Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the Quarterly Period Ended March 31, 2010

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 001-33103

CADENCE PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**41-2142317**
(State or other jurisdiction of incorporation)	**(I.R.S. Employer Identification No.)**

12481 High Bluff Drive, Suite 200
San Diego, CA 92130
(Address of principal executive offices) (Zip code)

(858) 436-1400
(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 has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

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

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

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

As of April 30, 2010, there were 50,520,929 shares of the registrant's Common Stock outstanding.

Table of Contents

CADENCE PHARMACEUTICALS, INC.

INDEX

Table of Contents

PART I. FINANCIAL INFORMATION

Item 1. ***Financial Statements***

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

CONDENSED BALANCE SHEETS

	March 31, 2010 (unaudited)	December 31, 2009
Assets		
Current assets:		
Cash and cash equivalents	$ 67,703,500	$ 75,859,035
Investments in marketable securities	-	6,147,118
Restricted cash	1,497,848	1,497,848
Prepaid expenses	465,302	517,987
Other current assets	5,567	31,256
Total current assets	69,672,217	84,053,244
Property and equipment, net	8,890,139	8,300,529
Restricted cash	189,738	189,738
Other assets	14,333	19,708
Total assets	$ 78,766,427	$ 92,563,219
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,672,396	$ 2,656,597
Accrued liabilities	6,354,034	7,739,527
Current debt, less discount of $115,305 and $158,545, respectively	4,975,781	6,442,327
Other current liabilities	-	22,048
Total current liabilities	14,002,211	16,860,499
Deferred rent	554,791	640,208
Total liabilities	14,557,002	17,500,707
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock, $0.0001 par value; 100,000,000 shares authorized, 50,519,929 shares and 50,484,588 shares issued and outstanding at March 31, 2010 and December 31, 2009, respectively	5,052	5,048
Additional paid-in capital	295,142,599	292,076,537
Accumulated other comprehensive income	-	60
Deficit accumulated during the development stage	(230,938,226)	(217,019,133)
Total stockholders' equity	64,209,425	75,062,512
Total liabilities and stockholders' equity	$ 78,766,427	$ 92,563,219

The accompanying notes are an integral part of these financial statements.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,		Period from May 26, 2004 (Inception) through March 31, 2010
	2010	2009	
Operating expenses:			
Research and development	$ 4,230,886	$ 6,139,342	$ 161,330,991
Sales and marketing	6,054,501	536,115	24,724,993
General and administrative	3,461,608	2,811,747	44,320,592
Other	11,983	650,786	2,808,575
Total operating expenses	13,758,978	10,137,990	233,185,151
Loss from operations	(13,758,978)	(10,137,990)	(233,185,151)
Other (expense) income:			
Interest income	23,500	84,023	7,349,902
Interest expense	(184,088)	(366,927)	(4,602,942)
Other expense	473	(16,469)	(500,035)
Total other (expense) income, net	(160,115)	(299,373)	2,246,925
Loss before income tax	(13,919,093)	(10,437,363)	(230,938,226)
Net loss	$(13,919,093)	$(10,437,363)	$(230,938,226)
Basic and diluted net loss per share[1]	$ (0.28)	$ (0.24)	
Shares used to compute basic and diluted net loss per share[1]	50,509,357	43,831,889	

(1) As a result of the issuance of 12,039,794 shares of common stock pursuant to a private placement in the first quarter of 2009, there is a lack of comparability in the per share amounts between the 2010 and 2009 periods presented. Please see Note 4 of the Notes to Financial statements for further discussion.

The accompanying notes are an integral part of these financial statements.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)

	Three Months Ended March 31,		Period from May 26, 2004 (Inception) through March 31,
	2010	2009	2010
Operating activities			
Net loss	$(13,919,093)	$ (10,437,363)	$ (230,938,226)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	158,092	135,025	2,007,806
Loss on disposal of assets	11,983	-	86,805
Impairment of long-lived assets	-	25,690	2,353,162
Adjustment to estimate of impairment of long-lived assets	-	-	(180,926)
Impairment of available-for-sale securities	-	-	450,000
Stock-based compensation	2,994,363	1,480,611	23,163,213
Non-cash interest expense	5,375	7,429	78,264
Amortization of discount on note payable	43,240	66,184	717,142
Amortization of premiums on available-for-sale securities, net of accretion of discounts	30,779	-	161,048
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	194,653	(93,127)	(561,164)
Accounts payable	(548,637)	(1,303,957)	2,242,691
Accrued liabilities and other liabilities	(977,223)	(3,324,320)	4,642,319
Net cash used in operating activities	(12,006,468)	(13,443,828)	(195,777,866)
Investing activities			
Purchases of marketable securities	-	-	(18,188,348)
Maturities of marketable securities	6,000,000	-	17,575,000
Restricted cash	-	347,848	(1,687,586)
Purchases of property and equipment	(679,734)	(34,595)	(10,458,194)
Proceeds from the sale of property and equipment	-	-	195
Net cash provided by (used in) investing activities	5,320,266	313,253	(12,758,933)
Financing activities			
Proceeds from issuance of common stock, net	71,703	86,242,720	192,560,790
Disbursements from repurchase of common stock	-	-	(19,075)
Proceeds from sale of preferred stock, net	-	-	78,933,748
Borrowings under debt agreements	-	-	21,955,000
Payments under debt agreements	(1,541,036)	(2,190,387)	(17,190,164)
Net cash (used in) provided by financing activities	(1,469,333)	84,052,333	276,240,299
Net (decrease) increase in cash and cash equivalents	(8,155,535)	70,921,758	67,703,500
Cash and cash equivalents at beginning of period	75,859,035	47,627,246	-
Cash and cash equivalents at end of period	$ 67,703,500	$118,549,004	$ 67,703,500
Supplemental disclosures			
Issuance of warrants in connection with loan and security agreement	$ -	$ -	$ 787,448
Assets acquired through lease concessions	$ -	$ -	$ 1,190,530
Property and equipment purchases in accounts payable and accrued expenses	$ 1,180,572	$ -	$ 1,180,572
Unrealized loss on investment securities	$ (60)	$ -	$ -
Cash paid for interest and fees	$ 114,202	$ 273,320	$ 3,444,364

The accompanying notes are an integral part of these financial statements.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)

1. The Company

Cadence Pharmaceuticals, Inc. (the "Company") was incorporated in the state of Delaware in May 2004. The Company is a biopharmaceutical company focused on in-licensing, developing and commercializing proprietary product candidates principally for use in the hospital setting. The Company's primary activities since incorporation have been conducting research and development activities, including clinical trials, of the product candidates in its portfolio; organizational activities, including recruiting personnel, establishing office facilities; establishing the commercial manufacturing and sales infrastructure for its OFIRMEV™ product candidate; and raising capital to fund these activities. In March 2006, the Company in-licensed the exclusive U.S. and Canadian rights to its product candidate, OFIRMEV, an intravenous formulation of acetaminophen, from Bristol-Myers Squibb Company ("BMS").

In May 2009, the Company submitted a New Drug Application ("NDA"), for OFIRMEV to the Food and Drug Administration ("FDA"). On February 10, 2010, the Company received a complete response letter from the FDA, which stated the NDA could not be approved due to deficiencies observed during the FDA's inspection of the facilities of the Company's third-party manufacturer. Following a meeting with FDA to discuss the observations, the Company re-submitted the NDA for OFIRMEV on May 4, 2010. Since the Company has not begun principal operations of commercializing OFIRMEV, the Company is considered to be a development stage company.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company has prepared the accompanying unaudited condensed financial statements in accordance with accounting principles generally accepted in the United States of America ("GAAP"). However, certain information and disclosures normally included in financial statements prepared in accordance with GAAP have been condensed, or omitted, pursuant to the rules and regulations of the U.S. Securities and Exchange Commission ("SEC"). In addition, the preparation of financial statements in conformity with GAAP requires management to make estimates and judgments that affect the amounts reported in the financial statements and accompanying notes. In the opinion of the Company's management, all adjustments consisting of normal, recurring adjustments considered necessary for a fair presentation of the results of the interim periods presented have been included. These condensed financial statements should be read in conjunction with the audited financial statements of the Company for the fiscal year ended December 31, 2009, as included in the Company's 2009 Annual Report on Form 10-K filed with the SEC on March 15, 2010.

Stock-Based Compensation

Stock option awards. Stock options are currently valued using the Black-Scholes option pricing model on the date of grant. This option pricing model involves a number of estimates, including the expected lives of stock options, the Company's anticipated stock volatility and interest rates. The following table summarizes the weighted average estimates the Company used in the Black-Scholes option-pricing model during the three months ended March 31, 2010 and 2009, to determine the fair value of employee and non-employee director stock options granted during each period:

	Three Months Ended March 31,	
	2010	2009
Risk free interest rates	2.8%	1.8%
Expected life in years	5.9 years	6.1 years
Expected dividend yield	0.0%	0.0%
Expected volatility	76.8%	71.8%

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued
(Unaudited)

Restricted stock units. Restricted stock units ("RSUs") are valued based on the fair market value of the Company's stock on the date of grant.

Compensation expense for all stock-based payment awards is recognized using the straight-line method. Stock-based compensation expense recognized during the period is based on the value of the portion of awards that is ultimately expected to vest. Hence, the gross expense is reduced for estimated forfeitures and adjusted for the probability of achieving performance criteria. The table below summarizes the total stock-based compensation expense included in the Company's statements of operations for the periods presented:

	Three Months Ended March 31,		Period from May 26, 2004 (Inception) through March 31,
	2010	2009	2010
Research and development	$ 979,882	$ 458,080	$ 7,328,790
Sales and marketing	485,554	15,741	1,082,432
General and administrative	1,528,927	1,006,790	14,751,991
Stock-based compensation expense included in operating expenses	2,994,363	1,480,611	23,163,213
Total stock-based compensation expense included in loss from operations	$2,994,363	$1,480,611	$ 23,163,213

Fair Value Reporting

The Company's financial instruments consist of cash and cash equivalents, marketable securities, restricted cash, accounts payable, accrued liabilities and long-term debt. Fair value estimates of these instruments are made at a specific point in time, based on relevant market information. These estimates may be subjective in nature and involve uncertainties and matters of significant judgment and therefore cannot be determined with precision. The carrying amount of cash and cash equivalents, restricted cash, accounts payable and accrued liabilities are generally considered to be representative of their respective fair values because of the short-term nature of those instruments. The fair value of marketable securities is based upon market prices quoted on the last day of the fiscal period.

Current accounting guidance defines fair value, establishes a framework for measuring fair value in accordance with GAAP, and requires certain disclosures about fair value measurements. The valuation techniques included in the guidance are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect market assumptions and are classified into the following fair value hierarchy:

Level 1 Inputs – Quoted prices for identical instruments in active markets.

Level 2 Inputs – Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs and significant value drivers are observable.

Level 3 Inputs – Valuation derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued
(Unaudited)

Currently, all of the Company's financial instruments are valued using level 1 inputs. The following table presents further detail of the financial instruments carried at fair value on the Company's balance sheet as of March 31, 2010. The table does not include assets and liabilities which are measured at historical cost or on any basis other than fair value:

Description	Total Carrying Value	Fair Value Measurements as of March 31, 2010			
		Level 1	Level 2	Level 3	Total Fair Value
Assets:					
Cash and cash equivalents:					
Money market funds	$66,903,241	$66,903,241	$ -	$ -	$ 66,903,241
Assets at fair value	$66,903,241	$66,903,241	$ -	$ -	$ 66,903,241

3. Recent Accounting Pronouncements

In May 2009, the Financial Accounting Standards Board ("FASB") issued guidance regarding subsequent events, which is intended to establish general standards of accounting for, and disclosure of, events that occur after the balance sheet date but before financial statements are issued or are available to be issued. Specifically, the guidance sets forth the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements, and the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. In February 2010, the FASB amended the guidance to remove the requirement for management to disclose the date through which the company had evaluated its subsequent events in issued and revised financial statements. The guidance is effective for financial statements issued for interim and annual financial periods ending after June 15, 2009 and the amended guidance is effective February 24, 2010. The Company adopted the provisions of the guidance which did not have a material effect on the Company's financial statements.

4. Net Loss Per Share

Net loss per share is presented as basic and diluted net loss per share. Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, stock options, restricted stock units and warrants are considered to be common stock equivalents and are not included in the calculations of diluted net loss per share as their effect is anti-dilutive. Additionally, the restricted stock units outstanding during the three months ended March 31, 2010 period were excluded from the basic net loss calculation as these units do not include dividend rights and therefore are not considered to be participating securities.

The actual net loss per share amounts for the three months ending March 31, 2010 and 2009 were computed based on the weighted average shares of common stock outstanding during the respective periods. The net loss per share for the periods presented include the effect of the 12,039,794 common shares issued pursuant to a private placement in the first quarter of 2009. As a result of the issuance of these common shares, there is a lack of comparability in the basic and diluted net loss per share amounts for the periods presented.

The following is a reconciliation of the basic and diluted shares for the periods presented:

	Three Months Ended March 31,	
	2010	2009
Shares for basic and dilutive net loss per share:		
Weighted average common shares outstanding	50,513,429	43,982,556
Weighted average unvested common shares subject to repurchase	(4,072)	(150,667)
Denominator for basic and diluted earnings per share	50,509,357	43,831,889

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued
(Unaudited)

At March 31, 2010 and 2009, stock options, restricted stock units, and warrants totaling 12,999,448 and 10,609,194 shares, respectively, were excluded from the calculations as their effect would have been antidilutive.

5. Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Components of comprehensive income (loss) include foreign currency translation adjustments and unrealized gains and losses on the changes in fair value of investments. These components are added, net of their related tax effect, to the reported net income (loss) to arrive at comprehensive income (loss). The components of other comprehensive loss for the periods presented were as follows:

	Three Months Ended March 31,		Period from May 26, 2004 (Inception) through March 31,
	2010	2009	2010
Net loss	$(13,919,093)	$(10,437,363)	$ (230,938,226)
Other comprehensive income (loss):			
Net unrealized loss on available-for-sale investments	(60)	-	-
Comprehensive loss	$(13,919,153)	$(10,437,363)	$ (230,938,226)

6. Property and Equipment

Property and equipment for operations were as follows:

	March 31, 2010	December 31, 2009
Property and equipment:		
Leasehold improvements	$ 1,610,250	$ 1,610,250
Computer equipment and software	1,416,019	840,604
Furniture and fixtures	445,995	469,423
Construction-in-process	7,231,143	7,059,969
	10,703,407	9,980,246
Less accumulated depreciation	(1,813,268)	(1,679,717)
Total	$ 8,890,139	$ 8,300,529

For the three months ended March 31, 2010 and 2009, the Company incurred depreciation expense of $158,092 and $135,025, respectively. Since May 26, 2004 (inception) through March 31, 2010, the Company has incurred depreciation expense of $2,007,806.

