ARADIGM CORP
Form 10-Q
August 06, 2009

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

(Mark One)

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

For the quarterly period ended June 30, 2009

Or

o **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 000-28402

Aradigm Corporation

(Exact name of registrant as specified in its charter)

California	**94-3133088**
(State or other jurisdiction of incorporation or organization)	*(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 þ No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes o No o

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

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

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

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

(Class)	*(Outstanding at July 31, 2009)*
Common	100,726,171

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PART I. FINANCIAL INFORMATION
Item 1. FINANCIAL STATEMENTS

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

	June 30, 2009 (Unaudited)	December 31, 2008 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,101	$ 16,741
Short-term investments	8,665	2,399
Receivables	230	393
Restricted cash	225	225
Prepaid and other current assets	630	387
Total current assets	16,851	20,145
Property and equipment, net	4,465	5,093
Notes receivable	50	34
Other assets	104	247
Total assets	$ 21,470	$ 25,519
LIABILITIES AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 1,463	$ 739
Accrued clinical and cost of other studies	173	94
Accrued compensation	1,190	1,051
Deferred revenue	4,832	
Facility lease exit obligation	254	318
Other accrued liabilities	402	630
Total current liabilities	8,314	2,832
Deferred rent	152	199
Facility lease exit obligation, non-current	967	1,056
Deferred revenue, non-current		4,122
Other non-current liabilities	75	82
Note payable and accrued interest	8,679	8,472
Total liabilities	18,187	16,763
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 June 30, 2009 and December 2008; issued and outstanding shares: 100,726,171 at June 30,	347,774	343,426

2009 and 55,029,384 at December 31, 2008		
Accumulated other comprehensive income (loss)	(4)	4
Accumulated deficit	(344,487)	(334,674)
Total shareholders equity	3,283	8,756
Total liabilities and shareholders equity	$ 21,470	$ 25,519

See accompanying Notes to Condensed Financial Statements

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ARADIGM CORPORATION

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Revenue:				
Contract revenue	$	$ 54	$	$ 54
Operating expenses:				
Research and development	2,927	5,364	6,653	9,693
General and administrative	1,368	1,825	2,766	3,374
Restructuring and asset impairment	205	20	223	42
Total operating expenses	4,500	7,209	9,642	13,109
Loss from operations	(4,500)	(7,155)	(9,642)	(13,055)
Interest income	14	202	42	563
Interest expense	(105)	(100)	(209)	(198)
Other income (expense), net	(3)	1	(4)	
Net loss	$ (4,594)	$ (7,052)	$ (9,813)	$ (12,690)
Basic and diluted net loss per common share	$ (0.05)	$ (0.13)	$ (0.12)	$ (0.23)
Shares used in computing basic and diluted net loss per common share	99,298	54,519	85,080	54,083

See accompanying Notes to Condensed Financial Statements

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ARADIGM CORPORATION

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

	Six Months Ended June 30,	
	2009	**2008**
Cash flows from operating activities:		
Net loss	$ (9,813)	$ (12,690)
Adjustments to reconcile net loss to cash used in operating activities:		
Impairment loss on property and equipment	31	
Amortization and accretion of investments	(5)	(6)
Depreciation	600	375
Stock-based compensation	384	482
Loss on retirement and sale of property and equipment	3	
Facility lease exit cost	158	
Changes in operating assets and liabilities:		
Receivables	163	282
Prepaid and other current assets	(243)	459
Restricted cash		(6)
Other assets	27	12
Accounts payable	724	(267)
Accrued compensation	139	3
Other accrued liabilities	51	83
Deferred rent	(47)	(37)
Deferred revenue	710	288
Facility lease exit obligation	(195)	(184)
Net cash used in operating activities	(7,313)	(11,206)
Cash flows from investing activities:		
Capital expenditures	(6)	(2,013)
Purchases of available-for-sale investments	(8,669)	(1,235)
Proceeds from sales and maturities of available-for-sale investments	2,400	10,547
Notes receivable payments	(16)	
Net cash provided by (used in) investing activities	(6,291)	7,299
Cash flows from financing activities:		
Proceeds from public offering of common stock, net	3,927	
Proceeds from issuance of common stock, net	37	143
Net cash provided by financing activities	3,964	143
Net decrease in cash and cash equivalents	(9,640)	(3,764)
Cash and cash equivalents at beginning of period	16,741	29,964

Cash and cash equivalents at end of period	$ 7,101	$ 26,200

See accompanying Notes to Condensed Financial Statements

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ARADIGM CORPORATION

NOTES TO THE UNAUDITED CONDENSED FINANCIAL STATEMENTS
June 30, 2009

1. Organization and Basis of Presentation

Organization

Aradigm Corporation (the Company, we, our, or us) is a California corporation focused on the development and commercialization of drugs delivered by inhalation for the treatment of severe respiratory diseases. The Company s principal activities to date have included conducting research and development and developing collaborations. Management does not anticipate receiving any revenues from the sale of products in the upcoming year. The Company operates as a single operating segment.

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with United States 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 United States generally accepted accounting principles have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission (the SEC). In the opinion of management, the financial statements reflect all adjustments, which are of a normal recurring nature, necessary for fair presentation. The accompanying unaudited condensed financial statements should be read in conjunction with the financial statements and notes thereto included in the Company s Annual Report on Form 10-K for the year ended December 31, 2008, as filed with the SEC on March 30, 2009 (the 2008 Form 10-K). 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, 2008 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by United States generally accepted accounting principles for complete financial statements. For further information, please refer to the financial statements and notes thereto included in the 2008 Form 10-K.

In accordance with SFAS 165 *Subsequent Events,* we have evaluated subsequent events through August 6, 2009, the date of issuance of the unaudited condensed financial statements. See Note 12, Subsequent Events.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements, in conformity with United States 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 revenue recognition, assumptions for valuing options and warrants, and income taxes. Actual results could differ materially from these estimates.

Cash and Cash Equivalents

The Company considers all liquid investments purchased with an initial maturity of three months or less to be cash equivalents. The Company invests cash and cash equivalents not needed for operations in money market funds, commercial paper, corporate bonds and government notes in accordance with its investment policy.

Investments

Management determines the appropriate classification of the Company s investments, which consist solely of debt securities, at the time of purchase. All investments are classified as available-for-sale, carried at estimated fair value and reported in cash and cash equivalents or short-term investments. Unrealized gains and losses on available-for-sale securities are excluded from earnings and losses and are reported as a separate component in accumulated other comprehensive income (loss) in shareholders equity until realized. Fair values of investments are based on quoted market prices where available. Interest income is recognized when earned and

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includes interest, dividends, amortization of purchase premiums and discounts, and realized gains and losses on sales of securities. The cost of securities sold is based on the specific identification method. The Company regularly reviews all of its investments for other-than-temporary declines in fair value. When the Company determines that the decline in fair value of an investment below the Company s accounting basis is other-than-temporary, the Company reduces the carrying value of the securities held and recognizes the loss in earnings for the amount of any such decline that is related to the credit loss component. If the Company has intent to sell the asset before maturity, the entire amount of the decline is recognized in earnings. No such reductions have been required during any of the periods presented.

