

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

The statements contained in the following Management's Discussion and Analysis of Financial Condition and Results of Operations of Akela Pharma, Inc., formerly Lab International Inc., other than statements of fact that are independently verifiable at the date hereof, may be forward-looking statements regarding the industry in which it operates and the Company's expectations as to its future performance, liquidity and capital resources. Forward-looking statements look into the future and may include such words as "plans", "trends", "anticipates", "should", "estimates", "expects", "believes", "indicates", "targeting", "suggests" and similar expressions. This MD&A contains forward-looking statements about the Company's objectives, strategies and financial condition, as well as statements with respect to our beliefs, expectations, estimations and intentions. These "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 14, 2007. We assume no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or for any other reason.

This analysis explains the material variations in the unaudited consolidated statements of operations, financial position and cash flows of the Company for the three and nine-month periods ended September 30, 2007 and 2006. The interim consolidated financial statements have not been reviewed by our auditors.

## Background

We are an integrated product development company primarily focused on therapeutics for pain that utilize our proprietary drug delivery technologies. Our lead product candidate is Fentanyl TAIFUN®, a fentanyl formulation specifically designed to be delivered with our TAIFUN® Multi-Dose Inhaler. We are developing Fentanyl TAIFUN® as a rapid-acting inhaled opioid analgesic for treatment of break through cancer pain. We believe, based upon the results of our clinical trials to date, that our Fentanyl TAIFUN® product candidate, if approved by the FDA, will deliver much faster onset of pain relief from break through cancer pain at lower dosages than other non-injectable products. Phase II studies of this product were completed in the third quarter of 2007, and we expect to commence Phase III studies in the first quarter of 2008.

We have also developed a proprietary abuse-resistant delivery platform, which we call EDACS®, or Extruded Deterrence of Abusable Controlled Substances, to address opioid abuse. EDACS® prevents dissolution in alcohol, known as dose dumping, and is crush-resistant, minimizing abusive dissolution and administration of controlled substances. We intend to initiate a Phase I clinical trial for our first product using EDACS® technology in the fourth quarter of 2007.

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

- CGRP (calcitonin gene related peptide)—an anti-asthmatic currently in a Phase II trial;
- GHRH (growth hormone releasing hormone)—a synthetic growth hormone analog which has recently completed a Phase II trial for treatment of patients with chronic renal failure; and
- PHARMAFILM®—a transmucosal drug delivery film, suitable for drugs with poor oral bioavailability.

In 2006, we effected a corporate reorganization that included the transfer to our newly incorporated subsidiary, LRI, which represented our pre-clinical contract research services business. In August and September 2006, we sold 64% of LRI in an initial public offering in Canada and in November 2006 we sold the remainder of our holdings. The corporate reorganization and disposition of LRI is referred to as the LRI

Spin-off. We recognized a gain of \$32.8 million on the disposal of LRI in 2006, which we are using for product research and development, opportunistic acquisitions and working capital.

In January 2007, we acquired Formulation Technologies, LLC (doing business as "PharmaForm"), a limited liability company, based in Austin, Texas, engaged in the business of research and development of specialty pharmaceutical products, for approximately \$13 million, including \$7.5 million of cash and common shares valued at \$4.4 million. Under the agreement, additional consideration is payable by us upon completion of certain milestones relating to PharmaForm's revenue and drug development programs. In total, the maximum contingent consideration payable is approximately \$13 million, most of which is payable in common shares.

Our headquarters are in Montreal, Canada and we have historically operated our research and development activities at our facilities in Turku, Finland. However, in the third quarter of 2007, we completed the relocation of our principal research, development and manufacturing activities from Finland to our facilities in Austin, Texas.

Additional information about the Company can be obtained on SEDAR at [www.sedar.com](http://www.sedar.com).

### **Functional and Reporting Currency**

As of January 1, 2007, our functional currency is the US dollar. Historically, we have reported our financial performance in Canadian dollars. Our consolidated financial statements have been translated into the US dollar using the current rate method. Under this method, the consolidated financial statements are converted as follows: assets and liabilities are translated at the exchange rate in effect at the balance sheet date and revenues and expenses are translated at the average exchange rate for the reporting period. All adjustments resulting from the translation of the financial statements into the reporting currency are included in accumulated other comprehensive income.

### **Reverse Stock Split**

The Company's Board of Directors, as authorized by the shareholders, declared effective October 10, 2007 a 1-for-7 reverse stock split, resulting in every seven shares of common stock being combined into one share of common stock. The stock split affects all of the Company's outstanding stock, stock options and warrants outstanding on the record date. The consolidated financial statements have been retroactively adjusted to reflect the stock split for all periods presented.

### **Operating Results**

#### ***Three-months ended September 30, 2007***

As a result of the LRI Spin-off and PharmaForm Acquisition, our 2007 operating results are distinctly different from our 2006 operating results as reflected in the unaudited consolidated financial statements and related notes thereto. This is principally because the LRI pre-clinical contract research services business, which was disposed of in the LRI Spin-off, provided a revenue and expense base substantially different from our continuing operations. In addition, the acquisition of PharmaForm resulted in a new revenue and cost base starting in late January 2007. Consequently, the following discussion of our consolidated operating results for the third quarter of 2007 is based on comparisons to its relevant historical segmented results which are referred to below as the "Pharma" segment. The term "Contract Research" is used to refer to the activities constituting our former LRI pre-clinical contract research services business segment.

Our results of operations for the three-months ended September 30, 2007 include the operations of PharmaForm since the date of acquisition on January 25, 2007.

	2007	2006		
	Consolidated	Pharma Segment	Contract Research Segment	Consolidated
Revenues	<b>\$3,144</b>	<b>\$1,077</b>	<b>\$3,246</b>	<b>\$4,323</b>
Direct costs	<b>1,293</b>	-	<b>2,010</b>	<b>2,010</b>
Selling, general and administrative	<b>3,953</b>	<b>2,241</b>	<b>681</b>	<b>2,922</b>
Research and development	<b>5,723</b>	<b>2,806</b>	-	<b>2,806</b>
Stock-based compensation	<b>331</b>	<b>191</b>	-	<b>191</b>
Amortization expense	<b>1,077</b>	<b>397</b>	<b>250</b>	<b>647</b>
Gain on disposal of LAB Research Inc.	-	<b>(18,630)</b>	-	<b>(18,630)</b>
Share in net income of a company subject to significant influence	-	<b>(124)</b>	-	<b>(124)</b>
Interest on long-term debt	<b>43</b>	<b>115</b>	<b>49</b>	<b>164</b>
Foreign exchange	<b>(662)</b>	<b>24</b>	<b>74</b>	<b>98</b>
Income taxes	<b>(16)</b>	<b>2,094</b>	<b>2,430</b>	<b>4,524</b>
Net earnings (loss)	<b>(\$8,598)</b>	<b>\$11,963</b>	<b>(\$2,248)</b>	<b>\$9,715</b>

## Revenues

We derive our revenues from licensing and co-development agreements and through providing contract research services such as drug formulation, drug development and limited run drug manufacturing for pharmaceutical and biotech companies. Revenues for the three-months ended September 30, 2007 and 2006 are as follows:

	<u>2007</u>	<u>2006</u>	<u>Change</u>
Co-development revenue	\$ 1,063	\$ 838	225
Contract services revenue	1,948	-	1,948
Interest revenue	133	239	(106)
Total revenue	<u>\$ 3,144</u>	<u>\$ 1,077</u>	<u>\$ 2,067</u>

*Co-development revenue.* 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, once commercialization begins. We currently have agreements for the South Korean, Chinese (excluding Hong Kong and Taiwan) and Japanese markets and in June 2007 signed a development and licensing agreement for Europe, the Middle East and Africa as discussed below. Co-development revenue increased to \$1.0 million for the three-months ended September 30, 2007 from \$0.8 million for the three-months ended September 30, 2006 reflecting the acceleration of our Fentanyl TAIFUN® inhaler development which completed Phase II studies during the third quarter of 2007. We expect our co-development revenue to increase as we meet development milestones and enter into new development agreements.

