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 September 30, 2012

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.

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 October 31, 2012, there were 85,559,869 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.

CONDENSED BALANCE SHEETS
(in thousands, except share and per share data)

	September 30, 2012 (unaudited)	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 69,370	$ 82,609
Investments in marketable securities	5,159	44,618
Restricted cash	450	450
Accounts receivable, net	6,848	2,703
Inventory	4,874	1,388
Prepaid expenses	660	1,071
Other current assets	81	90
Total current assets	87,442	132,929
Property and equipment, net	10,004	10,569
Intangible assets, net	12,425	13,433
Restricted cash	190	190
Other assets	7,021	7,039
Total assets	$ 117,082	$ 164,160
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,313	$ 3,801
Accrued liabilities	12,283	10,945
Deferred revenue	2,001	1,291
Current debt, less discount of $243 and $—, respectively	7,912	-
Total current liabilities	28,509	16,037
Long-term debt, less current portion and discount of $652 and $1,304, respectively	21,193	28,696
Other liabilities	602	117
Total liabilities	50,304	44,850
Commitments and contingencies (Note 11)		
Stockholders' equity :		
Common stock, $0.0001 par value; 200,000,000 shares authorized and 85,559,869 shares issued and outstanding at September 30, 2012 and 100,000,000 shares authorized and 85,511,607 shares issued and outstanding at December 31, 2011	9	9
Additional paid-in capital	493,004	485,982
Accumulated other comprehensive income	-	2
Accumulated deficit	(426,235)	(366,683)
Total stockholders' equity	66,778	119,310
Total liabilities and stockholders' equity	$ 117,082	$ 164,160

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

CADENCE PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF OPERATIONS

(Unaudited)

(in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Revenues:				
Product revenue, net	$ 13,898	$ 3,541	$ 32,977	$ 5,597
License revenue	-	-	33	5,210
Total revenues	13,898	3,541	33,010	10,807
Costs and expenses:				
Cost of product sales	6,076	2,318	16,078	3,588
Amortization of patent license	336	336	1,008	1,232
Research and development	2,235	1,656	5,446	7,002
Selling, general and administrative	20,039	19,943	66,811	61,003
Other	13	-	14	(1)
Total costs and expenses	28,699	24,253	89,357	72,824
Loss from operations	(14,801)	(20,712)	(56,347)	(62,017)
Other (expense) income:				
Interest income	34	25	97	104
Interest expense	(1,122)	(1,142)	(3,331)	(3,495)
Other (expense) income	(1)	-	29	(7)
Total other expense, net	(1,089)	(1,117)	(3,205)	(3,398)
Net loss	$(15,890)	$(21,829)	$(59,552)	$(65,415)
Basic and diluted net loss per share[1]	$ (0.19)	$ (0.34)	$ (0.70)	$ (1.03)
Shares used to compute basic and diluted net loss per share[1]	85,560	63,613	85,544	63,410

(1) There is a lack of comparability in the per share amounts between the periods presented as a result of the issuance of shares of common stock pursuant to a public offering in November 2011. Please see Note 4 of the Notes to Condensed Financial Statements for further discussion.

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

CADENCE PHARMACEUTICALS, INC.

CONDENSED STATEMENTS OF COMPREHENSIVE INCOME

(Unaudited)

(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net loss	$(15,890)	$(21,829)	$(59,552)	$(65,415)
Other comprehensive income (loss):				
Net unrealized loss on securities available for sale	-	-	(2)	-
Other comprehensive income (loss)	-	-	(2)	-
Comprehensive loss	$(15,890)	$(21,829)	$(59,554)	$(65,415)

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

CADENCE PHARMACEUTICALS, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2012	2011
Operating activities		
Net loss	$ (59,552)	$ (65,415)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1,226	1,253
Loss (gain) on disposal of assets	14	(1)
Inventory write-down	224	-
Stock-based compensation	6,925	6,998
Non-cash interest expense	21	43
Amortization of intangible assets	1,008	1,232
Amortization of discount on note payable	409	322
Amortization of premiums (accretion of discounts) on available-for-sale securities	(14)	17
Changes in operating assets and liabilities:		
Accounts receivable	(4,145)	(1,890)
Inventory	(3,710)	(7,208)
Prepaid expenses and other current assets	425	634
Accounts payable	2,658	(360)
Deferred revenue	710	798
Accrued liabilities and other liabilities	2,459	2,760
Net cash used in operating activities	(51,342)	(60,817)
Investing activities		
Purchases of marketable securities	(1,396)	(40,620)
Maturities and sales of marketable securities	40,860	57,746
Payment for option purchase right	-	(3,500)
Restricted cash	-	(300)
Purchases of property and equipment	(1,460)	(1,712)
Proceeds from the sale of property and equipment	2	1
Net cash provided by investing activities	38,006	11,615
Financing activities		
Proceeds from issuance of common stock, net	97	1,598
Principal payments under debt agreements	-	(1,755)
Net cash provided by (used in) financing activities	97	(157)
Net increase (decrease) in cash and cash equivalents	(13,239)	(49,359)
Cash and cash equivalents at beginning of period	82,609	112,175
Cash and cash equivalents at end of period	$ 69,370	$ 62,816
Supplemental disclosures		
Property and equipment purchases in accounts payable and accrued expenses at period end	$ 109	$ 1,270
Unrealized loss on investment securities	$ (2)	$ -
Cash paid for interest and fees	$ 2,290	$ 2,448

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

CADENCE PHARMACEUTICALS, INC.

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 acquiring, in-licensing, developing and commercializing proprietary products principally for use in the hospital setting. In March 2006, the Company in-licensed the exclusive U.S. and Canadian rights to OFIRMEV® (acetaminophen) injection, an intravenous formulation of acetaminophen, from Bristol-Myers Squibb Company ("BMS"). In November 2010, the Food and Drug Administration ("FDA") approved the Company's New Drug Application ("NDA") for OFIRMEV for the management of mild to moderate pain, moderate to severe pain with adjunctive opioid analgesics, and the reduction of fever in adults and children two years of age and older. In January 2011, the Company commenced commercial sales of the product in the U.S.

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, 2011, as included in the Company's 2011 Annual Report on Form 10-K filed with the SEC on March 13, 2012.

Revenue Recognition

The Company recognizes revenue when there is persuasive evidence that an arrangement exists, title has passed, collection is reasonably assured and the price is fixed or determinable. It sells OFIRMEV mostly to wholesalers who, in-turn, sell the product to hospitals and other end-user customers. Sales to wholesalers provide for selling prices that are fixed on the date of sale, although the Company offers certain discounts to group purchasing organizations and governmental programs. The wholesalers take title to the product, bear the risk of loss of ownership, and have economic substance to the inventory. Further, the Company has no significant obligations for future performance to generate pull-through sales, however it does allow wholesalers to return product that is damaged or received in error. In addition, the Company allows for product to be returned beginning six months prior to, and ending twelve months following, product expiration. As OFIRMEV is the Company's first and only commercially available product and there is a limited amount of product return data, the Company does not believe it has sufficient sales and returns history at this time to reasonably estimate product returns from its wholesaler distribution channel. Therefore, the Company is deferring the recognition of revenue until the wholesalers sell OFIRMEV to hospitals or other end-user customers. It will continue to defer revenue recognition until the point at which it has obtained sufficient sales history to reasonably estimate returns from the wholesalers. Shipments of product that are not recognized as revenue are treated as deferred revenue until evidence exists to confirm that pull-through sales to hospitals or other end-user customers have occurred.

The Company records certain sales reserves and allowances as a reduction to gross revenue and deferred revenue, as applicable. These reserves and allowances include distribution service fees, a prompt payment reserve, a group purchasing discount and chargeback reserve, and discounts to governmental programs, as applicable. Distribution service fees arise from contractual agreements the Company has with certain wholesalers for distribution services they provide with respect to OFIRMEV. These fees are generally a fixed percentage of the price of the product purchased by these wholesalers. The prompt payment reserve is based upon cash discounts the Company offers certain wholesalers as an incentive to meet certain payment terms. It accounts for these cash discounts at the time the sale is made to the wholesalers and reduces its accounts receivable accordingly. The group purchasing discount and chargeback reserve is based upon contracted discounts the Company provides to members of certain purchasing groups. The Company estimates the sales through its wholesalers to these group purchasing organizations and accrues for the chargebacks it anticipates from its wholesalers for the difference between the current retail price and the reduced price paid by the members of the group purchasing organizations. A group purchasing organization fee the Company incurs for these transactions is also recorded at the time of sale. The Company also provides governmental programs a predetermined discount that is recorded at the time of sale.

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

Accounts Receivable

The Company extends credit to its customers in the normal course of business based upon an evaluation of the customer's credit history, financial condition and other factors. Trade accounts receivable are recorded on gross sales to wholesalers, net of allowances for prompt payment and other discounts, chargebacks and doubtful accounts. Wholesaler distribution fees are recorded as accounts payable and accrued liabilities. Estimates of allowances for doubtful accounts are determined by evaluating individual customer circumstances, historical payment patterns, length of time past due and economic and other factors. As of September 30, 2012 and December 31, 2011, the Company had no reserves for doubtful accounts on its balance sheets. Further, during the three and nine months ended September 30, 2012 and 2011, no charges were incurred to reserve or write-off past due accounts.

Stock-Based Compensation

Stock option awards. Stock options are 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. If option awards are modified, they are subsequently revalued at the time of modification, and the incremental expense is recognized over the remaining vesting term, if any.

The following table summarizes the weighted average estimates the Company used in the Black-Scholes option-pricing model during the periods presented, to determine the fair value of employee and non-employee director stock options granted during each period:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Risk-free interest rates	0.8%	1.2%	0.9%	2.2%
Expected life in years	6.1 years	6.1 years	5.7 years	6.3 years
Expected dividend yield	0.0%	0.0%	0.0%	0.0%
Expected volatility	69.58%	73.1%	72.0%	73.9%

Compensation expense for 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, as applicable. If awards are forfeited prior to vesting, all previous expense recognized for unvested awards is recovered during the period in which the forfeiture occurs.

The table below summarizes the total stock-based compensation expense included in the Company's statements of operations for the periods presented (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Cost of product sales	$ 77	$ 87	$ 264	$ 219
Research and development	597	570	1,483	1,791
Selling, general and administrative	1,500	1,771	5,178	4,988
Total stock-based compensation expense included in loss from operations	$ 2,174	$ 2,428	$ 6,925	$ 6,998

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

Fair Value Reporting

The Company's financial instruments consist of cash and cash equivalents, marketable securities, restricted cash, trade receivables and payables, an option purchase right, equity securities of an unconsolidated privately-held entity, 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, trade receivables and payables and accrued liabilities are generally considered to be representative of their respective fair values because of the short-term nature of those instruments. Further, based on the borrowing rates currently available to the Company for loans with similar terms, the Company believes the fair value of long-term debt approximates its carrying value. The Company's option purchase right and equity securities of an unconsolidated privately-held entity have been initially valued based upon the transaction price under the cost method of accounting. These assets are subject to fair value adjustments in certain circumstances, such as when there is evidence of impairment. 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.

The following tables present further detail of the financial instruments carried at fair value on the Company's balance sheets as of September 30, 2012 and December 31, 2011. The tables do not include assets and liabilities that are measured at historical cost or on any basis other than fair value (in thousands):

Description	Balance at September 30, 2012	Fair Value Measurements as of September 30, 2012		
		Level 1	Level 2	Level 3
Assets:				
Cash equivalents:				
Money market funds	$ 67,812	$ 67,812	$ -	$ -
Investments in marketable securities – short-term:				
Debt instruments – Municipal debt obligations	2,762	-	2,762	-
Debt instruments – Corporate debt obligations	1,397	-	1,397	-
Certificates of deposit	1,000	-	1,000	-
Assets at fair value	$ 72,971	$ 67,812	$ 5,159	$ -

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

Description	Balance at December 31, 2011	Fair Value Measurements as of December 31, 2011		
		Level 1	Level 2	Level 3
Assets:				
Cash equivalents:				
Money market funds	$ 74,389	$ 74,389	$ -	$ -
Debt instruments – Corporate debt obligations	6,346	-	6,346	-
Investments in marketable securities – short-term:				
Debt instruments – Corporate debt obligations	37,394	-	37,394	-
Debt instruments – Municipal debt obligations	6,224	-	6,224	-
Certificates of deposit	1,000	-	1,000	-
Assets at fair value	$ 125,353	$ 74,389	$ 50,964	$ -

The Company's Level 2 financial instruments are valued using market prices on less active markets and model-derived valuations with observable valuation inputs such as interest rates and yield curves. The Company obtains the fair value of Level 2 financial instruments from a third-party pricing service, which the Company validates through independent valuation testing and review of portfolio valuations provided by the Company's investment managers.

3. Recent Accounting Pronouncements

There were no new accounting pronouncements issued during the three months ended September 30, 2012 that are expected to have a material impact on the Company's financial position, operating results or disclosures.

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 unvested restricted stock units outstanding during 2011 and 2012 have been 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 and nine months ended September 30, 2012 and 2011 were computed based on the weighted average shares of common stock outstanding during the respective periods. The net loss per share for the three and nine months ended September 30, 2012 includes the effect of the 21,800,000 common shares issued pursuant to a public offering in November 2011. There is a lack of comparability in the basic and diluted net loss per share amounts for the periods presented as a result of the issuance of these common shares.

The following is a reconciliation of the basic and diluted shares for the periods presented (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Shares for basic and dilutive net loss per share:				
Weighted average common shares outstanding	85,560	63,613	85,544	63,410
Denominator for basic and diluted earnings per share	85,560	63,613	85,544	63,410

At September 30, 2012 and 2011, stock options, restricted stock units, and warrants totaling 16,790,000 and 14,593,000 shares, respectively, were excluded from the calculations as their effect would have been antidilutive.

