

ARADIGM CORP
Form 10-Q
November 12, 2008

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, 2008

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, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company
(Do not check if a smaller reporting company)

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.

<i>(Class)</i>	<i>(Outstanding at October 31, 2008)</i>
Common	55,076,979

**ARADIGM CORPORATION
TABLE OF CONTENTS**

	Page
<u>PART I. FINANCIAL INFORMATION</u>	
<u>Item 1. Financial Statements</u>	3
<u>Condensed Balance Sheets at September 30, 2008 (unaudited) and December 31, 2007</u>	3
<u>Condensed Statements of Operations for the three and nine months ended September 30, 2008 and 2007 (unaudited)</u>	4
<u>Condensed Statements of Cash Flows for the nine months ended September 30, 2008 and 2007 (unaudited)</u>	5
<u>Notes to Unaudited Condensed Financial Statements</u>	6
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	14
<u>Item 3. Quantitative and Qualitative Disclosure About Market Risk</u>	25
<u>Item 4. Controls and Procedures</u>	25
<u>PART II. OTHER INFORMATION</u>	26
<u>Item 1A. Risk Factors</u>	26
<u>Item 6. Exhibits</u>	37
<u>Signatures</u>	38
<u>EX-10.33</u>	
<u>EX-31.1</u>	
<u>EX-31.2</u>	
<u>EX-32.1</u>	

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

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

	September 30, 2008 (Unaudited)	December 31, 2007 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 21,319	\$ 29,964
Short-term investments		10,546
Receivables	413	500
Restricted cash	314	152
Prepaid and other current assets	502	971
Total current assets	22,548	42,133
Property and equipment, net	5,238	3,223
Notes receivable from officers and employees	34	33
Restricted cash		153
Other assets	253	271
Total assets	\$ 28,073	\$ 45,813
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 1,122	\$ 1,658
Accrued clinical and cost of other studies	126	789
Accrued compensation	1,029	1,252
Deferred revenue	1,145	880
Facility lease exit obligation	353	376
Other accrued liabilities	722	584
Total current liabilities	4,497	5,539
Deferred rent	222	283
Facility lease exit obligation	1,115	1,373
Other non-current liabilities	86	248
Note payable and accrued interest to related party	8,369	8,071
Total liabilities	14,289	15,514
Commitments and contingencies		
Shareholders' equity:		
Preferred stock, 2,950,000 shares authorized, none outstanding		
Common stock, no par value; authorized shares: 150,000,000 at September 30, 2008 and 100,000,000 at December 2007; issued and	343,136	342,355

Edgar Filing: ARADIGM CORP - Form 10-Q

outstanding shares: 54,923,839 at September 30, 2008 and 54,772,705 at
December 31, 2007

Accumulated other comprehensive income		10
Accumulated deficit	(329,352)	(312,066)
Total shareholders' equity	13,784	30,299
Total liabilities and shareholders' equity	\$ 28,073	\$ 45,813

See accompanying Notes to Condensed Financial Statements
p 3 of 42

Table of Contents

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

	Three Months Ended		Nine months Ended	
	September 30,		September 30,	
	2008	2007	2008	2007
Revenues:				
Contract revenues from related parties	\$	\$	\$	\$ 23
Contract revenues from unrelated parties	197	230	251	920
Total revenues	197	230	\$ 251	943
Operating expenses:				
Research and development	3,199	3,899	12,892	11,147
General and administrative	1,615	1,757	4,989	6,372
Restructuring and lease exit activities	19	2,059	61	2,157
Total operating expenses	4,833	7,715	17,942	19,676
Loss from operations	(4,636)	(7,485)	(17,691)	(18,733)
Interest income	146	684	709	2,020
Interest expense	(105)	(101)	(303)	(293)
Other income (expense), net	(1)		(1)	16
Net loss	\$ (4,596)	\$ (6,902)	\$ (17,286)	\$ (16,990)
Basic and diluted net loss per common share	\$ (0.08)	\$ (0.13)	\$ (0.32)	\$ (0.34)
Shares used in computing basic and diluted net loss per common share	54,165	53,948	54,111	49,617

See accompanying Notes to Condensed Financial Statements
p 4 of 42

Table of Contents

ARADIGM CORPORATION
CONDENSED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Nine months Ended	
	September 30,	
	2008	2007
Cash flows from operating activities:		
Net loss	\$ (17,286)	\$ (16,990)
Adjustments to reconcile net loss to cash used in operating activities:		
Impairment loss on property and equipment		180
Amortization and accretion of investments	1	(26)
Depreciation and amortization	590	589
Stock-based compensation	638	1,097
Loss on retirement and sale of property and equipment	1	10
Facility lease exit cost		1,459
Changes in operating assets and liabilities:		
Receivables	87	341
Prepaid and other current assets	469	190
Restricted cash	(9)	(302)
Other assets	17	168
Accounts payable	(563)	(378)
Accrued compensation	(223)	(175)
Other accrued liabilities	(495)	894
Deferred revenue	265	440
Facility lease exit obligation	(281)	(235)
Deferred rent	(61)	(114)
Net cash used in operating activities	(16,850)	(12,852)
Cash flows from investing activities:		
Capital expenditures	(2,473)	(946)
Purchases of available-for-sale investments	(1,235)	(13,494)
Proceeds from sales and maturities of available-for-sale investments	11,770	1,500
Proceeds from sales and of property and equipment		11
Net cash provided by (used in) investing activities	8,062	(12,929)
Cash flows from financing activities:		
Proceeds from public offering of common stock, net		33,178
Proceeds from issuance of common stock, net	143	103
Advances to officers and employees on notes receivable		(1)
Net cash provided by financing activities	143	33,280
Net increase (decrease) in cash and cash equivalents	(8,645)	7,499
Cash and cash equivalents at beginning of period	29,964	27,013

Edgar Filing: ARADIGM CORP - Form 10-Q

Cash and cash equivalents at end of period	\$ 21,319	\$ 34,512
Supplemental disclosure of non-cash financing activities:		
Conversion of convertible preferred stock to common stock	\$	\$ 23,669
Supplemental disclosure of non-cash investing activities:		
Purchases of property and equipment through accounts payable	\$ 605	\$ 307

See accompanying Notes to Condensed Financial Statements
p 5 of 42

Table of Contents

ARADIGM CORPORATION
NOTES TO THE UNAUDITED CONDENSED FINANCIAL STATEMENTS
September 30, 2008

1. Organization and Basis of Presentation***Organization***

Aradigm Corporation (the Company, we, our) is a California corporation focused on the development and commercialization of drugs delivered by inhalation for the treatment of severe respiratory diseases by pulmonologists. The Company's principal activities to date have included research and development, securing operating facilities, expanding commercial production capabilities, recruiting management and technical personnel, and obtaining financing. The Company does not anticipate receiving any revenue from the sale of products in the near term. The Company's ability to continue its 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 as of September 30, 2008 are sufficient to enable the Company to meet its obligations through at least the second quarter of 2009. Management plans to continue to obtain funds through collaborative arrangements, equity issuances and debt arrangements. If we are unable to complete a debt or equity offering or otherwise obtain sufficient financing when and if needed, we may be required to reduce, defer, or discontinue one or more of our product development programs, or we may not be able to continue as a going concern entity. The Company operates as a single operating segment.

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 have been condensed or omitted pursuant to the Securities and Exchange Commission's rules and regulations. 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 unaudited condensed financial statements should be read in conjunction with the financial statements and notes thereto included with the Company's Annual Report on Form 10-K for the year ended December 31, 2007, as filed with the Securities and Exchange Commission (SEC). The results of the Company's 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, 2007 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements.

Reclassifications

The Company reclassified restructuring activity expenses incurred during 2007 from the general and administrative expense line item to the restructuring and lease exit activities line item in the accompanying unaudited condensed statements of operations to conform to the presentation for the current periods.

2. Summary of Significant Accounting Policies***Use of Estimates***

The preparation of financial statements in conformity with U.S. generally accepted accounting principles 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, assumptions for valuing options and warrants, and income taxes. Actual results could differ from these estimates.

Revenue Recognition

Contract revenues consist of revenues from grants, collaboration agreements and feasibility studies. The Company recognizes revenue under the provisions of the SEC Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104) and Emerging Issues Task

Table of Contents

Force (EITF) Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21). Revenue for arrangements not having multiple deliverables, as outlined in EITF 00-21, is recognized once costs are incurred and collectability is reasonably assured. Under some agreements the Company's 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 acceptance of the work and confirmation of the amount to be paid by the collaborator. Deferred revenue represents the portion of all refundable and nonrefundable research payments received that have 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 recognized as revenue either upon 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 agreement 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 specific performance criteria are achieved. Refundable development and license fee payments are generally not refundable once specific performance criteria are achieved and accepted.

