

## **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 November 15, 2010. 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 (formerly 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 November 15, 2010. 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 analysis explains the material variations in the unaudited consolidated statements of operations, financial position and cash flows of Akela for the three and nine months ended September 30, 2010 and 2009.

This document should be read in conjunction with our unaudited interim consolidated financial statements for the three and nine months ended September 30, 2010 and related notes included therein and our annual consolidated financial statements and notes thereto included in the Company's annual report for the year ended December 31, 2009 which have been prepared in accordance with Canadian generally accepted accounting principles ("GAAP"). 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.

## ***Corporate Restructuring and Reorganization***

In 2009 we announced and undertook two corporate restructuring initiatives. On February 9, 2009 we announced the implementation of measures to cut costs and preserve cash. The reduction in costs targeted the Pharmaceutical Development programs as well as PharmaForm. On September 3, 2009, we announced a comprehensive corporate restructuring designed to achieve several operational objectives. As part of its efforts to preserve its ability to execute on its development strategy for Fentanyl TAI FUN® and to optimize the infrastructure required to support its PharmaForm clients, the Company reduced its head count by 32 employees. Akela also announced the closure of its international operations and the centralization of the Company's operational headquarters in Austin, Texas. We further streamlined our PharmaForm operations and increased operating margins and efficiencies during the first three quarters of 2010. These changes included the departure of the senior vice president, business development and the vice president of manufacturing. We currently operate with a workforce of 67 employees.

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

## ***Business Acquisition***

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

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

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

## ***Other Recent Events***

On October 29, 2010, we were awarded through the United States Qualifying Therapeutic Discovery Grant Program federal grants of \$0.5 million to facilitate continued development of our research programs.

## **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 will continue to incur significant operating losses. Our consolidated net loss for the nine months ended September 30, 2010 and 2009 was \$247, and \$6,934, respectively. As of September 30, 2010, we had cash of \$930, net current liabilities of \$8,670 and an accumulated deficit of \$25,924.

The unaudited interim 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 quarters prior to the third quarter of 2010 have also been reclassified in order to conform to the presentation adopted in the three and nine months ended September 30, 2010.

### **Three months ended September 30, 2010**

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

During the three months ended September 30, 2010, the Company reported net income of \$0.1 million compared with a net loss of \$3.2 million in the prior year.

	2010	2009
Revenues	\$ 3,984	\$ 3,053
Direct costs	1,307	2,756
Selling, general and administrative	1,231	851
Research and development	21	343
Stock-based compensation	7	44
Amortization expense	405	817
Interest on long-term debt	103	72
Unrealized loss (gain) on securities held for trading	2	(15)
Foreign exchange	793	868
Restructuring	-	527
Net income (loss)	\$ 115	\$ (3,210)

#### **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 September 30, 2010 and 2009 were as follows:

	2010	2009	Change
Co-development revenue	\$ 837	\$ 878	\$ (41)
Contract services revenue	3,147	2,175	972
Total revenue	\$ 3,984	\$ 3,053	\$ 931

*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 7<sup>th</sup> 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.

Co-development revenue decreased to \$0.8 million for the three months ended September 30, 2010 from \$0.9 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 30, 2016.

*Contract services revenue.* Contract services revenue increased to \$3.1 million for the three months ended September 30, 2010 from \$2.2 million in 2009. The third quarter of 2010 saw increased revenue growth that is the result of the comprehensive corporate restructuring begun in September 2009. During the first half of 2010 operations were further 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. Direct costs declined to \$1.3 million for the three months ended September 30, 2010 from \$2.8 million during the previous year primarily as a result of the Company’s restructuring initiatives started in 2009.

*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. The Company recorded SG&A of \$1.2 and \$0.9 million for the three months ended September 30, 2010 and 2009, respectively. The increase in SG&A over the previous year resulted from legal charges related to the resolution of litigation involving former executives as well as other one time charges. These charges were partially offset by cost reductions resulting from the Company’s restructuring initiative started in 2009.

*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 September 30, 2010 decreased to nil from \$0.3 million for the same period in 2009 as a direct result of the Company’s cost reduction effort. As part of this initiative, no new patients are being enrolled into the Fentanyl TAIFUN® clinical program until additional sources of funding are secured. The Company has terminated its licensing agreement to CGRP, and the GHRH program has been placed on hold until an out-licensing agreement is achieved, program specific financing is secured or the programs are sold. Akela’s international operations were closed during the fourth quarter of 2009.

