

ARADIGM CORP  
Form 10-Q  
November 14, 2007

Table of Contents

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**  
**Washington, DC 20549**  
**Form 10-Q**

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the quarterly period ended September 30, 2007**

**Or**

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

**For the transition period from**

**to .**

**Commission File Number 0-28402**

**Aradigm Corporation**

*(Exact name of registrant as specified in its charter)*

**California**

*(State or other jurisdiction of  
incorporation or organization)*

**94-3133088**

*(I.R.S. Employer  
Identification No.)*

**3929 Point Eden Way**

**Hayward, CA 94545**

*(Address of principal executive offices including zip code)*

**(510) 265-9000**

*(Registrant's telephone number, including area code)*

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer or a non-accelerated filer. See details of accelerated filer or large accelerated filer as defined in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

*(Class)*

*Common*

*(Outstanding at October 31, 2007)*

*54,046,705*

**ARADIGM CORPORATION  
TABLE OF CONTENTS**

	Page
<b><u>PART I. FINANCIAL INFORMATION</u></b>	
<u>Item 1. Financial Statements:</u>	
<u>Condensed Balance Sheets at September 30, 2007 and December 31, 2006 (unaudited)</u>	3
<u>Condensed Statements of Operations for the three months and nine months ended September 30, 2007 and 2006 (unaudited)</u>	4
<u>Condensed Statements of Cash Flows for the nine months ended September 30, 2007 and 2006 (unaudited)</u>	5
<u>Condensed Statement of Shareholders' Equity (Deficit) for the nine months ended September 30, 2007 (unaudited)</u>	6
<u>Notes to Condensed Financial Statements (unaudited)</u>	7
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	17
<u>Item 3. Quantitative and Qualitative Disclosure About Market Risk</u>	33
<u>Item 4. Controls and Procedure</u>	33
 <b><u>PART II. OTHER INFORMATION</u></b>	 34
<u>Item 1. Legal Proceedings</u>	34
<u>Item 1A. Risk Factors</u>	34
<u>Item 6. Exhibits</u>	45
<b><u>SIGNATURES</u></b>	46
<u>EXHIBIT 10.4</u>	
<u>EXHIBIT 10.5</u>	
<u>EXHIBIT 31.1</u>	
<u>EXHIBIT 31.2</u>	
<u>EXHIBIT 32.1</u>	

**Table of Contents****PART I. FINANCIAL INFORMATION****Item 1. CONDENSED FINANCIAL STATEMENTS**

**ARADIGM CORPORATION**  
**CONDENSED BALANCE SHEETS**  
(In thousands, except share data)

	<b>September 30, 2007 (unaudited)</b>	<b>December 31, 2006 (Note 1)</b>
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 34,512	\$ 27,013
Short-term investments	12,509	501
Restricted cash	74	
Receivables	302	643
Prepaid expenses and other current assets	812	1,002
Total current assets	48,209	29,159
Property and equipment, net	3,055	2,592
Notes receivable from officers and employees	32	31
Restricted cash	228	
Other assets	276	444
Total assets	\$ 51,800	\$ 32,226
<b>LIABILITIES, CONVERTIBLE PREFERRED STOCK AND SHAREHOLDERS EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 1,080	\$ 1,151
Accrued cost of clinical and other studies	734	278
Accrued compensation	1,639	1,814
Facility lease exit obligation	377	
Other accrued liabilities	366	511
Total current liabilities	4,196	3,754
Deferred revenue	440	
Deferred rent	301	1,035
Facility lease exit obligation	1,467	
Other non-current liabilities	325	29
Note payable and accrued interest to related party	7,973	7,686
Commitments and contingencies		
Convertible preferred stock, no par value; 2,050,000 shares authorized; issued and outstanding shares: none outstanding at September 30, 2007 and 1,544,626 at December 31, 2006; liquidation preference of \$0 at September 30, 2007 and \$41,866 at December 31, 2006		23,669
Shareholders' equity (deficit):		
Preferred stock, 2,950,000 shares authorized, none issued and outstanding		

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Common stock, no par value, 100,000,000 shares authorized; issued and outstanding shares: 54,046,705 at September 30, 2007 and 14,765,474 at December 31, 2006	341,961	283,914
Accumulated other comprehensive income (loss)	(8)	4
Accumulated deficit	(304,855)	(287,865)
Total shareholders' equity (deficit)	37,098	(3,947)
Total liabilities, convertible preferred stock and shareholders' equity (deficit)	\$ 51,800	\$ 32,226

See accompanying Notes to Condensed Financial Statements

3

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**Table of Contents**

**ARADIGM CORPORATION**  
**CONDENSED STATEMENTS OF OPERATIONS**  
(In thousands, except per share data)  
(unaudited)

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Contract and milestone revenues:				
Related parties	\$	\$ 9	\$ 23	\$ 59
Unrelated parties	230	1,117	920	3,947
Total revenues	230	1,126	943	4,006
Operating expenses:				
Research and development	3,899	4,547	11,147	17,645
General and administrative	1,757	3,514	6,470	9,051
Restructuring and asset impairment	2,059	347	2,059	5,717
Total operating expenses	7,715	8,408	19,676	32,413
Loss from operations	(7,485)	(7,282)	(18,733)	(28,407)
Gain on sale of patent and royalty interest to related party		20,000		20,000
Interest income	684	459	2,020	839
Interest expense	(101)	(95)	(293)	(101)
Other income (expense)		(7)	16	26
Net income (loss)	\$ (6,902)	\$ 13,075	\$ (16,990)	\$ (7,643)
Basic net income (loss) per common share	\$ (0.13)	\$ 0.89	\$ (0.34)	\$ (0.52)
Diluted net income (loss) per common share	\$ (0.13)	\$ 0.82	\$ (0.34)	\$ (0.52)
Shares used in computing basic net income (loss) per common share	53,948	14,660	49,617	14,625
Shares used in computing diluted net income (loss) per common share	53,948	15,982	49,617	14,625

See accompanying Notes to Condensed Financial Statements

**Table of Contents**

**ARADIGM CORPORATION**  
**CONDENSED STATEMENTS OF CASH FLOWS**  
(In thousands)  
(unaudited)

	<b>Nine Months Ended September 30,</b>	
	<b>2007</b>	<b>2006</b>
Cash flows from operating activities:		
Net loss	\$ (16,990)	\$ (7,643)
Adjustments to reconcile net loss to cash used in operating activities:		
Impairment loss on property and equipment	180	4,014
Amortization and accretion of investments	(26)	
Depreciation and amortization	589	698
Stock-based compensation	1,097	1,286
Loss on retirement and sale of property and equipment	10	21
Facility lease exit cost	1,459	
Gain on sale of patents and royalty interest		(20,000)
Changes in operating assets and liabilities:		
Receivables	341	(222)
Prepaid expenses and other current assets	190	84
Restricted cash	(302)	
Other assets	168	12
Accounts payable	(378)	(2,329)
Accrued compensation	(175)	(1,344)
Other accrued liabilities	894	(79)
Deferred revenue	440	(118)
Deferred rent	(114)	214
Facility lease exit obligation	(235)	
Net cash used in operating activities	(12,852)	(25,406)
Cash flows from investing activities:		
Capital expenditures	(946)	(1,329)
Purchases of available-for-sale investments	(13,494)	(507)
Proceeds from sales and maturities of available-for-sale investments	1,500	
Proceeds from sales of property and equipment	11	4,000
Proceeds from sale of patents and royalty interest		20,000
Net cash provided by (used in) investing activities	(12,929)	22,164
Cash flows from financing activities:		
Proceeds from public offering of common stock, net	33,178	
Proceeds from issuance of common stock	103	286
Proceeds from exercise of options and warrants from common stock		2
Proceeds from issuance of note payable to related party		7,500
(Advances) payments received on notes receivable from officers and employees	(1)	40

Net cash provided by financing activities	33,280	7,828
Net increase in cash and cash equivalents	7,499	4,586
Cash and cash equivalents at beginning of period	27,013	27,694
Cash and cash equivalents at end of period	\$ 34,512	\$ 32,280
Supplemental schedule of non-cash financing activities:		
Conversion of redeemable convertible preferred stock to common stock	\$ 23,669	\$
Supplemental disclosure of non-cash investing activities		
Purchase of property and equipment in trade accounts payable	\$ 307	\$

See accompanying Notes to Condensed Financial Statements

5



Table of Contents

**ARADIGM CORPORATION**  
**CONDENSED STATEMENT OF SHAREHOLDERS' EQUITY (DEFICIT)**  
(In thousands, except share data)

	Series A Convertible Preferred Stock		Common Stock		Accumulated Other Comprehensive Income	Accumulated Deficit	Total Shareholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	(loss)	Deficit	(Deficit)
Balances at December 31, 2006	1,544,626	\$ 23,669	14,765,474	\$ 283,914	\$ 4	\$ (287,865)	\$ (3,947)
Issuance of common stock in public offering, net (unaudited)			37,950,000	33,178			33,178
Issuance of common stock upon conversion of preferred stock related to public offering (unaudited)	(1,544,626)	(23,669)	1,235,699	23,669			23,669
Issuance of common stock under the employee stock purchase plan (unaudited)			100,407	103			103
Reversal of restricted stock award due to forfeiture (unaudited)			(4,875)				
Stock-based compensation related to issuance of stock option grants (unaudited)				1,097			1,097
Comprehensive loss: Net loss (unaudited)						(16,990)	(16,990)
Net change in unrealized gain (loss) on available-for-sale investments (unaudited)					(12)		(12)
Total comprehensive loss (unaudited)							(17,002)
		\$	54,046,705	\$ 341,961	\$ (8)	\$ (304,855)	\$ 37,098

Balances at  
September 30, 2007  
(unaudited)

See accompanying Notes to Condensed Financial Statements  
6

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**Table of Contents**

**ARADIGM CORPORATION**  
**NOTES TO THE UNAUDITED CONDENSED FINANCIAL STATEMENTS**  
**September 30, 2007**

**1. Organization and Basis of Presentation**

***Organization***

Aradigm Corporation (the Company, Aradigm, we, us, and/or our) is a California corporation focused on the development and commercialization of a portfolio of drugs delivered by inhalation for the treatment of severe respiratory diseases by pulmonologists. Our principal activities to date have included obtaining financing, recruiting management and technical personnel, securing operating facilities, conducting research and development, and expanding commercial production capabilities. We do not anticipate receiving any revenue from the sale of products for at least the next several years. Our ability to continue our development and commercialization activities is dependent upon the ability of management to obtain additional financing as required. Management believes that cash, cash equivalents and short-term investments at September 30, 2007 are sufficient to enable us to meet our obligations through 2008. Management expects to be able to obtain additional funds through collaborative arrangements, equity issuances and/or debt arrangements. We operate as a single operating segment, the development and eventual commercialization of a portfolio of drugs delivered by inhalation for the treatment and prevention of severe respiratory diseases by pulmonologists.

***Basis of Presentation***

The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. generally accepted accounting principles (GAAP) have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). In the opinion of management, the financial statements reflect all adjustments, which are only of a normal recurring nature, necessary for a fair presentation. The accompanying condensed financial statements should be read in conjunction with the financial statements and notes thereto included with our Annual Report on Form 10-K for the year ended December 31, 2006, as filed with the Securities and Exchange Commission. The results of our operations for the interim periods presented are not necessarily indicative of operating results for the full fiscal year or any future interim period.

The balance sheet at December 31, 2006 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by GAAP for complete financial statements.

**2. Summary of Significant Accounting Policies**

***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. These estimates include useful lives for property and equipment and related depreciation calculations, estimated amortization period for payments received from product development and license agreements as they relate to the revenue recognition of deferred revenue and assumptions for valuing options, warrants and other stock-based compensation. Actual results could differ from these estimates.

***Revenue Recognition***

Contract revenues consist of revenues from grants, collaboration agreements and feasibility studies. Under the agreements, revenue is recognized once costs are incurred and collectibility is reasonably assured. Under some agreements our collaborators have the right to withhold reimbursement of costs incurred until the work performed under the agreement is mutually agreed upon. For these agreements revenue is recognized upon confirmation from the collaborator of acceptance of work performed and payment amount. Deferred revenue represents the portion of the nonrefundable research payment received that has not been earned. In accordance with contract terms, milestone payments from collaborative

**Table of Contents**

research agreements are considered reimbursements for costs incurred under the agreements and, accordingly, are generally recognized as revenue either upon the completion of the milestone effort, when payments are contingent upon completion of the effort, or are based on actual efforts expended over the remaining term of the agreements when payments precede the required efforts. Costs of contract revenues are approximate to or are greater than such revenues and are included in research and development expenses. Refundable development and license fee payments are deferred until the specified performance criteria are achieved. Refundable development and license fee payments are generally not refundable once the specific performance criteria are achieved and accepted.

We recognize revenue in accordance with Emerging Issues Task Force ( EITF ) Issue 00-21, *Revenue Arrangements with Multiple Deliverables* and SEC Staff Accounting Bulletin No. 104. Revenue arrangements with multiple components are divided into separate units of accounting if certain criteria are met, including whether the delivered component has stand-alone value to the customer, and whether there is objective reliable evidence of the fair value of the undelivered items. Consideration received is allocated among the separate units of accounting based on their relative fair values, and the applicable revenue recognition criteria are identified and applied to each of the units.

***Impairment or Disposal of Long-Lived Assets***

In accordance with Statement of Financial Accounting Standard ( SFAS ) No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* ( SFAS 144 ), we review for impairment whenever events or changes in circumstances indicate that the carrying amount of property and equipment may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values and the loss is recognized in the statements of operations.

***Accounting for Costs Associated with Exit or Disposal Activities***

In accordance with Statement of SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* ( SFAS 146 ), we recognize a liability for the cost associated with an exit or disposal activity that is measured initially at its fair value in the period in which the liability is incurred, except for a liability for one-time termination benefits that is incurred over time. According to SFAS 146, costs to terminate an operating lease or other contracts are (a) costs to terminate the contract before the end of its term or (b) costs that will continue to be incurred under the contract for its remaining term without economic benefit to the entity. In periods subsequent to initial measurement, changes to the liability shall be measured using the credit-adjusted risk-free rate that was used to measure the liability initially.

***Recent Accounting Pronouncements***

In July 2006, the Financial Accounting Standards Board ( FASB ) issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes – an interpretation of FASB Statement No. 109* ( FIN 48 ), which provides clarification related to the process associated with accounting for uncertain tax positions recognized in financial statements. FIN 48 prescribes a more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken, or expected to be taken, in a tax return. FIN 48 also provides guidance related to, among other things, classification, accounting for interest and penalties associated with tax positions, and disclosure requirements. We adopted FIN 48 on January 1, 2007 and there was no impact to our financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurement* ( SFAS 157 ). SFAS 157 provides enhanced guidance for using fair value to measure assets and liabilities. The guidance clarifies the principle for assessing fair value based on the assumptions market participants would use when pricing the asset or liability. In support of this principle, the guidance establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. The fair value hierarchy gives the highest priority to quoted prices in active markets and the lowest priority to unobservable data such as companies' own data. Under this guidance, fair value measurements would be separately disclosed by level within the

**Table of Contents**

fair value hierarchy. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. We will adopt this guidance beginning on January 1, 2008.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* ( SFAS 159 ). SFAS 159 expands opportunities to use fair value measurement in financial reporting and permits entities to choose to measure many financial instruments and certain other items at fair value. SFAS 159 is effective for fiscal years beginning after November 15, 2007. We have not yet decided if we will choose to measure any eligible financial assets and liabilities at fair value.

In June 2007, the FASB issued EITF Issue No. 07-03, *Accounting for Non-Refundable Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ( EITF 07-03 ). EITF 07-03 provides guidance on whether non-refundable advance payments for goods that will be used or services that will be performed in future research and development activities should be accounted for as research and development costs or deferred and capitalized until the goods have been delivered or the related services have been rendered. EITF 07-03 is effective for fiscal years beginning after December 15, 2007. We do not expect our adoption of this new standard to have a material impact on our financial position and results of operations.