7. Investments in Marketable Securities

At December 31, 2009, the Company held investments in marketable securities. No such investments were held at March 31, 2010. The cost, gross unrealized holding gains, gross unrealized holding losses and fair value of available-for-sale investments by types and classes of security at December 31, 2009 consisted of the following:

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued
(Unaudited)

At December 31, 2009	Amortized Cost Basis	Other-than-temporary Impairments	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Available-for-sale:					
Debt instruments – U.S. Government agencies	$6,147,058	$ -	$ 786	$ (726)	$6,147,118
	$6,147,058	$ -	$ 786	$ (726)	$6,147,118

Investments by contractual maturity are as follows:

	December 31, 2009	
	Cost	Fair Value
Due or callable in one year or less	$6,147,058	$6,147,118
Due after one year	$ -	$ -

Investments are considered to be impaired when a decline in fair value is judged to be other-than-temporary. The Company employs a methodology that reviews specific securities in evaluating potential impairment of its investments. In the event that the cost of an investment exceeds its fair value, the Company evaluates, among other factors, the Company's intent and ability to hold the investment and extent to which the fair value is less than cost; the financial health of and business outlook for the issuer; and operational and financing cash flow factors. During the three months ended March 31, 2009, the Company recorded an impairment charge of $25,690, to impair the balance of the Migenix, Inc. ("Migenix") common stock acquired as partial consideration from the Company's acquisition of the development and commercialization rights to the omiganan pentahydrochloride product candidate as the decrease in market value of the securities were considered to be other-than-temporary. The Company's Migenix common stock holdings had no value at March 31, 2010 and December 31, 2009, respectively

8. Omigard Restructuring Charges

In March 2009, the Company announced its decision to discontinue the development of its omiganan pentahydrochloride product candidate. This decision was due to the failure of the Company's Phase III clinical trial of omiganan pentahydrochloride to meet its primary endpoint and the Company's belief that the results of this clinical trial would not support an NDA submission. In connection with the discontinuation of the development of omiganan pentahydrochloride, the Company implemented a corporate restructuring in order to reduce, and eventually eliminate, costs associated with the omiganan pentahydrochloride program, including the termination of 11 employees. The Company recorded impairment charges in the fourth quarter of 2008 of $2,353,162 with respect to certain omiganan pentahydrochloride manufacturing equipment, based upon management estimates of the salvage value of the equipment at the time the impairment charge was taken. Further, the Company recorded restructuring charges of $650,786 in the first quarter of 2009 for severance-related costs and the termination of contractual obligations, based upon management estimates of the termination costs at the time they were recorded. These estimates can change depending upon changes in facts and circumstances subsequent to the date the original liability was recorded.

The Company recorded adjustments to the impairment charge taken on the manufacturing equipment in 2009, reducing the charge by an aggregate $180,926 during the third and fourth quarters of 2009 as actual costs incurred in disposing of the assets were less than anticipated. Additionally, adjustments totaling $64,219 were recorded to the severance obligation during 2009. All of the charges and adjustments are included in the Company's "Other" operating expenses on the statement of operations. As of March 31, 2010, no liability remained for severance-related costs and termination of contractual obligations. Further, there was no such liability at March 31, 2010 or December 31, 2009.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued
(Unaudited)

The following table details the restructuring charges for severance-related costs and termination of contractual obligations for the periods presented:

	Three Months Ended March 31,		Period from May 26, 2004 (Inception) through March 31,
	2010	2009	2010
Beginning restructuring liability	$ -	$ -	$ -
Severance and termination charges incurred	-	650,786	650,786
Adjustments to severance and termination charges	-	(13,077)	(64,219)
Severance and termination disbursements	-	-	(586,567)
Ending restructuring liability	$ -	$ 637,709	$ -

Further, on May 8, 2009, the Company notified Migenix of the termination of the license agreement for omiganan pentahydrochloride, and informed Solvay, S.A. ("Solvay") of its intention to terminate the long-term supply agreement and a related license agreement for the active ingredient in omiganan pentahydrochloride. The termination of the long-term supply agreement and related license agreement became effective on July 7, 2009. No charges were incurred from the termination of these agreements.

9. Loan and Security Agreement

In February 2006, the Company entered into a $7,000,000 Loan and Security Agreement (the "Agreement") with Silicon Valley Bank and Oxford Finance Corporation to provide growth capital to the Company. In June 2006, the Company drew down $7,000,000 under the Agreement at a fixed interest rate of 11.47%. In August 2006, the Company began making the first of six monthly interest-only payments on the $7,000,000 balance and in February 2007 began making equal monthly principal and interest payments. The Company made the final payment to retire the obligation in July 2009.

In November 2007, the Company amended the Agreement and entered into the Second Amendment to Loan and Security Agreement (the "Second Amendment") with the same parties and GE Business Financial Services Inc. (formerly known as Merrill Lynch Business Financial Services Inc.), to secure an additional $15,000,000 credit facility. In December 2007, the Company drew down $15,000,000 under the Second Amendment in two separate draws of $5,000,000 and $10,000,000 with fixed interest rates of 7.83% and 7.74%, respectively, net of a $45,000 loan fee (the "loan fee"). In January 2008, the Company began making the first of six monthly interest-only payments on the $15,000,000 balance and in July 2008 began making the first of 30 equal monthly principal and interest payments.

In addition to the principal and interest, the Company is required to pay $375,000 at the termination of the Second Amendment (the "term loan final payment"). The loan fee and the warrants issued in connection with the loan (as described below), have been recognized as a discount on the loan issuance which, together with the fixed interest rates, will be amortized to interest expense throughout the life of the loan using an effective interest rate of 9.56%. The term loan final payment is being accrued through interest expense over the life of the loan. All interest payable under the Second Amendment and the full amount of the term loan final payment must be paid upon any prepayment of the loan. The loans are collateralized by substantially all the assets of the Company (excluding intellectual property). Under the terms of the Agreement, the Company may be precluded from entering into certain financing and other transactions, including disposing of certain assets and paying dividends, and is subject to certain non-financial covenants and prepayment penalties. Upon the occurrence of an event of default, including a Material Adverse Change (as defined in the Agreement), the lenders may declare all outstanding amounts due and payable under the Agreement.

As of March 31, 2010 and December 31, 2009, the aggregate principal balance of the loans, net of the loan discount, included on the Company's balance sheets was $4,975,781 and $6,442,327, respectively.

Warrants

In connection with the Second Amendment to the Agreement with Silicon Valley Bank, Oxford Finance Corporation and GE Business Financial Services Inc., the Company issued six fully exercisable warrants to the lenders to purchase an aggregate of 50,331 shares of the Company's common stock at an exercise price of $12.67 per share, expiring November 30, 2014. The Company determined the fair value of these warrants to be $473,876, using the Black-Scholes valuation model. The value of the warrants was recorded as a discount to the note payable, and will be amortized to interest expense over the expected term of the loan agreement. The warrants were valued using the following assumptions: risk-free interest rate of 3.64%; dividend yield of 0.0%; expected volatility of 70.0%; and a contractual term of seven years. As of March 31, 2010, all warrants related to the Second Amendment were outstanding.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued
(Unaudited)

10. Commitments and Contingencies

Leases

In May 2006, the Company entered into a six-year operating lease for 23,494 square feet of office space. The Company received certain tenant improvement allowances and rent abatement and has an option to extend the lease for five years following the expiration of the initial term. Monthly rental payments are adjusted on an annual basis and the lease expires in September 2012. As security for the lease, a letter of credit in the initial amount of $1,581,130 was required by the landlord. The letter of credit is collateralized by a certificate of deposit in the same amount that is classified as restricted cash in the Company's balance sheet. The required amount subject to the letter of credit and corresponding certificate of deposit may be reduced by 22% on each of the first four anniversaries of the commencement of the lease. During the fourth quarter of 2007, the first quarter of 2009 and the fourth quarter of 2009, the letter of credit was reduced by $347,848 each in accordance with the agreement and the related restricted cash was adjusted by a like amount. As of March 31, 2010, the value of the letter of credit and corresponding certificate of deposit, classified as restricted cash on the Company's balance sheet was $537,586.

In January 2007, the Company entered into a sublease agreement for a portion of its unused office space. The sublease agreement expired in September 2009 and the Company has since recaptured the space to support its growth. Rent expense, net of sublease rent income, for the three months ended March 31, 2010 and 2009 was $214,703 and $142,387, respectively. Since May 26, 2004 (inception) through March 31, 2010, the Company has incurred total net rent expense of $2,989,409.

Corporate Credit Card

In 2009, the Company entered into a pledge agreement pursuant to the establishment of a corporate credit card program whereby the Company pledged $150,000 in a certificate of deposit as collateral. These funds are therefore classified as restricted cash on the Company's balance sheet at March 31, 2010 and December 31, 2009, respectively.

Supply Agreement

In July 2007, the Company entered into a development and supply agreement (the "Supply Agreement") with Baxter Healthcare Corporation ("Baxter") for the completion of pre-commercialization manufacturing development activities and the manufacture of commercial supplies of the finished drug product for OFIRMEV. The Supply Agreement has an initial term of five years and will automatically renew for consecutive one-year terms thereafter unless either party provides at least two-years' prior written notice of termination to the other party. Pursuant to the terms of the Supply Agreement, Baxter is entitled to receive development fees from the Company upon the completion of specified development activities, which the Company expenses as these costs are being incurred. In addition, Baxter will receive a set manufacturing fee based on the amount of the finished OFIRMEV drug product produced, which prices may be adjusted by Baxter, subject to specified limitations. The Company is also obligated to purchase a minimum number of units each year following regulatory approval, or pay Baxter an amount equal to the per-unit purchase price multiplied by the amount of the shortfall. Further, the Company is obligated to reimburse Baxter for all reasonable costs directly related to work performed by Baxter in support of any change in the active pharmaceutical ingredient ("API") source or API manufacturing process.

The Supply Agreement also requires the Company to fund specified improvements at Baxter's manufacturing facility and purchase certain equipment for use by Baxter in manufacturing OFIRMEV. As of March 31, 2010, the Company has reimbursed Baxter for a portion of the facility improvements and has expensed the costs as they have been incurred. The equipment purchased for the manufacturing of OFIRMEV to which the Company retains title is being capitalized as it has alternative future uses and will be amortized over the life of the equipment. At the time of termination, the Supply Agreement requires the Company to reimburse Baxter for all reasonable costs for the de-installation of the Company's equipment and the restoration of Baxter's manufacturing facility to its pre-installation condition. The Company is not able to reasonably estimate the cost and the timing of these expenses at this time and therefore cannot reasonably estimate the fair value of the retirement obligation.

In anticipation of the execution of the Supply Agreement, the Company entered into an irrevocable standby letter of credit in favor of Baxter in January 2007. The letter of credit was for an initial amount of $3,268,000 and was based on anticipated costs to be

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued
(Unaudited)

incurred by Baxter for the improvements at Baxter's manufacturing facility and the purchase of equipment to be used by Baxter in the manufacturing of the finished drug product. Under the terms of the Supply Agreement, the amount of the letter of credit may be reduced on a quarterly basis following the execution of the Supply Agreement for the costs the Company has reimbursed Baxter to fund the specified facility improvements or equipment purchases. As of March 31, 2010, at the request of the Company and based upon the costs reimbursed to Baxter by the Company, the letter of credit had been reduced by $2,268,000 to $1,000,000. The letter of credit in favor of Baxter is collateralized by a certificate of deposit which may be drawn down in part or in whole by Baxter in the event the Company fails to perform its obligations to fund the specified facility improvements or equipment purchases. As of March 31, 2010, the certificate of deposit, classified as restricted cash on the Company's balance sheets, had been reduced to $1,000,000 in accordance with the reduction in the letter of credit.

License Agreements and Acquired Development and Commercialization Rights

In March 2006, the Company in-licensed the technology and the exclusive development and commercialization rights to its OFIRMEV product candidate in the U.S. and Canada from Bristol-Myers Squibb Company ("BMS"). BMS sublicensed these rights to the Company under a license agreement with SCR Pharmatop S.A. As consideration for the license, the Company paid a $25,000,000 up-front fee, and may be required to make future milestone payments totaling up to $40,000,000 upon the achievement of various milestones related to regulatory and commercial events, including payments totaling $15,000,000 upon the approval of the Company's NDA for OFIRMEV. In addition, the Company is obligated to pay a royalty on net sales of the licensed products and has the right to grant sublicenses to third parties. All payments made to date related to the BMS agreement have been recognized as research and development expense.

As a result of the discontinuation of the Company's omiganan pentahydrochloride development program, on May 8, 2009, the collaboration and license agreement between the Company and Migenix for this product candidate was terminated. No charges were incurred from the termination of this agreement.

11. Stockholder's Equity

Private Placement

In February 2009, the Company issued 12,039,794 shares of its common stock at a purchase price of $7.13 per share pursuant to a private placement. In addition to the shares of the Company's common stock, warrants to purchase up to 6,019,897 additional shares of the Company's common stock were also issued as part of the transaction at a price of $0.125 per warrant. Each warrant is immediately exercisable and has a five-year term. The warrants may be exercised through either cash or net exercise for one share of common stock at a price of $7.84 and have been accounted for as permanent equity. As of March 31, 2010, all warrants related to the private placement were outstanding.

The private placement raised proceeds, net of offering costs, of $86,242,720. The purchasers in the offering consisted of new investors and existing stockholders of the Company, including six funds affiliated with three directors of the Company. In March 2009, we filed a registration statement covering the resale of the shares of common stock acquired by the investors in this offering, which was declared effective by the SEC in May 2009. The Company is required to maintain the effectiveness of the registration statement and may be subject to liquidated damages of one percent per month of the aggregate purchase price of the common shares then held by the investor that are registrable securities, subject to an aggregate cap of eight percent per calendar year. The Company has not recorded a liability for the potential damages associated with these liquidated damages provisions, as it does not currently believe that the transfer of consideration is probable under the agreement.

Shelf Registration

On September 4, 2009, the Company filed a universal shelf registration statement (the "Universal Shelf Registration Statement") to allow the Company to sell up to $100,000,000 of debt securities, preferred stock, common stock, debt warrants and equity warrants. The Universal Shelf Registration Statement was subsequently declared effective on September 17, 2009 by the SEC. As of March 31, 2010, the Company has not sold any shares under this registration statement.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued
(Unaudited)

12. Income Taxes

The Company is subject to taxation in the U.S. and various state jurisdictions. The Company's tax years for 2004 and forward are subject to examination by the Federal and California tax authorities due to the carryforward of unutilized net operating losses and research and development credits. The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrued interest and/or penalties related to income tax matters in the Company's balance sheets at March 31, 2010 and December 31, 2009, and has recognized no interest and/or penalties in the Company's statement of operations for the three months ended March 31, 2010 and 2009, respectively. As of March 31, 2010, the Company had not recorded any unrecognized tax benefits.

Pursuant to Internal Revenue Code ("IRC") Sections 382 and 383, annual use of the Company's net operating loss and research and development credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period. The Company has not completed an IRC Section 382/383 analysis regarding the limitation of net operating loss and research and development credit carryforwards. Until this analysis has been completed, the Company has removed the deferred tax assets for net operating losses of approximately $69,631,000 and research and development credits of approximately $5,043,000 generated through 2009 from its deferred tax asset schedule, and has recorded a corresponding decrease to its valuation allowance. When this analysis is finalized, the Company plans to update its unrecognized tax benefits accordingly. The Company expects to begin the Section 382/383 analysis in the near future and will update the unrecognized tax benefits at the time the analysis is completed. The Company does not anticipate any additional changes to their unrecognized tax benefits the next 12 months outside of the area of Section 382/383. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact the Company's effective tax rate.