*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. The decline in stock-based compensation from the previous year reflects 1.6 million employee stock option cancellations which occurred primarily as a result of the Company’s reduction in force which took effect in February and September of 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 September 30, 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. The increase in expense over the previous year reflects interest associated with the Company's provision for repayment of government grants. (See "*Provision for Repayment of Government Grants*").

*Unrealized loss on securities held for trading.* A decline in the fair value of common stock purchase warrants received as part of a settlement with LAB Research Inc. (LRI) resulted in an unrealized loss on securities held for trading for the three months ended September 30, 2010. An increase in the fair value these securities resulted in an unrealized gain during the same period of the previous year. (See "*Settlement with LRI*").

*Foreign Exchange.* Although our functional currency is the US dollar, a significant portion of our assets and liabilities are denominated in Canadian dollars and Euros. The weakening of the US dollar and its impact on the balance of Euro denominated debt and trade payables resulted in foreign exchange losses during the three months ended September 30, 2010 and 2009, respectively.

*Corporate Restructuring.* On September 3, 2009, Akela announced a comprehensive corporate restructuring in order to preserve cash for continuing operations. In connection with this cost reduction effort, the Company terminated approximately 32 employees and recorded restructuring charges of \$527, which included an \$84 impairment loss on property and equipment, \$251 for employee severance and \$214 in non-recoverable costs associated with the abandonment of business software systems. These charges were partially offset by \$22 in one time non-cash gains resulting from management's successful negotiation of settlement plans to repay outstanding current obligations to various claimants for the Company's product development program. Gains from settlement negotiations during the third quarter of 2009 were ultimately reversed during the 4th quarter of 2009 when the Company did not meet its payment obligations under these arrangements. (See notes 1, 8 and 10).

## ***Nine months ended September 30, 2010***

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

During the nine months ended September 30, 2010, the Company reported a net loss of \$0.2 million compared with \$6.9 million in the prior year.

	2010	2009
Revenues	\$ 9,635	\$ 10,845
Direct costs	4,138	6,803
Selling, general and administrative	4,292	4,098
Research and development	279	2,624
Stock-based compensation	22	201
Amortization	1,138	2,391
Interest on long-term debt	283	187
Unrealized loss (gain) on securities held for trading	78	(69)
Foreign exchange (gain) loss	(348)	788
Settlement with LRI		(1,664)
Provision for repayment of government grants		1,544
Restructuring costs	-	876
Income (loss)	\$ (247)	\$ (6,934)

### ***Revenues***

Revenues for the Nine months ended September 30, 2010 and 2009 were as follows:

	2010	2009	Change
Co-development revenue	\$ 2,126	\$ 2,697	\$ (571)
Contract services revenue	7,508	8,139	(631)
Interest revenue	1	9	(8)
Total revenue	\$ 9,635	\$ 10,845	\$ (1,210)

*Co-development revenue.* Co-development revenue decreased to \$2.1 million for the nine months ended September 30, 2010 from \$2.7 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 30, 2016.

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.

*Contract services revenue.* Contract services revenue decreased to \$7.5 million for the nine months ended September 30, 2010 from \$8.1 million in 2009. A contraction of the economy and limited funding of core research and development projects for corporations and clients within the pharmaceutical and biotech industries has adversely impacted our contract services operations. We anticipate this trend to gradually reverse in the months ahead as the economy slowly recovers from its recent recessionary lows.

*Interest revenue.* Interest revenue relates to interest earned on restricted cash balances. The decrease in interest revenue is due to a decrease in these balances.

## ***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 \$4.1 million for the nine months ended September 30, 2010 from \$6.8 million during the previous year primarily as a result of the Company's restructuring initiatives started in 2009.

*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. The Company recorded SG&A of \$4.3 million and \$4.1 million for the nine months ended September 30, 2010 and 2009, respectively. The increase in SG&A over the previous year resulted from legal charges related to the resolution of litigation involving former executives as well as other one time charges. These charges were partially offset by cost reductions resulting from the Company's restructuring initiative started in 2009.