In June 2007, we signed a licensing and development agreement with Janssen Pharmaceutica NV for Fentanyl TAIFUN®. The licensing agreement covers the European Union, Eastern Europe, Russia, the Middle East and Africa. We will collaborate with Janssen Pharmaceutica to develop the product for the initial indication of break through cancer pain. We will manufacture and the Janssen Pharmaceutica will market and distribute the product. Under the terms of the agreement, we received a signing fee of \$10.8 million (€ 8.0 million) which has been deferred and is being recognized rateably over the estimated

development period. In addition, we can receive up to an additional \$74.4 million (€55.0 million) for meeting development, regulatory, and commercial sales milestones and could receive royalty revenues and revenues from the sales of the product to Janssen Pharmaceutica.

*Contract services revenue.* Contract services revenue was \$2.0 million for the three-months ended September 30, 2007. This contract services revenue base was acquired in the acquisition of PharmaForm in January 2007 therefore no such revenue was recorded in 2006. Revenue from service contracts with milestone delivery terms are recognized as milestones are reached. As such, contract services revenue can fluctuate between quarters.

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

## **Expenses**

*Direct costs.* Direct costs for the three-months ended September 30, 2007 related to the costs associated with providing contract services and include the cost of raw materials, direct and indirect labor, supplies and related equipment and facility overheads. These contract services are associated with activities acquired in the acquisition of PharmaForm in January 2007; therefore no such expense was recorded in 2006.

*Selling, general and administrative (SG&A).* SG&A expenses consisted of salary and benefits for the executive, accounting, administrative and business development personnel, professional fees and other corporate expenses. SG&A expense for the three-months ended September 30, 2007 increased to \$4.0 million from \$2.2 million. The increase in SG&A is due to the acquisition of PharmaForm and additional salary and overhead associated with supporting the expansion of our development operations. In addition, the Company incurred approximately \$0.5 million in recruiting and relocation costs associated with the expansion of our operations in Austin. These costs were offset, in-part, by reductions in SG&A associated with the down-sizing of our Finnish operation which was completed late in the third quarter.

*Research and Development (R&D).* R&D expenses consisted primarily of third-party pre-clinical and clinical trial providers, salary and benefits for scientists and technicians, testing material, consultants and related overheads. R&D expense for the three-months ended September 30, 2007 increased to \$5.7 million from \$2.8 million. The increase in R&D expenses relates to increased third-party pre-clinical and clinical trial provider fees, salaries and benefits, material and overhead primarily associated with the development and advancement of our Fentanyl TAIFUN® product which completed Phase II trial programs during the third quarter and is planned to enter phase III trials in the first quarter of 2008. In addition, research and development expense included costs associated with the development of our other products including GHRH which completed pilot Phase II trials and CGRP which is currently in Phase IIb studies.

*Stock-based compensation.* Stock-based compensation expense relates to stock options granted to employees. Employee stock options are accounted for using the fair value method. Under this method, compensation cost is measured at fair value at the date of grant and is expensed over the award's vesting period. Stock-based compensation for the three-months ended September 30, 2007 increased to \$0.3 million from \$0.2 million. The increase is due to the expense associated with the approximately 0.3 million employee stock options granted in early 2007.

*Amortization expense.* Amortization expense includes amortization of property and equipment as well as intangible assets. Amortization expense increased to \$1.1 million for the three-months ended September 30, 2007 from \$0.4 million for the three-months ended September 30, 2006. The increase relates to the January 2007 acquisition of PharmaForm, which resulted in \$4.4 million in intangible assets which are being amortized over a period of between three and five years and \$2.7 million in property and equipment which are being amortized over a period of between two and ten years.

*Interest expense.* Long-term interest expense relates to capital loans, notes payable and various capital lease obligations. The decrease in interest expense reflects the settlement of a Laurus convertible debenture which had been fully converted into 659,778 common shares of the Company by August 3, 2006.

*Foreign Exchange Gain.* Although our functional currency is the US dollar, a significant portion of our assets and liabilities are in Canadian dollars and Euros. The increase in the foreign exchange gains over the previous year reflected the strengthening of the Euro and Canadian dollar to the US dollar.

**Nine-months ended September 30, 2007**

As a result of the LRI Spin-off and PharmaForm Acquisition, our 2007 operating results are distinctly different from our 2006 operating results as reflected in the unaudited consolidated financial statements and related notes thereto. This is principally because the LRI pre-clinical contract research services business, which was disposed of in the LRI Spin-off, provided a revenue and expense base substantially different from our continuing operations. In addition, the acquisition of PharmaForm resulted in a new revenue and cost base starting in late January 2007. Consequently, the following discussion of our consolidated operating results for the nine-months ended September 30, 2007 is based on comparisons to its relevant historical segmented results which are referred to below as the "Pharma" segment. The term "Contract Research" is used to refer to the activities constituting our former LRI pre-clinical contract research services business segment.

Our results of operations for the nine-months ended September 30, 2007 include the operations of PharmaForm since the date of acquisition on January 25, 2007.

	2007	2006		
	Consolidated	Pharma Segment	Contract Research Segment	Consolidated
Revenues	<b>\$7,927</b>	<b>\$1,483</b>	<b>\$23,187</b>	<b>\$24,670</b>
Direct costs	<b>3,534</b>	-	<b>14,104</b>	<b>14,104</b>
Selling, general and administrative	<b>10,491</b>	<b>6,337</b>	<b>4,712</b>	<b>11,049</b>
Research and development	<b>15,361</b>	<b>7,648</b>	-	<b>7,648</b>
Stock-based compensation	<b>828</b>	<b>560</b>	<b>30</b>	<b>590</b>
Amortization expense	<b>2,720</b>	<b>1,115</b>	<b>1,679</b>	<b>2,794</b>
Gain on disposal of LAB Research Inc.	-	<b>(18,630)</b>	-	<b>(18,630)</b>
Share in net income of a company subject to significant influence	-	<b>(124)</b>	-	<b>(124)</b>
Interest on long-term debt	<b>140</b>	<b>1,315</b>	<b>304</b>	<b>1,619</b>
Foreign exchange	<b>(1,376)</b>	<b>418</b>	<b>23</b>	<b>441</b>
Income taxes	<b>42</b>	<b>2,020</b>	<b>2,615</b>	<b>4,635</b>
Net earnings (loss)	<b>(\$23,813)</b>	<b>\$824</b>	<b>(\$280)</b>	<b>\$544</b>

**Revenues**

We derive our revenues from licensing and co-development agreements and through providing contract research services such as drug formulation, drug development and limited run drug manufacturing for pharmaceutical and biotech companies. Revenues for the nine-months ended September 30, 2007 and 2006 are as follows:

	<u>2007</u>	<u>2006</u>	<u>Change</u>
Co-development revenue	\$1,646	\$1,200	\$446
Contract services revenue	5,723	-	5,723
Interest revenue	558	283	275
Total revenue	<u>\$7,927</u>	<u>\$1,483</u>	<u>\$6,444</u>

*Co-development revenue.* 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, once commercialization begins. We currently have agreements for the South Korean, Chinese (excluding Hong Kong and Taiwan) and Japanese markets and in June 2007 signed a development and licensing agreement for Europe, the Middle East and Africa as discussed below. Co-development revenue increased to \$1.6 million for the nine-months ended September 30, 2007 from \$1.2 million for the three-months ended September 30, 2006 reflecting the acceleration of our Fentanyl TAIFUN® inhaler development which completed Phase II studies during the third quarter of 2007. We expect our co-development revenue to increase as we meet development milestones and enter into new development agreements.