Item 2. *Management's Discussion and Analysis of Financial Condition and Results of Operations*

Introduction

This discussion may contain forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in any forward-looking statements as a result of many factors, including those set forth below under the caption "Risk Factors." The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2009 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2009.

Overview

We are a biopharmaceutical company focused on in-licensing, developing and commercializing proprietary product candidates principally for use in the hospital setting. We intend to build a leading franchise in the hospital setting, continuing to focus on products that are in late stages of development, currently commercialized outside the U.S., or approved in the U.S. but with significant commercial potential for proprietary new uses or formulations. In March 2006, we in-licensed the exclusive U.S. and Canadian rights to our product candidate, OFIRMEV™, an intravenous formulation of acetaminophen, from BMS, and in May 2009 we submitted a New Drug Application, or NDA, for OFIRMEV to the U.S. Food and Drug Administration, or FDA. On February 10, 2010, we received a complete response letter from the FDA, which stated the NDA could not be approved due to deficiencies observed during the FDA's inspection of the facilities of our third-party manufacturer. Following the meeting with FDA to discuss the observations, we re-submitted the NDA for OFIRMEV on May 4, 2010.

We were incorporated under the laws of the State of Delaware in May 2004. Our principal executive offices are located at 12481 High Bluff Drive, Suite 200, San Diego, California 92130 and our telephone number is (858) 436-1400. Information about the company is also available on our website at www.cadencepharm.com, which includes links to reports we have filed with the Securities and Exchange Commission, or SEC, which are available free of charge. The contents of our website are not incorporated by reference in this Quarterly Report on Form 10-Q.

The U.S. Patent and Trademark Office has issued a Notice of Allowance in connection with our intent-to-use trademark application for the mark Cadence™, and we have applied for U.S. trademark registration of OFIRMEV™. This report also contains trademarks of others, including Caldolor® and Perfalgan®.

Background

We were incorporated in May 2004 and during that year we focused on hiring our management team and initial operating employees, but substantial operations did not commence until September 2004. Since that time, we have in-licensed rights to two late-stage product candidates.

OFIRMEV™

In March 2006, we in-licensed rights to OFIRMEV, a proprietary intravenous formulation of acetaminophen, from Bristol-Myers Squibb Company, or BMS, which currently markets the product in Europe and several other markets under the brand name Perfalgan®. In October 2006, we initiated our Phase III clinical development program for this product candidate for the management of pain and reduction of fever in adults and children. In May 2009, we completed our clinical development program for OFIRMEV and submitted an NDA to the FDA, requesting marketing approval of OFIRMEV for the management of pain and reduction of fever in adults and children. Our NDA was accepted for filing by the FDA and designated for priority review in July of that year. Pursuant to Prescription Drug User Fee Act, or PDUFA, guidelines, the FDA was expected to complete its review and provide an action letter with respect to the NDA in November 2009; however, the agency instead indicated that its review would be extended for up to three additional months, resulting in a new PDUFA goal date in February 2010.

On February 10, 2010, we received a complete response letter from the FDA, which stated that the NDA could not be approved in its present form due to deficiencies with respect to good manufacturing practices observed during the agency's inspection of the facilities of our third-party manufacturer, which was completed on February 5, 2010. In the complete response letter, the FDA did not indicate that the completion of any additional clinical trials were required in order to approve the NDA for OFIRMEV and did not cite any safety or efficacy deficiencies. On February 18, 2010, our third-party manufacturer submitted a response to the FDA, and on April 16, 2010 a meeting was held with the FDA, our third-party manufacturer and ourselves to discuss the deficiencies. Based upon this meeting, we resubmitted our NDA for OFIRMEV on May 4, 2010. The FDA will determine the classification of the resubmission (Class 1 or Class 2) and the resulting review timeline (two months or six months, respectively) shortly after receipt of the resubmitted NDA.

We believe that, if approved by the FDA, OFIRMEV may fulfill significant unmet needs in the hospital setting. We also believe that the hospital pharmaceuticals market is both concentrated and underserved and intend to focus our sales and marketing efforts primarily on hospital-based physicians who manage patients with mild to severe pain who cannot take oral medications.

Omiganan pentahydrochloride

In 2005, we completed a special protocol assessment, or SPA, for omiganan pentahydrochloride 1% aqueous gel, and initiated Phase III clinical trials for this product candidate. In March 2009, we announced that our Phase III clinical trial of omiganan pentahydrochloride did not meet its primary endpoint and discontinued our development efforts for this product candidate because we believed that the results of the study did not support applications for marketing approval. At the same time, we implemented cost reduction measures and restructured our operations to make additional resources available for our OFIRMEV development program and other operating activities.

We are a development stage company and we have incurred significant net losses since our inception. As of March 31, 2010, we had an accumulated deficit of $230.9 million. These losses have resulted principally from costs incurred in connection with research and development activities, including license fees, costs of clinical trial activities associated with our product candidates, pre-commercialization manufacturing development activities, the establishment of our commercial infrastructure and general and administrative expenses. We expect to continue to incur operating losses for the foreseeable future as we commercialize OFIRMEV, if approved by the FDA, and acquire or in-license additional products, technologies or businesses that are complementary to our own.

We have financed our operations primarily through the issuance of equity securities in both public and private offerings. In October 2006, we completed an initial public offering in which we sold 6.0 million shares of our common stock at $9.00 per share and received aggregate net proceeds of $48.4 million (after underwriting discounts and offering costs). In November 2006, following exercise of the underwriters' over-allotment option, we sold 0.9 million shares of our common stock at $9.00 per share and received aggregate net proceeds of $7.5 million (after underwriting discounts). In February 2008, we completed a registered direct offering pursuant to an effective shelf registration statement under which we issued and sold 9.2 million shares of common stock at $5.34 per share and received aggregate net proceeds of approximately $49.1 million (after offering costs). In February 2009, we raised additional funds by completing a private placement of approximately 12.0 million shares of common stock at a price of $7.13 per share, and warrants to purchase up to approximately 6.0 million additional shares of common stock at a price of $0.125 per warrant, for aggregate net proceeds of $86.2 million (after offering costs). Each warrant has a five-year term and is exercisable in cash or by net exercise for one share of common stock at a price of $7.84. As of March 31, 2010, all of the warrants remain outstanding.

Revenues

We have not generated any revenues to date, and we do not expect to generate any revenues from licensing, achievement of milestones or product sales until we are able to commercialize our OFIRMEV product candidate ourselves or execute a collaboration arrangement with a third party.

Research and Development Expenses

Our research and development expenses consist primarily of license fees, salaries and related employee benefits, costs associated with clinical trials managed by our contract research organizations, or CROs, costs associated with non-clinical activities, such as regulatory expenses, and pre-commercialization manufacturing development activities. The clinical trial expenses include payments to vendors such as CROs, investigators, clinical suppliers and related consultants. License fees are paid to the patent holders of our product candidates that give us the exclusive licenses to the patent rights and know-how for selected indications and territories. Manufacturing development activities include the costs to develop facilities for the commercial production of our drug products prior to approval, the production of supply and validation lots, and other manufacturing support activities related to the requirements for submitting NDAs for our product candidates.

Our historical research and development expenses relate predominantly to OFIRMEV and our discontinued omiganan pentahydrochloride product candidate. We have expensed these charges as they have been incurred as the underlying technology associated with these expenditures relates to our research and development efforts and has no alternative future uses. A substantial portion of these external costs are tracked on a project basis. However, our internal research and development resources are used in several projects and may not be attributable to a specific product candidate. For example, a substantial portion of our internal costs, including personnel and facility related costs, is not tracked on a project basis. We have summarized these costs in the following table.

Costs that are not attributable to a specific product candidate, including salaries and related personnel costs, are included in the "other supporting costs" category (in thousands):

	Three Months Ended March 31,		Period from May 26, 2004 (Inception) through March 31,
	2010	2009	2010
OFIRMEV[1]	$ 1,457	$ 1,839	$ 65,864
Omigard[2][3]	1	1,470	57,460
Other supporting costs	2,773	2,830	38,007
	$ 4,231	$ 6,139	$ 161,331

(1) We paid an up-front license fee of $25.0 million in 2006 for OFIRMEV, which is included in the amount for the period from May 26, 2004 (inception) through March 31, 2010. We may be required to make future milestone payments totaling up to $40.0 million upon the achievement of various milestones related to regulatory and commercial events in addition to royalties on the sales of the licensed products, including payments totaling $15.0 million upon the approval of our NDA by the FDA.

(2) We paid an up-front license fee of $2.0 million in 2004 for omiganan pentahydrochloride, of which $1.5 million is included in the costs for the period from May 26, 2004 (inception) through March 31, 2010. As a result of the termination of our collaboration and license agreement with Migenix, Inc., or Migenix, on May 8, 2009, we will not be obligated to make any future milestone or royalty payments with respect to this product candidate.

(3) During the fourth quarter of 2008, we recorded an impairment charge of $2.4 million on our omiganan pentahydrochloride manufacturing equipment due to the discontinuance of our omiganan pentahydrochloride program. During 2009, we recorded adjustments to this impairment charge, reducing the charge by $0.2 million as actual costs incurred in disposing of the assets were less than anticipated. Further, in 2009 we recorded a restructuring charge of $0.6 million related to the discontinuation of our omiganan pentahydrochloride development program. These charges are presented separately on our statement of operations in "Other" operating expenses and is not included in the table above.

It is difficult to anticipate the scope and magnitude of our future research and development expenses. The FDA may require us to perform additional studies or to provide other information in order to secure approval or require post-approval studies and clinical trials. Further, we plan to initiate additional clinical studies in children in an effort to obtain a six-month pediatric extension of market exclusivity for OFIRMEV, if approved, and may look to expand the indications for this product candidate in the future which could require further studies. Moreover, any product candidates we may in-license or acquire in the future would likely require significant research and development resources. Therefore, we are unable to estimate with any certainty the costs we will incur in completing our development efforts for OFIRMEV or any other product candidate we might acquire or in-license.

Sales and Marketing Expenses

Our sales and marketing expenses consist primarily of market research studies and pre-launch marketing activities, costs related to the establishment of our commercial infrastructure, salaries, benefits and professional fees related to building our sales and marketing capabilities. In 2009 we began to focus significant resources on establishing our commercial infrastructure in preparation for the commercial launch of OFIRMEV, including by increasing our sales and marketing staff from two at the end of 2008 to 40 at the end of 2009. Further, we have been preparing to hire approximately 150 sales representatives if OFIRMEV is approved by the FDA.

We anticipate our sales and marketing expenses will continue to increase as we move forward with preparations for the potential commercial launch of OFIRMEV including, and if our NDA for this product candidate is approved, hiring our sales force to begin marketing OFIRMEV to physicians, nurses, group purchasing organizations and third-party payors.

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries, benefits and related personnel costs for our administrative, finance, human resources, legal, business development and internal systems support functions; as well as the related professional fees for these functions, insurance and facility costs. We anticipate increases in general and administrative expenses as we continue to build our corporate infrastructure and support the potential commercial operations for OFIRMEV, if approved by the FDA.

Interest and Other Income and Expense

Our interest income consists primarily of interest earned on our cash, cash equivalents and short-term investments. Interest expense consists of the interest we have incurred under our amended loan and security agreement and the amortization of debt issuance costs. Other expense includes charges we have incurred to recognize other-than-temporary declines in the market value of our available-for-sale securities and the gains or losses recognized on transactions denominated in foreign currencies.

Income Taxes

We assess income tax positions and record tax benefits for all years subject to examination based upon our evaluation of the facts, circumstances and information available at the reporting date. For those tax positions where there is a greater than 50% likelihood that a tax benefit will be sustained, we have recorded the largest amount of tax benefit that may potentially be realized upon ultimate settlement with a taxing authority that has full knowledge of all relevant information. For those income tax positions where there is less than 50% likelihood that a tax benefit will be sustained, no tax benefit has been recognized in the financial statements.

As of December 31, 2009, we had federal and state net operating loss carryforwards of approximately $171.4 million and $170.6 million, respectively. If not utilized, the net operating loss carryforwards will begin expiring in 2024 for federal purposes and 2014 for state purposes. Additionally, we had both federal and state research and development tax credit carryforwards of approximately $3.8 million and $1.9 million, respectively. The federal tax credits will begin expiring in 2024 unless previously utilized and the state tax credits carryforward indefinitely. Under Section 382/383 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, substantial changes in our ownership may limit the amount of net operating loss carryforwards and development tax credit carryforwards that could be utilized annually in the future to offset taxable income. Any such annual limitation may significantly reduce the utilization of the net operating losses and tax credits before they expire. We have not completed a Section 382/383 study at this time to determine the impact ownership changes have had on our carryforwards. In each period since our inception, we have recorded a valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As a result, we have not recognized any federal or state income tax benefit in our statement of operations.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the U.S., or GAAP, requires us to make certain estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting period. Some of our accounting policies require us to make difficult and subjective judgments, often as a result of the need to make estimates of matters that are inherently uncertain. The following accounting policies involve critical accounting estimates because they are particularly dependent on estimates and assumptions made by management about matters that are highly uncertain at the time the accounting estimates are made. In addition, while we have used our best estimates based on facts and circumstances available to us at the time, different estimates reasonably could have been used. Changes in the accounting estimates we use are reasonably likely to occur from time to time, which may have a material impact on the presentation of our financial condition and results of operations.

Our most critical accounting estimates include our recognition of research and development expenses, which impacts operating expenses and accrued liabilities; stock-based compensation which impacts operating expenses, and the assessment of recoverability of long-lived assets, which primarily impacts operating expenses when we impair assets or accelerate depreciation. We also have other policies that we consider to be key accounting policies, such as our policies for deferred income tax assets and liabilities; and our reserves for commitments and contingencies; however, these policies either do not meet the definition of critical accounting estimates described above or are not currently material items in our financial statements. We review our estimates, judgments, and assumptions periodically and reflect the effects of revisions in the period in which they are deemed to be necessary. We believe that these estimates are reasonable; however, actual results could differ from these estimates.

Research and Development Expenses

A substantial portion of our research and development activities is performed under agreements we enter into with external service providers, including CROs, which conduct many of our research and development activities. We accrue for costs incurred under these contracts based on factors such as estimates of work performed, milestones achieved, patient enrollment and experience with similar contracts. As actual costs become known, we adjust our accruals. To date, our accruals have been within management’s estimates. Subsequent changes in estimates may result in a change in our accruals, which could also materially affect our results of operations.

Stock-Based Compensation

We account for stock-based compensation by calculating the fair value of the award on the date of grant and recognize the expense over the applicable vesting period. We calculate the fair value of stock options using the Black-Scholes pricing model, which requires a number of estimates, including the expected lives of awards, interest rates, stock volatility and other assumptions. Restricted stock units, or RSUs, are measured based on the fair market values of the underlying stock on the dates of grant. We apply a forfeiture rate to estimate the number of grants that will ultimately vest. If the awards are performance based, we also assess the likelihood of the vesting conditions occurring and apply an appropriate factor in recognizing the expense.