**3. Stock-Based Compensation**

The following table shows the stock-based employee compensation expense included in the statement of operations for the three and nine-month periods ended September 30, 2007 and 2006 (in thousands, except per share amounts):

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
Costs and expenses:				
Research and development	\$ 183	\$ 196	\$ 438	\$ 666
General and administrative	211	236	575	620
Total stock-based compensation expense	\$ 394	\$ 432	\$ 1,013	\$ 1,286
Impact on basic and diluted net income (loss) per common share	\$ (0.01)	\$ (0.03)	\$ (0.02)	\$ (0.09)

There was no capitalized stock-based employee compensation cost as of September 30, 2007. Because we have cumulative net losses as of September 30, 2007, there was no recognized tax benefit associated with stock-based compensation expense.

Total compensation expense for restricted stock awards was \$18,000 and \$25,000 for the three-month period ended September 30, 2007 and 2006, respectively, and was \$54,000 and \$67,000 for the nine-month period ended September 30, 2007 and 2006, respectively. As of September 30, 2007, 49,691 shares subject to unvested restricted share awards are outstanding. As of September 30, 2007, \$185,000 of total unrecognized compensation expense, net of forfeitures, related to non-vested stock awards is expected to be recognized over a weighted average period of 2.4 years.

Total compensation expense for employee stock options and stock purchases under the employee stock purchase plan was \$376,000 and \$407,000 for the three-month period ended September 30, 2007 and 2006, respectively, and was \$959,000 and \$1,219,000 for the nine-month period ended September 30, 2007 and 2006, respectively. As of September 30, 2007, \$1.9 million of total unrecognized compensation expense, net of forfeitures, related to non-vested stock options and stock purchases is expected to be recognized over a weighted average period of 2.4 years.

Total compensation expense for stock options issued to consultants was \$14,000 and \$500 for the three-month period ended September 30, 2007 and 2006, respectively, and was \$84,000 and \$0 for the nine-month period ended September 30, 2007 and 2006, respectively.



**Table of Contents**

As of September 30, 2007, we had outstanding shares or options under the following share-based compensation plans, which are more fully described in our 2006 Annual Report on Form 10-K:

***2005 Equity Incentive Plan***

The 1996 Equity Incentive Plan (the 1996 Plan ) and the 2005 Equity Incentive Plan (the 2005 Plan ), which amended, restated and retitled the 1996 Plan, were adopted to provide a means by which our selected officers, directors, scientific advisory board members, employees, consultants, and affiliates could be given an opportunity to acquire an equity interest in us. All employees, directors, officers, scientific advisory board members and consultants are eligible to participate in the 2005 Plan. As of September 30, 2007, we had 3,307,448 shares of common stock available for future issuance under the 2005 Plan.

***1996 Non-Employee Directors Plan***

The 1996 Non-Employee Directors Stock Option Plan (the Directors Plan ) had 45,000 shares of common stock authorized for issuance. Options granted under the Directors Plan expire no later than 10 years from date of grant. The option price shall be at 100% of the fair value on the date of grant as determined by the board of directors. The options generally vest quarterly over a period of one year. During 2000, the board of directors approved the termination of the Directors Plan. No more options can be granted under the plan after its termination. The termination of the Directors Plan had no effect on the options already outstanding. There was no activity in the Directors Plan during the nine months ended September 30, 2007 or the year ended December 31, 2006. As of September 30, 2007, options to purchase an aggregate of 14,643 shares remain outstanding with exercise prices ranging from \$41.25 to \$120.63, with no additional shares available for grant.

***Employee Stock Purchase Plan***

In April 1996, our Board of Directors adopted the Employee Stock Purchase Plan (the Purchase Plan ) and our shareholders approved the adoption of the Purchase Plan in June 1996. Employees generally are eligible to participate in the Purchase Plan if they have been continuously employed by us for at least 10 days prior to the first day of the offering period and are customarily employed at least 20 hours per week and at least five months per calendar year and are not a 5% or greater stockholder. Shares may be purchased under the Purchase Plan at 85% of the lesser of the fair market value of the common stock on the grant date or purchase date. Employee contributions, through payroll deductions, are limited to the lesser of fifteen percent of earnings or \$25,000. As of September 30, 2007 a total of 809,560 shares have been issued under the Purchase Plan, leaving a balance of 240,440 shares available for future issuance.

***Valuation Assumptions***

The fair value of options was estimated at the date of grant using the Black-Scholes option pricing model. The assumptions used for the three and nine months ended September 30, 2007 and 2006 and the resulting estimates of weighted-average fair value per share of options granted and shares purchased during these periods are as follows:

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	<b>2007</b>	<b>2006</b>	<b>2007</b>	<b>2006</b>
<b>The 2005 Plan</b>				
Dividend yield	0.0%	0.0%	0.0%	0.0%
Volatility factor	72.8%	87.4%	81.2%	86.7%
Risk-free interest rate	4.0%	4.8%	4.9%	4.9%
Expected life (years)	4.0	4.2	4.0	4.2
Weighted-average fair value of options granted during the periods	\$0.76	\$1.22	\$0.82	\$1.42
<b>The Purchase Plan</b>				
Dividend yield	0.0%	0.0%	0.0%	0.0%
Volatility factor	82.7%	85.7%	82.7%	85.7%
Risk-free interest rate	4.8%	4.8%	4.8%	4.8%

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Expected life (years)	1.3	0.7	1.3	0.7
Weighted-average fair value of employee stock purchases during the periods	\$0.61	\$1.33	\$0.61	\$1.33
	10			

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**Table of Contents***Stock Option Activity*

A summary of the status of our stock option plans at September 30, 2007 and changes during the nine months then ended is presented in the table below (share numbers and aggregate intrinsic value in thousands):

	Number of  shares	Weighted- average exercise  price	Weighted- average remaining contractual life in years	Aggregate intrinsic  value
Options outstanding at January 1, 2007	3,064	\$ 8.90	8.28	\$
Options granted	728	1.30	9.56	
Options exercised				
Options cancelled	(943)	10.33		
Options outstanding at September 30, 2007	2,849	6.49	8.20	44
Options exercisable at September 30, 2007	1,368	11.57	7.26	15

During the three months ended September 30, 2007, we did not grant options to employees, Board members or consultants to purchase shares of common stock and for the nine months ended September 30, 2007, we granted options to employees, Board members and consultants to purchase 529,650, 95,000 and 103,600 shares of common stock, respectively. There were no options exercised during the nine months ended September 30, 2007.

The following table summarizes information about stock options outstanding and exercisable at September 30, 2007:

Range of Exercise Price	Options Outstanding			Options Exercisable	
	Number outstanding (in thousands)	Weighted- average remaining contractual life (in years)	Weighted- average exercise price	Number exercisable (in thousands)	Weighted- Average Exercise Price
\$1.02-\$1.15	47	9.12	\$ 1.07	23	\$ 1.02
\$1.23-\$1.23	316	9.37	\$ 1.23	77	\$ 1.23
\$1.37-\$1.37	370	9.72	\$ 1.37	37	\$ 1.37
\$1.41-\$1.64	90	8.71	\$ 1.61	69	\$ 1.61
\$1.70-\$1.70	300	8.69	\$ 1.70	94	\$ 1.70
\$1.80-\$1.80	544	8.91	\$ 1.80	339	\$ 1.80
\$1.87-\$1.87	500	8.86	\$ 1.87	135	\$ 1.87
\$3.14-\$5.95	317	7.18	\$ 5.04	235	\$ 5.22
\$6.25-\$61.25	297	4.32	\$24.06	291	\$24.30
\$62.81-\$120.63	68	2.15	\$91.27	68	\$91.27
	2,849			1,368	

**4. Net Income (Loss) Per Share**

Basic net income (loss) is computed using the weighted-average number of shares of common stock outstanding less the weighted-average number of shares subject to repurchase. There were no shares subject to repurchase in the nine months ended September 30, 2007.

The calculation of basic and diluted net income (loss) per share is summarized as follows (in thousands, except per share amounts):

11

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**Table of Contents**

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	2007	2006	2007	2006
Numerator:				
Net income (loss)	\$ (6,902)	\$ 13,075	\$ (16,990)	\$ (7,643)
Denominator:				
Basic weighted average number of common shares outstanding	53,948	14,660	49,617	14,625
Effect of dilutive securities:				
Restricted stock awards		86		
Convertible preferred stock		1,236		
Shares used in calculating diluted net income (loss) per share	53,948	15,982	49,617	14,625
Basic net income (loss) per common share	(0.13)	0.89	(0.34)	(0.52)
Diluted net income (loss) per common share	(0.13)	0.82	(0.34)	(0.52)

The effects of including the incremental shares associated with options and warrants are anti-dilutive, and are not included in diluted weighted average common shares outstanding for the three months ended September 30, 2006. For the three months ended September 30, 2007 and nine months ended September 30, 2007 and 2006, we excluded common stock equivalents consisting of outstanding stock options, warrants, unvested restricted stock and convertible preferred stock from the calculation of diluted loss per share because these securities were anti-dilutive due to the net loss in the respective period. The following securities were excluded from the calculation of diluted loss per as their effect would be anti-dilutive (in thousands):

	<b>Three months ended September 30,</b>		<b>Nine months ended September 30,</b>	
	2007	2006	2007	2006
Outstanding stock options	2,849	2,919	2,849	2,232
Convertible preferred stock				1,236
Unvested restricted stock	50		50	86
Warrants to purchase common shares	836	2,120	836	2,120
	3,735	5,039	3,735	5,674

**5. Comprehensive Income (Loss)**

Comprehensive income (loss) includes net income (loss) and other comprehensive income (loss), which for us is primarily comprised of unrealized holding gains and losses on our available-for-sale securities that are excluded from the statement of operations in computing net loss and reported separately in shareholders' equity (deficit). Comprehensive income (loss) and its components are as follows (in thousands):

	<b>Three months ended</b>	<b>Nine months ended</b>
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	<b>September 30,</b>		<b>September 30,</b>	
	2007	2006	2007	2006
Net income (loss)	\$ (6,902)	\$ 13,075	\$ (16,990)	\$ (7,643)
Other comprehensive income (loss):				
Change in unrealized gain (loss) on available-for-sale securities	(8)	4	(12)	(2)
Comprehensive income (loss)	\$ (6,910)	\$ 13,079	\$ (17,002)	\$ (7,645)

**Table of Contents****6. Cash, Cash Equivalents and Short-Term Investments**

The following summarizes the fair value of our cash, cash equivalents and short-term investments (in thousands):

	<b>September 30, 2007</b>	<b>December 31, 2006</b>
Cash and cash equivalents:		
Cash and money market fund	\$ 353	\$ 1,248
Commercial paper	34,159	25,765
	<b>\$ 34,512</b>	<b>\$ 27,013</b>
Short-term investments:		
Corporate and government notes	\$ 12,509	\$ 501

We consider all highly liquid investments purchased with a maturity of three months or less to be cash equivalents. All short-term investments at September 30, 2007 mature in less than one year. We place our cash, cash equivalents and short term investments in money market funds, commercial paper and corporate and government notes.

**7. Restricted Cash**

In accordance with the terms of our sublease agreement with Mendel Biotechnology, Inc. ( Mendel ) dated July 18, 2007 (see Note 16), we are maintaining a certificate of deposit in the amount of \$300,000 as collateral against a letter of credit to secure the refund to Mendel of any unapplied portion of the \$300,000 in prepaid rent paid by Mendel. The prepaid rent, of which \$72,000 was included in other current accrued liabilities and the remaining balance of \$228,000 was included in other non-current liabilities line items in the accompanying balance sheets, will be applied to the 12<sup>th</sup>, 18<sup>th</sup>, 24<sup>th</sup> and 27<sup>th</sup> monthly rent of the sublease. The letter of credit expires on November 18, 2009.

**8. Restructuring and Asset Impairment**

On May 15, 2006 we announced the implementation of a strategic restructuring of our business operations to focus resources on advancing the current product pipeline and developing products focused on respiratory disease, leveraging our core expertise and intellectual property. We accounted for the restructuring activity in accordance with FAS No. 146, *Accounting for Costs Associated with Exit or Disposal*. The restructuring included a reduction in workforce, the majority of which were research personnel, sale of Intraject\*-related assets and vacating part of our leased facility.

For the three and nine months ended September 30, 2007, we recorded a restructuring and asset impairment charge of \$2.1 million relating to the expected loss associated with the subleasing of the office space to Mendel because the monthly payments we expect to receive under the sublease are less than the amounts we will owe the lessor for the sublease space (see Note 16).

For the three and nine months ended September 30, 2006, we recorded a restructuring and asset impairment charge of \$333,000 and \$1.7 million, respectively, primarily related to the reduction in our workforce. This expense was included in the restructuring and asset impairment expense line item on the statement of operations. In addition, we recorded non-cash impairment charges of \$4.0 million during the three months ended June 30, 2006, which were incurred to write down our Intraject-related assets to their net realizable value. The net realizable value did not include any potential future contingent milestones or royalties. We sold these assets to Zogenix, Inc. ( Zogenix ) during the three months ended September 30, 2006 for an initial payment of \$4.0 million and recorded an additional impairment charge of \$14,000 (see Note 10).

**9. Related Party Transactions**

On August 31, 2007, we and CyDex, Inc. ( CyDex ) entered into a Collaboration Agreement (the CyDex Agreement ), which contemplates that the parties will collaborate on the development and commercialization of products that utilize our AERx® pulmonary delivery technology and CyDex's solubilization and stabilization technologies to deliver inhaled corticosteroids, anticholinergics and beta-2 agonists for the treatment of asthma and

chronic obstructive pulmonary diseases (COPD). John Siebert, a member of our Board of Directors, is the Chief Executive Officer of CyDex.

Under the terms of the CyDex Agreement, the parties will share in the revenue from sales and licensing of such products to a third party for further development and commercialization. Details of each collaboration project will be determined by a joint steering committee consisting of members appointed by each of the

**Table of Contents**

parties. Costs of each collaboration project will be borne 60% by us and 40% by CyDex. Revenues from each collaboration project will be shared in the same ratio. The CyDex Agreement commenced on August 31, 2007 and, unless terminated earlier, will extend for a minimum period of two years. Either party may terminate the Agreement upon advance notice to the other party, and the non-terminating party will retain an option to continue the development and commercialization of any terminated product, subject to payment of a royalty to the terminating party.

We did not recognize any revenue or any significant expense relating to CyDex during the three months and nine months ended September 30, 2007.

On July 3, 2006, we and Novo Nordisk A/S ( Novo Nordisk ), a less than 1% holder of our common stock, entered into a Second Amended and Restated License Agreement to reflect: (i) the transfer by us of certain intellectual property, including all rights, title and interest to the patents that contain claims that pertain generally to breath control or specifically to the pulmonary delivery of monomeric insulin and monomeric insulin analogs, together with interrelated patents, which are linked via terminal disclaimers, as well as certain pending patent applications and continuations thereof by us for a cash payment to us of \$12.0 million, with Aradigm retaining exclusive, royalty-free control of these patents outside the field of glucose control; (ii) our receipt of a royalty prepayment of \$8.0 million in exchange for a one percent reduction on our average royalty rate for the commercialized AERx<sup>®</sup> insulin Diabetes Management System (iDMS) product and; (iii) a loan to us in the principal amount of \$7.5 million.

The \$12.0 million and the \$8.0 million were included in gain on sale of patent and royalty interest line item in the accompanying statements of operations for the three and nine month periods ended September 30, 2006. The loan bears interest accruing at 5% per annum and the principal along with the accrued interest was payable in three equal payments of \$3.5 million at July 2, 2012, July 1, 2013 and June 30, 2014. The loan was secured by a pledge of the net royalty stream payable to us by Novo Nordisk pursuant to the License Agreement.

During the three months and nine months ended September 30, 2007, we have \$0 and \$23,000 related party revenues with Novo Nordisk and its subsidiary, Novo Nordisk Delivery Technologies ( NNDT ), respectively, and \$1,000 and \$6,000 related party research and development expenses, respectively.

