currently on hold.

On June 17, 2009, we announced the signing of an amendment to our Fentanyl TAIFUN® license and co-development agreement with Teikoku Seiyaku Co. Ltd., in order to advance certain milestone payments to support the continued development of the product. According to the amendment to the original agreement announced in January 2006, milestone payments of up to $2,000 will be advanced to be payable earlier than originally intended. Akela received $200 upon signing of the amendment. On February 11, 2010, Akela achieved a near term development milestone in the pharmaceutical development of the Fentanyl TAIFUN® inhaler. Although the Company achieved the milestone during the first quarter of 2010, it remains uncertain as to the timing or ability of the Company to collect the funds related to the $1,800 development milestone. In the future should the Company receive the milestone payment, all funds will be committed to the ongoing development of Fentanyl TAIFUN®.

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 enrolment 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 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, 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 FFDCA, 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 paediatric 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 shipee 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 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 U.S. 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 wilfully 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.

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 Barbadian subsidiaries. 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 Barbadian subsidiaries 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 does 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.

Additional information relating to the Company is available on SEDAR's website @ www.sedar.com.

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

BDO LLP 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, 2010. Our auditors , BDO LLP, 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 June 30, 2010.

Additional financial information is provided in the Company's audited financial statements and the MD&A for the year ended December 31, 2010.

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

All of the following members of the audit committee have:

(i) An understanding of the accounting principles used by the Company to prepare its financial statements;

(ii) The ability to assess the general application of such accounting principles in connection with the accounting for estimates, accruals and reserves;

(iii) Experience preparing, auditing, analyzing or evaluation financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of issues that can be reasonably expected to be raised by the Company's financial statements, or experience actively supervising one or more individuals engaged in such activities; and

(iv) An understanding of internal controls and procedures for financial reporting.

Robert Rieder has served on our board since June 2009. Mr. Rieder is currently Chairman and Chief Executive Officer of Cardiome Pharma Corp., a publicly traded company. Mr. Rieder joined Cardiome in April of 1988 as President and Chief Executive Officer, and was appointed as Cardiome's Chairman of the Board of Directors in March 2007. Mr. Rieder also serves as a member of the Board of Directors of publicly traded Inovio Biomedical Corporation. Mr. Rieder has extensive experience in venture capital and in operational management. Prior to joining Cardoime, he was Vice President at MDS Ventures Pacific Inc., the Vancouver-based affiliate of MDS Capital Corp., and has serviced as a director for nine public and private technology companies. In his venture capital career, Mr. Rieder led several rounds of financing for Stressgen Boitechnologies Corporation and was a director of the Company from 1992 to 2000. Prior to joining MDS, Mr. Rieder was President and Chief Executive Officer of Synapse Technologies and Chief Operating Officer of DBA Telecom Inc. Mr. Rieder received his BASc (Chem. Eng.) from the University of British Columbia and his MBA from the University of Western Ontario.

Gordon Busenbark has served on our board since June 2009. Mr. Busenbark is currently Senior Vice President and Chief Financial Officer of Inspiration Biopharmaceuticals, Inc. Prior to joining Inspiration Biopharmaceuticals, he served as Chief Financial Officer of Xytis Pharmaceuticals, Inc., a biotechnology company, engaged in the development of central nervous system (CNS) drug candidates, from October 2007 through October 2009, and as Chief Financial Officer of Encysive Pharmaceuticals, a biopharmaceutical company engaged in the discovery, development, and commercialization of novel synthetic small molecule compounds for the treatment of various cardiovascular, vascular, and related inflammatory diseases, from October 2005 through July 2007. From 1981 through September 2004, Mr. Busenbark held a number of key management positions including Vice President Finance, Controller and Plasma Business President at Baxter International Inc., a global medical products and services company which develops, manufactures and markets products for the treatment of hemophilia, immune disorders, infectious diseases, kidney disease, trauma, and other chronic and acute medical conditions. Mr. Busenbark received his MBA from the University of Utah - David Eccles School of Business in 1979.

Beng Lai is the founder and President of Intrynsyc Capital Corporation, a registered Canadian securities dealer that provides investment banking services to growth companies and accredited investors. He was previously an investment banker at Jennings Capital Inc. with responsibility for the healthcare/biotechnology, technology and industrial sectors. His prior investment banking experience was with Barclays de Zoete Wedd Ltd. and N.M. Rothschild & Sons Ltd., both in the UK. He has also been the investment manager of a Canadian venture capital fund and has had board positions in public and private companies in Canada. Beng has a degree in Dental Surgery and a Masters in Business Administration.

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:

	2010	2009
Audit fees	$ 341,057	$ 205,761
Audit related services	-	-
Other services	-	-
Tax fees	-	9,974
	$ 341,057	$ 215,735