Collaborative license and development agreements that require the Company to provide multiple deliverables, such as a license, research and product steering committee services and other performance obligations, are accounted for in accordance with EITF

00-21. Under EITF 00-21, delivered items are evaluated to determine whether such items have value to the Company's collaborators on a stand-alone basis and whether objective reliable evidence of fair value of the undelivered items exists. Deliverables that meet these criteria are considered a separate unit of accounting. Deliverables that do not meet these criteria are combined and accounted for as a single unit of accounting. The appropriate revenue recognition criteria are identified and applied to each separate unit of accounting.

Accounting for Costs Associated with Exit or Disposal Activities

In accordance with Statement of Financial Accounting Standards (SFAS) No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* (SFAS 146), the Company recognizes a liability for the cost associated with an exit or disposal activity measured initially at its fair value in the period in which the liability is incurred, except for liabilities for one-time termination benefits that are 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 are measured using the credit-adjusted risk-free rate that was used to measure the liability initially.

Research and Development

Research and development expenses consist of costs incurred for company-sponsored, collaborative and contracted research and development activities. These costs include direct and research-related overhead expenses. Research and development expenses under collaborative and government grants approximate the revenue recognized under such agreements. The Company expenses research and development costs as such costs are incurred.

Income Taxes

The Company uses the asset and liability method to account for income taxes as required by SFAS No. 109, *Accounting for Income Taxes*. Under this method, deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes as well as net operating loss and tax credit carryforwards. Valuation allowances are established to reduce deferred tax assets to amounts more likely than not to be realized. The Company currently maintains a full valuation allowance.

Stock-Based Compensation Expense

The Company measures stock-based compensation at the grant date based on the award's fair value and recognizes 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.

The Company has 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.

p 7 of 42

Table of Contents**Recently Issued Accounting Pronouncements**

In February 2008, the Financial Accounting Standards Board (FASB) issued FASB Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157* (FSP FAS 157-2), which defers the effective date of SFAS 157 for all non-financial assets and non-financial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), for fiscal years beginning after November 15, 2008 and interim periods within those fiscal years for items within the scope of FSP FAS 157-2. Management does not expect that the adoption of FSP FAS 157-2 will have a material impact on the Company's financial position and results of operations.

In November 2007, the EITF issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property* (EITF 07-1). Companies may enter into arrangements with other companies to jointly develop, manufacture, distribute, and market a product. Often the activities associated with these arrangements are conducted by the collaborators without the creation of a separate legal entity (that is, the arrangement is operated as a virtual joint venture). The arrangements generally provide that the collaborators will share, based on contractually defined calculations, the profits or losses from the associated activities. Periodically, the collaborators share financial information related to product revenues generated (if any) and costs incurred that may trigger a sharing payment for the combined profits or losses. The consensus requires collaborators in such an arrangement to present the result of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. EITF 07-1 is effective for collaborative arrangements in place at the beginning of the annual period beginning after December 15, 2008. Management does not expect that the adoption of EITF 07-1 will have a material impact on the Company's financial position and results of operations.

3. Stock-Based Compensation

The following table shows the effect of SFAS 123R, *Share Based Payment* on stock-based compensation expense included in the statement of operations for the three and nine month periods ended September 30, 2008 and 2007 (in thousands, except per share amounts):

	Three Months Ended		Nine months Ended	
	September 30,		September 30,	
	2008	2007	2008	2007
Research and development expense	\$ 66	\$ 183	\$ 427	\$ 438
General and administrative expense	90	225	211	659
Total stock-based compensation with adoption of SFAS 123R	\$ 156	\$ 408	\$ 638	\$ 1,097
Total stock-based compensation without the adoption of SFAS 123R	\$ 2	\$ 14	\$ 67	\$ 84
Impact on basic and diluted net loss per common share	\$	\$ (0.01)	\$ (0.01)	\$ (0.02)

Following are the components of total stock-based compensation expense recognized for the three and nine month periods ended September 30, 2008 and 2007 (in thousands):

	Three Months Ended		Nine months Ended	
	September 30,		September 30,	
	2008	2007	2008	2007
	\$ 97	\$ 376	\$ 423	\$ 959

Employee stock option plans and employee stock purchase plan (ESPP)				
Restricted stock awards to employees	57	18	148	54
Total employee stock-based compensation expense	154	394	571	1,013
Stock options and restricted stock awards to consultants	2	14	67	84
Total stock-based compensation	\$ 156	\$ 408	\$ 638	\$ 1,097

No stock-based employee compensation cost was capitalized for the three or nine month periods ended September 30, 2008 or 2007. Because the Company incurred net losses during each of those periods, there was no recognized tax benefit associated with stock-based compensation expense.

As of September 30, 2008, there was \$1.5 million of total unrecognized compensation costs, net of forfeitures, related to non-vested stock options, stock purchases and restricted stock awards to employees, which is expected to be recognized over a weighted average period of 2.8 years.

p 8 of 42

Table of Contents*Valuation Assumptions*

The fair value of options was estimated at the date of grant using the Black-Scholes option pricing model. The weighted-average assumptions used for the three and nine months ended September 30, 2008 and 2007 and the resulting estimates of weighted-average fair value per share of options granted and shares purchased during these periods were as follows:

	Three Months Ended September 30,		Nine months ended September 30,	
	2008	2007	2008	2007
<i>Employee Stock Options</i>				
Dividend yield	0.0%	0.0%	0.0%	0.0%
Volatility	67.1%	72.8%	67.7%	81.2%
Risk-free interest rate	2.8%	4.0%	2.8%	4.9%
Expected life (years)	4.0	4.0	3.8	4.0
Weighted-average fair value of options granted during the periods	\$ 0.30	\$ 0.76	\$ 0.33	\$ 0.82
<i>ESPP</i>				
Dividend yield	0.0%	0.0%	0.0%	0.0%
Volatility	59.9%	82.7%	59.9%	82.7%
Risk-free interest rate	1.6%	4.8%	1.6%	4.8%
Expected life (years)	0.8	1.3	0.8	1.3
Weighted-average fair value of employee stock purchases during the periods	\$ 0.39	\$ 0.61	\$ 0.39	\$ 0.61

Stock Option Activity

Following is a summary of the status of the Company's stock option plans at September 30, 2008 and changes during the nine months then ended:

	Number of shares	Weighted- average exercise price	Weighted- average remaining contractual life in years	Aggregate intrinsic value
Options outstanding at December 31, 2007	3,493,154	\$ 5.37	8.34	\$ 167,000
Options granted	898,000	0.80		
Options exercised	(3,750)	1.15		
Options cancelled	(124,961)	11.02		
Options outstanding at September 30, 2008	4,262,443	4.25	7.93	
Options exercisable at September 30, 2008	2,178,921	\$ 7.06	6.87	

4. Net Loss Per Share

The Company computes basic net loss per share using the weighted-average number of shares of common stock outstanding less the weighted-average number of shares subject to repurchase. The effects of including the incremental shares associated with options, warrants and unvested restricted stock were antidilutive, and therefore were not included in diluted weighted average common shares outstanding for the three or nine month periods ended

Edgar Filing: ARADIGM CORP - Form 10-Q

September 30, 2008 and 2007.

The following securities were excluded from the calculation of diluted loss per share for the three and nine months ended September 30, 2008 and 2007, respectively, as their effect would be anti-dilutive (in thousands):

	September 30,	
	2008	2007
Outstanding stock options	4,262	2,849
Unvested restricted stock	754	50
Warrants to purchase common stock	417	836
Performance bonus stock award		100

p 9 of 42

Table of Contents**5. Comprehensive Loss**

Comprehensive loss includes net loss and other comprehensive income (loss). Other comprehensive income (loss) includes certain changes in shareholders' equity that are excluded from net loss. Comprehensive loss and its components were as follows (in thousands):

	Three Months Ended		Nine months Ended	
	September 30,		September 30,	
	2008	2007	2008	2007
Net loss	\$ (4,596)	\$ (6,902)	\$ (17,286)	\$ (16,990)
Other comprehensive loss:				
Change in unrealized gain (loss) on available-for-sale securities	(1)	(8)	(10)	(12)
Comprehensive loss	\$ (4,597)	\$ (6,910)	\$ (17,296)	\$ (17,002)

6. Cash, Cash Equivalents and Short-Term Investments

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

	September	December
	30,	31,
	2008	2007
Cash and cash equivalents:		
Cash and money market funds	\$ 2,013	\$ 1,345
Commercial paper	13,522	28,619
U.S. government agency notes	5,784	
	\$ 21,319	\$ 29,964
Short-term investments:		
Corporate and U.S. government agency notes	\$	\$ 10,546

The Company considers all highly liquid investments with a maturity of three months or less at the purchase date to be cash equivalents. The Company places its cash, cash equivalents and short term investments in money market funds, commercial paper and corporate and government notes.