**10. Sale of Intraject-Related Assets**

In August 2006, we sold all of our assets related to the Intraject technology platform and products, including 12 United States patents along with any foreign counterparts corresponding to those United States patents, to Zogenix, a newly created private company that had some officers who were former officers of our company. Zogenix is responsible for further development and commercialization efforts of Intraject. We received a \$4.0 million initial payment and will be entitled to a milestone payment upon initial commercialization and royalty payments upon any commercialization of products that may be developed and sold using the Intraject technology. We recorded non-cash impairment charges of \$14,000 and \$4.0 million during the three and nine months ended September 30, 2006, respectively, which were incurred to write down our Intraject-related assets to their net realizable value. The net book value of these assets at the time of sale was \$4.0 million. The net realizable value did not include any potential future contingent milestones or royalties. We sold these assets to Zogenix during the three months ended September 30, 2006 for an initial payment of \$4.0 million.

**11. Exclusive License, Development and Commercialization Agreement**

On August 30, 2007, we signed an Exclusive License, Development and Commercialization Agreement (the Lung Rx Agreement ) with Lung Rx, Inc. ( Lung Rx ), a wholly-owned subsidiary of United Therapeutics Corporation, pursuant to which we granted Lung Rx an exclusive license to develop and commercialize inhaled treprostinil using our AERx Essence<sup>®</sup> technology for the treatment of pulmonary arterial hypertension (PAH) and other potential therapeutic indications.

Under the terms of the Lung Rx Agreement, we received an upfront fee of \$440,000 from Lung Rx, which will be followed by an additional fee of \$440,000 four months after the signing date. The upfront fee of \$440,000 we received has been reflected as deferred revenue in the accompanying balance sheet. Under the terms of the Lung Rx Agreement, we will initiate and be responsible for conducting and funding a study that includes a bridging clinical trial intended to compare the AERx Essence technology to the nebulizer used in the recently completed Phase 3 registration trial conducted by United Therapeutics for treprostinil with a nebulizer. We expect the bridging clinical

trial will be completed in 2008.



## **Table of Contents**

Following successful completion of the bridging study, we will receive from Lung Rx certain milestone payments and license fees. These fees are expected to be paid within three years of signing the Lung Rx Agreement and total up to \$9.65 million. In addition, Lung Rx will purchase \$3.47 million of our common stock at the average closing price for the thirty day period prior to specified events. Under the terms of the Lung Rx Agreement, following successful completion of the bridging study, Lung Rx will also pay for the remaining development costs to commercialize and be responsible for manufacturing inhaled treprostinil with AERx Essence technology.

Following commercialization of the product, we will receive royalties from Lung Rx on a tiered basis of up to 10% of net sales of any licensed products.

### **12. Manufacturing and Supply Agreement**

On August 8, 2007, we entered into a Manufacturing and Supply Agreement (the "Enzon Agreement") with Enzon Pharmaceuticals, Inc. ("Enzon") related to our ARD-3100 program, an inhaled formulation of Liposomal Ciprofloxacin for the treatment and control of respiratory infections common to patients with cystic fibrosis. Under the Enzon Agreement, Enzon will manufacture and supply us with Ciprofloxacin, Liposomal Ciprofloxacin, and other products that may be identified by us. For manufacturing the initial two products, we will pay Enzon costs and fees totaling \$3,294,500 in addition to costs and fees for stability studies or other services that may be agreed by both parties. The agreement commenced on August 8, 2007, and will extend for a period of five years, unless terminated earlier by either party.

### **13. Income Taxes**

We adopted the provisions of FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes* (an Interpretation of FASB Statement No. 109), or FIN 48, on January 1, 2007. We did not have any unrecognized tax benefits and there was no effect on our financial condition or results of operations as a result of implementing FIN 48.

We recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. As of the date of adoption of FIN 48, we did not have any accrued interest or penalties associated with any unrecognized tax benefits, nor was any interest expense recognized for the period ended September 30, 2007.

The Tax Reform Act of 1986 under Section 382, as amended, limits the annual use of net operating loss and tax credit carry forwards in certain situations where changes occur in stock ownership of a company. We are currently in the process of performing this ownership analysis and it is possible that there has been a Section 382 change in ownership. In the event we have a change in ownership, as defined, the annual utilization of such carry forwards could be limited and our loss and credit carry forwards may expire unused. Our net operating losses and tax credit carry forwards are more fully described in our 2006 Annual Report on Form 10-K.

We file income tax returns in the U.S. federal jurisdiction and various state and foreign jurisdictions. We are subject to U.S. federal or state income tax examinations by tax authorities for all years in which we reported net operating losses that are being carried forward for tax purposes. We do not believe there will be any material changes in our unrecognized tax positions over the next 12 months.

### **14. Public Offering of Common Shares**

On January 30, 2007, we received \$33.9 million from the closing of a public offering of 37,950,000 shares of common stock in an underwritten public offering with net proceeds, after underwriting discount and expenses, of approximately \$33.2 million. This public offering triggered the automatic conversion of all outstanding shares of Series A convertible preferred stock to common stock and eliminated the Series A liquidation preference of \$41.9 million, equal to the original issue price plus all accrued and unpaid dividends (as adjusted for any stock dividends, combinations, splits, recapitalizations and other similar events). Following the offering, the 1,544,626 shares of Series A convertible preferred stock was converted to 1,235,699 shares of common stock, and no liquidation preference or other preferential rights remained. As of September 30, 2007, we had 54,046,705 common shares outstanding.

### **15. CFO Departure**

On June 5, 2007, we announced the departure of Mr. Thomas C. Chesterman as our Senior Vice President, Chief Financial Officer and Secretary, effective June 20, 2007. Under the terms of our severance benefit agreement, Mr. Chesterman was entitled to a severance package including his annual base salary of \$306,000, a bonus in the amount of \$116,531 representing his 2007 target bonus award



**Table of Contents**

multiplied by the average annual percentage achievement of corporate goals for the three complete fiscal years preceding his departure date, and the continuation of his health insurance benefits for twelve months from the date of departure. In addition, Mr. Chesterman was paid his accrued vacation balance of \$48,842 at the time of his departure. We recorded severance expense of \$306,000 in June 2007 and expect to complete payment of the remaining severance by July 2008.

**16. Sublease Agreement**

On July 18, 2007, we entered into a sublease agreement with Mendel, to sublease approximately 48,000 square feet of the 72,000 square foot facility located at 3929 Point Eden Way, Hayward, CA. The sublease consists of approximately 46,000 square feet of office and laboratory space and an additional rentable space of 2,000 square feet to be vacated by us no later than March 15, 2008. We lease the space pursuant to a lease agreement dated January 28, 1998, as amended (the "Master Lease"), between us and Hayward Point Eden I Limited Partnership.

The sublease commenced on July 18, 2007 and expires on July 8, 2016. Mendel will make monthly base rent payments totaling \$4.6 million through August 2012 that will offset a portion of our existing building lease obligation. Mendel has the option to terminate the sublease early on September 1, 2012 for a termination fee of \$225,000. If the option to terminate the sublease is not exercised by Mendel, we will receive an additional \$4.0 million through the expiration of the sublease in 2016. Mendel will also pay us its share of all pass through costs such as taxes, operating expenses, and utilities based on the percentage of the facility space occupied by them. On July 18, 2007, Mendel paid \$75,000 in cash and provided a letter of credit in the amount of \$150,000 as collateral for a security deposit. The letter of credit expires on July 3, 2012.

During the third quarter of 2007, we recorded a \$2.1 million lease exit liability and related expense for our expected loss on the sublease, in accordance with SFAS 146, because the monthly payments we expect to receive under the sublease are less than the amounts we will owe the lessor for the sublease space. The fair value of the lease exit liability was determined using a credit-adjusted risk-free rate to discount the estimated future net cash flows, consisting of our minimum lease payments to the lessor for the sublease space and payments we will receive under the sublease. The sublease loss and ongoing accretion expense required to record the lease exit liability at its fair value using the interest method have been recorded as part of restructuring and asset impairment expense in the statements of operations.

The lease exit liability activity for the third quarter of 2007 is as follows (in thousands):

Loss on sublease	\$ 2,063
Accretion expense	16
Lease payments	(235)
Balance at September 30, 2007	\$ 1,844

We recorded \$377,000 of the \$1.8 million lease exit liability at September 30, 2007 in current liabilities and the remaining \$1.5 million in non-current liabilities in the accompanying balance sheet.

In addition to recording the lease exit liability and related loss, we reversed the deferred rent liability, and wrote off leasehold improvements, related to the sublease space. These amounts are included in restructuring and asset impairment expense for the third quarter of 2007 and are summarized as follows (in thousands):

Loss on sublease	\$ 2,063
Lease commission	420
Accretion expense	16
Reversal of deferred rent liability related to sublease space	(620)
Write-off of leasehold improvements and equipment related to sublease space, net	180

Total restructuring and asset impairment expense	\$ 2,059
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**Table of Contents**

**Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

*The discussion below contains forward-looking statements that are based on the beliefs of management, as well as assumptions made by, and information currently available to, management. Our future results, performance or achievements could differ materially from those expressed in, or implied by, any such forward-looking statements as a result of certain factors, including, but not limited to, those discussed in this section as well as in the section entitled Risk Factors and elsewhere in our filings with the Securities and Exchange Commission.*

*Our business is subject to significant risks including, but not limited to, our ability to implement our new product development strategy, our ability to obtain additional financing, the success of product development efforts, our dependence on collaborators for certain programs, obtaining and enforcing patents important to our business, clearing the lengthy and expensive regulatory approval process and possible competition from other products. Even if product candidates appear promising at various stages of development, they may not reach the market or may not be commercially successful for a number of reasons. Such reasons include, but are not limited to, the possibilities that the potential products may be found to be ineffective during clinical trials, may fail to receive necessary regulatory approvals, may be difficult to manufacture on a large scale, are uneconomical to market, may be precluded from commercialization by proprietary rights of third parties or may not gain acceptance from health care professionals and patients.*

**Overview**

We are an emerging specialty pharmaceutical company focused on the development and commercialization of a portfolio of drugs delivered by inhalation for the treatment of severe respiratory diseases by pulmonologists. Over the last decade, we have invested a large amount of capital to develop drug delivery technologies, particularly the development of a significant amount of expertise in pulmonary drug delivery. We have also invested considerable effort into the generation of a large volume of laboratory and clinical data demonstrating the performance of our AERx pulmonary drug delivery platform. We have not been profitable since inception and expect to incur additional operating losses over at least the next several years as we expand product development efforts, preclinical testing and clinical trial activities and possible sales and marketing efforts and as we secure production capabilities from outside contract manufacturers. To date, we have not had any significant product sales and do not anticipate receiving any revenues from the sale of products for at least the next several years. As of September 30, 2007, we had an accumulated deficit of \$304.9 million. Historically, we have funded our operations primarily through private placements and public offerings of our capital stock, proceeds from equipment lease financings, license fees and milestone payments from collaborators, proceeds from the January 2005 restructuring transaction with Novo Nordisk and interest earned on investments. On January 30, 2007, we closed the sale of 37,950,000 shares of common stock in an underwritten public offering with net proceeds, after underwriting discount and expenses, of approximately \$33.2 million. (See Note 14 of the notes to the condensed financial statements.)

We have performed initial feasibility work and conducted early stage clinical work on a number of potential products and have been compensated for expenses incurred while performing this work in several cases pursuant to feasibility study agreements and other collaborative arrangements. We will seek to develop certain potential products ourselves, including those that can benefit from our experience in pulmonary delivery, that have markets we can address with a targeted sales and marketing force and that we believe are likely to provide a superior therapeutic profile or other valuable benefits to patients when compared to existing products. For other potential products with larger or less concentrated markets, we may seek to enter into development and commercialization agreements with collaborators.

***Restructured Relationship with Novo Nordisk***

During 2005, our collaborative agreement with Novo Nordisk and its subsidiary, NNDT, contributed approximately 76% of our total contract revenues. From the inception of our collaboration in June 1998 through December 31, 2006, we have received from Novo Nordisk approximately \$137.1 million in product development payments, approximately \$13.0 million in milestone payments and \$35.0 million from the purchase of our common stock by Novo Nordisk and its affiliates. All product development and milestone payments received to date have been recognized as revenue.



## **Table of Contents**

As of January 26, 2005, we restructured the AERx iDMS program, pursuant to a restructuring agreement entered into with Novo Nordisk and NNDT in September 2004. Under the terms of the restructuring agreement we sold certain equipment, leasehold improvements and other tangible assets used in the AERx iDMS program to NNDT, for a cash payment of approximately \$55.3 million (before refund of cost advances made by Novo Nordisk). Our expenses related to this transaction for legal and other consulting costs were approximately \$1.1 million. In connection with the restructuring transaction, we entered into various related agreements with Novo Nordisk and NNDT effective January 26, 2005, including the following:

- an amended and restated license agreement amending the development and license agreement previously in place with Novo Nordisk, expanding Novo Nordisk's development and manufacturing rights to the AERx iDMS program and providing for royalties to us on future AERx iDMS net sales in lieu of a percentage interest in the gross profits from the commercialization of the AERx iDMS, which royalties run until the later of last patent expiry or last use of our intellectual property and which apply to future enhancements or generations of our AERx delivery technology;

- a three-year agreement under which NNDT agreed to perform contract manufacturing of AERx iDMS-identical devices and AERx Strip® dosage forms filled with compounds provided by us in support of preclinical and initial clinical development of other products that incorporate our AERx delivery system; and

- an amendment of the common stock purchase agreement in place with Novo Nordisk prior to the closing of the restructuring transaction, (i) deleting the provisions whereby we can require Novo Nordisk to purchase certain additional amounts of common stock, (ii) imposing certain restrictions on the ability of Novo Nordisk to sell shares of our common stock and (iii) providing Novo Nordisk with certain registration and information rights with respect to these shares.

In addition, pursuant to the restructuring agreement, we terminated a manufacturing and supply agreement and a patent cooperation agreement, each previously in place with Novo Nordisk and dated October 22, 2001.

On July 3, 2006, we further restructured our relationship with Novo Nordisk by entering into a Second Amended and Restated License Agreement to reflect the following:

- our transfer to Novo Nordisk of certain intellectual property, including all rights, title and interest to the patents that contain claims that pertain generally to breath control or specifically to the pulmonary delivery of monomeric insulin and monomeric insulin analogs, together with interrelated patents, which are linked via terminal disclaimers, as well as certain pending patent applications and continuations thereof by us for a cash payment to us of \$12.0 million, with Aradigm retaining exclusive, royalty-free control of these patents outside the field of glucose control.

- our receipt of a royalty prepayment of \$8.0 million in exchange for a one percent reduction on our average royalty rate for the commercialized AERx iDMS product. As a result, we will receive royalty rates, should commercialization occur, under our agreement with Novo Nordisk that will rise to an average of five percent or higher (instead of six percent or higher) by the fifth year after commercialization.

- our issuance of an eight-year promissory note to Novo Nordisk in connection with our receipt from Novo Nordisk of a loan in the principal amount of \$7.5 million with interest at 5% per year that will be payable to Novo Nordisk in three equal annual payments commencing in July 2012. Our obligations under the note are secured by royalty payments upon any commercialization of the AERx iDMS product.

We and Novo Nordisk continue to cooperate and share in technology development, as well as intellectual property development and defense. Both we and Novo Nordisk have access to any developments or improvements the other might make to the AERx delivery system, within their respective

**Table of Contents**

fields of use. Novo Nordisk is a less than 1% holder of our common stock and is restricted from disposing of the common stock until January 1, 2009 or the earlier occurrence of certain specified events.

In August 2006, Novo Nordisk announced that it had filed a lawsuit against Pfizer claiming that Pfizer's inhaled insulin product, Exubera\*, which Pfizer has been developing with Nektar Therapeutics, infringes a patent originally owned by us and now owned by Novo Nordisk with rights retained by us outside the field of glucose control. We could be entitled to a portion of any proceeds received by Novo Nordisk from a favorable outcome. On October 18, 2007, Pfizer announced that it will no longer make Exubera available to patients and that it will be returning the rights for the product to Nektar. The future of this lawsuit is unknown at this stage.