The table below summarizes the stock-based compensation expense included in our statements of operations for the periods indicated (in thousands):

	Three Months Ended March 31,		Period from May 26, 2004 (Inception) through March 31, 2010
	2010	2009	
Research and development	$ 980	$ 458	$ 7,329
Sales and marketing	485	16	1,082
General and administrative	1,529	1,007	14,752
Stock-based compensation expense included in operating expenses	2,994	1,481	23,163
Total stock-based compensation expense included in loss from operations	$ 2,994	$ 1,481	$ 23,163

As of March 31, 2010, the total future compensation expense related to the current unvested stock options and RSUs is approximately $22.0 million.

Long-Lived Assets

We evaluate long-lived assets for impairment of their carrying value when events or circumstances indicate that the carrying value may not be recoverable. Factors we consider in deciding when to perform an impairment review include significant negative industry or economic trends, significant changes or planned changes in our use of the assets, technological obsolescence, or other changes in circumstances which indicate the carrying value of the assets may not be recoverable. If such an event occurs, we evaluate whether the sum of the estimated undiscounted cash flows attributable to the assets in question is less than their carrying value. If this is the case, we recognize an impairment loss to the extent that carrying value exceeds fair value. Fair value is determined based on market prices or discounted cash flow analysis, depending on the nature of the asset and the availability of market data. Any estimate of future cash flows is inherently uncertain. The factors we take into consideration in making estimates of future cash flows include product life cycles, pricing trends, future capital needs, cost trends, product development costs, competitive factors and technology trends as they each affect cash inflows and outflows. If an asset is written down to fair value, that value becomes the asset's new carrying value and is depreciated over the remaining useful life of the asset.

As the result of the discontinuation of our omiganan pentahydrochloride program, we recorded an impairment charge of $2.4 million on our omiganan pentahydrochloride manufacturing equipment during the fourth quarter of 2008. In the third quarter of 2009, we recorded adjustments to this impairment charge, reducing the charge by $0.2 million as actual costs incurred in disposing of the assets were less than anticipated. No similar impairments or adjustments were recorded in the first quarter of 2010.

Results of Operations

Three-Month Periods Ended March 31, 2010 and 2009

Operating expenses

Research and Development Expenses. Research and development expenses decreased $1.9 million to $4.2 million for the three months ended March 31, 2010, from $6.1 million for the comparable period in 2009. This reduction was primarily due to a $1.5 million decrease in spending on our omiganan pentahydrochloride product candidate as we discontinued our development efforts for this product candidate in March 2009 following the results of our Phase III clinical trial for this drug. Additionally, research and development spending on our OFIRMEV product candidate decreased $0.4 million in 2010 as compared to 2009, primarily due to a

reduction in clinical development for OFIRMEV costs as we filed our NDA for OFIRMEV with the FDA in May 2009. Partially offsetting the reduction in clinical development expenses was an increase in pre-commercialization manufacturing costs incurred during the three months ended March 31, 2010 as we continue to prepare our manufacturing operations for the potential commercialization of OFIRMEV.

Sales and Marketing Expenses. Sales and marketing expenses increased to $6.1 million for the three months ended March 31, 2010, compared to $0.5 million for the comparable period in 2009. This increase was primarily due to the development of our commercial and supply operations functions for OFIRMEV during 2009 as we established our commercial infrastructure in preparation for the potential commercial launch of the product. As part of our development efforts, we increased our sales and marketing staff from two at the end of 2008 to 40 as of March 31, 2010, which significantly increased our salaries and personnel costs for the current period. Moreover, we incurred additional outside service fees and advertising and promotion costs as we continued our commercial readiness preparations to ensure a successful launch of OFIRMEV, if approved by the FDA.

General and Administrative Expenses. General and administrative expenses increased $0.7 million to $3.5 million for the three months ended March 31, 2010, compared to $2.8 million for the same period in 2009. This increase was primarily due to increases in salaries and related personnel costs, mostly attributable to stock-based compensation charges from additional equity awards outstanding in 2010 as compared to 2009. Additionally, we incurred additional costs to enhance our information technology infrastructure during the current period in support of the potential commercialization of our OFIRMEV product, if approved by the FDA.

Other income and expense net

Net other expense decreased $0.1 million to $0.2 million for the three months ended March 31, 2010, compared to $0.3 million for the comparable period in 2009. The decrease in expense was primarily due to a reduction in the interest incurred on our outstanding debt arrangements due to a lower average principal balance in 2010 as compared to 2009. The balance of our debt obligations, net of the loan discount, on our balance sheet at March 31, 2010 and December 31, 2009 was $5.0 million and $6.4 million, respectively.

Liquidity and Capital Resources

As a biopharmaceutical company focused on in-licensing, developing and commercializing proprietary pharmaceutical product candidates, we enter into license agreements to acquire the rights to develop and commercialize product candidates. We obtained the exclusive patent rights and know-how for OFIRMEV, currently our only product candidate, for the U.S. and Canada pursuant to our license agreement with BMS. Under this agreement, we paid to BMS a $25.0 million up-front fee and may be required to make future milestone payments totaling up to $40.0 million upon the achievement of various milestones related to regulatory and commercial events, including payments totaling $15.0 million upon the approval of our NDA for OFIRMEV. In addition, we are also obligated to pay royalties on any net sales of the licensed product.

We had also previously entered into a license agreement for our former omiganan pentahydrochloride product candidate under which we paid to Migenix an aggregate of $2.0 million in the form of an up-front fee, including the purchase of 617,284 shares of Migenix common stock. In May 2009, we terminated our license agreement with Migenix, and we will not be required to make future milestone or royalty payments under this agreement.

Our future capital uses and requirements depend on numerous forward-looking factors. These factors include, but are not limited to, the following:

- the potential for delays in our efforts to seek regulatory approval for OFIRMEV, and any costs associated with delays;
- the costs of establishing a commercial organization to sell, market and distribute OFIRMEV;
- the rate of progress and costs of our efforts to prepare for the submission of an NDA for any product candidates that we may in-license or acquire in the future, and the potential that we may need to conduct additional clinical trials to support applications for regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates, including any such costs we may be required to expend if our licensors are unwilling or unable to do so;
- the cost and timing of securing sufficient supplies of OFIRMEV from our contract manufacturers in preparation for commercialization;

- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish;
- if OFIRMEV is approved, the potential that we may be required to file a lawsuit to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of intravenous acetaminophen; and
- the success of the commercialization of OFIRMEV.

As of March 31, 2010, we had $67.7 million in cash and cash equivalents, a decrease of $8.2 million from the $75.9 million at December 31, 2009. This decrease was primarily due to cash used in operations ($12.0 million), principal payments on our debt obligations ($1.5 million) and purchases of property and equipment ($0.7 million), partially offset by the maturities of marketable securities ($6.0 million) which were reinvested in money market funds and categorized as cash equivalents.

The $12.0 million of cash used in operations during the three months ended March 31, 2010 represents a $1.4 million decrease from the $13.4 million of cash used in operations during the comparable 2009 period. Although we incurred a larger operating loss during the three months ended March 31, 2010 as compared to 2009, approximately one-half of the increased loss was related to non-cash charges. Also favorably impacting the cash used in operations was a less significant net decrease in our accounts payable and accrued liabilities during the three months ended March 31, 2010, as compared to the 2009 period. Specifically, our net accounts payable and accrued liabilities balances decreased $1.4 million, to $9.0 million at March 31, 2010, from $10.4 million at December 31, 2009. For the same 2009 period, our net accounts payable and accrued liabilities balances decreased $4.6 million.

The principal payments of $1.5 million made during the three months ended March 31, 2010 reduced our net debt balance to $5.0 million. As of March 31, 2010, nine equal monthly payments remained on our debt, along with the term loan final payment.

Our net property and equipment balance increased $0.6 million during the three months ended March 31, 2010, to $8.9 million. This increase was due to $0.7 million of capital equipment expenditures to be used primarily for the commercial manufacturing of OFIRMEV, partially offset by depreciation on our assets that were in service during the year.

Sources of Liquidity

Since inception, our operations have been financed primarily through the issuance of equity securities, in both public and private offerings. From our inception through March 31, 2010, we have received net proceeds of approximately $271.1 million from the sale of our preferred stock, common stock and warrants to purchase common stock. Through March 31, 2010, the sales of shares of our preferred stock, common stock and warrants were as follows:

- from July 2004 to March 2010 (excluding our initial public offering, our February 2008 registered direct offering and our February 2009 private placement), we issued and sold a total of 2,369,144 shares of common stock to our founders, employees, directors and consultants for aggregate net proceeds of $1.0 million;
- from July 2004 to August 2004, we issued and sold a total of 8,085,108 shares of Series A-1 preferred stock for aggregate net proceeds of $7.5 million;
- from June 2005 to September 2005, we issued and sold a total of 17,675,347 shares of Series A-2 preferred stock for aggregate net proceeds of $17.6 million;
- in March 2006, we issued and sold a total of 53,870,000 shares of Series A-3 preferred stock for aggregate net proceeds of $53.8 million;
- in the fourth quarter of 2006, we completed our initial public offering in which we issued and sold a total of 6,900,000 shares of our common stock for aggregate net proceeds of $55.9 million;
- in February 2008, we completed a registered direct offering pursuant to an effective shelf registration in which we issued and sold a total of 9,240,307 shares of our common stock for aggregate net proceeds of $49.1 million; and
- in February 2009, we raised aggregate net proceeds of approximately $86.2 million through a private placement transaction in which we issued 12,039,794 shares of common stock and warrants to purchase up to 6,019,897 additional shares of common stock.

Additionally, in February 2006, we entered into a $7.0 million loan and security agreement with Silicon Valley Bank and Oxford Finance Corporation to provide us with growth capital. We drew down $7.0 million in June 2006 and in July 2009 we made the final payment to retire the $7.0 million obligation. In November 2007, we amended the $7.0 million loan and security agreement

and entered into the Second Amendment to Loan and Security Agreement with the same parties and GE Business Financial Services Inc. (formerly known as Merrill Lynch Business Financial Services, Inc.), to secure an additional $15.0 million credit facility. In December 2007, we drew down $15.0 million under the Second Amendment in two separate draws of $5.0 million and $10.0 million with fixed interest rates of 7.83% and 7.74%, respectively, net of a loan fee of less than $0.1 million. In February 2007, we began making the first of 30 equal monthly principal and interest payments on the $7.0 million loan and in July 2008 we began making the first of 30 equal monthly principal and interest payments to fully amortize the balance on the $15.0 million credit facility. As of March 31, 2010, we had no further credit available under these agreements. In connection with each credit facility, we issued warrants to the lenders to purchase shares of our stock.

Capital Resources

Our cash, cash equivalent and short-term investment balances are our primary source of liquidity and will continue to be our only source until we are able to obtain approval and successfully commercialize OFIRMEV. We believe we have sufficient financial resources to fund our operations, at a minimum, through the next nine months, including our requirements for projected working capital, capital expenditures and debt servicing. However, we may not have sufficient financial resources to meet all of our objectives once approval is obtained, which could require us to postpone, scale back or eliminate some, or all, of these objectives, including our potential launch activities. Our future funding requirements will depend on many factors, including, but not limited to costs associated with our efforts to:

- obtain regulatory approval for OFIRMEV, or any other product candidates that we may license or acquire;
- manufacture commercial quantities of OFIRMEV, if approved, at acceptable cost levels; and
- develop a commercial organization and the supporting infrastructure required to successfully market and sell OFIRMEV, if it is approved.

Until we can generate significant cash from our operations, we expect to continue to fund our operations with our available financial resources, generated from the proceeds of offerings of our equity securities and our existing borrowings under our amended loan and security agreement. These financial resources may not be adequate to sustain our operations until we are able to generate significant positive cash from operations and we may be required to finance future cash needs through the sale of additional equity securities, strategic collaboration agreements and debt financing. However, we have drawn down all available amounts under our existing amended loan and security agreement, and we may not be successful in obtaining strategic collaboration agreements. Further, we cannot be certain that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or our stockholders. The capital markets have experienced volatility in recent years and the availability of credit has been adversely affected by illiquid credit markets and wide credit spreads. Further, concern about the stability of the markets in general, and the strength of counterparties specifically, has led many lenders and institutional investors to reduce, and in some cases, cease to provide funding to borrowers. Continued turbulence in the U.S. and international markets and economies may adversely affect our ability to obtain additional financing on terms acceptable to us, or at all. If these market conditions continue, they may limit our ability to timely replace maturing liabilities and to access the capital markets to meet liquidity needs. Having insufficient funds may require us to delay, scale-back or eliminate some or all of our development programs or renegotiate less favorable terms than we would otherwise choose. Failure to obtain adequate financing also may adversely affect our ability to operate as a going concern. Additionally, if we raise funds by issuing equity securities, dilution to existing stockholders would result, and if we raise funds by incurring additional debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

We have invested a substantial portion of our available cash in money market funds placed with reputable financial institutions and debt instruments of agencies of the U.S. government for which credit loss is not anticipated. The capital markets have been highly volatile and there has been a lack of liquidity for certain financial instruments, especially those with exposure to mortgage-backed securities and auction rate securities. This lack of liquidity has made it difficult for the fair value of these types of instruments to be determined. As of March 31, 2010 our money market fund holdings did not hold auction rate securities.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of March 31, 2010.

Recent Accounting Pronouncements

See Note 3 to the Notes to Condensed Financial Statements in Item 1 above for further discussion of recent accounting pronouncements.

Caution on Forward-Looking Statements

This Quarterly Report on Form 10-Q, or Quarterly Report, includes forward-looking statements that are subject to risks and uncertainties, many of which are beyond our control. Forward-looking statements discuss matters that are not historical facts, and include, but are not limited to, discussions regarding our business, regulatory and commercialization strategies, growth strategy, competition, industry, regulatory environment, economic conditions, financial condition, liquidity and capital resources and results of operations. In this Quarterly Report, for example, we make forward-looking statements regarding: the timeframe and potential for approval of our re-submitted NDA for OFIRMEV; the sufficiency of our third-party manufacturer's corrective actions; and all financial estimates or projections related to our company. Such statements include, but are not limited to, statements preceded by, followed by or that otherwise include the words, "believe," "may," "might," "can," "could," "will," "would,", "should," "estimate," "continue," "anticipate," "intend," "seek," "plan," "project," "expect," or similar expressions.

