

ARADIGM CORP
Form 10-Q
November 14, 2006

Table of Contents

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

(Mark One)

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

For the quarterly period ended September 30, 2006

Or

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

For the transition period from to .

**Commission File Number 0-28402
Aradigm Corporation**

(Exact name of registrant as specified in its charter)

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

94-3133088
*(I.R.S. Employer
Identification No.)*

**3929 Point Eden Way
Hayward, CA 94545**
(Address of principal executive offices including zip code)
(510) 265-9000
(Registrant's telephone number, including area code)

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

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

Large accelerated filer Accelerated filer Non-accelerated filer

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

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

(Class)
Common

(Outstanding at October 31, 2006)
14,776,412

**ARADIGM CORPORATION
TABLE OF CONTENTS**

	Page
<u>PART I. FINANCIAL INFORMATION</u>	3
<u>Item 1. Financial Statements:</u>	3
<u>Condensed Balance Sheets at September 30, 2006 and December 31, 2005 (unaudited)</u>	3
<u>Condensed Statements of Operations for the three months ended September 30, 2006 and 2005 (unaudited)</u>	4
<u>Condensed Statements of Operations for the nine months ended September 30, 2006 and 2005 (unaudited)</u>	5
<u>Condensed Statements of Cash Flows for the nine months ended September 30, 2006 and 2005 (unaudited)</u>	6
<u>Notes to Condensed Financial Statements (unaudited)</u>	7
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	16
<u>Item 3. Quantitative and Qualitative Disclosure About Market Risk</u>	31
<u>Item 4. Controls and Procedures</u>	31
<u>PART II. OTHER INFORMATION</u>	32
<u>Item 1A. Risk Factors</u>	32
<u>Item 6. Exhibits</u>	42
<u>Signatures</u>	43
<u>EXHIBIT 31.1</u>	
<u>EXHIBIT 31.2</u>	
<u>EXHIBIT 32.1</u>	

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

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

	September 30, 2006 (Unaudited)	December 31, 2005 (Note 1)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 32,280	\$ 27,694
Short-term investments	504	
Receivables	623	400
Current portion of notes receivable from officers and employees		62
Prepaid expenses and other current assets	790	874
Total current assets	34,197	29,030
Property and equipment, net	2,471	9,875
Non-current portion of notes receivable from officers and employees	151	129
Other assets	451	463
Total assets	\$ 37,270	\$ 39,497
LIABILITIES, CONVERTIBLE PREFERRED STOCK AND SHAREHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 705	\$ 3,034
Accrued clinical and cost of other studies	205	398
Accrued compensation	2,471	3,814
Deferred revenue	104	222
Other accrued liabilities	496	475
Total current liabilities	3,981	7,943
Non-current portion of deferred rent	927	714
Note payable to related party	7,593	
Commitments and contingencies		
Convertible preferred stock, no par value; 2,050,000 shares authorized; issued and outstanding shares: 1,544,626 at September 30, 2006 and December 31, 2005; liquidation preference of \$41,866 at September 30, 2006 and December 31, 2005	23,669	23,669
Shareholders' equity:		
Common stock, no par value; authorized shares; 100,000,000 at September 30, 2006 and 150,000,000 at December 31, 2005; issued and outstanding shares: 14,776,412 at September 30, 2006 and 14,562,809 at December 31, 2005	283,578	282,004
Accumulated other comprehensive income	3	5

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Accumulated deficit	(282,481)	(274,838)
Total shareholders' equity	1,100	7,171
Total liabilities, convertible preferred stock and shareholders' equity	\$ 37,270	\$ 39,497

See accompanying Notes to Condensed Financial Statements

3

Table of Contents

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

	Three months ended	
	September 30,	
	2006	2005
Contract and milestone revenues (including amounts from related parties 2006 - \$9 2005 - \$200)	\$ 1,126	\$ 719
Operating expenses:		
Research and development	4,547	6,471
General and administrative	3,514	2,326
Restructuring and asset impairment	347	
Total operating expenses	8,408	8,797
Loss from operations	(7,282)	(8,078)
Gain on sale of patent and royalty interest (to related parties)	20,000	
Interest income	459	342
Interest expense	(95)	
Other income (expense)	(7)	8
Net income (loss)	\$ 13,075	\$ (7,728)
Basic net income (loss) per common share	\$ 0.89	\$ (0.53)
Diluted net income (loss) per common share	\$ 0.82	\$ (0.53)
Shares used in computing basic net income (loss) per common share	14,660	14,518
Shares used in computing diluted net income (loss) per common share	15,982	14,518

See accompanying Notes to Condensed Financial Statements

Table of Contents

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

	Nine months ended September 30,	
	2006	2005
Contract and milestone revenues (including amounts from related parties: 2006 - \$59; 2005 - \$7,911)	\$ 4,006	\$ 9,645
Operating expenses:		
Research and development	17,645	20,858
General and administrative	9,051	8,274
Restructuring and asset impairment	5,717	
Total operating expenses	32,413	29,132
Loss from operations	(28,407)	(19,487)
Gain on sale of patent and royalty interest (to related parties)	20,000	
Interest income	839	980
Interest expense	(101)	
Other income (expense)	26	(37)
Net loss	\$ (7,643)	\$ (18,544)
Basic and diluted net (loss) per common share	\$ (0.52)	\$ (1.28)
Shares used in computing basic and diluted net (loss) per common share	14,625	14,497

See accompanying Notes to Condensed Financial Statements

Table of Contents

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

	Nine months ended	
	September 30,	
	2006	2005
Cash flows from operating activities:		
Net loss	\$ (7,643)	\$ (18,544)
Adjustments to reconcile net loss to cash used in operating activities:		
Non-cash asset impairment charge on property and equipment	4,014	
Depreciation and amortization	698	1,074
Stock-based compensation expense related to employee stock options and employee stock purchases	1,286	
Loss on retirement and sale of property and equipment	21	25
Cost of warrants and stock options for services		94
Amortization of deferred compensation		10
Amortization and accretion of investments		6
Gain on sale of patents and royalty interest	(20,000)	
Changes in operating assets and liabilities:		
Receivables	(222)	(187)
Prepaid and other current assets	84	629
Other assets	12	(111)
Accounts payable	(2,329)	(975)
Accrued compensation	(1,344)	421
Other accrued liabilities	(79)	(795)
Deferred rent	214	(1,283)
Deferred revenue	(118)	(7,201)
Net cash used in operating activities	(25,406)	(26,837)
Cash flows from investing activities:		
Capital expenditures	(1,329)	(4,047)
Proceeds from the sale of property and equipment	4,000	50,292
Purchases of available-for-sale investments	(507)	(5,330)
Proceeds from maturities and sales of available-for-sale investments		4,457
Proceeds from sale of patents and royalty interest	20,000	
Net cash provided by (used in) investing activities	(22,164)	45,372
Cash flows from financing activities:		
Proceeds from issuance of note payable to related party	7,500	
Proceeds from issuance of common stock, net	286	457
Proceeds from exercise of options and warrants for common stock	2	42
Payments received on notes receivable from officers and employees	40	58
Net cash provided by financing activities	7,828	557

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Net increase in cash and cash equivalents	4,586	19,092
Cash and cash equivalents at beginning of period	27,694	14,308
Cash and cash equivalents at end of period	\$ 32,280	\$ 33,400

See accompanying Notes to Condensed Financial Statements

6

Table of Contents

ARADIGM CORPORATION
NOTES TO THE UNAUDITED CONDENSED FINANCIAL STATEMENTS
September 30, 2006

1. Organization and Basis of Presentation

Organization

Aradigm Corporation (the Company) is a California corporation focused on the development and commercialization of a portfolio of drugs delivered by inhalation for the treatment of severe respiratory diseases by pulmonologists. The Company's principal activities to date have included obtaining financing, recruiting management and technical personnel, securing operating facilities, conducting research and development, and expanding commercial production capabilities. The Company does not anticipate receiving any revenue from the sale of products in the upcoming year. The Company's ability to continue its development and commercialization activities is dependent upon the ability of management to obtain additional financing as required. The Company operates as a single operating segment.

Basis of Presentation

The accompanying unaudited condensed financial statements have been prepared in accordance with U.S. generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. generally accepted accounting principles have been condensed or omitted pursuant to the Securities and Exchange Commission's rules and regulations. In the opinion of management, the financial statements reflect all adjustments, which are only of a normal recurring nature, necessary for a fair presentation. The accompanying condensed financial statements should be read in conjunction with the financial statements and notes thereto included with the Company's Annual Report on Form 10-K for the year ended December 31, 2005, as filed with the Securities and Exchange Commission. 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, 2005 has been derived from the audited financial statements at that date, but does not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements.

2. Summary of Significant Accounting Policies

Use of Estimates

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

Revenue Recognition

Contract revenues consist of revenues from collaboration agreements and feasibility studies. The Company recognizes revenues under the provisions of the Securities and Exchange Commission issued Staff Accounting Bulletin, or SAB, No. 104, Revenue Recognition. Under collaboration agreements, revenues are recognized as costs are incurred. Deferred revenue represents the portion of all refundable and nonrefundable research payments received that have not been earned. In accordance with contract terms, milestone payments from collaborative research agreements are considered reimbursements for costs incurred under the agreements and, accordingly, are generally recognized as revenues either upon the completion of the milestone effort when payments are contingent upon completion of the effort or are based on actual efforts expended over the remaining term of the agreements when payments precede the required efforts. Costs of contract revenues are approximately equal to or are greater than such revenues.

Table of Contents

These costs are included in research and development expenses when incurred. Refundable development and license fee payments are deferred until the specified performance criteria are achieved. Refundable development and license fee payments are generally not refundable once the specific performance criteria are achieved and accepted.