Effective January 1, 2008, the Company adopted SFAS No. 157, *Fair Value Measurements* (SFAS 157). SFAS 157 applies to all fair value measurements not otherwise specified in an existing standard, clarifies how to measure fair value and expands fair value disclosures. SFAS No. 157 does not significantly change the Company's previous practice with regard to asset valuation. All of the Company's fair market value measurements utilize quoted prices in active markets for its short-term investments, and as such, are valued at Level 1 of the fair value hierarchy defined in SFAS 157.

7. Related Parties*CyDex*

On August 31, 2007, the Company and CyDex Pharmaceuticals, 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 combinations of 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, was the Chief Executive Officer and a member of the board of directors of CyDex until October 2008.

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 parties. Costs of each collaboration project will be borne 60% by the Company 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. The Company has not recognized any revenue under the agreement since inception. The Company incurred expenses under the agreement of \$25,000 during the third quarter of 2008, \$120,000 during the first nine months of 2008 and none in the first nine months of 2007.

p 10 of 42

Table of Contents*Novo Nordisk*

In May 2008, the Second Amended and Restated License Agreement between Novo Nordisk and Aradigm (the July 3, 2006 License Agreement) was terminated, ending a business collaboration between the two companies to develop a pulmonary delivery system for administering insulin by inhalation using the AERx insulin Diabetes Management System (iDMS). There are various consequences for the Company as a result of the termination by Novo Nordisk of the July 3, 2006 License Agreement, including the following:

All rights to the inhaled insulin program. Novo Nordisk must enable the Company to continue to pursue commercialization of inhaled insulin. In order to do this, Novo Nordisk must:

Supply the Company with insulin for use in continuing development of inhaled insulin.

Identify in writing the patent claims that describe the insulin formulation used by Novo Nordisk in its development of inhaled insulin so that the Company can make such formulation (and permitted alternatives).

Provide the Company full access to the data generated in the development of inhaled insulin, including data from all the clinical trials, as well as relevant sections of applicable regulating filings.

Transfer of technology. Novo Nordisk transferred the AERx iDMS technology documentation to the Company. The technology transfer also included certain AERx iDMS-related development and production equipment at its fair market value.

Intellectual Property transfer. In September 2008, Novo Nordisk transferred to the Company, at no charge, a portfolio of U.S. and foreign patents related to inhaled insulin. The Company assumes responsibility for the maintenance of this portfolio.

Prior to the Company's follow-on public offering completed on January 30, 2007, Novo Nordisk and its affiliate, Novo Nordisk Pharmaceuticals, Inc., were considered related parties. At December 31, 2006, Novo Nordisk beneficially owned 1,573,674 shares of the Company's common stock, representing 10.6% of the Company's total outstanding common stock (9.8% on an as-converted basis). As a result of the Company's public offering on January 30, 2007, Novo Nordisk's ownership was reduced to approximately 3.0% of the Company's stock on an as-converted basis, and as of September 30, 2008 and December 31, 2007, Novo Nordisk owned less than 1% of the Company's common stock.

Pursuant to the July 3, 2006 License Agreement, Novo Nordisk loaned the Company a principal amount of \$7.5 million under a Promissory Note and Security Agreement (Promissory Note). The Promissory Note bears interest accruing at 5% per annum and the principal, along with the accrued interest, is payable in three equal payments of \$3.5 million at July 2, 2012, July 1, 2013 and June 30, 2014. The balance outstanding under the Promissory Note, including accrued interest, was \$8.4 million and \$8.1 million as of September 30, 2008 and December 31, 2007, respectively. The Promissory Note does contain a number of covenants that include restrictions in the event of changes to corporate structure, change in control and certain asset transactions. The Promissory Note was also secured by a pledge of the net royalty stream payable to the Company by Novo Nordisk pursuant to the July 3, 2006 License Agreement. The termination of the July 3, 2006 License Agreement does not accelerate any of the payment provisions under the Promissory Note.

8. Revenue and Deferred Revenue

Payments from and amounts billed to collaborators, revenue recognized and deferred revenue were as follows (thousands):

	Three Months Ended September 30, 2008	Nine Months Ended September 30, 2008
Deferred revenue beginning balance	\$ 1,168	\$ 880

Edgar Filing: ARADIGM CORP - Form 10-Q

Amounts billed or received for collaborator funded programs	174	516
Revenues recognized for collaborator funded programs	(197)	(251)
Deferred revenue September 30, 2008	1,145	1,145
Less: non-current portion of deferred revenue		
Current portion of deferred revenue	\$ 1,145	\$ 1,145

p 11 of 42

Table of Contents

The Company receives payments from collaborator-funded programs that are generally early-stage feasibility programs. These programs may not necessarily develop into long-term development agreements with the collaborators.

9. Property Tax Assessment

In March 2008, the Company received assessments of \$508,000 from the Alameda County Tax Collector for personal property taxes for the period July 2004 through June 2007, for which the Company recorded an expense of \$194,000 in the second quarter of 2008. Of the \$508,000 total assessment, \$194,000 relates to property owned and used by the Company during the assessment periods, and \$314,000 relates to property the Company sold to Novo Nordisk as part of a January 26, 2005 restructuring agreement (the January 26, 2005 Agreement) and owned by Novo Nordisk during the tax assessment period. Under the terms of the January 26, 2005 Agreement, Novo Nordisk is responsible for tax assessments on property it owned during the assessment period, and therefore the Company believes the likelihood that the Company will ultimately bear the cost of the related \$314,000 assessment is remote. Accordingly, no accrual was recorded for this portion of the assessment. Management has filed an appeal with the Alameda County Tax Collector to dispute portions of the total assessment, and believes there is at least a reasonable possibility that the Company's \$194,000 liability ultimately will be reduced upon resolution of the appeal. However, at this time management cannot estimate the ultimate outcome of the appeal. Accordingly, management's current best estimate of the Company's ultimate liability for the property tax assessment is \$194,000.

10. Sublease Agreement and Lease Exit Liability

On July 18, 2007, the Company entered into a sublease agreement with Mendel Biotechnology, Inc. (Mendel) to lease approximately 48,000 square feet of the Company's 72,000 square foot facility in Hayward, CA. During the year ended December 31, 2007, the Company recorded a \$2.1 million lease exit liability and related expense for the expected loss on the sublease, in accordance with SFAS 146, because the monthly payments the Company expects to receive under the sublease are less than the amounts that the Company will owe the lessor for the subleased 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, which consisted of the minimum lease payments to the lessor for the sublease space and payments the Company 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 lease exit activities in the accompanying condensed statements of operations. The lease exit liability activity from inception in July 2007 through September 30, 2008 is as follows (in thousands):

Loss on sublease to Mendel in July 2007	\$ 2,063
Accretion of imputed interest expense	39
Lease payments	(353)
Balance at December 31, 2007	1,749
Accretion of imputed interest expense	22
Lease payments	(117)
Balance at March 31, 2008	1,654
Accretion of imputed interest expense	20
Lease payments	(109)
Balance at June 30, 2008	1,565
Accretion of imputed interest expense	20
Lease payments	(117)
Balance at September 30, 2008	\$ 1,468

11. 2006 Restructuring

During 2006, the Company announced the implementation of a strategic restructuring of its business operations to focus resources on advancing the current product pipeline and developing products focused on respiratory disease, leveraging the Company's core expertise and intellectual property. The Company accounted for the restructuring activity in accordance with SFAS 146. The restructuring included a reduction in force, the majority of which were research personnel. The Company recorded the final remaining charge of \$98,000 from the 2006 restructuring during the second quarter of 2007. The Company also paid the severance-related expenses in full by the end of 2007. These charges are included in the restructuring and lease exit activities expense line item in the accompanying condensed statements of operations.

p 12 of 42

Table of Contents**12. Tekmira License Agreement**

In February 2008, the Company signed an amendment to its license agreement from December 2004 with Tekmira Pharmaceuticals Corporation (Tekmira), formerly known as Inex Pharmaceuticals Corporation. Under the amended agreement, Tekmira granted the Company a license to certain technology relating to the delivery of liposomal ciprofloxacin. The Company paid Tekmira \$250,000 upon execution of the amendment. Should the Company utilize the technology licensed from Tekmira, the Company may be required to make milestone payments of up to \$4.75 million in the aggregate for each disease indication, up to a maximum of two indications, pursued by the Company for liposomal ciprofloxacin. Should the Company commercialize products incorporating the licensed technology, Tekmira will have the right to royalty payments.