***Purchase and Sale of Intraject Technology***

In May 2003, we acquired selected assets from the Weston Medical Group, a company based in the United Kingdom, including the Intraject needle-free delivery technology, related manufacturing equipment and intellectual property and associated transfer costs, for a total of \$2.9 million. The purchase price and additional costs were allocated to the major pieces of purchased commercial equipment for the production of Intraject and were recorded in property and equipment as construction-in-progress. No costs or expenses were allocated to intellectual property or in-process research and development on a pro-rata basis, because of the lack of market information, the early stage of development and the immateriality of any allocation to intellectual property or in-process research and development based on the substantial value of the tangible assets acquired.

In August 2006, we sold all of our assets related to the Intraject technology platform and products, including 12 United States patents along with any foreign counterparts corresponding to those United States patents, to Zogenix, a newly created private company that had some officers who were former officers of our company. Zogenix is responsible for further development and commercialization efforts of Intraject. We recorded a non-cash impairment charge of \$4.0 million in the third quarter of 2006 to write down our Intraject-related assets, based solely on their net realizable value without giving effect to any future milestone or royalty payments. We sold these assets for a \$4.0 million initial payment and we are entitled to a milestone and royalty payments upon any commercialization of products that may be developed and sold using the Intraject technology.

**Product Candidates**

Products in development include both our own proprietary products and products under development with collaborators. They consist of approved drugs combined with our controlled inhalation delivery and/or formulation technologies. The following table shows the disease indication and stage of development for each product candidate in our portfolio.

<b>Product Candidate</b>	<b>Indication</b>	<b>Stage of Development</b>
<b>Proprietary Programs Under Development</b>		
ARD-3100 (Liposomal ciprofloxacin)	Cystic Fibrosis	Preclinical
ARD-1100 (Liposomal ciprofloxacin)	Inhalation Anthrax	Preclinical
ARD-1600 (Nicotine)	Tobacco Smoking Cessation	Phase 1
<b>Collaborative Programs Under Development</b>		
AERx iDMS (Insulin)	Type 1 and Type 2 Diabetes	Phase 3
ARD-1300 (Hydroxychloroquine)	Asthma	Phase 2 (1)
ARD-1550 (Trepstinil)	Pulmonary Arterial Hypertension	Preclinical
ARD-1700 (combination products)	Asthma	Preclinical

- (1) A Phase 2a clinical study did not meet pre-specified



clinical  
endpoints. The  
program is  
currently under  
review by APT  
Pharmaceuticals  
( APT ), and is in  
our view,  
unlikely to  
continue.

**Table of Contents**

In addition to these programs, we are continually evaluating opportunities for product development where we can apply our expertise and intellectual property to produce better therapies and where we believe the investment could provide significant value to our shareholders.

*Liposomal Ciprofloxacin*

Ciprofloxacin is approved by the FDA as an anti-infective agent and is widely used for the treatment of a variety of bacterial infections. Today ciprofloxacin is delivered by oral or intravenous administration. We believe that delivering this potent antibiotic directly to the lung may improve its safety and efficacy in the treatment of pulmonary infections. We believe that our novel sustained release formulation of ciprofloxacin may be able to maintain therapeutic concentrations of the antibiotic within infected lung tissues, while reducing systemic exposure and the resulting side effects seen with currently marketed ciprofloxacin products. To achieve this sustained release, we employ liposomes, which are lipid-based nanoparticles dispersed in water that encapsulate the drug during storage and release the drug slowly upon contact with fluid covering the airways and the lung. In an animal experiment, ciprofloxacin delivered to the lung of mice appeared to be rapidly absorbed into the bloodstream, with no drug detectable four hours after administration. In contrast, the liposomal formulation of ciprofloxacin produced significantly higher levels of ciprofloxacin in the lung at all time points and was still detectable at 12 hours. We also believe that for certain respiratory disease indications it may be possible that a liposomal formulation enables better interaction of the drug with the disease target, leading to improved effectiveness over other therapies. We have at present two target indications with distinct delivery systems for this formulation that share much of the laboratory and production development efforts, as well as a common safety data base.

ARD-3100 Liposomal Ciprofloxacin for the Treatment of Cystic Fibrosis and Bronchiectasis

One of our liposomal ciprofloxacin programs is a proprietary program using our liposomal formulation of ciprofloxacin for the treatment and control of respiratory infections common to patients with cystic fibrosis, or CF. CF is a genetic disease that causes thick, sticky mucus to form in the lungs, pancreas and other organs. In the lungs, the mucus tends to block the airways, causing lung damage and making these patients highly susceptible to lung infections. According to the Cystic Fibrosis Foundation, CF affects roughly 30,000 children and adults in the United States and roughly 70,000 children and adults worldwide. According to the American Lung Association, the direct medical care costs for an individual with CF are currently estimated to be in excess of \$40,000 per year.

The inhalation route affords direct administration of the drug to the infected part of the lung, maximizing the dose to the affected site and minimizing the wasteful exposure to the rest of the body where it could cause side effects. Therefore, treatment of CF-related lung infections by direct administration of antibiotics to the lung may improve both the safety and efficacy of treatment compared to systemic administration by other routes, as well as improving patient convenience as compared to injections. Oral and injectable forms of ciprofloxacin are approved for the treatment of *Pseudomonas aeruginosa*, a lung infection to which CF patients are vulnerable. Currently, there is only one inhalation antibiotic approved for the treatment of this infection. We believe that local lung delivery via inhalation of ciprofloxacin in a sustained release formulation could provide a convenient, effective and safe treatment of the debilitating and often life-threatening lung infections that afflict patients with CF.

Our liposomal ciprofloxacin CF program represents the first program in which we intend to retain full ownership and development rights. We believe we have the preclinical development, clinical and regulatory knowledge to advance this product through development in the most efficient manner. We intend to commercialize this program on our own.

*Development*

We have received orphan drug designations from the FDA for this product for the management of CF, and for the treatment of respiratory infections associated with non-CF bronchiectasis—a chronic pulmonary disease with symptoms similar to cystic fibrosis affecting over 100,000 patients in USA. As a designated orphan drug, liposomal ciprofloxacin is eligible for tax credits based upon its clinical development costs, as well as assistance from the FDA to coordinate study design. The designation also

**Table of Contents**

provides the opportunity to obtain market exclusivity for seven years from the date of New Drug Application, or NDA, approval.

We initiated preclinical studies for liposomal ciprofloxacin in 2006 and we also continued to work on new innovative formulations for this product with the view to maximize the safety, efficacy and convenience to patients. We are currently conducting additional preclinical development and we have initiated human clinical studies in the second half of 2007, with Phase 2a efficacy results in cystic fibrosis patients expected by the end of the first quarter of 2008. We expect to incur expenses of up to \$5.6 million in 2007 to complete preclinical studies and fund early stage clinical trials and related manufacturing requirements for ARD-3100. In order to reach commercialization of ARD-3100, we estimate we will need to spend an additional \$15 million to \$20 million. In order to expedite anticipated time to market and increase market acceptance, we have elected to deliver ciprofloxacin via nebulizer, as most CF patients already own a nebulizer and are familiar with this method of drug delivery. We intend to examine the potential for delivery of ciprofloxacin via our AERx delivery system. We share the formulation and manufacturing development as well as the safety data developed for our inhalation anthrax program discussed below in the development of this CF opportunity. We also intend to explore the utility of liposomal ciprofloxacin for the treatment of other serious respiratory infections.

**ARD-1100 Liposomal Ciprofloxacin for the Treatment of Inhalation Anthrax**

The second of our liposomal ciprofloxacin programs is for the prevention and treatment of pulmonary anthrax infections. Anthrax spores are naturally occurring in soil throughout the world. Anthrax infections are most commonly acquired through skin contact with infected animals and animal products or, less frequently, by inhalation or ingestion of spores. With inhalation anthrax, once symptoms appear, fatality rates are high even with the initiation of antibiotic and supportive therapy. Further, a portion of the anthrax spores, once inhaled, may remain dormant in the lung for several months and germinate. Anthrax has been identified by the Centers for Disease Control as a likely potential agent of bioterrorism. In the fall of 2001, when anthrax-contaminated mail was deliberately sent through the United States Postal Service to government officials and members of the media, five people died and many more became sick. These attacks highlighted the concern that inhalation anthrax as a bio-terror agent represents a real and current threat.

Ciprofloxacin has been approved orally and via injection for the treatment of inhalation anthrax (post-exposure) since 2000. This ARD-1100 research and development program has been funded by Defence Research and Development Canada, or DRDC, a division of the Canadian Department of National Defence. We believe that this product candidate may potentially be able to deliver a long acting formulation of ciprofloxacin directly into the lung and could have fewer side effects and be more effective to prevent and treat inhalation anthrax than currently available therapies.

**Development**

We began our research into liposomal ciprofloxacin under a technology demonstration program funded by DRDC as part of their interest to develop products to counter bioterrorism. DRDC had already demonstrated the feasibility of inhaled liposomal ciprofloxacin for post-exposure prophylaxis of *Francisella tularensis*, a potential bioterrorism agent similar to anthrax. Mice were exposed to a lethal dose of *F. tularensis* and then 24 hours later were exposed via inhalation to a single dose of free ciprofloxacin, liposomal ciprofloxacin or saline. All the mice in the control group and the free ciprofloxacin group were dead within 11 days post-infection; in contrast, all the mice in the liposomal ciprofloxacin group were alive 14 days post-infection. The same results were obtained when the mice received the single inhaled treatment as late as 48 or 72 hours post-infection. The DRDC has funded our development efforts to date and additional development of this program is dependent on negotiating for and obtaining continued funding from DRDC or on identifying other collaborators or sources of funding. We plan to use our preclinical and clinical safety data from our CF program to supplement the data needed to have this product candidate considered for approval for use in treating inhalation anthrax and possibly other inhaled life-threatening bioterrorism infections.

If we can obtain sufficient additional funding, we would anticipate developing this drug for approval under FDA regulations relating to the approval of new drugs or biologics for potentially fatal diseases where human studies cannot be conducted ethically or practically. Unlike most drugs, which require large,



**Table of Contents**

well controlled Phase 3 clinical trials in patients with the disease or condition being targeted, these regulations allow for a drug to be evaluated and approved by the FDA on the basis of demonstrated safety in humans combined with studies in animal models to show effectiveness.

*AERx iDMS Inhaled Insulin for the Treatment of Diabetes*

AERx iDMS is being developed by Novo Nordisk to control blood glucose levels in patients with diabetes. This product is currently in nine Phase 3 clinical trials, and our licensee, Novo Nordisk, is responsible for all remaining development, manufacturing and commercialization. We will receive royalties under our license agreement that will rise to an average of five percent or higher by the fifth year after commercialization, from any sales of this product as well as from future enhancements or generations of this technology. According to 2005 statistics from the American Diabetes Association, approximately 20.8 million Americans suffer from either Type 1 or Type 2 diabetes. Over 90% of these Americans have Type 2 diabetes, the prevalence of which is increasing dramatically due to lifestyle factors such as inappropriate diet and lack of physical activity. Patients with Type 1 diabetes do not have the ability to produce their own insulin and must administer insulin injections to survive. Patients with Type 2 diabetes are insulin resistant and unable to efficiently use the insulin that their bodies produce. While many Type 2 patients can initially maintain adequate control over blood glucose through diet, exercise and oral medications, most Type 2 patients progress within three years to where they cannot maintain adequate control over their glucose levels and insulin therapy is needed. However, given the less acute nature of Type 2 diabetes, many of these patients are reluctant to take insulin by injection despite the risks. Inadequate regulation of glucose levels in diabetes patients is associated with a variety of short and long-term effects, including blindness, kidney disease, heart disease, amputation resulting from chronic or extended periods of reduced blood circulation to body tissue and other circulatory disorders. The global market for diabetes therapies in 2005 was in excess of \$18 billion, according to Business Insights. The majority of this amount was from sales of oral anti-diabetics, while insulin and insulin analogues accounted for \$7.3 billion, a 17% increase over the prior year. Sales of insulin and insulin analogues are forecast to grow to \$9.8 billion in 2011. Type 2 patients consume the majority of insulin used in the United States. We believe that when patients are provided a non-invasive delivery alternative to injection, they will be more likely to self-administer insulin as often as needed to keep tight control over their blood-glucose levels.

We believe that AERx iDMS possesses features that will benefit diabetes patients and will provide an advantage over competitive pulmonary insulin products or can be used as a replacement for or adjunct to currently available therapies. Some of the other key features of the AERx iDMS system are also quite different from other inhaled insulin products such as Exubera, the inhaled insulin product that was developed by Pfizer with Nektar. Our patented breath control methods and technologies guide patients into the optimal breathing pattern for effective insulin deposition in and absorption from the lung. An optimal breathing pattern for insulin delivery depends on several elements: actuation of drug delivery at the early part of inspiration, control of inspiratory flow rate, and the state of inflation of the lung after the insulin is deposited, with the fully inflated lung providing the most desirable absorption profile. We believe a patient's ability to breathe reproducibly will be required to assure adequate safety and efficacy of inhaled insulin for the treatment of Type 1 and Type 2 diabetes. Our system also allows patients to adjust dosage in single unit increments, which is key to proper glucose control in diabetes. AERx iDMS offers the ability for patients and physicians to monitor and review a patient's dosing regimen. We believe the combination of breath control, high efficiency of delivery to the lung and single unit adjustable dosing in an inhalation device will make AERx iDMS a competitively attractive product.

*Development*

Over a decade ago, we initiated research and development into the inhalation delivery of insulin to meet a major unmet medical need in the treatment of Type 1 and Type 2 diabetes: a system that could provide similar levels of safety and efficacy as injected insulin but with the added benefit of a non-invasive route of delivery. We successfully completed a Phase 1 clinical study and filed an Investigational New Drug application, or IND, relating to our AERx iDMS program in 1998. After our initial work, we entered into collaboration for our AERx iDMS in June 1998 with a world leader in the treatment of diabetes, Novo Nordisk. From 1998 to January 2005, we received an aggregate of \$150.1 million from Novo Nordisk to fund development of the AERx delivery system for delivering insulin, production for preclinical and clinical testing and process development and scale up. In January 2005, we transferred

the partially completed initial commercial production facility and associated personnel to Novo Nordisk for  
22

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## **Table of Contents**

\$55.3 million, and Novo Nordisk assumed responsibility for continuing production and bringing the facility up to its planned capacity of 750 million dosage forms per year.

AERx iDMS is currently undergoing testing in Phase 3 clinical trials, begun in May 2006 by Novo Nordisk. These trials follow significant prior clinical work that showed AERx iDMS to be comparable to injectable insulin in the overall management of Type 1 and Type 2 diabetes. Past clinical testing has shown:

HbA1c levels, a key marker of blood glucose control, are statistically the same in patients using AERx iDMS and patients using subcutaneous insulin injections.

The onset of action of inhaled insulin via AERx iDMS is not significantly different from subcutaneous injection of rapid-acting insulin, but significantly faster than subcutaneous injection of human regular insulin.

The duration of action of inhaled insulin via AERx iDMS is not significantly different from subcutaneous injection of human regular insulin, but significantly longer than subcutaneous injection of rapid-acting insulin.

Although small declines were seen on some pulmonary function parameters following 12-24 months of dosing on AERx iDMS, these declines were not considered to be of clinical significance, and the findings are not expected to have an impact on overall pulmonary safety of the product.

The Phase 3 clinical trials are expected to include a total of approximately 3,000 Type 1 and Type 2 diabetes patients. The trials include treatment comparisons with other medicaments for the treatment of diabetes. The longest trial is expected to last 27 months. Novo Nordisk announced in October 2006 that it expects approval of the product in 2010 with a second generation device that is significantly smaller and lighter than its predecessor. As with any clinical program, there are many factors that could delay the launch or could result in AERx iDMS not receiving or maintaining regulatory approval.

In January 2005 and in July 2006, we announced restructurings of the AERx iDMS program. Under the new arrangements, Novo Nordisk is responsible for all further clinical, manufacturing and commercial development, while we and Novo Nordisk continue to cooperate and share in technology development, as well as intellectual property development and defense. We will receive royalty payments on any commercial sales.