Impairment or Disposal of Long-Lived Assets

In accordance with Statement of Financial Accounting Standard, or 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. The Company recorded a non-cash impairment charge of \$4.0 million during the nine months ended September 30, 2006 related to the Company's estimate of the net realizable value of the Intraject-related assets, based on the expected sale of those assets. (See note 8 and note 10)

Recent Accounting Pronouncements

In September 2006, the SEC Staff published Staff Accounting Bulletin (SAB) No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, (SAB 108). SAB 108 addresses quantifying the financial statement effects of misstatements and considering the effects of prior year uncorrected errors on the income statements as well as the balance sheets. SAB 108 does not change the requirements under SAB 99 regarding qualitative considerations in assessing the materiality of misstatements. The Company will adopt SAB 108 in the fourth quarter of 2006 and is currently evaluating the impact on its financial statements from the adoption of this guidance.

In September 2006, the FASB issued FASB Statement (SFAS) No. 157, *Fair Value Measurement*, (SFAS 157). SFAS 157 provides enhanced guidance for using fair value to measure assets and liabilities. The guidance clarifies the principle for assessing fair value based on the assumptions market participants would use when pricing the asset or liability. In support of this principle, the guidance establishes a fair value hierarchy that prioritizes the information used to develop those assumptions. The fair value hierarchy gives the highest priority to quoted prices in active markets and the lowest priority to unobservable data such as companies' own data. Under this guidance, fair value measurements would be separately disclosed by level within the fair value hierarchy. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company is currently evaluating SFAS 157 and expects to adopt this guidance beginning on January 1, 2008.

3. Stock-Based Compensation

Prior to January 1, 2006, the Company accounted for its stock-based employee compensation arrangements under the intrinsic value method prescribed by Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* (APB No. 25), as allowed by SFAS No.123, *Accounting for Stock-Based Compensation* (SFAS No. 123), as amended by SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure* (SFAS No. 148). As a result, no expense was recognized for options to purchase the Company's common stock that were granted with an exercise price equal to fair market value at the date of grant and no expense was recognized in connection with purchases under the Company's employee stock purchase plan.

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123 (revised 2004) *Share-Based Payment* (SFAS No. 123R), which replaces SFAS No. 123 and supersedes APB No. 25. SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options, restricted stock awards and employee stock purchases related to the Company's employee stock purchase plan, to be recognized in the financial statements based on their fair values. Subsequent to the effective date, the pro forma disclosures previously permitted under SFAS No. 123 are no longer an alternative to financial statement recognition. Effective January 1, 2006, the Company has adopted SFAS No. 123R using the modified-prospective transition method. Under this method, compensation cost recognized during the three-month and nine-month periods ended September 30, 2006 includes: (a) compensation cost for all

Table of Contents

share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS No. 123 amortized on a straight-line basis over the options vesting period, and (b) compensation cost for all share-based payments, including employee stock options, restricted stock awards and employee stock purchases related to the Company's employee stock purchase plan, granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123R amortized on a straight-line basis over the awards vesting period. Results for prior periods have not been restated. As a result of adopting SFAS No. 123R on January 1, 2006, the Company's net loss for the three-month and nine month periods ended September 30, 2006 is higher by \$425,000 and \$1.3 million respectively, than if it had continued to account for stock-based employee compensation under APB No.25. Basic and diluted net loss per common share for the three-month and nine-month periods ended September 30, 2006 are \$0.03 and \$0.09 higher respectively, than if the Company had continued to account for share based compensation under APB No.25. As stock-based compensation expense recognized in the statement of operations for the periods subsequent to the adoption of SFAS No. 123R is based on awards ultimately expected to vest, it has been reduced for estimated forfeitures. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In the Company's pro forma information required under SFAS No. 123 for the periods prior to January 1, 2006, the Company accounted for forfeitures as they occurred. Since the Company continues to operate at a net loss, the adoption of SFAS No.123R had no tax-related effects on cash flow from operations and cash flow from financing activities for the three-month and nine-month periods ended September 30, 2006.

Employee Stock Plans

As of September 30, 2006, the Company had outstanding shares or options under the following share-based compensation plans:

2005 Equity Incentive Plan

The 1996 Equity Incentive Plan (the "1996 Plan") and the 2005 Equity Incentive Plan (the "2005 Plan"), which amended, restated and retitled the 1996 Plan, were adopted to provide a means by which 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, scientific advisory board members and consultants of the Company are eligible to participate in the 2005 Plan.

In April 1996, the Company's Board of Directors adopted and the Company's shareholders approved the 1996 Plan, which amended and restated an earlier stock option plan. The 1996 Plan reserved 960,000 shares for future grants. During May 2001, the Company's shareholders approved an amendment to the Plan to include an evergreen provision. In 2003, the 1996 Plan was amended, to increase the maximum number of shares available for issuance under the evergreen feature of the 1996 Plan by 400,000 shares to 2,000,000 shares. The evergreen provision automatically increased the number of shares reserved under the 1996 Plan, subject to certain limitations, by 6% of the issued and outstanding shares of common stock of the Company or such lesser number of shares as determined by the board of directors on the date of the annual meeting of shareholders of each fiscal year beginning 2001 and ending 2005.

Options granted under the 1996 Plan may be immediately exercisable if permitted in the specific grant approved by the Company's board of directors and, if exercised early, the issued shares may be subject to repurchase provisions. The shares acquired generally vest over a period of four years from the date of grant. The 1996 Plan also provides for a transition from employee to consultant status without termination of the vesting period as a result of such transition. Any unvested stock issued is subject to repurchase agreements whereby the Company has the option to repurchase unvested shares upon termination of employment at the original issue price. The common stock subject to repurchase has voting rights but does not have resale rights prior to vesting. The Company has repurchased a total of 7,658 shares in accordance with these agreements through December 31, 1998. Subsequently, no grants with early exercise provisions have been made under the 1996 Plan and no shares have been repurchased.

In March 2005, the Company's board of directors adopted and in May 2005 the Company's shareholders approved the 2005 Plan. All outstanding awards granted under the 1996 Plan remain subject to the terms of the 1996 Plan. All stock awards granted on or after the adoption date are subject to the terms of the 2005

Table of Contents

Plan. No shares were added to the share reserve under the 2005 Plan other than the shares available for future issuance under the 1996 Plan. Pursuant to the 2005 Plan, the Company initially had 2,918,638 shares of common stock available for future issuance. Options (net of canceled or expired options) covering an aggregate of 1,999,252 shares of the Company's Common Stock had been granted under the 1996 Plan, and 919,386 shares became available for future grant under the 2005 Plan. In March 2006 the Company's board of directors amended and in May 2006 the Company's shareholders approved the amendment to the 2005 Plan, increasing the shares of common stock authorized for issuance by 2,000,000.

Options granted under the 2005 Plan expire no later than 10 years from the date of grant. Options granted under the 2005 Plan may be either incentive or non-statutory stock options. For incentive and non-statutory stock option grants, the option price shall be at least 100% and 85%, respectively, of the fair value on the date of grant, as determined by the Company's board of directors. If at any time the Company grants an option, and the optionee directly or by attribution owns stock possessing more than 10% of the total combined voting power of all classes of stock of the Company, the option price shall be at least 110% of the fair value and shall not be exercisable more than five years after the date of grant.

Options granted under the 2005 Plan may be immediately exercisable if permitted in the specific grant approved by the board of directors and, if exercised early may be subject to repurchase provisions. The shares acquired generally vest over a period of four years from the date of grant. The 2005 Plan also provides for a transition from employee to consultant status without termination of the vesting period as a result of such transition. Under the 2005 Plan, employees may exercise options in exchange for a note payable to the Company, if permitted under the applicable grant. As of September 30, 2006 there were no outstanding notes receivable from shareholders. Any unvested stock issued is subject to repurchase agreements whereby the Company has the option to repurchase unvested shares upon termination of employment at the original issue price. The common stock subject to repurchase has voting rights but cannot be resold prior to vesting. No grants with early exercise provisions have been made under the 2005 Plan and no shares have been repurchased.

During 2006, the Company granted options to purchase 2,361,000 shares of common stock under the 2005 Plan. As of September 30, 2006, the Company had 1,293,151 shares of common stock available for future issuance under the 2005 Plan (including 22,157 shares forfeited under restricted stock awards).

1996 Non-Employee Directors' Plan

The 1996 Non-Employee Directors' Stock Option Plan (the Directors' Plan) had 45,000 shares of common stock authorized for issuance. Options granted under the Directors' Plan expire no later than 10 years from date of grant. The option price shall be at 100% of the fair value on the date of grant as determined by the board of directors. The options generally vest quarterly over a period of one year. During 2000, the board of directors approved the termination of the Directors' Plan. No more options can be granted under the plan after its termination. The termination of the Directors' Plan had no effect on the options already outstanding. There was no activity in the Directors' Plan during the year ended December 31, 2005 or the nine months ended September 30, 2006. As of September 30, 2006, options to purchase an aggregate of 21,186 remain outstanding with exercise prices ranging from \$41.25 to \$120.63, with no additional shares available for grant.

Employee Stock Purchase Plan

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

As of September 30, 2006 a total of 709,153 shares have been issued under the Purchase Plan, leaving a balance of 340,847 shares available for future issuance.

Table of Contents***Pro Forma Information for Periods Prior to Adoption of SFAS No.123R***

The following table illustrates the effect on net loss and net loss per common share had the Company applied the fair value recognition provisions of SFAS No. 123 to account for the Company's employee stock option and employee stock purchase plans for the three and nine months ended September 30, 2005. For purposes of pro forma disclosure, the estimated fair value of the stock awards, as prescribed by SFAS No. 123, is amortized, on a straight line basis, to expense over the vesting period of such awards (in thousands, except per share data):

	Three months ended September 30, 2005	Nine months ended September 30, 2005
Net loss, as reported	\$ (7,728)	\$ (18,544)
Add: Stock-based employee compensation expense included in reported net loss	3	10
Less: Total stock-based employee compensation expense determined under fair value method	(827)	(2,432)
Pro forma net loss	\$ (8,552)	\$ (20,966)
Basic and diluted net loss per share, as reported	\$ (0.53)	\$ (1.28)
Basic and diluted pro forma loss per share	\$ (0.59)	\$ (1.45)

Note that the above pro forma disclosure was not presented for the three and nine months ended September 30, 2006 because stock-based employee compensation has been accounted for and recognized in the statement of operations using the fair value recognition method under SFAS No. 123R for these periods.