13. Feasibility Study

In March 2008, the Company entered into an agreement with a third party to conduct a feasibility study. The purpose of the study was to evaluate in the laboratory the delivery of certain compounds using the AERx system. The Company was to be fully reimbursed for costs it incurred under the agreement. The agreement had an initial one year term with potential successive one year renewals. In September 2008, the third party notified the Company that the study was terminating. The Company billed and recorded as deferred revenue \$148,000 and \$248,000 in the third quarter and first nine months of 2008, respectively, related to the agreement. The Company recognized revenue of \$193,000 and \$248,000 in the third quarter and first nine months of 2008, respectively, under the agreement.

14. Manufacturing and Supply Agreement

On August 8, 2007, the Company entered into a Manufacturing and Supply Agreement (the Enzon Agreement) with Enzon Pharmaceuticals, Inc. (Enzon) related to its ARD-3100 and ARD-3150 programs, inhaled formulations of liposomal ciprofloxacin for the treatment and control of respiratory infections common to patients with cystic fibrosis and bronchiectasis. Under the Enzon Agreement, Enzon will manufacture and supply the Company with ciprofloxacin formulations and other products that may be identified by management. For manufacturing the initial products, the Company will pay Enzon costs and fees totaling \$3.3 million 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 extends for a period of five years unless terminated earlier by either party. The Company incurred research and development expenses under the Enzon Agreement of \$108,000 and \$36,000 for the third quarter of 2008 and 2007, respectively, and \$1.3 million and \$36,000 for the first nine months of 2008 and 2007, respectively.

15. Shareholders Equity

On January 30, 2007, the Company received \$33.9 million from the closing of its 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 were converted to 1,235,699 shares of common stock, and no liquidation preference or other preferential rights remained.

On December 21, 2007, the Company filed a shelf registration statement on Form S-3 (No. 333-148263) covering the sale of \$60 million of common stock. The registration statement became effective on January 25, 2008.

On April 1, 2008, the Company issued 147,384 shares of common stock pursuant to the ESPP at an average price of \$0.94 per share.

On May 15, 2008, the shareholders approved an amendment to Aradigm s Amended and Restated Articles of Incorporation to increase the authorized number of shares of common stock from 100,000,000 to 150,000,000 shares. The shareholders also approved an amendment to the 2005 Equity Incentive Plan to increase the aggregate number of shares of common stock authorized for issuance under such plan by 2,700,000 shares, and an amendment to the ESPP to increase the aggregate number of shares of common stock authorized for issuance under such plan by 1,000,000 shares. As of September 30, 2008, the Company had 3,761,386 shares of common stock available for future issuance under the 2005 Equity Incentive Plan.

Table of Contents

In September 2008 the Company adopted an amended and restated shareholder rights plan, which replaced the rights plan originally adopted in August 1998. Pursuant to the rights plan, as amended and restated, the Company distributed rights to purchase shares of Series A Junior Participating Preferred Stock as a dividend at the rate of one right for each share of common stock outstanding. The rights are designed to guard against partial tender offers and other abusive and coercive tactics that might be used in an attempt to gain control of the Company or to deprive the Company's shareholders of their interest in the Company's long-term value. The shareholder rights plan seeks to achieve these goals by encouraging a potential acquirer to negotiate with the Company's board of directors. The rights will expire at the close of business on September 8, 2018.

16. Subsequent Event

On October 31, 2008 Zogenix, Inc. (Zogenix), a private company to which the Company sold its assets related to the Intraject (now rebranded under the name DosePro™) needle-free delivery system, received a Complete Response Letter from the Food and Drug Administration (FDA) on its New Drug Application submitted in December 2007 for the migraine drug sumatriptan. Zogenix believes that it has timely and clear direction from the FDA to address the issue raised in the Complete Response Letter. The Company 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 DosePro technology.

In November 2008, the Company received \$2.75 million from Lung Rx, Inc. (Lung Rx), which included the first milestone payment of \$2.0 million and \$750,000 for development costs.

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 obtain additional financing, our ability to implement our product development strategy, 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. Further, even if our product candidates appear promising at various stages of development, our share price may decrease such that we are unable to raise additional capital without dilution that may be unacceptable to our shareholders. Investors are cautioned not to place undue reliance on the forward-looking statements contained herein. We undertake no obligation to update these forward-looking statements in light of events or circumstances occurring after the date hereof or to reflect the occurrence of unanticipated events.

Overview

We are an emerging specialty pharmaceutical company focused on the development and commercialization of drugs delivered by inhalation for the treatment of severe respiratory diseases by pulmonologists. Over the last decade, we 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 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 in the near term. As of September 30, 2008, we had an accumulated deficit of \$329.4 million. Historically, we have funded our operations primarily through public offerings and private placements 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, borrowings from Novo Nordisk, sale of Intraject related assets 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 15 of the notes to the condensed financial statements).

p 14 of 42

Table of Contents

Recently our business has focused on opportunities for product development for treatment of severe respiratory disease that we could develop and commercialize in the United States without a partner. In selecting our proprietary development programs, we primarily seek drugs approved by the United States Food and Drug Administration (FDA) that can be reformulated for both existing and new indications in respiratory disease. Our intent is to use our pulmonary delivery methods and formulations to improve their safety, efficacy and convenience of administration to patients. We believe that this strategy will allow us to reduce cost, development time and risk of failure, when compared to the discovery and development of new chemical entities. We intend to commercialize our respiratory product candidates with our own focused sales and marketing force addressing pulmonary specialty doctors in the United States, where we believe that a proprietary sales force will enhance the return to our shareholders. Where our products can benefit a broader population of patients in the United States or in other countries, we may enter into co-development, co-promotion or other marketing arrangements with collaborators, thereby reducing costs and increasing revenues through license fees, milestone payments and royalties. Our lead development candidate in Phase 2 clinical trials is a proprietary liposomal formulation of the antibiotic ciprofloxacin that is delivered by inhalation for the treatment of infections associated with the severe respiratory diseases cystic fibrosis and bronchiectasis. The same formulation could also be potentially used also for the prevention and treatment of inhaled anthrax.

Historically, our development activities consisted primarily of collaborations and product development agreements with third parties. The most notable collaboration was with Novo Nordisk on the AERx iDMS for the treatment of Type I and Type II diabetes. This program began in 1998 and included nine Phase 3 clinical trials in Type I and Type II diabetes patients. On April 30, 2008, Novo Nordisk announced that following recent reports of lung cancer in Type II diabetes patients treated with Exubera*, an inhaled insulin product from Pfizer, the likelihood of achieving a positive benefit/risk ratio for future pulmonary diabetes projects had become more uncertain, and as a result, Novo Nordisk had decided to stop all research and development activities in the field. In May 2008, the July 3, 2006 License Agreement between us and Novo Nordisk was terminated. Pursuant to the License Agreement, on September 25, 2008, Novo Nordisk assigned, at no charge to us; the inhaled insulin-related patents, which Novo purchased from us in July 2006, as well as certain related patents that originate from Novo Nordisk. The portfolio includes both U.S. and foreign patents. We assume the responsibility for the maintenance of this portfolio.

Our current collaborations include a collaboration with Lung Rx, Inc. (Lung Rx), a wholly owned subsidiary of United Therapeutics Corporation (United Therapeutics), for the development of inhalation treatments for pulmonary arterial hypertension, and a collaboration with CyDex Pharmaceuticals, Inc. (CyDex) for inhalation treatments of asthma and chronic obstructive pulmonary disease. We have a proprietary program for smoking cessation treatment for which we are currently seeking a partner.