*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 nine months ended September 30, 2010 decreased to \$0.3 million from \$2.6 million for the same period in 2009, in part, as a result of the Company's cost reduction efforts. As part of this initiative, no new patients are being enrolled into the Fentanyl TAIFUN® clinical program until additional sources of funding are secured. The Company has terminated its licensing agreement to CGRP, and the GHRH program has been placed on hold until an out-licensing agreement is achieved, program specific financing is secured or the programs are sold. Akela's international operations were closed during the fourth quarter of 2009.

*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. The decline in stock-based compensation from the previous year reflects 1.6 million employee stock option cancellations which occurred primarily as a result of the Company's reduction in force which took effect in February and September of 2009.

*Amortization expense.* Amortization includes amortization of property and equipment as well as intangible assets. Amortization expense decreased to \$1.1 million for the nine months ended September 30, 2010 from \$2.4 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. The increase in expense over the previous year reflects interest associated with the Company's provision for repayment of government grants. (See "*Provision for Repayment of Government Grants*").

*Unrealized loss on securities held for trading.* A decline in the fair value of common stock purchase warrants received as part of a settlement with LAB Research Inc. (LRI) resulted in an unrealized loss on securities held for trading for the nine months ended September 30, 2010. An increase in the fair value these securities resulted in an unrealized gain during the same period of the previous year. (See "*Settlement with LRI*").

*Foreign Exchange.* Although our functional currency is the US dollar, a significant portion of our assets and liabilities are denominated in Canadian dollars and Euros. The strengthening of the US dollar and its impact on the balance of Euro denominated debt and trade payables resulted in foreign exchange gains during the nine months ended September 30, 2010. A weakening of the US dollar and its impact on the balance of Euro denominated debt and trade payables resulted in foreign exchange losses during the same respective period in 2009.

*Settlement with LRI.* On March 10, 2009, the Company agreed to accept a payment of \$2,000 Cdn (\$1,562 US) and 500,000 common share purchase warrants with an exercise price of \$0.50 Cdn (\$0.39 US) from LRI as full and final settlement of its lawsuit relating to a failed Fentanyl TAIFUN® toxicology study. The fair value of the warrants, \$130 Cdn (\$101 US), together with the cash proceeds received as part of this settlement resulted in a one-time gain of \$1,664.

*Provision for Repayment of Government Grants.* In 2004 and 2005, 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 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 the loans would not be collected prematurely but made a demand for repayment of the grants, together with interest. In April 2009 the Company's appeal against this decision 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, a charge of \$1,544, the US dollar equivalent of the grants received \$1,269 (€956), together with interest from July 2007 through June 30, 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, the Company's \$1,544 provision associated with Tekes' claim has been classified as long-term debt (see note 8). Upon the advice of legal counsel, the Company's estimated obligation, \$1,602 (€1,309), has 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. The Company continues to accrue interest on the Tekes' claim at a provisional rate of 9.5% until a formal amortization schedule is received.

*Corporate Restructuring.* In February and September of 2009, the Company undertook measures to cut costs in order to preserve cash for its continued operations. In connection with this cost reduction effort, the Company terminated approximately 72 employees and recorded restructuring charges of \$876, which included a \$220 impairment loss on property and equipment, \$395 for employee severance, \$356 in capital expenditures associated with the development of commercial TAIFUN® injection moulds, \$214 in non-recoverable costs associated with the abandonment of business software systems, \$79 in charges resulting from the termination of the Company's license agreement to CGRP, a former non-pain product candidate, and \$68 in charges to settle current outstanding trade payables. These charges were partially offset by \$456 in one time non-cash gains resulting from management's successful negotiation of settlement plans to repay outstanding current obligations to various claimants for the Company's product development program. Gains from settlement negotiations during the second and third quarter of 2009 were ultimately reversed during the 4th quarter of 2009 when the Company did not meet its payment obligations under these arrangements. (See notes 1, 8 and 10).

## QUARTERLY RESULTS

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

Quarter	Revenues	Net Income (Loss)		
		Basic	Diluted	
Quarter ended September 30, 2010	3,984	115	0.0	0.0
Quarter ended June 30, 2010	3,050	77	0.0	0.0
Quarter ended March 31, 2010	2,601	(439)	(0.01)	(0.01)
Quarter ended December 31, 2009	3,048	(14,063)	(0.46)	(0.46)
Quarter ended September 30, 2009	3,053	(3,210)	(0.10)	(0.10)
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)
Quarter ended December 31, 2008	3,527	(13,604)	(0.63)	(0.63)

## LIQUIDITY AND CAPITAL RESOURCES

### *Going Concern Uncertainty*

Akela historically has incurred significant net losses (see note 1). The Company has funded such losses with external debt, share issuances, exclusive licensing and development agreements, government grants and working capital. Our consolidated net loss for the nine months ended September 30, 2010 and 2009 was \$247, and \$6,934, respectively. As of September 30, 2010, we had cash of \$930, net current liabilities of \$8,670 and an accumulated deficit of \$25,924.