Valuation Assumptions

SFAS No.123 and SFAS No.123R require companies to estimate the fair value of stock-based payment awards on the date of grant using an option-pricing model. The Company has elected to use the Black-Scholes option-pricing model to determine the fair-value of stock based awards under SFAS No.123 and SFAS No.123R. The Black-Scholes option-pricing model incorporates various assumptions including volatility, expected life, and risk-free interest rates. The expected volatility is based on the historical volatility of the Company's common stock over the most recent period commensurate with the expected life of the Company's stock options. The expected life of an award is based on historical experience and on the terms and conditions of the stock awards granted to employees.

The assumptions used for the three and nine months ended September 30, 2006 and 2005 and the resulting estimates of weighted-average fair value per share of options granted and shares purchased during these periods are as follows:

Table of Contents

	Three months ended September 30,		Nine months ended September 30,	
	2006	2005	2006	2005
Employee Stock Options				
Dividend yield	0.0%	0.0%	0.0%	0.0%
Volatility factor	87.4%	86.3%	86.7%	97.8%
Risk-free interest rate	4.8%	4.1%	4.9%	3.7%
Expected life (years)	4.2	4.0	4.2	4.0
Weighted-average fair value of options granted during the periods	\$ 1.22	\$ 3.50	\$ 1.42	\$ 4.20
Employee Stock Purchase Plan				
Dividend yield	0.0%	0.0%	0.0%	0.0%
Volatility factor	85.7%	87.3%	85.7%	87.3%
Risk-free interest rate	4.8%	3.5%	4.8%	3.5%
Expected life (years)	0.7	1.2	0.7	1.2
Weighted-average fair value of employee stock purchases during the periods	\$ 1.33	\$ 2.67	\$ 1.33	\$ 2.67
Adoption of SFAS No.123R				

The following table shows the effect of stock-based compensation expense included in the condensed statement of operations under SFAS No.123R for the three and nine months ended September 30, 2006 (in thousands, except per share data):

	Three months ended September 30, 2006	Nine months ended September 30, 2006
Costs and expenses:		
Research and development	\$ 196	\$ 665
General and administrative	229	614
Total stock-based compensation expense	\$ 425	\$ 1,279
Impact on basic and diluted net loss per share	\$ (0.03)	\$ (0.09)

There was no capitalized stock-based employee compensation cost as of September 30, 2006. Since the Company incurred net losses in 2006, there was no recognized tax benefit during the three and nine months ended September 30, 2006 associated with stock-based compensation expense.

For restricted common stock issued at discounted prices, the Company recognizes compensation expense over the vesting period for the difference between the exercise or purchase price and the fair market value on the measurement date. There are 101,405 shares subject to restricted share awards issued and outstanding as of September 30, 2006. Total compensation expense for restricted stock awards recognized by the Company under SFAS No. 123R was \$25,374 and \$66,999 for the three and nine months ended September 30, 2006, respectively.

Stock Option Activity

A summary of the status of the Company's stock option plans at September 30, 2006 and changes during the nine months then ended is presented in the table below (share numbers and aggregate intrinsic value in thousands):

Table of Contents

	Number of shares	Weighted- average exercise price	Weighted- average remaining contractual life (in years)	Aggregate intrinsic value \$
Options outstanding at January 1, 2006	1,730	\$ 19.47	7.10	\$
Options granted	2,361	2.15		
Options exercised	(645)	2.83		
Options cancelled	(836)	10.18		
Options outstanding at September 30, 2006	3,254	9.29	8.4	120
Options exercisable at September 30, 2006	1,294	\$ 19.92	6.48	\$ 30

During the three and nine months ended September 30, 2006, the Company granted options to purchase approximately 1,216,100 and 2,361,000 shares of common stock respectively, with an estimated weighted-average fair value of \$1.22 per share and \$1.42 per share, respectively, on the date of grant. There were no options exercised during the three months ended September 30, 2006.

The following table summarizes information about stock options outstanding and exercisable at September 30, 2006:

Range of Exercise Price	Options Outstanding			Options Exercisable	
	Number outstanding (in thousands)	Weighted- average remaining contractual life (in years)	Weighted- average exercise price	Number exercisable (in thousands)	Weighted- Average Exercise Price
\$1.29-\$1.70	616	9.71	\$ 1.50	98	\$ 1.38
\$1.80-\$1.80	685	9.91	\$ 1.80	91	\$ 1.80
\$1.87-\$1.87	500	9.86	\$ 1.87	0	\$ 0.00
\$3.14-\$5.20	330	8.54	\$ 3.93	103	\$ 4.61
\$5.30-\$5.95	330	8.05	\$ 5.65	238	\$ 5.64
\$6.25-\$17.20	335	6.78	\$ 11.76	306	\$ 11.78
\$17.25-\$60.00	331	4.56	\$ 28.44	331	\$ 28.44
\$60.31-\$112.50	120	2.67	\$ 81.49	120	\$ 81.49
\$115.00-\$115.00	1	4.08	\$ 115.00	1	\$ 115.00
\$120.63-\$120.63	7	3.36	\$ 120.63	7	\$ 120.63
	3,254			1,294	

The weighted-average period over which compensation expense related to these options is expected to be recognized is 1.39 years.

4. Net Income (Loss) Per Share

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

	Three months ended September 30, 2006		Nine months ended September 30, 2006	
	2006	2005	2006	2005
Numerator:				
Net income (loss)	\$ 13,075	\$ (7,728)	\$ (7,643)	\$ (18,544)
Denominator:				
Basic Weighted average number of common shares outstanding	14,660	14,518	14,625	14,497
Effect of dilutive securities:				
Restricted stock awards	86			
Convertible preferred stock	1,236			
Shares used in calculating diluted net income (loss) per share	15,982	14,518	14,625	14,497
Basic net income (loss) per common share	0.89	(0.53)	(0.52)	(1.28)
Diluted net income (loss) per common share	0.82	(0.53)	(0.52)	(1.28)

Table of Contents

The effects of including the incremental shares associated with options and warrants are antidilutive, and are not included in diluted weighted average common shares outstanding for the three months ended September 30, 2006. For the three months ended September 30, 2005 and nine months ended September 30, 2006 and 2005, the Company excluded common stock equivalents consisting of outstanding stock options from the calculation of diluted loss per share because these securities were anti-dilutive due to the net loss in the respective period. The following securities were excluded from the calculation of diluted loss per share for the three months ended September 30, 2006 and 2005 and nine months ended September 30, 2006 and 2005 as their effect would be anti-dilutive (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2006	2005	2006	2005
Common stock equivalents from stock options	2,919	1,654	2,232	1,730
Convertible shares		1,236	1,236	1,236
Unearned restricted stock			86	
Warrants to purchase common shares	2,120	2,130	2,120	2,130

5. Comprehensive Income (Loss)

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

	Three months ended September 30,		Nine months ended September 30,	
	2006	2005	2006	2005
Net income (loss)	\$ 13,075	\$ (7,728)	\$ (7,634)	\$ (18,544)
Other comprehensive income (loss):				
Change in unrealized gain (loss) on available-for-sale securities	4	4	(2)	3
Comprehensive income (loss)	\$ 13,079	\$ (7,724)	\$ (7,636)	\$ (18,541)

6. Cash, Cash Equivalents and Investments

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

	September 30, 2006	December 31, 2005
Cash and cash equivalents:		
Money market fund	\$ 1,426	\$ 1,321
Commercial paper	30,854	26,373
	\$ 32,280	\$ 27,694
Short-term investments:		
Corporate and government notes	\$ 504	\$

The Company considers all highly liquid investments purchased with a maturity of three months or less to be cash equivalents. All short-term investments at September 30, 2006 mature in less than one year. The Company places its cash and cash equivalents in money market funds, commercial paper and corporate and government notes.

Table of Contents**7. Reverse Stock Split**

On January 4, 2006, the Company filed a Certificate of Amendment to its Amended and Restated Certificate of Incorporation with the California Secretary of State effecting a 1-for-5 reverse split of the Company's common stock. All share and per share amounts have been retroactively restated in the accompanying condensed financial statements, notes to the condensed financial statements and elsewhere in this document for all periods presented.

8. Restructuring and Asset Impairment

On May 15, 2006 the Company announced the implementation of a strategic restructuring of its business operations to focus resources on advancing the current product pipeline and developing products focused on respiratory disease, leveraging the Company's core expertise and intellectual property. The Company accounted for the restructuring activity in accordance with FAS No. 146, *Accounting for Costs Associated with Exit or Disposal*. The restructuring included a reduction in force of 36 employees, the majority of which were research personnel. For the three and nine months ended September 30, 2006, the Company recorded a net restructuring charge of \$333,000 and \$1.7 million respectively, primarily related to the reduction in its workforce. This expense is included in the restructuring and asset impairment expense line item on the statement of operations. On August 25, 2006, the Company recorded an additional restructuring charge of \$566,000 in severance expense related to the resignation of V. Bryan Lawlis, the Company's former President and Chief Executive Officer, and Bobba Venkatadri, the Company's former Senior Vice President of Operations, offset by a reduction of previously recognized severance costs of \$233,000 related to the departure of employees in connection with the sale of Intraject-related assets to Zogenix. The Company expects to pay the severance-related expenses in full by the end of 2007. The accrual for the employee related expenses is included in accrued compensation in the accompanying balance sheet as of September 30, 2006.

The Company recorded non-cash impairment charges of \$4.0 million during the three months ended June 30, 2006, which were incurred to write down its Intraject-related assets to their net realizable value. The net realizable value did not include any potential future contingent milestones or royalties. The Company sold these assets to Zogenix during the three months ended September 30, 2006 for an initial payment of \$4.0 million and recorded an additional impairment charge of \$14,000. (See note 10) The following table summarizes the adjustments to the Company's restructuring and asset impairment expenses during the nine months ended September 30, 2006 (in thousands):

Type of Liability	Restructuring Charges	Non-cash impairment	Adjustments	Payments	Balance at September 30, 2006
Nine months ended September 30, 2006					
Severance and related benefits	\$ 1,866	\$	\$ (233) ²	\$ (948)	\$ 685
Out-placement services	70			(42)	28
Impairment on Intraject-related assets		4,014			
	\$ 1,936	\$ 4,014	\$ (233)	\$ (990)	\$ 713

1. Initial restructuring charges of \$1.3 million and an increase of \$566,000 in severance charges related

to V. Bryan Lawlis the Company's former President and Chief Executive Officer, and Bobba Venkatadri the Company's former Senior Vice President of Operations.