In August 2006, we sold all of our assets related to the Intraject needle-free injector technology platform and products, including 12 United States patents along with foreign counterparts, to Zogenix, Inc., a private company. Zogenix is responsible for further development and commercialization efforts of Intraject (now rebranded under the name DosePro™). We received a \$4 million initial payment from Zogenix, and we 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 DosePro technology. In December 2007, Zogenix submitted a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for the migraine drug sumatriptan using the needle-free injector DosePro (Sumavel™ DosePro). The NDA was accepted for filing by the FDA in March 2008. Zogenix has publicly stated that if Sumavel DosePro is approved by the FDA, Zogenix intends to launch the product in the first quarter of 2009 in the U.S. On October 31, 2008 Zogenix received a Complete Response Letter from the FDA on its NDA. Zogenix believes that it has timely and clear direction from the FDA to address the issue raised in the Complete Response Letter. In March 2008, Zogenix entered into a license agreement to grant exclusive rights in the European Union to Desitin Pharmaceuticals, GmbH to develop and commercialize Sumavel DosePro in the European Union.

Product Candidates

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

Table of Contents

Product Candidate	Indication	Stage of Development
Proprietary Programs Under Development		
ARD-3100 (Liposomal ciprofloxacin)	Cystic Fibrosis	Phase 2
ARD-3150 (Liposomal ciprofloxacin)	Bronchiectasis	Phase 2
ARD-1100 (Liposomal ciprofloxacin)	Inhalation Anthrax	Preclinical
ARD-1600 (Nicotine)	Tobacco Smoking Cessation	Phase 1 Completed
Collaborative Programs Under Development		
ARD-1550 (Inhaled treprostinil) (1)	Pulmonary Arterial Hypertension	Bridging study
ARD-1500 (Inhaled liposomal treprostinil)	Pulmonary Arterial Hypertension	Preclinical
ARD-1700 (combination products) (2)	Asthma, COPD	Preclinical

(1) A bridging clinical study began in April 2008 to compare delivery with the AERx Essence® system against the nebulizer used in the completed Phase 3 TRIUMPH (TReprostinil Sodium Inhalation Used in the Management of Pulmonary Arterial Hypertension) study with our partner Lung Rx.

(2) The Asthma and COPD program is being conducted pursuant to the Collaboration Agreement with CyDex.

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. We periodically conduct feasibility studies with other parties in an effort to identify formulations and combinations that may be suitable candidates for additional development.

Proprietary Programs Under Development:

Liposomal Ciprofloxacin

This product candidate is currently in Phase 2 programs for respiratory infections associated with cystic fibrosis and bronchiectasis. Ciprofloxacin is an FDA-approved 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 three target indications that share much of the laboratory and production development efforts, as well as a common safety data base.

ARD-3100 and ARD 3150-Liposomal Ciprofloxacin for the Treatment of Infections in Cystic Fibrosis and Non-CF Bronchiectasis Patients

We have two proprietary liposomal ciprofloxacin programs for the treatment and control of respiratory infections associated with chronic diseases – one common to patients with cystic fibrosis, or CF, and the other for infections associated with non-cystic fibrosis bronchiectasis.

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.

p 16 of 42

Table of Contents

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, which is administered twice a day. 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. In particular, an important consideration in the development of new treatments for this disease is the reduction of the burden of therapy for patients, their relatives and healthcare providers. Our goal is to develop a convenient, once-a-day inhalation product in order to reduce the amount of time and effort associated with administration of the therapy. Our liposomal ciprofloxacin CF program represents the first program in which we would like to retain full ownership and development rights for the United States. We believe we have the preclinical development, clinical and regulatory expertise to advance this product through development in the most efficient manner.

We are also developing inhaled liposomal ciprofloxacin for pulmonary infections associated with non-CF bronchiectasis – a chronic pulmonary disease with symptoms similar to cystic fibrosis affecting over 100,000 patients in the United States. This is an orphan drug disease with an unmet medical need; there is currently no approved drug treatment in the United States for this indication.

Development

We 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. 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 provides the opportunity to obtain market exclusivity for seven years from the date of New Drug Application (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. In October 2007, we completed a Phase 1 clinical trial in 20 healthy volunteers in Australia. This was a safety, tolerability and pharmacokinetic study that included single dose escalation followed by dosing for one week. Administration of the liposomal formulation by inhalation was well tolerated and no serious adverse reactions were reported. The pharmacokinetic profile obtained by measurement of blood levels of ciprofloxacin following the inhalation of the liposomal formulation was consistent with the profile from sustained release of ciprofloxacin; the blood levels of ciprofloxacin were much lower than those that would be observed following administration of therapeutic doses of ciprofloxacin by injection or via the gastrointestinal tract. We believe that this is a desirable pharmacokinetic profile likely to result in reduction of the incidence and severity of systemic side effects of ciprofloxacin and to be less likely to lead to evolution of resistant microorganisms.

In June 2008, we completed a multi-center 14-day treatment Phase 2a trial in Australia and New Zealand in 21 CF patients to investigate safety, efficacy and pharmacokinetics, with the primary efficacy endpoint being the reduction in the density of the pathogenic microorganism *Pseudomonas aeruginosa*. The primary efficacy endpoint in this Phase 2a study was the change from baseline in the sputum *Pseudomonas aeruginosa* colony forming units (CFU), an objective measure of the reduction in pulmonary bacterial load. Data analysis in 21 patients who completed the study demonstrated that the *Pseudomonas* CFU decreased by a mean 1.43 log over the 14-day treatment period ($p < 0.0001$). Evaluation one week after study treatment was discontinued showed that the *Pseudomonas* bacterial density in the lung was still reduced from the baseline without additional antibiotic use. Pulmonary function testing as measured by the forced expiratory volume in one second (FEV1) showed a significant mean increase of 6.86% from baseline after 14 days of treatment ($p = 0.04$). The study drug was well tolerated, and there were no serious adverse events reported during the trial.

Following the trial we intend to finalize development plans and budgets for this program in conjunction with discussions with the FDA. In order to expedite anticipated time to market and increase patient acceptance, we elected

to deliver our initial formulation of 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 as well, as it could provide additional convenience for the patient in the form of a small portable device with a faster administration time than a nebulizer.

p 17 of 42

Table of Contents

In June 2008, we initiated a multicenter Phase 2 clinical trial of our inhaled liposomal ciprofloxacin in adult patients with non-CF bronchiectasis. As of October 2008 and following an antibiotic washout period, all of the intended 36 patients were enrolled to receive daily inhaled liposomal ciprofloxacin for a period of 28 consecutive days. We intend to release data from this trial no later than the first quarter of 2009. The primary efficacy endpoint will be treatment of respiratory infection measured as the change in the density of *Pseudomonas aeruginosa* bacterial colony forming units (CFU) in the sputum over the treatment period. Secondary endpoints will include pulmonary function measurements and respiratory symptoms. The study is being conducted in leading bronchiectasis centers in the United Kingdom.

ARD-1100 Liposomal Ciprofloxacin for the Treatment of Inhalation Anthrax

The third 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 bioterror agent represents a real and current threat.

Ciprofloxacin is approved by the FDA for use orally and via injection for the treatment of inhalation anthrax (post-exposure) since 2000. Our ARD-1100 research and development program was funded by Defence Research and Development Canada, or DRDC, a division of the Canadian Department of National Defence. We believe that our 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 the DRDC as part of their interest in developing products to counter bioterrorism. The 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 still 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 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. We anticipate developing this drug for approval under FDA regulations relating to the approval of new drugs or biologics for potentially fatal diseases where human efficacy studies cannot be conducted ethically or practically. 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. Our intention is to continue the development of this potential product for the treatment and prevention of anthrax only if we can obtain future funding for it from a partner, or secure a government contract for it.

Smoking Cessation Therapy**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 smoke 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. Quitting tobacco use is

difficult and often requires multiple attempts, as users frequently 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 cigarette smoking and from the nicotine addiction.

p 18 of 42

Table of Contents*Development*

The initial laboratory work on this program was partly funded under grants from the National Institutes of Health. In October 2007, we 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 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 are currently exploring collaborations with government and non-government organizations to further develop this product.

Collaborative Programs Under Development:**ARD-1550 and 1500 Treprostinil for the Treatment of Pulmonary Arterial Hypertension**

The ARD-1550 program is a collaboration with Lung Rx and is investigating an inhaled aqueous formulation of a prostacyclin analogue for administration using our AERx delivery system for the treatment of pulmonary arterial hypertension, or PAH. In April 2008, we initiated a bridging clinical trial in conjunction with our agreement with Lung Rx to evaluate lung distribution, pharmacokinetics and safety of inhaled treprostinil delivered by the AERx Essence system versus delivery with the Nebu-Tec OPTINEB(1)-ir nebulizer. Lung Rx used the latter device in its Phase 3 TRIUMPH study of inhaled treprostinil in patients with PAH. 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 Datamonitor, in 2005 the more than 146,000 people worldwide affected by PAH purchased over \$800 million of PAH-related medical treatments, and sales are expected to reach \$2.0 billion per year by 2015.

