

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

This "Management's Discussion and Analysis of Financial Condition and Results of Operations" (MD&A) is dated as of March 31, 2011. It contains statements which, to the extent that they are not recitations of historical fact may constitute forward-looking information under applicable Canadian securities legislation or forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. The statements contained in the following Management's Discussion and Analysis of Financial Condition and Results of Operations of Akela Pharma (formally LAB International Inc.) ("Akela" or the "Company"), other than statements of fact that are independently verifiable at the date hereof, may be forward-looking statements regarding the industry in which Akela operates and the Company's expectations as to its future performance, liquidity and capital resources. Such forward-looking statements or information may include clinical and other projections as well as statements regarding our future plans, objectives, performance, operating expenses, revenues, growth, profits or the Company's underlying assumptions. Forward-looking statements look into the future and may include such words as "may", "would", "could", "will", "likely", "intend", "forecast", "project", "plans", "trends", "anticipates", "should", "estimates", "expects", "believes", "indicates", "targeting", "suggests" and similar expressions. This MD&A contains forward-looking statements about Akela's objectives, strategies and financial condition, as well as statements with respect to our beliefs, expectations, estimations and intentions. Forward-looking statements are based on current expectations and various factors and assumptions. Accordingly, these statements entail various risks both known and unknown, including those set forth in the "Risks and Uncertainties" section of this document. Consequently, actual future results may differ materially from the anticipated results expressed in the forward-looking statements. It is important to note that, unless otherwise indicated, forward-looking statements in this MD&A describe our expectations as of March 31, 2011. 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, except as required by law.

Forward-looking statements or information in this MD&A include, but are not limited to statements or information concerning: our belief that we can create a proprietary portfolio of break-through cancer pain pharmaceuticals; our belief that a manufacturing process for Fentanyl TAIFUN® can be validated for commercial use; our plan to successfully complete a six month inhalation toxicology study of Fentanyl TAIFUN® in the United States; our plan to continue enrollment of patients in our ongoing European Phase III clinical trial; our plan to successfully license development and commercialization of Fentanyl TAIFUN® in the United States; our plan that our international development partners will complete Phase III clinical trials and gain commercial approval of Fentanyl TAIFUN® in their licensed markets; our plan to pursue initiatives to continue our operations.

Such forward-looking statements or information involve known and unknown risks, uncertainties and other factors that may cause our actual results, events or developments, or industry results, to be materially different from any future results, events or developments expressed or implied by such forward-looking statements or information. Such factors include, among others, our need for capital; the risk that our manufacturing process will not be validated; risks associated with requirements for approvals by government agencies, such as the U.S. Food and Drug Administration ("FDA"), or The European Agency for the Evaluation of Medicinal Products ("EMA") before products can be tested in clinical trials and ultimately marketed; the possibility that such governmental agency approvals will not be obtained in a timely manner or at all; risks associated with the requirement that a drug be found safe and effective after extensive clinical trials and the possibility that the results of such trials, if commenced and completed, will not establish the safety or efficacy of our products; our dependence on suppliers of clinical trial materials, collaborative partners and other third parties and the prospects and timing for negotiating supply agreements, corporate collaborations or licensing arrangements; that we will be able to obtain the clinical trial materials necessary to conduct our clinical trials in a timely manner; risks associated with recruiting patients for clinical trials; uncertainties as to future expense levels and the possibility of unanticipated costs or expenses or cost overruns; our ability to attract and retain key personnel; our ability to protect and practice our intellectual property; risks associated with the development and manufacturing of our products; the risk that competitors may develop and market drugs that are less expensive, more effective or safer than ours; and other factors as described in detail in our filings with the Canadian securities regulatory authorities at <http://www.sedar.com>. Given these risks and uncertainties, you are cautioned not to place undue reliance on such forward-looking statements and information, which are qualified in their entirety by this cautionary statement.

Assumptions underlying our expectations regarding forward-looking statements or information contained in this MD&A include, among others, that we will raise enough capital on reasonable terms and in a timely manner; that we will retain our key personnel; that we will successfully complete a six month inhalation toxicology study of Fentanyl TAIFUN®; that we will successfully complete Phase III clinical trials of Fentanyl TAIFUN®; that we will obtain timely approval from Institutional Review Boards, or IRBs; that the results from additional preclinical work, if any, will be consistent with the results we have already obtained; that we will be able to continue to develop and protect our core technologies; that a sufficient number of patients will be available to conduct successful clinical trials; that sufficient data will be generated to support an Investigational New Drug (IND) or a New Drug Application (NDA) or amendment; and that we will be able to establish and/or maintain necessary relationships with key suppliers, collaborative partners or third-party contractors.

In the event that any of these assumptions prove to be incorrect, or in the event that we are impacted by any of the risks identified above, we may not be able to continue our business as planned, or at all.

For a complete discussion of the assumptions, risks and uncertainties related to our business, you are encouraged to review our filings with Canadian securities regulatory authorities, including our 2009 Annual Information Form filed on SEDAR at <http://www.sedar.com>. Historical filings relating to the Company prior to the completion of the Company's June 2007 corporate renaming, including LAB International Inc's 2007 Annual Information Form dated May 28, 2008 may be reviewed on SEDAR at <http://www.sedar.com> under the SEDAR profile GVIC Communications Corp.

This document should be read in conjunction with the audited consolidated financial statements of Akela and related notes included therein which have been prepared in accordance with Canadian generally accepted accounting principles ("GAAP") for the years ended December 31, 2010 and 2009. All amounts are presented in thousands of US dollars unless otherwise indicated.

Our Business

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 with clinical and small scale commercial manufacturing 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.

PharmaForm operates a 50,000 sq. ft. facility located in Austin, Texas providing drug formulation solutions and product manufacturing to pharmaceutical and biotechnology companies. 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.

The specific types of service offered by PharmaForm include:

- Formulation and process development
- Analytical development
- GMP clinical and small scale commercial manufacturing
- Custom labeling and packaging
- QC testing and ICH stability storage
- Patent litigation support
- Consulting (IP validation and contestation)

Our 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.

Other 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.

Operating Results

Basis of Presentation

The accompanying unaudited interim consolidated financial statements have been prepared in accordance with Canadian generally accepted accounting principles ("GAAP") on a going concern basis which contemplates that Akela will continue in operation for the foreseeable future and will be able to realize its assets and discharge its liabilities in the normal course of business. The Company has and may continue to incur significant net losses and negative cash flows from operations. The Company has funded such losses with external debt, share issuances, exclusive licensing and development agreements, government grants and working capital. We have never had any products available for commercial sale, and we have not generated any revenue from product sales. We do not anticipate that we will generate revenues from the sale of products for the foreseeable future, but we continue to incur expenses related to our operations. 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. Our consolidated net results for the twelve months ended December 31, 2010 was \$1.2 million gain compared to a net loss of \$21.0 million for the same period ending 2009. As of December 31, 2010, we had cash of \$474, net current liabilities of \$8,173 and an accumulated deficit of \$24,369.

The audited financial statements which follow do not include any adjustments relating to the recoverability and classification of recorded asset amounts, the amount and classification of liabilities and the reported revenue and expenses that would be necessary should the Company be unable to continue as a going concern.

Certain comparative figures for years prior to 2010 have also been reclassified in order to conform to the presentation adopted for the year ending December 31, 2010.

Select Annual Information

For the year ending December, 31 2010, the Company reported net income of \$1.3 million compared with a net loss of \$20.9 million in the prior year.