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

5. Inventory

Inventories, stated at the lower of cost or market, consisted of the following (in thousands):

	September 30, 2012	December 31, 2011
Inventory:		
Raw material	$ 95	$ 96
Finished goods	4,779	1,292
Total	$ 4,874	$ 1,388

In February 2012, the Company announced a voluntary recall of a single lot of OFIRMEV that was manufactured at Baxter Healthcare Corporation's ("Baxter") facility due to the presence of an unidentified visible particle in that lot during routine stability testing. The Company also placed certain finished product inventory of OFIRMEV manufactured by Baxter on indefinite hold pending the outcome of its investigation into unidentified particulate matter observed during routine product stability testing. As a result, the Company recorded charges of $5,574,000 for the fourth quarter of 2011 and $224,000 for the first quarter of 2012 to fully write-down the value of the inventory placed on hold due to uncertainty as to the amount of time that would be required to complete the investigation and whether the product would have sufficient remaining shelf life or otherwise be saleable after the investigation is completed. Further, in July 2012, the Company announced a second voluntary recall of product manufactured at Baxter's facility due to the presence of unidentified visible particles in a limited number of vials from one lot of the product, which were detected during routine stability testing. As a result, the Company has decided to destroy the product that was previously placed on hold. See "Supply Agreements" in Note 11 below for further information.

6. Property and Equipment

Property and equipment for operations were as follows (in thousands):

	September 30, 2012	December 31, 2011
Property and equipment:		
Manufacturing equipment	$ 6,925	$ 6,925
Leasehold improvements	1,637	1,610
Computer equipment and software	1,478	1,629
Furniture and fixtures	422	458
Construction-in-process	4,571	3,965
	15,033	14,587
Less accumulated depreciation	(5,029)	(4,018)
Total	$ 10,004	$ 10,569

For the three months ended September 30, 2012 and 2011, the Company incurred depreciation expense of $401,000 and $431,000, respectively. For the nine months ended September 30, 2012 and 2011, the Company incurred depreciation expense of $1,226,000 and $1,253,000, respectively.

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

7. Investments in Marketable Securities

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 September 30, 2012 and December 31, 2011 consisted of the following (in thousands):

At September 30, 2012	Amortized Cost Basis	Other-than-temporary Impairments	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Available-for-sale:					
Debt instruments – Municipal debt obligations	$ 2,762	$ -	$ -	$ -	$ 2,762
Debt instruments – Corporate debt obligations	1,397	-	-	-	1,397
Certificates of deposit	1,000	-	-	-	1,000
	$ 5,159	$ -	$ -	$ -	$ 5,159

At December 31, 2011	Amortized Cost Basis	Other-than-temporary Impairments	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Available-for-sale:					
Debt instruments – Corporate debt obligations	$ 37,392	$ -	$ 3	$ (1)	$ 37,394
Debt instruments – Municipal debt obligations	6,224	-	-	-	6,224
Certificates of deposit	1,000	-	-	-	1,000
	$ 44,616	$ -	$ 3	$ (1)	$ 44,618

Investments by contractual maturity are as follows (in thousands):

	September 30, 2012		December 31, 2011	
	Cost	Fair Value	Cost	Fair Value
Due or callable in one year or less	$5,159	$ 5,159	$44,616	$ 44,618
Due after one year	$ -	$ -	$ -	$ -

No gains or losses were realized on the sale of marketable securities using the specific identification method during the three and nine months ended September 30, 2012 and 2011. Further, as of September 30, 2012 the Company held no investments in an unrealized loss position. As of December 31, 2011, the Company held two investments in an unrealized loss position, each of which had been in such a position for less than twelve months. During the nine months ended September 30, 2012, these positions matured and no gains or losses were recognized.

8. Investment in Incline

On June 21, 2010, the Company entered into an option agreement (the “Option Agreement”) with Incline Therapeutics, Inc. (“Incline”), a privately held specialty pharmaceutical company, pursuant to which the Company obtained an exclusive, irrevocable option to acquire Incline during two option periods, and has additional rights after the expiration of the second period. Incline is developing IONSYS™ (fentanyl iontophoretic transdermal system), an investigational product candidate intended to provide patient-controlled analgesia for adult inpatients requiring opioids following surgery. As consideration for the option, the Company paid Incline a $3,500,000 upfront option fee in June 2010 and made a second payment of $3,500,000 in September 2011 upon Incline’s receipt of the second tranche of its Series A financing. The Company is currently in the second of two option periods, which extends until the earliest to occur of (1) 30 days after the date on which Incline submits a supplemental NDA for IONSYS to the FDA, (2) 30 days after the filing of an initial public offering by Incline, or (3) 42 months after the effective date of the option (December 21, 2013). During this second option period, the Company may acquire Incline for an amount not to exceed $228,000,000, plus payment of an additional amount not to exceed $57,000,000 upon FDA approval of IONSYS. The Company has an exclusive right of first negotiation to acquire

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

Incline for the six-month period following the expiration of the second option period. In addition, the Company may elect to extend the second option period for two additional three-month periods upon the payment of $2,500,000 to Incline for each period. Incline will remain primarily responsible for the development of IONSYS. However, the Company and Incline have formed a joint development committee to oversee the global development and regulatory approval for the IONSYS product candidate.

The Company has determined that Incline is a variable interest entity ("VIE"). However, because it will not absorb a disproportionate amount of Incline's expected losses or receive a disproportionate amount of Incline's expected residual returns, the Company is not the primary beneficiary of this entity at this time. Further, the Company will have no oversight of the day-to-day operations of Incline, nor does it have sufficient rights or voting representation to influence the operating or financial decisions of Incline. Additionally, the Company was not a founder of Incline and has no additional equity or funding requirements in future financings or otherwise. Therefore, the Company is not required to consolidate Incline into its financial statements. This consolidation status could change in the future if the option agreement is exercised, or if other changes occur in the relationship between the Company and Incline. Frazier Healthcare VI, L.P. owns approximately 22.4% of Incline's Series A Preferred Stock. Alan D. Frazier, one of the Company's directors, has an ownership interest in Frazier Healthcare VI, L.P., and is a member of the general partner of the entity that serves as general partner of Frazier Healthcare VI, L.P.

In consideration of the Company's expenditure of funds in connection with conducting due diligence on IONSYS, the Company received $500,000 of Incline Series A preferred stock, or 500,000 shares, on terms generally consistent with Incline's other Series A preferred stock investors. The Company has valued the investment in the option, and the shares received from the due diligence, using the cost method and classified these investments as Level 3 in the fair value hierarchy. At the time of the first option payment in June 2010, the Company assigned $500,000 to the preferred stock and $3,000,000 to the option. The value of the second option payment in September 2011 was fully applied to the option, resulting in an aggregate option value of $6,500,000. Under the cost method, the fair value of the investment is not estimated if there are no identified events or changes in circumstances that may have a significant adverse effect on the fair value of the investment. The Company has reviewed the value allocated from the June 2010 and September 2011 payments and is not aware of any such adverse events which would be expected to negatively influence these values at September 30, 2012. As a result, no fair value estimate has been prepared with respect to this investment as the costs associated with an independent evaluation would be excessive and the available information on which to base such an assessment is both limited and highly subjective. Therefore, there have been no reductions to the aggregate $7,000,000 carrying value of the investments, which represents the Company's maximum loss exposure to Incline at September 30, 2012. Both assets are recorded as other long-term assets on the Company's balance sheets at September 30, 2012 and December 31, 2011, respectively.

9. Restructuring and Impairment Charges

In November 2011, the Company commenced a restructuring of its workforce to focus its resources on the commercialization of OFIRMEV and reduce program costs not directly associated with such efforts. As a result of the 2011 restructuring, the Company recorded one-time employee termination charges of $1,142,000 in connection with the termination of 17 employees.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Beginning restructuring liability	$ 13	$ -	$ 931	$ -
Severance and termination charges incurred	-	-	-	-
Severance and termination disbursements	(6)	-	(924)	-
Ending restructuring liability	$ 7	$ -	$ 7	$ -

The balance of the restructuring liability at September 30, 2012 is anticipated to be fully distributed in 2012.

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

10. Loan and Security Agreement

In December 2011, the Company entered into a Second Amended and Restated Loan and Security Agreement (the "Second Amended Agreement") with Oxford Finance LLC ("Oxford"), Silicon Valley Bank ("SVB") and General Electric Capital Corporation ("GECC") (collectively, the "Lenders"). The Second Amended Agreement amends and restates the Company's previous Amended and Restated Loan and Security Agreement (the "Restated Agreement") entered into in June 2010 with the Lenders, and provided the Company with $3,434,000 of additional net capital after deducting a $954,000 term loan final payment paid under the Restated Agreement and customary closing fees and expenses of $63,000 paid in connection with the closing of the Second Amended Agreement. The interest rate under the Second Amended Agreement is 10.99% and the Company will be required to make a final payment of 6% of the total advance at the termination of the loan.

Pursuant to the terms of the Second Amended Agreement, the Company will make interest only payments through December 2012, and in January 2013, will begin to make equal monthly payments of principal and interest to fully amortize the balance over the remaining 30-month term. The Company issued warrants to purchase 158,311 shares of the Company's common stock to the Lenders in connection with the Second Amended Agreement at an exercise price $3.79 per share. The warrants were immediately exercisable, and excluding certain mergers or acquisitions, will expire on the seven-year anniversary of the date of issuance. The Company determined the relative fair value of these warrants, as detailed below, and has classified the warrants as equity, recognizing the cost as a discount on the loan issuance. The credit facility contains customary default and acceleration provisions and is secured by the Company's assets, excluding intellectual property. The Company was required to make a negative pledge of its intellectual property, which generally prohibits the Company from granting liens on its intellectual property. Under the terms of the Second Amended 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 Second Amended Agreement), the Lenders may declare all outstanding amounts due and payable under the Second Amended Agreement. As of September 30, 2012, the Company believed it was in compliance will all covenants under the Second Amended Agreement.

The Company determined that the terms of Second Amended Agreement were not substantially different than the Restated Agreement and hence has accounted for the transaction as a loan modification. As such, the fair value of the warrants issued in connection with the Second Amended Agreement and the carrying value of the issuance costs and discount related to the Restated Agreement were aggregated and are being amortized to interest expense throughout the life of the Second Amended Agreement using an effective interest rate of 15.31%.

In connection with the establishment of the $30,000,000 credit facility in June 2010 under the Restated Agreement, the outstanding balance of the Company's previous $15,000,000 credit facility established in 2007 was paid in full, including accrued interest, and a $375,000 term loan final payment. The transaction was accounted for as a loan extinguishment and upon the repayment of the $15,000,000 facility, the Company recorded a charge of approximately $145,000 in the second quarter of 2010 to (1) fully amortize the balance of the loan discount and related issuance costs and (2) fully accrue the term loan final payment. The warrants issued and the upfront fees paid in connection with the Restated Agreement were recognized as a discount on the loan issuance and the legal and related expenses were recognized as debt issuance costs on the Company's balance sheets. The carrying value of these costs at the time of the loan modification in December 2011 were aggregated with the relative fair value of the warrants issued in connection with the Second Amended Agreement and are being amortized throughout the life of the Second Amended Agreement as noted above.

Warrants

In connection with the establishment of the Company's $15,000,000 credit facility with the Lenders in 2007, 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 $474,000 under the Black-Scholes valuation model 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 September 30, 2012, all of these warrants were outstanding.

In connection with the Restated Agreement, the Company issued three fully exercisable warrants to the Lenders in June 2010 to purchase an aggregate of 254,793 shares of the Company's common stock at an exercise price of $7.0645 per share, expiring June 18, 2017. The Company classified the warrants as equity and determined their relative fair value to be $1,237,000, using the Black-Scholes valuation model. The value of the warrants was recorded as a discount to the loan and is

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

currently being amortized to interest expense over the term of the Second Amended Agreement pursuant to the loan modification. The warrants were valued using the following assumptions: risk-free interest rate of 2.7%; dividend yield of 0.0%; expected volatility of 76.5%; and a contractual term of seven years. As of September 30, 2012, all warrants related to the Restated Agreement were outstanding.

In connection with the Second Amended Agreement, the Company issued four exercisable warrants to the Lenders in December 2011 to purchase an aggregate of 158,311 shares of the Company's common stock at an exercise price of $3.79 per share, expiring December 22, 2018. The Company classified the warrants as equity and determined their relative fair value to be $390,000, 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 Second Amended Agreement. The warrants were valued using the following assumptions: risk-free interest rate of 1.4%; dividend yield of 0.0%; expected volatility of 72.4%; and a contractual term of seven years. As of September 30, 2012, all warrants related to the Second Amended Agreement were outstanding.

11. Commitments and Contingencies

Leases

In May 2006, the Company entered into a six-year operating lease for office space. In December 2011, the Company amended the lease to reduce the monthly rent charge, extend the lease term and terminate a portion of the leased space. Pursuant to the terms of the amended agreement, the basic monthly per square foot fee was reduced commencing in April 2012 and the Company returned a portion of the leased space in September 2012. The lease will expire in December 2013 with no option to extend the term.

As security for the initial lease, a letter of credit in the initial amount of $1,581,000 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 was eligible to be reduced by 22% on each of the first four anniversaries of the commencement of the lease and as of December 31, 2011, the letter of credit had been reduced by $1,391,000 in accordance with the agreement and the related restricted cash had been adjusted by a like amount. The value of the letter of credit and corresponding certificate of deposit, classified as restricted cash on the Company's balance sheet at September 30, 2012 and December 31, 2011, was $190,000.

Rent expense for operating leases is recorded on a straight-line basis over the life of the lease term. If a lease has a fixed and determinable escalation clause, the difference between the rent expense and rent paid is recorded as deferred rent. Rent expense under the Company's lease agreement for the three months ended September 30, 2012 and 2011 was $236,000 and $215,000, respectively. Rent expense under the Company's lease agreement for the nine months ended September 30, 2012 and 2011 was $709,000 and $643,000, respectively.

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. During 2011, the Company increased its pledged amount by $300,000 related to an increase in its credit limit. These funds are therefore classified as restricted cash on the Company's balance sheet at September 30, 2012 and December 31, 2011, respectively.

Supply Agreements

Baxter Healthcare Corporation

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 with an initial term of five years. Pursuant to the terms of the Supply Agreement, Baxter received development fees from the Company upon the completion of specified development activities, which the Company expensed as these activities had no alternative future uses at the time they were incurred. The Supply Agreement also required the Company to fund specified improvements at Baxter's manufacturing facility and purchase certain equipment for use by Baxter in manufacturing OFIRMEV. All development fees and facility improvements under this agreement had been completed and paid as of December 31, 2010, and the equipment to which the Company has title has been capitalized on the Company's balance sheet as property and equipment.