In November 2008, we announced data from the clinical trial, which showed that the AERx Essence delivery system efficiently delivered aerosolized treprostinil deeper into the lung than delivery by the OPTINEB nebulizer. Inhaled treprostinil was well tolerated from both delivery systems, and no serious adverse events were reported in the study. The AERx Essence delivery system is expected to deliver medication to the patient in 2 to 4 breaths, significantly reducing the burden of therapy for PAH patients.

Prostacyclin analogues are an important class of drugs used for the treatment of pulmonary arterial 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. Remodulin accounted for approximately \$200 million of United Therapeutics' revenue in 2007. We believe that the ARD-1550 product candidate could offer a non-invasive, more direct and patient-friendly approach compared to 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 ten minutes. We believe administration of treprostinil by inhalation using our convenient palm-sized 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 (ARD-1500) may lead to a reduction in the number of daily administrations that are needed to be effective when compared to existing inhaled therapies.

Development

We conducted two collaborative research projects on inhaled treprostinil using Aradigm's AERx delivery system. The first project was with an aqueous formulation of treprostinil. The second project involved development of a slow-acting liposomal formulation of treprostinil (ARD-1500), with the view to achieve once-a-day dosing. On August 30, 2007, we signed an Exclusive License, Development and Commercialization Agreement with Lung Rx

pursuant to which we granted Lung Rx a license, which becomes exclusive upon the payment of specified sums, to develop and commercialize inhaled treprostinil using our AERx Essence technology for the treatment of PAH and other potential therapeutic indications. As a part of this collaboration, we began a bridging study for this product, ARD-1550, in April 2008 to compare an aqueous solution of treprostinil delivered by inhalation using the AERx Essence system to the nebulizer used in the United Therapeutics Phase 3 trial and announced results in November 2008.

We are now in discussions with Lung Rx regarding the next steps required on the clinical, manufacturing and regulatory paths toward the approval and launch of this product. Lung Rx will be responsible for funding the remainder of the development of treprostinil in the AERx delivery system through registration and commercial launch.

p 19 of 42

Table of Contents**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 have 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 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. As a result, in September 2008, our agreement with APT was terminated. No serious adverse effects were noted or associated with the aerosolized HCQ or with the AERx system.

ARD-1700 (combination products) and Other Potential Applications

To date, we have demonstrated in human clinical trials 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 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:

Combination Products for Asthma, Cystic Fibrosis and other Chronic Obstructive Pulmonary Disease (COPD).

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 society. According to the American Lung Association, asthma accounted for \$14.7 billion in direct healthcare costs each year in the United States, of which the largest single expenditure, at \$6.2 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, in 2005 asthma affected 41.5 million people in developed countries, 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. In August 2007, we and CyDex began 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. The initial focus of the collaboration is on formulation development and market research.

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 postsurgical patients.

Other Programs. We are currently examining our other previously conducted preclinical and clinical programs to identify molecules that may be suitable for further development consistent with our current business strategy to focus on the U.S. severe respiratory disease market and sell or license our non-strategic assets.

Critical Accounting Policies and Estimates

We consider certain accounting policies related to revenue recognition, stock-based compensation, impairment of long-lived assets, exit/disposal activities and income taxes 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 United States 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 condensed financial statements. These estimates include useful lives for property and equipment and related depreciation calculations,

p 20 of 42

Table of Contents

estimated amortization periods for payments received from product development and license agreements as they relate to the revenue recognition and assumptions for valuing options, warrants and incomes taxes. Our actual results could differ from these estimates.

Revenue Recognition

Contract revenues consist of revenues from grants, collaboration agreements and feasibility studies. We recognize revenue under the provisions of the Securities and Exchange Commission issued Staff Accounting Bulletin No. 104, *Revenue Recognition* (SAB 104) and Emerging Issues Task Force (EITF) Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables* (EITF 00-21). Revenue for arrangements not having multiple deliverables, as outlined in EITF 00-21, is recognized once costs are incurred and collectability 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, we recognize revenue upon acceptance of the work and confirmation of the amount to be paid by the collaborator. Deferred revenue represents the portion of all refundable and nonrefundable research payments received that have 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 recognized as revenue either upon 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 agreement 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. We defer refundable development and license fee payments until specific performance criteria are achieved. Refundable development and license fee payments are generally not refundable once specific performance criteria are achieved and accepted. Collaborative license and development agreements that require us to provide multiple deliverables, such as a license, research and product steering committee services and other performance obligations, are accounted for in accordance with EITF 00-21. Under EITF 00-21, delivered items are evaluated to determine whether such items have value to our collaborators on a stand-alone basis and whether objective reliable evidence of fair value of the undelivered items exists. Deliverables that meet these criteria are considered a separate unit of accounting. Deliverables that do not meet these criteria are combined and accounted for as a single unit of accounting. The appropriate revenue recognition criteria are identified and applied to each separate unit of accounting.

Accounting for Costs Associated with Exit or Disposal Activities

In accordance with 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 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 are measured using the credit-adjusted risk-free rate that was used to measure the liability initially.

Research and Development

Research and development expenses consist of costs incurred for company-sponsored, collaborative and contracted research and development activities. These costs include direct and research-related overhead expenses. Research and development expenses under collaborative and government grants approximate the revenue recognized under such agreements. We expense research and development costs as such costs are incurred.

Income Taxes

We make certain estimates and judgments in determining income tax expense for financial statement purposes. These estimates and judgments occur in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenue and expense for tax and financial statement purposes. As part of the process of preparing our financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves us estimating our current tax exposure under the most recent tax laws and assessing temporary differences resulting from differing treatment of items for tax and accounting purposes.

We assess the likelihood that we will be able to recover our deferred tax assets. We consider all available evidence, both positive and negative, including our historical levels of income and losses, expectations and risks associated with

estimates of future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. If we do not consider

p 21 of 42

Table of Contents

it more likely than not that we will recover our deferred tax assets, we will record a valuation allowance against the deferred tax assets that we estimate will not ultimately be recoverable. At September 30, 2008 and December 31, 2007, we believed that the amount of our deferred income taxes would not be ultimately recovered. Accordingly, we recorded a full valuation allowance for deferred tax assets. However, should there be a change in our ability to recover our deferred tax assets, we would recognize a benefit to our tax provision in the period in which we determine that it is more likely than not that we will recover our deferred tax assets.

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.

Results of Operations*Revenue*

	Three Months Ended		Nine months Ended		Increase (Decrease)			
	September 30, 2008	2007	September 30, 2008	2007	Three Months		Nine months	
	(\$ s in thousands)				(\$ s in thousands)			
Revenues from related parties	\$	\$	\$	\$ 23	\$	%	\$ (23)	(100)%
Revenues from unrelated parties	197	230	251	920	(33)	(14)%	(669)	(73)%
Total revenues	\$ 197	\$ 230	\$ 251	\$ 943	\$ (33)	(14)%	\$ (692)	(73)%

We recorded no related party revenue in 2008, and recorded related party revenue from Novo Nordisk of \$23,000 for the first nine months of 2007. The reason for the decrease in 2008 was the conclusion of the restructuring agreement with Novo Nordisk. We recorded revenues from unrelated parties of \$197,000 and \$251,000 for the third quarter and first nine months of 2008, respectively, primarily related to a feasibility study evaluating the delivery of certain compounds using the AERx system. We recorded collaborative revenues for the third quarter of 2007 of \$192,000 for our final payment from APT related to ARD-1300, and \$38,000 from our transition agreement with Zogenix. We recorded collaborative revenues for the first nine months of 2007 of \$566,000 related to ARD-1100, \$192,000 for our final payment from APT related to ARD-1300, \$141,000 from our transition agreement with Zogenix and \$21,000 from Respiroics. The primary reason for the decrease in unrelated party revenue in 2008 compared to 2007 was our focus towards advancing our own product candidates.