In June 2007, we signed a licensing and development agreement with Janssen Pharmaceutica NV for Fentanyl TAIFUN. The licensing agreement covers the European Union, Eastern Europe, Russia, the Middle East and Africa. We will collaborate with Janssen Pharmaceutica to develop the product for the initial indication of break through cancer pain. We will manufacture and the Janssen Pharmaceutica companies will market and distribute the product. Under the terms of the agreement, we received a signing fee of \$10.8 million (€8.0 million) which has been deferred and is being recognized ratably over the estimated development period. In addition, we can receive up to an additional \$74.4 million (€55.0 million) for meeting development, regulatory, and commercial sales milestones and could receive royalty revenues and revenues from the sales of the product to Janssen Pharmaceutica.

*Contract services revenue.* Contract services revenue was \$5.7 million for the nine-months ended September 30, 2007. This contract services revenue base was acquired in the acquisition of PharmaForm in January 2007 therefore no such revenue was recorded in 2006. Revenue from service contracts with milestone delivery terms are recognized as milestones are reached. As such, contract services revenue can fluctuate between quarters.

*Interest revenue.* Interest revenue relates to interest earned on invested cash balances. The increase in interest revenue is due to an increase in invested cash balances.

## **Expenses**

*Direct costs.* Direct costs for the nine-months ended September 30, 2007 related to the costs associated with providing contract services and include the cost of raw materials, direct and indirect labor, supplies and related equipment and facility overheads. These contract services are associated with activities acquired in the acquisition of PharmaForm in January 2007; therefore no such expense was recorded in 2006.

*Selling, general and administrative (SG&A).* SG&A expenses consist of salary and benefits for the executive, accounting, administrative and business development personnel, professional fees and other corporate expenses. SG&A expense for the nine-months ended September 30, 2007 increased to \$10.5 million from \$6.3 million. The increase in SG&A is due to the acquisition of PharmaForm and additional salary and overhead, associated with supporting the expansion of our development operations. In addition, the Company incurred approximately \$0.9 million in recruiting and relocation expenses associated with the expansion of our Austin operations. These costs were offset, in-part, by reductions in SG&A associated with the down-sizing of our Finnish operations which we completed late in the third quarter.

*Research and Development (R&D).* R&D expenses consists primarily of third-party clinical trial providers, salary and benefits for scientists and technicians, testing material, consultants and related overheads. R&D expense for the nine-months ended September 30, 2007 increased to \$15.4 million from \$7.6 million. The increase in R&D expenses relates to increased third-party pre-clinical and clinical trial provider fees, salaries and benefits, material and overhead primarily associated with the development and advancement of our Fentanyl TAIFUN® product which completed Phase II trial programs during the third quarter and is

planned to enter phase III trials in the first quarter of 2008. In addition, research and development expense also included costs associated with the development of our other products including GHRH which completed pilot Phase II trials and CGRP which is currently in Phase IIb studies.

*Stock-based compensation.* Stock-based compensation expense relates to stock options granted to employees. Employee stock options are accounted for using the fair value method. Under this method, compensation cost is measured at fair value at the date of grant and is expensed over the award's vesting period. Stock-based compensation for the nine-months ended September 30, 2007 increased to \$0.8 million from \$0.6 million. The increase is due to the expense associated with the approximately 0.3 million employee stock options granted in early 2007.

*Amortization expense.* Amortization expense includes amortization of property and equipment as well as intangible assets. Amortization expense increased to \$2.7 million for the nine-months ended September 30, 2007 from \$1.1 million for the nine-months ended September 30, 2006. The increase in amortization expense relates to the January 2007 acquisition of PharmaForm, which resulted in \$4.4 million in intangible assets which are being amortized over a period of between three and five years and \$2.7 million in property and equipment which are being amortized over a period of between two and ten years.

*Interest expense.* Long-term interest expense of \$1.3 million for the first nine months of 2006 included \$0.8 million of interest on the Laurus convertible debenture, and \$0.5 million for "loss on early settlement" recorded on its partial conversion. By August 3, 2006, this debenture had been fully converted into 659,778 common shares of the Company resulting in lower interest expense in 2007.

*Foreign Exchange Gain.* Although our functional currency is the US dollar, a significant portion of our assets and liabilities are in Canadian dollars and Euros. The increase in the foreign exchange gains over the previous year reflected the strengthening of the Euro and Canadian dollar to the US dollar.

## Quarterly results

<u>Quarter</u>	<u>Revenues</u>	<u>Net Income</u> <u>(loss)</u>	<u>Net income (loss) per share</u>	
			<u>Basic</u>	<u>Diluted</u>
Quarter ended September 30, 2007	3,144	(8,598)	(0.73)	(0.73)
Quarter ended June 30, 2007	3,409	(7,108)	(0.63)	(0.63)
Quarter ended March 31, 2007	1,374	(8,107)	(0.70)	(0.70)
Quarter ended December 31, 2006	1,062	(740)	(0.06)	(0.06)
Quarter ended September 30, 2006	4,027	9,860	0.94	0.94
Quarter ended June 30, 2006	10,639	(4,807)	(0.49)	(0.49)
Quarter ended March 31, 2006	9,708	(4,364)	(0.42)	(0.42)
Quarter ended December 31, 2005	9,631	(2,846)	(0.35)	(0.35)

The quarterly results include the results of LRI to the date of the IPO, August 3, 2006. The Company ceased consolidating the results of operations of LRI in the third quarter of 2006, which accounts for the reduction in revenues in this period and the fourth quarter. The Company also recorded gains on disposal of its interest in LRI in both the third and fourth quarters of 2006.

## Liquidity and Capital Resources

We incur significant net losses and use our cash reserves and cash from contract services revenues to fund the development of our product candidates. We are actively pursuing additional financing which will be necessary to continue our development efforts. To the extent that we raise additional capital through the sale of equity securities, the issuance of such securities will likely result in dilution to our existing shareholders. If we raise additional funds through the issuance of debt securities, the terms of such debt could impose additional restrictions on our operations. Additional capital may not be available on acceptable terms, if at all. If we are unable to obtain additional financing, we believe that our current cash and expected future cash generated from operations will satisfy our needs through the next twelve months, however, we would be required to reduce the scope of our planned development efforts which would impact our ability to bring our products to market under our current timelines.

Cash and cash equivalent balances at September 30, 2007 were \$15.1 million compared with \$35.3 million at December 31, 2006. Net cash flows for the nine-months ended September 30, are summarized as follows:

	<u>2007</u>	<u>2006</u>	<u>Change</u>
Cash used in operating activity	\$ (9,144)	\$ (9,876)	\$ 718
Cash used in financing activities	(1,327)	(972)	(355)
Cash provided by (used in) investing activities	(10,077)	18,304	(28,515)
Net cash outflow	<u>\$ (20,548)</u>	<u>\$ 7,456</u>	<u>\$(28,152)</u>

### *Operating Activity*

Net cash used in operating activities decreased to \$9.1 million for the nine-months ended September 30, 2007 compared to \$9.9 million for the same period in 2006. This decline in operating cash outflows is primarily due to \$10.8 million in signing fees received from Janssen Pharmaceutica for a licensing and development agreement signed in June 2007, which offset our operation cash burn as well as expenses associated with the downsizing of our Finnish subsidiary.