Property and Equipment

The Company records property and equipment at cost and calculates depreciation using the straight-line method over the estimated useful lives of the respective assets. Machinery and equipment includes external costs incurred for validation of the equipment. The Company does not capitalize internal validation expense. Computer equipment and software includes capitalized computer software. All of the Company s capitalized software is purchased; the Company has not internally developed computer software. Leasehold improvements are depreciated over the shorter of the term of the lease or useful life of the improvement.

Impairment of Long-Lived Assets

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

Accounting for Costs Associated with Exit or Disposal Activities

In accordance with 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 that is measured initially at its fair value in the period in which the liability is incurred. 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.

Revenue Recognition

Contract revenues consist of revenues from grants, collaboration agreements and feasibility studies. The Company recognizes revenue under the provisions of the SEC s Staff Accounting Bulletin 104, Topic 13, *Revenue Recognition Revised and Updated* (SAB 104) and Emerging Issues Task Force 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 includes 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.

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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.

Stock-Based Compensation

The Company accounts for share-based payment arrangements in accordance with SFAS No. 123(R), *Share-Based Payment* (SFAS 123(R)) which requires the recognition of compensation expense, using a fair-value based method, for all costs related to share-based payments including stock options and restricted stock awards and stock issued under the employee stock purchase plan. SFAS 123(R) requires companies to estimate the fair value of share-based payment awards on the date of the grant using an option-pricing model. The Company has adopted the simplified method to calculate the beginning balance of the additional paid-in capital, or APIC, pool of excess tax benefits, and to determine the subsequent effect on the APIC pool and statement of cash flows of the tax effects of stock-based compensation awards.

Income Taxes

The Company makes 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 the financial statements, the Company is required to estimate income taxes in each of the jurisdictions in which it operates. This process involves the Company estimating its current tax exposure under the most recent tax laws and assessing temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included in the balance sheets.

The Company assesses the likelihood that it will be able to recover its deferred tax assets. It considers all available evidence, both positive and negative, including the 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 the Company does not consider it more likely than not that it will recover its deferred tax assets, the Company records a valuation allowance against the deferred tax assets that it estimates will not ultimately be recoverable. At June 30, 2009 and December 31, 2008, the Company believed that the amount of its deferred income taxes would not be ultimately recovered. Accordingly, the Company recorded a full valuation allowance for deferred tax assets. However, should there be a change in the Company s ability to recover its deferred tax assets, the Company would recognize a benefit to its tax provision in the period in which it determines that it is more likely than not that it will recover its deferred tax assets.

Net Loss Per Common Share

Basic net loss per common share is computed using the weighted-average number of shares of common stock outstanding during the period less the weighted-average number of shares of common stock subject to repurchase. Potentially dilutive securities were not included in the net loss per common share calculation for the three months and six months ended June 30, 2009 and 2008, because the inclusion of such shares would have had an anti-dilutive effect.

Recently Issued Accounting Pronouncements

In June 2009, the Financial Accounting Standards Board (FASB) issued SFAS 168, *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles a replacement of FAS No 162 (SFAS 168).* SFAS 168 states that that the codification will become the source of authoritative United States generally accepted accounting principles (GAAP). Once the codification is in effect, all of its content will carry the same level of authority. Thus, the GAAP hierarchy will be modified to include only two levels of GAAP, authoritative and nonauthoritative. SFAS 168 will be effective for us in the quarter ended September 30, 2009. The Company does not expect the adoption of SFAS 168 to have an impact on its financial position or results of operations.

In May 2009, the FASB issued SFAS 165, *Subsequent Events* (SFAS 165). SFAS 165 provides guidance on management s assessment of subsequent events. SFAS 165 includes existing guidance that was previously included in United States auditing

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literature. In addition, SFAS 165 clarifies that management is responsible for evaluating events and transactions occurring after the balance sheet date and through the financial statement issuance date that should be disclosed as subsequent events. The evaluation and assessment must be performed for interim and annual reporting periods. SFAS 165 is effective for the Company for the quarter ending June 30, 2009. The adoption of SFAS 165 did not have a material impact of the Company s financial position or results of operations.

In April 2009, the FASB issued FASB Staff Position No. FAS 115-2 and FAS 124-2, *Recognition and Presentation of Other-Than-Temporary Impairments (* FSP FAS 115-2 and FSP FAS 124-2). FSP FAS 115-2 and FSP FAS 124-2 are intended to provide greater clarity to investors about the credit and noncredit component of another-than-temporary impairment event and to more effectively communicate when an other than temporary impairment event has occurred. This guidance applies to debt securities only and requires separate display of losses related to credit deterioration and losses related to other market factors. When an entity does not intend to sell the security and it is more likely than not that an entity will not have to sell the security before recovery of its cost basis, it must recognize the credit component of an other than temporary impairment in earnings and the remaining portion in other comprehensive income. FSP FAS 115-2 and FSP FAS 124-2 are effective for the Company for the quarter ending June 30, 2009. The adoption of FSP FAS 115-2 and FSP FAS 124-2 did not have a material impact of the Company s financial position or results of operations.

In April 2009, the FASB issued FASB Staff Position No. FAS 157-4, *Determining Fair Value When the Volume and Level of Activity for the Asset or Liability Have Significantly Decreased and Identifying Transactions That Are Not Orderly (* FSP FAS 157-4). FSP FAS 157-4 provides additional authoritative guidance to assist both issuers and users of financial statements in determining whether a market is active or inactive, and whether a transaction is distressed. FSP FAS 154-4 is effective for the Company for the quarter ending June 30, 2009. The adoption of FSP FAS 157-4 did not have a material impact on our financial position or results of operations.

In April 2009, the FASB issued FASB Staff Position No. FAS 107-1 and APB 28-1, *Interim Disclosures about Fair Value of Financial Instruments* (FSP FAS 107-1 and APB 28-1). FSP FAS 107-1 and APB 28-1 requires disclosures about fair value of financial instruments for interim reporting periods of publicly traded companies as well as in annual financial statements. FSP FAS 107-1 and APB 28-1 will be effective for us for the quarter ending June 30, 2009. The adoption of FAS 107-1 and APB 28-1 did not have an impact on our financial position or results of operations.

In February 2008, the FASB issued FASB Staff Position No. FSP FAS 157-2, *Effective Date of FASB Statement No. 157* (FSP FAS 157-2), which defers the effective date of SFAS No. 157, *Fair Value Measurements*, 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. The adoption of FSP FAS 157-2 did not have a material impact on the Company s financial position and results of operations.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations* (SFAS 141(R)), which replaced SFAS No. 141, *Business Combinations*. SFAS 141(R) establishes principles and requirements for how an acquirer in a business combination recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, and any controlling interest; recognizes and measures the goodwill acquired in the business combination or a gain from a bargain purchase; and determines what information to disclose to enable users of the financial statements to evaluate the nature and financial effects of the business combination. SFAS 141(R) is to be applied prospectively to business combinations for which the acquisition date is on or after an entity s fiscal year that begins after December 15, 2008. The Company will assess the impact of SFAS 141(R) if and when a future acquisition occurs.