Research and Development Expenses

	Three Months Ended		Nine months Ended		Increase (Decrease)			
	September 30, 2008	2007	September 30, 2008	2007	Three Months		Nine months	
	(\$ s in thousands)				(\$ s in thousands)			
Collaborative	\$ 430	\$ (46)	\$ 1,777	\$ 759	\$ 476	1,035%	\$ 1,018	134%
Self-initiated	2,769	3,945	11,115	10,388	(1,176)	(30)%	727	7%

Total research and development expenses	\$ 3,199	\$ 3,899	\$ 12,892	\$ 11,147	\$ (700)	(18)%	\$ 1,745	16%
---	----------	----------	-----------	-----------	----------	-------	----------	-----

Research and development expenses represent proprietary research expenses and costs related to contract research revenue, including 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. The increase in collaborative program expenses in the third quarter and first nine months of 2008 compared to the same periods in 2007 was primarily due to activities related to the ARD-1550 bridging study and the AERx technology feasibility study with another third party. Research and development expense for self-initiated projects decreased in the third quarter of 2008 from the third quarter of 2007, primarily due to lower spending for ARD-3100 and ARD-1600. On a year-to-date basis, research and development expense for self-initiated projects increased in 2008 over the comparable period in 2007 as a result of the focus on advancing our current product candidates, including

p 22 of 42

Table of Contents

primarily ARD-3100, and the AERx technology contract manufacturing capabilities. The decrease in total research and development costs for the third quarter of 2008 from the third quarter of 2007 was primarily due to lower spending for clinical supply manufacturing and testing. For the year-to-date period, total research and development costs increased in 2008 over 2007, primarily attributable to higher clinical supply manufacturing and clinical trial costs. Stock-based compensation expense included in research and development was \$66,000 and \$183,000 for the third quarter of 2008 and 2007, respectively and \$427,000 and \$438,000 for the first nine months of 2008 and 2007, respectively. We expect that our research and development expenses will decrease over the next few quarters in order to balance the desirability of continuing the development of our product candidates against the need to contain our expenditures.

General and Administrative Expenses

	Three Months Ended		Nine months Ended		Increase (Decrease)			
	September 30,	September 30	September 30	September 30	Three Months		Nine months	
	2008	2007	2008	2007	(\$ s in thousands)			
General and administrative expenses	\$1,615	\$1,757	\$4,989	\$6,372	\$(142)	(8)%	\$(1,383)	(22)%

General and administrative expenses are comprised of salaries, legal fees including patent related costs, insurance, marketing research, contractor and consultant fees, stock-based compensation expense and other support costs including facilities, depreciation and travel. General and administrative expenses for the third quarter of 2008 decreased from the comparable period in 2007, primarily due to a reduction in headcount. For the first nine months of 2008, general and administrative expenses decreased from the comparable period in 2007 primarily due to a reduction in headcount, as well as a reduction in building rent stemming from the subleasing of a portion of our office space to Mendel Biotechnology, Inc. (Mendel) in July 2007. Stock-based compensation expense included in general and administrative expenses was \$90,000 and \$225,000 for the third quarter of 2008 and 2007, respectively, and \$211,000 and \$659,000 for the first nine months of 2008 and 2007 respectively. We expect that our general and administrative expenses will remain relatively constant over the next few quarters.

Restructuring and lease exit activities

	Three Months Ended		Nine months Ended		Increase (Decrease)			
	September 30,	September 30	September 30	September 30	Three Months		Nine months	
	2008	2007	2008	2007	(\$ s in thousands)			
Restructuring and lease exit activities expense	\$19	\$2,059	\$61	\$2,157	\$(2,040)	(99)%	\$(2,096)	(97)%

Restructuring and lease exit activities expense in 2008 represented the accretion of interest associated with the exit obligation recorded in 2007 upon the subleasing of office space to Mendel. Restructuring and lease exit activities expense in the third quarter of 2007 represented the recording of the expected loss associated with the subleasing of office space to Mendel, because the sublease payments we receive from Mendel are less than the amounts we owe on the subleased space. For the first nine months of 2007, restructuring and lease exit activities expense consisted of the recording of the Mendel sublease loss and related interest accretion, as well as \$98,000 of severance-related costs relating to our 2006 restructuring efforts.

Interest income, interest expense and other income

Three Months Ended	Nine months Ended
---------------------------	--------------------------

	September 30, 2008	September 30, 2007	September 30, 2008	September 30, 2007	Increase (Decrease)			
					Three Months		Nine months	
	(in thousands)				(\$ s in thousands)			
Interest income	\$ 146	\$ 684	\$ 709	\$2,020	\$(538)	(79)%	\$(1,311)	(65)%
Interest expense	(105)	(101)	(303)	(293)	4	4%	10	3%
Other income (expense), net	(1)		(1)	16	(1)		(17)	(106)%

Interest income for the third quarter and first nine months of 2008 decreased from the comparable periods in 2007 due to lower average invested balances and lower effective interest rates earned. Interest expense primarily reflects interest on the \$7.5 million promissory note issued to Novo Nordisk in July 2006 with an interest rate of 5%. Other income in the first nine months of 2007 primarily reflected gains on the sale of assets.

p 23 of 42

Table of Contents**Liquidity and Capital Resources**

As of September 30, 2008, we had cash, cash equivalents and short-term investments of \$21.3 million, down from \$40.5 million at December 31, 2007. The \$19.2 million decrease primarily resulted from the use of cash and the proceeds from investment maturities to fund operations. Working capital was \$18.1 million at September 30, 2008, down from \$36.6 as of December 31, 2007. The decrease primarily was due to the lower balances of cash, cash equivalents and short-term investments.

Net cash used in operating activities in the first nine months of 2008 was \$16.9 million and primarily resulted from our net loss of \$17.3 million. Net cash provided by investing activities was \$8.1 million in the first nine months of 2008 and represented proceeds from the maturity of investments, net of investment purchases, of \$10.5 million, partly offset by the use of \$2.5 million to purchase property and equipment. Net cash provided by financing activities was \$0.1 million in the first nine months of 2008 and consisted primarily of cash receipts from employee purchases through the Employee Stock Purchase Plan.

Net cash used in operating activities in the first nine months of 2007 was \$12.9 million and primarily resulted from our net loss of \$17.0 million as adjusted for non-cash expenses including restructuring and lease exit cost and stock-based compensation. Net cash used in investing activities in the first nine months of 2007 was \$12.9 million and reflected primarily purchases of investments, net of maturities, of \$12.0 million. Net cash provided by financing activities was \$33.3 million in the first nine months of 2007 and consisted primarily of proceeds from our public offering of common stock in January 2007.

As of September 30, 2008, we had an accumulated deficit of \$329.4 million and total shareholders' equity of \$13.8 million. We believe that our cash and cash equivalents as of September 30, 2008 will be sufficient to enable us to meet our obligations through at least the second quarter of 2009. Our principal activities to date have included research and development, securing operating facilities, expanding commercial production capabilities, recruiting management and technical personnel and obtaining financing. We do not anticipate receiving any revenue from the sale of products in the near term. Our ability to continue our development and commercialization activities is dependent upon the ability of management to obtain additional financing as required. We plan to continue to obtain funds through collaborative arrangements, equity issuances and debt arrangements. If we are unable to complete a debt or equity offering or otherwise obtain sufficient financing when and if needed, we may be required to reduce, defer, or discontinue one or more of our product development programs, or we may not be able to continue as a going concern entity.

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.

Contractual Obligations

Our non-cancelable contractual obligations and future minimum lease payments as of September 30, 2008 were as follows:

	Total	2008(1)	2009-2010	2011-2012	2013 and later
			(In thousands)		
Operating lease obligations	\$ 17,065	\$ 601	\$ 4,532	\$ 4,060	\$ 7,872
Promissory note (2)	10,543			3,514	7,029
Unconditional capital purchase obligations	581	581			
Unconditional purchase obligations	1,737	1,737			
Total contractual commitments	29,926	2,919	4,532	7,574	14,901

Less-sublease payments from Mendel (3)	(3,881)	(223)	(1,828)	(1,830)	
Total contractual commitments, net	\$ 26,045	\$ 2,696	\$ 2,704	\$ 5,744	\$ 14,901

(1) For the three months ending December 31, 2008.

(2) Represents total principal and interest payments due on the Novo Nordisk promissory note through the 2014 maturity date. As of September 30, 2008, the balance outstanding on the note was \$8.4 million. The note contains a number of covenants that include restrictions in the event of changes to corporate structure, change in control and certain asset transactions.

Table of Contents

(3) Included to demonstrate the effect of the sublease with Mendel entered into in July 2007. Mendel has the option to terminate the sublease early on September 1, 2012 for a termination fee of \$225,000. In the event that the sublease is not terminated early in 2012, \$4.0 million in additional payments will be received through August 2016.