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 (see notes 8 and 10). 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 we announced and undertook two corporate reorganizations. On February 9, 2009 we announced the implementation of measures to cut costs and preserve cash. The reduction in costs targeted the Pharmaceutical Development programs as well as, PharmaForm. On September 3, 2009, we announced a comprehensive corporate restructuring designed to achieve several operational objectives. As part of its efforts to preserve its ability to execute on its development strategy for Fentanyl TAIFUN® and to optimize the infrastructure required to support its PharmaForm clients, the Company reduced its head count by 32 employees to a workforce of 65. Further, we also announced the closure of our 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 our proprietary compounds from our current and new commercial partners. Until we succeed in raising additional capital through partner funding, equity or debt financing we are not recruiting any further patients into clinical studies.
- c) We are no longer funding the scientific development of GHRH, HspE7, AKL 0721 or Poly ICR. While we are actively seeking licensing arrangements as well as other external development strategies, we 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, we may be forced to terminate these programs as we look to strategically focus our current remaining capital resources on Fentanyl TAIFUN®.
- d) On April 16, 2010, we announced that we 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 instalments of \$10 through March 2020. (See note 7).
- e) 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. ("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. 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, 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 September 24, 2010, we established a fully secured line of credit, bearing annual interest at 15% with certain shareholders. MacBay Partners LP agreed to extend the line of credit for working capital in an amount not to exceed \$0.5 million. The line of credit facility replaced the previously announced line of credit with of January, May and June of 2010. The previous line of credit with shareholders Ingalls & Snyder Value Partners LP, and MacBay Partners LP was terminated on September 24, 2010. Outside of their respective holdings in the Company, neither Ingalls & Snyder Value Partners LP, nor MacBay Partners LP are insiders to the company.
- g) On October 29, 2010, we were awarded through the United States Qualifying Therapeutic Discovery Grant Program federal grants of \$0.5 million to facilitate continued development of research programs.
- h) In order to ensure the availability of current capital resources, we 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.

### ***Cash Position***

Our cash balance at September 30, 2010 was \$0.9 million compared with \$0.1 million at December 31, 2009. Net cash flows for the nine months ended September 30, 2010 and 2009 are summarized as follows:

	2010	2009	Change
Cash provided by (used in) operating activities	\$ 698	\$ (926)	\$ 1,624
Cash used in financing activities	(773)	(620)	(153)
Cash provided by investing activities	898	8	890
Net increase (decrease) in cash	<u>\$ 823</u>	<u>\$ (1,538)</u>	<u>\$ 2,361</u>

### **Operating Activity**

Net cash provided by operations for the nine months ended September 30, 2010 was \$0.7 million as compared to \$0.9 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 7<sup>th</sup> patient in Akela's Fentanyl Taifun® Phase III clinical study. Excluding these one time events, a \$1.6 million improvement in operating cash flow for the nine months ended September 30, 2010 over the previous year resulted from cost reductions associated with the Company's restructuring initiatives announced in February and September of 2009.

### **Financing Activity**

Net cash used by financing activities for the nine months ended September 30, 2010 was \$0.8 million as compared to \$0.6 million used by financing activities for the same period during the previous year. Net cash used by financing activities for the nine months ended September 30, 2010 and 2009 consisted of repayments on long-term debt and capital leases.