### **ARD-1300 Hydroxychloroquine for the Treatment of Asthma**

The ARD-1300 program was investigating a novel aerosolized formulation of hydroxychloroquine, or HCQ, as a treatment for asthma under collaboration with APT, a privately held biotechnology company. Data from studies in which HCQ was orally administered to humans suggested that HCQ could be effective in the treatment of asthma. We and APT hypothesized that targeted delivery of HCQ to the airways may enhance the effectiveness of the treatment of asthma relative to systemic delivery of HCQ while reducing side effects by decreasing exposure of the drug to other parts of the body.

#### ***Development***

APT has funded all activities in the development of this program. The ARD-1300 program advanced into Phase 2 clinical trials following positive preclinical testing and Phase 1 clinical results. The results of the Phase 2a clinical study of inhaled HCQ as a treatment for patients with moderate-persistent asthma did not meet the pre-specified clinical efficacy endpoints. No serious adverse effects were noted or associated with the aerosolized HCQ or with the AERx system. APT has not indicated its intentions to pursue any further studies in asthma, and we believe it is unlikely that this program will continue.

### **ARD-1550 Treprostinil for the Treatment of Pulmonary Arterial Hypertension**

On August 30, 2007, we signed the Lung Rx Agreement with Lung Rx, a wholly-owned subsidiary of United Therapeutics Corporation, pursuant to which we granted Lung Rx an exclusive license to develop and

## **Table of Contents**

commercialize inhaled treprostinil using our AERx Essence technology for the treatment of PAH and other potential therapeutic indications.

Under the terms of the Lung Rx Agreement, we will initiate and be responsible for conducting and funding a study that includes a bridging clinical trial intended to compare the AERx Essence technology to the nebulizer used in United Therapeutics' recently completed Phase 3 registration trial TRIUMPH for treprostinil. We expect the bridging clinical trial will be completed in 2008. Following successful completion of the bridging study Lung Rx will pay for the remaining development costs to commercialize and be responsible for manufacturing inhaled treprostinil with AERx Essence technology.

PAH is a rare disease that results in the progressive narrowing of the arteries of the lungs, causing continuous high blood pressure in the pulmonary artery and eventually leading to heart failure. According to Decision Resources, in 2003, the more than 130,000 people worldwide affected by PAH purchased \$600 million of PAH-related medical treatments and sales are expected to reach \$1.2 billion per year by 2013.

Prostacyclin analogues are an important class of drugs used for the treatment of hypertension. However, the current methods of administration of these drugs are burdensome on patients. Treprostinil is marketed by United Therapeutics under the name Remodulin\* and is administered by intravenous or subcutaneous infusion. We believe that our ARD-1550 product candidate potentially could offer a non-invasive, more direct and patient-friendly approach to treatment to replace or complement currently available treatments. Actelion Pharmaceuticals Ltd. markets in the United States another prostacyclin analogue, iloprost, under the name Ventavis\* that is administered six to nine times per day using a nebulizer, with each treatment lasting four to nine minutes. We believe administration of treprostinil by inhalation using our AERx delivery system may be able to deliver an adequate dose for the treatment of PAH in a small number of breaths. Based on our previous work with United Therapeutics, we also believe that in the future our sustained release formulation may lead to a reduction in the number of daily administrations that are needed to be effective when compared to existing therapies.

### *Development*

We are currently preparing for a bridging study in 2008 to compare treprostinil delivered by inhalation using the AERx Essence system to the nebulizer used in the United Therapeutics' recently completed Phase 3 trial.

### **ARD-1600 (Nicotine) Tobacco Smoking Cessation Therapy**

According to the National Center for Health Statistics ( NCHS ), 21% of the U.S. population age 18 and above currently smokes cigarettes. The World Health Organization estimates that 650 million people worldwide are smokers, which results in a health cost equivalent to \$200 billion, \$75 billion in the U.S. alone. Further, the NCHS indicates that nicotine dependence is the most common form of chemical dependence in this country. As a result, quitting tobacco use is difficult and oftentimes requires multiple attempts, as users often relapse because of withdrawal symptoms. Our goal is to develop an inhaled nicotine product that would address effectively the acute craving for cigarettes and through gradual reduction of the peak nicotine levels wean-off the patients from cigarettes smoking and from the nicotine addiction.

### *Development*

The initial laboratory work on this program was partly funded under grants from the National Institutes of Health.

We have recently completed the first human clinical trial delivering aqueous solutions of nicotine using the palm-size AERx Essence system. Our randomized, open-label, single-site Phase 1 trial evaluated arterial plasma pharmacokinetics and subjective acute cigarette craving when one of three nicotine doses was administered to 18 adult male smokers. Blood levels of nicotine rose much more rapidly following a single-breath inhalation compared to published data on other approved nicotine delivery systems. Cravings for cigarettes were measured on a scale from 0-10 before and after dosing for up to four hours. Prior to dosing, mean craving scores were 5.5, 5.5 and 5.0, respectively, for the three doses. At five minutes



## Table of Contents

following inhalation of the nicotine solution through the AERx Essence device, craving scores were reduced to 1.3, 1.7 and 1.3, respectively, and did not return to pre-dose baseline during the four hours of monitoring. Nearly all subjects reported an acute reduction in craving or an absence of craving immediately following dosing. No serious adverse reactions were reported in the study.

We believe these results provide the foundation for further research with the AERx Essence device as a means toward smoking cessation. We will be seeking collaborations with government and non-government organizations to further develop this product.

### *Additional Potential Product Applications*

We have demonstrated in human clinical trials to date effective deposition and, where required, systemic absorption of a wide variety of drugs, including small molecules, peptides and proteins, using our AERx delivery system. We intend to identify additional pharmaceutical product opportunities that could potentially utilize our proprietary delivery systems for the pulmonary delivery of various drug types, including proteins, peptides, oligonucleotides, gene products and small molecules. We have demonstrated in the past our ability to successfully enter into collaborative arrangements for our programs, and we believe additional opportunities for collaborative arrangements exist outside of our core respiratory disease focus, for some of which we have data as well as intellectual property positions. The following are descriptions of two potential opportunities:

***Cyclodextrin Combination Products for Asthma and other Chronic Obstructive Pulmonary Disease.*** Asthma is a common chronic disorder of the lungs characterized by airway inflammation, airway hyper-responsiveness or airway narrowing due to certain stimuli. Despite several treatment options, asthma remains a major medical problem associated with high morbidity and large economic costs to the society. According to the American Lung Association, asthma accounts for \$11.5 billion in direct healthcare costs annually in the United States, of which the largest single expenditure, at \$5 billion, was prescription drugs. Primary symptoms of asthma include coughing, wheezing, shortness of breath and tightness of the chest with symptoms varying in frequency and degree. According to Datamonitor, asthma affected 41.5 million people in developed countries in 2005, with 9.5 million of those affected being children. The highest prevalence of asthma occurs in the United States and the United Kingdom. According to the American Lung Association, non-asthma COPD was the fourth leading cause of death in America, claiming the lives of 118,171 Americans in 2004. In 2005, an estimated 8.9 million Americans reported a physician diagnosis of chronic bronchitis, an obstructive disease of the lung. We and CyDex began in August 2007 to collaborate on the development and commercialization of products that utilize our AERx pulmonary delivery technology and CyDex's solubilization and stabilization technologies to deliver inhaled corticosteroids, anticholinergics and beta-2 agonists for the treatment of asthma and COPD.

***Pain Management System.*** Based on our internal work and a currently dormant collaboration with GlaxoSmithKline, we have developed a significant body of preclinical and Phase 1 clinical data on the use of inhaled morphine and fentanyl, and Phase 2 clinical data on inhaled morphine, with our proprietary AERx delivery system for the treatment of breakthrough pain in cancer and post-surgical patients.

We are currently examining our previously conducted preclinical and clinical programs to identify molecules that may be suitable for further development consistent with our current business strategy. In most cases, we have previously demonstrated the feasibility of delivering these compounds via our proprietary AERx delivery system but we have not been able to continue development due to a variety of

**Table of Contents**

reasons, most notably the lack of funding provided from collaborators. If we identify any such programs during this review, we will consider continuing the development of such compounds on our own.

**Critical Accounting Policies and Estimates**

We consider certain accounting policies related to revenue recognition, stock-based compensation, and impairment of long-lived assets to be critical accounting policies that require the use of significant judgments and estimates relating to matters that are inherently uncertain and may result in materially different results under different assumptions and conditions. The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires us to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes to the financial statements. These estimates include useful lives for property and equipment and related depreciation calculations, estimated amortization periods for payments received from product development and license agreements as they relate to the revenue recognition of deferred revenue, and assumptions for valuing options, warrants and other stock-based compensation. Our actual results could differ from these estimates.

***Revenue Recognition***

Contract revenues consist of revenues from grants, collaboration agreements and feasibility studies. Under the agreements, revenue is recognized once costs are incurred and collectibility is reasonably assured. Under some agreements our collaborators have the right to withhold reimbursement of costs incurred until the work performed under the agreement is mutually agreed upon. For these agreements revenue is recognized upon confirmation from the collaborator of acceptance of work performed and payment amount. Deferred revenue represents the portion of the nonrefundable research payment received that has not been earned. In accordance with contract terms, milestone payments from collaborative research agreements are considered reimbursements for costs incurred under the agreements and, accordingly, are generally recognized as revenue either upon the completion of the milestone effort, when payments are contingent upon completion of the effort, or are based on actual efforts expended over the remaining term of the agreements when payments precede the required efforts. Costs of contract revenues are approximate to or are greater than such revenues and are included in research and development expenses. Refundable development and license fee payments are deferred until the specified performance criteria are achieved. Refundable development and license fee payments are generally not refundable once the specific performance criteria are achieved and accepted.

We recognize revenue in accordance with EITF Issue 00-21, *Revenue Arrangements with Multiple Deliverables* and the SEC Staff Accounting Bulletin No. 104. Revenue arrangements with multiple components are divided into separate units of accounting if certain criteria are met, including whether the delivered component has stand-alone value to the customer, and whether there is objective reliable evidence of the fair value of the undelivered items. Consideration received is allocated among the separate units of accounting based on their relative fair values, and the applicable revenue recognition criteria are identified and applied to each of the units.

***Impairment of Long-Lived Assets***

We review for impairment whenever events or changes in circumstances indicate that the carrying amount of property and equipment may not be recoverable in accordance with SFAS 144. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. Future cash flows that are contingent in nature are generally not recognized. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values and the loss is recognized on the statements of operations.

***Accounting for Costs Associated with Exit or Disposal Activities***

In accordance with SFAS 146, we recognize a liability for the cost associated with an exit or disposal activity that is measured initially at its fair value in the period in which the liability is incurred, except for a liability for

**Table of Contents**

one-time termination benefits that is incurred over time. According to SFAS 146, costs to terminate an operating lease or other contracts are (a) costs to terminate the contract before the end of its term or (b) costs that will continue to be incurred under the contract for its remaining term without economic benefit to the entity. In periods subsequent to initial measurement, changes to the liability shall be measured using the credit-adjusted risk-free rate that was used to measure the liability initially.

***Stock-Based Compensation Expense***

We measure stock-based compensation at the grant date based on the award's fair value and we recognize the expense ratably over the requisite vesting period, net of estimated forfeitures, for all stock-based awards granted after January 1, 2006 and all stock-based awards granted prior to, but not vested as of, January 1, 2006.

We have elected to calculate an award's fair value based on the Black-Scholes option-pricing model. The Black-Scholes model requires various assumptions, including expected option life and volatility. If any of the assumptions used in the Black-Scholes model or the estimated forfeiture rate change significantly, stock-based compensation expense may differ materially in the future from that recorded in the current period.

For the three months ended September 30, 2007 and 2006, we recognized stock-based expense of \$394,000 and \$432,000, respectively. We recognized expense for stock-based compensation of \$1.0 million and \$1.3 million for the nine months ended September 30, 2007 and 2006, respectively.

**Results of Operations*****Three months ended September 30, 2007 and 2006******Revenues***

	Three months ended		Change in Percent
	September 30,		
	2007	2006	
	(in thousands)		
Revenues:			
Related parties	\$	\$ 9	(100)%
<i>Percentage of total revenues</i>	0%	1%	
Unrelated parties	230	1,117	(79)%
<i>Percentage of total revenues</i>	100%	99%	
Total Revenues	\$ 230	\$ 1,126	(80)%

We did not have any revenue from the related parties in the three months ended September 2007 compared to the same quarter in 2006 due to the fact that we did not perform any contract work for NNDT during this period. The decrease in the unrelated party revenues was mainly due to the conclusion of most of our collaboration agreements in 2006 and our shift in focus away from collaborations and towards self-funded product development. For the three months ended September 30, 2007, the unrelated party revenues consist of \$38,000 from our transition agreement with Zogenix and \$192,000 for final payment from our collaboration with APT for ARD-1300.

***Research and Development Expenses***

	Three months ended		Change in Percent
	September 30,		
	2007	2006	
	(in thousands)		
Research and development expenses:			
Collaborative	\$ (46)	\$ 999	(105)%
Self-funded	3,945	3,548	11%

Total research and development expenses	\$ 3,899	\$ 4,547	(14)%
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27

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**Table of Contents**

Research and development expenses represent proprietary research expenses and costs related to contract research revenue, which include salaries, payments to contract manufacturers and contract research organizations, contractor and consultant fees, stock-based compensation expense and other support costs including facilities, depreciation and travel costs. The decrease in collaborative program expenses in the three months ended September 30, 2007 over the comparable period in fiscal 2006 was due primarily to the completion of collaborative agreements and the transition from contract research agreements to focus on the development of our lead candidate, ARD-3100. The increase in research and development expense for self-funded projects was due primarily to a strategic restructuring of our business to focus resources on advancing our current product candidates. In August 2006, we sold all of our assets related to the Intraject technology platform to Zogenix (see Note 10 of the notes to the condensed financial statements). We expect that our research and development expenses will increase over the next few quarters as we continue the development of our lead candidate, ARD-3100, and other self-funded product opportunities, which will be slightly offset by a decrease in the facility expense as a result of our facility sublease agreement with Mendel (see Note 16 of the notes to the condensed financial statements).

Stock-based compensation expense charged to research and development for the three months ended September 30, 2007 and 2006 was \$183,000 and \$196,000, respectively.

*General and Administrative Expenses*

	Three months ended		Change in Percent
	September 30, 2007	2006	
	(in thousands)		
General and administrative expenses	\$ 1,757	\$ 3,514	(50)%

General and administrative expenses are comprised of salaries, legal fees including those associated with the establishment and protection of our patents, trademarks, insurance, marketing research, contractor and consultant fees, stock-based compensation expense and other support costs including facilities, depreciation and travel costs. General and administrative expenses for the three months ended September 30, 2007 decreased over the comparable period in 2006 primarily as a result of the reduction in force announced in May 2006 and October 2006, the reduction in legal expenses in 2007 compared to the same period in 2006 when we incurred substantial legal expenses resulting from our restructuring and financing activities, and the reduction in building lease expense due to the sublease to Mendel. Our general and administrative expenses are expected to continue to decrease as a result of our facility sublease agreement with Mendel (see Note 16 of the notes to the condensed financial statements).

Stock-based compensation expense charged to general and administrative expenses for the three months ended September 30, 2007 and 2006 were \$211,000 and \$236,000, respectively.

*Restructuring and Asset Impairment*

	Three months ended		Change in Percent
	September 30, 2007	September 30, 2006	
	(in thousands)		
Restructuring and asset impairment expenses	\$ 2,059	\$ 347	493%

Restructuring and asset impairment expenses for the three months ended September 30, 2007 were related to the expected loss associated with the subleasing of the office space to Mendel because the monthly payments we expect to receive from Mendel under the sublease are less than the amounts we will owe to the lessor for the sublease space (see Note 16 of the notes to the condensed financial statements). Restructuring and asset impairment expenses for the three months ended September 30, 2006 were primarily comprised of severance related expenses including payroll, health

insurance expenses, and outplacement expenses.