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

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for collaborative arrangements in place at the beginning of the annual period beginning after December 15, 2008. The adoption of EITF 07-1 did not have a material impact on the Company s financial position and results of operations.

3. Cash, Cash Equivalents and Short-Term Investments

A summary of cash and cash equivalents and short-term investments, classified as available-for-sale and carried at fair value is as follows (in thousands):

	Amortized Cost	Gross Unrealized Gain	Gross Unrealized (Loss)	Estimated Fair Value
June 30, 2009				
Cash and cash equivalents	$ 7,101	$	$	$ 7,101
Short-term investments:				
Commercial paper	$ 2,948	$	$ (1)	$ 2,947
Certificates of deposit	3,671		(4)	3,667
U.S. Treasury and agencies	2,050	1		2,051
Total	$ 8,669	$ 1	$ (5)	$ 8,665
December 31, 2008				
Cash and cash equivalents	$ 16,741	$	$	$ 16,741
Short-term investments:				
Commercial paper	$ 2,395	$ 4	$	$ 2,399
U.S. Treasury and agencies				
Total	$ 2,395	$ 4	$	$ 2,399

All short-term investments at June 30, 2009 and December 31, 2008 mature in less than one year. Unrealized holding gains and losses on securities classified as available-for-sale are recorded in accumulated other comprehensive income (loss). All certificates of deposit (CDs) held by the Company are insured by the FDIC and that none of the individual CDs exceed the current FDIC limit of $250,000.

The Company considers all liquid investments purchased with a maturity of three months or less to be cash equivalents. The Company invests its cash and cash equivalents and short-term investments in money market funds, certificates of deposit, commercial paper and corporate and government notes.

4. Fair Value Measurements

Effective January 1, 2008, the Company adopted SFAS 157, *Fair Value Measurements.* SFAS 157 clarifies the definition of fair value, prescribes methods for measuring fair value, establishes a fair value hierarchy based on the inputs used to measure fair value and expands disclosures about the use of fair value measurements. The fair value hierarchy has three levels based on the reliability of the inputs used to determine fair value. Level 1 values are based on quoted prices in active markets. Level 2 values are based on significant other observable inputs. Level 3 values are based on significant unobservable inputs. The following table presents the fair value level for our cash and cash equivalents and short-term investments, which represent the assets that are measured at fair value on a recurring basis and are categorized using the fair value hierarchy. The Company does not have any liabilities that are measured at fair value.

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Description	Balance June 30, 2009	Fair Value Measurements at Reporting Date Using Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
		(in thousands)		
Cash and cash equivalents	$ 7,101	$ 6,699	$ 402	$
Short-term investments	8,665		8,665	
Total	$ 15,766	$ 6,699	$ 9,067	$

The Company s cash and cash equivalents at June 30, 2009 consist of cash, money market funds and corporate bonds. Money market funds are valued using quoted market prices. The Company uses an independent third party pricing service to value its commercial paper and other Level 2 investments. The pricing service uses observable inputs such as new issue money market rates, adjustment spreads, corporate actions and other factors and applies a series of matrices pricing model. The Company performs a review of prices received from third parties to determine if whether they are reasonable estimates of fair values. In addition, the Company performs a review to determine if our securities are properly classified in accordance with the fair value hierarchy.

5. Sublease Agreement and Lease Exit Liability

In July, 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, California.

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.

In April 2009, the Company entered into an amendment to its sublease agreement with Mendel to sublease an additional 1,550 square feet. The Company recorded an additional sublease loss on the amendment since the monthly payments the Company expects to receive is less that the Company will owe the lessor for the subleased space.

The lease exit liability activity for the six months ended June 30, 2009 is as follows (in thousands):

	Six Months Ended June 30, 2009
Balance at January 1, 2009	$ 1,374
Accretion expense	32
Lease payments	(227)
Loss on sublease of additional space	42
Balance at June 30, 2009	$ 1,221

As of June 30, 2009, $254,000 of the $1,221,000 balance was recorded as a current liability and $967,000 was recorded as a non-current liability.

6. Shareholders Equity

On February 26, 2009, the Company closed a registered direct offering covering the sale of an aggregate of 44.7 million shares under a shelf registration statement on Form S-3 (No. 333-148263) that was previously filed by the Company on December 21, 2007 and declared effective by the SEC on January 25, 2008. The Company received net proceeds, after offering expenses, of $3.9 million.

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On April 1, 2009, the Company issued 306,591 shares of common stock pursuant to the Employee Stock Purchase Plan (ESPP) at an average price of $0.12 per share.

On May 15, 2009, the Company s shareholders approved an amendment to the ESPP to increase the aggregate number of shares of common stock authorized for issuance under the plan by 2,500,000 shares.

7. Related Parties

Novo Nordisk

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 of the Company. At December 31, 2006, Novo Nordisk had 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 total outstanding stock on an as-converted basis. Thus, Novo Nordisk was no longer considered a related party. Novo Nordisk owned less that 1% of the Company s common stock as of as of December 31, 2007.

In June 1998, the Company executed a Development and Commercialization Agreement with Novo Nordisk to jointly develop a pulmonary delivery system for administering insulin by inhalation by using the AERx insulin Diabetes Management System (iDMS). Under the terms of the agreement, Novo Nordisk was granted exclusive worldwide sales and marketing rights to any products developed. On July 3, 2006, the Company and Novo Nordisk entered into the Second Amended and Restated License Agreement (the July 3, 2006 License Agreement). 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 (the Promissory Note). The Promissory Note bears interest accruing at a rate of 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 amount outstanding under the Promissory Note, including accrued interest, was $8.7 million and $8.5 million as of June 30, 2009 and December 31, 2008, respectively. The Promissory Note contains 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 secured by a pledge of the net royalty stream payable to the Company by Novo Nordisk pursuant to the July 3, 2006 License Agreement. On January 14, 2008, Novo Nordisk issued a press release announcing the termination of its Phase 3 clinical trials for fast-acting inhaled insulin delivered via the AERx iDMS. Also on January 14, 2008, the Company received a 120-day notice from Novo Nordisk terminating the July 3, 2006 License Agreement between the Company and Novo Nordisk. The termination of the July 3, 2006 License Agreement does not accelerate any of the payment provisions under the Promissory Note.

8. Collaborations and Licensing Agreements

Lung Rx

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

On June 1, 2009, the Company received a written notice from United Therapeutics Corporation seeking to terminate the Lung Rx Agreement. The Company does not believe that Lung Rx is entitled to terminate the Lung Rx Agreement and is engaged in discussions regarding Lung Rx s payment obligations under the Lung Rx Agreement. The Company has not recognized any revenue under the Lung Rx Agreement due to the existence of undelivered elements. In the event of termination of the Lung Rx Agreement, the Company anticipates recording all revenue for contract elements that were previously deferred. Previously deferred revenue totaled $4,832,000 at June 30, 2009.