The following is selected financial information for the three most recent fiscal years:

	2010	2009	2008
Revenues	\$13,302	\$13,893	\$14,774
Direct costs	5,446	\$8,158	7,730
Selling, general and administrative	4,953	6,183	7,103
Research and development	118	3,711	11,563
Stock-based compensation	64	238	477
Amortization of property and equipment	1,437	1,464	4,741
Amortization of intangible assets	58	1,693	-
Interest on long-term debt	1,090	268	158
Unrealized loss on securities held for trading	78	23	-
Foreign exchange	(466)	600	471
Impairment of intangible, goodwill and other assets	-	9,601	9,635
Settlement with LRI	-	(1,664)	-
Lease termination	-	1,936	-
Provision for repayment of government grants	-	1,544	-
Restructuring	-	1,071	-
Provision for (recovery of) income taxes	(707)	64	(1,115)
Net income (loss) and comprehensive income (loss)	\$1,231	(\$20,997)	(\$25,989)
Cash	\$474	\$107	\$2,345
Accounts receivable	1,590	1,679	6,070
Prepaid expenses and other current assets	302	417	346
Restricted cash and deposits	-	938	1,858
Property and equipment	3,085	4,165	5,229
Intangible assets	74	52	4,755
Goodwill	-	-	6,457
Other assets	67	598	1,397
Total assets	\$5,592	\$7,956	\$28,457
Accounts payable and accrued liabilities	\$5,709	\$7,801	\$7,307
Deferred revenue	16,506	17,425	20,781
Long-term debt	7,480	7,630	6,205
Income Taxes	266	799	610
Total liabilities	\$29,961	\$33,655	\$34,903

Three-months ended December 31, 2010

	2010	2009
Revenues	\$3,667	\$3,048
Direct costs	1,308	\$1,773
Selling, general and administrative	661	1,667
Research and development	(161)	1,019
Stock-based compensation	42	37
Amortization of property and equipment	299	766
Amortization of intangible assets	58	-
Interest on long-term debt	807	81
Unrealized loss on securities held for trading	-	92
Foreign exchange	(118)	(188)
Impairment of intangible, goodwill and other assets	-	9,601
Lease termination	-	1,936
Restructuring	-	263
Provision for (recovery of) income taxes	(707)	64
Net gain (loss)	\$1,418	(\$14,063)

Revenues

We derive our revenues from licensing and co-development agreements and through providing contract development and manufacturing services. Revenues for the three months ended December 31, 2010 and 2009 were as follows:

	2010	2009	Change
Co-development revenue	\$ 644	\$ 644	\$ -
Contract services revenue	3,023	2,401	622
Total revenue (Excluding interest)	\$ 3,667	\$ 3,045	\$ 622

Co-development revenue. Co-development revenue is derived from amortization of previously received license fees and milestones related to our product development program. We have entered into development and license agreements for our Fentanyl TAIFUN® inhaler. Under these agreements, we have granted development, marketing and distribution rights in specified world markets in return for co-development fees in the form of up-front payments, fees for development activities and payments tied to meeting development milestones. Also under the agreements, we will earn revenues for supplying the finished product, along with royalties on future sales. We currently have agreements for the South Korean, Chinese (excluding Hong Kong and Taiwan) and Japanese markets. In June 2007 we signed a licensing and development agreement with Janssen Pharmaceuticals NV covering the European Union, Eastern Europe, Russia, the Middle East and Africa. Under the terms of the agreement, we received a signing fee of \$10.7 million (€8.0 million) and can receive up to an additional \$63.0 million (€44.0 million) for meeting development, regulatory and commercial sales milestones. The agreement also entitles us to royalties and revenues from sales of the product to Janssen. In December 2007, we extended the territory coverage of the agreement to include Canada for a signing fee of \$1.1 million. In May 2008 the original agreement was amended to secure advanced milestones of \$3.5 million (€2.5 million) on the first local regulatory approval of the Phase III protocol and \$2.8 million (€2.0 million) on clinical site readiness. An additional milestone of \$3.6 million (€2.5 million) was due as of the inclusion of the 7th patient in the study. The Company triggered the

advance milestones in August, September and December of 2008. The resulting proceeds, \$10.2 million, have been deferred and are being recognized ratably over the estimated development period.

On June 17, 2009, we announced that we had signed 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 Fentanyl TAIFUN® inhaler (the “Product”). 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. We 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, this milestone was achieved, and the remaining \$1.8 million was received on August 6, 2010. As with our previous development and license agreements, the resulting proceeds have been deferred and are being recognized ratably over the estimated development period. All milestone funding is contractually committed to the ongoing development of Fentanyl TAIFUN®.

Co-development revenue did not change for the three months ended December 31, 2010 from the same period in 2009.

Contract services revenue. Contract services revenue increased by \$0.6 million for the three months December 31, 2010 from \$2.4 million to \$3.0 million for the three months ended December 31, 2009. The increase was primarily due to the weaker demand of contract services related to the effect of the global economy downturn within pharmaceutical research and development in 2009.

Expenses

Direct costs. Direct costs represent the costs of providing contract services which includes raw materials, direct and indirect labor, supplies, related equipment, and overhead. Direct costs declined to \$1.3 million for the three months ended December 31, 2010 from \$1.8 million during the previous year. Reduction in direct costs is the effect of cost reduction initiatives the Company had in place during 2010.

Selling, general and administrative (SG&A). SG&A includes salary and benefits for the executive, accounting, administrative and business development personnel, professional fees and other corporate expenses. SG&A for the three months ended December 31, 2010 decreased to \$0.7 million from \$1.7 million for the same period in 2009. Reduction in SG&A is the effect of cost reduction initiatives the Company had in place during 2010.

Research and Development (R&D) R&D is primarily third-party pre-clinical and clinical trial services, salary and benefits for scientists and technicians, testing material, consultants and related overhead. R&D for the three months ended December 31, 2010 decreased by \$1.2 from \$1.0 million for the same period in 2009 as a direct result of the Company’s cost reduction efforts. The R&D expense was also reduced by a write back associated with the settlement of the Canada Revenue Agency audit (see income taxes).

Stock-based compensation. Stock-based compensation relates to stock options granted to employees. Employee stock options are accounted for using the fair value method. Under this method, compensation cost is measured at fair value at the date of grant and is expensed over the award’s vesting period. Stock based compensation increased in the fourth quarter 2010 by \$0.5 over the same period in 2009.

Amortization expense. Amortization includes amortization of property and equipment as well as intangible assets. Amortization expense decreased to \$0.4 million for the three months ended December 31, 2010 from \$0.8 million for the same period in 2009. The decrease over the previous year reflects \$9.6 million of intangibles which were written off in the fourth quarter of 2009 as result of management’s review for impairment.

Interest expense. Long-term interest expense relates to capital loans, notes payable and various capital lease obligations. Interest expense increased in the fourth quarter by \$0.7 million over the same period in 2009. This increase is related to the Tekes debt provision (see note 6 to the financial statements).

Foreign Exchange. Although our functional currency is the US dollar, a significant portion of our liabilities are denominated primarily in Euros and also Canadian Dollars. The strengthening of the US dollar and its

impact on the balance of Euro denominated debt resulted in foreign exchange gains during the three months ended December 31, 2010 and 2009, respectively.

Income Taxes. Income taxes for the period includes a \$0.7 million write back for losses associated with resolution of potential claims related to audits of the Company's 2005 and 2006 tax returns in by the Canadian Revenue Agency and the Company's 2007 SRED Claim with the Canadian Revenue Agency and the Province of Quebec. (See note 16 to the financial statements).

Provision for Repayment of Government Grants and Loans. 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).

Twelve months ended December 31, 2010

During the twelve months ended December, 31 2010, the Company reported net income of \$1.3 million compared with a net loss of \$20.9 million in the prior year.