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

In January 2011, the Company amended and restated the Supply Agreement (the "Amended Supply Agreement") in connection with a plan to expand the manufacturing capacity for OFIRMEV at Baxter. Under this agreement, the Company will pay Baxter a per unit purchase price based on the amount of finished OFIRMEV drug product produced, which price will be increased annually, and may be adjusted to reflect an increase or decrease, as the case may be, in the cost of material required to manufacture OFIRMEV, subject to specified limitations. The Company is obligated to purchase a minimum number of units of OFIRMEV each year or pay Baxter an amount equal to the purchase price multiplied by the shortfall in units. In addition, Baxter will be the Company's primary supplier of OFIRMEV up to a specified number of units in each year, subject to Baxter's ability to timely supply the specified volumes required by the Company. However, if Baxter fails or declines to supply a sufficient quantity of OFIRMEV in accordance with the Company's purchase orders during a specified period of time, then the Company may purchase that quantity of OFIRMEV from third party suppliers and such quantity will be deducted from the quantity of OFIRMEV that the Company otherwise would have been required to purchase from Baxter. The Company is also 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.

In February 2012, the Company announced a voluntary recall of a single lot of OFIRMEV that was manufactured at Baxter's facility due to the presence of an unidentified, visible particle in that lot during routine stability testing. The Company also placed certain finished product inventory of OFIRMEV manufactured by Baxter on indefinite hold pending the outcome of the Company's investigation into unidentified particulate matter observed during routine product stability testing and decided to temporarily suspend further production by Baxter until the investigation has been completed and any necessary corrective and preventative actions have been implemented. Further, in July 2012, the Company announced a second voluntary recall of the remaining 41 unexpired lots of OFIRMEV manufactured at Baxter's facility due to the presence of unidentified, visible particles in a limited number of vials from one lot of the product, which were detected during routine stability testing. Although the Company received no adverse event reports associated with the particulate matter, and no product complaints involving similar particulate matter have been received, the Company decided to recall the remaining lots of OFIRMEV manufactured by Baxter as a precautionary measure. All of the 41 recalled lots, which were manufactured between January and March 2011, had expired by September 30, 2012.

As a result of the initial recall, the Company recorded charges of $5,574,000 for the fourth quarter of 2011 and $224,000 for the first quarter of 2012 to fully write-down the value of the inventory placed on hold due to uncertainty as to the amount of time that would be required to complete the investigation and whether the product would have sufficient remaining shelf life or otherwise be saleable after the investigation is completed. As a result of the second recall, the Company decided to destroy the product that was previously placed on hold. In addition, the Company has incurred costs associated with these recalls, including administration costs of the recalls, of approximately $300,000 through September 30, 2012, and the Company will continue to incur storage fees for the quarantined product until the time of its destruction. The Company may also incur costs to destroy the quarantined product. Through September 30, 2012, fewer than 4,000 vials had been returned as a result of these recalls, and the Company believes that the potential number of additional vials that will be returned is minimal. The costs related to the recalls are being recognized as selling, general and administrative expenses on the Company's statement of operations as they are incurred. The charge to reduce the value of the inventory was recorded as a cost of product sales on the Company's statement of operations during the period in which the impairment was taken.

The investigation into the particulate matter which resulted in these recalls has not been completed and the suspension of Baxter's manufacturing of product remains in effect pending the completion of the investigation to determine the root cause of the particulate matter. In addition, until the investigation into the particulate matter has been completed, the Company has suspended its negotiations with Baxter regarding the plan to expand Baxter's manufacturing capacity for OFIRMEV. As a result, the Company cannot reasonably estimate the cost of any such expansion at this time. However, under the Amended Supply Agreement, the Company would be required to fund all capital equipment and facility improvements included in the plan. The amount of time that will be required to complete the investigation is uncertain. Although the Company does not presently believe it is probable, it is reasonably possible that the manufacturing concerns may not be resolved in a timely manner, or at all. If this should occur, the Company's estimate that it would recover the carrying amount of its equipment from future operations could change and it may be required to record an impairment charge to reduce the carrying value of its manufacturing assets, as well as certain manufacturing equipment and facility construction assets in process. In addition, if the manufacturing concerns are resolved, but the Company does not complete the planned

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

capacity expansion in a timely manner, or at all, it may still be required to record an impairment charge to reduce the carrying value of manufacturing equipment and facility construction assets in processes and record early-termination liabilities, if any. At September 30, 2012, the carrying value of the manufacturing assets on the Company's balance sheet was $5,148,000 and the manufacturing equipment and facility construction assets in process was $4,251,000.

For the year ended December 31, 2011, the Company had reimbursed Baxter approximately $262,000 for facility improvements pursuant to the Amended Supply Agreement, including $53,000 and $213,000 during the three and nine months ended September 30, 2011, respectively. No reimbursements under the Amended Supply Agreement were made during the three and nine months ended September 30, 2012.

The initial term of the Amended Supply Agreement will terminate on November 1, 2015, and will automatically renew for successive one-year periods thereafter, unless either party provides at least two years prior written notice of termination to the other party. In addition, either party may terminate the Amended Supply Agreement (1) within 90 days, after written notice in the event of a material uncured breach by the other party or (2) immediately, upon the filing of a petition of bankruptcy by the other party. The Company may also terminate the Amended Supply Agreement, effective 30 days after providing written notice, in the event that Baxter does not agree to the Company's assignment of the agreement to a competitor of Baxter. Baxter has agreed that, for the initial term and any renewals or extensions of the Agreement, neither it nor any of its affiliates will develop or commercially produce, for itself or for any third party, any intravenous formulation of a product containing acetaminophen for distribution or sale in the United States.

If the Amended Supply Agreement with Baxter is terminated, except as a result of a material uncured breach or bankruptcy by Baxter, the Company will reimburse Baxter for all materials ordered prior to termination that are not cancelable without cost to Baxter. Upon termination of the Amended Supply Agreement and subject to certain exceptions, the Company will purchase from Baxter all undelivered products manufactured or packaged under a purchase order from the Company, at the price in effect at the time the purchase order was placed. The Company is also obligated to reimburse Baxter for reasonable costs incurred in returning all Company-owned equipment and for restoring Baxter's manufacturing facility to its condition prior to the installation of OFIRMEV-related improvements, other than restoration costs for changes that Baxter reasonably agrees are usable by Baxter at the time of removal of the Company-owned equipment. However, until the Company completes the capacity expansion negotiations with Baxter under the Amended Supply Agreement, which are currently suspended, the Company is not able to reasonably estimate the cost and the timing of the restoration expenses or the fair value of the retirement obligation.

Lawrence Laboratories (BMS)

In December 2010, the Company entered into a supplemental Supply Agreement (the "Supplemental Agreement") with Lawrence Laboratories ("Lawrence"), an indirectly wholly-owned subsidiary of BMS, for the manufacture of commercial supplies of the finished drug product for OFIRMEV. Bristol-Myers Squibb Srl ("BMS Anagni"), an indirect subsidiary of BMS, manufactures the product on behalf of Lawrence. BMS Anagni has manufactured the product for more than ten years for sale and distribution by BMS and its affiliates in a number of countries outside of the U.S. and Canada. BMS Anagni is presently acting as the Company's sole supplier of OFIRMEV until the investigation into the particulate matter observed in product manufactured at Baxter's facility has been completed and any necessary corrective and preventative actions have been implemented.

Pursuant to the terms of the Supplemental Agreement, Lawrence will receive from the Company a set price for the OFIRMEV purchased, which prices may be adjusted by Lawrence, subject to specified limitations. In addition, the Company is obligated to purchase a minimum number of units each year following regulatory approval of OFIRMEV manufactured on behalf of Lawrence, or pay Lawrence an amount equal to the per-unit purchase price less Lawrence's average material and direct labor costs for OFIRMEV, multiplied by the amount of the shortfall.

The Supplemental Agreement has an initial term that ends in March 2014, unless the Supplemental Agreement is terminated sooner: (1) by mutual agreement of the parties, (2) by either party for convenience following eighteen months' prior written notice of termination to the other party, (3) upon the termination of the Company's license agreement for the product with BMS, or (4) upon the dissolution or termination of the Company, other than in connection with or following the assignment of the Supplemental Agreement. In addition, either party may terminate the Supplemental Agreement: (a) within 60 days after written notice in the event of a material uncured breach of the Supplemental Agreement by the other party, or (b) immediately, if the other party becomes insolvent or admits in writing its inability to pay its debts as they become due, files a petition for bankruptcy, makes an assignment for the benefit of its creditors or has a receiver or other court officer appointed for its properties or assets.

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

If the Supplemental Agreement is terminated by the Company for its convenience or by Lawrence due to the Company's material breach of the agreement, the Company will reimburse Lawrence for: (1) any product ordered under a firm order and received by the Company, and (2) any inventory of materials used to manufacture OFIRMEV that are specific to OFIRMEV and that Lawrence is unable to reasonably utilize. Additionally, the Company's minimum purchase requirement for the year in which the termination takes effect will be reduced proportionally, and the Company will not be required to fulfill the minimum purchase requirement for any subsequent contract year. If the Supplemental Agreement is terminated for any reason other than by the Company for its convenience or by Lawrence due to the Company's material breach of the agreement, the Company will not be required to reimburse Lawrence for any inventory of materials used to manufacture OFIRMEV, and will have no obligation to purchase the minimum purchase requirement for the year in which the termination takes effect, or for any subsequent contract year.

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 OFIRMEV in the U.S. and Canada from BMS. BMS sublicensed these rights to the Company under a license agreement with Pharmatop. As consideration for the license, the Company paid a $25,000,000 up-front fee and, as a result of the approval of the Company's NDA for OFIRMEV in the November 2010, the Company paid an additional milestone payment of $15,000,000 in November 2010. The Company may be required to make future milestone payments totaling up to $25,000,000 upon the achievement of certain levels of net sales. 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. The amount of such royalty ranges from the mid-teens to the mid-twenties, depending on the aggregate amount of net sales, and is subject to annual minimum royalty obligations. The $25,000,000 up-front fee was recognized as research and development expense at the time the payment was made. The $15,000,000 milestone payment was recorded as an intangible asset on the Company's balance sheets and is being amortized on a straight-line basis over the estimated useful life of the licensed patents. Royalty liabilities are recognized at the time the product is sold or, for minimum royalty obligations that are not anticipated to be met, over the period in which the minimum liability is incurred.

In November 2010, the Company entered into a data license agreement among Terumo Corporation ("Terumo"), the Company and SCR Pharmatop S.A. ("Pharmatop"). Under the data license agreement, the Company provided to Terumo certain data and information resulting from the Company's clinical development program for OFIRMEV for Terumo's use in obtaining regulatory approval for and commercializing the same intravenous formulation of acetaminophen in Japan. Further, the Company will provide to Terumo, without charge, up to 500 hours of technical assistance and consulting services regarding the licensed technical information, data and know-how, as reasonably necessary to assist Terumo in obtaining regulatory approval and manufacturing capacity for the product candidate. In April 2011, the Company received an upfront payment of $5,329,000 under the terms of the data license agreement. If Terumo is successful in obtaining regulatory approval for and commercializing the product in Japan, the Company may also be entitled to an additional lump-sum payment upon the first commercial sale of the product candidate and royalty payments on any commercial sales of the product in Japan.

In accordance with multiple-element arrangement guidance, the Company determined both the data license and consulting service deliverables were separate units of accounting, each having value on a standalone basis. The Company estimated the fair value of the data license based upon similar proposals from third parties and internal costs incurred in developing the data and obtaining similar rights. The value of the consulting services was based on contracts the Company had engaged with third parties for similar services. The Company allocated the value of the payment received on a relative fair value basis and will recognize the consideration allocated to the data license upon delivery and the consideration allocated to the consulting services as such services are rendered. There is no right of return or similar refund provisions in the data license agreement. During 2011, the Company transferred the data and related information to Terumo and provided a portion of the consulting hours and in April 2011, the Company recognized $5,210,000 of licensing revenue pursuant to the agreement for the data transfer and consulting hours provided. During the nine months ended September 30, 2012, the Company recognized an additional $33,000 of licensing revenue for consulting hours rendered by the Company during the periods. No licensing revenue was recognized for the three months ended September 30, 2011 or 2012. The remaining balance of the payment of $86,000 reflects the value of the outstanding consulting hours the Company is obligated to provide under the terms of the contract through November 2012. The Company has recorded the balance of the payment as deferred revenue on the Company's balance sheet at September 30, 2012 and December 31, 2011, and will recognize the balance as revenue as the consulting services are rendered or the contract term expires. Any milestones or royalties received from potential sales of the product candidate will be recognized as revenue in the period earned.

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

Legal Matters

In August 2011, the Company and Pharmatop filed suit in the United States District Court for the District of Delaware against Paddock Laboratories, Inc., Perrigo Company and Paddock Laboratories, LLC (collectively, "Paddock") and against Exela Pharma Sciences, LLC, Exela PharmaSci, Inc. and Exela Holdings, Inc. (collectively, "Exela"). The lawsuit follows the notices that the Company received in July 2011 from each of Paddock and Exela concerning their filings of Abbreviated New Drug Applications, or ANDAs, containing a "Paragraph IV" patent certification with the FDA for a generic version of OFIRMEV. In the lawsuit the Company alleges that Paddock and Exela have each infringed U.S. Patent Nos. 6,028,222 (the "'222 patent"), and 6,992,218 (the "'218 patent"), by filing their respective ANDAs seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. The '222 and the '218 patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). The intellectual property lawsuit was filed within 45 days of receipt of the pertinent notice letters, thereby triggering a stay of FDA approval of the Paddock ANDA and the Exela ANDA until the earlier of the expiration of a 30-month period, the expiration of the '222 and '218 patents, the entry of a settlement order or consent decree stating that the '222 and '218 patents are invalid or not infringed, a decision in the case concerning infringement or validity that is favorable to Paddock or Exela, or such shorter or longer period as the Court may order. Each of Paddock and Exela has filed an answer in the case that asserts, among other things, non-infringement and invalidity of the asserted patents, and has also filed counterclaims. On August 22, 2012, after comprehensive briefing and oral argument, Judge Leonard P. Stark issued an order adopting the Company's proposed patent term constructions with respect to a majority of the disputed issues. Judge Stark's ruling is available on the District Court's website at http://www.ded.uscourts.gov/judges-info/opinions. A date for the bench trial in this case has been tentatively scheduled for May 2013. In addition, in May 2012, Exela informed the Court that it filed suit in the United States District Court for the Eastern District of Virginia against the United States Patent and Trademark Office ("USPTO"), for declaratory judgment seeking a reversal of the decision by the USPTO refusing to act on a petition by Exela to vacate the USPTO's April 2003 order reviving the international application for the '218 patent. The lawsuit followed the USPTO's rejection of Exela's petition to the USPTO filed in November 2011, which sought to vacate the April 23, 2003 order granting Pharmatop's petition to revive the '218 patent. The USPTO determined that Exela lacks standing to seek such relief. Exela also seeks declaratory judgment that the USPTO's rules and regulations that allow for revival of abandoned, international patent applications under the "intentional" standard are invalid, and similar relief in connection with one or more counterclaims it has filed in the Delaware litigation. The Court denied the USPTO's motion to dismiss Exela's lawsuit. A decision by the Court in favor of Exela could result in the invalidation of the '218 patent.