Zogenix

In August 2006, the Company sold all of its 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). Under the terms of the asset

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sale agreement, the Company received a $4.0 million initial payment from Zogenix and it will be entitled to a $4.0 million milestone payment upon initial U.S. commercialization as well as royalty payments upon commercialization of DosePro products. 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. The same month, 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.

On July 16, 2009, Zogenix announced that it had received approval from the FDA for its NDA for Sumavel DosePro needle-free delivery system. On August 3, 2009, Zogenix and Astellas Pharma US, Inc. announced that they had entered into an exclusive co-promotion agreement in the U.S. for the Sumavel DosePro needle-free delivery system. Sumavel DosePro is expected to be commercially available in January 2010. Under the announced terms of the agreement, the companies will collaborate on the promotion and marketing of Sumavel DosePro with Zogenix focusing their sales activities primarily on the neurology market while Astellas will focus mostly on primary care physicians. Zogenix will have responsibility for manufacturing and distribution of the product.

The Company did not receive any payments or recognize any revenue under the Zogenix agreement for the three months and six months ended June 30, 2009 and 2008.

9. Stock-Based Compensation and Stock Options and Awards

The following table shows the stock-based compensation expense included in the accompanying condensed statements of operations for the three and six months ended June 30, 2009 and 2008 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Costs and expenses:				
Research and development	$ 44	$ 162	$ 160	$ 361
General and administrative	127	112	224	121
Total stock based compensation expense	$ 171	$ 274	$ 384	$ 482

There was no capitalized stock-based employee compensation cost for the three and six months ended June 30, 2009 and 2008. Since the Company incurred net losses during the first quarter of 2009 and 2008, there was no recognized tax benefit associated with stock-based compensation expense.

The total amount of unrecognized compensation cost related to non-vested stock options and stock purchases, net of forfeitures, was $0.7 million as of June 30, 2009. This amount will be recognized over a weighted average period of 2.44 years.

For restricted stock awards, the Company recognizes compensation expense over the vesting period for the fair value of the stock award on the measurement date. The total fair value of restricted stock awards that vested during the six months ended June 30, 2009 was $1,000. The Company retained purchase rights to 1,423,626 shares of unvested restricted stock awards issued pursuant to stock purchase agreements at no cost per share as of June 30, 2009. As of June 30, 2009, there is $0.3 million of total unrecognized compensation costs, net of forfeitures, related to non-vested stock awards which are expected to be recognized over a weighted average period of 3.00 years.

Stock Option Plans: 1996 Equity Incentive Plan, 2005 Equity Incentive Plan and 1996 Non-Employee Directors Plan

The 1996 Equity Incentive Plan (the 1996 Plan) and the 2005 Equity Incentive Plan (the 2005 Plan), which amended, restated and retitled the 1996 Plan, were adopted to provide a means by which selected officers, directors, scientific advisory board members and employees of and consultants to the Company and its affiliates could be given an opportunity to acquire an equity interest in the Company. All employees, directors, officers, scientific advisory board members and consultants of the Company are eligible to participate in the 2005 Plan. During 2000, the board of directors approved the termination of the 1996 Non-Employee Directors Stock Option Plan (the Directors Plan). The

termination had no effect on options already outstanding.

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Stock Option Activity

The following is a summary of activity under the 1996 Plan, the 2005 Plan and the Directors Plan for the six months ended June 30, 2009:

		Options Outstanding		
	Shares Available for Grant of Option or Award	Number of Shares	Exercise Price Range	Weighted Average Exercise Price
Balance at January 1, 2009	3,987,599	4,185,061	$ .39 $120.63	$ 4.09
Options authorized				
Options granted	(2,068,000)	2,068,000	$ .16 $ .25	$ .22
Options exercised				
Options cancelled	875,747	(875,747)	$ .25 $112.50	$ 3.40
Restricted share awards granted	(820,750)			
Restricted share awards cancelled	93,625			
Plan shares cancelled and not reauthorized	(3,407)		$41.25 $ 42.19	$41.78
Balance at June 30, 2009	2,064,814	5,377,314	$ .16 $120.63	$ 2.75

Aggregate intrinsic value is the sum of the amounts by which the quoted market price of the Company s stock exceeded the exercise price of the stock options at June 30, 2009 for those stock options for which the quoted market price was in excess of the exercise price (in-the-money options). As of June 30, 2009, options to purchase 2,378,704 shares of common stock were exercisable and had an aggregate intrinsic value of zero. In addition, options that were not yet exercisable also had an intrinsic value of $55,000. No options were exercised during the six months ended June 30, 2009.

A summary of the Company s unvested restricted stock and performance bonus stock award activities as of June 30, 2009 is presented below representing the maximum number of shares that could be earned or vested under the 2005 Plan:

	Number of Shares	Weighted Average Grant Date Fair Value
Balance at January 1, 2009	703,535	$ 1.60
Restricted share awards issued	820,750	.19
Restricted share awards vested	(7,034)	3.63
Restricted share awards cancelled	(93,625)	1.05
Balance at June 30, 2009	1,423,626	$ .79

10. 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 six month periods ended June 30, 2009 and 2008.

The following securities were excluded from the calculation of diluted loss per share for the three and six months ended June 30, 2009 and 2008, respectively, as their effect would be anti-dilutive (in thousands):

	June 30,	
	2009	**2008**
Outstanding stock options	5,377	3,664
Unvested restricted stock	1,423	761
Warrants to purchase common stock		421
Performance bonus stock award		100

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11. 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 June 30,		Six Months Ended June 30,	
	2009	2008	2009	2008
Net loss	$ (4,594)	$ (7,052)	$ (9,813)	$ (12,690)
Other comprehensive loss:				
Change in unrealized gain (loss) on available-for-sale securities	(4)	(15)	(8)	(9)
Comprehensive loss	$ (4,598)	$ (7,067)	$ (9,821)	$ (12,699)

12. Subsequent Events

Zogenix

As explained in Note 8, the Company is entitled to milestone and royalty payments beginning with the first U.S. commercial sale by Zogenix of its DosePro products. On July 16, 2009, Zogenix announced that it had received approval from the FDA for its NDA for Sumavel DosePro needle-free delivery system.

On August 3, 2009, Zogenix and Astellas Pharma US, Inc. announced that they had entered into an exclusive co-promotion agreement in the U.S. for the Sumavel DosePro needle-free delivery system. Sumavel DosePro is expected to be commercially available in January 2010. Under the announced terms of the agreement, the companies will collaborate on the promotion and marketing of Sumavel DosePro with Zogenix focusing their sales activities primarily on the neurology market while Astellas will focus mostly on primary care physicians. Zogenix will have responsibility for manufacturing and distribution of the product.