2. Reduction of \$233,000 related to former employees transferred as part of the sale of Intraject-related assets to Zogenix.

9. Related Party Transactions

Novo Nordisk, A/S and its affiliates, Novo Nordisk Pharmaceuticals, Inc. and NNDT, are considered related parties, and at September 30, 2006 owned approximately 10.8% of the Company's total outstanding common stock (9.9% on an as-converted basis).

On July 3, 2006, the Company and Novo Nordisk A/S entered into a Second Amended and Restated License Agreement (the License Agreement) to reflect: (i) the transfer by the Company of certain intellectual property, including all right, title and interest to its patents that contain claims that pertain generally to breath control or specifically to the pulmonary delivery of monomeric insulin and monomeric insulin analogs, together with interrelated patents, which are linked via terminal disclaimers, as well as certain pending patent applications and continuations thereof by the Company for a cash payment to the

Table of Contents

Company of \$12.0 million, with the Company retaining exclusive, royalty-free control of these patents outside the field of glucose control; (ii) a reduction by 100 basis points of each royalty rate payable by Novo Nordisk to the Company for a cash payment to the Company of \$8.0 million; and (iii) a loan to the Company in the principal amount of \$7.5 million.

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

10. Sale of Intraject-Related Assets

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

On August 25, 2006, pursuant to the sale of its Intraject platform, the Company entered into an agreement with Zogenix for transitional support through December 31, 2006. The Company is to be reimbursed for the provision of consulting services, information technology and document control support and office facilities. For the three months ended September 30, 2006 the Company recorded revenues of \$360,000 from Zogenix.

11. Subsequent Event

On October 24, 2006 the Company announced that it had filed a preliminary registration statement on Form S-1 with the Securities and Exchange Commission for a proposed public offering of up to twenty-three million shares (including an over-allotment option of up to three million shares) of its common stock. The Company expects proceeds from the offering will be used primarily to fund the Company's ARD-3100 (liposomal ciprofloxacin) program, to complete the development of its Essence delivery platform and for general corporate and working capital purposes. Upon completion of the proposed public offering, the Company expects all shares of its convertible preferred stock will be converted to common stock and the associated liquidation preference will be eliminated.

On November 8, 2006 the Company was informed by the Nasdaq Listing Qualifications Panel, that the Company's shares were to be delisted from the Nasdaq capital market, due to non-compliance with the continued listing standards. The Company intends to request a review of his decision, but neither said request or a granting of a review will stay the delisting. The company expects to be immediately eligible for quotation on the Pink Sheets, and will investigate other quotation and trading alternatives.

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

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

Table of Contents

Our business is subject to significant risks including, but not limited to, 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.

Investors are cautioned not to place undue reliance on the forward-looking statements contained herein. We undertake no obligation to update these forward-looking statements in light of events or circumstances occurring after the date hereof or to reflect the occurrence of unanticipated events.

Overview

We are an emerging specialty pharmaceutical company focused on the development and commercialization of a portfolio of drugs delivered by inhalation for the treatment of severe respiratory diseases by pulmonologists. Over the last decade, we have invested a large amount of capital to develop drug delivery technologies, particularly the development of a significant amount of expertise in pulmonary drug delivery. We have also invested considerable effort into the generation of a large volume of laboratory and clinical data demonstrating the performance of our AERx pulmonary drug delivery platform. We have not been profitable since inception and expect to incur additional operating losses over at least the next several years as we expand product development efforts, preclinical testing and clinical trial activities and possible sales and marketing efforts and as we secure production capabilities from outside contract manufacturers. To date, we have not had any significant product sales and do not anticipate receiving any revenues from the sale of products for at least the next several years. As of September 30, 2006 we had an accumulated deficit of \$282.5 million. Historically we have funded our operations primarily through private placements and public offerings of our capital stock, proceeds from equipment lease financings, license fees and milestone payments from collaborators, proceeds from the January 2005 restructuring transaction with Novo Nordisk and interest earned on investment. In 2006, we received \$27.5 million in proceeds from another restructuring agreement transaction with Novo Nordisk, and \$4.0 million from the sale of assets.

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

Restructured Relationship with Novo Nordisk

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

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

NNDT effective January 26, 2005, including the following:

an amended and restated license agreement amending the development and license agreement previously in place with Novo Nordisk, expanding Novo Nordisk's development and manufacturing rights to the AER[®] iDMS program and providing for royalties to us on future AERx[®] iDMS net sales in lieu of a percentage interest in the gross profits from the commercialization of the AERx[®] iDMS, which royalties run until the later of last patent expiry or

Table of Contents

last use of our intellectual property and which apply to future enhancements or generations of our AERx[®] delivery technology;

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

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

As a result of this transaction, we recorded our final project development revenues from Novo Nordisk in the first quarter of 2005 and, as we were no longer obligated to continue work related to the non-refundable milestone payment from Novo Nordisk in connection with the commercialization of AERx[®], we recognized the remaining balance of the deferred revenue associated with the milestone of \$5.2 million as revenue in the first quarter of 2005. In 2005 we recorded revenues of approximately \$727,000 from NNDT related to transition and support agreements. As a result of this transaction, we were released from our contractual obligations relating to future operating lease payments for two buildings assigned to NNDT and accordingly reversed the deferred rent liability related to the two buildings of \$1.4 million, resulting in a reduction of operating expenses in 2005. In addition, pursuant to the restructuring agreement, we terminated a manufacturing and supply agreement and a patent cooperation agreement, each previously in place with Novo Nordisk and dated October 22, 2001.

On July 3, 2006, we further restructured our relationship with Novo Nordisk by entering into an intellectual property assignment, a royalty prepayment and an eight-year promissory note with Novo Nordisk. The promissory note was secured by the royalty payments on any AERx[®] iDMS sales by Novo Nordisk under the license with us. The key features of this restructuring include:

our transfer to Novo Nordisk of the ownership of 23 issued United States patents and their corresponding non-United States counterparts, if any, as well as related pending applications, in exchange for \$12.0 million paid to us in cash. We retained exclusive, royalty-free control of these patents outside the field of glucose control and will continue to be entitled to royalties with respect to any inhaled insulin products marketed or licensed by Novo Nordisk.

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

our issuance of an eight-year promissory note to Novo Nordisk in connection with our receipt from Novo Nordisk of a loan in the principal amount of \$7.5 million that will be payable to Novo Nordisk in three equal annual payments commencing in six years at a five percent annual interest rate. Our obligations under the note are secured by royalty payments upon any commercialization of the AERx[®] iDMS product.

We and Novo Nordisk continue to cooperate and share in technology development, as well as intellectual property development and defense. Both we and Novo Nordisk have access to any developments or improvements the other might make to the AERx delivery system, within their respective fields of use. Novo Nordisk also remains a substantial holder of our common stock and is restricted from disposing of the common stock until January 1, 2009 or the earlier occurrence of certain specified events.

In August 2006, Novo Nordisk announced that it had filed a lawsuit against Pfizer claiming that Pfizer's inhaled insulin product, Exubera, which Pfizer has been developing with Nektar Therapeutics, infringes a patent originally owned by us and now owned by Novo Nordisk with rights retained by us

Table of Contents

outside the field of glucose control. Depending on the outcome of this lawsuit, which is highly uncertain, we could be entitled to a portion of any proceeds received by Novo Nordisk from a favorable outcome.

Purchase and Sale of Intraject Technology

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

In October 2004, we announced positive results from the clinical performance verification trial of the Intraject needle-free delivery system. Following the results from the configuration trial, we initiated a pilot pharmacokinetic study comparing Intraject with sumatriptan, a treatment for migraines, to the currently marketed needle-injected product. In June 2005, we announced results from this study, which showed that Intraject sumatriptan was bioequivalent to the marketed injectable product and that patients were able to self-administer using Intraject.

We recorded a non-cash impairment charge of \$4.0 million during the nine months ended September 30, 2006, which was incurred to write down our Intraject-related assets to their net realizable value.

In August 2006, we sold all of our assets related to the Intraject technology platform and products, including 12 United States patents along with any foreign counterparts corresponding to those United States patents, to Zogenix, a newly created private company that has some officers who were former officers of our company. Zogenix is responsible for further development and commercialization efforts of Intraject. We received a \$4.0 million initial payment and we are entitled to a milestone and royalty payments upon any commercialization of products that may be developed and sold using the Intraject technology.

Product Candidates

Products in development include both our own proprietary products and products under development with collaborators. They consist of approved drugs combined with our controlled inhalation delivery and/or

formulation technologies. The following table shows the disease indication and stage of development for each product candidate in our portfolio.

Product Candidate	Indication	Stage of Development
Proprietary Programs Under Development		
ARD-3100 (Liposomal ciprofloxacin)	Cystic Fibrosis	Preclinical
ARD-1100 (Liposomal ciprofloxacin)	Inhalation Anthrax	Preclinical
Collaborative Programs Under Development		
AERx iDMS (Insulin)	Type 1 and Type 2 Diabetes	In Phase 3
ARD-1300 (Hydroxychloroquine)	Asthma	In Phase 2
ARD-1500 (Liposomal trestatinil)	Pulmonary Arterial Hypertension	Preclinical

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

Liposomal Ciprofloxacin

Ciprofloxacin is approved by the FDA as an anti-infective agent and is widely used for the treatment of a variety of bacterial infections. Today ciprofloxacin is delivered by oral or intravenous administration. We believe that delivering this potent antibiotic directly to the lung may improve its safety and efficacy in the

Table of Contents

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

ARD-3100 Liposomal Ciprofloxacin for the Treatment of Cystic Fibrosis

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

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

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

Development

We have received orphan drug designation from the FDA for this product for the management of CF. As a designated orphan drug, liposomal ciprofloxacin is eligible for tax credits based upon its clinical development costs, as well as assistance from the FDA to coordinate study design. The designation also provides the opportunity to obtain market exclusivity for seven years from the date of New Drug Application, or NDA, approval.