	<u>2010</u>	<u>2009</u>
Revenues	\$13,302	\$13,893
Direct costs	5,446	\$8,158
Selling, general and administrative	4,953	6,183
Research and development	118	3,711
Stock-based compensation	64	238
Amortization of property and equipment	1,437	1,464
Amortization of intangible assets	58	1,693
Interest on long-term debt	1,090	268
Unrealized loss on securities held for trading	78	23
Foreign exchange	(466)	600
Impairment of intangible, goodwill and other assets	-	9,601
Settlement with LRI	-	(1,664)
Lease termination	-	1,936
Provision for repayment of government grants	-	1,544
Restructuring	-	1,071
Provision for (recovery of) income taxes	(707)	64
Net gain (loss)	<u>\$1,231</u>	<u>(\$20,997)</u>

Revenues

We derive our revenues from licensing and co-development agreements and through providing contract development and manufacturing services. Revenues for the year ended December 31, 2010 and 2009 were as follows:

	<u>2010</u>	<u>2009</u>	<u>Change</u>
Co-development revenue	\$ 3,147	\$ 3,275	\$ (128)
Contract services revenue	10,155	10,618	(463)
Total revenue (Excluding interest)	<u>\$ 13,302</u>	<u>\$ 13,893</u>	<u>\$ (591)</u>

Co-development revenue. Co-development revenue is derived from amortization of previously received license fees and milestones related to our product development program. We have entered into development and license agreements for our Fentanyl TAIFUN® inhaler. Under these agreements, we have granted development, marketing and distribution rights in specified world markets in return for co-development fees in the form of up-front payments, fees for development activities and payments tied to meeting development milestones. Also under the agreements, we will earn revenues for supplying the finished product, along with royalties on future sales. We currently have agreements for the South Korean, Chinese (excluding Hong Kong and Taiwan) and Japanese markets. In June 2007 we signed a licensing and development agreement with Janssen Pharmaceuticals NV

covering the European Union, Eastern Europe, Russia, the Middle East and Africa. Under the terms of the agreement, we received a signing fee of \$10.7 million (€8.0 million) and can receive up to an additional \$63.0 million (€44.0 million) for meeting development, regulatory and commercial sales milestones. The agreement also entitles us to royalties and revenues from sales of the product to Janssen. In December 2007, we extended the territory coverage of the agreement to include Canada for a signing fee of \$1.1 million. In May 2008 the original agreement was amended to secure advanced milestones of \$3.5 million (€2.5 million) on the first local regulatory approval of the Phase III protocol and \$2.8 million (€2.0 million) on clinical site readiness. An additional milestone of \$3.6 million (€2.5 million) was due as of the inclusion of the 7th patient in the study. The Company triggered the advance milestones in August, September and December of 2008. The resulting proceeds, \$10.2 million, have been deferred and are being recognized ratably over the estimated development period.

On June 17, 2009, we announced that we had signed 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 Fentanyl TAIFUN® inhaler (the “Product”). 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. We 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, this milestone was achieved, and the remaining \$1.8 million was received on August 6, 2010. As with our previous development and license agreements, the resulting proceeds have been deferred and are being recognized ratably over the estimated development period. All milestone funding is contractually committed to the ongoing development of Fentanyl TAIFUN®.

Co-development revenue decreased to \$3.1 million for the year ended December 31, 2010 from \$3.3 million for the same period in 2009. The decline from the previous year reflects a revision in the amortization of deferred revenue from license fees and milestones associated with Fentanyl TAIFUN® which took effect October 1, 2009. The result is a delay in revenue recognition based on management’s re-assessment of projected commercialization, from May 2012 to June 2016.

Contract services revenue. Contract services revenue decreased to \$10.1 million for the twelve months December 31, 2010 from \$10.6 million in 2009. During 2010 operations were streamlined with a goal of optimizing infrastructure and client support. These initiatives have resulted in greater operating efficiencies, an increased and diverse client and revenue base as well as increased margins.

Expenses

Direct costs. Direct costs represent the costs of providing contract services which includes raw materials, direct and indirect labor, supplies, related equipment, and overhead. The decrease in direct costs to \$5.4 million for the year ended December 31, 2010 from \$8.1 million during the previous year reflects the reductions in overhead and strategic planning instituted in 2010 to increase efficiencies and margins within the PharmaForm subsidiary.

Selling, general and administrative (SG&A). SG&A includes salary and benefits for the executive, accounting, administrative and business development personnel, professional fees and other corporate expenses. SG&A for the twelve months ended December 31, 2010 decreased to \$5.0 million from \$6.1 million for the same period in 2009 reflects the strategic planning instituted in 2010 to increase efficiencies and margins within the PharmaForm subsidiary.

Research and Development (R&D) R&D is primarily third-party pre-clinical and clinical trial services, salary and benefits for scientists and technicians, testing material, consultants and related overhead. R&D for the twelve months ended December 31, 2010 decreased to \$0.1 from \$3.7 million for the same period in 2009 as a direct result of the Company’s cost reduction efforts. The R&D expense was also reduced by a write back associated with the settlement of the Canada Revenue Agency audit (see income taxes).

Stock-based compensation. Stock-based compensation relates to stock options granted to employees. Employee stock options are accounted for using the fair value method. Under this method, compensation cost is measured at fair value at the date of grant and is expensed over the award's vesting period. Stock based compensation decreased by \$174 in the twelve months ending December 31, 2010 over the same period in 2009.

Amortization expense. Amortization includes amortization of property and equipment as well as intangible assets. Amortization expense decreased for the twelve months ended December 31, 2010 by \$1.7 compared with the same period in 2009. The decrease is related to the impairment of intangibles in 2009.

Interest expense. Long-term interest expense relates to capital loans, notes payable and various capital lease obligations. 2010 interest includes a \$0.8 million expense related to the Company's revision of provisional interest calculations related to government loans and grants. See Provision for Repayment of Government Grants and Loans.

Foreign Exchange. Although our functional currency is the US dollar, a significant portion of our liabilities are denominated Euros. The strengthening of the US dollar and its impact on the balance of Euro denominated debt resulted in foreign exchange gains during the twelve months ended December 31, 2010 versus the loss for the same period in 2009.

Income Taxes. Income taxes for 2010 includes a \$0.7 million write back for losses associated with resolution of potential claims related to audits of the Company's 2005 and 2006 tax returns in by the Canadian Revenue Agency and the Company's 2007 SRED Claim with the Canadian Revenue Agency and the Province of Quebec. (See note 16 to the financial statements).

Provision for Repayment of Government Grants and Loans. 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).

Settlement with Lab Research Inc. (LRI) On March 10, 2009, the Company agreed to accept a payment of \$2,000 CDN (\$1,563 US) and 500,000 common share purchase warrants with an exercise price of \$0.50 CDN (\$0.39 US) from LAB Research Inc. (LRI) as full and final settlement of its lawsuit relating to a failed Fentanyl

TAIFUN® toxicology study. The fair value of the warrants together with the cash proceeds received as part of this settlement resulted in a gain of \$1,664 that was recorded in 2009. The fair value of the warrants as of March 10, 2009 was \$130 CDN (\$101 US). A decline in the fair value of the warrants subsequent to the settlement resulted in an unrealized loss of \$78 and \$23 on securities held for trading for the year ended December 31, 2010 and December 31, 2009. Based on the remaining life of the warrants, which were to expire on December 30, 2010, together with the prevailing market price and expected volatility of LRI's common stock at nominal risk free interest rates, the Company concluded that the fair value of the warrants was nil. Subsequent to the year end, on February 21, 2011 LRI was forced into Bankruptcy and Insolvency in the Commercial Chamber of the Superior Court of Laval, Canada. On March 25, 2011 the shares of LRI were delisted from trading by the Toronto Stock Exchange (see note 7 to the financial statements).