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

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements that are based on the beliefs of management, as well as assumptions made by, and information currently available to, management. Words such as anticipate, expect, intend, plan, believe, may, will, could, continue, seek, estimate, or the nega expressions also identify forward-looking statements. These forward-looking statements are subject to risks and uncertainties that could cause our future actual results, performance or achievements to 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 risks and uncertainties discussed in this section, as well as in the section entitled Risk Factors in this Quarterly Report on Form 10-Q, and elsewhere in the 2008 Form 10-K and our other filings with the SEC. Forward-looking statements include our belief that our cash, cash equivalents and short-term investments as of June 30, 2009 and the anticipated Zogenix milestone payment will be sufficient to enable us meet our obligations through at least the second quarter of 2010.

These forward-looking statements and our business are 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.

You are cautioned not to place undue reliance on the forward-looking statements contained herein, which speak only as of the date of the filing of this Quarterly Report on Form 10-Q. We undertake no obligation to update these forward-looking statements in light of events or circumstances occurring after the date of the filing of this Quarterly Report on Form 10-Q or to reflect the occurrence of unanticipated events.

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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 have invested a large amount of capital to develop drug delivery technologies, particularly the development of a significant amount of expertise in pulmonary drug delivery. We have also invested considerable effort into the generation of a large volume of laboratory and clinical data demonstrating the performance of our AERx pulmonary drug delivery platform. We have not been profitable since inception and expect to incur additional operating losses over at least the next several years as we expand product development efforts, preclinical testing and clinical trial activities, and possible sales and marketing efforts, and as we secure production capabilities from outside contract manufacturers. To date, we have not had any significant product sales and do not anticipate receiving any revenues from the sale of products in the near term. As of June 30, 2009, we had an accumulated deficit of $344.5 million. Historically, we have funded our operations primarily through public offerings and private placements of our capital stock. Most recently, in February 2009, we closed the sale of 44,663,071 shares of common stock in a registered direct offering with net proceeds, after offering expenses, of $3.9 million. In the past, we have also funded our operations through license fees and milestone payments from collaborators, proceeds from the January 2005 restructuring transaction with Novo Nordisk, borrowings from Novo Nordisk, sale of a technology platform (Intraject) and interest earned on investments.

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® insulin Diabetes Management System (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 July 3, 2006 License Agreement, on September 25, 2008, Novo Nordisk assigned to us at no charge, the inhaled insulin-related patents. These patents were either previously purchased from us in July 2006 or had originated from Novo Nordisk. The portfolio includes both U.S. and foreign patents. We assume the responsibility for the maintenance of this portfolio. Novo Nordisk is also providing us with the data from the preclinical and clinical research generated during the collaboration. We do not intend to complete the development of AERx iDMS on our own. We are attempting to out-license or sell the assets associated with inhaled insulin.

Over the last three years, our business has focused on opportunities for product development for treatment of severe respiratory disease that we could potentially 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. It is our longer term strategy 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 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 non-cystic fibrosis bronchiectasis. We received orphan drug designations for both of these indications in the U.S. We recently reported the results of two successful Phase 2a trials with this product candidate in cystic fibrosis (CF) and non-cystic fibrosis bronchiectasis, respectively, as described below.

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In June 2008, we completed a multi-center 14-day treatment Phase 2a trial in Australia and New Zealand in 21 CF patients with once daily dosing of 6mL of inhaled liposomal ciprofloxacin. 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 CFUs 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).

In December 2008, we completed an open-label, four week treatment study with once daily inhaled liposomal ciprofloxacin in patients with non-CF bronchiectasis. The study was conducted at eight leading centers in the United Kingdom and enrolled a total of 36 patients. The patients were randomized into two equal size groups, one receiving 3 mL of inhaled liposomal ciprofloxacin and the other receiving 6 mL of inhaled liposomal ciprofloxacin, once-a-day for the four-week treatment period. The primary efficacy endpoint was the change from baseline in the sputum of *Pseudomonas aeruginosa* CFUs, the standard objective measure of the reduction in pulmonary bacterial load. The 3 mL and 6 mL doses of inhaled liposomal ciprofloxacin in the evaluable patient population demonstrated significant mean decreases against baseline in the CFUs over the 28-day treatment period of 3.5 log (p<0.001) and 4.0 log (p<0.001) units, respectively.

In July 2009, we received clearance from the U.S. FDA for our inhaled liposomal ciprofloxacin Investigational New Drug (IND) application. The initial clinical protocol under this IND is an international, randomized, double-blind, placebo-controlled Phase 2b study designed to evaluate inhaled liposomal ciprofloxacin in patients with non-cystic fibrosis bronchiectasis. We plan in the Phase 2b study to enroll 96 patients and the primary efficacy endpoint will be the change from baseline in the sputum of *Pseudomonas Aeruginosa* colony forming units following once-daily dosing of two different dose levels vs. placebo for a four-week treatment period. Secondary endpoints will include quality of life measurements and improvement of outcomes with respect to exacerbations. Lung function changes will be monitored for safety.

In August 2009, we announced that the European Medicines Agency (EMEA) granted Orphan Drug Designation to the Company s inhaled liposomal ciprofloxacin drug product candidate for the treatment of lung infections associated with cystic fibrosis. Under European guidelines, Orphan Medicinal Product Designation provides 10 years of potential market exclusivity if the product candidate is the first product candidate for the indication approved for marketing in the European Union. Orphan drug designation also allows the candidate s sponsor to seek assistance from the EMEA in optimizing the candidate s clinical development through participation in designing the clinical protocol and preparing the marketing application. Additionally, a drug candidate designated by the Commission as an Orphan Medicinal Product may qualify for a reduction in regulatory fees as well as a European Union-funded research grant. The Company was granted previously orphan drug designations by the U.S. Food and Drug Administration for inhaled liposomal ciprofloxacin for the management of CF and for non-cystic fibrosis bronchiectasis.

In 2004, we executed a development agreement with Defence Research and Development Canada, a division of the Canadian Department of National Defence, for the development of liposomal ciprofloxacin for the treatment of biological terrorism-related inhalation anthrax. If we apply in the future for approval of this product candidate for the prevention and treatment of inhalation anthrax and possibly other inhaled life-threatening bioterrorism infections, we anticipate using safety data from the cystic fibrosis and bronchiectasis studies to support our application. Our plan is to seek U.S. and other government funding to complete the development of this product.