We initiated preclinical studies for liposomal ciprofloxacin in 2006 and expect to initiate human clinical studies in the first half of 2007. We expect to use approximately \$20 million of the net proceeds from this offering to complete preclinical studies and fund early stage clinical trials and related manufacturing requirements for ARD-3100. In order to reach commercialization of ARD-3100, we estimate we will need to spend an additional \$15 million to \$20 million. In order to expedite anticipated time to market and increase market acceptance, we have elected to deliver ciprofloxacin via nebulizer, as most CF patients already own a nebulizer and are familiar with this method of drug delivery. We intend to examine the potential for delivery of ciprofloxacin via our AERx delivery system. We share the formulation and manufacturing development as well as the safety data developed for our inhalation anthrax program discussed below in the development of this CF opportunity. We also intend to explore the utility of

Table of Contents

liposomal ciprofloxacin for the treatment of serious infections associated with other respiratory diseases, such as chronic obstructive pulmonary disease and bronchiectasis.

ARD-1100 Liposomal Ciprofloxacin for the Treatment of Inhalation Anthrax

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

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

Development

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

If we can obtain sufficient additional funding, we would anticipate developing this drug for approval under FDA regulations relating to the approval of new drugs or biologics for potentially fatal diseases where human studies cannot be conducted ethically or practically. Unlike most drugs, which require large, well controlled Phase 3 clinical trials in patients with the disease or condition being targeted, these regulations allow for a drug to be evaluated and approved by the FDA on the basis of demonstrated safety in humans combined with studies in animal models to show effectiveness.

AERx iDMS Inhaled Insulin for the Treatment of Diabetes

AERx iDMS is being developed to control blood glucose levels in patients with diabetes. This product is currently in Phase 3 clinical trials, and our licensee, Novo Nordisk, is responsible for all remaining development, manufacturing and commercialization. We will receive royalties from any sales of this product as well as from future enhancements or generations of this technology. According to 2005 statistics from the American Diabetes Association, approximately 20.8 million Americans suffer from either Type 1 or Type 2 diabetes. Over 90% of these Americans have Type 2 diabetes, the prevalence of which is increasing dramatically due to lifestyle factors such as inappropriate diet and lack of physical activity. Patients with Type 1 diabetes do not have the ability to produce their own insulin and must administer insulin injections to survive. Patients with Type 2 diabetes are insulin resistant and unable to efficiently use the insulin that their bodies produce. While many Type 2 patients can initially maintain adequate control over blood glucose through diet, exercise and oral medications, most Type 2 patients progress within three

Table of Contents

years to where they cannot maintain adequate control over their glucose levels and insulin therapy is needed. However, given the less acute nature of Type 2 diabetes, many of these patients are reluctant to take insulin by injection despite the risks. Inadequate regulation of glucose levels in diabetes patients is associated with a variety of short and long-term effects, including blindness, kidney disease, heart disease, amputation resulting from chronic or extended periods of reduced blood circulation to body tissue and other circulatory disorders. The global market for diabetes therapies in 2005 was in excess of \$18 billion, according to Business Insights. The majority of this amount was from sales of oral antidiabetics, while insulin and insulin analogues accounted for \$7.3 billion, a 17% increase over the prior year. Sales of insulin and insulin analogues are forecast to grow to \$9.8 billion in 2011. Type 2 patients consume the majority of insulin used in the United States. We believe that when patients are provided a non-invasive delivery alternative to injection, they will be more likely to self-administer insulin as often as needed to keep tight control over their blood-glucose levels.

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

Development

Over a decade ago, we initiated research and development into the inhalation delivery of insulin to meet a major unmet medical need in the treatment of Type 1 and Type 2 diabetes: a system that could provide similar levels of safety and efficacy as injected insulin but with the added benefit of a non-invasive route of delivery. We successfully completed a Phase 1 clinical study and filed an Investigational New Drug application, or IND, relating to our AERx iDMS program in 1998. After our initial work, we entered into a collaboration for our AERx iDMS in June 1998 with a world leader in the treatment of diabetes, Novo Nordisk. From 1998 to January 2005, we received an aggregate of \$150.1 million from Novo Nordisk to fund development of the AERx delivery system for delivering insulin, production for preclinical and clinical testing and process development and scale up. In January 2005, we transferred the partially completed initial commercial production facility and associated personnel to Novo Nordisk for \$55.3 million, and Novo Nordisk assumed responsibility for continuing production and bringing the facility up to its planned capacity of 750 million dosage forms per year.

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

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

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

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

Although small declines were seen on some pulmonary function parameters following 12-24 months of dosing on AERx iDMS, these declines were not considered to be of clinical significance, and the findings are not

expected to have an impact on overall pulmonary safety of the product.

Table of Contents

The Phase 3 clinical trials are expected to include a total of approximately 3,400 Type 1 and Type 2 diabetes patients. The trials include treatment comparisons with other antidiabetics. The longest trial is expected to last 27 months. Novo Nordisk announced in October 2006 that it expects the commercial launch of the product in 2010. As with any clinical program, there are many factors that could delay the launch or could result in AERx iDMS not receiving or maintaining regulatory approval.

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

ARD-1300 *Hydroxychloroquine for the Treatment of Asthma*

The ARD-1300 program is currently in Phase 2 clinical trials and is investigating a novel aerosolized formulation of hydroxychloroquine, or HCQ, as a treatment for asthma under a collaboration with APT Pharmaceuticals, a privately held biotechnology company. Asthma is a common chronic disorder of the lungs characterized by airway inflammation, airway hyper-responsiveness or airway narrowing due to certain stimuli. Despite several treatment options, asthma remains a major medical problem associated with high morbidity and large economic costs to the society. According to the American Lung Association, asthma accounts for \$11.5 billion in direct healthcare costs annually in the United States, of which the largest single expenditure, at \$5 billion, was prescription drugs. Primary symptoms of asthma include coughing, wheezing, shortness of breath and tightness of the chest with symptoms varying in frequency and degree. According to Datamonitor, asthma affected 41.5 million people in developed countries in 2005, with 9.5 million of those affected being children. The highest prevalence of asthma occurs in the United States and the United Kingdom.

The most common treatment for the inflammatory condition causing chronic asthma is inhaled steroid therapy via metered dose inhalers, dry powder inhalers or nebulizers. While steroids are effective, they have side effects, including oral thrush, throat irritation, hoarseness and growth retardation in children, particularly at high doses and with prolonged use. HCQ is an FDA-approved drug that has been used for over 20 years in oral formulations as an alternative to steroid therapy for treatment for lupus and rheumatoid arthritis. We believe targeted delivery of HCQ to the airway will enhance the effectiveness of the treatment of asthma relative to systemic delivery while reducing side effects by decreasing exposure of the drug to other parts of the body. We believe that our ARD-1300 product candidate may potentially provide a treatment for asthma that could have anti-inflammatory properties similar to inhaled steroids but with reduced side effects as compared to long-term steroid treatment.

Development

APT has funded all activities in the development of this program to date. The ARD-1300 program has advanced into Phase 2 clinical trials following positive preclinical testing and Phase 1 clinical results. In preclinical testing, the efficacy of once-daily aerosolized HCQ was compared to that of budesonide, a leading inhaled steroid, in an asthma sheep model. Both drugs significantly suppressed the clinically relevant late phase asthmatic response and airway hyper-reactivity to a similar extent during 28 days of administration. However, the HCQ group showed significant continued suppression of these factors 14 days after cessation of treatment, with no post-treatment suppression detected in the budesonide group. We then conducted a Phase 1 clinical trial of both single dose and seven day dosing of AERx-delivered HCQ in approximately 30 healthy volunteers that indicated that AERx-delivered HCQ has a favorable safety and tolerability profile.

We began the Phase 2 clinical trial in March 2006. The Phase 2 clinical trial is a randomized, double-blind, placebo-controlled, multi-dose study in patients with asthma. The trial enrolled 100 patients with moderate-persistent asthma who were randomized to one of two treatment groups: either aerosolized placebo or aerosolized HCQ given once daily for 21 consecutive days. Both treatment groups were administered the drug via our AERx delivery system with efficacy, safety and tolerability assessments being performed throughout the study. The dosing of patients in the trial was completed in August 2006, and we are now in the data analysis phase of this trial, with the results expected to be announced by the end

Table of Contents

of 2006. The outcome of this Phase 2 clinical study will form the basis of our and APT's decision as to whether to continue this program and, if so, what the design and funding of future studies should be.

ARD-1500 Treprostinil for the Treatment of Pulmonary Arterial Hypertension

The ARD-1500 program is being developed as part of a commercial agreement with United Therapeutics and is investigating a sustained-release liposomal formulation of a prostacyclin analogue for administration using our AERx delivery system for the treatment of pulmonary arterial hypertension, or PAH. PAH is a rare disease that results in the progressive narrowing of the arteries of the lungs, causing continuous high blood pressure in the pulmonary artery and eventually leading to heart failure. According to Decision Resources, in 2003, the more than 130,000 people worldwide affected by PAH purchased \$600 million of PAH-related medical treatments and sales are expected to reach \$1.2 billion per year by 2013.

Prostacyclin analogues are an important class of drugs used for the treatment of pulmonary arterial hypertension. However, the current methods of administration of these drugs are burdensome on patients. Treprostinil is marketed by United Therapeutics under the name Remodulin and is administered by intravenous or subcutaneous infusion. CoTherix markets in the United States another prostacyclin analogue, iloprost, under the name Ventavis that is administered six to nine times per day using a nebulizer, with each treatment lasting four to six minutes. We believe administration of liposomal treprostinil by inhalation using our AERx delivery system may be able to deliver an adequate dose for the treatment of PAH in a small number of breaths. We also believe that our sustained release formulation may lead to a reduction in the number of daily administrations that are needed to be effective when compared to existing therapies. We believe that our ARD-1500 product candidate potentially could offer a non-invasive, more direct and patient-friendly approach to treatment to replace or complement currently available treatments.