### *Financing Activity*

Net cash used in financing activities for the nine-months ended September 30, 2007 and 2006 was \$1.3 million and \$0.9 million, respectively. Finance activity during 2007 included the replacement of \$1.2 million of debt acquired in the PharmaForm acquisition with new debt as well as the payments under existing debt facilities. Our new long-term debt bears interest at 8.75% and is due in monthly installments over the next 5 years. Under the terms of the debt agreement, we are required to maintain \$0.6 million in a restricted certificate of deposit account. The debt is secured by a first lien on the accounts receivable and property and equipment of PharmaForm. Financing activity in 2006 related primarily to the payment of outstanding debt, offset in part by proceeds from the issuance of shares and long-term debt.

### *Investing Activity*

Net cash used in investing activities for the nine-months ended September 30, 2007 was \$10.1 million versus cash provided by investing activities of \$18.3 million for the same respective period in 2006. Investing activities in 2007 principally related to the January 25, 2007 acquisition of PharmaForm, an Austin, Texas based specialty pharmaceutical company. Under the terms of the acquisition, we paid \$13 million, including cash and transaction costs totaling \$8.5 million (excluding net cash acquired of \$0.4 million) and shares valued at \$4.4 million. The sellers will be eligible for additional amounts payable in shares upon PharmaForm's completion of certain milestones relating to specific revenue targets and to its drug delivery platforms currently under development. We are currently transferring all of our product development activities and most of our administrative activities to Austin, Texas to leverage the assets

acquired. Investing activity in 2007 also included \$0.9 million in property and equipment purchases, primarily related to product development. Investing activity in 2006 reflects the disposition of LAB Research, which generated proceeds of approximately \$27.4 million, partially offset by the purchase of property and equipment and other assets.

## Commitments and Contingencies

The aggregate maturities of the contractual obligations are as follows:

	2007	2008	2009	2010	2011+	Total
Operating leases	\$ 428	407	259	-	-	\$ 1,094
Capital leases	61	146	146	85	-	438
Service contracts	820	835	796	717	607	3,775
Clinical studies	3,421	4,384	-	-	-	7,805
Long-term debt	1,856	402	402	402	4,776	7,838
	<b>\$ 6,586</b>	<b>6,174</b>	<b>1,603</b>	<b>1,204</b>	<b>5,383</b>	<b>\$ 20,950</b>

- (a) We are party to an exclusive world-wide master license agreement whereby we were granted licenses to further develop and exploit commercial applications to be derived from a specific invention bearing a United States patent serial number. Under the license agreement, we undertake to pay a royalty of 1.5% to 5% of specified sales, with a minimum annual amount of \$10. This license agreement will expire when the last of the patent rights expire.
- (b) We are required to pay Auxilium Pharmaceutical ("Auxilium") 75% of any sublicense fees received by us from certain products jointly developed by the Company and Auxilium. To date, we have not received any such sublicense fees. In the event that certain license agreements with certain parties are terminated during the term of our agreement with Auxilium, the Company shall pay Auxilium one-half of all direct expenses and costs Auxilium has incurred related to the research and development of the compounds, technology or products pursued under the agreement which exceed the cumulative gross profit earned by Auxilium as of the date of termination. As of September 30, 2007, the minimum contingency associated with this agreement is \$1.4 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.
- (c) Our Finnish subsidiary has received certain low interest loan and subsidies from a Finnish governmental agency. Following our decision to close the Finnish subsidiary, we recently have been notified that this agency is reviewing loans and subsidies previously granted to us totalling €2,556 and €954, respectively. Discussions with the agency are ongoing and we cannot, at this time, determine if such review will lead to changes to the terms of the original agreement or demands for repayment of all or a portion of amounts received. Accordingly, all loans received from the Finnish governmental agency continue to be presented as long-term debt in accordance with the original terms of the agreement and no additional provision has been made with respect to this matter.

## Related Party Transactions

We incurred legal and tax consulting fees totaling \$62 and \$68 during the three-months ended September 30, 2007 and 2006, respectively and fees totaling \$344 and \$203 during the nine-months ended September 30, 2007 and 2006 from two firms associated with members of our Board of Directors.

During the three-months ended September 30, 2007 and 2006, we incurred fees totaling \$106 and \$2,350 as remuneration for services rendered by PRI International Consulting Inc., a company directly controlled by our Chief Executive Officer (CEO). During the nine-months ended September 30, 2007 and 2006, we incurred total fees of \$312 and \$2,546, respectively for these services.

During the three-months ended September 30, 2007 and 2006, we incurred IT consulting fees totaling \$54 and \$95, respectively from a firm owned by our CEO. The IT consulting fees incurred during the nine-months ended September 30, 2007 and 2006 were \$166 and \$130, respectively.

Our long-term debt includes \$998 due to a non-controlling shareholder bearing interest of 8% which was repaid in October 2007. During the three-months ended September 30, 2007 and 2006, we incurred interest expense of \$20 and \$28, respectively associated with the loan. The interest expense incurred was \$64 and \$83 during the nine-months ended September 30, 2007 and 2006 for the same loan. We also incurred rent expense of \$242 and \$225 during the three-months ended September 30, 2007 and 2006 associated with a facilities lease held by this non-controlling shareholder. During the nine-months ended September 30, 2007 and 2006, we incurred rent expense of \$1,845 and \$642, respectively.

During the three and nine-month periods ended September 30, 2007, we incurred expenses totaling \$190 and \$539 respectively for consulting services paid to three current shareholders and the former principal owners of PharmaForm. One of these shareholders is also a member of our Board of Directors.

### **Outstanding Share Capital**

As of October 31, 2007, the Company had 11,768,294 issued and outstanding shares and 1,118,890 options and 252,898 warrants outstanding.

### **Outlook**

The most important trends affecting the healthcare products industry are demographic changes and the growing influence of managed care. Shifting demographics will drive industry growth in the years ahead as an aging population provides further stimulus for industry demand.

The search for improved routes of administration and the desire for non-invasive delivery methods for self-medication of chronic conditions represent therapeutic application opportunities for developers of inhalation drug delivery based products like ours.

Advances in inhaler design and powder engineering should drive growth in dry powder inhalation for both upper respiratory tract and systemic applications. The inherent advantages of dry powder formulations for large molecule drug compounds and new dry powder inhalers specifically engineered to deliver these expensive new chemical entities to the deep lung should serve as a catalyst for the adoption of dry powder inhalers as the technology of choice.

Inhalation forms the basis for the treatment and control of upper respiratory tract diseases such as asthma and chronic obstructive pulmonary disease and is expected to continue to experience steady growth over the next several years. The systematic delivery of drugs through the lungs is now a reality for diabetes, paving the way for other major indications such as cancer and post-operative pain, Parkinson's disease and erectile dysfunction.

In summary, the factors that will influence the total demand for inhalation-based therapeutics include:

- the growth in the number of cases of upper respiratory disease;
- the expected increase in self-administration for the treatment of chronic conditions;
- the pulmonary administration of therapeutics for systemic delivery; and

- Technological improvements in inhalation delivery.