Regardless of the outcome of any litigation, no ANDA can receive final approval from the FDA before expiration of the regulatory exclusivity period for OFIRMEV. Specifically, the FDA has granted OFIRMEV three years of regulatory exclusivity, which expires November 2, 2013. The Company intends to vigorously enforce its intellectual property rights relating to OFIRMEV to prevent the marketing of infringing generic products prior to the expiration of its patents. The '222 patent expires August 5, 2017 (or February 5, 2018 if pediatric exclusivity is granted) and the '218 patent expires June 6, 2021 (or December 6, 2021 if pediatric exclusivity is granted). However, given the unpredictability inherent in litigation, the Company cannot predict the outcome of this matter or any other litigation. At this time, the Company is unable to estimate possible losses or ranges of losses for current litigation, and it has not accrued any amounts for current litigation other than ongoing attorney's fees.

12. Stockholders' Equity

Authorized Shares

In June 2012, following approval by the Company's stockholders, the Company filed a Certificate of Amendment of Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware, which increased the number of authorized shares of common stock of the Company from 100,000,000 to 200,000,000.

Public Offering

In May 2011, the Company established a universal shelf registration statement to permit it, from time to time, to offer and sell up to $150,000,000 of equity or debt securities. In November 2011, the Company issued an aggregate of 21,800,000 shares of its common stock at a purchase price of $3.75 per share pursuant to a public offering. The offering raised proceeds, net of offering costs and underwriting discounts and commissions, of $77,302,000.

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

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 September 30, 2012, all warrants related to the private placement were outstanding.

The private placement raised proceeds, net of offering costs, of $86,243,000. 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, the Company 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.

13. Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker, or decision-making group, in making decisions regarding resource allocation and assessing performance and the Company operates and manages its business as principally one segment. It sells its only product, OFIRMEV, primarily to established wholesale distributors in the pharmaceutical industry, including the nation's three leading wholesale pharmaceutical distributors: Cardinal Health, Inc., AmerisourceBergen Corporation and McKesson Corporation.

Shipments to wholesalers representing approximately 10% or more of total product revenue for the periods presented were as follows (as a percentage of total gross product revenue):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Cardinal Health, Inc.	33%	39%	34%	37%
AmerisourceBergen Corporation	34%	31%	33%	33%
McKesson Corporation	26%	25%	26%	24%

14. 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 state 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 September 30, 2012 and December 31, 2011, and has recognized no interest and/or penalties in the Company's statement of operations for the three and nine months ended September 30, 2012 and 2011. Further, as of September 30, 2012, the Company had not recorded any unrecognized tax benefits.

Pursuant to Internal Revenue Code 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 of a cumulative change in ownership of more than 50% within a three-year period. The Company has not completed this analysis regarding the limitation and therefore has removed the (1) deferred tax assets for net operating losses of approximately $123,436,000 and (2) research and development credits of approximately $6,562,000 generated through 2011 from its deferred tax asset schedule. Further, the Company has recorded a corresponding decrease to its valuation allowance. When this analysis is finalized, the Company plans to update its deferred tax asset and valuation allowance accordingly. The Company expects to complete this analysis within the next

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

six months and, as a result, the Company may have a change in the unrecognized tax benefits that are recorded. 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. As used herein, the terms "we," "us," or "our" refer to Cadence Pharmaceuticals, Inc., a Delaware corporation. 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, 2011 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, 2011 as filed with the Securities and Exchange Commission, or SEC, on March 13, 2012.

Overview

We are a biopharmaceutical company focused on acquiring, in-licensing, developing and commercializing proprietary products 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 unmet commercial potential. We will also consider strategically attractive opportunities to co-promote commercialized hospital products.

In 2006, we in-licensed the exclusive U.S. and Canadian rights to OFIRMEV® (acetaminophen) injection, an 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 November 2010, OFIRMEV was approved by the U.S. Food and Drug Administration, or FDA, and we commercially launched OFIRMEV in the U.S. in January 2011. Our near-term business strategy since the launch of OFIRMEV has been, and continues to be, working with physicians and hospitals to increase demand for OFIRMEV and ensure formulary adoption. We believe this strategy will position us well for continued revenue growth.

As part of our long-term business strategy, we entered into an agreement with Incline Therapeutics, Inc., or Incline, in June 2010 that provides us with the exclusive, irrevocable option to acquire Incline within a specified future time period. Incline is developing IONSYS™ (fentanyl iontophoretic transdermal system), an investigational product candidate intended to provide patient-controlled analgesia for adult inpatients requiring opioids following surgery. We believe that, if approved by the FDA, IONSYS could represent a potentially significant commercial opportunity and be an excellent strategic fit with OFIRMEV. As consideration for the option, we paid Incline a $3.5 million upfront option fee in June 2010 and made a second payment of $3.5 million in September 2011 upon Incline's receipt of the second tranche of its Series A financing. We are currently in the second of two option periods, which extends until the earliest to occur of (1) 30 days after the date on which Incline submits a supplemental NDA for IONSYS to the FDA, (2) 30 days after the filing of an initial public offering by Incline, or (3) 42 months after the effective date of the option (December 21, 2013). During this second option period, we may acquire Incline for an amount not to exceed $228.0 million plus payment of an additional amount not to exceed $57.0 million upon FDA approval of IONSYS. We have an exclusive right of first negotiation to acquire Incline for the six-month period following the expiration of the second option period. In addition, we may elect to extend the second option period for two additional three-month periods upon the payment of $2.5 million to Incline for each period. Incline will remain primarily responsible for the development of IONSYS. However, we and Incline have formed a joint development committee to oversee the global development and regulatory approval for the IONSYS product candidate.

In executing our business strategy, we have incurred significant net losses since our inception and have financed our operations primarily through the sale of equity securities in both public and private offerings. Most recently, we sold 21.8 million shares of common stock in a public offering in November 2011 and received aggregate net proceeds of approximately $77.3 million (after underwriting discounts and offering costs). From inception through September 30, 2012, we have received net proceeds of approximately $443.7 million from the sale of our preferred stock, common stock and warrants to purchase common stock. Additionally, we have entered into multiple loan and security agreements with Oxford Finance LLC, Silicon Valley Bank and General Electric Capital Corporation to provide us with growth capital. As of September 30, 2012, the principal balance outstanding on our current facility with this loan syndicate was $30.0 million.

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 us is also available on our website at www.cadencepharm.com, which includes links to reports we have filed with the 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.

We own or have rights to various trademarks, copyrights and tradenames used in our business, including the following: Cadence®, OFIRMEV® and the OFIRMEV logo. This report also contains trademarks of other companies, including IONSYS™, a registered trademark of Incline, Perfalgan®, a registered trademark of BMS, and Caldolor® a registered trademark of Cumberland Pharmaceuticals, Inc.

Revenue

Our primary source of revenue is from the sale of OFIRMEV to hospitals and other end-user customers. Additionally, we have licensed certain data, and are providing on-going consulting support, to Terumo Corporation, or Terumo, for their use in seeking regulatory approval and commercializing the same intravenous formulation of acetaminophen in Japan. Further detail of these sources of revenue is provided below:

Product Revenue

In January 2011, we launched commercial sales of OFIRMEV and began shipping product to independent wholesalers, which sell OFIRMEV to hospitals and other end-user customers. Our initial focus for revenue growth was to promote rapid hospital formulary adoption of the product and, as of September 30, 2012, OFIRMEV had received formulary acceptance at over 2,000 institutions. During the second half of 2011, our sales force placed additional emphasis on generating pull-through hospital sales of OFIRMEV from these institutions. During 2012, we have continued our focus on generating pull-through sales by actively promoting the product through a variety of marketing programs to inform customers about OFIRMEV.

As a result of these campaigns, nearly 3,500 unique accounts had ordered OFIRMEV as of September 30, 2012, which represents an increase of approximately 10% from June 30, 2012, and 54% from December 31, 2011. Further, our customers have increased the frequency with which they place orders and the average size of their orders. Specifically, the average frequency of customer orders was approximately 11% higher for the third quarter of 2012 than for the fourth quarter of 2011, and the average size of customer orders for the third quarter of 2012 was over 30% higher than for the fourth quarter of 2011.

The impact of the growth in these metrics is evident in our net product revenue growth. Specifically, our net product revenue for the nine months ended September 30, 2012 increased $27.4 million, or nearly five times, to $33.0 million, from the comparable period in 2011. Furthermore, our quarterly net product revenue has grown over 135% over the past three quarters, from $5.9 million for the fourth quarter of 2011 to $13.9 million for the third quarter of 2012.

We intend to continue our marketing strategies to promote OFIRMEV for the foreseeable future and we believe that there are substantial growth opportunities through continued promotion of the product.

License Revenue

In November 2010 we entered into a data license agreement with Terumo and SCR Pharmatop S.A., or Pharmatop. As part of the data license agreement, we provided to Terumo certain data and information resulting from our clinical development program for OFIRMEV for Terumo's use in seeking regulatory approval for and commercializing the same intravenous formulation of acetaminophen in Japan. Further, we are obligated to provide to Terumo, without charge, up to 500 hours of technical assistance and consulting services in relation to the licensed technical information, data and know-how in order to assist Terumo in seeking regulatory approval and manufacturing capacity for the product. In April 2011, we received an upfront payment of $5.3 million under the terms of the data license agreement and during the nine months ended September 30, 2011, we recognized $5.2 million of the payment as revenue for data provided and consulting hours incurred. During the nine months ended September 30, 2012, less than $0.1 million of revenue was recognized for additional consulting hours we provided to Terumo. No consulting revenue was recognized for the three months ended September 30, 2012 or 2011, respectively. As of September 30, 2012, the remaining payment balance of less than $0.1 million remains on our balance sheet as deferred revenue and reflects the value of the outstanding consulting hours we are obligated to provide under the terms of the contract through November 2012.

If Terumo is successful in its efforts to obtain regulatory approval for and commercialize the product in Japan, we may be entitled to an additional lump-sum payment upon the first commercial sale of the product and royalty payments upon any commercial sales of the product in Japan. However, as these payments are dependent upon future regulatory approval and commercial success, we are unable to estimate with any certainty if, or when, such payments would be received.

Cost of Sales

Our cost of sales consists primarily of our third-party manufacturing costs, indirect and personnel overhead costs, freight, excess or obsolete inventory adjustment charges and, if applicable, internal manufacturing overhead and the cost of purchasing the active pharmaceutical ingredient for OFIRMEV, acetaminophen. Further, cost of sales includes the royalties due under our license agreement with BMS, which range from the mid-teens to the mid-twenties, depending on the aggregate amount of net sales we record per contract year. The cost of sales we report for the quarterly and annual periods are primarily driven by sales volume, however, they are also impacted by production volumes of our product, manufacturing efficiencies during the production of our product, price variances of our manufacturing input costs and any inventory adjustment charges we may record.

The finished product, OFIRMEV, may be supplied to us by two third-party manufacturers, Baxter Healthcare Corporation, or Baxter, and Bristol-Myers Squibb Srl, or BMS Anagni. In February 2012, we temporarily suspended production of OFIRMEV by Baxter due to the investigation into unidentified particulate matter observed during routine product stability testing. Production at Baxter remained suspended through September 30, 2012, and we are uncertain when Baxter will be able to resume production. We continue to incur certain manufacturing costs related to Baxter during this suspension, which are included in cost of sales for the three and nine months ended September 30, 2012, and will continue to recognize these costs as period expenses until the related investigation is complete and manufacturing is resumed by Baxter. We placed certain inventory produced by Baxter on indefinite hold in February 2012 as a result of our February 2012 voluntary recall of product manufactured by Baxter. We decided to destroy that product inventory as a result of a second voluntary recall of product manufactured by Baxter. The suspension of production by Baxter remains in effect, pending the completion of our investigation to determine the root cause of the particulate matter. The amount of time that will be required to complete the investigation is uncertain. Although we do not presently believe it is probable, it is reasonably possible that the manufacturing concerns may not be resolved timely, or at all. If this should occur, our estimate that we would recover the carrying amount of the equipment from future cash flows could change and we may be required to record an impairment to reduce the carrying value of our manufacturing assets and our manufacturing equipment and facility construction assets in process. In addition, if the manufacturing concerns are resolved, but we do not complete our planned capacity expansion at the Baxter facility timely, or at all, we may still be required to record an impairment charge to reduce the carrying value of our manufacturing equipment and facility construction assets in process and record early-termination liabilities, if any. At September 30, 2012, the carrying value of the manufacturing assets on our balance sheet was $5.1 million and the manufacturing equipment and facility construction assets in process was $4.3 million.

During this suspension of production by Baxter, we have transitioned our supply of OFIRMEV to BMS Anagni, which is presently acting as our sole supplier for the product. As a result of this transition, and in an effort to minimize any potential short-term supply disruption, we incurred expedited freight costs on certain shipments of OFIRMEV during the first half of 2012. These expedited freight costs have mostly been recognized through the sale of the related inventory and we do not anticipate further impact from these shipments on our costs of sales in future periods. No further supply shortages are anticipated as a result of suspending production at Baxter, as we continue to distribute product manufactured by BMS Anagni.