Development

United Therapeutics has funded our activities in this program to date. We have completed initial preclinical testing of selected formulations and are now examining performance of the formulations in the AERx delivery system before a joint decision is taken with our collaborator as to whether and how to proceed with the next steps of the program.

Additional Potential Product Applications

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

Smoking Cessation. Based on internal work and work funded under grants from the National Institutes of Health, we are developing intellectual property in the area of smoking cessation. To date, we have two issued United States patents containing claims directed towards the use of titrated nicotine replacement therapy for smoking cessation.

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

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

Table of Contents

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

Critical Accounting Policies and Estimates

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

Revenue Recognition

Contract revenues consist of revenue from collaboration agreements and feasibility studies. We recognize revenue under the provisions of the Securities and Exchange Commission issued Staff Accounting Bulletin No. 104, Revenue Recognition (SAB 104). Under the agreements, revenue is recognized as costs are incurred. Deferred revenue represents the portion of all refundable and nonrefundable research payments received that have not been earned. In accordance with contract terms, milestone payments from collaborative research agreements are considered reimbursements for costs incurred under the agreements and, accordingly, are generally recognized as revenue either upon the completion of the milestone effort when payments are contingent upon completion of the effort or are based on actual efforts expended over the remaining term of the agreements when payments precede the required efforts. Costs of contract revenues are approximate to or are greater than such revenue and are included in research and development expenses. Refundable development and license fee payments are deferred until the specified performance criteria are achieved. Refundable development and license fee payments are generally not refundable once the specific performance criteria are achieved and accepted.

Impairment of Long-Lived Assets

We review for impairment whenever events or changes in circumstances indicate that the carrying amount of property and equipment may not be recoverable in accordance with Statement of Financial Accounting Standard No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets (SFAS No.144). Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. Future cash flows that are contingent in nature are generally not recognized. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written down to their estimated fair values and the loss is recognized on the statements of operations. We recorded a non-cash impairment charge of \$4.0 million during the nine months ended September 30, 2006 related to our estimate of the net realizable value sale of the Intraject related assets based on the expected sale of these assets.

Stock-Based Compensation Expense

Effective January 1, 2006, we adopted the fair value recognition provisions of Statement of Financial Accounting Standard No. 123 (revised 2004) *Share-Based Payment*, (SFAS No.123R) using the modified prospective transition method and, therefore, have not restated prior periods' results. Under this method, we recognize compensation expense, net of estimated forfeitures, for all stock-based payments granted after January 1, 2006 and all stock based payments granted prior to but not vested as of January 1, 2006.

Under the provisions of SFAS No. 123R, stock-based compensation cost is estimated at the grant date based on the award's fair value and is recognized as expense, net of estimated forfeitures, ratably over the requisite vesting period. We have elected to calculate an award's fair value based on the Black-Scholes option-pricing model. The Black-Scholes model requires various assumptions including expected option life and volatility. If any of the assumptions used in the Black-Scholes model or the estimated forfeiture

Table of Contents

rate change significantly, stock-based compensation expense may differ materially in the future from that recorded in the current period.

Under SFAS No. 123R, we recognized expense for stock-based compensation of \$425,000 and \$1.3 million respectively, for the three and nine months ended September 30, 2006.

Results of Operations**Three Months Ended September 30, 2006 and 2005***Revenues:*

	Three months ended September 30 (in thousands)		Change in Dollars	Change in Percent
	2006	2005		
Revenues:				
Contract revenues	\$ 1,029	\$ 638	\$ 391	61%
<i>Percentage of total revenues</i>	91%	89%		
Milestone revenues	97	81	16	20%
<i>Percentage of total revenues</i>	9%	11%		
Total revenues	\$ 1,126	\$ 719	\$ 407	57%

Total revenues consist of contract and milestone revenues. Total contract revenues increased \$391,000 for the three months ended September 30, 2006 over the comparable period in 2005 due to increases of \$438,000 from our ARD-1300 program and \$360,000 related to our consulting agreement with Zogenix, which is offset by decreases in revenues of \$191,000 from a consulting agreement with Novo Nordisk that ended on January 26, 2006, \$138,000 related to the ARD-3100 program and \$78,000 related to the AERx Pulmoshield program completed in the second quarter of 2006. Milestone revenues increased \$16,000 for the three months ended September 30, 2006 due to our ARD-1300 development program which continued from 2005. The Company expects contract revenues to decrease as it decreases its collaborative activities in favor of self-initiated development activities.

Research and Development:

	Three months ended September 30, (in thousands)		Change in Dollars	Change in Percent
	2006	2005		
Research and development expense:				
Collaborative	\$ 999	\$ 1,140	\$ (141)	(12)%
Self-initiated	3,548	5,331	(1,783)	(33)%
Total research and development expense	\$ 4,547	\$ 6,471	\$ (1,924)	(30)%

Research and development expenses include salaries, payments to contract manufacturers, and contract research organizations, contractor and consultant fees, stock-based compensation expense, and other support costs including facilities, depreciation and travel costs. Stock based compensation expense charged to research and development for the three months ended September 30, 2006 was \$196,000 due to the adoption of SFAS No.123R effective January 1, 2006.

Collaborative research and development expense decreased \$141,000 due primarily to the continuing development of our existing AERx programs including the AERx Smoking Cessation and ARD-1500 programs. Self initiated research and development expense decreased \$1.8 million due primarily to the completion of the Intraject program clinical batch registration lot activities, substantially completed at year-end 2005 and finalized in early 2006. In August 2006, we sold all of our assets related to the Intraject technology platform to Zogenix, a newly created private company that is responsible for further development and commercialization efforts of Intraject.

Table of Contents

We expect that research and development expenses will remain relatively flat, with the effects of the recent corporate restructuring initiatives somewhat offset by increased focus on self-initiated development programs such as the Liposomal Ciprofloxacin program and the other AERx programs.

General and Administrative:

	Three months ended September 30, (in thousands)			Change in Percent
	2006	2005	Change in Dollars	
General and administrative expenses	\$3,514	\$2,326	\$1,188	51%

General and administrative expenses are comprised of salaries, legal fees including those associated with the establishment and protection of our patents, insurance, marketing research, contractor and consultant fees, stock based compensation expense, and other support costs including facilities, depreciation and travel costs. Stock based compensation expense charged to general and administrative expenses for the three months ended September 30, 2006 was \$229,000 due to the adoption of SFAS No.123R effective January 1, 2006.

General and administrative expenses for the three months ended September 30, 2006 increased \$1.3 million over the comparable period in 2005 due primarily to an increase in associated legal expenses resulting from our restructuring activity and an increase in employee stock based compensation. The increase was offset by a reduction in associated costs for building and maintenance costs, labor benefits, insurance expense and marketing expense. We expect that general and administrative expenses will decrease over the next few quarters, however, it may be offset by increased legal and other expenses associated with additional financings.

Restructuring and Asset Impairment:

Restructuring and asset impairment expenses are comprised of severance related expenses including payroll, health insurance expenses, outplacement expenses and Intraject related asset impairment expenses. Severance related expense for the three months ended September 30, 2006 was \$333,000. On August 25, 2006, we recorded a restructuring charge of \$566,000 in severance expense related to the resignation of V. Bryan Lawlis, our former President and Chief Executive Officer, and Bobba Venkatadri, the Company's former Senior Vice President of Operations, which was offset by a reduction of \$233,000 related to previously recorded expense due to the departure of employees in connection with the sale of Intraject-related assets to Zogenix. We expect to pay the severance-related balance in full by the end of 2007.

Gain on sale of patents and royalty interest:

The gain on sale of patents and royalty interest reflects two transactions entered into by the Company with Novo Nordisk, a related party; (i) the transfer by the Company of certain intellectual property, including all right, title and interest to its patents that contain claims that pertain generally to breath control or specifically to the pulmonary delivery of monomeric insulin and monomeric insulin analogs, together with interrelated patents, which are linked via terminal disclaimers, as well as certain pending patent applications and continuations thereof by the Company for a cash payment to the Company of \$12.0 million, with the Company retaining exclusive, royalty-free control of these patents outside the field of glucose control; and (ii) a reduction by 100 basis points of each royalty rate payable by Novo Nordisk to the Company for a cash payment to the Company of \$8.0 million.

Table of Contents*Interest income, interest expense and other income (expense):*

	Three months ended September 30, (in thousands)		Change in Dollars	Change in Percent
	2006	2005		
Interest income, interest expense and other income (expense):				
Interest income	\$ 459	\$ 342	\$ 117	34%
Interest expense	(95)		(95)	(100)%
Other income (expense)	(7)	8	(15)	(188)%
Total interest income, interest and other expense	\$ 357	\$ 350	\$ 7	2%

Interest income for the three months ended September 30, 2006 increased over the comparable period in 2005 due to higher average invested balance. Interest expense for the three months ended September 30, 2006 consists primarily of interest expense related to the \$7.5 million note payable issued to Novo Nordisk. Other income and expense reflects loss on asset disposals.

Nine months ended September 30, 2006 and 2005*Revenues:*

	Nine months ended September 30, (in thousands)		Change in Dollars	Change in Percent
	2006	2005		
Revenues:				
Contract revenues	\$3,715	\$4,378	\$ (663)	(15%)
<i>Percentage of total revenues</i>	93%	45%		
Milestone revenues	291	5,267	(4,976)	(94%)
<i>Percentage of total revenues</i>	7%	55%		
Total Revenues	\$4,006	\$9,645	\$(5,639)	(58%)

Total revenues consist of contract and milestone revenues. Total revenues decreased \$5.7 million for the nine months ended September 30, 2006 over the comparable period in fiscal 2005 due to decreases in both contract and milestone revenues. The primary reason for the decreases in both milestone and contract revenues were the result of concluding the restructuring agreement with Novo Nordisk on January 26, 2005. In the nine months ended September 30, 2006, we recorded revenues from the transition agreement with Zogenix of \$360,000 and increased contract revenues of \$1.8 million from our AERx programs including the ARD-3100, ARD-1500, ARD-1300 and AERx Smoking Cessation programs for \$545,000, \$378,000, \$679,000 and \$166,000 respectively. This increase was primarily offset by a net decrease in contract revenues of \$2.1 million due to the restructuring agreement with Novo Nordisk and \$566,000 from a transition service agreement with Novo Nordisk that ended on January 27, 2006 and a decrease of \$170,000 in our AERx Pulmoshield program. Milestone revenues for the nine month period ended September 30, 2006 decreased by approximately \$5.0 million due primarily to the conclusion of Novo Nordisk restructuring agreement on January 26, 2005 which resulted in a decrease of \$5.2 million, offset by an increase of \$210,000 for our ARD-1300 development program.