While we believe that the expectations reflected in this Quarterly Report are reasonable, the inclusion of any forward-looking statements should not be regarded as a representation that any of our plans will be achieved. Our actual results will differ from those anticipated in our forward looking statements as a result of various factors, including those set forth below under the caption "Part II, Item 1A – Risk Factors," and the differences may be material. These risk factors include, but are not limited to: the potential for the FDA to require additional data or information as part of its review of our resubmitted NDA for OFIRMEV, including requirements for additional stability batches or other manufacturing data, which may require significant time and expense to produce; our reliance on our third-party manufacturer to respond to the FDA's concerns and address any manufacturing facility deficiencies; the timeframe in which FDA will review our re-submitted NDA for OFIRMEV, including the possibility that the FDA will decide to re-inspect the manufacturing facility prior to completing its review of the NDA; the risk that further FDA scrutiny of the manufacturing site may raise additional issues that must be resolved prior to obtaining approval of our NDA, causing further delay and expense; the risk that we may not receive regulatory approval for OFIRMEV on a timely basis or at all; our dependence on the success of OFIRMEV as our only product candidate; the potential we will require substantial additional funding in order to obtain regulatory approval for and commercialize OFIRMEV, and the risk that we may not be able to raise sufficient capital when needed, or at all; the risk that delays in approval of our NDA for OFIRMEV and our commercial launch will enable competitors to further entrench their existing products or develop and bring new products to market before OFIRMEV; the impact of healthcare reform legislation; and other risks detailed in our periodic public filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement and we undertake no obligation to revise or update such statements to reflect events or circumstances after the date hereof. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

Item 3. ***Quantitative and Qualitative Disclosures about Market Risk***

Our cash equivalents and short-term investments are classified as available-for-sale. As of March 31, 2010 our holdings consisted solely of money market funds made in accordance with an investment policy approved by our board of directors which specifies the categories, allocations, and ratings of securities we may consider for investment. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. Some of the financial instruments that we invest in could be subject to market risk. This means that a change in prevailing interest rates may cause the value of the instruments to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of that security will probably decline. To minimize this risk, we intend to maintain a portfolio which may include cash, cash equivalents and investment securities available-for-sale in a variety of securities which may include money market funds, government and non-government debt securities and commercial paper, all with various maturity dates. Based on our current investment portfolio, we do not believe that our results of operations would be materially impacted by an immediate change of 10% in interest rates.

We do not hold or issue derivatives, derivative commodity instruments or other financial instruments for speculative trading purposes. Further, we do not believe our cash, cash equivalents and investment securities have significant risk of default or illiquidity. We made this determination based on discussions with our investment advisors and a review of our holdings. While we believe our cash, cash equivalents and investment securities do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. All of our investments are held at fair value. The following table shows the fair value of our cash equivalents and investments as of March 31, 2010 (in thousands):

	Amortized Cost Basis	Fair Value
Cash equivalents	$ 66,903	$ 66,903

Debt

The loans under our amended loan and security agreement have fixed interest rates. Consequently, we do not have significant interest rate cash flow exposure on our debt. The aggregate balance of the loans, net of the loan discount, under the agreement at March 31, 2010 was $5.0 million, and is collateralized by substantially all of our assets (excluding intellectual property). Under the terms of the agreement, we are precluded from entering into certain financing and other transactions, including disposing of certain assets and paying dividends, and are subject to various non-financial covenants and prepayment penalties.

Item 4. ***Controls and Procedures***

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder, is recorded, processed, summarized and reported within the time periods specified in the U.S. Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Evaluation of disclosure controls and procedures. As required by U.S. Securities and Exchange Commission Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report. Based on the foregoing, our chief executive officer and chief financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in internal control over financial reporting. There was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. ***Legal Proceedings***

Not applicable.

Item 1A. ***Risk Factors***

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report on Form 10-Q and those we may make from time to time. If any of the following risks actually occur, our business, operating results, prospects or financial condition could be harmed. Additional risks not presently known to us, or that we currently deem immaterial, may also affect our business operations.

We have marked with an asterisk (*) those risk factors that reflect substantive changes from the risk factors included in our previously filed Annual Report on Form 10-K for the year ended December 31, 2009.

Risks Related to Our Business and Industry

We currently have no drug products for sale, and only one drug product candidate, OFIRMEV™. We are dependent on the success of OFIRMEV™, and cannot guarantee that this product candidate will receive regulatory approval or be successfully commercialized.

Our business success depends on our ability to obtain regulatory approval for and successfully commercialize our only product candidate, OFIRMEV, and any significant delays in obtaining approval for and commercializing OFIRMEV will have a substantial adverse impact on our business and financial condition.

If approved, our ability to generate revenues from OFIRMEV will depend on our ability to:

- hire, train, deploy and support our sales force;
- create market demand for OFIRMEV through our own marketing and sales activities, and any other arrangements to promote this product candidate we may later establish;
- obtain sufficient quantities of OFIRMEV from our third-party manufacturers as required to meet commercial demand at launch and thereafter;
- establish and maintain agreements with wholesalers, distributors and group purchasing organizations on commercially reasonable terms; and
- maintain patent protection and regulatory exclusivity for OFIRMEV.

We may not receive regulatory approval for OFIRMEV, or its approval may be further delayed, which would have a material adverse effect on our business and financial condition.*

The process for obtaining approval of an NDA is time consuming, subject to unanticipated delays and costs, and requires the commitment of substantial resources. For example, we submitted a New Drug Application, or NDA, for OFIRMEV to the U.S. Food and Drug Administration, or FDA, in May 2009. The NDA was accepted for filing in July 2009, and designated for priority review. Pursuant to Prescription Drug User Fee Act, or PDUFA, guidelines, the FDA was expected to complete its review and provide an action letter with respect to the NDA in November 2009; however, the agency instead indicated that its review would be extended for up to three additional months, resulting in a new PDUFA goal date in February 2010. On February 10, 2010, we received a complete response letter from the FDA, which stated that the NDA could not be approved in its present form due to deficiencies with respect to good manufacturing practices observed during the agency's inspection of the facilities of our third-party manufacturer, which was completed on February 5, 2010.

On April 16, 2010, we and our third-party manufacturer met with the FDA to discuss our third-party manufacturer's response to the FDA's inspectional observations. Following this meeting, on May 4, 2010, we re-submitted our 505(b)(2) NDA for OFIRMEV.

The approval of our re-submitted NDA for OFIRMEV may be delayed if the FDA is not satisfied with our third-party manufacturer's response to the FDA's inspectional observations. If the FDA determines that it must re-inspect the facilities used to manufacture OFIRMEV before agreeing that the inspectional observations have been adequately addressed, the submission will be categorized as a Class 2 submission, which will result in a six-month review timeline. If no re-inspection is required, the submission may be categorized as a Class 1 submission, which will result in a two-month review timeline.

Although the FDA did not request that we complete new stability studies during the meeting, the agency may require additional data or information as part of its review of the submission. If the FDA requires additional stability data or other manufacturing data that we do not currently have, such data may not be available for a significant amount of time, which could delay the approval of our NDA for OFIRMEV and cause us to incur significant additional expenses.

As part of its standard procedures, the FDA required us to provide updated safety information when we re-submitted the NDA for OFIRMEV, including safety information derived from the use of this product candidate in other countries. This information could influence the FDA's decision as to whether to approve our NDA, or cause the FDA to re-evaluate previously reviewed portions of the NDA and lead to new data requests, which could result in additional delays or cause the agency to require that we add unfavorable statements, such as new warnings or contraindications, to the labeling for OFIRMEV, if approved.

Additionally, our NDA for OFIRMEV may not be approved, or approval may be delayed, as a result of changes in FDA policies for drug approval during the review period. For example, although many products have been approved by the FDA in recent years under Section 505(b)(2) under the Federal Food, Drug and Cosmetic Act, objections have been raised to the FDA's interpretation of Section 505(b)(2). If challenges to the FDA's interpretation of Section 505(b)(2) are successful, the agency may be required to change its interpretation, which could delay or prevent the approval of our NDA for OFIRMEV. The review of our re-submitted NDA may also be delayed due to the FDA's internal resource constraints.

Any significant delay in our third-party manufacturer's resolution of the inspectional observations, or our receipt of a second complete response letter denying approval of OFIRMEV, could negatively impact our ability to ultimately obtain marketing authorization for this product candidate and would have a material adverse effect on our business and financial condition.

If our contract manufacturer fails to complete pre-commercialization manufacturing development activities for OFIRMEV on a timely basis or fails to comply with stringent regulatory requirements, we will face delays in our ability to obtain regulatory approval for, and to commercialize, this product candidate, and our costs will increase.*

We do not manufacture OFIRMEV, and do not currently plan to develop any capacity to do so. Instead, we have relied on a third-party manufacturer, Baxter Healthcare Corporation, or Baxter, to manufacture and perform important pre-commercialization manufacturing development activities for this product candidate. As part of the process for obtaining regulatory approval, we must demonstrate that the facilities, equipment and processes used to manufacture OFIRMEV are capable of consistently producing a product that meets all applicable quality criteria, and that is comparable to the product that was used in our clinical trials. We must also provide the FDA with information regarding the validation of the manufacturing facilities, equipment and processes of our third-party manufacturer, and data supporting the stability of our product candidate. If Baxter is not in compliance with current good manufacturing practice requirements, the approval of our marketing application may be delayed, existing product batches may be compromised, and we may experience delays in the availability of this product candidate for commercial distribution.

For example, on February 10, 2010 we received a complete response letter from the FDA regarding our NDA submission for OFIRMEV which stated that the NDA could not be approved in its present form due to deficiencies observed during an inspection of the facilities used by Baxter to produce this product candidate, which was completed on February 5, 2010. On February 18, 2010, Baxter submitted a response to the FDA, and on April 16, 2010 we and Baxter met with the FDA to discuss Baxter's response to the inspectional observations. Following that meeting, we re-submitted our 505(b)(2) NDA for OFIRMEV on May 4, 2010. The approval of our re-submitted NDA for OFIRMEV may be delayed if the FDA is not satisfied with Baxter's response to its inspectional observations, or if the FDA determines that it must re-inspect the facilities used to manufacture OFIRMEV before agreeing that the inspectional observations have been adequately addressed. If a re-inspection is required, the submission will be categorized as a Class 2 submission, which will result in a six-month review timeline. If no re-inspection is required, the submission may be categorized as a Class 1 submission, which will result in a two-month review timeline.

If OFIRMEV is approved and our contract manufacturer fails to produce the product in the volumes that we require on a timely basis, or to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the commercialization of this product candidate or be unable to meet market demand, and may lose potential revenues.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls, and the use of specialized processing equipment. We have entered into a development and supply agreement with Baxter for the completion of pre-commercialization manufacturing development activities and the manufacture of commercial supplies of OFIRMEV. Any termination or disruption of our relationships with Baxter may materially harm our business and financial condition, and frustrate any commercialization efforts for this product candidate.

In order to meet anticipated demand for OFIRMEV if this product candidate is approved, Baxter has initiated planning activities to install additional production lines, and we have ordered additional, specialized processing equipment to expand the manufacturing capacity for OFIRMEV. This processing equipment is currently available from a single source, and if this equipment is not delivered on time or at all, Baxter's ability to increase the manufacturing capacity for OFIRMEV to keep pace with anticipated demand will be substantially impacted.

We are currently negotiating a supply agreement for the commercial supply of the active pharmaceutical ingredient, or API, for OFIRMEV. If we need to change to another manufacturer or significantly change the manufacturing processes for this product, we may be required to repeat or perform additional pre-clinical or clinical testing, which could increase our costs and cause delays in our ability to obtain regulatory approval for and commercialize the product.

All of our contract manufacturers must comply with strictly enforced federal, state and foreign regulations, including current Good Manufacturing Practice requirements enforced by the FDA through its facilities inspection program, and we have little control over their compliance with these regulations. Any failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval, and would limit the availability of our product. Any manufacturing defect or error discovered after products have been produced and distributed could result in even more significant consequences, including costly recall procedures, re-stocking costs, damage to our reputation and potential for product liability claims.

If the commercial manufacturers upon whom we rely to manufacture OFIRMEV, and any other product candidates we may in-license, fail to deliver the required commercial quantities on a timely basis at commercially reasonable prices, we would likely be unable to meet demand for our products and we would lose potential revenues.

The FDA may determine that OFIRMEV has undesirable side effects that could delay or prevent its regulatory approval or commercialization.

If concerns are raised regarding the safety of a new drug as a result of undesirable side effects identified during clinical testing, the FDA may decline to approve the drug at the end of the NDA review period or issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve the drug. The number of such requests for additional data or information issued by the FDA in recent years has increased, and resulted in substantial delays in the approval of several new drugs. Undesirable side effects caused by OFIRMEV could also result in the inclusion of unfavorable information in our product labeling, denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing and generating revenues from the sale of this product candidate.

For example, the adverse events observed in the OFIRMEV clinical trials completed to date include transient liver enzyme elevations, nausea or vomiting, allergic reactions, and pain or local skin reactions at the injection site. When used in excess of the current guidelines for administration, acetaminophen has an increased potential to cause liver toxicity. While the rate of adverse events in our clinical trials was comparable between the group of patients who received OFIRMEV and those who were in the placebo or control groups and, as a result, we do not expect the administration of acetaminophen in intravenous form will result in an increased risk of toxicity to the liver compared with an equivalent dose of acetaminophen administered orally, we cannot be certain that increased liver toxicity or other drug-related side effects will not be observed in future clinical trials, or as a result of sales of the same formulation of intravenous acetaminophen by BMS in European and other countries, or that the FDA will not require additional trials or impose more severe labeling restrictions due to liver toxicity or other concerns. In June 2009, the FDA convened an advisory panel to make recommendations regarding minimization of the risk of significant liver toxicity due to overdoses with oral acetaminophen, primarily in the outpatient setting. While we do not believe that the panel's specific recommendations will negatively affect OFIRMEV, the FDA may take actions different from, or in addition to, those recommended by the panel.

If OFIRMEV receives marketing approval and we or others later identify undesirable side effects caused by this product:

- regulatory authorities may require the addition of unfavorable labeling statements, specific warnings or a contraindication;
- regulatory authorities may suspend or withdraw their approval of the product, or require it to be removed from the market;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of OFIRMEV or could substantially increase our commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from its sale.

Even if OFIRMEV receives regulatory approval, it and any other products we may market will remain subject to substantial regulatory scrutiny.

OFIRMEV and any other product candidates we may license or acquire will also be subject to ongoing FDA requirements with respect to the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. In addition, the subsequent discovery of previously unknown problems with a product may result in restrictions on the product, including withdrawal of the product from the market.

If OFIRMEV or any other product we may license or acquire fails to comply with applicable regulatory requirements, such as current Good Manufacturing Practices, a regulatory agency may:

- issue warning letters or untitled letters;
- require our contract manufacturer to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- impose fines other civil or criminal penalties;
- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require a product recall.

In addition to FDA restrictions, numerous other federal, state and local laws and regulations apply to the promotion and sale of pharmaceutical products, such as federal anti-kickback and false claims statutes. For example, the federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn are used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer’s products from reimbursement under government programs, criminal fines and imprisonment.

Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have a material adverse effect on our business, financial condition and results of operations.

Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated.

Any regulatory approval is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians may choose to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the U.S. generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to suspend or withdraw an approved product from the market, require a recall or institute fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business.

Although the FDA has indicated that our proposed trade name for intravenous acetaminophen, OFIRMEV™, is acceptable, the agency may not ultimately approve this trade name.