License Fees and Patent Amortization

As a result of the FDA's approval of OFIRMEV, we paid a $15.0 million license fee in the fourth quarter of 2010 pursuant to the term of our license agreement with BMS. This payment was capitalized on our balance sheets as an intangible asset and we are amortizing the balance on a straight-line basis, based upon the estimated life of the underlying patent assets. We may be required to make two additional milestone payments totaling up to $25.0 million based upon the achievement of certain levels of net sales of OFIRMEV, which will be recognized as license fees in the period they are incurred, as appropriate. However, as these payments are dependent upon future levels of net sales, we are unable to estimate with any certainty the timing of when these charges may be incurred.

Research and Development Expenses

Our research and development expenses consist of salaries and related employee benefits for our research and development team, manufacturing development activities, costs associated with clinical trials, and costs associated with non-clinical activities, such as expenses related to regulatory submissions. Our research and development expenses in 2011 were significantly lower than in 2010 because fewer resources were being utilized by the program since we received approval for OFIRMEV in November 2010. In addition, in November 2011, we implemented a restructuring of our workforce to focus our resources on the commercialization of OFIRMEV and reduce program costs that were not directly related to such efforts. This action resulted in a reduction in force of twelve employees in research and development, which has led to reduced research and development costs in 2012. However, we expect to incur additional research and development expenses related to OFIRMEV in future periods, specifically related to an FDA required post-approval clinical trial for OFIRMEV in pediatric patients under two years of age. We began enrolling patients in this clinical trial during the third quarter of 2012. However, it is difficult to anticipate the scope and magnitude of our future research and development expenses related to this trial and we may conduct additional clinical studies to expand the indications for OFIRMEV. Moreover, any product candidates we may in-license or acquire in the future may 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.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses consist primarily of salaries and related employee benefits for our sales and marketing staff; advertising, marketing and other promotional costs for OFIRMEV; selling expenses for our sales representatives, including travel-related costs; salaries and related employee benefits for our administrative, finance, human resources, legal, business development and internal systems support functions; costs incurred in relation to our medical affairs programs, including salaries, related employee benefits and costs incurred by our medical science liaisons; as well as the related professional fees for these functions, insurance and facility costs.

Our selling, general and administrative costs increased significantly following the approval of OFIRMEV in November 2010 as we hired our sales force and related personnel to support the commercial efforts for OFIRMEV and we continue to incur these costs. Further, we have incurred additional legal costs in 2012 related to our intellectual property litigation and we will continue to incur these costs as we enforce our intellectual property rights. Therefore, we expect to continue to incur significant selling, general and administrative expenses as we continue to execute our marketing and sales strategies for OFIRMEV, enforce our intellectual property rights and operate our business.

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 incur under our loan and security agreements and the amortization of debt issuance costs. Other income and expense includes gains or losses recognized on transactions denominated in foreign currencies and other transactions not related to our operations.

Our current loan and security agreement had a principal balance of $30.0 million as of September 30, 2012 and we are currently making interest-only payments on the outstanding balance of this facility, which will continue through December 2012. In January 2013, we will begin making equal monthly principal and interest payments to fully amortize the balance over a 30-month term. This facility has a fixed interest rate of 10.99% and, as we begin making principal payments, we anticipate that our interest expense will decline.

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, 2011, we had federal and state net operating loss carryforwards of approximately $306.5 million and $310.0 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 $4.8 million and $2.8 million, respectively. The federal tax credits will begin expiring in

2024 unless previously utilized and the state tax credits carryforward indefinitely. Under Sections 382 and 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 to determine the impact ownership changes have had on our carryforwards, but expect to complete the analysis within the next six months. When the Section 382/383 study is completed, we may be required to change the unrecognized tax benefits recorded in our financial statements. 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 and, due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact our effective tax rate.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America, 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 the recognition of revenue; the valuation of our inventory, which impacts costs of sales and gross margin; 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 review our estimates, judgments, and assumptions used in our accounting practices 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, our actual results may differ from these estimates.

Revenue Recognition

We sell OFIRMEV to wholesalers and directly to hospitals and other end-user customers. Our primary distribution channel for OFIRMEV involves our third party logistics distributor, which distributes the product to independent wholesalers, which in turn distribute the product directly to hospitals and other end-user customers. We also sell the product directly to hospitals and other end-user customers, and we have contracted with group purchasing organizations which, along with our sales representatives, increase awareness of, and reduce market barriers for, OFIRMEV.

Our wholesaler agreements provide selling prices that are fixed on the date of sale, although we offer certain discounts to group purchasing organizations and governmental programs. The wholesalers take title to the product, bear the risk of loss of ownership and have economic substance to the inventory. Further, we have no significant obligations for future performance to generate pull-through sales, however we do allow our wholesalers to return product that is damaged or received in error. Additionally, we allow for product to be returned beginning six months prior to, and ending twelve months following, product expiration. As OFIRMEV is our first and only commercially available product and we have a limited amount of product return data, we do not believe we currently have sufficient history to reasonably estimate product returns from our wholesaler distribution channel. Therefore, we are deferring the recognition of revenue until the wholesalers sell OFIRMEV to hospitals or other end-user customers. We will continue to defer recognition until the point at which we have obtained sufficient sales history to reasonably estimate returns from the wholesalers, which to date have been minimal. Shipments of product that are not recognized as revenue are treated as deferred revenue until evidence exists to confirm that pull-through sales to hospitals or other end-user customers have occurred.

We record certain fees, sales reserves and allowances as a reduction to gross revenue and deferred revenue, as applicable. These reserves and allowances include distribution service fees, a prompt payment reserve, a group purchasing discount and administrative service fee, and discounts to governmental programs, as applicable. Distribution service fees arise from contractual agreements between us and certain wholesalers for distribution services they provide with respect to OFIRMEV. These fees are generally a fixed percentage of the price of the product purchased by these wholesalers. The prompt payment reserve is based upon cash discounts we offer certain wholesalers as an incentive to meet certain payment terms. We account for these cash discounts at the time the sale is made to the wholesalers and reduce our accounts receivable

accordingly. The group purchasing discount and administrative service fee is based upon contracted discounts we provide to members of certain purchasing groups. We estimate the sales through our wholesalers to the group purchasing organization members and accrue for the chargebacks we anticipate from such sales based on the difference between the current retail price and the reduced price paid by the group purchasing organization members. A group purchasing organization administrative fee that we incur in exchange for administrative services provided by the group purchasing organizations for these transactions is also recorded at the time of sale. We also provide governmental programs a predetermined discount that is recorded at the time of sale.

Revenue from our data license agreement with Terumo is recognized upon delivery of the goods and services provided, based upon the consideration allocated to each deliverable. We allocated the consideration to each deliverable based upon our review of the agreement pursuant to multiple-element arrangement guidance. We determined both the data license and consulting service deliverables were separate units of accounting, each having value on a standalone basis, and estimated the fair value of each item. The value of the data license was based upon similar proposals from third parties and internal costs we incurred in developing the data and obtaining similar rights. The value of the consulting services was based on contracts we had engaged with third parties for similar services. These values were consolidated and adjusted based upon the relative fair value of the consideration received pursuant to the agreement and there is no right of return or similar refund provisions in the data license agreement. Consideration allocated to the data license was recognized as revenue upon delivery of the data during the three months ended June 30, 2011. Consideration allocated to the consulting services is being recognized as revenue as such services are rendered.

Inventories

We state our inventories at the lower of cost or market. We use a combination of standard and actual costing methodologies to determine the cost basis for our inventories. These methodologies approximate actual costs on a first-in, first-out basis. In addition to stating inventory at the lower of cost or market, we also evaluate our inventories each period for excess quantities and obsolescence. This evaluation includes identifying those items specifically identified as obsolete and analyzing forecasted demand versus quantities on hand so that this inventory can be valued appropriately.

Our inventory costs consist primarily of our third-party manufacturing fees, indirect and personnel overhead costs, freight-in, and, if applicable, internal manufacturing overhead, as well as the cost of purchasing acetaminophen, the active pharmaceutical ingredient for OFIRMEV. Fixed production overheads are allocated to the unit production costs based upon normal production capacity. Unallocated overhead costs incurred during periods of abnormally low production or unplanned facility downtime are recognized as expense in the period in which they are incurred.

In February 2012, we placed certain inventory produced by Baxter on indefinite hold and temporarily suspended production of OFIRMEV by Baxter pending the outcome of an investigation into unidentified particulate matter observed during routine product stability testing. We recorded charges of $5.6 million for the fourth quarter of 2011 and $0.2 million for the first quarter of 2012 in cost of sales to fully write-down the value of this inventory. In July 2012, we decided to destroy this product as a result of a second voluntary recall of product manufactured by Baxter. The suspension of Baxter's production remains in effect, pending the completion of the investigation into the root cause of the particulate matter. During this suspension, we transitioned the supply of OFIRMEV to BMS Anagni, which is presently acting as our sole supplier for the product. No supply shortages are anticipated as a result of suspending production at Baxter as we continue to distribute product manufactured by BMS Anagni.

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 date 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.

Long-Lived Assets

A substantial portion of our capital assets are associated with our manufacturing equipment at Baxter, our initial third-party manufacturer. In building these assets and creating additional capacity, we have entered into agreements whereby we fund specified improvements to the facilities and the construction of the manufacturing equipment to be used for the production of OFIRMEV. During the build-out of the facility and construction of our equipment, we accrue for costs incurred based on factors such as estimates of work performed, milestones achieved and experience with similar contracts. As actual costs become known, we adjust our accruals accordingly.

We evaluate these 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.

In February 2012, we temporarily suspended production of OFIRMEV by Baxter due to our investigation into unidentified particulate matter in the product, which was observed during routine product stability testing. Production by Baxter remained suspended through September 30, 2012, and we are uncertain when Baxter will be able to resume production. The amount of time that will be required to complete the investigation is uncertain. Although we do not presently believe it is probable, it is reasonably possible that the manufacturing concerns may not be resolved timely, or at all. If this should occur, our estimate that we would recover the carrying value of the equipment from future operations could change and we may be required to record an impairment charge to reduce the carrying value of our manufacturing assets and our manufacturing equipment and facility construction assets in process. In addition, if the manufacturing concerns are resolved, but we do not complete our planned capacity expansion at the Baxter facility timely, or at all, we may still be required to record an impairment charge to reduce the carrying value of our manufacturing equipment and facility construction assets in process and record early-termination liabilities, if any. At September 30, 2012, the carrying value of the manufacturing assets on our balance sheet was $5.1 million and the manufacturing equipment and facility construction assets in process was $4.3 million.

Results of Operations

Three-Month Periods Ended September 30, 2012 and 2011

Revenue

During the three months ended September 30, 2012, we recognized $13.9 million of net revenue from the sale of OFIRMEV to hospitals and other end-users, an increase of $10.4 million, or approximately 300%, from the $3.5 million recognized during the three months ended September 30, 2011. This increase was primarily due to continued growth in our customer base since the launch of OFIRMEV in January 2011, an increase in the utilization of the product by these customers and the effect of a price increase in July 2012.

Cost and Expenses

Cost of Sales. Our cost of sales for the three months ended September 30, 2012, was $6.1 million, or 44% of net product revenue, as compared to $2.3 million, or 65% of net product revenue, for the comparable period in 2011. The increase in the total cost of sales for the three months ended September 30, 2012, was primarily due to our increased sales during the current period as compared to the 2011 period. As a percentage of net product revenue, our costs of sales during the 2012 period declined as we realized economies of scale on increased sales volume. Further, we realized additional margin on sales as a result of our July 2012 price increase. However, the efficiencies and price increase impact realized during the three months ended September 30, 2012 were partially offset by unabsorbed manufacturing costs that we continued to incur related to our Baxter manufacturing assets. Our costs of sales for the three months ended September 30, 2011, were negatively impacted by inefficiencies in our manufacturing operations and an accrual for minimum royalty obligations.

Research and Development Expenses. Research and development expenses increased $0.5 million for the three months ended September 30, 2012, to $2.2 million, from $1.7 million for the three months ended September 30, 2011. This increase was primarily due to severance obligations related to the departure of two officers. The severance obligations related to these terminations, which were consistent with the Company's current focus on commercialization rather than new product development, included approximately $0.3 million of non-cash stock-based compensation expense for the three months ended September 30, 2012.

We began enrollment in our FDA required post-approval clinical trial for OFIRMEV in pediatric patients under two years of age during the three months ended September 30, 2012, resulting in approximately $0.2 million of incremental expenses related to this trial.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $0.1 million, to $20.0 million, for the three months ended September 30, 2012, compared to $19.9 million for the comparable period in 2011. This increase was mostly attributable to additional legal expenses incurred during the 2012 period related to our intellectual property litigation as compared to the 2011 period. These additional costs were mostly offset by a reduction in selling-related costs, primarily from a reduction in marketing program expenditures incurred during the three months ended September 30, 2012 as compared to the 2011 period.

Nine-Month Periods Ended September 30, 2012 and 2011

Revenue

During the nine months ended September 30, 2012, we recognized $33.0 million of net product revenue from the sale of OFIRMEV to hospitals and other end-users, an increase of $27.4 million from the $5.6 million recognized during the nine months ended September 30, 2011. This increase was primarily related to the continued growth in our customer base and the increase in utilization by these customers since we launched the product in January 2011.

During the nine months ended September 30, 2011, we also recognized $5.2 million of revenue related to our data license agreement with Terumo, for which data was provided and consulting hours were incurred pursuant to the terms of the agreement. During the nine months ended September 30, 2012, less than $0.1 million of revenue related to this agreement was recognized for additional consulting hours rendered during the period and as of September 30, 2012, we continued to record less than $0.1 million of deferred revenue on our balance sheet related to un-recognized consulting revenue.