Our programs included 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. We conducted two collaborative research projects on inhaled treprostinil using our AERx delivery system with United Therapeutics. The first project was with an aqueous formulation of treprostinil. The second project involved development of a slow-acting liposomal formulation of treprostinil, with the view to achieving once-a-day dosing. On August 30, 2007, we signed an Exclusive License, Development and Commercialization Agreement with Lung Rx (Lung Rx Agreement), pursuant to which we granted Lung Rx, upon payment of specified amounts, an

exclusive license to develop and commercialize inhaled treprostinil using our AERx Essence® technology for the treatment of pulmonary arterial hypertension, or PAH, and other potential therapeutic indications. Under the terms of the Lung Rx Agreement, we received an upfront fee of $440,000 and an additional fee of $440,000 four months after the signing date. These fees are nonrefundable and were included in deferred revenue in the balance sheet at December 31, 2007. Under the terms of the Lung Rx Agreement, we were responsible for conducting and funding the feasibility study that included a clinical trial to compare AERx Essence to a nebulizer used in a completed Phase 3 registration trial conducted by United Therapeutics. We began this study in April

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2008 and announced results in November 2008. At the same time, we announced receipt of $2.75 million from Lung Rx which included the first milestone of $2.0 million and development costs. Lung Rx was to pay a $650,000 license fee for an exclusive license and had the right under the Lung Rx Agreement to purchase $3.47 million of our common stock at an average closing price over a certain trailing period within 15 days of Lung Rx s determination that the feasibility study was successful. Lung Rx determined that, while the results of the clinical trial warranted continuation of the development of AERx Essence technology with treprostinil, the performance of the AERx Essence inhaler in the clinical study was different from the nebulizer. As such, they did not pay the license fee or purchase our stock.

On June 1, 2009, we received a written notice from United Therapeutics seeking to terminate the Lung Rx Agreement effective July 1, 2009. Lung Rx did not assert the existence of any technical problems with our AERx technology or any safety or efficacy concerns. We believe that Lung Rx is not entitled to terminate the Lung Rx Agreement and we are engaged in discussions concerning Lung Rx s payment obligations to us under the Lung Rx Agreement. There is no assurance that these discussions will result in a favorable outcome for the Company. We discontinued certain business activities that we were undertaking to support the collaboration and eliminated the positions of personnel who were devoting all or substantially all of their time to supporting the collaboration.

We have a proprietary product candidate for smoking cessation treatment. We have encouraging data from our first human clinical trial delivering aqueous solutions of nicotine using the palm-sized 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 seeking collaborations with government, non-government and commercial organizations to further develop this product candidate.

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 $4.0 million initial payment from Zogenix, and we will be entitled to a $4.0 million milestone payment upon initial U. S. commercialization, and royalty payments upon any commercialization of products in the U.S. and other countries, including the European Union, that may be developed and sold using the DosePro technology. In December 2007, Zogenix submitted a New Drug Application (NDA) with the U.S. 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. The same month, 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.

On July 16, 2009, Zogenix announced that it was granted approval by the FDA of the Sumavel DosePro (sumatriptan injection) needle-free delivery system for the treatment of acute migraine and cluster headache. On August 3, 2009, Zogenix and Astellas Pharma US, Inc. (Astellas) announced that they had entered into an exclusive co-promotion agreement in the U.S. for the Sumavel DosePro needle-free delivery system. Sumavel DosePro is expected to be commercially available in January 2010. Under the announced terms of the agreement, Zogenix and Astellas will collaborate on the promotion and marketing of Sumavel DosePro with Zogenix focusing their sales activities primarily on the neurology market while Astellas will focus mostly on primary care physicians. Zogenix will have responsibility for manufacturing and distribution of the product.

Critical Accounting Policies and Estimates

We consider certain accounting policies related to revenue recognition, impairment of long-lived assets, exit/disposal activities, research and development, income taxes and stock-based compensation 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 financial statements. These estimates include useful lives for property and equipment and related depreciation calculations, estimated amortization periods for payments received from product development and license agreements as

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they relate to revenue recognition, and assumptions for valuing options, warrants and other stock-based compensation. Our actual results could differ from these estimates.

Revenue Recognition

Contract revenues consist of revenue from grants, collaboration agreements and feasibility studies. We recognize revenue under the provisions of the SEC s Staff Accounting Bulletin 104, Topic 13, *Revenue Recognition Revised and Updated* (SAB 104) and Emerging Issues Task Force 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 includes the portion of all refundable and nonrefundable research billings and payments that have been received, but not 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 often require us to provide multiple deliverables, such as a license, research and development, product steering committee services and other performance obligations. These agreements 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.

Impairment of Long-Lived Assets

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

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 that is measured initially at its fair value in the period in which the liability is incurred, except for a liability for one-time termination benefits that is incurred over time. According to SFAS 146, costs to terminate an operating lease or other contracts are (a) costs to terminate the contract before the end of its term or (b) costs that will continue to be incurred under the contract for its remaining term without economic benefit to the entity. In periods subsequent to initial measurement, changes to the liability 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.

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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. These differences result in deferred tax assets and liabilities, which are included in our balance sheets.

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 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 June 30, 2009 and December 31, 2008, 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

We follow the fair value method of accounting for stock-based compensation arrangements in accordance with SFAS No. 123(R), *Share-Based Payment* (SFAS 123(R)). We adopted SFAS 123(R) effective January 1, 2006 using the modified prospective method of transition. Under SFAS 123(R), the estimated fair value of share-based compensation, including stock options and restricted stock awards and purchases of common stock by our employees under the Employee Stock Purchase Plan is recognized as compensation expense.

We used the Black-Scholes option-pricing model to estimate the fair value of share-based awards as of the grant date. The Black-Scholes model, by its design, is highly complex, and dependent upon key data inputs estimated by management. We use a lattice model to estimate the expected term as an input into the Black-Scholes option pricing model. We determine expected volatility using the historical method, which is based on the daily historical daily trading data of our common stock over the expected term of the option.

Recent Accounting Pronouncements

See Note 2 to the accompanying unaudited condensed financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for information on recent accounting pronouncements.

Results of Operations

Revenue

	Three Months Ended June 30,		Six Months Ended June 30,		Increase (Decrease)			
	2009	2008	2009	2008	Three Months		Six Months	
	(in thousands)				($ s in thousands)			
Contract revenue	$	$54	$	$54	$(54)	(100)%	$(54)	(100)%

We did not record any revenue for the three and six months ended June 30, 2009. Through June 30, 2009, we have not recorded any revenue related with our collaboration with Lung Rx. We have not delivered certain elements and in accordance with our revenue recognition policy, we have deferred revenue recognition for all amounts received.

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Research and Development Expenses

	Three Months Ended June 30,		Six Months Ended June 30,		Increase (Decrease)			
	2009	2008	2009	2008	Three Months		Six Months	
	(in thousands)				($ s in thousands)			
Collaborative	$ 352	$ 810	$ 1,442	$ 1,347	$ (458)	(57)%	$ 95	7%
Self-initiated	2,575	4,554	5,211	8,346	(1,979)	(43)%	(3,135)	(38)%
Total research and development expenses	$ 2,927	$ 5,364	$ 6,653	$ 9,693	$ (2,437)	(45)%	$ (3,040)	(31)%

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.

Collaborative program expenses decreased for the three months ended June 30, 2009 as compared with the prior year. The decrease was due to a significant reduction in development activities related to the Lung Rx collaboration. The reduction was due to cost reduction actions undertaken by the Company in response to Lung Rx s communication that they were seeking to terminate the Lung Rx Agreement. For the six months ended June 30, 2009, expenses were flat since the aforementioned decrease offset the increase in Lung Rx development activities during the first quarter of 2009.