We are well positioned to take advantage of these and other trends such as the growing demand for drug abuse deterrence solutions, given its current product development and drug delivery platform portfolios. We will continue to focus on those therapeutic opportunities which can be accelerated to market and facilitate licensing and co-development agreements to offset product development costs and risk. The acquisition of PharmaForm is a key to our strategy, by adding FDA and DEA approved specialized drug formulation and manufacturing capabilities and unique patent pending abuse deterrent and trans-mucosal drug delivery systems.

In order to maximize value creation in the short-term, we intend to:

- Complete the Fentanyl Taifun Phase IIb program and start Phase III.
- Centralize all formulation, manufacturing and product / platform development in Austin, Texas.
- Complete Calcitonin Gene Related Peptide (CGRP) Phase IIb anti-inflammatory trials.
- Complete the Growth Hormone Release Hormone (GHRH) Phase IIa study and, depending on the final results, start a larger scope Phase IIb trial.
- Accelerate the development of PharmaForm's abuse deterrent platforms.
- Out-license the Company's products and inhalation platforms in the U.S.
- Broaden delivery platforms and product offerings with a focus on reformulated generics for pain and CSN indications through co-sponsored programs, and/or strategic alliances.
- Aggressively pursue other synergistic acquisition opportunities.

### **Critical Accounting Policies**

In preparing our consolidated financial statements in conformity with GAAP, management is required to make certain estimates, judgments and assumptions that we believe are reasonable based upon the information available. These estimates and assumptions affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the periods presented. The accounting policies which we consider to be critical are those that require the most difficult, subjective, or complex judgments and that are the most important to aid in fully understanding and evaluating our consolidated financial statements. These accounting policies are discussed in the following paragraphs.

**Property, equipment and intangible assets** are stated at cost and are amortized over their estimated useful lives on a straight-line basis. We regularly review property, equipment and intangible asset costs for impairment whenever events or changes in business circumstances indicate that the carrying amount of the assets exceed the sum of the expected cash flows from their uses and disposal. Management's judgment regarding the existence of impairment indicators is based on legal factors, market conditions and operating performances. Future events could cause management to conclude that impairment indicators exist and that the carrying values of our property, equipment or intangible asset costs are impaired. Any resulting impairment loss could have a material adverse impact on our financial position and results of operations. In 2006, we recorded an impairment loss of \$3.6 million related to property and equipment in Finland.

**Income taxes** are accounted for under the asset and liability method. Future tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry-forwards. Future tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on future tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. Management provides valuation allowances against the future tax assets for amounts which are not considered "more likely than not" to be realized. In assessing the realizability of tax assets, management considers whether it is more likely than not that some portion or all of

the tax assets will not be realized. The ultimate realization of future tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. Management considers the scheduled reversal of tax liabilities, projected future taxable income, and tax planning strategies in making this assessment. We have recorded a 100% valuation allowance against our future tax assets due to uncertainties relating to our ability to utilize our future tax assets, consisting primarily of non-capital losses and unclaimed deductions, before they expire.

**Research and development** costs consist of direct and indirect expenditures, including a reasonable allocation of overhead expenses, associated with our various research and development programs. Research and development costs are expensed as incurred. Overhead expenses comprise general and administrative support provided to the research and development programs and involve costs associated with support activities such as facility maintenance, utilities, office services, information technology and human resources. We review and accrue clinical trial expenses based on work performed, which relies on estimates of total costs incurred based on completion of patient studies and other events. We follow this method since reasonable, dependable estimates of the costs applicable to various stages of a research agreement of clinical trials can be made. Accrued clinical costs are subject to revisions as trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

**Stock-based compensation** is recorded using the fair value method for all issued options. Under this method, compensation cost is measured at fair value at the date of grant and is expensed over the requisite service period. We use the Black-Scholes options pricing model to calculate stock option values, which requires certain assumptions, including 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 our earnings.

**Revenue from development and license agreements** that include multiple elements are considered to be revenue arrangements with multiple deliverables. Under this type of arrangement, the identification of separate units of accounting is required and revenue is allocated among the separate units based on their relative fair values or using the residual method. Payments received under these agreements may include up-front payments, regulatory based milestones for specific achievements, as well as fees for development funding, sales and royalties. Up-front and regulatory milestone payments, which require our ongoing involvement, are deferred and amortized into income on a straight-line basis over the estimated period of service. When a milestone is achieved, a portion of the milestone revenue equal to the progress toward completion would be recognized. The remaining portion of the milestone is amortized into future periods as additional progress toward completion is achieved. Fees for development funding, sales and royalties are recognized when the service is rendered or the product is delivered and the amount is determinable and collectability is reasonably assured. Revenue consists of development services performed on behalf of third parties. Revenues are recognized at the time research activities are performed under the agreement. Revenue consists of development services performed on behalf of third parties. Revenues are recognized at the time research activities are performed under the agreement.

**Revenue for contract services** is recognized as work is performed, and amounts are earned. The timing of cash received from our contract services agreements can differ from when revenue is recognized. We consider 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, we recognize revenue 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, our 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.

## Risks Related to Financing Our Business

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

We are a clinical-stage specialty pharmaceutical company and our proposed products are currently in research and development. We are not profitable and have incurred continuing operating losses. We have never had any products available for commercial sale and we have not generated any revenue from product sales. We do not anticipate that we will generate revenues from the sale of products for the foreseeable future, but we continue to incur expenses related to our operations. Our consolidated net loss for the nine-months ended September 30, 2007 was \$23.7 million. As of September 30, 2007, we had an accumulated deficit of \$50.4 million. We expect to continue to incur losses for the foreseeable future, and we expect these losses to persist as we continue our research activities and conduct development of, and seek regulatory approvals for, our product candidates, and prepare for and begin to commercialize any approved products. We may never become profitable. Even if we achieve profitability in the future, we may not be able to sustain profitability. Any failure to successfully develop and obtain regulatory approval for product candidates that are currently under development would have a material adverse effect on our business, financial condition and results of operations.

**We will have additional future capital needs and there are uncertainties as to our ability to raise additional funding. We are actively pursuing additional financing which fund the development of our product candidates. 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:

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

Our future cash requirements may, however, vary materially from those now expected. For example, our future capital requirements may increase if we:

- experience scientific progress sooner than expected in our discovery, research and development projects, if we expand the magnitude and scope of these activities, or if we modify our focus as a result of our discoveries;
- experience setbacks in our progress with pre-clinical 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, eliminate or divest of 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 are 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®. We anticipate that in the near term our ability to generate significant revenues will depend primarily on the successful development and commercialization of this product candidate, especially in Europe and the United States. Although we have several other products under development, they are at an earlier stage of development.

Fentanyl TAIFUN® completed Phase II clinical trials. In order to market Fentanyl TAIFUN® we will have to conduct additional clinical trials, including a Phase III clinical trial, to demonstrate safety and efficacy. We have not initiated any Phase III clinical trials with any of our product candidates; however, we expect to commence Phase III clinical trials for Fentanyl TAIFUN® in the first quarter of 2008.

Our other product candidates focusing on pain that utilize our abuse-deterrent EDACS™ technology are currently in preclinical development. Our other non-pain product candidates, a GHRH analogue and a calcitonin composition, are also in Phase II clinical trials and are subject to the risk that Phase III clinical trials may be delayed, altered or not initiated, that regulatory approval may never be achieved and that these products, if commercialized, may not be successful.

Our clinical development programs for each of these three product candidates may fail to receive regulatory approval if we are not able to demonstrate that the relevant product candidate is safe and effective in clinical trials, and consequently we may fail to obtain necessary approvals from the U.S. Food and Drug Administration (FDA), or similar non-U.S. regulatory agencies in Canada and elsewhere.