### **Investing Activity**

Net cash provided by investing activities for the nine months ended September 30, 2010 was \$0.9 million as compared to \$0.0 million used by investing during 2009. Investing activities during the first and second quarter of 2010 includes \$0.9 million of draws on restricted cash held on deposit as security for the Davis Spring Facility to satisfy current lease payments. Investing activities for the prior year benefited from the acquisition of Nventa, which netted the Company cash of approximately \$1.1 million after transaction costs (see note 3), partially offset by \$1.0 million in capital expenditures, primarily for tenant improvements associated with the Davis Spring Facility 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:

	2010	2011	2012	2013	2014	2015+	Total
Operating leases	378	623	-	-	-		\$ 1,001
Capital leases *	135	198	-	-	-	-	333
Service contracts	280	560	47	-	-	-	887
Long-term debt *	779	894	814	734	411	4,348	7,980
	<b>1,572</b>	<b>2,275</b>	<b>861</b>	<b>734</b>	<b>411</b>	<b>4,348</b>	<b>\$ 10,201</b>

\* Long-term debt and capital leases include principal and related interest.

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 former 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 September 30, 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 September 30, 2010, the Company believes it has complied with the terms of the advance milestones.

On June 17, 2009, the Company announced that we had signed an amendment to our 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 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. 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®.

(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 Lermer. In Michael Crowley vs. Formulation Technologies, LLC doing business as (“d/b/a”) PharmaForm, the arbitrator found in favor of Mr. Crowley. As a result, Mr. Crowley has been awarded \$325 for payment under Mr. Crowley’s employment agreement, commissions and vacation accruals earned over his employment period, partial payment of Mr. Crowley’s legal fees and Mr. Crowley’s out-of-pocket expenses. In February 2010, Mr. Crowley filed suit against Formulation Technologies, LLC (“d/b/a”) PharmaForm to confirm an arbitration award. On July, 2, 2010 the Court appointed receiver levied \$442 from PharmaForm’s financial accounts. October 25, 2010 the Court agreed to discharge the receiver and released \$92 plus interest as reimbursement to PharmaForm for the original levy. In the separate matter of Lermer vs. Akela Pharma Inc. and Formulation Technologies, LLC d/b/a/ PharmaForm, a jury sided with Mr. Lermer and awarded him \$189 in severance pay and approximately \$47 in vacation pay earned during the period which he was employed by the company in addition to out of pocket legal expenses. The judgment was solely against Akela Pharma. After reviewing the evidence and hearing the arguments of counsel, the District Court of Travis County, Texas denied the jury’s award of severance in the Lermer suit, and on May 11, 2010, the court issued a final verdict awarding Mr. Lermer unused vacation pay and out of pocket legal expenses. Akela’s provisions for unpaid losses on these legal actions, totaling \$437, have been recorded in accounts payable and accrued liabilities as of September 30, 2010.

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. Provisions were previously recorded related to these litigation matters.

On September 30, 2010, the Company did not meet its obligation to pay Tekes, the Finnish Funding Agency for Technology and Innovation, an initial quarterly instalment of approximately \$0.1 million as part of a litigation settlement arrangement between Tekes and Akela’s Finnish subsidiary (see notes 5 and 8). 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 September 30, 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.

In addition to the Tekes matter and executive employment termination litigation resulting from recent organizational changes at Akela, 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). 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 September 30, 2010 and December 31, 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.

## **RELATED PARTY TRANSACTIONS**

During the three and nine months ended September 30, 2010 and 2009, we incurred expenses totaling \$140 and \$420 and \$147 and \$420, for consulting services from the former principal owners and founders of PharmaForm. One of the PharmaForm founders, Robert O. Williams III, Ph.D., served as a member of the Board of Directors of the Company until June 2010. As of September 30, 2010, accounts payable includes a \$513 outstanding liability to the founders of PharmaForm for previously rendered consulting services.

During the three and nine months ended September 30, 2009, we incurred legal and tax consulting fees totaling nil and \$73 for services provided by Knorr Rechtsanwälte, a firm associated with Dr. Günter Knorr, our former Chairman of the Board. This related party relationship was terminated in 2009.

During the three and nine months ended September 30, 2009, we also incurred nil and \$71 in expenses for IT consulting services provided by Guardus Corporation, a firm owned by Dr. Halvor Jaeger, the Company's former Chief Executive Officer (CEO). This related party relationship was terminated in 2009.

In addition, during the three and nine months ended September 30, 2009, we incurred expenses of nil and \$114 for management services provided by PRI International Consulting Inc., a company directly controlled by Dr. Halvor Jaeger. This related party relationship was terminated in 2009.

In addition, during the three and nine months ended September 30, 2009 we incurred nil and \$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 measured at the exchange amount of consideration established and agreed to by the related parties.