QUARTERLY RESULTS

(in thousands of US dollars, except per share data)

Quarter	Revenues	Net income (loss)	Net Income (Loss) per share	
			Basic	Diluted
Quarter ended December 31, 2010	3,667	1,418	0.05	0.05
Quarter ended September 30, 2010	3,984	115	nil	Nil
Quarter ended June 30, 2010	3,050	77	nil	Nil
Quarter ended March 31, 2010	2,601	(439)	(0.01)	(0.01)
Quarter ended December 31, 2009	3,048	(13,999)	(0.48)	(0.48)
Quarter ended September 30, 2009	3,053	(3,210)	(0.13)	(0.13)
Quarter ended June 30, 2009	4,022	(1,091)	(0.04)	(0.04)
Quarter ended March 31, 2009	3,770	(2,633)	(0.12)	(0.12)

LIQUIDITY AND CAPITAL RESOURCES

Going Concern 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 are 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 look 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. (See note 5 to the financial statements).
- 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 have effectively reduced operating costs and increased margins within the PharmaForm subsidiary. These continued efforts to strive for profitability have seen the generation of consolidated positive EBIDTA for the fiscal year ending 2010 as well as the first year of positive net income in recent operating history for the Company.
- 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.

Cash Position

Our cash balance at December 31, 2010 was \$0.5 million compared with \$0.1 million at December 31, 2009. Net cash flows for the twelve months ended December 31, 2010 and 2009 are summarized as follows:

	2010	2009	Change
Cash provided by (used in) operating activities	\$ (133)	\$ (1,762)	\$ 1,629
Cash used in financing activities	(410)	(1,517)	1,107
Cash provided by investing activities	910	1,041	(131)
Net increase (decrease) in cash	<u>\$ 367</u>	<u>\$ (2,238)</u>	<u>\$ 2,605</u>

Operating Activity

Net cash provided by operations for the twelve months ended December 31, 2010 was \$0.1 million as compared to \$1.8 million used by operating activities for the same period in 2009. Operating cash flow during 2010 benefited from Akela's collection of a \$1.8 million milestone in August 2010 from Teikoku triggered by meeting a near term development milestone related to the pharmaceutical development of the Fentanyl TAIFUN® inhaler. Operating cash flow during 2009 benefited from Akela's collection of a \$3.6 million (€ 2.5 million) milestone from Janssen in January 2009, triggered by the inclusion of a 7th patient in Akela's Fentanyl Taifun® Phase III clinical study.

Financing Activity

Net cash used by financing activities for the twelve months ended December 31, 2010 was \$0.4 million as compared to \$1.5 million used by financing activities for the same period during the previous year. Net cash used by financing activities for the twelve months ended December 31, 2010 and 2009 consisted of repayments on long-term debt and capital leases.

Investing Activity

Net cash provided by investing activities for the twelve months ended December 31, 2010 was \$1.1 million as compared to \$0.9 million used by investing during 2009. Investing activities for the prior year benefited from the acquisition of Nventa, which netted the Company cash of approximately \$1.0 million after transaction costs (see note 4 to the financial statements), partially offset by \$1.0 million in capital expenditures, primarily for tenant improvements associated with the HEP Davis Spring LP lease, which was terminated on April 2, 2010.

COMMITMENTS, CONTINGENCIES AND GUARANTEES

(a) *Commitments:*

The annualized aggregate maturities of the Company's contractual obligations are as follows:

	2011	2012	2013	2014	2015	2016+	Total
Operating Leases	400	317	-	-	-	-	717
Service Contracts	149	13					162
	549	330	-	-	-	-	879

The Company is party to license agreements with Auxilium Pharmaceutical, Inc. ("Auxilium") granting Auxilium an exclusive, worldwide royalty-bearing license to develop, make and sell products that contain oral transmucosal film technology for which there is an issued patent in the United States. The terms of these license agreements are for the life of the licensed patents.

To increase the speed of the development of products using the licensed technology, Auxilium entered into a research and development agreement with PharmaForm, on a fee-for-service basis. Auxilium will be the sole owner of any intellectual property rights developed in connection with this agreement.

The intellectual rights associated with this agreement are based on sublicense agreements with the University of Mississippi and the University of Texas. In the event that the University of Mississippi or the University of Texas license agreements are terminated during the term of the Auxilium agreement, PharmaForm shall pay to Auxilium one-half of all direct expenses and costs Auxilium has incurred relating to the research and development of the compounds, technology, or products pursued under the Agreement which exceed the cumulative gross profit earned by Auxilium on such products, as of the date of the termination of such agreement. With respect to each of the University of Mississippi sublicense agreement, the right to terminate for convenience may only be exercised by all inventors as a group. One of the Company's board members is an inventor. The University of Texas license agreement may only be terminated for convenience by mutual agreement of the parties thereto. As of December 31, 2010, the minimum amount of this contingency is \$2.3 million, representing one-half of amounts received by the Company from Auxilium, and is subject to upward adjustment for any additional amounts incurred by Auxilium on this project. The Company has not recorded a liability with respect to this guarantee as the Company does not expect to make any payments for this item and the standby liability is nominal.

The Company is party to a royalty bearing license for a drug delivery system in which it is required to pay 75% of any sublicense fees received by the Company to the licensors. The Company's sublicense to Auxilium is subject to these agreements.

In May 2008, Akela's original license and development agreement with Janssen for Fentanyl TAIFUN® was amended to secure advanced milestones of €2.5 million on the first local regulatory approval of the Phase III protocol and €2.0 million on clinical site readiness. As part of this agreement, Akela agreed to use the funds to prepare and conduct the Phase III clinical and long-term toxicology studies and finance other project critical expenses. Failure to comply with these conditions would result in an obligation to refund all of the funds to Janssen. The Company triggered the advance milestones in August and September 2008 and the resulting proceeds were dedicated to the Fentanyl program under the supervision of the Joint Development Team (JDT) which is comprised of six members; three representatives of Akela and three representatives of Janssen. As the advanced milestones were invested to sustain the clinical program and timely progress toward the development of Fentanyl TAIFUN®

from the date of the amendment (May 23, 2008) through December 31, 2010, the Company believes it has complied with the terms of the advance milestones.

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"), in order to advance certain milestone payments to support the continued development of the Fentanyl TAIFUN® inhaler (the "Product"). 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 was entitled to the \$1.8 million on February 11, 2010 when the milestone was achieved relating to the pharmaceutical development of the Product. The \$1.8 million was received by Akela on August 6, 2010. All milestone funding is contractually committed to the ongoing development of Fentanyl TAIFUN®. All milestone funding is contractually committed to the ongoing development of Fentanyl TAIFUN®.

(b) Contingencies:

In February 2010, Akela and its wholly owned subsidiary, PharmaForm, announced the outcomes of two legal cases involving former employees, Michael Crowley and Stephen Lerner. 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 Lerner vs. Akela Pharma Inc. and Formulation Technologies, LLC d/b/a/ PharmaForm, a jury sided with Mr. Lerner 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 Lerner suit, and on May 11, 2010, the court issued a final verdict awarding Mr. Lerner 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 September 30, 2010.