**The results of pre-clinical 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.**

Pre-clinical 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 pre-clinical 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. Favorable 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 pre-clinical 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, clinical research organizations (CRO), Institutional Review Boards (IRB) or ethics committees, Data Safety Monitoring Boards (DSMB), and government regulators.

Even after the completion of Phase III clinical trials, the FDA or other non-U.S. 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.

**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. The timing of the commencement, continuation and completion of clinical trials may be subject to significant delays relating to various causes, including:

- the inability to manufacture or obtain sufficient quantities of materials for use in clinical trials;
- delays arising from collaborative arrangements;
- delays in obtaining regulatory approvals to commence a study, or government intervention to suspend or terminate a study;
- delays, suspension, or termination of the clinical trials due to the independent ethics board responsible for overseeing the study to protect research subjects at a particular study site;
- delays in identifying and reaching agreement on acceptable terms with prospective clinical trial sites;
- difficulty recruiting and enrolling sufficient numbers of patients, which is affected by:
  - design of the protocol;
  - the size of the patient population;
  - eligibility criteria for the study in question;
  - perceived risks and benefits of the drug under study;

- availability of competing therapies;
- efforts to facilitate timely enrollment in clinical trials;
- public reputation of the investigator(s) or study site(s);
- patient referral practices of physicians; and
- availability of clinical trial sites.
- uncertain dosing issues;
- inability or unwillingness of medical investigators to follow clinical protocols or drug control procedures;
- variability in the number and types of subjects available for each study and resulting difficulties in identifying and enrolling subjects who meet trial eligibility criteria;
- scheduling conflicts with participating clinicians and clinical institutions;
- difficulty in maintaining contact with subjects after treatment, resulting in incomplete data;
- unforeseen safety issues or side effects;
- lack of efficacy during the clinical trials;
- reliance on CROs to conduct clinical trials, which may not conduct those trials with good clinical or laboratory practices; and
- other regulatory delays.

Break through pain is a condition that typically occurs in patients with terminal cancer and a short life expectancy. During the clinical trials performed with Fentanyl TAIFUN®, we have encountered some difficulty enrolling patients in short-term controlled trials, due to the limited time that the patients may benefit from the trial product. To overcome the difficulty, we have increased the number of study sites and clinical investigators in order to interview and screen more potential patients. In the planned Phase III trials for Fentanyl TAIFUN®, treatment may be extended up to three months, and hence we expect to provide a higher benefit to the enrolled patients and obtain faster patient enrollment. Nevertheless, if we have difficulty enrolling a sufficient number of patients to conduct clinical trials as planned, we may need to delay, suspend or terminate ongoing clinical trials.

Our clinical trials may be suspended or terminated at any time by the FDA, 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 or 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. In addition, if our product candidates receive marketing approval and we or others later identify undesirable side effects caused by the product:

- regulatory authorities may withdraw their approval of the product;
- we may be required to recall the product, change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- a product may become less competitive and product sales may decrease; or
- our reputation may suffer.

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

To implement our product development strategies, we rely, in part, on third parties, such as CROs, medical institutions, clinical investigators and contract laboratories, to conduct the clinical trials of our product candidates. One CRO, Allied Research International, is conducting the CGRP Phase II clinical trial; Encorium Oy, a Finnish CRO, is conducting the GHRH Phase II clinical trial; and two CROs, Hyperphar N.V. and Pharos GmbH, are conducting the Fentanyl TAIFUN® Phase II clinical trial. 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. 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 federal or state government regulators against us or the third parties.

**Our drug development and formulation services business is regulated by numerous federal, state, and local governmental authorities 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 allow us to accelerate our product development strategy, 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 including, but not limited to, good laboratory practices, GCPs, and current Good Manufacturing Practices (cGMP). We must maintain our facility's U.S. Drug Enforcement Agency (DEA) and FDA registrations. Failure to do so would require new testing and compliance inspections. Compliance with all federal, state, and local requirements 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 above-listed 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 could result in a higher cost, a delay of the clinical program, or both.

**FDA approval for our product candidates 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) New Drug Application (NDA), instead of a "stand-alone" or "full" NDA filing under Section 505(b)(1). Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA), was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, 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, newly-approved drugs and indications benefit from a statutory period of non-patent marketing exclusivity. The Hatch-Waxman Amendments prohibit the submission of an abbreviated new drug application (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, 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 Biologics License Application (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 pre-clinical studies and clinical trials. The number of pre-clinical 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 pre-clinical 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 foreign 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 shut-down 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 state and foreign 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, non-U.S. regulatory authorities' 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 and its amendments and implementing regulations. Under U.S. federal law, a person, including an individual or corporation, who manufactures, distributes, dispenses, imports, or exports any controlled substance, or who proposes to engage in these activities, must register with the DEA, unless exempt. In addition, manufacturers are subject to DEA-established procurement, production, and manufacturing quotas. Registrants must comply with a series of regulatory requirements, and have detailed procedures in place, relating to drug labeling, packaging, security, shipment and disposal; customer, clinical investigator, or other shipee licensure; employee limitations and controls; transaction reporting; records accountability; inventory maintenance; and diversion control procedures. Although we have taken steps to ensure compliance with DEA requirements, including DEA registration and licensure, we cannot guarantee that the 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 abroad.**

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 non-U.S. 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 FDA or other regulatory authorities does not ensure approval by regulatory authorities in other countries, and approval by one or more non-U.S. regulatory authorities does not ensure approval by regulatory authorities in other countries or by the FDA. The non-U.S. regulatory approval process may include all of the risks associated with obtaining FDA approval. We may not obtain non-U.S. regulatory approvals on a timely basis, if at all. We may not be able to file for non-U.S. regulatory approvals and may not receive necessary approvals to commercialize our product candidates in any market. Once we obtain regulatory approvals in non-U.S. jurisdictions, 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 record-keeping 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 the United States including federal and state 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 United States or Canada;
- detention or destruction of imported product;
- restrictions on operations, including costly new manufacturing requirements; and

- product recalls or seizures.

In addition, the FDA 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 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 such as our lead product candidate, Fentanyl TAIFUN®, the prices at which such products are sold and the revenues we receive may be reduced. However, 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 FDA-required 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 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. For example, we have licensed to SK Chemicals Co. Ltd. the rights to market Fentanyl TAIFUN® in South Korea and China (excluding Taiwan and Hong Kong), to Teikoku Seiyaku Co. Ltd. the rights to market Fentanyl TAIFUN® in Japan and Janssen Pharmaceutica, NV the right to market Fentanyl TAIFUN® in the European Union, Eastern Europe, Russia, the Middle East and Africa. Should any of these arrangements be terminated for any reason, we would need to find a new marketing partner or undertake this marketing on our own. Furthermore, we currently have no similar arrangement for the rest of the world. Accordingly, if we are able to commercialize any of our other product candidates, we would either have to develop a marketing capability (including a sales force) or attempt to enter into a joint venture, license, or other arrangement with third parties to provide the financial and other resources needed to market such products. We do not currently employ any sales personnel and we have no experience in hiring and managing such personnel. Our ability to develop our own marketing capability is untested. Our ability to negotiate favorable terms in connection with additional arrangements to market our product candidates, if and when approved, through joint venture, license or other arrangements is unknown at this time. If we fail to successfully find marketing partners or fail to develop a sales force, the sales of our products and, therefore, our revenues, results of operations and losses could be materially adversely affected.