OFIRMEV, or any other trade name that we intend to use for intravenous acetaminophen, must be approved by the FDA irrespective of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office. The FDA conducts a rigorous review of proposed product names, and may reject a product name if it believes that the name inappropriately implies medical claims or if it poses the potential for confusion with other product names. For example, the FDA previously rejected our proposed product name, Acetavance, based on the agency's assertion that the name is unacceptable from a promotional perspective. Following that rejection, we submitted alternative product names to the agency for review, and have been informed by the agency that the trade name, OFIRMEV, is acceptable. However, the FDA will not approve this trade name until the NDA for intravenous acetaminophen is approved. If the FDA determines that the trade names of other products that are approved prior to the approval of intravenous acetaminophen may present a risk of confusion with our proposed trade name, the FDA may not ultimately approve OFIRMEV. If our trade name, OFIRMEV, is rejected, we will lose the benefit of any brand equity that may already have been developed for this product candidate, as well as the benefit of our existing trademark applications for this trade name. Additionally, if the FDA does not approve one of our alternative product names for intravenous acetaminophen prior to the NDA approval date, we may be required to launch this product candidate without a brand name, and our efforts to build a successful brand identity for, and commercialize, this product candidate may be adversely impacted.

We are subject to new legislation, regulatory proposals and managed care initiatives that may increase our costs of compliance and adversely affect our ability to market our products, obtain collaborators and raise capital.*

In March 2010, the President signed the Patient Protection and Affordable Care Act, which makes extensive changes to the delivery of health care in the United States. This act includes numerous provisions that affect pharmaceutical companies, some of which are effective immediately and others of which will be taking effect over the next several years. For example, the act seeks to expand health care coverage to the uninsured through private health insurance reforms and an expansion of Medicaid. The act will also impose substantial costs on pharmaceutical manufacturers, such as an increase in liability for rebates paid to Medicaid, new drug discounts that must be offered to certain enrollees in the Medicare prescription drug benefit, an annual fee imposed on all manufacturers of brand prescription drugs in the United States, and an expansion of an existing program requiring pharmaceutical discounts to certain types of hospitals and federally subsidized clinics. The act also contains cost containment measures that could reduce reimbursement levels for health care items and services generally, including pharmaceuticals. It also will require reporting and public disclosure of payments and other transfers of value provided by pharmaceutical companies to physicians and teaching hospitals. These measures could result in decreased net revenues from our pharmaceutical products and decrease potential returns from our development efforts.

In addition, there have been a number of other legislative and regulatory proposals aimed at changing the pharmaceutical industry. In particular, California has enacted legislation that requires development of an electronic pedigree to track and trace each prescription drug at the saleable unit level through the distribution system. California's electronic pedigree requirement is scheduled to take effect in January 2015. Compliance with California and future federal or state electronic pedigree requirements may increase our

operational expenses and impose significant administrative burdens. As a result of these and other new proposals, we may determine to change our current manner of operation, provide additional benefits or change our contract arrangements, any of which could have a material adverse effect on our business, financial condition and results of operations.

Our reporting and payment obligations under the Medicaid rebate program and other governmental purchasing and rebate programs are complex and may involve subjective decisions, and any failure to comply with those obligations could subject us to penalties and sanctions, which could in turn have a material adverse effect on our business and financial condition.

As a condition of reimbursement by various federal and state healthcare programs, we must calculate and report certain pricing information to federal and state healthcare agencies. The regulations regarding reporting and payment obligations with respect to Medicaid reimbursement and rebates and other governmental programs are complex. Our calculations and methodologies are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could result in material changes. In addition, because our processes for these calculations and the judgments involved in making these calculations involve subjective decisions and complex methodologies, these calculations are subject to the risk of errors. Any failure to comply with the government reporting and payment obligations could result in civil and/or criminal sanctions.

We may never receive approval to commercialize OFIRMEV or any other product candidates we may acquire outside of the U.S.

Our rights to OFIRMEV are limited to the U.S. and Canada. In order to market OFIRMEV and any product candidates we may acquire in Canada or other jurisdictions outside of the U.S., we must comply with numerous and varying regulatory requirements of other countries regarding non-clinical testing, manufacturing, safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the U.S. as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the U.S. As described above, such effects include the risks that our products may not be approved for all indications requested, which could limit the uses of our products and have an adverse effect on product sales and potential royalties, and that any regulatory approvals we may obtain may be subject to limitations on the indicated uses for which our products may be marketed or require us to perform costly, post-marketing follow-up studies.

Public concern regarding the safety of drug products such as OFIRMEV could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs.

In light of widely publicized events concerning the safety risk of certain drug products, the FDA, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and the establishment of risk management programs that may, for example, restrict distribution of drug products after approval. The Food and Drug Administration Amendments Act of 2007, or FDAAA, grants significant expanded authority to the FDA, much of which is aimed at improving the safety of drug products before and after approval. In particular, the new law authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. It also significantly expands the federal government’s clinical trial registry and results databank, which we expect will result in significantly increased government oversight of clinical trials. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of data from our clinical trials. Data from clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional preclinical studies or clinical trials. If the FDA requires us to conduct additional preclinical studies or clinical trials prior to approving OFIRMEV, our ability to obtain approval of this product candidate will be delayed. If the FDA requires us to provide additional clinical or preclinical data following the approval of OFIRMEV, the indications for which this product candidate is approved may be limited or there may be specific warnings or limitations on dosing, and our efforts to commercialize OFIRMEV may be otherwise adversely impacted.

We expect intense competition for OFIRMEV, and new products may emerge that provide different or better therapeutic alternatives for our targeted indications.

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition in the development and marketing of OFIRMEV from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. There can be no assurance that developments by others will not render OFIRMEV obsolete or noncompetitive. Furthermore, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical industry at a rapid pace. These developments may render OFIRMEV obsolete or noncompetitive.

OFIRMEV will compete with well-established products with similar indications. Competing products available for the treatment of pain include opioids such as morphine, fentanyl, meperidine and hydromorphone, each of which is available generically from several manufacturers, and several of which are available as proprietary products using novel delivery systems. Ketorolac, an injectable non-steroidal anti-inflammatory drug, or NSAID, is also available generically in the U.S. from several manufacturers, and Caldolor (ibuprofen for injection), an NSAID, was approved by the FDA in June 2009 for the treatment of pain and fever in adults. Competing products available for the treatment of fever in the hospital setting include acetaminophen administered orally and rectally, aspirin and NSAIDs, which may be administered orally, topically or intravenously. Additional products may be developed for the treatment of acute pain, including new injectable NSAIDs, novel opioids, new formulations of currently available opioids and NSAIDS, long-acting local anesthetics and new chemical entities as well as alternative delivery forms of various opioids and NSAIDs.

Competitors may seek to develop alternative formulations of intravenous acetaminophen for our targeted indications that do not directly infringe on our in-licensed patent rights. For example, we are aware of several U.S. and Canadian patents and patent applications covering various potential injectable formulations of acetaminophen, including intravenous formulations, as well as methods of making and using these potential formulations. The commercial opportunity for OFIRMEV could be significantly harmed if competitors are able to develop alternative formulations outside the scope of our in-licensed patents. Compared to us, many of our potential competitors have substantially greater:

- capital resources;
- development resources, including personnel and technology;
- clinical trial experience;
- regulatory experience;
- expertise in prosecution of intellectual property rights; and
- manufacturing, distribution and sales and marketing experience.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize OFIRMEV. Our competitors may also develop drugs that are more effective, useful and less costly than ours and may be more successful than us in manufacturing and marketing their products. We expect to face similar competition in our efforts to identify appropriate collaborators or partners to help develop or commercialize OFIRMEV in Canada.

If OFIRMEV does not achieve broad market acceptance, the revenues that we generate from its sales will be limited.

The commercial success of OFIRMEV, if approved, will depend upon its acceptance by the medical community, our ability to ensure that the drug is included in hospital formularies, and coverage and reimbursement for OFIRMEV by third-party payors, including government payors. The degree of market acceptance of OFIRMEV or any other product candidate we may license or acquire will depend on a number of factors, including:

- limitations or warnings contained in the product's FDA-approved labeling, including potential limitations or warnings for OFIRMEV that may be more restrictive than oral formulations of acetaminophen;
- changes in the standard of care for the targeted indications for our product candidates, which could reduce the marketing impact of any superiority claims that we could make following FDA approval; and
- potential advantages over, and availability of, alternative treatments, including, in the case of OFIRMEV, a number of products already used to treat pain or fever in the hospital setting.

Our ability to effectively promote and sell OFIRMEV and any other product candidates we may license or acquire in the hospital marketplace will also depend on pricing and cost effectiveness, including our ability to produce a product at a competitive price and achieve acceptance of the product onto hospital formularies, as well as our ability to obtain sufficient third-party coverage or reimbursement. Since many hospitals are members of group purchasing organizations, which leverage the purchasing power of a group of entities to obtain discounts based on the collective buying power of the group, our ability to attract customers in the hospital marketplace will also depend on our ability to effectively promote our product candidates to group purchasing organizations. We will also need to demonstrate acceptable evidence of safety and efficacy, as well as relative convenience and ease of administration. Market acceptance could be further limited depending on the prevalence and severity of any expected or unexpected adverse side effects associated with our product candidates. If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

We have never marketed a drug before, and if we are unable to establish an effective commercial infrastructure, we will not be able to successfully commercialize OFIRMEV.

We are planning to build our own sales and marketing capabilities in order to market OFIRMEV directly to physicians, nurses, hospitals, group purchasing organizations and third-party payors. The development of a hospital-focused sales, marketing and distribution infrastructure for our domestic operations will be expensive and time consuming and, if not completed on time, could delay the launch of OFIRMEV, if approved, and may otherwise negatively impact our commercialization efforts. If we are not successful in attracting or retaining a full complement of qualified sales and marketing personnel in time for the launch of this product candidate, we may not achieve our initial sales objectives. We will incur significant additional expenses associated with the recruitment, training and compensation of our new sales representatives and, because we have elected to begin hiring key sales and marketing management personnel and implementing other pre-commercialization activities prior to the date on which we know whether OFIRMEV will be approved, we will incur significant commercialization costs for this product candidate before we know when, or if, it will be approved. If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate any product revenue, may experience increased expenses, and may never become profitable.

We will rely on third parties to perform many essential services for any products that we commercialize, including services related to warehousing and inventory control, distribution, customer service, accounts receivable management, cash collection and adverse event reporting, and if such third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to commercialize OFIRMEV will be significantly impacted and we may be subject to regulatory sanctions.

We have retained third-party service providers to perform a variety of functions related to the sale and distribution of OFIRMEV, key aspects of which will be out of our direct control. These service providers will provide key services related to warehousing and inventory control, distribution, customer service, accounts receivable management and cash collection, and, as a result, most of our inventory will be stored at a single warehouse maintained by one such service provider. We will substantially rely on this provider as well as other third-party providers that perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter physical or natural damage at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired. In addition, we have engaged third parties to perform various other services for us relating to adverse event reporting, safety database management, fulfillment of requests for medical information regarding our product candidate and related services. If the quality or accuracy of the data maintained by these service providers is insufficient, we could be subject to regulatory sanctions.

If the government or third-party payors fail to provide coverage and adequate coverage and payment rates for OFIRMEV or any future products we may license or acquire, if any, or if hospitals choose to use therapies that are less expensive, our revenue and prospects for profitability will be limited.

In both domestic and foreign markets, our sales of any future products will depend in part upon the availability of coverage and reimbursement from third-party payors. Such third-party payors include government health programs such as Medicare, managed care providers, private health insurers and other organizations. In particular, many U.S. hospitals receive a fixed reimbursement amount per procedure for certain surgeries and other treatment therapies they perform. Because this amount may not be based on the actual expenses the hospital incurs, hospitals may choose to use therapies which are less expensive when compared to our product

candidates. Accordingly, OFIRMEV or any other product candidates that we may in-license or acquire, if approved, will face competition from other therapies and drugs for these limited hospital financial resources. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to the satisfaction of hospitals, other target customers and their third-party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Our future products might not ultimately be considered cost-effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

Governments continue to propose and pass legislation designed to reduce the cost of healthcare. In some foreign markets, such as Canada, the government controls the pricing of prescription pharmaceuticals. In these countries, pricing negotiated with governmental authorities can take six to 12 months or longer after the receipt of regulatory marketing approval for a product. In the U.S., we expect that there will be an increase in federal and state proposals to implement pricing controls for prescription drugs, and new legislation and regulations affecting the pricing of pharmaceuticals might change before our product candidates are approved for marketing. For example, the U.S. Congress is considering a number of legislative and regulatory proposals with an objective of ultimately reducing healthcare costs. Legislative and regulatory actions under consideration in the U.S. include health care reform initiatives that could significantly alter the market for pharmaceuticals (such as private health insurance expansion, the creation of competing public health insurance plans, a variety of proposals that would reduce government expenditures for prescription drugs to help finance healthcare reform, or the eventual transition of the U.S. multiple payer system to a single payer system). Other actions under consideration include proposals for government intervention in pharmaceutical pricing, changes in government reimbursement, an accelerated approval process for “follow-on” biologics, legalization of commercial drug importation into the U.S., and involuntary approval of medicines for over-the-counter, or OTC, use. Such legislation could result in the exclusion of OFIRMEV and any other product candidates we may license or acquire from coverage and reimbursement programs, or lower the prices we would receive for our product candidates. Our revenues from the sale of any approved products could be significantly reduced as a result of these cost containment measures and reforms, which would negatively impact our profitability.

If we breach any of the agreements under which we license rights to OFIRMEV from others, we could lose the ability to continue to develop and commercialize this product candidate.

In March 2006, we entered into an exclusive license agreement with BMS relating to OFIRMEV for the U.S. and Canada. Because we have in-licensed the rights to this product candidate from a third party, if there is any dispute between us and our licensor regarding our rights under our license agreement, our ability to develop and commercialize this product candidate may be adversely affected. Any uncured, material breach under our license agreement could result in our loss of exclusive rights to our product candidate and may lead to a complete termination of our related product development efforts.

If BMS breaches the underlying agreement under which we sublicense the rights to OFIRMEV, we could lose the ability to develop and commercialize this product candidate.

Our license for FIRMEV is subject to the terms and conditions of a license from SCR Pharmatop to BMS, under which BMS originally licensed the intellectual property rights covering OFIRMEV. If BMS materially breaches the terms or conditions of this underlying license from SCR Pharmatop, and neither BMS nor we adequately cure that breach, or BMS and SCR Pharmatop otherwise become involved in a dispute, the breach by BMS or disputes with SCR Pharmatop could result in a loss of, or other material adverse impact on, our rights under our license agreement with BMS. While we would expect to exercise all reasonable rights and remedies available to us, including seeking to cure any breach by BMS, and otherwise seek to preserve our rights under the patents licensed by SCR Pharmatop, we may not be able to do so in a timely manner, at an acceptable cost or at all. Any uncured, material breach under the license from SCR Pharmatop to BMS could result in our loss of exclusive rights to our OFIRMEV product candidate and may lead to a complete termination of our product development and any commercialization efforts for OFIRMEV.

We will need to increase the size of our organization, and we may experience difficulties in managing growth.