28

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**Table of Contents***Gain on Sale of Patents and Royalty Interest*

	<b>Three months ended September 30, 2007      2006</b>		<b>Change in Percent</b>
	(in thousands)		
Gain on sale of patents and royalty interest	\$	\$ 20,000	(100)%

The \$20 million gain on sale of patents and royalty interest in the three month ended September 30, 2006 reflected two transactions entered into by us with Novo Nordisk, a related party; (i) the transfer by us of certain intellectual property, including all rights, title and interest to the patents that contained claims that pertained generally to breath control or specifically to the pulmonary delivery of monomeric insulin and monomeric insulin analogs, together with interrelated patents, which were linked via terminal disclaimers, as well as certain pending patent applications and continuations thereof by us for a cash payment to us of \$12.0 million, with us retaining exclusive, royalty-free control of these patents outside the field of glucose control; and (ii) a reduction by 100 basis points of each royalty rate payable by Novo Nordisk to us for a cash payment to us of \$8.0 million (see Note 9 of the notes to the condensed financial statements). We did not sell any patents and royalty interest in the three months ended September 30, 2007.

*Interest Income, Interest Expense and Other Expense*

	<b>Three months ended September 30, 2007      2006</b>		<b>Change in Percent</b>
	(in thousands)		
Interest income, interest expense and other expense:			
Interest income	\$ 684	\$ 459	49%
Interest expense	(101)	(95)	6%
Other expense		(7)	(100)%
Total interest income, interest expense and other expense	\$ 583	\$ 357	63%

Interest income for the three months ended September 30, 2007 increased \$225,000 over the comparable period in 2006 due to a higher average invested balance. Interest expense primarily reflects the interest expense on the \$7.5 million note payable with an interest rate of 5%, issued to Novo Nordisk in July 2006 (see Note 9 of the notes to the condensed financial statements).

*Nine Months Ended September 30, 2007 and 2006**Revenues*

	<b>Nine months ended September 30, 2007      2006</b>		<b>Change in Percent</b>
	(in thousands)		
Revenue:			
Related parties	\$ 23	\$ 59	(61)%
<i>Percentage of Total Revenue</i>	2%	1%	
Unrelated parties	920	3,947	(77)%
<i>Percentage of Total Revenue</i>	98%	99%	
Total Revenue	\$ 943	\$ 4,006	(76)%





**Table of Contents**

The primary reason for the decreases in related party revenues was due to the conclusion of the restructuring agreement with Novo Nordisk in January 2006. For the nine-month period ended September 30, 2007, we recorded \$23,000 in related party revenue from our contract with NNDT. Similarly, the primary reason for the decrease in unrelated party revenues was the conclusion of most of our collaboration agreements in 2006 and our shift in focus away from collaborations and towards self-funded product development. For the nine-month period ended September 30, 2007, we recorded collaborative revenues of \$566,000 related to ARD-1100 funded by DRDC, \$141,000 from our transition agreement with Zogenix, \$192,000 from APT and \$21,000 from Respiroics.

*Research and Development Expenses*

	<b>Nine months ended</b>		<b>Change</b>
	<b>September 30,</b>	<b>September 30,</b>	<b>in</b>
	<b>2007</b>	<b>2006</b>	<b>Percent</b>
	(in thousands)		
Research and development expenses:			
Collaborative	\$ 759	\$ 4,107	(82)%
Self-funded	10,388	13,538	(23)%
Total research and development expenses	\$ 11,147	\$ 17,645	(37)%

Research and development expenses represent proprietary research expenses and costs related to contract research revenue, which include salaries, payments to contract manufacturers and contract research organizations, contractor and consultant fees, stock-based compensation expense and other support costs including facilities, depreciation and travel costs. The decrease of \$3.3 million in collaborative program expenses in the nine months ended September 30, 2007 was due primarily to the transition from contract research agreements to focus on the development of our lead candidate, ARD-3100. Similarly, the decrease of \$3.2 million in research and development expense for self-funded projects was due primarily to a strategic restructuring of our business to focus resources on advancing our lead product candidate and the sale of Intraject-related assets to Zogenix in August 2006 (see Note 10 of the notes to the condensed financial statements). We expect that our research and development expenses will increase over the next few quarters as we continue the development of our lead candidate, ARD-3100, and other self-funded product opportunities, which will be slightly offset by a decrease in the facility expense as a result of our facility sublease agreement with Mendel (see Note 16 of the notes to the condensed financial statements).

Stock-based compensation expense charged to research and development was \$438,000 and \$666,000 for the nine-month period ended September 30, 2007 and 2006, respectively.

*General and Administrative Expenses*

	<b>Nine months ended</b>		<b>Change in</b>
	<b>September 30,</b>	<b>September 30,</b>	<b>Percent</b>
	<b>2007</b>	<b>2006</b>	
	(in thousands)		
General and administrative expenses	\$ 6,470	\$ 9,051	(29)%

General and administrative expenses are comprised of salaries, legal fees including those associated with the establishment and protection of our patents, trademarks, insurance, marketing research, contractor and consultant fees, stock-based compensation expense, and other support costs including facilities, depreciation and travel costs. General and administrative expenses for the nine months ended September 30, 2007 decreased over the comparable period in 2006 primarily as a result of the reduction in force announced in May 2006 and October, 2006, and a reduction in legal expenses. We expect that our general and administrative expenses will continue to decrease as a result of our facility sublease agreement with Mendel (See Note 16 of the notes to the condensed financial statements).



**Table of Contents**

Stock-based compensation expense charged to general and administrative expenses were \$575,000 and \$620,000 for the nine months period ended September 30, 2007 and 2006, respectively.

*Restructuring and Asset Impairment*

	Nine months ended		Change in Percent
	September 30, 2007	2006	
	(in thousands)		
Restructuring and asset impairment expenses	\$ 2,059	\$ 5,717	(64)%

Restructuring and asset impairment expenses for the nine months ended September 30, 2007 were related to the expected loss associated with the subleasing of the office space to Mendel because the monthly payments we expect to receive from Mendel under the sublease are less than the amounts we will owe to the lessor for the sublease space (see Note 16 of the notes to the condensed financial statements).

Restructuring and asset impairment expenses in the same period in 2006 were comprised of severance-related expenses including payroll, health insurance payments, outplacement expenses and Intraject-related asset impairment expenses. Severance-related expenses for the nine months ended September 30, 2006 were approximately \$1.7 million due to the reduction in workforce announced on May 15, 2006 and the departure of our former President and Chief Executive Officer, our former Senior Vice President of Operations, and our former Senior Vice President and Chief Scientific Officer, in August 2006. In addition, we recorded an asset impairment expense of \$4.0 million during the nine months ended September 30, 2006 to reflect the write-down of our Intraject-related assets to their net realizable value.

*Gain on Sale of Patents and Royalty Interest*

	Nine months ended		Change in Percent
	September 30,		
	2007	2006	
	(in thousands)		
Gain on sale of patents and royalty interest	\$	\$ 20,000	(100)%

The \$20 million gain on sale of patents and royalty interest in the nine months ended September 30, 2006 reflected two transactions entered into by us with Novo Nordisk, a related party; (i) the transfer by us of certain intellectual property, including all rights, title and interest to the patents that contained claims that pertained generally to breath control or specifically to the pulmonary delivery of monomeric insulin and monomeric insulin analogs, together with interrelated patents, which were linked via terminal disclaimers, as well as certain pending patent applications and continuations thereof by us for a cash payment to us of \$12.0 million, with us retaining exclusive, royalty-free control of these patents outside the field of glucose control; and (ii) a reduction by 100 basis points of each royalty rate payable by Novo Nordisk to us for a cash payment to us of \$8.0 million (see Note 9 of the notes to the condensed financial statements). We did not sell any patents and royalty interest in the nine months ended September 30, 2007.

*Interest Income, Interest Expense and Other Income*

	Nine months ended		Change in Percent
	September 30,		
	2007	2006	
	(in thousands)		
Interest income, interest expense and other income:			
Interest income	\$ 2,020	\$ 839	141%

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Interest expense	(293)	(101)	190%
Other income	16	26	(38)%
Total interest income, interest expense and other income	\$ 1,743	\$ 764	128%

31

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## **Table of Contents**

Interest income for the nine months ended September 30, 2007 increased \$1.2 million over the comparable period in 2006 due to a higher average invested balance. Interest expense primarily reflects the expense on the \$7.5 million note payable, with an interest rate of 5%, issued to Novo Nordisk in July 2006. The decrease in other income primarily reflects the decrease in realized gain from exchange rate transactions with the Canadian government.

### **Liquidity and Capital Resources**

As of September 30, 2007, we had cash, cash equivalents and short-term investments of \$47.0 million and total working capital of \$43.9 million. Our principal requirements for cash are to fund working capital needs, and, to a lesser extent, capital expenditures for equipment purchases.

For the nine months ended September 30, 2007, our operating activities used net cash of \$12.9 million reflecting our net loss of \$17.0 million offset by non-cash charges including leased facility exit cost, stock-based compensation expense, depreciation and amortization expense. Cash was used to pay for invoices outstanding for the Intraject project and to pay for severance related expenses related to the reduction in workforce and to fund accounts receivable, primarily related to the partnered programs.

This compares to the net cash used in our operating activities for the nine months ended September 30, 2006 of \$25.4 million reflecting our net loss of \$7.6 million offset by non-cash charges including stock-based compensation expense, impairment charges on property and equipment and depreciation expense, and our use of cash to fund changes in operating assets and liabilities. Cash was used to pay for an increase in invoices outstanding for the Intraject project, to pay for severance related expenses related to the reduction in workforce and to fund accounts receivable, primarily related to the partnered programs.

For the nine-month period ended September 30, 2007, our net cash used in investing activities was \$12.9 million. We used \$946,000 for purchases of equipment primarily for the ARD-3100 program and \$13.5 million for purchase of short-term investments, which was offset by \$1.5 million in proceeds from sales of short-term investments. This compares to net cash provided by investing activities for the nine-month period ended September 30, 2006 of \$22.2 million which consisted primarily of our purchase of \$1.3 million of fixed assets relating to our Intraject platform and our purchases of \$507,000 in securities classified as short-term investments, offset by \$4.0 million proceeds from the sale of property and equipment resulting from the restructuring activities and \$20.0 million proceeds from sale of patents and royalty and interest to Novo Nordisk.

Net cash provided by financing activities was \$33.3 million for the nine months ended September 30, 2007, due primarily to the proceeds from our public financing completed on January 30, 2007, compared to \$7.8 million for the comparable period in the prior year attributable primarily to the proceeds from the \$7.5 million promissory note payable issued to Novo Nordisk.

As of September 30, 2007, we had an accumulated deficit of \$304.9 million, working capital of \$43.9 million, and a shareholders' equity of \$37.1 million. Management believes that cash and cash equivalents on hand at September 30, 2007 will be sufficient to fund operations through 2008.

**Table of Contents*****Contractual Obligations***

Our contractual obligations and future minimum lease payments that are non-cancelable at September 30, 2007 are disclosed in the following table.

	Total	2007(1)	Payment due by period (amounts in thousands)				
			2008	2009	2010	2011	2012+
Contractual obligations:							
Operating lease obligations	\$ 19,565	\$ 597	\$ 2,421	\$ 2,367	\$ 2,248	\$ 1,992	\$ 9,940
Unconditional capital purchase obligations	669	669					
Unconditional purchase obligations	4,879	4,879					
Total contractual commitments	25,113	6,145	2,421	2,367	2,248	1,992	9,940
Less sublease payments from Mendel (2)	(8,548)	(207)	(866)	(900)	(927)	(955)	(4,693)
Total contractual commitments net (2)	\$ 16,565	\$ 5,938	\$ 1,555	\$ 1,467	\$ 1,321	\$ 1,037	\$ 5,247

(1) For three months ending December 31, 2007

(2) Included to demonstrate the effect of the sublease with Mendel entered on July 18, 2007. Mendel has the option to terminate the sublease early on September 1, 2012 for a termination fee of \$225,000 (see

Note 16 of the  
notes to the  
condensed  
financial  
statements).

***Off-Balance Sheet Financings and Liabilities***

Other than contractual obligations incurred in the normal course of business, we do not have any off-balance sheet financing arrangements or liabilities, guarantee contracts, retained or contingent interests in transferred assets or any obligation arising out of a material variable interest in an unconsolidated entity. We do not have any majority-owned subsidiaries.

**Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

**Market Risk Disclosures**

In the normal course of business, our financial position is routinely subject to a variety of risks, including market risk associated with interest rate movement. We regularly assess these risks and have established policies and business practices to protect against these and other exposures. As a result, we do not anticipate material potential losses in these areas.

As of September 30, 2007, we had cash, cash equivalents and short-term investments of \$47.0 million, consisting of cash, cash equivalents and highly liquid short-term investments. Our short-term investments will likely decline by an immaterial amount if market interest rates increase, and therefore, we believe our exposure to interest rate changes will be immaterial. Declines of interest rates over time will, however, reduce our interest income from short-term investments

**Item 4. CONTROLS AND PROCEDURES**

*Evaluation of Disclosure Controls and Procedures.* Based on their evaluation of our disclosure controls and procedures (as defined in the rules promulgated under the Securities Exchange Act of 1934), our chief executive officer and our interim chief financial officer concluded that our disclosure controls and procedures were effective as of the end of the period covered by this report to ensure that information required to be disclosed in this report was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

*Changes in internal control.* There were no significant changes in our internal control over financial reporting during the period covered by this report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

*Limitations on the effectiveness of controls.* We believe that a controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives, and our chief executive officer and our chief financial officer have concluded that these controls and procedures are effective at the reasonable assurance level.

**Table of Contents**

**PART II. OTHER INFORMATION**

**Item 1. LEGAL PROCEEDINGS**

None.

**Item 1A. RISK FACTORS**

*In addition to the other information contained in this Form 10-Q, and risk factors set forth in our most recent SEC filings, the following risk factors should be considered carefully in evaluating our business. Our business, financial condition, or results of operations could be materially adversely affected by any of these risks. Additional risks not presently known to us or that we currently deem immaterial may also impair our business and operations.*

*The risk factors included herein include any material changes to and supersede the risk factors associated with our business previously disclosed in Item 1A to Part I of our Annual Report on Form 10-K for the fiscal year ended December 31, 2006. We have marked with an asterisk (\*) those risk factors that reflect substantive changes from the risk factors included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission for the fiscal year ended December 31, 2006.*

**Risks Related to Our Business**

***We are an early-stage company.***

You must evaluate us in light of the uncertainties and complexities present in an early-stage company. All of our potential products are in an early stage of research or development. Our potential drug delivery products require extensive research, development and pre-clinical and clinical testing. Our potential products also may involve lengthy regulatory reviews before they can be sold. Because none of our product candidates has yet received approval by the FDA, we cannot assure you that our research and development efforts will be successful, any of our potential products will be proven safe and effective or regulatory clearance or approval to sell any of our potential products will be obtained. We cannot assure you that any of our potential products can be manufactured in commercial quantities or at an acceptable cost or marketed successfully. We may abandon the development of some or all of our product candidates at any time and without prior notice. We must incur substantial up-front expenses to develop and commercialize products and failure to achieve commercial feasibility, demonstrate safety, achieve clinical efficacy, obtain regulatory approval or successfully manufacture and market products will negatively impact our business.

***\* We recently changed our product development strategy, and if we do not successfully implement this new strategy our business and reputation will be damaged.***

Since our inception in 1991, we have focused on developing drug delivery technologies to be partnered with other companies. In May 2006, we began transitioning our business focus from the development of delivery technologies to the application of our pulmonary drug delivery technologies and expertise to the development of novel drug products to treat or prevent respiratory diseases. As part of this transition we have implemented workforce reductions in an effort to reduce our expenses and improve our cash flows. We are in the early stages of implementing various aspects of our new strategy, and we may not be successful in implementing our new strategy. Even if we are able to implement the various aspects of our new strategy, it may not be successful.

***We will need additional capital, and we may not be able to obtain it.***

Our operations to date have consumed substantial amounts of cash and have generated no product revenues. While our refocused development strategy will reduce capital expenditures, we expect negative operating cash flows to continue for at least the foreseeable future. Even though we do not plan to engage in drug discovery, we will nevertheless need to commit substantial funds to develop our product candidates and we may not be able to obtain sufficient funds on acceptable terms or at all. Our future capital requirements will depend on many factors, including:



**Table of Contents**

our progress in the application of our delivery and formulation technologies, which may require further refinement of these technologies;

the number of product development programs we pursue and the pace of each program;

our progress with formulation development;

the scope, rate of progress, results and costs of preclinical testing and clinical trials;

the time and costs associated with seeking regulatory approvals;

our ability to outsource the manufacture of our product candidates and the costs of doing so;

the time and costs associated with establishing in-house resources to market and sell certain of our products;

our ability to establish and maintain collaborative arrangements with others and the terms of those arrangements;

the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims, and

our need to acquire licenses, or other rights for our product candidates.