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

The life sciences industry is highly competitive, and we face significant competition from many pharmaceutical, biopharmaceutical and biotechnology companies that are researching and marketing products designed to address the indications for which we are currently developing products or for which we may develop products in the future. We are aware of several other companies, including BioDelivery Sciences International, Nektar Therapeutics, Aradigm Corporation and Alexza Pharmaceuticals, Inc., 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.**

As a technology-driven company, intellectual input from key management, particularly Halvor Jaeger, our Chief Executive Officer, Taneli Jouhikainen, our Vice President Corporate Development, 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. Mr. Jaeger's employment agreement expires in 2010. These arrangements are terminable at will by the Company 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.

Further, 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, 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. If we elect to manufacture our products ourselves, we would expose ourselves to numerous operational and regulatory risks.

Furthermore, 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. Reliance on these agreements exposes us to a number of risks, including the following:

- our partners may not devote sufficient resources to our products or product candidates;
- disputes may arise with respect to strategy and payments that we believe are due under such partnering agreements;
- we may face unwillingness on the part of partners to keep us informed regarding the progress of their activities, including development, commercialization or marketing activities, or to permit public disclosure of these activities;
- our partners may terminate the relationship;
- disputes may arise in the future with respect to the ownership of rights to technology developed with collaborators;
- disagreements with partners could delay or terminate the research and development, regulatory approval, commercialization or marketing of product candidates, or result in litigation or arbitration;
- our collaborators may elect to pursue the development of any additional product candidates and pursue technologies or products either on their own or in collaboration with other parties, including our competitors whose technologies or products may be competitive with ours;
- our partners may pursue higher priority programs or change the focus of their programs, which could affect the collaborators' and distributors' commitments; and
- our partners may develop or distribute products that compete with our products.

The occurrence of any of these or other events may delay product development or impair commercialization of our product candidates.

**We may encounter difficulties in relocating operations to our facility in Austin, Texas.**

A number of our activities designed to advance our product candidates through development and clinical trials have been moved from their current locations, including in Finland, and consolidated in our facility in Austin, Texas. The transfer of all of our product development activities to our facility in Austin was completed by September 30, 2007.

The Austin relocation and consolidation places added strain on our management capabilities and may detract from management's efforts to develop our product candidates or our development, regulatory, manufacturing, marketing and sales capabilities. Our future financial performance will depend, in part, on our ability to successfully establish and effectively run our integrated facility. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from advancing our product candidates through development, clinical trials and commercialization.

**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. 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.

Third-party manufacturers may fail to perform under their contractual obligations, or may fail to deliver the required commercial quantities of bulk drug substance or finished product on a timely basis and at commercially reasonable prices. Any performance failure on the part of our contract manufacturers could delay:

- clinical development;
- regulatory approval; or
- commercialization

of our product candidates, depriving us of potential product revenue and resulting in additional losses. If our contract manufacturers fail to achieve and maintain high manufacturing standards in compliance with cGMP regulations, we may experience manufacturing errors resulting in:

- patient injury or death;
- product recalls or withdrawals;
- delays or interruptions of production or failures in product testing or delivery;
- delay or prevention of filing or approval of marketing applications for our product candidates;
- cost overruns; or
- other problems that could seriously harm our business.

If we are required to identify and qualify an alternate manufacturer, we may be forced to delay or suspend our:

- clinical trials;
- regulatory submissions;
- required approvals; or
- commercialization

of our product candidates, which may cause us to incur higher costs and could prevent us from commercializing our product candidates successfully. If we are unable to find one or more replacement manufacturers capable of production at a reasonably favorable cost, in adequate volumes, of adequate quality, and on a timely basis, we would likely be unable to meet demand for our product candidates and our clinical trials could be delayed or we could lose potential revenue. Our ability to replace an existing active pharmaceutical ingredient manufacturer may be difficult because:

- the number of potential manufacturers is limited; and
- the FDA or other non-U.S. regulatory authority must approve any replacement manufacturer before it can begin manufacturing our product candidates.

Such approval would require new testing and compliance inspections. It may be difficult or impossible for us to identify and engage a replacement manufacturer on acceptable terms in a timely manner, or at all. We expect to continue to depend on third-party contract manufacturers for the foreseeable future.

**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 in the future. 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 Formulation Technologies, L.L.C. (PharmaForm). We acquired our EDACS™ and PHARMAFILM™ technologies 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 in the future, which may harm our business.

**If government and third-party payors fail to provide coverage and adequate reimbursement rates for our product candidates, our revenues and potential for profitability will be reduced.**

Our product revenues will depend principally upon the reimbursement rates established by third-party payors, including:

- government health administration authorities;
- managed-care providers;
- public health insurers;
- private health insurers; and
- other organizations.

These third-party payors are increasingly challenging the price, and examining the cost-effectiveness, of medical products and services. In addition, significant uncertainty exists as to the reimbursement status, if any, of newly approved drugs, pharmaceutical products or product indications. In some countries other than the United States, particularly the countries of the European Union and Canada, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, obtaining pricing approval from governmental authorities can take six to twelve months or longer after the receipt of regulatory marketing approval of a product for an indication. We may need to conduct costly and time-consuming post-marketing clinical trials in order to demonstrate the comparative cost-effectiveness of our products, when and if we have any, as compared to available therapies. If reimbursement of such product is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, our revenues could be reduced. Furthermore, we cannot predict whether similar governmental price controls may be implemented in the United States in the future.

Domestic and foreign governments continue to propose and pass legislation designed to reduce the cost of healthcare generally, and government reimbursement in particular, including the cost of drugs. In the United States, there have been, and we expect that there will continue to be, federal and state proposals to implement similar governmental control. In addition, increasing emphasis on managed care in the United States will continue to put pressure on the pricing of pharmaceutical products. For example, the Medicare Prescription Drug Improvement and Modernization Act of 2003 reformed the way Medicare covers and reimburses for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for certain drugs. In addition, the new legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of outpatient drugs that will be covered in any therapeutic class. As a result of the new legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. The Medicaid program and state healthcare laws and regulations may also be modified to change the scope of covered products and reimbursement methodology. Cost control initiatives could decrease the established reimbursement rates that we receive for any product candidates in the future, which would limit our revenues and profitability. Legislation and regulations affecting the pricing of pharmaceutical products, may change at any time, which could further limit or eliminate reimbursement rates for our product candidates.

### **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 US 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 US 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 have international operations that expose us to additional business risks.**

We have expanded, and will continue to expand, our operations outside of Canada, primarily in the United States, in order to develop and eventually market and distribute our product candidates. Any expansion in international markets requires additional resources and management attention and subjects us to new business risks, including the following:

- different regulatory requirements for approval of our product candidates;

- dependence on local distributors;
- longer payment cycles and problems in collecting accounts receivable;
- adverse changes in trade and tax regulations;
- the absence or significant lack of legal protection for intellectual property rights;
- difficulty in managing widespread operations;
- unfavorable labor regulations;
- political and economic instability; and
- currency risks.

The occurrence of any of these or other factors may cause our international operations not to be successful or otherwise have an adverse effect on our operating results.

**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 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 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. In addition, we cannot guarantee that:

- we or our licensors were the first to make the inventions covered by each of our issued patents and pending patent applications;
- we or our licensors were the first to file patent applications for these inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our or our licensors' pending patent applications will result in issued patents;
- any of our or our licensors' patents will be valid or enforceable;
- any patents issued to us or our licensors and collaboration partners will provide us with any competitive advantages, will not be challenged by third parties, or will not be invalidated;
- any relevant patent will not expire or remain in force for sufficient time for us to capitalize on such patent;
- we will develop additional proprietary technologies that are patentable; or
- the patents of others will not have an adverse effect on our business.