(c) Guarantees:

The Company has entered into a number of standard indemnification agreements in the ordinary course of its business. Pursuant to these agreements, the Company indemnifies, holds harmless, and agrees to reimburse the indemnified party for losses suffered or incurred by the indemnified party, who are generally the Company's business partners or customers. The Company agrees to indemnify for claims, demands or judgments that arise out of negligence or misconduct of the Company, or act of alleged infringement of intellectual property by any third-party with respect to the Company's activities under the agreement. At December 31, 2010 and 2009, the Company has not recorded a liability with respect to these guarantees as the Company is not aware of any such claim and does not expect to make any payments for the aforementioned items and the standby liability is nominal.

Financial Instruments

All financial instruments are classified into one of the following five categories: held for trading, held-to-maturity investments, loans and receivables, available-for-sale financial assets, or other financial liabilities. All financial instruments, including derivatives, are included on the consolidated balance sheet and are measured initially at fair value. Loans and receivables, investments held-to-maturity and other financial liabilities are subsequently measured at amortized cost. Held-for-trading financial investments are measured at fair value and all gains and losses are included in net income in the period in which they arise. Available-for-sale financial instruments are measured at fair value with revaluation gains and losses included in other comprehensive income until the assets are removed from the balance sheet or the losses are other than temporarily impaired.

Cash is classified as held for trading and is categorized as Level 1. Restricted cash and deposits are classified as held to maturity. Accounts receivable are classified as loans and receivables, and accounts payable, accrued liabilities and long-term debt are classified as other financial liabilities.

The Company categorizes its financial assets and liabilities measured at fair value into one of three different levels depending on the ability to observe the inputs used in their measurement:

Level 1: This level includes assets including securities held for trading and liabilities measured at fair value based on unadjusted quoted price for identical assets and liabilities in active markets that are accessible at the measurement date.

Level 2: This level includes valuations determined using directly or indirectly observable inputs other than quoted prices included within Level 1. The instruments in this category are valued using models or other industry standard valuation techniques derived from observable market inputs.

Level 3: This level includes valuations based on inputs which are less observable, unavailable or where the observable data does not support a significant portion of the instruments' fair value.

OFF-BALANCE SHEET ARRANGEMENTS

As of December 31, 2010 the Company had no off-balance sheet arrangements.

RELATED PARTY TRANSACTIONS

One of the Company's consultants, Robert O. Williams III, Ph.D., also served as a member of the Board of Directors until June 2010. For consulting services rendered to the Company, during 2010 the Company paid \$31 and at December 31, 2010 had a \$62 current liability and \$94 long term liability payable to Robert Williams related to an October 2010 negotiated settlement of outstanding payables and termination of a consulting agreement between the Company and Robert Williams. During 2009 the Company incurred expenses totaling \$280 related to Robert Williams consulting and the current liability in 2009 was \$187. This related party transaction ended in 2010 when Dr. Williams did not stand for re-election to the Akela Board of Directors and the Company and Robert Williams terminated the consulting agreement.

During 2009, the Company incurred legal and tax consulting fees totaling \$73, for legal services provided by Knorr Rechtsanwälte, a firm associated with Dr. Günter Knorr, the Company's former Chairman of the Board. This related party relationship was terminated in 2009.

In addition, during 2009, the Company incurred expenses of \$114, for management services provided by PRI International Consulting Inc., a company directly controlled by Dr. Jaeger, a former CEO of the Company. This related party relationship was terminated in 2009.

In addition, during 2009 the Company incurred \$53 in expenses for financial consulting services performed by Charlestown Capital Advisors, LLC, a private investment company founded and managed by Raj Maheshwari, a former board member of the Company. This related party relationship was terminated in 2009.

These transactions are in the normal course of operations and are measured at the exchange amount of consideration established and agreed to by the related parties.

OUTSTANDING SHARE DATA

At March 31, 2011, the number of common shares issued and outstanding was 32,390,338. As of December 31, 2010, 2,161,893 options remained available for issuance under the Company's stock option plan and 6,228,758 warrants to purchase an equivalent amount of common shares at a prices ranging from Cdn \$1.50 to Cdn \$7.04.

DISCLOSURE CONTROLS AND PROCEDURES

Disclosure controls and procedures are designed to provide reasonable assurance that material information is gathered and reported to senior management on a timely basis so that appropriate decisions can be made regarding public disclosure. The Company's Chief Executive Officer and its Chief Financial Officer are responsible for establishing and maintaining disclosure controls and procedures. Based on an evaluation of the Company's disclosure controls and procedures (as defined in National Instrument 52-109 of the Canadian Securities Administrators), the Chief Executive Officer and Chief Financial Officer have concluded that the design and implementation of disclosure controls and procedures were effective as of December 31, 2010. However, they do not expect that the disclosure controls and procedures will prevent all errors and/or fraud. A control system, no matter how well conceived or operated, can provide only reasonable, not absolute assurance that the objectives of the control system are met.

CHANGES IN INTERNAL CONTROLS OVER FINANCIAL REPORTING

The Chief Executive Officer (CEO) and Chief Financial Officer (CFO) are responsible for designing internal control over financial reporting or causing it to be designed under their supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with Canadian generally accepted accounting principles. The CEO and CFO assessed the design and implementation of the Company's internal control over financial reporting as of December 31, 2010 and deemed them to be effective with no material weaknesses.

There have been no changes in the Company's internal control over financial reporting during the year ended December 31, 201 that have materially affected or are reasonably likely to materially affect its internal control over financial reporting.

OUTLOOK

Our proprietary drug development programs are characterized by extensive research efforts, rapid technology developments and intense competition. Our competitors include large and small pharmaceutical 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 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.

PharmaForm, our subsidiary focusing on contract drug formulation development and manufacturing services, has experienced significant increases in margins and we anticipate continued growth even as our drug delivery technologies compete with other existing drug delivery technologies and new drug delivery techniques that may be developed or commercialized in the future.

Various impacts to PharmaForm also include the risk that clients' drugs may not receive government approval, gain market acceptance, offer therapeutic or cost advantages over competing product candidates or may not be developed for a variety of other reasons.

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

- the efficacy, safety and reliability of our and our clients' product candidates;
- the timing and scope of regulatory approval of our and our clients' product candidates;
- the competitive landscape with respect to other contract development and manufacturing service organizations;
- our clients' ability to fund the development of their product pipeline;
- the speed at which we and our clients develop product candidates;
- product acceptance by physicians and other health care providers;
- the robustness of our technology;
- our ability to recruit and retain skilled employees; and
- the strength 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 recently launched a formulation of fentanyl using a buccal soluble film. Additionally, Nycomed has recently gained approval for a nasal formulation of fentanyl, and a similar product from Archimedes has been accepted for filing.

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.

CRITICAL ACCOUNTING ESTIMATES

(a) Property and equipment

Property and equipment are recorded at cost. Assets under capital leases are recorded at the present value of future minimum lease payments.

Amortization is computed over the estimated useful lives using the straight-line method over the following periods:

Laboratory equipment	5 to 7 years
Computer equipment	3 to 5 years
Furniture and office equipment	3 to 7 years
Leasehold improvements	Term of lease

(b) Intangible assets

The capitalized amount with respect to patents relates to direct costs incurred in connection with securing the patents. Patents are stated at cost and amortized using the straight-line method over the estimated useful lives ranging from ten to twenty years. Licenses, trademarks and intellectual property rights acquired are stated at cost and are amortized over their estimated useful lives of ten years using the straight-line method.