Research and Development:

**Nine months ended
September 30,**
(in thousands)

	2006	2005	Change in Dollars	Change in Percent
Research and development expense:				
Collaborative	\$ 4,107	\$ 4,372	\$ (265)	(6)%
Self-initiated	13,538	16,486	(2,948)	(18)%
Total research and development expense	\$ 17,645	\$ 20,858	\$ (3,213)	(15)%

Research and development expenses include salaries, payments to contract manufacturers, and contract research organizations, contractor and consultant fees, stock-based compensation expense, and other support costs including facilities, depreciation and travel costs. Stock based compensation expense charged to research and development for the nine months ended September 30, 2006 was \$665,000 due to the adoption of SFAS No.123R effective January 1, 2006.

Table of Contents

The decrease in collaborative program expenses in the nine months ended September 30, 2006 was due primarily to the conclusion of the restructuring agreement with Novo Nordisk in January 2005. Similarly, the decrease in research and development expense for self-initiated projects was due primarily to a decrease in our Intraject clinical batch registration lot activities substantially completed at year-end 2005 and finalized in early 2006. In August 2006, we sold all of our assets related to the Intraject technology platform to Zogenix, a newly created private company that is responsible for further development and commercialization efforts of Intraject. We expect that our research and development expenses will remain relatively constant over the next few quarters as we redirect our focus from Intraject programs to our AERx programs.

General and Administrative:

	Nine months ended September 30, (in thousands)		Change in Dollars	Change in Percent
	2006	2005		
General and administrative expenses	\$9,051	\$8,274	\$777	9%

General and administrative expenses are comprised of salaries, legal fees including those associated with the establishment and protection of our patents, insurance, marketing research, contractor and consultant fees, stock-based compensation expense and other support costs including facilities, depreciation and travel costs. Stock-based compensation expense charged to general and administrative expenses for the nine months ended September 30, 2006 was \$614,000 due to the adoption of SFAS 123R effective January 1, 2006.

General and administrative expenses for the nine months ended September 30, 2006 increased over the comparable period in 2005 primarily as a result of legal expenses incurred related to the restructuring transaction entered into with Novo Nordisk in July 2006 and an increase in stock-based compensation. We expect that our general and administrative expenses will remain relatively constant over the next few quarters, however, there may be increased legal expenses associated with additional financings.

Restructuring and Asset Impairment:

Restructuring and asset impairment expenses are comprised of severance-related expenses including payroll, health insurance payments, outplacement expenses and Intraject-related asset impairment expenses. Severance-related expense for the nine months ended September 30, 2006 was \$1.7 million and is primarily related to the reduction in workforce announced on May 15, 2006. In addition, we recorded \$566,000 in severance expense related to the resignation of V. Bryan Lawlis, our former President and Chief Executive Officer, and Bobba Venkatadri, our former Senior Vice President of Operations, in August 2006, which was offset by a reduction in previously recorded severance expense of \$233,000 related to the departure of employees in connection with the sale of Intraject-related assets to Zogenix. We expect to pay the severance related balance in full by the end of 2007. The asset impairment charge of \$4.0 million during the nine months ended September 30, 2006 is related to our estimate of the net realizable value of the Intraject-related assets, based on the expected sale of those assets.

Gain on sale of patents and royalty interest:

The gain on sale of patents and royalty interest reflects two transactions entered into by the Company with Novo Nordisk, a related party; (i) the transfer by the Company of certain intellectual property, including all right, title and interest to its patents that contain claims that pertain generally to breath control or specifically to the pulmonary delivery of monomeric insulin and monomeric insulin analogs, together with interrelated patents, which are linked via terminal disclaimers, as well as certain pending patent applications and continuations thereof by the Company for a cash payment to the Company of \$12.0 million, with the Company retaining exclusive, royalty-free control of these patents outside the field of glucose control; and (ii) a reduction by 100 basis points of each royalty rate payable by Novo Nordisk to the Company for a cash payment to the Company of \$8.0 million.

Table of Contents

Interest income, interest expense and other income (expense):

	Nine months ended September 30, (in thousands)		Change in Dollars	Change in Percent
	2006	2005		
Interest income, interest expense and other income (expense):				
Interest Income	\$ 839	\$ 980	\$ (141)	(14)%
Interest expense	(101)		(101)	(100)%
Other Income (Expense)	26	(37)	63	170%
Total interest income, interest and other expense	\$ 764	\$ 943	\$ (179)	(19)%

Interest income for the nine months ended September 30, 2006 decreased \$141,000 over the comparable period in 2005 due to a lower average invested balance. Interest expense, primarily reflects the interest expense on the \$7.5 million note payable with an interest rate of 5%, issued to Novo Nordisk. The increase in other income and expenses primarily represents realized gains from exchange rate transactions offset by the loss on the disposition of assets.

Liquidity and Capital Resources

As of September 30, 2006, we had cash, cash equivalents and short-term investments of \$32.8 million and total working capital of \$30.2 million. During the quarter ended September 30, 2006 we received proceeds of \$20.0 million from the sale of patents and royalty rights to Novo Nordisk, proceeds from a \$7.5 million promissory note we issued to Novo Nordisk and proceeds of \$4.0 million from the sale of assets to Zogenix. Our principal requirements for cash are to fund working capital needs and, to a lesser extent, capital expenditures for equipment purchases.

For the nine months ended September 30, 2006, our operating activities used net cash of \$25.4 million and reflect our net loss of \$7.6 million offset by non-cash charges including stock-based compensation expense under SFAS No. 123R an asset impairment charge on property and equipment and depreciation expense and our use of operating cash to fund changes in operating assets and liabilities. Cash was used to pay for an increase in invoices outstanding for the Intraject program, to pay for severance related expenses accrued for the reduction in workforce and to fund accounts receivable, primarily related to the partnered programs. This compares to the net cash used in our operating activities for the nine months ended September 30, 2005 of \$26.8 million reflecting our net loss of \$18.5 million offset by non-cash charges including depreciation expense and our use of cash to fund changes in operating assets and liabilities. The primary changes in operating assets and liabilities is the recognition of the deferred revenues of \$7.2 million, and reduction of deferred rent of \$1.3 million, recognized in the statement of operations in the nine month period ended September 30, 2005 in conjunction with the Novo Nordisk restructuring agreement.

For the nine month period ended September 30, 2006, net cash provided by investing activities was \$22.2 million, which consisted primarily of \$20.0 million in proceeds from the sale of patents and royalty interest and \$4.0 million in proceeds from the sale of Intraject-related assets. This was partly offset by \$1.3 million for purchases of equipment primarily for the Intraject commercialization program and \$507,000 was used to purchase short term investments. This compares to net cash provided by investing activities for the nine months ended September 30, 2005 of \$45.4 million which consisted primarily of \$50.3 million in net proceeds from NNDT in connection with the restructuring agreement and \$4.5 million in proceeds from sale of investments, offset by our purchase of \$4.0 million of fixed assets relating to our Intraject platform and our purchases of \$5.3 million in securities classified as short-term investments with funds received in connection with the restructuring agreement.

Net cash provided by financing activities was \$7.8 million primarily representing proceeds from the \$7.5 million promissory note issued to Novo Nordisk and net cash provided by purchases under our employee stock plans for the

nine months ended September 30, 2006, compared to \$557,000 for the comparable period in the prior year.

Table of Contents

As of September 30, 2006, we had an accumulated deficit of \$282.6 million, working capital of \$30.1 million and shareholders' equity of \$1.0 million. Management believes that cash and cash equivalents on hand at September 30, 2006, together with expected funding to be received under additional collaborative arrangements, will be sufficient to enable us to meet our obligations through at least the next 18 months.

Contractual Obligations

Our contractual obligations and future minimum lease payments that are non-cancelable at September 30, 2006 are disclosed in the following table.

	Total	Payment Due by Period (amounts in thousands)			
		2006(1)	1 - 2 years	3-5 years	+5 years
Contractual obligations:					
Operating lease obligations	\$ 21,766	\$ 404	\$ 4,798	\$ 4,631	\$ 11,933
Unconditional purchase obligations	2,352	2,352			
Total contractual commitments	\$ 24,118	\$ 2,756	\$ 4,798	\$ 4,631	\$ 11,933

(1) For three months ending December 31, 2006

Off-Balance Sheet Financings and Liabilities

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

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**Market Risk Disclosures**

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

As of September 30, 2006, we had cash, cash equivalents and short-term investments of \$32.8 million, consisting of cash, cash equivalents and highly liquid short-term investments. Our short-term investments will likely decline by an immaterial amount if market interest rates decrease, and therefore, we believe our exposure to interest rate changes has been immaterial. Declines of interest rates over time will, however, reduce our interest income from short-term investments.

Item 4. CONTROLS AND PROCEDURES

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

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

Limitations on the effectiveness of controls. We believe that a controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected. Our disclosure controls and procedures are designed to

Table of Contents

provide reasonable assurance of achieving their objectives, and our chief executive officer and our chief financial officer have concluded that these controls and procedures are effective at the reasonable assurance level.

PART II. OTHER INFORMATION

Item 1A. RISK FACTORS

The risk factors included herein include any material changes to and supersede the risk factors associated with our business previously disclosed in Item A to Part I of our 2005 Annual Report on Form 10-K. In addition to the other information contained in this Form 10-Q, and risk factors set forth in our most recent SEC filings, the following risk factors should be considered carefully in evaluating our business. Our business, financial condition, or results of operations could be materially adversely affected by any of these risks. Additional risks not presently known to us or that we currently deem immaterial may also impair our business and operations.