The actual protection afforded by a patent varies on a product-by-product basis, from country to country and depends upon many factors, including:

- the type of patent;
- the scope of its coverage;
- the availability of regulatory related extensions;
- the availability of legal remedies in a particular country; and
- the validity and enforceability of the patents.

Our ability to maintain and solidify our proprietary position for our product candidates will depend on our success in obtaining effective claims and enforcing those claims once granted.

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-U.S. courts are sometimes less willing than U.S. courts to protect trade secrets. If our competitors independently develop equivalent knowledge, methods and know-how, we would not be able to assert our trade secrets against them and our business could be harmed.

**Certain proposed changes in U.S. law and regulatory schemes may negatively impact the current protection provided by our U.S. patents.**

Protection afforded by U.S. patents may be adversely affected by proposed changes to patent-related U.S. statutes and to U.S. Patent and Trademark Office (U.S. PTO) rules and FDA rules, especially changes to rules concerning the filing of continuation applications. If implemented, these rules may require that second or subsequent continuing application filings be supported by a showing as to why the new amendments or claims, argument or evidence presented could not have been previously submitted. Other rules, if implemented, may limit consideration by the U.S. PTO of up to only ten claims per application. It is common practice to file multiple patent applications with many claims in an effort to maximize patent protection. If the first set of proposed U.S. PTO rules is implemented, they may limit our ability to file continuing applications directed to our product candidates and methods and related competing products and methods. In addition, if the second set of U.S. PTO rules is implemented, they may limit our ability to patent a number of claims sufficient to cover our product candidates and methods and related competing products and methods. Other changes to the patent statutes may adversely affect the protection afforded by U.S. patents or open U.S. patents up to third party attack in non-litigation settings or both.

**Certain existing patents may adversely impact our ability to commercialize our product candidates that utilize the TAIFUN® inhaler.**

We are aware of a granted European patent owned by another entity which contains claims directed to an inhalation device that could be asserted against our TAIFUN® inhalation device. We have initiated an Opposition proceeding before the European Patent Office in order to challenge this granted patent in view of certain prior art references not previously considered by the European Patent Office during the procurement process. An Opposition is an administrative *inter partes* proceeding, the outcome of which is appealable. Based on the advice and analysis of our European patent attorney, we reasonably believe that the outcome of this Opposition proceeding will be favorable to us; either the granted European patent will likely be withdrawn in its entirety or the claims that survive the Opposition likely will not cover our TAIFUN® inhalation device. However, if the outcome is not favorable to us, this may adversely affect our ability to commercialize our product candidates utilizing our TAIFUN® inhalation device in Europe. We are also aware of a counterpart patent that has issued in the United States. However, we reasonably believe that the claims of this U.S. patent, which are not the same as those in the European patent, do not cover our TAIFUN® inhalation device and that our device should not be found to infringe the claims of this U.S. patent.

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

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

**Certain existing patents may adversely impact our ability to commercialize our CGRP product candidate.**

We are aware of at least one issued U.S. patent owned by another entity relating to our CGRP product candidate which expires prior to 2012. Our CGRP product candidate is expected to enter the market no earlier than 2012 following completion of the requisite clinical trials and regulatory approval processes. In the United States, and numerous jurisdictions outside of the United States, a patent owner can not

successfully assert its patent against a party engaged in acts related to the regulatory and product approval processes.

**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 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 non-U.S. countries do not protect intellectual property rights to the same extent as the laws of 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 licensed certain intellectual property to our Barbados subsidiary. There is no assurance these arrangements will be respected by the applicable authorities or that the relevant regulations will not be changed.**

We have licensed certain intellectual property to our Barbados subsidiary and organized our foreign operations in part based on assumptions about the application of various tax laws, foreign currency exchange and capital repatriation laws and other relevant laws of a number of jurisdictions. While we believe that such assumptions are reasonable, there can be no assurance that taxing or other authorities will reach the same conclusion. In addition, if such jurisdictions were to change or modify such laws, we could also suffer adverse tax and financial consequences.

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

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

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

We are primarily responsible for the maintenance of our patents and enforcement of our rights with respect thereto, even where such patents are licensed from third parties. If we choose to go to court to stop someone else from using the inventions claimed in our patents or our licensed patents, that individual or company has the right to ask the court to rule that these patents are invalid and should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are invalid or unenforceable and that we do not have the

right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that its activities do not infringe our rights. In some cases, these lawsuits would involve the government's application of patent-related rules to our situation and, therefore, the lawsuits could include government entities such as the FDA.

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

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

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

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

If another party files a United States patent application on an invention similar to ours, we may elect to participate in or be drawn into an interference proceeding declared by the U.S. PTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our United States patent position with respect to such inventions. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations. We cannot predict whether third parties will assert these claims against us or against the licensors of technology licensed to us, or whether those claims will harm our business. If we are forced to defend against these claims, whether they are with or without any merit, whether they are resolved in favor of or against us or our licensors, we

may face costly litigation and diversion of management's attention and resources. As a result of these disputes, we may have to develop costly non-infringing technology, or enter into licensing agreements.

**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, maintaining goodwill, and maintaining or increasing market share. 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. At present, we anticipate that the first of our product candidates will be commercialized in the latter part of 2010. Consequently, 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.

Regardless of merit or eventual outcome, liability claims either during clinical trials or following commercial introduction may result in:

- decreased demand for our product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- significant litigation costs;
- substantial monetary awards to or costly settlement with patients;
- product recalls;
- loss of revenue; and
- the inability to commercialize our product candidates.

We could also be adversely affected if any of our product candidates or any similar products distributed by other companies prove to be, or are asserted to be, harmful to consumers.

**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 federal, provincial, state, local and foreign 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 federal, provincial, state, local and foreign 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.

**We could be negatively impacted by the application or enforcement of federal and state fraud and abuse laws, including anti-kickback laws and other federal and state referral laws.**

We are subject to various federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state healthcare programs, including the Medicare, Medicaid, and Veterans Administration health programs. Because of the broad nature of these laws, we may be required to alter or discontinue one or more of our practices to be in compliance with these laws. Healthcare fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. Any violation of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our business, financial condition and results of operations. If there is a change in law, regulation, or administrative or judicial interpretations, we may have to change or discontinue our business practices or our existing business practices could be challenged as unlawful, which could have a material adverse effect on our business, financial condition and results of operations.

We could also become subject to false claims litigation under federal statutes, which can lead to:

- treble damages based on the reimbursements by federal health care programs;
- civil money penalties (including penalties levied on a per false claim basis);
- restitution, criminal fines and imprisonment; and
- exclusion from Medicare and Medicaid and other federal and state healthcare programs.

These false claims statutes include the False Claims Act, which allows any person to bring suit on behalf of the federal government alleging the submission of false or fraudulent claims, or causing to present such false or fraudulent claims, under federal programs or contracts claims or other violations of the statute and to share in any amounts paid by the entity to the government in fines or settlement. Pursuant to the federal Deficit Reduction Act of 2005, states are encouraged to enact state versions of the False Claims Act to establish liability for false and fraudulent Medicaid claims. We cannot assure you that we will not become subject to such litigation or, if we are not successful in defending against such actions, that such actions or the costs of defending claims or allegations will not 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 read 'A. Reiter', located in the upper left quadrant of the page.

**Andrew Reiter, CA**  
**Chief Financial Officer**  
Montreal, Quebec, Canada

November 14, 2007