Since inception, we have financed our operations primarily through private placements and public offerings of our capital stock, proceeds from equipment lease financings, contract research funding and interest earned on investments. We believe that our existing cash and cash equivalent balances at September 30, 2007, which include net proceeds from our public offering that closed on January 30, 2007 and interest earned on our investments, should be sufficient to fund operations through 2008. We will need to obtain substantial additional funds before we would be able to bring any of our product candidates to market. Our estimates of future capital use are uncertain, and changing circumstances, including those related to implementation of our new development strategy or further changes to our development strategy, could cause us to consume capital significantly faster than currently expected, and our expected sources of funding may not be sufficient. If adequate funds are not available, we will be required to delay, reduce the scope of, or eliminate one or more of our product development programs and reduce personnel-related costs, or to obtain funds through arrangements with collaborators or other sources that may require us to relinquish rights to certain of our technologies or products that we would not otherwise relinquish. If we are able to obtain funds through the issuance of debt securities or borrowing, the terms may restrict our operations. If we are able to obtain funds through the issuance of equity securities, your interest will be diluted and our stock price may drop as a result.

***We have a history of losses, we expect to incur losses for at least the foreseeable future, and we may never attain or maintain profitability.***

We have never been profitable and have incurred significant losses in each year since our inception. As of September 30, 2007, we have an accumulated deficit of \$304.9 million. We have not had any product sales and do not anticipate receiving any revenues from product sales for at least the next few years, if ever. While our recent shift in development strategy may result in reduced capital expenditures, we expect to continue to incur substantial losses over at least the next several years as we:

expand drug product development efforts;

conduct preclinical testing and clinical trials;

pursue additional applications for our existing delivery technologies;

outsource the commercial-scale production of our products; and

establish a sales and marketing force to commercialize certain of our proprietary products if these products obtain regulatory approval.

## **Table of Contents**

To achieve and sustain profitability, we must, alone or with others, successfully develop, obtain regulatory approval for, manufacture, market and sell our products. We expect to incur substantial expenses in our efforts to develop and commercialize products and we may never generate sufficient product or contract research revenues to become profitable or to sustain profitability.

### ***Our dependence on collaborators may delay or prevent the progress of certain of our programs.***

Our commercialization strategy for certain of our product candidates depends on our ability to enter into agreements with collaborators to obtain assistance and funding for the development and potential commercialization of our product candidates. Collaborations may involve greater uncertainty for us, as we have less control over certain aspects of our collaborative programs than we do over our proprietary development and commercialization programs. We may determine that continuing a collaboration under the terms provided is not in our best interest, and we may terminate the collaboration. Our existing collaborators could delay or terminate their agreements, and our products subject to collaborative arrangements may never be successfully commercialized. For example, Novo Nordisk has control over and responsibility for development and commercialization of AERx iDMS. The development and commercialization of AERx iDMS could be delayed further or terminated if Novo Nordisk fails to conduct these activities in a timely manner or at all. For example, in 2004, Novo Nordisk amended the protocols of a Phase 3 clinical program, which resulted in a significant delay of the development of the product. If, due to delays or otherwise, we do not receive development funds or achieve milestones set forth in the agreements governing our collaborations, or if any of our collaborators breach or terminate their collaborative agreements or do not devote sufficient resources or priority to our programs, our business prospects and potential to receive revenues would be hurt.

Further, our existing or future collaborators may pursue alternative technologies or develop alternative products either on their own or in collaboration with others, including our competitors, and the priorities or focus of our collaborators may shift such that our programs receive less attention or resources than we would like. Any such actions by our collaborators may adversely affect our business prospects and ability to earn revenues. In addition, we could have disputes with our existing or future collaborators regarding, for example, the interpretation of terms in our agreements. Any such disagreements could lead to delays in the development or commercialization of any potential products or could result in time-consuming and expensive litigation or arbitration, which may not be resolved in our favor.

Even with respect to certain other programs that we intend to commercialize ourselves, we may enter into agreements with collaborators to share in the burden of conducting clinical trials, manufacturing and marketing our product candidates or products. In addition, our ability to apply our proprietary technologies to develop proprietary drugs will depend on our ability to establish and maintain licensing arrangements or other collaborative arrangements with the holders of proprietary rights to such drugs. We may not be able to establish such arrangements on favorable terms or at all, and our existing or future collaborative arrangements may not be successful.

### ***The results of later stage clinical trials of our product candidates may not be as favorable as earlier trials and that could result in additional costs and delay or prevent commercialization of our products.***

Although we believe the limited and preliminary data we have regarding our potential products is encouraging, the results of initial preclinical testing and clinical trials do not necessarily predict the results that we will get from subsequent or more extensive preclinical testing and clinical trials. Clinical trials of our product candidates may not demonstrate that they are safe and effective to the extent necessary to obtain regulatory approvals. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after receiving promising results in earlier trials. If we cannot adequately demonstrate through the clinical trial process that a therapeutic product we are developing is safe and effective, regulatory approval of that product would be delayed or prevented, which would impair our reputation, increase our costs and prevent us from earning revenues.

***If our clinical trials are delayed because of patient enrollment or other problems, we would incur additional cost and postpone the potential receipt of revenues.***

**Table of Contents**

Before we or our collaborators can file for regulatory approval for the commercial sale of our potential products, the FDA will require extensive preclinical safety testing and clinical trials to demonstrate their safety and efficacy. Completing clinical trials in a timely manner depends on, among other factors, the timely enrollment of patients. Our collaborators' and our ability to recruit patients depends on a number of factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study and the existence of competing clinical trials. Delays in planned patient enrollment in our current or future clinical trials may result in increased costs, program delays or both, and the loss of potential revenues.

***We are subject to extensive regulation, including the requirement of approval before any of our product candidates can be marketed. We may not obtain regulatory approval for our product candidates on a timely basis, or at all.***

We, our collaborators and our products are subject to extensive and rigorous regulation by the federal government, principally the FDA, and by state and local government agencies. Both before and after regulatory approval, the development, testing, manufacture, quality control, labeling, storage, approval, advertising, promotion, sale, distribution and export of our potential products are subject to regulation. Pharmaceutical products that are marketed abroad are also subject to regulation by foreign governments. Our products cannot be marketed in the United States without FDA approval. The process for obtaining FDA approval for drug products is generally lengthy, expensive and uncertain. To date, we have not sought or received approval from the FDA or any corresponding foreign authority for any of our product candidates.

Even though we intend to apply for approval of most of our products in the United States under Section 505(b)(2) of the United States Food, Drug and Cosmetic Act, which applies to reformulations of approved drugs and that may require smaller and shorter safety and efficacy testing than that for entirely new drugs, the approval process will still be costly, time-consuming and uncertain. We or our collaborators may not be able to obtain necessary regulatory approvals on a timely basis, if at all, for any of our potential products. Even if granted, regulatory approvals may include significant limitations on the uses for which products may be marketed. Failure to comply with applicable regulatory requirements can, among other things, result in warning letters, imposition of civil penalties or other monetary payments, delay in approving or refusal to approve a product candidate, suspension or withdrawal of regulatory approval, product recall or seizure, operating restrictions, interruption of clinical trials or manufacturing, injunctions and criminal prosecution.

***Regulatory authorities may not approve our product candidates even if the product candidates meet safety and efficacy endpoints in clinical trials or the approvals may be too limited for us to earn sufficient revenues.***

The FDA and other foreign regulatory agencies can delay approval of or refuse to approve our product candidates for a variety of reasons, including failure to meet safety and efficacy endpoints in our clinical trials. Our product candidates may not be approved even if they achieve their endpoints in clinical trials. Regulatory agencies, including the FDA, may disagree with our trial design and our interpretations of data from preclinical studies and clinical trials. Even if a product candidate is approved, it may be approved for fewer or more limited indications than requested or the approval may be subject to the performance of significant post-marketing studies. In addition, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any limitation, condition or denial of approval would have an adverse affect on our business, reputation and results of operations.

***Even if we are granted initial FDA approval for any of our product candidates, we may not be able to maintain such approval, which would reduce our revenues.***

Even if we are granted initial regulatory approval for a product candidate, the FDA and similar foreign regulatory agencies can limit or withdraw product approvals for a variety of reasons, including failure to comply with regulatory requirements, changes in regulatory requirements, problems with manufacturing facilities or processes or the occurrence of unforeseen problems, such as the discovery of previously undiscovered side effects. If we are able to obtain any product approvals, they may be limited or withdrawn or we may be unable to remain in compliance with regulatory requirements. Both before and after approval

**Table of Contents**

we, our collaborators and our products are subject to a number of additional requirements. For example, certain changes to the approved product, such as adding new indications, certain manufacturing changes and additional labeling claims are subject to additional FDA review and approval. Advertising and other promotional material must comply with FDA requirements and established requirements applicable to drug samples. We, our collaborators and our manufacturers will be subject to continuing review and periodic inspections by the FDA and other authorities where applicable and must comply with ongoing requirements, including the FDA's Good Manufacturing Practices, or GMP, requirements. Once the FDA approves a product, a manufacturer must provide certain updated safety and efficacy information, submit copies of promotional materials to the FDA and make certain other required reports. Product approvals may be withdrawn if regulatory requirements are not complied with or if problems concerning safety or efficacy of the product occur following approval. Any limitation or withdrawal of approval of any of our products could delay or prevent sales of our products, which would adversely affect our revenues. Further continuing regulatory requirements involve expensive ongoing monitoring and testing requirements.

***Since one of our key proprietary programs, the ARD-3100 liposomal ciprofloxacin program, relies on the FDA's granting of orphan drug designation for potential market exclusivity, the product may not be able to obtain market exclusivity and could be barred from the market for up to seven years.***

The FDA has granted orphan drug designation for our proprietary liposomal ciprofloxacin for the management of cystic fibrosis. Orphan drug designation is intended to encourage research and development of new therapies for diseases that affect fewer than 200,000 patients in the United States. The designation provides the opportunity to obtain market exclusivity for seven years from the date of the FDA's approval of a new drug application, or NDA. However, the market exclusivity is granted only to the first chemical entity to be approved by the FDA for a given indication. Therefore, if another inhaled ciprofloxacin product were to be approved by the FDA for a cystic fibrosis indication before our product, then we may be blocked from launching our product in the United States for seven years, unless we are able to demonstrate to the FDA clinical superiority of our product on the basis of safety or efficacy. We may seek to develop additional products that incorporate drugs that have received orphan drug designations for specific indications. In each case, if our product is not the first to be approved by the FDA for a given indication, we will be unable to access the target market in the United States, which would adversely affect our ability to earn revenues.

***We have limited manufacturing capacity and will have to depend on contract manufacturers and collaborators; if they do not perform as expected, our revenues and customer relations will suffer.***

We have limited capacity to manufacture our requirements for the development and commercialization of our product candidates. We intend to use contract manufacturers to produce key components, assemblies and subassemblies in the clinical and commercial manufacturing of our products. We may not be able to enter into or maintain satisfactory contract manufacturing arrangements. Specifically, an affiliate of Novo Nordisk has agreed to supply devices and dosage forms to us for use in the development of our products that incorporate our proprietary AERx technology through January 27, 2008. We may not be able to extend this agreement at satisfactory terms, if at all, and we may not be able to find a replacement contract manufacturer at satisfactory terms.

We may decide to invest in additional clinical manufacturing facilities in order to internally produce critical components of our product candidates and to handle critical aspects of the production process, such as assembly of the disposable unit-dose packets and filling of the unit-dose packets. If we decide to produce components of any of our product candidates in-house, rather than use contract manufacturers, it will be costly and we may not be able to do so in a timely or cost-effective manner or in compliance with regulatory requirements.

With respect to some of our product development programs targeted at large markets, either our collaborators or we will have to invest significant amounts to attempt to provide for the high-volume manufacturing required to take advantage of these product markets, and much of this spending may occur before a product is approved by the FDA for commercialization. Any such effort will entail many significant risks. For example, the design requirements of our products may make it too costly or otherwise infeasible for us to develop them at a commercial scale, or manufacturing and quality control problems may arise as we attempt to expand production. Failure to address these issues could delay or prevent late-stage clinical testing and commercialization of any products that may receive FDA approval.



## **Table of Contents**

Further, we, our contract manufacturers and our collaborators are required to comply with the FDA's GMP requirements that relate to product testing, quality assurance, manufacturing and maintaining records and documentation. We, our contract manufacturers or our collaborators may not be able to comply with the applicable GMP and other FDA regulatory requirements for manufacturing, which could result in an enforcement or other action, prevent commercialization of our product candidates and impair our reputation and results of operations.

***We rely on a small number of vendors and contract manufacturers to supply us with specialized equipment, tools and components; if they do not perform as we need them to, we will not be able to develop or commercialize products.***

We rely on a small number of vendors and contract manufacturers to supply us and our collaborators with specialized equipment, tools and components for use in development and manufacturing processes. These vendors may not continue to supply such specialized equipment, tools and components, and we may not be able to find alternative sources for such specialized equipment and tools. Any inability to acquire or any delay in our ability to acquire necessary equipment, tools and components would increase our expenses and could delay or prevent our development of products.

***In order to market our proprietary products, we are likely to establish our own sales, marketing and distribution capabilities. We have no experience in these areas, and if we have problems establishing these capabilities, the commercialization of our products would be impaired.***

We intend to establish our own sales, marketing and distribution capabilities to market products to concentrated, easily addressable prescriber markets. We have no experience in these areas, and developing these capabilities will require significant expenditures on personnel and infrastructure. While we intend to market products that are aimed at a small patient population, we may not be able to create an effective sales force around even a niche market. In addition, some of our product development programs will require a large sales force to call on, educate and support physicians and patients. While we intend to enter into collaborations with one or more pharmaceutical companies to sell, market and distribute such products, we may not be able to enter into any such arrangement on acceptable terms, if at all. Any collaborations we do enter into may not be effective in generating meaningful product royalties or other revenues for us.

***If any products that we or our collaborators may develop do not attain adequate market acceptance by healthcare professionals and patients, our business prospects and results of operations will suffer.***

Even if we or our collaborators successfully develop one or more products, such products may not be commercially acceptable to healthcare professionals and patients, who will have to choose our products over alternative products for the same disease indications, and many of these alternative products will be more established than ours. For our products to be commercially viable, we will need to demonstrate to healthcare professionals and patients that our products afford benefits to the patient that are cost-effective as compared to the benefits of alternative therapies. Our ability to demonstrate this depends on a variety of factors, including:

- the demonstration of efficacy and safety in clinical trials;

- the existence, prevalence and severity of any side effects;

- the potential or perceived advantages or disadvantages compared to alternative treatments;

- the timing of market entry relative to competitive treatments;

- the relative cost, convenience, product dependability and ease of administration;

- the strength of marketing and distribution support;

- the sufficiency of coverage and reimbursement of our product candidates by governmental and other third-party payors; and





## **Table of Contents**

the product labeling or product insert required by the FDA or regulatory authorities in other countries.

Our product revenues will be adversely affected if, due to these or other factors, the products we or our collaborators are able to commercialize do not gain significant market acceptance.

***We depend upon our proprietary technologies, and we may not be able to protect our potential competitive proprietary advantage.***

Our business and competitive position is dependent upon our and our collaborators' ability to protect our proprietary technologies related to various aspects of pulmonary drug delivery and drug formulation. While our intellectual property rights may not provide a significant commercial advantage for us, our patents and know-how are intended to provide protection for important aspects of our technology, including methods for aerosol generation, devices used to generate aerosols, breath control, compliance monitoring, certain pharmaceutical formulations, design of dosage forms and their manufacturing and testing methods. In addition, we are maintaining as non-patented trade secrets some of the key elements of our manufacturing technologies, for example, those associated with production of disposable unit-dose packets for our AERx delivery system.