Self-initiated program expenses decreased for the three and six months ended June 30, 2009 as compared with the same periods in the prior year. The decrease was due to lower headcount, lower contract manufacturing expense and lower clinical and contract testing expense, partially offset by higher severance expenses. Lower expense levels are due to the Company s ongoing cost reduction efforts and timing of expenditures related to the on-going clinical trials of our inhaled liposomal ciprofloxacin development program.

General and Administrative Expenses

	Three Months Ended June 30,		Six Months Ended June 30,		Increase (Decrease)			
	2009	2008	2009	2008	Three Months		Six Months	
	(in thousands)				($ s in thousands)			
General and administrative expenses	$1,368	$1,825	$2,766	$3,374	$(457)	(25)%	$(608)	(18)%

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 costs. General and administrative expenses for the three months and six months ended June 30, 2009 decreased from the comparable periods in 2008, primarily due to a reduction in headcount, lower market research expenses and lower property taxes. Note that in the 2008 periods, the Company recorded its share of personal property tax assessments that it received from the County of Alameda. These assessments were for the tax periods from July 2004 to June 2007.

We expect that our general and administrative expenses will remain relatively constant as compared with the expense level for the three months and six months ended June 30, 2009.

Restructuring and Asset Impairment

	Three Months Ended June 30,		Six Months Ended June 30,		Increase (Decrease)			
	2009	2008	2009	2008	Three Months		Six Months	
	(in thousands)				($ s in thousands)			
Restructuring and asset impairment	$ 205	$ 20	$ 223	$ 42	$185	925%	$181	431%

The increase in restructuring and asset impairment expense for the three and six months ended June 30, 2009 was due to additional expenses recognized in 2009 related to the loss on the Mendel sublease.

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Interest income, Interest expense and Other Income

	Three Months Ended June 30,		Six Months Ended June 30,		Increase (Decrease)			
	2009	2008	2009	2008	Three Months		Six Months	
	(in thousands)				($ s in thousands)			
Interest income	$ 14	$ 202	$ 42	$ 563	$ (188)	(93)%	$ (521)	(93)%
Interest expense	(105)	(100)	(209)	(198)	(5)	5%	(11)	(6)%
Other income (expense), net	(3)	1	(4)		(4)	(400)%	(4)	(100)%
Total interest income, interest expense and other income (expense)	$ (94)	$ 103	$ (171)	$ 365	$ (197)	(191)%	$ (536)	(147)%

Interest income for the three and six months ended June 30, 2009 decreased from the comparable period in 2008 due to lower average invested balances as well as significantly lower interest yields earned. During the second half of 2008, interest rates decreased significantly due to the worldwide economic slowdown. 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%.

Liquidity and Capital Resources

As of June 30, 2009, we had cash, cash equivalents and short-term investments of $15.8 million, down from $19.1 million at December 31, 2008. The $3.3 million decrease primarily resulted from the use of cash to fund operations, partially offset by the $3.9 million proceeds from the registered direct offering of our common stock.

Net cash used in operating activities in the first half of 2009 was $7.3 million and primarily resulted from our net loss of $9.8 million, partially offset by non-cash expenses for depreciation, stock based compensation and facility lease exit expenses. Net cash used by investing activities was $6.3 million in the first half 2009 and represented the net purchase of short-term investments. Net cash provided by financing activities was $3.9 million which was due to the sale of the Company s common stock in our February 2009 registered direct offering.

Net cash used in operating activities in the first half of 2008 was $11.2 million and primarily resulted from our net loss of $12.7 million. Net cash provided by investing activities in the first half of 2008 was $7.3 million and reflected primarily maturities of investments, net of purchases, of $9.3 million, partly offset by the use of $2.0 million to purchase property and equipment.

As of June 30, 2009, we had an accumulated deficit of $344.5 million and total shareholders equity of $3.3 million. We believe that our cash, cash equivalents and short-term investments as of June 30, 2009 and the anticipated Zogenix milestone payment will be sufficient to enable us meet our obligations through at least the second quarter of 2010. To the extent that such sources of funds are not sufficient, we may also seek to raise additional funds through public or private equity or debt financings or from other sources. No assurances can be given that additional financing will be available or that, if available, such financing would be obtainable on terms satisfactory to us.

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 have one inactive, wholly-owned subsidiary domiciled in the United Kingdom.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The disclosures in this section are not required since the Company qualifies as a smaller reporting company.

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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.

Changes in Internal Controls over Financial Reporting

There were no changes in our internal controls over financial reporting that occurred during the three months ended June 30, 2009 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

Item 1. LEGAL PROCEEDINGS

The Company is not involved in any significant legal proceedings.

Item 1A. RISK FACTORS

In addition to the other information contained in this Quarterly Report on Form 10-Q, and risk factors set forth in the 2008 Form 10-K and our other filings with the SEC, the following risk factors should be considered carefully before you decide whether to buy, hold or sell our common stock. Our business, financial condition, results of operations and stock price 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, financial conditions, results of operations and stock price.

The risk factors included herein include any material changes to and supersede the risk factors associated with our business previously disclosed in Part I, Item 1A, Risk Factors of the 2008 Form 10-K. We have marked with a double asterisk (**) those risk factors that reflect substantive changes from the risk factors included in the 2008 Form 10-K.

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 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.

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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 continue to implement 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 significant 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:

- 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, contract research funding and interest earned on investments. We believe that our cash and cash equivalents at June 30, 2009 and the anticipated Zogenix milestone payment will be sufficient to fund operations at least through the second quarter of 2010. 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, 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 June 30, 2009, we have an accumulated deficit of $344.5 million. We have not had any significant product sales and do not anticipate receiving any revenues from product sales for at least the next few years, if ever. While our 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:

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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.

***** 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 collaborators could delay or terminate their agreements, and our products subject to collaborative arrangements may never be successfully commercialized. For example, on June 1, 2009, we received a written notice from United Therapeutics seeking to terminate the Lung Rx Agreement effective July 1, 2009.

Any delay in, or failure to receive, milestone payments or royalties could also adversely affect our financial position and we may not be able to find another source of cash to continue our operations. For example, Zogenix may not be able to 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 from Zogenix.

Further, our 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, or they may be terminated altogether. 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, such as the interpretation of terms in our agreements. For example, we currently have a disagreement with United Therapeutics concerning their right to terminate the Lung Rx Agreement. 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. For example, while our Phase 2a clinical trials with inhaled liposomal ciprofloxacin showed promising initial efficacy and safety results both in patients with cystic fibrosis and non-cystic fibrosis bronchiectasis, there is no guarantee that the current Phase 2 program or

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longer term studies and studies in larger patient populations will confirm these results or that we will satisfy all efficacy and safety endpoints required by the regulatory authorities.

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.

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

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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.

Because our proprietary liposomal ciprofloxacin programs rely on the FDA s and European Medicines Agency s grant 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 in USA for up to seven years or European Union for up to ten years.