As of March 31, 2010, we had 90 employees. We will need to substantially expand our managerial, commercial, financial and other personnel resources in order to manage our operations and prepare for the commercialization of OFIRMEV, if approved. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth, and we may not be able to recruit and retain qualified personnel in the future, particularly for sales and marketing positions, due to competition for personnel among pharmaceutical businesses, and the failure to do so could have a significant negative impact on our future product revenues and business results. Our need to effectively manage our operations, growth and various projects requires that we:

- continue the hiring and training of an effective commercial organization in anticipation of the potential approval of OFIRMEV, and establish appropriate systems, policies and infrastructure to support that organization;
- ensure that our consultants and other service providers successfully carry out their contractual obligations, provide high quality results, and meet expected deadlines;
- continue to carry out our own contractual obligations to our licensors and other third parties; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our development and commercialization goals.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel.

We may not be able to attract or retain qualified management and commercial, scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Diego, California area. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the product acquisition, development, regulatory and commercialization expertise of our senior management, particularly Theodore R. Schroeder, our President and Chief Executive Officer, James B. Breitmeyer, M.D., Ph.D., our Executive Vice President, Development and Chief Medical Officer, William R. LaRue, our Senior Vice President, Chief Financial Officer, Treasurer and Assistant Secretary, and Scott A. Byrd, our Senior Vice President and Chief Commercial Officer. If we lose one or more of these key employees, our ability to successfully implement our business strategy could be seriously harmed. Replacing key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel. Although we have employment agreements with Mr. Schroeder, Dr. Breitmeyer, Mr. LaRue and Mr. Byrd, these agreements are terminable at will at any time with or without notice and, therefore, we may not be able to retain their services as expected.

In addition, we have scientific and clinical advisors who assist us in our product development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, or may have arrangements with other companies to assist in the development of products that may compete with ours.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for OFIRMEV or other product candidates we may license or acquire and may have to limit their commercialization.

The use of OFIRMEV and any other product candidates we may license or acquire in clinical trials and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- decreased demand for our product candidates;
- impairment of our business reputation;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues; and
- the inability to commercialize our product candidates.

We have obtained limited product liability insurance coverage for our clinical trials with a $15.0 million annual aggregate coverage limit. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidate in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Our future growth depends on our ability to identify and acquire or in-license products and if we do not successfully identify and acquire or in-license related product candidates or integrate them into our operations, we may have limited growth opportunities.

We in-licensed the rights to OFIRMEV from a third party who conducted the initial development of this product candidate, which is currently our only product candidate. An important part of our business strategy is to continue to develop a pipeline of product candidates by acquiring or in-licensing products, businesses or technologies that we believe are a strategic fit with our focus on the hospital marketplace. Future in-licenses or acquisitions, however, may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- difficulty or inability to secure financing to fund development activities for such acquired or in-licensed technologies in the current economic environment;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. In particular, we may compete with larger pharmaceutical companies and other competitors in our efforts to establish new collaborations and in-licensing opportunities. These competitors likely will have access to greater financial resources than us and may have greater expertise in identifying and evaluating new opportunities. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts.

Our business involves the use of hazardous materials and we and our third-party manufacturer must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our third-party manufacturer's activities and, to a lesser extent, our own activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidate and other hazardous compounds. We and our manufacturer are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. Although we believe that the safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, state or federal authorities may curtail our use of these materials and interrupt our business operations.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed clinical trials for OFIRMEV could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of our product candidate may be delayed.

Risks Related to Intellectual Property

The patent rights that we have in-licensed covering OFIRMEV are limited to a specific intravenous formulation of acetaminophen, and our market opportunity for this product candidate may be limited by the lack of patent protection for the active ingredient itself and other formulations that may be developed by competitors.

The active ingredient in OFIRMEV is acetaminophen. Patent protection for the acetaminophen molecule itself in the territories licensed to us, which include the U.S. and Canada, is not available. As a result, competitors who obtain the requisite regulatory approval can offer products with the same active ingredient as OFIRMEV so long as the competitors do not infringe any process or formulation patents that we have in-licensed from BMS and its licensor, SCR Pharmatop. We are aware of a number of third-party patents in the U.S. that claim methods of making acetaminophen. If a supplier of the API for our OFIRMEV product candidate is found to infringe any of these method patents covering acetaminophen, our supply of the API could be delayed and we may be required to locate an alternative supplier. We are also aware of several U.S. and Canadian patents and patent applications covering various potential injectable formulations of acetaminophen as well as methods of making and using these potential formulations. For example, Injectapap, a liquid formulation of acetaminophen for intramuscular injection, was approved by the FDA for the reduction of fever in adults in March 1986, although it was subsequently withdrawn from the market by McNeil Pharmaceutical in July 1986.

The number of patents and patent applications covering products in the same field as OFIRMEV indicates that competitors have sought to develop and may seek to market competing formulations that may not be covered by our licensed patents and patent applications. In addition, the Canadian patent applications that we have in-licensed have yet to be examined by the Canadian Patent Office. Thus, they may issue with claims that cover less than the corresponding in-licensed U.S. patents, or simply not issue at all. The commercial opportunity for OFIRMEV could be significantly harmed if competitors are able to develop an alternative formulation of acetaminophen outside the scope of our in-licensed patents.

If OFIRMEV is approved by the FDA, one or more third parties may challenge the patents covering this product, which could result in the invalidation or unenforceability of some or all of the relevant patent claims. For example, if a third party files an Abbreviated New Drug Application, or ANDA, for a generic drug product containing acetaminophen and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA for FIRMEV; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third-party's generic drug product. A certification that the new product will not infringe the Orange Book-listed patents for OFIRMEV, or that such patents are invalid, is called a paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third-party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third-party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45-day period, the third-party's ANDA will not be subject to the 30-month stay. Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could adversely impact our ability to prevent third parties from competing with our products.

We depend on our licensors for the maintenance and enforcement of our intellectual property and have limited control, if any, over the amount or timing of resources that our licensors devotes on our behalf, or whether any financial difficulties experienced by our licensors could result in their unwillingness or inability to secure, maintain and enforce patents protecting our intellectual property.

We depend on our licensor, BMS, and its licensor SCR Pharmatop, to protect the proprietary rights covering OFIRMEV and we have limited, if any, control over the amount or timing of resources that BMS or SCR Pharmatop devote on our behalf, or the priority they place on, maintaining patent rights and prosecuting patent applications to our advantage.

Either BMS or SCR Pharmatop, depending on the patent or application, is responsible for maintaining issued patents and prosecuting patent applications. SCR Pharmatop is under a contractual obligation to BMS to diligently prosecute their patent applications and allow BMS the opportunity to consult, review and comment on patent office communications. However, we cannot be sure that SCR Pharmatop will perform as required. Should BMS decide it no longer wants to maintain any of the patents licensed to us, BMS is required to afford us the opportunity to do so at our expense. However, we cannot be sure that BMS will perform as required. If BMS does not perform, and if we do not assume the maintenance of the licensed patents in sufficient time to make required payments or filings with the appropriate governmental agencies, we risk losing the benefit of all or some of those patent rights. Moreover, either BMS or SCR Pharmatop may experience serious difficulties related to their overall business or financial stability, and they may be unwilling or unable to continue to expend the financial resources required to maintain and prosecute these patents and patent applications. While we intend to take actions reasonably necessary to enforce our patent rights, we depend, in part, on our licensors to protect a substantial portion of our proprietary rights. BMS has the first right to prosecute a third-party infringement of the SCR Pharmatop patents, and has the sole right to prosecute third-party infringement of the BMS patents. We will have the ability to cooperate with BMS in third-party infringement suits involving the SCR Pharmatop patents. It is possible that SCR Pharmatop or BMS could take some action or fail to take some action that could harm the SCR Pharmatop patents. In certain instances, we may be allowed to pursue the infringement claim ourselves.

Our licensors may also be notified of alleged infringement and be sued for infringement of third-party patents or other proprietary rights. We may have limited, if any, control or involvement over the defense of these claims, and our licensors could be subject to injunctions and temporary or permanent exclusionary orders in the U.S. or other countries. Our licensors are not obligated to defend or assist in our defense against third-party claims of infringement. We have limited, if any, control over the amount or timing of resources, if any, that our licensors devote on our behalf or the priority they place on defense of such third-party claims of infringement.

For a third-party challenge to the SCR Pharmatop in-licensed patents relating to OFIRMEV, we will have some ability to participate in either SCR Pharmatop's or BMS' defense thereof. In the case that neither party elects to defend the third-party challenge, we may have the opportunity to defend it. For a third-party challenge to the in-licensed BMS patents relating to OFIRMEV, BMS has the sole right to defend such challenge. If it chooses not to defend such challenge, we may have the right to renegotiate or terminate the license regarding the in-licensed BMS patents.

Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we or our licensors may not be successful in defending claims of intellectual property infringement by third parties, which could have a material adverse affect on our results of operations. Regardless of the outcome of any litigation, defending the litigation may be expensive, time-consuming and distracting to management.

Because it is difficult and costly to protect our proprietary rights, we may not be able to ensure their protection.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection for OFIRMEV or any other product candidates that we may license or acquire and the methods we use to manufacture them, as well as successfully defending these patents and trade secrets against third-party challenges. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in pharmaceutical or biotechnology patents has emerged to date in the U.S. The patent situation outside the U.S. is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the U.S. and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

The degree of future protection for our proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;
- our licensors might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our product candidates or technologies;
- it is possible that none of the pending patent applications licensed to us will result in issued patents;
- the issued patents covering our product candidates may not provide a basis for commercially viable active products, may not provide us with any competitive advantages, or may be challenged by third parties;
- we may not develop additional proprietary technologies that are patentable; or
- patents of others may have an adverse effect on our business.

Patent applications in the U.S. are maintained in confidence for at least 18 months after their earliest effective filing date. Consequently, we cannot be certain that our licensors were the first to invent or the first to file patent applications on our product candidates. In the event that a third party has also filed a U.S. patent application relating to our product candidates or a similar invention, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention in the U.S. The costs of these proceedings could be substantial and it is possible that our efforts would be unsuccessful, resulting in a material adverse effect on our U.S. patent position. Furthermore, we may not have identified all U.S. and foreign patents or published applications that affect our business either by blocking our ability to commercialize our drugs or by covering similar technologies that affect our drug market.

In addition, some countries, including many in Europe, do not grant patent claims directed to methods of treating humans, and in these countries patent protection may not be available at all to protect our product candidates. Even if patents issue, we cannot guarantee that the claims of those patents will be valid and enforceable or provide us with any significant protection against competitive products, or otherwise be commercially valuable to us.

We also rely on trade secrets to protect our technology, particularly where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. While we use reasonable efforts to protect our trade secrets, our licensors, employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

If our licensors or we fail to obtain or maintain patent protection or trade secret protection for OFIRMEV or any other product candidate we may license or acquire, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and achieve profitability.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in any litigation would harm our business.

Our ability to develop, manufacture, market and sell OFIRMEV or any other product candidates that we may license or acquire depends upon our ability to avoid infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the general fields of pain treatment and cover the use of numerous compounds and formulations in our targeted markets. Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we and our licensors may not be successful in defending intellectual property claims by third parties, which could have a material adverse affect on our results of operations. Regardless of the outcome of any litigation, defending the litigation may be expensive, time-consuming and distracting to management. In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that OFIRMEV may infringe. There could also be existing patents of which we are not aware that OFIRMEV may inadvertently infringe.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that we infringe on their products or technology, we could face a number of issues, including:

- infringement and other intellectual property claims which, with or without merit, can be expensive and time consuming to litigate and can divert management's attention from our core business;
- substantial damages for past infringement which we may have to pay if a court decides that our product infringes on a competitor's patent;
- a court prohibiting us from selling or licensing our product unless the patent holder licenses the patent to us, which it would not be required to do;
- if a license is available from a patent holder, we may have to pay substantial royalties or grant cross licenses to our patents; and
- redesigning our processes so they do not infringe, which may not be possible or could require substantial funds and time.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Our Finances and Capital Requirements

We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.

We are a development stage company with a limited operating history. We have focused primarily on in-licensing and developing OFIRMEV and our former product candidate, omiganan pentahydrochloride, with the goal of supporting regulatory approval for these product candidates. We have incurred losses in each year since our inception in May 2004, including net losses of $45.5 million, $57.1 million and $51.7 million for the years ended December 31, 2009, 2008 and 2007, respectively. As of March 31, 2010, we had an accumulated deficit of $ 230.9 million. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital. For example, our development expenses decreased in 2009 due to the completion of our clinical development program for OFIRMEV, and the discontinuation of our development program for our omiganan pentahydrochloride product candidate. However, we incurred increased pre-commercialization expenses during 2009 as we prepared for the potential market launch of OFIRMEV, and we expect to incur significant sales, marketing and outsourced manufacturing expenses, as well as continued development expenses related to the commercialization of this product, if approved by the FDA. As a result, we expect to continue to incur significant operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

We currently have no source of revenue and may never be profitable.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from our development stage products, and we do not know when, or if, we will generate any revenue. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- obtain regulatory approval for OFIRMEV, or any other product candidates that we may license or acquire;
- manufacture commercial quantities of OFIRMEV, if approved, at acceptable cost levels; and
- develop a commercial organization and the supporting infrastructure required to successfully market and sell OFIRMEV, if it is approved.

If OFIRMEV is approved for commercial sale, we anticipate incurring significant costs associated with its commercialization. We also do not anticipate that we will achieve profitability for a period of time after generating material revenues, if ever. If we are unable to generate revenues, we will not become profitable and may be unable to continue operations without continued funding.

Our short operating history makes it difficult to evaluate our business and prospects.

We were incorporated in May 2004 and have only been conducting operations with respect to OFIRMEV since March 2006 and our discontinued omiganan pentahydrochloride product candidate since July 2004. Our operations to date have been limited to organizing and staffing our company, in-licensing and conducting product development activities, including clinical trials and manufacturing development activities, for OFIRMEV and omiganan pentahydrochloride. Further, in 2009 we began to establish our commercial infrastructure for OFIRMEV. We have not yet demonstrated an ability to obtain regulatory approval for or successfully commercialize a product candidate. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

We will need additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

Developing products for use in the hospital setting, conducting clinical trials, establishing outsourced manufacturing relationships and successfully manufacturing and marketing drugs that we may develop is expensive. We will need to raise additional capital to:

- fund our operations and continue our efforts to hire additional personnel and build a commercial infrastructure to prepare for the commercialization of OFIRMEV, if approved by the FDA;
- qualify and outsource the commercial-scale manufacturing of our products under current good manufacturing practices; and
- in-license and develop additional product candidates.

In February 2009, we completed a private placement of common stock and warrants to purchase common stock, raising net proceeds of approximately $86.2 million. We believe that with our currently available cash and cash equivalent balance, we have sufficient funds to meet our projected operating requirements, at a minimum, through the next nine months. We have based this estimate on assumptions that may prove to be wrong and we could spend our available financial resources faster than we currently expect. Further, we may not have sufficient financial resources to meet all of our objectives if OFIRMEV is approved, which could require us to postpone, scale back or eliminate some, or all, of these objectives, including our potential launch activities. Our future funding requirements will depend on many factors, including, but not limited to:

- the potential for delays in our efforts to seek regulatory approval for OFIRMEV, and any costs associated with such delays;
- the costs of establishing a commercial organization to sell, market and distribute OFIRMEV;
- the rate of progress and costs of our efforts to prepare for the submission of an NDA for any product candidates that we may in-license or acquire in the future, and the potential that we may need to conduct additional clinical trials to support applications for regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates, including any such costs we may be required to expend if our licensors are unwilling or unable to do so;
- the cost and timing of securing sufficient supplies of OFIRMEV from our contract manufacturers in preparation for commercialization;
- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish;
- if OFIRMEV is approved, the potential that we may be required to file a lawsuit to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of intravenous acetaminophen; and
- the success of the commercialization of OFIRMEV.

Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies, but we currently have no commitments or agreements relating to any of these types of transactions.

Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, as well as through interest income earned on cash and investment balances. We cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts.

Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- whether the FDA requires us to complete additional, unanticipated studies, tests or other activities prior to approving OFIRMEV, which would likely further delay any such approval;
- if OFIRMEV is approved, our ability to establish the necessary commercial infrastructure to launch this product candidate without substantial delays, including hiring sales and marketing personnel and contracting with third parties for warehousing, distribution, cash collection and related commercial activities;
- our execution of other collaborative, licensing or similar arrangements and the timing of payments we may make or receive under these arrangements;
- variations in the level of expenses related to our future development programs;
- any product liability or intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting OFIRMEV or the product candidates of our competitors; and
- if OFIRMEV receives regulatory approval, the level of underlying hospital demand for this product candidate and wholesalers' buying patterns.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Raising additional funds by issuing securities may cause dilution to existing stockholders and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership will be diluted. If we raise additional funds through licensing arrangements, it may be necessary to relinquish potentially valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. Any debt financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. For example, in February 2006, we entered into a $7.0 million loan and security agreement with Silicon Valley Bank and Oxford Finance Corporation, and in December 2007, we amended this agreement and secured an additional $15.0 million loan from the same parties and GE Business Financial Services Inc. Our amended loan and security agreement contains a variety of affirmative and negative covenants, including required financial reporting, limitations on the disposition of assets other than in the ordinary course of business, limitations on the incurrence of additional debt and other requirements. To secure our performance of our obligations under our amended loan and security agreement, we pledged substantially all of our assets other than intellectual property assets, to the lenders. Our failure to comply with the covenants in the amended loan and security agreement could result in an event of default that, if not cured or waived, could result in the acceleration of all or a substantial portion of our debt.

We will continue to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses under the Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the SEC and The NASDAQ Stock Market LLC, or NASDAQ. These rules impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and appropriate corporate governance practices. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. As a result, we are required to periodically perform an evaluation of our internal

controls over financial reporting to allow management to report on the effectiveness of those controls, as required by Section 404 of the Sarbanes-Oxley Act. Additionally, our independent auditors are required to perform a similar evaluation and report on the effectiveness of our internal controls over financial reporting. These efforts to comply with Section 404 and related regulations have required, and continue to require, the commitment of significant financial and managerial resources. While we anticipate maintaining the integrity of our internal controls over financial reporting and all other aspects of Section 404, we cannot be certain that a material weakness will not be identified when we test the effectiveness of our control systems in the future. If a material weakness is identified, we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources, costly litigation or a loss of public confidence in our internal controls, which could have an adverse effect on the market price of our stock.

The use of our net operating loss carryforwards and research tax credits may be limited.

Our net operating loss carryforwards and research and development tax credits may expire and not be used. As of December 31, 2009, we have generated federal and state net operating loss carryforwards of approximately $171.4 million and $170.6 million, respectively. We also have federal and state research and development tax credit carryforwards of approximately $3.8 million and $1.9 million, respectively. Our net operating loss carryforwards will begin expiring in 2024 for federal purposes and 2014 for state purposes if we have not used them prior to that time, and our federal tax credits will begin expiring in 2024 unless previously used. Our state tax credits carryforward indefinitely. Additionally, our ability to use any net operating loss and credit carryforwards to offset taxable income in the future will be limited under Internal Revenue Code Sections 382 and 383 if we have a cumulative change in ownership of more than 50% within a three-year period. We have not completed an analysis as to whether such a change of ownership has occurred, but in such an event, may be limited to the amount of net operating loss carryforwards and research tax credits that could be utilized annually in the future to offset taxable income. Any such annual limitation may significantly reduce the utilization of the net operating loss carryforwards and research tax credits before they expire. In addition, California and certain states have suspended use of net operating loss carryforwards for certain taxable years, and other states are considering similar measures. As a result, we may incur higher state income tax expense in the future. Depending on our future tax position, continued suspension of our ability to use net operating loss carryforwards in states in which we are subject to income tax could have an adverse impact on our operating results and financial condition.

Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturn.

Our results of operations could be materially negatively affected by economic conditions generally, both in the U.S. and elsewhere around the world. Continuing concerns over inflation, energy costs, geopolitical issues, the availability and cost of credit, the U.S. mortgage market and a declining residential real estate market in the U.S. have contributed to increased volatility and diminished expectations for the economy and the markets going forward. These factors, combined with volatile oil prices, declining business and consumer confidence and increased unemployment, have precipitated an economic recession and fears of a possible depression. Domestic and international equity markets continue to experience heightened volatility and turmoil. These events and the continuing market upheavals may have an adverse effect on us. In the event of a continuing market downturn, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may further decline.

Risks Relating to Securities Markets and Investment in Our Stock

There may not be a viable public market for our common stock.

Our common stock had not been publicly traded prior to our initial public offering, which was completed in October 2006, and an active trading market may not be sustained. We have never declared or paid any cash dividends on our capital stock, and we currently intend to retain all available funds and any future earnings to support operations and finance the growth and development of our business and do not intend to pay cash dividends on our common stock for the foreseeable future. Furthermore, our amended loan and security agreement with Silicon Valley Bank, Oxford Finance Corporation and GE Business Financial Services Inc. restricts our ability to pay cash dividends. Therefore, investors will have to rely on appreciation in our stock price and a liquid trading market in order to achieve a gain on their investment.

Our stock may be subject to substantial price and volume fluctuations due to a number of factors, many of which are beyond our control and may prevent our stockholders from reselling our common stock at a profit.

The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. For example, the volatility in the overall capital markets reached unprecedented levels during 2008 and 2009, which affected most equity securities. Similar market volatility could reduce the market price of our common stock in spite of our operating performance. Further, high stock price volatility could result in higher stock-based compensation expense.

The trading prices for our common stock during the 52 weeks ending March 31, 2010 ranged from a high of $12.68 to a low of $8.25. The market price of our common stock is likely to continue to be highly volatile and may fluctuate substantially due to many factors, including:

- announcements concerning the progress of our efforts to obtain regulatory approval for and commercialize OFIRMEV, including any requests we receive from the FDA for additional studies or data that result in delays in obtaining regulatory approval or launching this product candidate, if approved;
- market conditions in the pharmaceutical and biotechnology sectors or the economy as a whole;
- price and volume fluctuations in the overall stock market;
- the failure of OFIRMEV, if approved, to achieve commercial success;
- announcements of the introduction of new products by us or our competitors;
- developments concerning product development results or intellectual property rights of others;
- litigation or public concern about the safety of our potential products;
- actual fluctuations in our quarterly operating results, and concerns by investors that such fluctuations may occur in the future;
- deviations in our operating results from the estimates of securities analysts or other analyst comments;
- additions or departures of key personnel;
- health care reform legislation, including measures directed at controlling the pricing of pharmaceutical products, and third-party coverage and reimbursement policies;
- developments concerning current or future strategic collaborations; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

The realization of any of the risks described in these “Risk Factors” could have a dramatic and material adverse impact on the market price of our common stock. In addition, class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such litigation brought against us could result in substantial costs and a diversion of our management’s attention and resources, which could hurt our business, operating results and financial condition.

Future sales of our common stock may cause our stock price to decline.

Persons who were our stockholders prior to the sale of shares in our initial public offering continue to hold a substantial number of shares of our common stock that they may now be able to sell in the public market. Significant portions of these shares are held by a small number of stockholders. Sales by our current stockholders of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. Moreover, the holders of a substantial number of shares of common stock may have rights, subject to certain conditions, to require us to file registration statements to permit the resale of their shares in the public market or to include their shares in registration statements that we may file for ourselves or other stockholders.

For example, in May 2009, we completed the registration of 18,059,691 shares of our common stock in connection with a financing transaction completed in February 2009. As a result, all of the shares currently outstanding may generally be freely sold in the public market, subject to volume and other limitations applicable to our affiliates. Additionally, in September 2009, we filed with the U.S. Securities and Exchange Commission, or SEC, a registration statement for $100.0 million of debt securities, preferred stock, common stock, debt warrants and equity warrants, which was subsequently declared effective by the SEC. We have also registered all common stock that we may issue under our employee benefits plans. As a result, these shares can be freely sold in the public market upon issuance, subject to restrictions under the securities laws.

In addition, certain of our officers have established, and other of our directors and executive officers may in the future establish, programmed selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended, for the purpose of effecting sales of our common stock. If any of these events cause a large number of our shares to be sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

Our executive officers and directors and their affiliates may exercise control over stockholder voting matters in a manner that may not be in the best interests of all of our stockholders.

As of March 31, 2010, our executive officers and directors and their affiliates together controlled approximately 50.9% of our outstanding common stock. As a result, these stockholders will collectively be able to significantly influence all matters requiring approval of our stockholders, including the election of directors and approval of significant corporate transactions. The concentration of ownership may delay, prevent or deter a change in control of our company even when such a change may be in the best interests of all stockholders, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets, and might affect the prevailing market price of our common stock.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, the president or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations;
- a requirement of approval of not less than 66 2 /3% of all outstanding shares of our capital stock entitled to vote to amend any bylaws by stockholder action, or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors, including to delay or impede a merger, tender offer or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

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

We have paid no cash dividends on any of our classes of capital stock to date and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Furthermore, our amended loan and security agreement with Silicon Valley Bank, Oxford Finance Corporation and GE Business Financial Services Inc., restricts our ability to pay dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We may become involved in securities class action litigation that could divert management's attention and harm our business.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biotechnology and pharmaceutical companies. These broad market fluctuations may cause the market

price of our common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business.

Item 2. ***Unregistered Sales of Equity Securities and Use of Proceeds***

Not applicable.

Item 3. ***Defaults Upon Senior Securities***

Not applicable.

Item 4. ***Reserved***

Item 5. ***Other Information***

Not applicable.

Item 6. ***Exhibits***

Exhibit Number	Description of Exhibit
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated herein by reference to the corresponding exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 001-33103) for the period ended September 30, 2006 as filed with the SEC on November 30, 2006
3.2	Amended and Restated Bylaws of the Registrant, incorporated herein by reference to the corresponding exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 001-33103) for the period ended September 30, 2006 as filed with the SEC on November 30, 2006
3.2.1	Amendment of Amended and Restated Bylaws of the Registrant, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 17, 2007
4.1	Form of the Registrant's Common Stock Certificate, incorporated herein by reference to the corresponding exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 001-33103) for the period ended September 30, 2006 as filed with the SEC on November 30, 2006
4.2	Amended and Restated Investor Rights Agreement dated February 21, 2006, incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on July 17, 2006
4.5	Registration Rights Waiver and Amendment dated November 29, 2007, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 3, 2007
4.6	Form of Warrant to Purchase Stock issued to Silicon Valley Bank on November 30, 2007, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 3, 2007
4.7	Form of Warrant to Purchase Stock issued to Oxford Finance Corporation on November 30, 2007, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 3, 2007
4.8	Form of Warrant to Purchase Stock issued to GE Business Financial Services Inc. (formerly known as Merrill Lynch Business Financial Services Inc.), on November 30, 2007, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 3, 2007
4.9	Form of Warrant to Purchase Stock issued on February 18, 2009, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on February 20, 2009
31.1±	Certification of Chief Executive Officer pursuant to Rule 13a – 14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2±	Certification of Chief Financial Officer pursuant to Rule 13a – 14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32±	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002

± Included in this Report.

SIGNATURES

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

CADENCE PHARMACEUTICALS, INC.

Dated: May 7, 2010

By: /s/ WILLIAM R. LARUE
William R. LaRue
Senior Vice President, Chief Financial Officer,
Treasurer and Assistant Secretary
(Principal Financial and Accounting Officer)

INDEX TO EXHIBITS

Exhibit Number	Description of Exhibit
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated herein by reference to the corresponding exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 001-33103) for the period ended September 30, 2006 as filed with the SEC on November 30, 2006
3.2	Amended and Restated Bylaws of the Registrant, incorporated herein by reference to the corresponding exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 001-33103) for the period ended September 30, 2006 as filed with the SEC on November 30, 2006
3.2.1	Amendment of Amended and Restated Bylaws of the Registrant, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 17, 2007
4.1	Form of the Registrant's Common Stock Certificate, incorporated herein by reference to the corresponding exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 001-33103) for the period ended September 30, 2006 as filed with the SEC on November 30, 2006
4.2	Amended and Restated Investor Rights Agreement dated February 21, 2006, incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on July 17, 2006
4.5	Registration Rights Waiver and Amendment dated November 29, 2007, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 3, 2007
4.6	Form of Warrant to Purchase Stock issued to Silicon Valley Bank on November 30, 2007, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 3, 2007
4.7	Form of Warrant to Purchase Stock issued to Oxford Finance Corporation on November 30, 2007, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 3, 2007
4.8	Form of Warrant to Purchase Stock issued to GE Business Financial Services Inc. (formerly known as Merrill Lynch Business Financial Services Inc.), on November 30, 2007, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on December 3, 2007
4.9	Form of Warrant to Purchase Stock issued on February 18, 2009, incorporated herein by reference to the corresponding exhibit to the Registrant's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on February 20, 2009
31.1±	Certification of Chief Executive Officer pursuant to Rule 13a – 14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2±	Certification of Chief Financial Officer pursuant to Rule 13a – 14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32±	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002

± Included in this Report.

Exhibit 31.1

CERTIFICATION

I, Theodore R. Schroeder, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cadence Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including any consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/S/ THEODORE R. SCHROEDER
Theodore R. Schroeder
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: May 7, 2010

Exhibit 31.2

CERTIFICATION

I, William R. LaRue, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Cadence Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including any consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ WILLIAM R. LARUE

William R. LaRue
Senior Vice President, Chief Financial Officer,
Treasurer and Assistant Secretary
(Principal Financial and Accounting Officer)

Date: May 7, 2010

Exhibit 32

CERTIFICATION PURSUANT TO SECTION 1350 OF CHAPTER 63 OF TITLE 18 OF THE UNITED STATES CODE AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the filing of the Quarterly Report on Form 10-Q of Cadence Pharmaceuticals, Inc. ("Cadence") for the quarterly period ended March 31, 2010, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of Cadence, hereby certifies, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that, to our knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d), as applicable, of the Securities Exchange Act of 1934, as amended, and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Cadence.

The undersigned have executed this Certification effective as of May 7, 2010.

/s/ THEODORE R. SCHROEDER
Theodore R. Schroeder
President, Chief Executive Officer and Director
(Principal Executive Officer)

/s/ WILLIAM R. LARUE
William R. LaRue
Senior Vice President, Chief Financial Officer,
Treasurer and Assistant Secretary
(Principal Financial and Accounting Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of Cadence, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to Cadence and will be retained by Cadence and furnished to the Securities and Exchange Commission or its staff upon request.