Other intangible assets are amortized using the straight-line method over the following periods:

Customer contracts and relationships	3 years
Non competition agreement	3 years
Computer software	3 years
FDA/DEA Certification	5 years

(c) *Impairment of long-lived assets and goodwill*

Long-lived assets, consisting of property and equipment and intangible assets with finite useful lives are tested for recoverability whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for long-lived assets, when the carrying amount of an asset to be held and used exceeds the sum of the undiscounted cash flows expected from its use and disposal; the impairment recognized is measured as the amount by which the carrying amount of the net asset exceeds its fair value. Fair value is the estimated value at which the asset would be bought or sold in a transaction between willing parties. The fair value against which the asset is measured may be established based on comparable information or transactions, or any other acceptable method of assessment.

Goodwill represents the excess of the cost of an acquired enterprise over the fair value of the assets acquired and liabilities assumed less any subsequent write downs for impairment. Goodwill is subject to an annual impairment test. Goodwill impairment is evaluated between annual tests upon the occurrence of certain events or circumstances. Goodwill impairment is assessed based on a comparison of the fair value of a reporting unit to the underlying carrying value of the reporting unit's net assets, including goodwill. When the carrying amount of the reporting unit exceeds its fair value, the fair value of the reporting unit's goodwill is compared with its carrying amount to measure the amount of impairment, if any.

(d) *Transaction costs*

Transaction costs related to held-for-trading financial assets are expensed as incurred. Transaction costs related to other liabilities and loans and receivables are added to the carrying value of the asset or netted against the carrying value of the liability and are then recognized over the expected life of the instrument using the effective interest method.

(e) *Income taxes*

The Company applies the asset and liability method to account for income taxes. Under this method, future income tax assets and liabilities are determined based on the differences between the financial reporting and the tax basis of assets and liabilities and are measured using substantively enacted tax rates and laws that are expected to be in effect in the periods in which the future tax assets or liabilities are expected to be realized or settled. The Company establishes a valuation allowance against future income tax assets if, based on available information, it is more likely than not that some or all of the future income tax assets will not be realized.

(f) *Revenue recognition*

The Company derives its revenues from licensing and co-development agreements and through providing contract services such as drug formulation, drug development and clinical drug manufacturing for pharmaceutical and biotech companies. Deferred revenues associated with co-development represent deferred license fees and payments received in advance of services being performed, milestones being reached or from final deliverables being provided. Revenues from licensing and co-development agreements are recognized as follows, for upfront and milestone payments which require the Company's ongoing involvement are deferred and amortized into income over the estimated development period, which is reviewed periodically and adjusted on a prospective basis.

Revenue for contract services is recognized as work is performed, and amounts are earned. The timing of cash received from contract services agreements can differ from when revenue is recognized. The Company considers amounts to be earned once evidence of an arrangement has been obtained, services are delivered, fees are fixed or determinable, and collectability is reasonably assured. For contracts with fees based on time and materials, revenue is recognized over the period of performance.

Revenues for fixed price contracts, depending on the specific contractual provisions and the nature of the deliverables, revenue may be recognized as milestones are achieved or when final deliverables have been provided.

At times, arrangements with customers involve multiple elements. The deliverables in each arrangement are evaluated at contract inception to determine whether they represent separate units of accounting. The total fee for the arrangement is allocated to each unit of accounting based on its relative fair value, taking into consideration any performance, cancellation or termination provisions. Fair value for each element is generally established based on the sales price charged when the same or similar services are sold separately to customers. Revenue is recognized when revenue recognition criteria for each unit of accounting is met.

Sales taxes collected from customers are presented on a net basis.

(g) Research and development expenses

Research and development costs (development costs did not meet the criteria for capitalization pursuant to GAAP) are expensed as incurred and include salaries, benefits and other operating costs such as outside services, supplies and allocated overhead costs. The Company performs research and development for its proprietary products and technology development and for others pursuant to collaboration agreements. For proprietary products and internal technology development programs, the Company invests its own funds without reimbursement from a third party. Costs associated with the treatment phase of clinical trials are accrued based on the total estimated cost of the clinical trials and are expensed ratably based on patient enrolment in the trials. Costs associated with the start-up and reporting phases of the clinical trials are expensed as incurred.

Collaboration agreements typically include the development and licensing of the Company's technology. Under these agreements, the Company may be reimbursed for development costs, entitled to milestone payments when and if certain development or regulatory milestones are achieved, compensated for the manufacture and supply of clinical and commercial product and entitled to royalties on sales of commercial product. All of the Company's collaboration agreements are generally cancellable by the partner without significant financial penalty.

(h) Government assistance

Amounts received resulting from government assistance programs, including grants and investment tax credits for research and development, are either reflected as a reduction of the cost of the asset or expense to which they relate at the time the eligible expenditures are incurred or are treated as other income for grants received in periods after the eligible expenditures occurred. Tax credits are recorded in the accounts when reasonable assurance exists that they will be realized. In 2010 the Company recorded revenue of \$727 in US Qualifying Therapeutic Discovery Grants. During 2010, \$238 was received and the balance is included in accounts receivable (2009 – nil). In 2009, the conditions relating to a Finnish grant were no longer respected and the grant was recorded as a long-term debt with a corresponding adjustment to net income being made (Note 15).

(i) Foreign currency transactions

The Company adopted the US dollar as its functional and reporting currency effective January 1, 2007, as a significant portion of its revenues, expenses, assets and liabilities were as of that date denominated in US dollars. Prior to that date, the Company's operations were measured in Canadian dollars and the consolidated financial statements were expressed in Canadian dollars. All opening assets and liabilities were translated into US dollars using the exchange rate in effect on January 1, 2007. The change in the functional currency resulted in a currency translation adjustment of \$3,110 as of December 31, 2006, which is reflected in accumulated other comprehensive income, a separate component of shareholders' deficiency.

Transactions denominated in currencies other than the functional currency are measured and recorded in the functional currency using the exchange rate in effect at the date of the transaction or the average rate for the period in the case of revenue and expense transactions. Monetary assets and liabilities are revalued into the functional currency at each balance sheet date using the exchange rate in effect at that date, with any resulting exchange gains or losses being credited or charged to the consolidated statements of operations.

The foreign subsidiaries of the Company are considered to be integrated. As a result, the subsidiary accounts are translated into US dollars using the temporal method. Under this method, monetary assets and liabilities are translated at the exchange rates in effect as the balance sheet date and any resulting foreign exchange gain or loss is reflected in the consolidated statement of operations. Non-monetary assets and liabilities are translated at historic

rates. Revenue and expenses are translated at the average exchange rate during the period. Foreign exchange gains or losses are included in the consolidated statement of operations

(j) Stock-based compensation

Employee stock options are accounted for using the fair value based method. Under this method, compensation cost is measured at fair value at the date of grant and is expensed over the award's vesting period using the straight line method. The Company determines the fair value of stock options granted using the Black-Scholes option pricing model. Forfeitures are recorded as incurred.

(k) Earnings per share

Basic earnings per share are computed by dividing net earnings by the weighted average number of common shares outstanding during the year. Diluted earnings per share are computed in a manner consistent with basic earnings per share except that the weighted average number of shares outstanding is increased to include additional shares from the assumed exercise of options and warrants, if dilutive. The number of additional shares is calculated by assuming that outstanding options and warrants were exercised and that the proceeds from such exercises are used to repurchase common shares at the average share price for the reporting period.

(l) Leases

Leases are classified as either capital or operating in nature. Capital leases are those which substantially transfer the benefits and risks of ownership to the lessee. Obligations under capital leases are reduced by the principle portion of lease payments. The imputed interest portion of lease payments is charged to expense. Payments required under operating leases are recorded as an expense.

(m) Use of estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and revenue and expenses for the period reported.