Cost and Expenses

Cost of Sales. Our cost of sales for the nine months ended September 30, 2012, was $16.1 million, or 49% of net product revenue, as compared to $3.6 million, or 64% of net product revenue, for the comparable period in 2011. The increase in the total cost of sales for the nine months ended September 30, 2012 was primarily due to the increased sales during the current period as compared to the 2011 period. As a percentage of net product revenue, our costs of sales were lower during the 2012 period as we realized economies of scale on increased sales volume. However, the efficiencies realized in 2012 were partially offset by higher freight costs related to our supply disruption during the first quarter of the year, unabsorbed manufacturing costs and an inventory write-down. These excess costs were mostly related to our suspension of production by Baxter in connection with an ongoing investigation into the cause of unidentified particulate matter observed in the product during routine product stability testing. More specifically, as a result of this investigation, we placed certain inventory produced by Baxter on indefinite hold and fully wrote-down the value of that inventory. We also incurred expedited freight costs on certain shipments of OFIRMEV from BMS Anagni in order to meet demand for OFIRMEV following the temporary suspension of manufacturing at Baxter's facility, and we continue to incur certain fixed manufacturing costs at the Baxter manufacturing site.

Research and Development Expenses. Research and development expenses decreased $1.6 million for the nine months ended September 30, 2012, to $5.4 million, from $7.0 million for the nine months ended September 30, 2011. This decrease was primarily due to a reduction in labor related costs as a result of a reduction in force implemented in the fourth quarter of 2011, partially offset by severance related costs incurred during the third quarter of 2012 related to the departure of two officers, a significant portion of which was related to non-cash stock-based compensation charges. These departures were made in connection with our current focus on commercialization, rather than new product development. The reduction in force implemented in 2011 mostly impacted our research and development group as we reallocated our resources to focus on the commercialization of OFIRMEV and reduce program costs that were not directly related to such efforts.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $5.8 million, to $66.8 million, for the nine months ended September 30, 2012, compared to $61.0 million for the comparable period in 2011. This increase was mostly attributable to higher legal expenses incurred related to our intellectual property litigation and increased commissions earned by our hospital sales force in 2012 as a result of our increased revenue during the current year.

Liquidity and Capital Resources

As a biopharmaceutical company focused on acquiring, in-licensing, developing and commercializing proprietary products principally for use in the hospital setting, we enter into agreements to acquire the rights to develop and commercialize product candidates. These agreements and related development programs consume significant resources and

may not result in a commercial product to generate revenue. For example, we obtained the exclusive patent rights and know-how for OFIRMEV, which is currently our only product, for the U.S. and Canada pursuant to our license agreement with BMS. Under this agreement, we have paid a total of $40.0 million in up-front fees and milestone payments, and we may be required to make two future milestone payments totaling up to $25.0 million upon the achievement of certain levels of net sales of the product. We are also obligated to pay royalties on any net sales of OFIRMEV, and are subject to annual minimum royalty obligations. Further, in the second quarter of 2010 we entered into an option agreement pursuant to which we obtained an option to acquire Incline. As consideration for this option, we have paid a total of $7.0 million to Incline. Our agreement with Incline is currently in the second of two option periods, during which we may acquire Incline for an amount not to exceed $228.0 million, plus payment of an additional amount not to exceed $57.0 million upon FDA approval of IONSYS.

In developing products we acquire or in-license, we may incur substantial capital resource outlays, which we may not recover quickly, or at all. For example, we have incurred over $44.3 million in research and development costs through September 30, 2012, specific to the OFIRMEV development program. However, our total investment in the OFIRMEV program is significantly higher, as these costs do not include a substantial portion of our internal costs, such as salaries and related personnel costs, which are not tracked on a project basis, as well as the up-front fee and milestone payments that we have already paid and that are potentially due in the future periods. In January 2011, we commenced sales of OFIRMEV, and as of September 30, 2012, we have realized over $44.0 million in total net revenue from OFIRMEV. However, we continue to operate at a loss and will remain in a loss position until we can generate a sufficient amount of revenue from sales of OFIRMEV to cover our costs, if ever.

We have incurred significant net losses since our inception and, as of September 30, 2012, we had accumulated a deficit of $426.2 million. A significant portion of these costs have been incurred in connection with research and development activities, including license fees, costs of clinical trial activities associated with our product candidates, our commercial operations and infrastructure, manufacturing development activities and general and administrative expenses. We have continued to incur operating losses in connection with our commercial launch of OFIRMEV, including the marketing and sales efforts for the product. Further, we could incur additional expenses, which may be significant, if we acquire or in-license additional products, technologies or businesses that are complementary to our own.

Since inception, our operations have been financed primarily through the sale of equity securities, in both public and private offerings. From our inception through September 30, 2012, we have received net proceeds of approximately $443.7 million from the sale of our preferred stock, common stock and warrants to purchase common stock. Through September 30, 2012, the sales of shares of our preferred stock, common stock and warrants were as follows:

- from July 2004 to September 2012 (excluding our initial public offering, our February 2008 registered direct offering, our February 2009 private placement and our 2010 and 2011 public offerings), we issued and sold a total of 3,109,084 shares of common stock to our founders, employees, directors and consultants for aggregate net proceeds of $2.7 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;

- 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 at a price of $7.84, all of which remain outstanding at June 30, 2012;

- in November and December 2010, we completed a public offering in which we issued and sold a total of 12,500,000 shares of our common stock for aggregate net proceeds of $93.6 million; and

- in November 2011, we completed a public offering in which we issued and sold a total of 21,800,000 shares of our common stock for aggregate net proceeds of $77.3 million.

Additionally, we have obtained growth capital through loans with Oxford Finance LLC, Silicon Valley Bank and General Electric Capital Corporation. As of September 30, 2012, the current secured credit facility with this syndicate had an outstanding principal balance of $30.0 million and we had no further credit available under this facility. We are currently making interest-only payments on the outstanding balance of this facility, which will continue through December 2012. In January 2013, we will begin making equal monthly principal and interest payments to fully amortize the balance over a 30-month term. In connection with the establishment of our loan agreements, we have issued warrants to the lenders to purchase shares of our stock. As of September 30, 2012, 63,079 shares of common stock had been issued from the exercise of such warrants. Warrants to purchase an additional 50,331 common shares at $12.67 per share, 254,793 common shares at $7.0645 per share and 158,311 common shares at $3.79 per share, remain outstanding from our loan agreements at September 30, 2012.

Liquidity

As of September 30, 2012, we had $69.4 million in cash and cash equivalents, a decrease of $13.2 million from $82.6 million at December 31, 2011. This decrease was primarily due to the cash used to fund our operations during the nine months ended September 30, 2012 of $51.3 million, $39.5 million of which was funded through net maturities of our marketable securities during the period. In addition, we used $1.5 million of cash for the purchase of property and equipment and received proceeds from stock option exercises of $0.1 million during the nine months ended September 30, 2012.

The $51.3 million of cash used in operations during the nine months ended September 30, 2012, represents a decrease of $9.5 million from the $60.8 million of cash used in operations during the nine months ended September 30, 2011. This reduced cash burn is primarily due to our reduced operating loss, combined with a reduction in our working capital requirements for the nine month ended September 30, 2012, as compared to the 2011 period. For example, during the nine months ended September 30, 2012, we recorded a net loss of $59.6 million, a decrease of $5.8 million from the $65.4 million recorded during the comparable period in 2011, primarily due to increased revenue during the 2012 period. Moreover, during the nine months ended September 30, 2012, we consumed approximately $1.6 million to support our working capital requirements, a reduction of $3.7 million from the approximately $5.3 million used during the same period in 2011. This reduction in cash expenditures primarily relates to the additional cash used in establishing our initial inventory levels during 2011, whereas during the 2012 period we spent fewer resources in maintaining an adequate supply of product as we transitioned between suppliers.

Due to our increased revenue in 2012 as compared to 2011, we have also experienced a corresponding increase in our accounts receivable balance. As of September 30, 2012, our accounts receivable balance was $6.8 million, an increase of $4.1 million from December 31, 2011. Despite this increase in our accounts receivable balance, however, our days sales outstanding, as calculated by wholesaler shipments, has remained low at approximately 36 days. Furthermore, we have not incurred bad debt expense on any customer through September 30, 2012. Similarly, our accounts payable and accrued expenses balances have also increased, from a consolidated balance of $14.7 million at December 31, 2011, to $18.6 million at September 30, 2012, or an increase of $3.9 million.

Our net property and equipment balance at September 30, 2012, decreased $0.6 million to $10.0 million from $10.6 million as of December 31, 2011, primarily due to depreciation taken during the nine months ended September 30, 2012, partially offset by purchases of manufacturing equipment. These capital purchases were mostly related to our plans to expand the manufacturing capacity at Baxter, which would include our funding of all capital and facility improvements, however, until the investigation into the cause of the particulate matter found in stability testing samples of product manufactured by Baxter is completed, we have suspended negotiations with Baxter regarding this expansion. As a result, we cannot reasonably estimate the cost, or timing, of any such expansion at this time.

As of September 30, 2012, our investments in marketable securities balance was $5.2 million, a decrease of $39.4 million from $44.6 million at December 31, 2011. The decrease was due to maturities of our investments which were used to support our operations during the nine months ended September 30, 2012.

Capital Resources

Our cash, cash equivalents and short-term investment balances and the revenue we generate from the sale of OFIRMEV are our primary source of liquidity and currently the only sources available to us. We believe that these sources will provide us with sufficient financial resources to fund our operations and service our existing debt, at a minimum, for the next twelve months. However, our future funding requirements will depend on many factors, including, but not limited to:

- our ability to successfully market and sell OFIRMEV;
- our capacity to manage our commercial infrastructure and related expenses, including our sales and marketing personnel and our agreements with third parties for warehousing, distribution, cash collection and related commercial activities;
- our execution of acquisition, in-licensing, co-promotion, or similar agreements for new products, and the timing of payments we may make or receive under these arrangements;
- variations in the level of expenses related to our development programs for any future product candidates;
- costs associated with our ongoing intellectual property lawsuits related to OFIRMEV, and any product liability or other litigation in which we may become involved;
- costs associated with any product recall or investigation into quality concerns;
- regulatory developments affecting OFIRMEV or the products or product candidates of our competitors;
- the level of underlying hospital demand for OFIRMEV and wholesalers' buying patterns; and
- any determination to acquire any other product or product candidates, including the exercise of our option to acquire Incline.

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 loan and security agreement. These financial resources may not be adequate to sustain our operations until we are able to generate significant positive cash flow from our operations and we may be required to finance future cash needs through the sale of additional equity securities, strategic collaboration agreements or debt financing. However, 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 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.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of September 30, 2012.

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, prospects, regulatory and commercialization strategies, growth strategy, future revenue, projected costs, 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 possibility that the manufacturing concerns with Baxter may not be resolved in a timely manner, or at all, and the prospect that this or the associated delay in the manufacturing capacity expansion could lead to carrying value impairments; statements regarding storage and destruction fees for the recalled lots of OFIRMEV and the potential for additional vials to be returned under the recall of Baxter-manufactured OFIRMEV; our expectation that no supply shortages or additional expedited freight charges will result from the recall of Baxter-manufactured OFIRMEV; our expectations regarding the sufficiency of our capital resources to fund our operations; the potential for us to ultimately acquire Incline or other products or product candidates; the potential for us to commercialize OFIRMEV in Canada; and our ability to execute our strategies for acquiring, in-licensing, developing and commercializing proprietary products principally for use in the hospital setting. 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 may 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: our dependence on the successful commercialization of OFIRMEV, which is our only product; our ability to achieve broad market acceptance and generate revenues from sales of OFIRMEV; our dependence on our contract manufacturers and our ability to ensure an adequate and continued supply of OFIRMEV to meet market demand, including timely resolution of our investigation and implementation of any necessary corrective and preventive actions related to the Baxter manufacturing process; our ability to successfully enforce our marketing exclusivities and intellectual property rights, and to defend the patents covering OFIRMEV, including in current intellectual property litigation with the parties that have submitted abbreviated new drug applications (“ANDAs”) for generic versions of OFIRMEV; the potential that we may be required to continue intellectual property litigation for substantial lengths of time or file additional lawsuits to defend our patent rights from challenges by companies that have submitted ANDAs for generic versions of OFIRMEV, and the substantial costs associated with such lawsuits; the potential introduction of generic competition to OFIRMEV in the event we are unsuccessful in current or future intellectual property litigation; our dependence on our licensors for the maintenance and enforcement of our intellectual property rights; the potential product liability exposure associated with pharmaceutical products such as OFIRMEV and other products we may in-license or acquire; our ability to fully comply with numerous federal, state and local laws and regulatory requirements that apply to our commercial activities; public concern regarding the safety of drug products such as OFIRMEV, which could result in the implementation by regulatory agencies of new requirements, including unfavorable information in the labeling for OFIRMEV; the risk that we may not be able to raise sufficient capital when needed, or at all; and other risks detailed below under Part II — Item 1A — Risk Factors and in our periodic public filings with the SEC; and other risks detailed below under Part II — Item 1A — Risk Factors and in our periodic public filings with the SEC. 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 September 30, 2012, our holdings consisted of investments in money market funds, corporate debt obligations, debt obligations of municipalities and certificates of deposit. These investments were 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 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 September 30, 2012 (in thousands):

	Amortized Cost Basis	Fair Value
Cash equivalents	$ 67,812	$ 67,812
Short-term investments	$ 5,159	$ 5,159

Debt

Our current loan and security agreement has a fixed interest rate. Consequently, we do not have significant interest rate cash flow exposure on our debt. The principal balance of the loan under the agreement at September 30, 2012 was $30.0 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. We believe we were in compliance will all such covenants under the agreement as of September 30, 2012.

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 SEC'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 SEC 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 as of the end of the period covered by this Quarterly Report.