## **OUTSTANDING SHARE DATA**

At November 15, 2010, the number of common shares issued and outstanding was 32,140,338. In addition, the Company had 208,667 outstanding options, and 6,340,168 warrants to purchase an equivalent amount of common shares at a prices ranging from Cdn \$1.50 to Cdn \$14.08.

## **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 September 30, 2010.

## **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, implementation and operation of the Company's internal control over financial reporting as of September 30, 2010 and deemed them to be effective.

There have been no changes in the Company's internal control over financial reporting during the year ended September 30, 2010 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**

### ***Goodwill and Other Intangibles***

We account for business acquisitions using the purchase method. Accordingly, the purchase price of a business acquisition is allocated to its identifiable net assets, including identifiable intangible assets, on the basis of estimated fair values as of the date of purchase, with any excess being assigned to goodwill. We estimate the fair value of assets and liabilities acquired at the date of acquisition using a projected discounted cash flow method and other valuation methods. We make a number of significant estimates when calculating fair value using a projected discounted cash flow method. These estimates include estimating projected cash flows, the number of years used, the discounted rate and others. We believe that our estimates and the valuation methods are reasonable. They are consistent with our inherent planning and reflect our best estimates, but they have inherent uncertainties that management may not be able to control.

Goodwill is not amortized but rather evaluated under an impairment approach. While other intangible assets with finite lives continue to be amortized over their estimated useful lives. The amounts recorded as intangible assets at the date of acquisition represent the estimated fair value of these assets based on estimate future cash flows discounted appropriate discount rates. In addition, in our assessment of impairment, we are required to determine the fair value of the businesses from which the goodwill and intangibles originated. For intangibles with finite lives, we make estimates of future cash flows to be generated from the related assets.

### ***Impairment of long-lived assets***

The Company tests long-lived assets or asset groups for future recoverability when events or changes in circumstances indicate that their carrying amount may not be recoverable. Circumstances which could trigger a review include, but are not limited to: significant decreases in the market price of the asset; significant adverse changes in the business climate or legal factors; accumulation of costs significantly in excess of the amount originally expected for the acquisition or construction of the asset; current period cash flow or operating losses with a history of losses or a forecast of continuing losses associated with the use of the asset; and current expectation that

the asset will more likely than not be sold or disposed of significantly before the end of its estimated useful life. The Company's long-lived assets consist primarily of property and equipment and intangible assets.

Recoverability of a long-lived asset is assessed by comparing the carrying amount of the asset to the sum of the estimated undiscounted future cash flows expected from its use and the eventual disposal of the asset. An impairment loss is recognized when the carrying amount of a long-lived asset is not recoverable and the amount of such impairment loss is determined as the excess of the carrying amount over the asset's fair value. Fair value is the estimated value at which the asset could 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.

### ***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.

### ***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 limited run 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. 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.

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.

Arrangements that include multiple elements are considered to be revenue arrangements with multiple deliverables. Under these arrangements, the identification of separate units of accounting is required and revenue is allocated among the separate units based on their relative fair values. Revenues for each unit of accounting are then recorded as described above.

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

### ***Research and development expenses***

Research and development costs 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 enrollment 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 cancelable by the partner without significant financial penalty.

### ***Government assistance***

Amounts received resulting from government assistance programs, including grants and investment tax credits for research and development, are reflected as a reduction of the cost of the asset or expense to which they relate at the time the eligible expenditures are incurred. Tax credits are recorded in the accounts when reasonable assurance exists that they will be realized.

### ***Foreign currency translation***

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.

### ***Stock-based compensation***

We account for stock-based compensation using the fair value method. This statement requires that all stock-based compensation costs be recognized as an expense in the financial statements and that such cost be measured at the fair value of the award. This compensation cost is recognized as an expense ratably over the estimated service period of the respective grantee.

The Company uses the Black-Scholes option pricing model to calculate stock option values, which requires certain assumptions, including the future stock price volatility and expected time to exercise. Changes to any of these assumptions, or the use of a different option pricing model could produce different fair values for stock-based compensation, which could have a material impact on the Company's earnings.