Our ability to compete effectively will also depend to a significant extent on our and our collaborators' ability to obtain and enforce patents and maintain trade secret protection over our proprietary technologies. The coverage claimed in a patent application typically is significantly reduced before a patent is issued, either in the United States or abroad. Consequently, any of our pending or future patent applications may not result in the issuance of patents and any patents issued may be subjected to further proceedings limiting their scope and may in any event not contain claims broad enough to provide meaningful protection. Any patents that are issued to us or our collaborators may not provide significant proprietary protection or competitive advantage, and may be circumvented or invalidated. In addition, unpatented proprietary rights, including trade secrets and know-how, can be difficult to protect and may lose their value if they are independently developed by a third party or if their secrecy is lost. Further, because development and commercialization of pharmaceutical products can be subject to substantial delays, patents may expire early and provide only a short period of protection, if any, following commercialization of products.

In July 2006, we assigned 23 issued United States patents to Novo Nordisk along with corresponding non-United States counterparts and certain related pending applications. In August 2006, Novo Nordisk brought suit against Pfizer, Inc. claiming infringement of certain claims in one of the assigned United States patents. In December 2006, Novo Nordisk's motion for a preliminary injunction in this case was denied. That patent is placed at risk in connection with this infringement lawsuit. Other patents assigned to Novo Nordisk may become the subject of future litigation. If all or any of the patents assigned to Novo Nordisk are invalidated, it may reduce Novo Nordisk's commitment to move forward with AERx iDMS and would adversely affect any royalties or other compensation which we might potentially otherwise receive based directly on such patents. Further, the patents assigned to Novo Nordisk encompass, in some instances, technology beyond inhaled insulin and, if all or any of these patents are invalidated, it could harm our ability to obtain market exclusivity with respect to other product candidates.

***We may infringe on the intellectual property rights of others, and any litigation could force us to stop developing or selling potential products and could be costly, divert management attention and harm our business.***

We must be able to develop products without infringing the proprietary rights of other parties. Because the markets in which we operate involve established competitors with significant patent portfolios, including patents relating to compositions of matter, methods of use and methods of drug delivery, it could be difficult for us to use our technologies or develop products without infringing the proprietary rights of others. We may not be able to design around the patented technologies or inventions of others and we may not be able to obtain licenses to use patented technologies on acceptable terms, or at all. If we cannot operate without infringing the proprietary rights of others, we will not earn product revenues.

If we are required to defend ourselves in a lawsuit, we could incur substantial costs and the lawsuit could divert management attention, regardless of the lawsuit's merit or outcome. These legal actions could seek damages and seek to enjoin testing, manufacturing and marketing of the accused product or process.

## **Table of Contents**

In addition to potential liability for significant damages, we could be required to obtain a license to continue to manufacture or market the accused product or process and any license required under any such patent may not be made available to us on acceptable terms, if at all.

Periodically, we review publicly available information regarding the development efforts of others in order to determine whether these efforts may violate our proprietary rights. We may determine that litigation is necessary to enforce our proprietary rights against others. Such litigation could result in substantial expense, regardless of its outcome, and may not be resolved in our favor.

Furthermore, patents already issued to us or our pending patent applications may become subject to dispute, and any disputes could be resolved against us. For example, Eli Lilly and Company brought an action against us seeking to have one or more employees of Eli Lilly named as co-inventors on one of our patents. This case was determined in our favor in 2004, but we may face other similar claims in the future and we may lose or settle cases at significant loss to us. In addition, because patent applications in the United States are currently maintained in secrecy for a period of time prior to issuance, and patent applications in certain other countries generally are not published until more than 18 months after they are first filed, and because publication of discoveries in scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first creator of inventions covered by our pending patent applications or that we were the first to file patent applications on such inventions.

***We are in a highly competitive market, and our competitors have developed or may develop alternative therapies for our target indications, which would limit the revenue potential of any product we may develop.***

We are in competition with pharmaceutical, biotechnology and drug delivery companies, hospitals, research organizations, individual scientists and nonprofit organizations engaged in the development of drugs and therapies for the disease indications we are targeting. Our competitors may succeed before we can, and many already have succeeded, in developing competing technologies for the same disease indications, obtaining FDA approval for products or gaining acceptance for the same markets that we are targeting. If we are not first to market, it may be more difficult for us and our collaborators to enter markets as second or subsequent competitors and become commercially successful. We are aware of a number of companies that are developing or have developed therapies to address indications we are targeting, including major pharmaceutical companies such as Bayer, Eli Lilly, Genentech, Gilead Sciences, Merck & Co., Novartis and Pfizer. Certain of these companies are addressing these target markets with pulmonary products that are similar to ours. These companies and many other potential competitors have greater research and development, manufacturing, marketing, sales, distribution, financial and managerial resources and experience than we have and many of these companies may have products and product candidates that are on the market or in a more advanced stage of development than our product candidates. Our ability to earn product revenues and our market share would be substantially harmed if any existing or potential competitors brought a product to market before we or our collaborators were able to, or if a competitor introduced at any time a product superior to or more cost-effective than ours.

***If we do not continue to attract and retain key employees, our product development efforts will be delayed and impaired.***

We depend on a small number of key management and technical personnel. Our success also depends on our ability to attract and retain additional highly qualified marketing, management, manufacturing, engineering and development personnel. There is a shortage of skilled personnel in our industry, we face intense competition in our recruiting activities, and we may not be able to attract or retain qualified personnel. Losing any of our key employees, particularly our President and Chief Executive Officer, Dr. Igor Gonda, who plays a central role in our strategy shift to a specialty pharmaceutical company, could impair our product development efforts and otherwise harm our business. Any of our employees may terminate their employment with us at will.

***Acquisition of complementary businesses or technologies could result in operating difficulties and harm our results of operations.***

While we have not identified any definitive targets, we may acquire products, businesses or technologies that we believe are complementary to our business strategy. The process of investigating, acquiring and

## **Table of Contents**

integrating any business or technology into our business and operations is risky and we may not be able to accurately predict or derive the benefits of any such acquisition. The process of acquiring and integrating any business or technology may create operating difficulties and unexpected expenditures, such as:

diversion of our management from the development and commercialization of our pipeline product candidates;

difficulty in assimilating and efficiently using the acquired assets or personnel; and

inability to retain key personnel.

In addition to the factors set forth above, we may encounter other unforeseen problems with acquisitions that we may not be able to overcome. Any future acquisitions may require us to issue shares of our stock or other securities that dilute the ownership interests of our other shareholders, expend cash, incur debt, assume liabilities, including contingent or unknown liabilities, or incur additional expenses related to write-offs or amortization of intangible assets, any of which could materially adversely affect our operating results.

***If we market our products in other countries, we will be subject to different laws and we may not be able to adapt to those laws, which could increase our costs while reducing our revenues.***

If we market any approved products in foreign countries, we will be subject to different laws, particularly with respect to intellectual property rights and regulatory approval. To maintain a proprietary market position in foreign countries, we may seek to protect some of our proprietary inventions through foreign counterpart patent applications. Statutory differences in patentable subject matter may limit the protection we can obtain on some of our inventions outside of the United States. The diversity of patent laws may make our expenses associated with the development and maintenance of intellectual property in foreign jurisdictions more expensive than we anticipate. We probably will not obtain the same patent protection in every market in which we may otherwise be able to potentially generate revenues. In addition, in order to market our products in foreign jurisdictions, we and our collaborators must obtain required regulatory approvals from foreign regulatory agencies and comply with extensive regulations regarding safety and quality. We may not be able to obtain regulatory approvals in such jurisdictions and we may have to incur significant costs in obtaining or maintaining any foreign regulatory approvals. If approvals to market our products are delayed, if we fail to receive these approvals, or if we lose previously received approvals, our business would be impaired as we could not earn revenues from sales in those countries.

***We may be exposed to product liability claims, which would hurt our reputation, market position and operating results.***

We face an inherent risk of product liability as a result of the clinical testing of our product candidates in humans and will face an even greater risk upon commercialization of any products. These claims may be made directly by consumers or by pharmaceutical companies or others selling such products. We may be held liable if any product we develop causes injury or is found otherwise unsuitable during product testing, manufacturing or sale. Regardless of merit or eventual outcome, liability claims would likely result in negative publicity, decreased demand for any products that we may develop, injury to our reputation and suspension or withdrawal of clinical trials. Any such claim will be very costly to defend and also may result in substantial monetary awards to clinical trial participants or customers, loss of revenues and the inability to commercialize products that we develop. Although we currently have product liability insurance, we may not be able to maintain such insurance or obtain additional insurance on acceptable terms, in amounts sufficient to protect our business, or at all. A successful claim brought against us in excess of our insurance coverage would have a material adverse effect on our results of operations.

***If we cannot arrange for adequate third-party reimbursement for our products, our revenues will suffer.***

In both domestic and foreign markets, sales of our potential products will depend in substantial part on the availability of adequate reimbursement from third-party payors such as government health administration authorities, private health insurers and other organizations. Third-party payors often challenge the price and cost-effectiveness of medical products and services. Significant uncertainty exists as to the adequate reimbursement status of newly approved health care products. Any products we are able

## **Table of Contents**

to successfully develop may not be reimbursable by third-party payors. In addition, our products may not be considered cost-effective and adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize a profit. Legislation and regulations affecting the pricing of pharmaceuticals may change before our products are approved for marketing and any such changes could further limit reimbursement. If any products we develop do not receive adequate reimbursement, our revenues will be severely limited.

### ***Our use of hazardous materials could subject us to liabilities, fines and sanctions.***

Our laboratory and clinical testing sometimes involve use of hazardous and toxic materials. We are subject to federal, state and local laws and regulations governing how we use, manufacture, handle, store and dispose of these materials. Although we believe that our safety procedures for handling and disposing of such materials comply in all material respects with all federal, state and local regulations and standards, there is always the risk of accidental contamination or injury from these materials. In the event of an accident, we could be held liable for any damages that result and such liability could exceed our financial resources. Compliance with environmental and other laws may be expensive and current or future regulations may impair our development or commercialization efforts.

### ***If we are unable to effectively implement or maintain a system of internal controls over financial reporting, we may not be able to accurately or timely report our financial results and our stock price could be adversely affected.***

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to evaluate the effectiveness of our internal controls over financial reporting as of the end of each fiscal year, and to include a management report assessing the effectiveness of our internal controls over financial reporting in our annual report on Form 10-K for that fiscal year. Section 404 also requires our independent registered public accounting firm, beginning with our fiscal year ending December 31, 2008, to attest to, and report on, management's assessment of our internal controls over financial reporting. Our ability to comply with the annual internal control report requirements will depend on the effectiveness of our financial reporting and data systems and controls across our company. We expect these systems and controls to involve significant expenditures and to become increasingly complex as our business grows and to the extent that we make and integrate acquisitions. To effectively manage this complexity, we will need to continue to improve our operational, financial and management controls and our reporting systems and procedures. Any failure to implement required new or improved controls, or difficulties encountered in the implementation or operation of these controls, could harm our operating results and cause us to fail to meet our financial reporting obligations, which could adversely affect our business and reduce our stock price.

### **Risks Related to Our Common Stock**

#### ***Our stock price is likely to remain volatile.***

The market prices for securities of many companies in the drug delivery and pharmaceutical industries, including ours, have historically been highly volatile, and the market from time to time has experienced significant price and volume fluctuations unrelated to the operating performance of particular companies. Prices for our common stock may be influenced by many factors, including:

investor perception of us;

research analyst recommendations and our ability to meet or exceed quarterly performance expectations of analysts or investors;

fluctuations in our operating results;

market conditions relating to our segment of the industry or the securities markets in general;

announcements of technological innovations or new commercial products by us or our competitors;

publicity regarding actual or potential developments relating to products under development by us or our competitors;

**Table of Contents**

failure to maintain existing or establish new collaborative relationships;

developments or disputes concerning patents or proprietary rights;

delays in the development or approval of our product candidates;

regulatory developments in both the United States and foreign countries;

concern of the public or the medical community as to the safety or efficacy of our products, or products deemed to have similar safety risk factors or other similar characteristics to our products;

period-to-period fluctuations in financial results;

future sales or expected sales of substantial amounts of common stock by shareholders;

our ability to raise financing; and

economic and other external factors.

In the past, class action securities litigation has often been instituted against companies promptly following volatility in the market price of their securities. Any such litigation instigated against us would, regardless of its merit, result in substantial costs and a diversion of management's attention and resources.

***Our common stock was delisted from the Nasdaq Capital Market; this delisting may reduce the liquidity of our common stock and the price may decline.***

On November 10, 2006, our common stock was delisted from the Nasdaq Capital Market due to non-compliance with Nasdaq's continued listing standards. Our common stock is currently quoted on the OTC Bulletin Board. This delisting may reduce the liquidity of our common stock, may cause investors not to trade in our stock and may result in a lower stock price. In addition, investors may find it more difficult to obtain accurate quotations of the share price of our common stock.

***We have implemented certain anti-takeover provisions, which make it less likely that we would be acquired and you would receive a premium price for your shares.***

Certain provisions of our articles of incorporation and the California Corporations Code could discourage a party from acquiring, or make it more difficult for a party to acquire, control of our company without approval of our board of directors. These provisions could also limit the price that certain investors might be willing to pay in the future for shares of our common stock. Certain provisions allow our board of directors to authorize the issuance, without shareholder approval, of preferred stock with rights superior to those of the common stock. We are also subject to the provisions of Section 1203 of the California Corporations Code, which requires us to provide a fairness opinion to our shareholders in connection with their consideration of any proposed interested party reorganization transaction.

We have adopted a shareholder rights plan, commonly known as a "poison pill." We have also adopted an Executive Officer Severance Plan and a Form of Change of Control Agreement, both of which may provide for the payment of benefits to our officers in connection with an acquisition. The provisions of our articles of incorporation, our poison pill, our severance plan and our change of control agreements, and provisions of the California Corporations Code may discourage, delay or prevent another party from acquiring us or reduce the price that a buyer is willing to pay for our common stock.

***We have never paid dividends on our capital stock, and we do not anticipate paying cash dividends for at least the foreseeable future.***

We have never declared or paid cash dividends on our capital stock. We do not anticipate paying any cash dividends on our common stock for at least the foreseeable future. We currently intend to retain all available funds and future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of potential gain for at least the foreseeable future.



**Table of Contents**

**Item 6. EXHIBITS**

<b>Exhibit Number</b>	<b>Description</b>
10.1(1)	Consulting Agreement effective as of July 2, 2007 by and between the Company and Norman Halleen.
10.2(2)	Sublease between the Company and Mendel Biotechnology, Inc., dated July 11, 2007, under the Lease Agreement by and between the Company and Hayward Point Eden I Limited Partnership, a Delaware limited partnership, as successor-in-interest to Britannia Point Eden, LLC, as amended, for 3929 Point Eden Way, Hayward, California.
10.3(3)	Manufacturing Agreement between the Company and Enzon Pharmaceuticals, Inc. dated August 8, 2007.
10.4#	Exclusive License, Development and Commercialization Agreement, dated as of August 30, 2007, by and between the Company and Lung Rx, Inc.
10.5#	Collaboration Agreement, dated as of August 31, 2007, by and between the Company and CyDex, Inc.
31.1	Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification by Interim Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification by Chief Executive Officer and Interim Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
#	Confidential treatment has been sought for portions of this exhibit.
(1)	Incorporated by reference to the Company's Form 8-K filed on July 11, 2007.
(2)	Incorporated by reference to the Company's Form 8-K filed on July 24, 2007.
(3)	Incorporated by reference to the Company's Form

8-K filed on  
August 14,  
2007.

Aradigm, AERx, AERx Essence and AERx Strip are registered trademarks of Aradigm Corporation. \*Other names and brands may be claimed as the property of others.



**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ARADIGM CORPORATION  
(Registrant)

/s/ Igor Gonda  
Igor Gonda  
*President and Chief Executive Officer*  
*(Principal Executive Officer)*

/s/ Norman Halleen  
Norman Halleen  
*Interim Chief Financial Officer*  
*(Principal Financial and Accounting Officer)*

Dated: November 14, 2007

**Table of Contents**

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