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***

In August 2011, we and SCR Pharmatop S.A., or Pharmatop, filed suit in the United States District Court for the District of Delaware against Paddock Laboratories, Inc., Perrigo Company and Paddock Laboratories, LLC, collectively referred to herein as Paddock, and against Exela Pharma Sciences, LLC, Exela PharmaSci, Inc. and Exela Holdings, Inc., collectively referred to herein as Exela. The lawsuit follows the notices that we received in July 2011 from each of Paddock and Exela concerning their filings of Abbreviated New Drug Applications, or ANDAs, containing a "Paragraph IV" patent certification with the FDA for a generic version of OFIRMEV. In the lawsuit, we allege that Paddock and Exela have each infringed U.S. Patent Nos. 6,028,222, or the '222 patent, and 6,992,218, or the '218 patent, by filing their respective ANDAs

seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. The ‘222 and the ‘218 patents are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. The intellectual property lawsuit was filed within 45 days of receipt of the pertinent notice letters, thereby triggering a stay of FDA approval of the Paddock ANDA and the Exela ANDA until the earlier of the expiration of a 30-month period, the expiration of the ‘222 and ‘218 patents, the entry of a settlement order or consent decree stating that the ‘222 and ‘218 patents are invalid or not infringed, a decision in the case concerning infringement or validity that is favorable to Paddock or Exela, or such shorter or longer period as the Court may order. Each of Paddock and Exela has filed an answer in the case that asserts, among other things, non-infringement and invalidity of the asserted patents, and has also filed counterclaims. On August 22, 2012, after comprehensive briefing and oral argument, Judge Leonard P. Stark issued an order adopting our proposed patent term constructions with respect to a majority of the disputed issues. Judge Stark’s ruling is available on the District Court’s website at http://www.ded.uscourts.gov/judges-info/opinions. A date for the bench trial in this case has been tentatively scheduled for May 2013. In addition, in May 2012, Exela informed the Court that it filed suit in the United States District Court for the Eastern District of Virginia against the United States Patent and Trademark Office, or USPTO, for declaratory judgment seeking a reversal of the decision by the USPTO refusing to act on a petition by Exela to vacate the USPTO’s April 2003 order reviving the international application for the ‘218 patent. The lawsuit followed the USPTO’s rejection of Exela’s petition to the USPTO filed in November 2011, which sought to vacate the April 23, 2003 order granting Pharmatop’s petition to revive the ‘218 patent. The USPTO determined that Exela lacks standing to seek such relief. Exela also seeks declaratory judgment that the USPTO’s rules and regulations that allow for revival of abandoned, international patent applications under the “intentional” standard are invalid, and similar relief in connection with one or more counterclaims it has filed in the Delaware litigation. The Court denied the USPTO’s motion to dismiss Exela’s lawsuit. A decision by the Court in favor of Exela could result in the invalidation of the ‘218 patent. Regardless of the outcome of any litigation, no ANDA can receive final approval from the FDA before expiration of the regulatory exclusivity period for OFIRMEV. Specifically, the FDA has granted OFIRMEV three years of regulatory exclusivity, which expires November 2, 2013. We intend to vigorously enforce our intellectual property rights relating to OFIRMEV to prevent the marketing of infringing generic products prior to the expiration of our patents. The ‘222 patent expires August 5, 2017 (or February 5, 2018 if pediatric exclusivity is granted) and the ‘218 patent expires June 6, 2021 (or December 6, 2021 if pediatric exclusivity is granted). However, given the unpredictability inherent in litigation, we cannot predict the outcome of this matter or any other litigation. Regardless of how this litigation is ultimately resolved, this matter may be costly, time-consuming and distracting to our management, which could have a material adverse effect on our business. At this time, we are unable to estimate possible losses or ranges of losses for current litigation, and we have not accrued any amounts for current litigation other than ongoing attorney’s fees.

Item 1A. *Risk Factors*

You should carefully consider the risks described below, in addition to the other information contained in this report, before making an investment decision. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair 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, 2011.

Risks Related to Our Business and Industry

Our success depends on our ability to successfully commercialize our only product, OFIRMEV®.*

Our success depends on our ability to effectively commercialize our only product, OFIRMEV, which was approved by the FDA in November 2010 for the management of mild to moderate pain, the management of moderate to severe pain with adjunctive opioid analgesics and the reduction of fever in adults and children two years of age and older.

We launched OFIRMEV in January 2011, but our ability to effectively commercialize and generate revenues from OFIRMEV will depend on several factors, including:

- our ability to create market demand for OFIRMEV through our own marketing and sales activities, and any other arrangements to promote this product we may later establish;
- our ability to maintain and defend our patent protection and regulatory exclusivity for OFIRMEV;

- our ability to procure a supply of OFIRMEV from our third-party manufacturers in sufficient quantities and at acceptable quality and pricing levels in order to meet commercial demand;
- the performance of our third-party manufacturers and our ability to ensure that our supply chain for OFIRMEV efficiently and consistently delivers OFIRMEV to our customers;
- our ability to train, deploy and support a qualified sales force;
- our ability to secure formulary approvals for OFIRMEV at a substantial number of targeted hospitals;
- our ability to implement and maintain agreements with wholesalers, distributors and group purchasing organizations on commercially reasonable terms;
- the occurrence of adverse side effects or inadequate therapeutic efficacy of OFIRMEV, and any resulting product liability claims or product recalls; and
- the availability of adequate levels of reimbursement coverage for OFIRMEV from third-party payors.

Any disruption in our ability to generate revenues from the sale of OFIRMEV or lack of success in its commercialization will have a substantial adverse impact on our results of operations.

Our efforts to successfully commercialize OFIRMEV are subject to many internal and external challenges and if we cannot overcome these challenges in a timely manner, our future revenues and profits could be materially and adversely impacted.

OFIRMEV was launched in January 2011. Since that time, we have continued to expend significant time and resources to train our sales force to be credible and persuasive in discussing OFIRMEV with physicians, nurses, hospitals and other customers, and to ensure that a consistent and appropriate message about OFIRMEV is being delivered to our potential customers. If we are unable to effectively train our sales force and equip them with effective materials, including medical and sales literature to help them inform and educate potential customers about the benefits and risks of OFIRMEV and its proper administration, our efforts to successfully commercialize OFIRMEV could be put in jeopardy, which could have a material adverse effect on our financial condition, stock price and operations.

In addition to extensive internal efforts, the successful commercialization of OFIRMEV requires many third parties, over whom we have no control, to decide to utilize OFIRMEV. These third parties include physicians, pharmacists, and hospital pharmacy and therapeutics committees, which are commonly referred to as P&T committees. Generally, before we can attempt to sell OFIRMEV in a hospital, OFIRMEV must be approved for addition to that hospital's list of approved drugs, or formulary list, by the hospital's P&T committee. A hospital's P&T committee typically governs all matters pertaining to the use of medications within the institution, including review of medication formulary data and recommendations for the appropriate use of drugs within the institution to the medical staff. The frequency of P&T committee meetings at various hospitals varies considerably, and P&T committees often require additional information to aide in their decision-making process, so we may experience substantial delays in obtaining formulary approvals. Additionally, hospital pharmacists may be concerned that the cost of acquiring OFIRMEV for use in their institutions will adversely impact their overall pharmacy budgets, which could cause pharmacists to resist efforts to add OFIRMEV to the formulary, or to implement restrictions on the usage of the drug in order to control costs. We cannot guarantee that we will be successful in getting the approvals we need from enough P&T committees and overcoming any financial objections raised by hospital pharmacists quickly enough to optimize hospital sales of OFIRMEV.

Even if we obtain hospital formulary approval for OFIRMEV, physicians must still prescribe OFIRMEV for its commercialization to be successful. Because OFIRMEV is a relatively new drug with no track record of sales in the U.S. prior to January 2011, any inability to timely supply OFIRMEV to our customers, or any unexpected side effects that develop from use of the drug, may lead physicians to not accept OFIRMEV as a viable treatment alternative.

We have no manufacturing capabilities and depend entirely upon our contract manufacturers to produce OFIRMEV. If our contract manufacturers fail to meet our requirements for OFIRMEV, or fail to fully comply with cGMP regulations, we may 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 no such manufacturing capabilities, so we have relied upon our contract manufacturers as our source for OFIRMEV.

In July 2007, we entered into a long-term development and supply agreement with Baxter, our initial contract manufacturer for OFIRMEV, which was amended and restated in January 2011. In December 2010, we entered into an agreement with a second supplier, Lawrence Laboratories, an indirect wholly-owned subsidiary of BMS, under which Bristol-Myers Squibb Srl, or BMS Anagni, an indirect subsidiary of BMS located in Anagni, Italy, manufactures OFIRMEV for us on behalf of Lawrence Laboratories. BMS Anagni has manufactured the product for more than ten years for sale and distribution by BMS and its affiliates in a number of countries outside of the U.S. and Canada.

Baxter and BMS Anagni must comply with strictly enforced federal, state and foreign regulations, including GMP regulations. The FDA will re-inspect our third party manufacturers' facilities from time to time and, in the event that any such inspection reveals that either facility is not in compliance with applicable regulations, the FDA may issue fines and civil penalties, suspend production, suspend or delay any subsequent product approvals, seize or recall our products, or withdraw our product approval, which would limit the availability of OFIRMEV. 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 our relationships with our customers, product liability claims and litigation.

We currently rely upon a single source for the manufacture of the active pharmaceutical ingredient, or API, for OFIRMEV, as well as for other critical components of OFIRMEV. We have entered into a supply agreement for the commercial supply of the API. If our supplier becomes unable to meet our demand for the API, the process of changing or adding a new API manufacturer may require additional testing and prior FDA approval and may be expensive and time-consuming. If we were unable to manage such changes effectively, we could face supply disruptions that could result in significant costs and delays, damage to our reputation or commercial prospects and cause us to lose potential revenues.

Although we actively manage these third party relationships to ensure continuity and quality, some events beyond our control could result in the complete or partial failure of these goods and services. Any such failure could have a material adverse effect on our financial condition and operations. In addition, as OFIRMEV is a relatively new product in the U.S., the effect of any delay or failure to deliver could be magnified due to the lack of a sales track record for OFIRMEV.

For example, in February 2012, we announced a voluntary recall of a single lot of OFIRMEV that was manufactured at Baxter's facility due to the presence of an unidentified, visible particle in that lot during routine stability testing. We also placed certain finished product inventory of OFIRMEV manufactured by Baxter on indefinite hold pending the outcome of our investigation into unidentified particulate matter observed during routine product stability testing and we decided to temporarily suspend further production by Baxter until the resolution of the investigation. As a result, BMS Anagni is presently acting as our sole supplier for OFIRMEV until our investigation at Baxter's facility has been completed and any necessary corrective and preventative actions have been implemented, and we are actively exploring other supply options for the product. During the first quarter of 2012, some of our customers experienced short-term supply delays due to the temporary suspension of shipments from Baxter before we were able to expedite sufficient shipments of OFIRMEV from BMS Anagni. In addition, during that time we incurred higher freight costs to expedite shipments of OFIRMEV from BMS Anagni in order to meet demand for the product following the temporary suspension at Baxter's facility. Since that time, we have continued to incur unabsorbed manufacturing costs due to fixed costs that continue to accrue under our supply agreement with Baxter.

Further, in July 2012, we announced a second voluntary recall of product manufactured at Baxter's facility due to the presence of unidentified, visible particles in a limited number of vials from one lot of the product, which were detected during routine stability testing. Although we have received no adverse event reports associated with the particulate matter, and no product complaints involving similar particulate matter have been received, we decided to recall all remaining lots of OFIRMEV manufactured by Baxter as a precautionary measure. All of the 41 recalled lots had expired as of September 30, 2012, and, as of that date, fewer than 4,000 vials from these lots had been returned. The suspension of Baxter's manufacturing of the product remains in effect pending our investigation to determine the root cause of the particulate matter.

As a result of the second recall, we decided to destroy the Baxter-manufactured finished product inventory that we previously placed on indefinite hold pending the outcome of our investigation into the cause of the unidentified particulate

matter identified during routine product stability testing. We previously recorded charges of $5.8 million in relation to this product due to uncertainty as to the amount of time that would be required to complete the investigation and whether the product would have sufficient remaining shelf life or otherwise be saleable after the investigation was completed.

Although we have not completed our investigation into the cause of the particulate matter discovered in the product manufactured by Baxter, our review of stability data for product manufactured by BMS Anagni has confirmed that no similar particulate material has been observed in any product manufactured there.

The two voluntary recalls of OFIRMEV, the outcome of our investigation into the cause of the particulate material, and any future recall or investigation that we may experience, could negatively affect customer perceptions and reduce revenue from OFIRMEV, and could also result in unexpected costs for replacement product, investigational costs and the write down of inventory. Any termination or disruption of our relationships with Baxter or BMS Anagni may materially harm our business and financial condition and adversely impact our commercialization and sales efforts with respect to OFIRMEV.

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 will continue to face competition in our efforts to market and sell OFIRMEV from other 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 injectable 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, is available 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 our in-licensed patent rights. 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. In August 2011, we and Pharmatop filed suit in the United States District Court for the District of Delaware against Paddock and Exela alleging that each has infringed the ‘222 and ‘218 patents, which are listed in the Orange Book for OFIRMEV, by filing their respective ANDA seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. The intellectual property lawsuit was filed within 45 days of receipt of the pertinent notice letters, thereby triggering a stay of FDA approval of the Paddock ANDA and the Exela ANDA. Regardless of the outcome of any litigation, no ANDA can receive final approval from the FDA before expiration of the regulatory exclusivity period for OFIRMEV. We intend to vigorously enforce our intellectual property rights relating to OFIRMEV to prevent the marketing of infringing generic products prior to the expiration of our patents. However, given the unpredictability inherent in litigation, we cannot predict the outcome of this matter or guarantee the outcome of any litigation. In addition, we are aware of several third-party U.S. and Canadian patents and patent applications directed to various potential injectable formulations of acetaminophen, including intravenous formulations, as well as methods of making and using these potential formulations. Compared to us, many of our potential competitors have substantially greater:

- capital resources;
- research 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 be able to obtain patent protection or other intellectual property rights that limit our ability to 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 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 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 or 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;
- 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 or product candidate 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 reasonable cost, achieve hospital formulary acceptance for the product and sell the product at a competitive price, 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 OFIRMEV and any other product to hospitals that are members of 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 OFIRMEV and any other product or product candidates we may license or acquire. If OFIRMEV, or any other product or product candidate that is approved, does 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 and risks of OFIRMEV or any other product or product candidate may require significant resources and may never be successful.

We rely on third parties to perform many essential services for OFIRMEV and any other 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 efforts to commercialize OFIRMEV or any other products may be significantly impacted and we may be subject to regulatory sanctions.