The FDA has granted orphan drug designation for our proprietary liposomal ciprofloxacin drug product candidate 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 is developing an inhaled powder formulation of ciprofloxacin for the treatment of respiratory infections in cystic fibrosis and bronchiectasis. In August 2009, we announced that the European Medicines Agency (EMEA) granted orphan drug designation to our inhaled liposomal ciprofloxacin drug product candidate for the treatment of lung infections associated with cystic fibrosis. Under European guidelines, Orphan Medicinal Product Designation provides 10 years of potential market exclusivity if the product candidate is the first product candidate for the indication approved for marketing in the European Union. 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 or EMEA for a given indication, we may not be able to access the target market in the United States and/or the European Union, 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. For example, our agreement with Enzon Pharmaceuticals, Inc.(Enzon) to manufacture liposomal ciprofloxacin and AERx Strip® dosage forms may be terminated for unforeseen reasons, or we may not be able to reach mutually satisfactory agreements with Enzon to manufacture these at a commercial scale. There may be a significant delay before we find an alternative contract manufacturer or we may not find an alternative contract manufacturer at all.

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 candidates 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 unfeasible 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

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our collaborators may not be able to comply with the applicable GMP and other FDA regulatory requirements for manufacturing, which could result in an enforcement or other action, prevent commercialization of our product candidates and impair our reputation and results of operations.

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

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

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

We intend to establish our own sales, marketing and distribution capabilities to market products to concentrated, easily addressable prescriber markets. We have no experience in these areas, and developing these capabilities will require significant expenditures on personnel and infrastructure. While we intend to market products that are aimed at a small patient population, we may not be able to create an effective sales force around even a niche market. In addition, some of our product candidates 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 patients 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

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significant commercial advantage for us, our patents and know-how are intended to provide protection for important aspects of our technology, including methods for aerosol generation, devices used to generate aerosols, breath control, compliance monitoring, certain pharmaceutical formulations, design of dosage forms and their manufacturing and testing methods. In addition, we are maintaining as non-patented trade secrets some of the key elements of our manufacturing technologies, for example, those associated with production of disposable unit-dose packets for our AERx delivery system.

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

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often lags behind actual discoveries, we cannot be certain that we were the first creator of inventions covered by our pending patent applications or that we were the first to file patent applications on such inventions.

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

We are in competition with pharmaceutical, biotechnology and drug delivery companies, hospitals, research organizations, individual scientists and nonprofit organizations engaged in the development of drugs and therapies for the disease indications we are targeting. Our competitors may succeed before we can, and many already have succeeded, in developing competing technologies for the same disease indications, obtaining FDA approval for products or gaining acceptance for the same markets that we are targeting. If we are not first to market, it may be more difficult for us and our collaborators to enter markets as second or subsequent competitors and become commercially successful. We are aware of a number of companies that are developing or have developed therapies to address indications we are targeting, including major pharmaceutical companies such as Bayer, Genentech (now a part of Roche), Gilead Sciences, GlaxoSmith Kline, 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 management, engineering and development personnel. There is a shortage of skilled personnel in our industry, we face 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

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make our expenses associated with the development and maintenance of intellectual property in foreign jurisdictions more expensive than we anticipate. We probably will not obtain the same patent protection in every market in which we may otherwise be able to potentially generate revenues. In addition, in order to market our products in foreign jurisdictions, we and our collaborators must obtain required regulatory approvals from foreign regulatory agencies and comply with extensive regulations regarding safety and quality. We may not be able to obtain regulatory approvals in such jurisdictions and we may have to incur significant costs in obtaining or maintaining any foreign regulatory approvals. If approvals to market our products are delayed, if we fail to receive these approvals, or if we lose previously received approvals, our business would be impaired as we could not earn revenues from sales in those countries.

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

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

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

In both domestic and foreign markets, sales of our potential products will depend in substantial part on the availability of adequate reimbursement from third-party payors such as government health administration authorities, private health insurers and other organizations. Third-party payors often challenge the price and cost-effectiveness of medical products and services. Significant uncertainty exists as to the adequate reimbursement status of newly approved health care products. Any products we are able 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 involves the 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 Annual Report on Form 10-K for the 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

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improved controls, or difficulties encountered in the implementation or operation of these controls, could harm our operating results and cause us to fail to meet our financial reporting obligations, which could adversely affect our business and reduce our stock price.

Risks Related to Our Common Stock

Our stock price is likely to remain volatile.

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

investor perception of us;

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

sales of our stock by certain large institutional shareholders to meet liquidity concerns during the current economic climate or bankruptcy of the institutions holding the shares of investors in our company, resulting in large quantities of our shares being traded at discount prices;

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;

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 is quoted on the OTC Bulletin Board, which may provide less liquidity for our shareholders than the national exchanges.

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. As compared to being listed on a national exchange, being quoted on the OTC Bulletin Board may result in reduced liquidity for our shareholders, 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.

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We have implemented certain anti-takeover provisions, which may make an acquisition less likely or might result in costly litigation or proxy battles.

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

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

One of our shareholders may choose to pursue a lawsuit or engage in a proxy battle with management to limit our use of one or more of these anti-takeover protections. Any such lawsuit or proxy battle would, regardless of its merit or outcome, result in substantial costs and a diversion of management s attention and resources.

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. Therefore, our stockholders will not receive any funds absent a sale of their shares. We cannot assure stockholders of a positive return on their investment if they sell their shares, nor can we assure that stockholders will not lose the entire amount of their investment.

Item 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Not applicable.

Item 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

At the Company s Annual Meeting of Shareholders held on May 15, 2009, three matters were voted upon. A description of each matter and tabulation of the votes for each of the matters is as follows:

1. Four directors were elected to hold offices until the next annual meeting of shareholders and until their successors are elected:

Nominee	For	Withheld
Frank H. Barker	73,256,900	4,338,855
Igor Gonda	73,263,565	4,332,190
John M. Siebert	73,264,767	4,330,998
Virgil D. Thompson	73,261,607	4,334,148

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2. The Company s shareholders approved an amendment to Aradigm s Employee Stock Purchase Plan to increase the aggregate number of shares of common stock authorized for issuance under such plan by 2,500,000 shares:

For	Against	Abstain
56,317,363	3,235,200	68,410

3. The shareholders ratified the selection of Odenberg, Ullakko, Muranishi & Co. LLP as the Company s independent registered public accounting firm for the fiscal year ending December 31, 2009:

For	Against	Abstain
76,829,193	706,210	60,352

Item 5. OTHER INFORMATION

Not applicable.

Item 6. EXHIBITS

Exhibit Number	Description
10.32 + (1)	Employee Stock Purchase Plan, as amended
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.

+ Represents a management contract or compensatory plan or arrangement.

(1) Incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed with the SEC on May 21, 2009.

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.

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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
(Principal Executive Officer)

/s/ Nancy E. Pecota
Nancy E. Pecota
Vice President, Finance and Chief Financial Officer
(Principal Financial Officer)

Dated: August 5, 2009

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INDEX TO EXHIBITS

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