Items requiring the use of significant management estimates include estimating the future cash flows for purposes of assessing the going concern assumption, the advancement of work on certain contracts for revenue recognition purposes, estimating the useful lives of long-lived assets, including property and equipment and intangible assets, estimating the fair value of assets and liabilities in connection with business acquisitions and impairments, as well as estimating stock-based compensation and the recoverability of research tax credits receivable and long-lived asset impairment assessments, future tax assets and the fair value of financial instruments. The reported amounts and note disclosures are determined to reflect the most probable set of economic conditions and planned courses of action. Actual results could differ from those estimates.

Future Accounting Changes

i) International Financial Reporting Standards - Background, project structure and project progress In March 2006, the CICA released its plan to adopt International Financial Reporting Standards as issued by the International Accounting Standards Board ("IFRS"). After a five year transitional period, at the end of 2011, Canadian Generally Accepted Accounting Principles ("Canadian GAAP") will cease to exist as a separate basis of financial reporting for public enterprises, with the Company's first IFRS financial information to be prepared from January 1, 2011.

The Company will issue consolidated financial statements in accordance with IFRS for the year ended December 31, 2011, with comparative information.

Preliminary Impact Assessment

The Company has completed in Q1 2011 a diagnostic study of the conversion of its consolidated financial statements to IFRS, with the assistance of external consultants. The study identified the principal differences between the Company's records using existing Canadian GAAP and IFRS standards, and evaluated the impact on the business processes information systems, developing an implementation program determine the full impact on the business.

The results of this assessment identified:

- Preliminary analysis of all Canadian GAAP to IFRS differences and IFRS 1 elections and resulting prioritization of high, medium and low impact areas of focus for the Company based on potential impact;
- Preliminary resource requirements;
- Preliminary training requirements; and
- A preliminary IFRS Transition Plan (details outlined below).

IFRS Transition Plan

During Q2 2011, the Company will complete its IFRS Transition Plan. This will include:

- Detailed analysis of all Canadian GAAP to IFRS differences;
- Detailed analysis and selection of any relevant IFRS 1 elections;
- An established project structure and governance practices;
- Identification and allocation of resources (combination of internal and external);
- Development and execution of a training program, and
- Assessment of impact on data systems, internal controls over financial reporting, and business activities, such as financing and compensation arrangements.

Potential accounting changes as a result of transition to IFRS

The Company has implemented a detailed review of the potential impact of International Financial Reporting Standards, IFRS, on our accounting policies, knowledge of staff and computerized system requirements. Outlined below is a brief summary of select IFRSs that may impact the Company, their differences from Canadian GAAP and their potential impact. The list is not comprehensive and does not include all of the differences from Canadian GAAP for the standards noted. Also, the list does not include all of the standards that may require changes for the transition to IFRS, as issues may arise during our detailed analysis assessment. Some of the standards not presented in the table could have a significant impact on the Company's consolidated financial statements.

Financial Instruments – Warrants

Under Canadian GAAP, the Company has warrants for shares that have been issued at fair value in Canadian Dollars. Such warrants have been accounted for as equity instruments.

Under IFRS, where such financial instruments are issued and the strike price is in a currency other than functional currency, the counterparty does not have a right to subscribe for a fixed number of the entity's shares for a fixed amount of cash and therefore is considered to be a liability rather than equity. When this "fixed-for-fixed" criterion is not met, and the warrants would be considered debt, this would result in them being remeasured at fair value at each reporting date, and could lead to volatility in earnings.

Foreign Exchange Translation

Under Canadian GAAP, the Company re-assessed its functional currency based on the criteria in Canadian GAAP and chose the US dollar as its functional and reporting currency effective January 1, 2007, as a significant portion of its revenues, expenses, assets and liabilities were as of that date denominated in US dollars.

Under IFRS, IAS 21 "Foreign Currency Translation" provides guidance on indicators that should be considered in determining the functional currency of an entity, including a hierarchy of primary and secondary indicators. The primary economic environment in which an entity operates is normally the one in which it primarily generates and expends cash. Such hierarchy of functional currency criteria could result in a different conclusion on the functional currency of the Company. Possible changes in functional currency determination may also affect accounting for Warrants.

Share-Based Payments

The Company has issued stock options with graded vesting. These are accounted for as one award under Canadian GAAP. In addition, the Company also currently accounts for forfeitures when they occur. Under Canadian GAAP, the Company has granted common share purchase warrants to the underwriters on its IPO, which expire 2 years from March 27, 2008. The Company has fair valued these warrants using the black-scholes pricing model.

Under IFRS 2, the awards with graded vesting must be accounted for as separate awards. Forfeitures must be estimated when the stock options are issued. Share-based payments to non-employees, including those provided to the underwriters fall under the auspices of IFRS 2 and generally are measured based on the fair value of the goods or services received.

The Company will also consider in the detailed analysis phase any possible IFRS 1 elections that affect its accounting under IFRS 2.

Revenue Recognition

Under Canadian GAAP, the Company derives its revenues from a variety of sources, notably from licensing and co-development agreements and through providing contract services such as drug formulation, drug development and limited run drug manufacturing for pharmaceutical and biotech companies. The Company recognizes revenues generally when work is performed and amounts are earned and/or when milestones are reached, except for instances where such which require the Company's ongoing involvement are deferred and amortized into income over the estimated development period, which is reviewed periodically and adjusted on a prospective basis.

Under IFRS, the Company will recognize revenue when it is probable that future economic benefits will flow to the entity and those benefits can be measured reliably. Revenue on sales of goods is only recognized when, inter alia, the significant risks and rewards of ownership have been transferred to the buyer and the seller does not retain either control of the goods, or continuing involvement, to the degree associated with ownership. For services, evidence is required that a service has been delivered by requiring the seller to be able to measure reliably the stage of completion of the transaction. The recognition of revenue by reference to the stage of completion of a transaction is often referred to as the percentage of completion method. Under this method, revenue is recognized in the accounting periods in which the services are rendered. The determination of the stage of completion may be made on either input or output measures and the most appropriate measure will depend on the nature of the contract. In the detailed assessment phase, the Company will be reviewing its significant revenue contracts to identify whether any differences could occur in the timing of revenue recognition.

Business Combinations

IFRS 3, Business Combinations, may be elected to be applied retrospectively or prospectively. The retrospective basis would require restatement of some or all of the business combinations that occurred prior to the transition date. The Company will avail itself of this exemption and will not restate its business acquisitions prior to the transition date. However, a determination is also required of existing assets and liabilities as at the date of transition to IFRS to ensure that such measurement previously performed under Canadian GAAP would be appropriate under IFRS. An exercise is currently in progress to determine any such items under IFRS 3 (Revised).

Property Plant & Equipment

Under IFRS, IAS 16 “Property Plant and Equipment” requires that each part of PP&E that has a cost significant in relation to the overall cost of the item should be depreciated separately. Under Canadian GAAP, there is less comprehensive guidance on componentization and as a result, upon adoption of IFRS there may be some adjustments as the Company will review its accounting in this area during the detailed assessment phase to consider whether any elements of its property, plant and equipment should be componentized.

Provisions

Under Canadian GAAP, the Company has recognized a number of provisions in relation to employee severance and other various non-recoverable costs associated with product development and an abandoned enterprise resource planning (ERP) system.

Under IFRS, the guidance used for determining when a contingent liability becomes recognized as a provision is different than under Canadian GAAP. The term probable is used for describing a situation in which the outcome is “more likely than not to occur”. This is normally denoted by a chance being greater than 50% probability, which is lower than Canadian GAAP, which generally uses 75%. The Company will review contingent liabilities at the each reporting date during its transition to IFRS and will determine whether any adjustments are required during the detailed assessment phase.