Recently Issued Accounting Pronouncements

In February 2008, the Financial Accounting Standards Board (FASB) issued FASB Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157* (FSP FAS 157-2), which defers the effective date of SFAS 157 for all non-financial assets and non-financial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), for fiscal years beginning after November 15, 2008 and interim periods within those fiscal years for items within the scope of FSP FAS 157-2. We do not expect that the adoption of FSP FAS 157-2 will have a material impact on our financial position and results of operations.

In November 2007, the EITF issued EITF Issue No. 07-1, *Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property* (EITF 07-1). Companies may enter into arrangements with other companies to jointly develop, manufacture, distribute, and market a product. Often the activities associated with these arrangements are conducted by the collaborators without the creation of a separate legal entity (that is, the arrangement is operated as a virtual joint venture). The arrangements generally provide that the collaborators will share, based on contractually defined calculations, the profits or losses from the associated activities. Periodically, the collaborators share financial information related to product revenues generated (if any) and costs incurred that may trigger a sharing payment for the combined profits or losses. The consensus requires collaborators in such an arrangement to present the result of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable GAAP or, in the absence of other applicable GAAP, based on analogy to authoritative accounting literature or a reasonable, rational, and consistently applied accounting policy election. EITF 07-1 is effective for collaborative arrangements in place at the beginning of the annual period beginning after December 15, 2008. We do not expect that the adoption of EITF 07-1 will have a material impact on our financial position and results of operations.

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, 2008, we had cash and cash equivalents of \$21.3 million. The fair market value of our fixed rate cash equivalents will decline if market interest rates increase. Because the maturities of our fixed rate cash equivalents are very short, we expect that if such decreases in fair value occur, they will be immaterial and, therefore, we believe our exposure to interest rate changes is immaterial. Declining interest rates over time would reduce our interest income from cash, cash equivalents and short-term investments.

Item 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Based on their evaluation as of the end of the period covered by this report, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) were effective as of the end of the period covered by this report to ensure that information that we are required to disclose in reports that management files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms.

Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives, and our chief executive officer and chief financial officer have concluded that these controls and procedures are effective at the reasonable assurance level. We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control 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.

p 25 of 42

Table of Contents

Changes in Internal Controls over Financial Reporting

There were no changes in our internal controls over financial reporting that occurred during this most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

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, 2007. We have marked with an asterisk () those risk factors that reflect substantive changes from the risk factors included in our Annual Report Form 10-K filed with the Securities and Exchange Commission for the fiscal year ended December 31, 2007.*

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 changed our product development strategy, and if we do not successfully implement this 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 development of delivery technologies to the application of our pulmonary drug delivery technologies and expertise to 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 strategy, and we may not be successful in implementing our strategy. Even if we are able to implement the various aspects of our strategy, it may not be successful.

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

We will 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 operations to date have consumed substantial amounts of cash and have generated no product revenues. We expect negative operating cash flows to continue for at least the foreseeable future. Our future capital requirements will depend on many factors, including:

p 26 of 42

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 cash and cash equivalents at September 30, 2008 will be sufficient to fund operations at least through the end of the second quarter of 2009. 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 or sell certain of our technologies or products that we would not otherwise relinquish or sell. If we are able to obtain funds through the issuance of debt securities or borrowing, the terms may significantly restrict our operations. If we are able to obtain funds through the issuance of equity securities, our shareholders may suffer significant dilution and our stock price may drop.

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, 2008, we have an accumulated deficit of \$329.4 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.

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.

p 27 of 42

Table of Contents

**** Our dependence on collaborators and other contracting parties may delay or terminate certain of our programs, and any such delay or termination would harm our business prospects and stock price.***

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 had control over and responsibility for development and commercialization of the AERx iDMS program. In January 2008, Novo Nordisk announced that it was terminating the AERx iDMS program and gave us a 120-day notice terminating the July 3, 2006 License Agreement between the companies. In May 2008, this termination became effective, ending our collaboration with Novo Nordisk for the AERx iDMS program. Identifying new collaborators for the further development and potential commercialization of the AERx iDMS program may take a significant amount of time and resources and ultimately may not be successful. Lung Rx may also elect to terminate our collaboration agreement. Further, some portion of the money we received from Lung Rx for development costs is pre-payment for future costs. If Lung Rx terminates our agreement we may have to remit to Lung Rx a portion of that pre-payment. If, due to delays or otherwise, we do not receive development funds or achieve milestones set forth in the agreements governing our collaborations, if we cannot timely find replacement collaborators, 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 our stock price would suffer. For example, Zogenix may not receive approval or launch their migraine drug sumatriptan using the DosePro needle-free delivery system, in which case we may not receive a milestone payment and/or receive royalty payments.

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 are 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 costs and postpone the potential receipt of revenues.

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.

p 28 of 42

Table of Contents

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 which 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 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.

p 29 of 42

Table of Contents

**** Because two of our key proprietary programs, the ARD-3100 and ARD-3150 liposomal ciprofloxacin programs, rely 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 and bronchiectasis. 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 or bronchiectasis 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. For example, Bayer HealthCare and Nektar Therapeutics are developing an inhaled powder formulation of ciprofloxacin for the treatment of respiratory infections in cystic fibrosis. 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, our agreement with an affiliate of Novo Nordisk to supply devices and dosage forms to us for use in the development of our products that incorporate our proprietary AERx technology expired on January 27, 2008. 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.

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.

p 30 of 42

Table of Contents

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

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

p 31 of 42

Table of Contents

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. Subsequently, Novo Nordisk and Pfizer settled this litigation out of court. In September 2008, Novo Nordisk informed us that they do not wish to maintain the assigned patents, and they assigned these patents back to us, at no charge to us. These patents may become the subject of future litigation. The patents 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 will no longer be able to rely upon Novo Nordisk to defend or enforce our rights related to the patents. If we are required to defend an action based on these patents or seek to enforce our rights under these patents, we could incur substantial costs and the action could divert management's attention, regardless of the lawsuit's merit or outcome.

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 on 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's 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. 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. If any of our collaboration partners terminate an agreement with us, we may face increased risk and/or costs associated with defense of intellectual property that was associated with the collaboration.

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, patent applications in certain other countries generally are not published until more than 18 months after they are first filed, and 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

p 32 of 42

Table of Contents

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 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.

p 33 of 42

Table of Contents***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 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 control 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 control over financial reporting as of the end of each fiscal year, and to include a management report assessing the effectiveness of our internal control over financial reporting in our annual report on Form 10-K for that fiscal year. Section 404 also currently requires our independent registered public accounting firm, beginning with our fiscal year ending December 31, 2009, to attest to, and report on our internal control 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:

p 34 of 42

Table of Contents

investor perception of us;

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

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

failure to maintain existing or establish new collaborative relationships;

fluctuations in our operating results;

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;

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 that 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

p 35 of 42

Table of Contents

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.

p 36 of 42

Table of Contents

Item 6. EXHIBITS

Exhibit Number	Description
3.1 (1)	Amended and Restated Articles of Incorporation of the Company.
10.29 (1) #	Development and License Agreement, dated June 2, 1998, by and between the Company and Novo Nordisk A/S.
10.30 (1) #	First Amendment to Development and License Agreement, dated October 22, 2001, by and between the Company and Novo Nordisk A/S.
10.31 (2) +	2005 Equity Incentive Plan, as amended
10.32 (2) +	Employee Stock Purchase Plan, as amended
10.33	Amended and Restated Rights Agreement, dated as of September 5, 2008, by and between the Company and ComputerShare Trust Company, N.A.
31.1	Certification by the Company's Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification by the Company's Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification by the Company's Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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.

p 37 of 42

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

Dr. Igor Gonda
President and Chief Executive Officer

/s/ Nancy E. Pecota

Nancy E. Pecota
Chief Financial Officer

Dated: November 12, 2008

p 38 of 42

Table of Contents

INDEX TO EXHIBITS

Exhibit Number	Description
3.1 (1)	Amended and Restated Articles of Incorporation of the Company.
10.29 (1) #	Development and License Agreement, dated June 2, 1998, by and between the Company and Novo Nordisk A/S.
10.30 (1) #	First Amendment to Development and License Agreement, dated October 22, 2001, by and between the Company and Novo Nordisk A/S.
10.31 (2) +	2005 Equity Incentive Plan, as amended
10.32 (2) +	Employee Stock Purchase Plan, as amended
10.33	Amended and Restated Rights Agreement, dated as of September 5, 2008, by and between the Company and ComputerShare Trust Company, N.A.
31.1	Certification by the Company's Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification by the Company's Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification by the Company's Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

p 39 of 42