Risks Related to Our Business

None of our product candidates has been approved or commercialized, and we may never successfully develop any products.

Most of our product candidates are in an early stage of development. Development of our products will require extensive additional time, effort and cost in preclinical testing and clinical trials. Our products also require lengthy regulatory reviews before they can be marketed. None of our products has yet received FDA approval, and our development efforts may never result in a commercialized product. We have spent more than 10 years developing AERx iDMS for the treatment of diabetes and it is still not on the market. 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 significantly hurt our results of operations.

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

Since our inception in 1991 we have focused on developing drug delivery technologies. We have recently transitioned our business focus from the development of delivery technologies to the application of our pulmonary drug delivery technologies and expertise to the development of novel drug products to treat 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 have not yet implemented or are only in the early stages of implementing various aspects of our new strategy, and we may not be successful in implementing our new strategy. Even if we are able to implement the various aspects of our new strategy, it may not be successful.

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

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

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;

Table of Contents

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

the time and costs associated with seeking regulatory approvals;

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

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

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

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

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

Since inception, we have financed our operations primarily through private placements and public offerings of our capital stock, proceeds from equipment lease financings, contract research funding and interest earned on investments. We believe that our existing cash and cash equivalent balances at September 30, 2006, together with funding commitments from collaborators and interest earned on our investments should be sufficient to meet our needs for at least the next 18 months. We will need to obtain substantial additional funds before we would be able to bring any of our product candidates to market. Our estimates of future capital use are uncertain, and changing circumstances, including those related to implementation of our new development strategy or further changes to our development strategy, could cause us to consume capital significantly faster than currently expected, and our expected sources of funding may not be sufficient. If adequate funds are not available, we will be required to delay, reduce the scope of, or eliminate one or more of our product development programs, or to obtain funds through arrangements with collaborators or other sources that may require us to relinquish rights to certain of our technologies or products that we would not otherwise relinquish, and to reduce personnel-related costs. If we are able to obtain funds through the issuance of debt securities or borrowing, the terms may restrict our operations, including a prohibition on paying dividends on our common stock. If we are able to obtain funds through the issuance of equity securities, your interest will be diluted and our stock price may drop as a result.

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

We have never been profitable and have incurred significant losses in each year since our inception. Through September 30, 2006, we have incurred a cumulative deficit of \$282.6 million. We have not had any product sales and do not anticipate receiving any revenues from product sales for at least the next few years, if ever. While our recent shift in development strategy may result in reduced capital expenditures, we expect to continue to incur substantial losses over at least the next several years as we:

expand drug product development efforts;

conduct preclinical testing and clinical trials;

pursue additional applications for our existing delivery technologies;

outsource the commercial-scale production of our products; and

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

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

profitable or to sustain profitability.

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

33

Table of Contents

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

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

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

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

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

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

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.

Table of Contents

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

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

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

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

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

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

Even if we are granted initial regulatory approval for a product candidate, the FDA and similar foreign regulatory agencies can limit or withdraw product approvals for a variety of reasons, including failure to comply with regulatory requirements, changes in regulatory requirements, problems with manufacturing facilities or processes or the occurrence of unforeseen problems, such as the discovery of previously undiscovered side effects. If we are able to obtain any product approvals, they may be limited or withdrawn or we may be unable to remain in compliance with regulatory requirements. Both before and after approval we, our collaborators and our products are subject to a number of additional requirements. For example, certain changes to the approved product, such as adding new indications, certain manufacturing changes and additional labeling claims are subject to additional FDA review and approval. Advertising and other promotional material must comply with FDA requirements and established requirements applicable to drug samples. We, our collaborators and our manufacturers will be subject to continuing review and periodic inspections by the FDA and other authorities where applicable and must comply with ongoing requirements, including the FDA's Good Manufacturing Practices, or GMP, requirements. Once the FDA approves a product, a manufacturer must provide certain updated safety and efficacy information, submit copies of promotional materials to the FDA and make certain other required reports. Product approvals may be withdrawn if regulatory requirements are not complied with or if problems concerning safety or efficacy

Table of Contents

of the product occur following approval. Any limitation or withdrawal of approval of any of our products could delay or prevent sales of our products, which would adversely affect our revenues. Further continuing regulatory requirements involve expensive ongoing monitoring and testing requirements.

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

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

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

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

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

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

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

Table of Contents

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

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

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

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

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

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

the demonstration of efficacy and safety in clinical trials;

the existence, prevalence and severity of any side effects;

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

the timing of market entry relative to competitive treatments;

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

the strength of marketing and distribution support;

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

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

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

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

Our business and competitive position is dependent upon our and our collaborators ability to protect our proprietary technologies related to various aspects of pulmonary drug delivery and drug formulation. While our intellectual property rights may not provide a significant commercial advantage for us, our patents and know-how are intended to provide protection for important aspects of our technology, including methods for aerosol generation, devices used to generate aerosols, breath control, compliance monitoring,

Table of Contents

certain pharmaceutical formulations, design of dosage forms and their manufacturing and testing methods. In addition, we are maintaining as non-patented trade secrets some of the key elements of our manufacturing technologies, for example, those associated with production of disposable unit-dose packets for our AERx delivery system.

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

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

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

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

If we are required to defend ourselves in a lawsuit, we could incur substantial costs and the lawsuit could divert management attention, regardless of the lawsuit's merit or outcome. These legal actions could seek damages and seek to enjoin testing, manufacturing and marketing of the accused product or process. In addition to potential liability for significant damages, we could be required to obtain a license to continue to manufacture or market the accused product or process and any license required under any such patent may not be made available to us on acceptable terms, if at all.

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

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

behind actual

Table of Contents

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

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

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

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

We depend on a small number of key management and technical personnel. Our success also depends on our ability to attract and retain additional highly qualified marketing, management, manufacturing, engineering and development personnel. There is a shortage of skilled personnel in our industry, we face intense competition in our recruiting activities, and we may not be able to attract or retain qualified personnel. Losing any of our key employees, particularly our new 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 use a portion of the proceeds from this offering to 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.

Table of Contents

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

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

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

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

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

In both domestic and foreign markets, sales of our potential products will depend in substantial part on the availability of adequate reimbursement from third-party payors such as government health administration authorities, private health insurers and other organizations. Third-party payors often challenge the price and cost-effectiveness of medical products and services. Significant uncertainty exists as to the adequate reimbursement status of newly approved health care products. Any products we are able to successfully develop may not be reimbursable by third-party payors. In addition, our products may not be considered cost-effective and adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize a profit. Legislation and regulations affecting the pricing of pharmaceuticals may change before our products are approved for marketing and any such changes could further limit reimbursement. If any products we develop do not receive adequate reimbursement, our revenues will be severely limited.

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

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

Table of Contents

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

Section 404 of the Sarbanes-Oxley Act of 2002 requires us to evaluate the effectiveness of our internal controls over financial reporting as of the end of each fiscal year, and to include a management report assessing the effectiveness of our internal controls over financial reporting in our annual report on Form 10-K for that fiscal year. Section 404 also requires our independent registered public accounting firm, beginning with our fiscal year ending December 31, 2007, to attest to, and report on, management's assessment of our internal controls over financial reporting. Our ability to comply with the annual internal control report requirements will depend on the effectiveness of our financial reporting and data systems and controls across our company. We expect these systems and controls to involve significant expenditures and to become increasingly complex as our business grows and to the extent that we make and integrate acquisitions. To effectively manage this complexity, we will need to continue to improve our operational, financial and management controls and our reporting systems and procedures. Any failure to implement required new or improved controls, or difficulties encountered in the implementation or operation of these controls, could harm our operating results and cause us to fail to meet our financial reporting obligations, which could adversely affect our business and jeopardize our listing on the Nasdaq Capital Market, either of which could reduce our stock price.

Risks Related to Our Common Stock

Our common stock is no longer listed on the Nasdaq Capital Market; our stock may have less market liquidity and the price may decline.

On November 8, 2006 the Company was informed by the Nasdaq Listing Qualifications Panel, that the Company's shares were to be delisted from the Nasdaq capital market, due to non-compliance with the continued listing standards. The Company intends to request a review of his decision, but neither said request nor a granting of such a review will stay the delisting. The company expects to be immediately eligible for quotation on the Pink Sheets, and will investigate other quotation and trading alternatives.

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;

our ability to maintain the listing of our common stock on the Nasdaq Capital Market;

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

fluctuations in our operating results;

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

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

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

failure to maintain existing or establish new collaborative relationships;

developments or disputes concerning patents or proprietary rights;

delays in the development or approval of our product candidates;

41

Table of Contents

regulatory developments in both the United States and foreign countries;

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

period-to-period fluctuations in financial results;

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

our ability to raise financing; and

economic and other external factors.

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

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

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

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

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

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

Item 6. EXHIBITS

Exhibit

Number

Description

10.2(1)+ 2005 Equity Incentive Plan, as amended.

10.7(1)+ Employee Stock Purchase Plan, as amended.

10.20(1) Promissory Note and Security Agreement, dated July 3, 2006, by and between the Company and Novo Nordisk A/S.

10.21(1)@ Asset Purchase Agreement, dated as of August 25, 2006, by and between the Company and Zogenix, Inc.

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- 10.22(1)+ Employment Agreement, dated as of August 10, 2006, with Dr. Igor Gonda.
- 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.

@ The Company has sought confidential treatment for portions of the referenced exhibit.

+ Represents a management contract or compensatory plan or arrangement.

(1) Incorporated by reference to the Company's Form S-1 (No. 333-138169) filed on October 24, 2006.

Table of Contents

SIGNATURES

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

ARADIGM CORPORATION
(Registrant)

/s/ Igor Gonda

Dr. Igor Gonda
President and Chief Executive Officer

/s/ Thomas C. Chesterman

Thomas C. Chesterman
*Senior Vice President and Chief
Financial Officer*

Dated: November 14, 2006

Table of Contents

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