Research & Development Costs

Under Canadian GAAP, the measurement and recognition of research and development costs are similar to IFRS.

Under IFRS, Research and development costs are considered separately. Internal research expenditure is expensed as incurred. Internal development expenditure is capitalized if specific criteria are met. Development is the application of research findings or other knowledge to a plan or design for the production of a new product before commercial production or use of the product has begun. Under IFRS, any possible development assets to be capitalized when measured would also be reviewed for impairment, and the Company will determine this during Q2 2011.

Presentation & Disclosure

IFRS requires significantly more disclosure than GAAP for certain standards. In some cases, IFRS also requires different presentation on the balance sheet and income statement.

At this time, the Company cannot quantify the impact of IFRS to its consolidated financial statements. The Company will finalize its quantification of differences and detailed analysis prior to the end of Q2 2011 when it will prepare its first IFRS financial statements for the period ended March 31, 2011. Those conclusions and accounting policy choices will be reported on when finalized.

IASB Project Timelines

The IASB has several projects slated for completion in 2011 that may significantly impact financial statements prepared under IFRS, and which will therefore be relevant to the Company when issued. The Company continues to monitor the IASB’s progress on these projects and their impact on the Company’s transition to IFRS.

Impact on Information Systems and Technology

It is anticipated that the adoption of IFRS will have some impact on information systems requirements. The Company is assessing, through discussion with external consultants, the need for systems upgrades or modifications to ensure an efficient conversion to IFRS, although management believes currently that it’s unlikely that there would be any significant modifications required to existing systems and processes. However, the impact and changes to systems are on-going and will be prioritized as part of the project.

Impact on Reporting and Internal Controls

In accordance with the Company’s approach to certification of internal controls required under Canadian Securities Administrators’ National Instrument 52-109, all entity-level, information technology, disclosure and business process controls will require updating and testing to reflect changes arising from the conversion to IFRS.

Where material changes are identified, these changes will be mapped and tested to ensure that no material control deficiencies exist as a result of the Company's conversion to IFRS.

Impact on Business

The Company anticipates that the transition to IFRS may have an impact on its business practices, and will review this further during the detailed assessment phase being carried out in Q2 1011.

ii) **Section 1582, Business Combinations:** This new Section will be applicable to business combinations for which the acquisition date is on or after the Company's interim and fiscal year beginning January 1, 2011. Early adoption is permitted. The section improves the relevance, reliability and comparability of the information that a reporting entity provides in its financial statements about a business combination and its effects. The Company has determined that Section 1582, Business Combinations will not have an impact on the Company's interim or annual financial statements beginning January 1, 2011.

iii) **Section 1601, Consolidated Financial Statements:** This new Section will be applicable to financial statements related to the Company's interim and fiscal year beginning on or after January 1, 2011. Early adoption is permitted. This section establishes standards for the preparation of the consolidated financial statements. The Company has determined that Section 1601, Consolidated Financial Statements will not have an impact on the Company's interim or annual financial statements beginning January 1, 2011.

iv) **Section 1602, Non-controlling interest:** This new Section will be applicable to financial statements related to the Company's interim and fiscal year beginning on or after January 1, 2011. Early adoption is permitted. This section establishes standards for accounting for a non-controlling interest in a subsidiary in consolidated financial statements subsequent to a business combination. The Company has determined that Section 1602, Non-controlling interest will not have an impact on the Company's interim or annual financial statements beginning January 1, 2011.

v) **In December 2009, the EIC** of the Accounting Standards Board issued EIC-175, *Multiple Deliverable Revenue Arrangements*, which addresses certain aspects of accounting by a vendor for arrangements under which it will perform multiple revenue-generating activities, amending the previous guidance under EIC-142, *Revenue Arrangements with Multiple Deliverables*. The amendments require a vendor to allocate arrangement consideration at the inception of an arrangement to all deliverables using the relative selling price method, thus prohibiting the use of the residual method. EIC-175 also changes the level of evidence of the standalone selling price required to separate deliverables when more objective evidence of the selling price is not available.

EIC-175 may be applied prospectively and must be applied to revenue arrangements with multiple deliverables entered into or materially modified in the first annual fiscal period beginning on or after January 1, 2011. Early adoption is permitted. The Company has determined that EIC-175, will not have an impact on the Company's interim or annual financial statements beginning January 1, 2011.

RISKS AND UNCERTAINTIES

Risks Related to Financing Our Business

We have incurred operating losses and anticipate that we may 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.

Akela historically has incurred significant net losses (see note 1 to the financial statements). The Company has funded such losses with external debt, share issuances, exclusive licensing and development agreements, government grants and working capital. Our consolidated net results for the twelve months ended December 31, 2010 and 2009 was \$1.3 million in net income and \$20.9 million in net loss, respectively. As of December 31, 2010, we had cash of \$447, net current liabilities of \$8,173 and an accumulated deficit of \$24,290.

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 8 and 10 to the financial statements). 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. (See note 5 to the financial statements).

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. These continued efforts to strive for profitability have seen the generation of consolidated positive EBIDTA for the fiscal year ending 2010 as well as the first year of positive net income in recent operating history for the Company.

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. We believe 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 (\$0.39 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 using a different CRO. The preparatory phase of these studies is complete but the program has been put on hold until additional sources of funding are secured.

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

On February 9, 2009, we announced the implementation of a significant cost reduction program in order to preserve cash for our continuing operations. The enrollment 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, this milestone was achieved. The remaining \$1,800 million was received by Akela on August 6, 2010. All milestone funding is contractually 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 favorable 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 FDCA, was enacted as part of the *Drug Price Competition and Patent Term Restoration Act of 1984* (United States), otherwise known as the Hatch-Waxman Amendments. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. This provision allows the FDA to rely for approval of the NDA on data not developed by the applicant, such as published literature or the agency’s finding of safety and effectiveness of a previously approved drug.

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

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

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

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

The FDA has substantial discretion in the drug approval process. Despite the time and expense exerted by us, failure can occur at any stage, and we could encounter problems that cause us to abandon clinical trials or to repeat or

perform additional preclinical studies and clinical trials. The number of preclinical studies and clinical trials that will be required for FDA approval varies depending on the drug candidate, the disease or condition that the drug candidate is designed to address, and the regulations applicable to any particular drug candidate. The FDA can delay, limit or deny approval of a drug candidate for many reasons, including:

- a drug candidate may not be deemed safe or effective;
- the FDA may not find the data from preclinical studies and clinical trials sufficient;
- the FDA may not approve our third-party manufacturer's processes or facilities;
- the FDA may change its approval policies or adopt new regulations; or
- third-party products may enter the market and change approval requirements.

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

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

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

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

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

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

Our product candidates may be strictly regulated by the DEA. The DEA closely regulates those drugs that are defined as controlled substances or listed chemicals by the *Controlled Substances Act* (United States) and its amendments and implementing regulations. Under U.S. federal law, a person, including an individual or corporation, who manufactures, distributes, dispenses, imports, or exports any controlled substance, or who proposes to engage in these activities, must register with the DEA, unless exempt. In addition, manufacturers are subject to DEA-established procurement, production, and manufacturing quotas. Registrants must comply with a series of regulatory requirements, and have detailed procedures in place, relating to drug labeling, packaging, security,

shipment and disposal; customer, clinical investigator, or other 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 willfully disclose our proprietary information to competitors. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time-consuming and uncertain. In addition, non-Canadian or U.S. courts are sometimes less willing than Canadian and U.S. courts to protect trade secrets. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secrets against them and our business could be harmed.

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

On behalf of Management,



Rudy J. Emmelot
Principal Financial Officer
Austin, Texas
March 31, 2011