## RECENT ACCOUNTING PRONOUNCEMENTS

### a) *New accounting policies:*

- i) *International Financial Reporting Standards:* In February 2008, Canada's Accounting Standards Board (AcSB) confirmed that Canadian GAAP, as used by publicly accountable enterprises, will be fully converged with International Financial Reporting Standards as issued by the International Accounting Standards Board ("IFRS-IASB"). As a result, the Company will be required, commencing with its first interim period following the changeover date (January 1, 2011) to report under IFRS-IASB standards instead of current Canadian GAAP. As of January 1, 2010, called the transition date, the Company will be required to prepare an opening balance sheet (called a Statement of Financial Position) under IFRS-IASB, however, the Company's interim and annual financial statements for the fiscal year-ending December 31, 2010 will continue to be prepared using Canadian GAAP.

The transition to IFRS requires the Company to apply IFRS 1 in order to prepare IFRS-IASB compliant financial statements in the first reporting period after the changeover date. IFRS 1 only applies at the time of changeover and includes a requirement for retrospective application of each IFRS as if it had always been in effect. IFRS 1 also mandates certain exceptions to retrospective application as well as certain optional exemptions from retrospective application in order to ease the burden of transition to IFRS-IASB from any previous GAAP.

The transition to IFRS-IASB will require the Company to do an in-depth analysis and review of its current accounting policies and business practices in order to ensure that its' systems and reporting methods are ready for the transition. As of June 30, 2010, the Company has not yet begun to work on its IFRS conversion plan, however, management intends to engage an IFRS specialist who will be able to assist the Company with its transition by commencing the required review, determining which IFRS's will apply to the Company, as well as where the major differences (if any) are between Canadian GAAP and IFRS-IASB. Management will then begin the process of implementing any required changes in order to be ready to report under IFRS as of the changeover date.

Given the current level of the Company's operations, management is of the opinion that this timeframe gives the Company sufficient time to meet its obligations with respect to the changeover to IFRS.

Further updates on implementation progress and potential reporting impact from the adoption of IFRS will be provided during the implementation period.

- 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 not yet determined the impact of the adoption of this new Section on its consolidated financial statements.
- 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 not yet determined the impact of the adoption of this new Section on its consolidated financial statements.
- 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 not yet determined the impact of the adoption of this new Section on its consolidated financial statements.

- 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 is currently evaluating the impact and effective date of EIC-175.

## 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). The Company has funded such losses with external debt, share issuances, exclusive licensing and development agreements, government grants and working capital. Our consolidated net loss for the nine months ended September 30, 2010 and 2009 was \$247, and \$6,934, respectively. As of September 30, 2010, we had cash of \$930, net current liabilities of \$8,670 and an accumulated deficit of \$25,924.

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

- b) As part of the Company's cost reduction effort, management has decided to continue the Fentanyl TAIFUN® program with focused scope by 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 through the sale of non-strategic assets and seek funding for our proprietary compounds from our current and new commercial partners. Until we succeed in raising additional capital through partner funding, equity or debt financing we are not recruiting any further patients into clinical studies.
- c) We are no longer funding the scientific development of GHRH, HspE7, AKL 0721 or Poly ICR. While we are actively seeking licensing arrangements as well as other external development strategies, we 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, we may be forced to terminate these programs as we look to strategically focus our current remaining capital resources on Fentanyl TAIFUN®.
- d) On April 16, 2010, we announced that we 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 instalments of \$10 through March 2020. (See note 7).
- e) 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. ("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. 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, 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 September 24, 2010, we established a fully secured line of credit, bearing annual interest at 15% with certain shareholders. MacBay Partners LP agreed to extend the line of credit for working capital in an amount not to exceed \$0.5 million. The line of credit facility replaced the previously announced line of credit with of January, May and June of 2010. The previous line of credit with shareholders Ingalls & Snyder Value Partners LP, and MacBay Partners LP was terminated on September 24, 2010. Outside of their respective holdings in the Company, neither Ingalls & Snyder Value Partners LP, nor MacBay Partners LP are insiders to the company.
- g) On October 29, 2010, we were awarded federal grants and tax credits of \$0.5 million to facilitate continued development of our research programs.
- h) We have and are continuing to implement plans to reduce operational costs. In order to ensure the availability of current capital resources, we will 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 shippee 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](http://www.sedar.com)

On behalf of Management,

A handwritten signature in black ink, appearing to be a stylized name, located below the text "On behalf of Management,".

**Rudy J. Emmelot**  
**Principal Financial Officer**  
Austin, Texas  
November 15, 2010