We rely on third-party service providers to perform a variety of functions related to the sale and distribution of OFIRMEV, key aspects of which are out of our direct control. The services provided by these third parties include warehousing and inventory control, distribution, customer service, accounts receivable management and cash collection. As a result, most of our inventory is stored at a single warehouse maintained by one such service provider. 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 if our products 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 OFIRMEV and related services. If the quality or accuracy of the data maintained or services performed by these third parties is insufficient, we could be subject to regulatory sanctions.

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

The use of OFIRMEV and any other products or 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:

- decreased demand for OFIRMEV or other products or product candidates;
- loss of revenues;
- impairment of our business reputation;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- withdrawal of clinical trial participants;
- significant distraction of our scientific and management personnel who may be involved in our efforts to defend against such claims; and
- the inability or lack of commercial rationale to continue commercialization of OFIRMEV or any other products or product candidates.

Although we currently have commercial product liability coverage for OFIRMEV, which includes coverage for any clinical trials we may perform, insurance coverage is becoming increasingly expensive and we may be unable to obtain commercially reasonable product liability insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. Our commercial product liability insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. 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.

We may require substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate some or all of our planned activities.

We began generating revenue from the launch of OFIRMEV in January 2011, however, we expect our negative cash flow from operations to continue until we are able to generate significant revenues from sales of OFIRMEV. As a result, we may need to raise additional capital to:

- fund our operations as we implement our marketing strategies, maintain our sales force and commercial infrastructure and commercialize OFIRMEV;
- purchase sufficient quantities of OFIRMEV from our contract manufacturers to meet customer demand or our minimum purchase obligations;
- continue to fund the expansion of our contract manufacturers' capacity to produce OFIRMEV in order to meet future demand for this product;
- complete our ongoing efficacy, pharmacokinetic and pharmacodynamic study of OFIRMEV in pediatric patients under two years of age, as required to comply with our post-commercialization commitment to the FDA;
- exercise our option to acquire Incline; or
- acquire or in-license other products, businesses or technologies that we believe are a strategic fit.

Our funding requirements related to the commercialization of OFIRMEV may exceed our current projections as a result of many factors, including, but not limited to:

- our sales of OFIRMEV may be lower than expected;
- the costs associated with our efforts to sell, market and distribute OFIRMEV, including costs associated with maintaining our sales force and commercial infrastructure, may be greater than anticipated;
- we may incur unexpected costs in order to ensure a sufficient supply of OFIRMEV from our contract manufacturers in order to meet customer demand, including any replacement of product or write down of inventory related to any product recall or other quality issue, or we may be required to pay fees based on minimum purchase obligations; and
- we may be required to file lawsuits to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of intravenous acetaminophen, such as our intellectual property litigation, including any such costs we may be required to expend if our licensors are unwilling or unable to do so.

Until we can generate a sufficient amount of revenue from sales of OFIRMEV, 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 have engaged in various financing activities in the past. In May 2011, for example, we established a universal shelf registration statement to permit us, from time to time, to offer and sell up to $150.0 million of equity or debt securities. In November 2011, we undertook a public offering of common stock using our universal shelf registration statement that raised net proceeds of approximately $77.3 million. In addition, in December 2011, we refinanced our $30.0 million secured credit facility with Oxford Finance LLC, Silicon Valley Bank and General Electric Capital Corporation. However, there can be no assurance in the future that we would be able to enter into similar financing arrangements or complete any securities offerings, including under our universal shelf registration statement, and to the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership will be diluted.

We believe we have sufficient financial resources to fund our projected operating requirements, at a minimum, for the next twelve months. This estimate does not reflect any exercise of our right to acquire Incline or participation in other strategic transactions. 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. 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 reduce the scope of or eliminate some or all of our sales, marketing and commercialization efforts for OFIRMEV, or we may not be able to adequately fund our intellectual property litigation, which could decrease sales of this product and have a material adverse effect on our financial condition, stock price and operations.

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

We have built our own sales and marketing capabilities in order to market OFIRMEV directly to physicians, nurses, hospitals, group purchasing organizations and other customers, and will continue to incur significant expenses associated with the recruitment, training and compensation of our sales representatives. The continued development of our hospital-focused sales, marketing and distribution infrastructure for our domestic operations will be expensive and time consuming, and there may be unforeseen costs and expenses or time-delays associated with such activities. If we are not successful in training and managing our sales and marketing personnel, we may not achieve our sales objectives. In addition, if we are unable to maintain adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue, may experience increased expenses, and may never become profitable.

Although OFIRMEV has received regulatory approval from the FDA, it remains subject to substantial, ongoing regulatory requirements.*

OFIRMEV remains subject to ongoing FDA requirements with respect to manufacturing, labeling, packaging, storage, distribution, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. The FDA has the authority to regulate the claims we make in marketing OFIRMEV to ensure that such claims are true, not misleading, supported by scientific evidence and consistent with the approved label for the drug. In addition, the discovery of

previously unknown problems with OFIRMEV, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, may result in the imposition of additional restrictions, including withdrawal of the product from the market.

For example, as a condition of the approval of OFIRMEV, we are required to complete an efficacy, pharmacokinetic and pharmacodynamic study of OFIRMEV in pediatric patients under two years of age, and to submit the final results of this clinical trial to the FDA. Depending on the outcome of this study, we may be unable to expand the indications for OFIRMEV or we may be required to include specific warnings or limitations on dosing this product, which could negatively impact our sales of OFIRMEV. Enrollment in this study began in the third quarter of 2012.

We have implemented a comprehensive compliance program and related infrastructure, but we cannot provide absolute assurance that we are or will be in compliance with all potentially applicable laws and regulations. If our operations in relation to OFIRMEV fail to comply with applicable regulatory requirements, the FDA or other regulatory agencies may:

- issue warning letters or untitled letters;
- impose consent decrees, which may include the 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;
- exclude us from participating in U.S. federal healthcare programs, including Medicaid or Medicare; 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. Regulatory authorities in the U.S. generally do not regulate the behavior of physicians in their choice of treatments, and such off-label uses by healthcare professionals are common. 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.

We are subject to new legislation, regulatory proposals and healthcare payor 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, or PPACA, which makes extensive changes to the delivery of health care in the U.S. The PPACA includes numerous provisions that affect pharmaceutical companies, some of which became effective immediately and others of which will be taking effect over the next several years. For example, the PPACA seeks to expand health care coverage to the uninsured through private health insurance reforms and an expansion of Medicaid. The PPACA 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 U.S., and an expansion of an existing program requiring pharmaceutical discounts to certain types of hospitals and federally subsidized clinics. The PPACA 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. We cannot predict what effect the PPACA or other healthcare reform initiatives that may be adopted in the future will have on our business. Several lawsuits were filed challenging the constitutionality of provisions of the PPACA, with varying results. Although the U.S. Supreme Court recently upheld most of the PPACA, it remains unclear whether there will be any changes made to provisions of the PPACA or other health care laws through acts of Congress in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care could result in decreased net revenues from our pharmaceutical products and decrease potential returns from our development efforts. Although there is some uncertainty as to the exact extent of the requirements and definitive guidance has not yet been provided by the government, it is currently anticipated that data collection requirements will begin no earlier than January 1, 2013. In addition, pharmaceutical and device manufacturers will also be required to report and disclose investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in civil monetary penalties for payments, transfers of value or ownership or investment interests not reported in an annual submission. Compliance with the PPACA and state laws with similar provisions is difficult and time consuming, and companies that do not comply with these state laws face civil penalties. 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, results of operations and growth prospects.

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.

Managed care organizations are increasingly challenging the prices charged for medical products and services and, in some cases, imposing restrictions on the coverage of particular drugs. Many managed care organizations negotiate the price of medical services and products and develop formularies which establish pricing and reimbursement levels. Exclusion of a product from a formulary can lead to its sharply reduced usage in the managed care organization's patient population. The process for obtaining coverage can be lengthy and costly, and we expect that it could take several months before a particular payor initially reviews our product and makes a decision with respect to coverage. For example, third-party payors may require cost-benefit analysis data from us in order to demonstrate the cost-effectiveness of OFIRMEV or any other product we might bring to market. For any individual third-party payor, we may not be able to provide data sufficient to gain reimbursement on a similar or preferred basis to competitive products, or at all.

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 outside of the U.S. to commercialize OFIRMEV or any other products or product candidates we may acquire.*

Our rights to OFIRMEV include Canada, as well as the U.S. In order to market OFIRMEV, and any other products or 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, clinical 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. For example, in July 2012, we filed a New Drug Submission for OFIRMEV with Health Canada which was accepted for review in August 2012. We are currently evaluating the commercial prospects and partnering opportunities for the product in Canada and anticipate that the product would not be approved by Canadian regulatory authorities for at least 18 months after this submission, if at all. The regulatory approval process in other countries may include all of the risks detailed above 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 OFIRMEV and any other 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 result in new requirements from regulatory agencies to include 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. For example, in January 2011, the FDA issued a press release and posted on its website a drug safety communication asking manufacturers of prescription drug products containing combinations of acetaminophen and opioid medications to limit the amount of acetaminophen to no more than 325 milligrams (mg) in each dosage unit (i.e. each tablet or caplet). In the announcement, the FDA also requested manufacturers to update labels for such products to include a boxed warning highlighting the potential for severe acetaminophen-induced liver injury and a warning highlighting the potential for allergic reactions. The boxed warning required for affected products reaffirms previous statements made by the FDA that most cases of liver injury are associated with acetaminophen doses that exceed 4,000 mg per day. While the FDA has indicated that this communication does not apply to intravenous acetaminophen, it is possible that the FDA may apply similar labeling requirements to OFIRMEV in the future. We reaffirmed our dosing recommendations for OFIRMEV in July 2011 following a news release by a major manufacturer of over-the-counter acetaminophen products announcing its plan to lower the recommended maximum daily dose of some oral acetaminophen products in an effort to reduce the risk of accidental acetaminophen overdose among its customers in the over-the-counter setting.

Also, the California “State’s Experts” acting under Proposition 65 have recommended a high priority for a review of acetaminophen by the Office of Environmental Health Hazard Assessment, which, depending on subsequent research and findings, could lead to the requirement for a warning statement to be added to the label for over-the-counter acetaminophen products that such products contain chemicals known to the State of California to cause cancer. We believe that OFIRMEV, like other prescription products, would be exempt from this additional labeling requirement. However, any perception or concern that acetaminophen is unsafe could harm our ability to successfully commercialize and sell OFIRMEV, which could have a material adverse effect on our business, financial condition and results of operations.

In addition, the Food and Drug Administration Amendments Act of 2007, or FDAAA, granted 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 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 that law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. 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 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 anticipated sales of OFIRMEV or 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 products. In addition, some third-party payors are emphasizing the substitution of branded pharmaceuticals with less expensive generic equivalents. An increase in the sales of generic pharmaceutical products could result in a decrease in revenues of branded pharmaceuticals. While there are no generic equivalents competing with OFIRMEV at this time, in the future we could face generic competition. In August 2011, we and Pharmatop filed suit in the United States District Court for the District of Delaware against Paddock and Exela alleging that each has infringed the ‘222 and ‘218 patents, which are listed in the Orange Book for OFIRMEV, by filing their respective ANDA seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. The intellectual property lawsuit was filed within 45 days of receipt of the pertinent notice letters, thereby triggering a stay of FDA approval of the Paddock ANDA and the Exela ANDA. Regardless of the outcome of any litigation, no ANDA can receive final approval from the FDA before expiration of the regulatory exclusivity period for OFIRMEV. We intend to vigorously enforce our intellectual property rights relating to OFIRMEV to prevent the marketing of infringing generic products prior to the expiration of our patents. However, given the unpredictability inherent in litigation, we cannot predict the outcome of this matter or guarantee the outcome of any litigation.

OFIRMEV or any other products or product candidates that we may in-license or acquire, if approved, will face competition from other therapies and drugs, as well as other routes of administration of acetaminophen, 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 twelve 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 or after our marketed products have been approved. 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 use. Such legislation could result in the exclusion of OFIRMEV and any other products or product candidates we may license or acquire from coverage and reimbursement programs, or lower the prices we would receive for our products or product candidates. Our revenues from the sale of OFIRMEV or any other 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 commercialize OFIRMEV.

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 from a third party, if there is any dispute between us and our licensor regarding our rights under our license agreement, our ability to continue to commercialize this product may be adversely affected. Any uncured, material breach under our license agreement could result in our loss of exclusive rights to OFIRMEV and may lead to a complete termination of our related commercialization efforts.

If BMS breaches the underlying agreement under which we sublicense the rights to OFIRMEV, we could lose the ability to commercialize OFIRMEV.

Our license for OFIRMEV is subject to the terms and conditions of a license from 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 Pharmatop, and neither BMS nor we adequately cure that breach, or BMS and Pharmatop otherwise become involved in a dispute, the breach by BMS or disputes with 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 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 Pharmatop to BMS could result in our loss of exclusive rights to OFIRMEV and may lead to a complete termination of our commercialization efforts for OFIRMEV.

We may experience difficulties in managing the growth of our organization.

As of September 30, 2012, we had approximately 215 employees. The commercial launch of OFIRMEV in January 2011 required us to substantially expand our managerial, commercial, financial and other personnel resources, particularly in sales and marketing positions. Additionally, beginning in November 2011, we implemented a reduction in force of 17 employees, or approximately 7% of our total work force at that time, primarily in our development and general and administrative areas. This action was taken in order to focus our resources on commercialization activities for OFIRMEV and to reduce programmatic costs not directly associated with such efforts. Despite these efforts, our management, personnel, systems and facilities currently in place may not be adequate to support our commercially-focused organization, and we may not be able to retain or recruit qualified personnel in the future due to competition for personnel among pharmaceutical businesses. 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:

- effectively train and manage our employees, and establish appropriate systems, policies and infrastructure to support our 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 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 expertise of our senior management, particularly Theodore R. Schroeder, our President and Chief Executive

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 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, 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. During the third quarter of 2012, our former Executive Vice President and Chief Medical Officer departed in connection with our current focus on commercialization, rather than new product development. Any attempt to develop new products in the future could be limited unless we were able to hire a suitable replacement.

In addition, we have scientific and clinical advisors who assist us in 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.

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. 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 our operations may be set back.

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 products or product candidates or integrate them into our operations, we may have limited growth opportunities.*

An important part of our business strategy is to continue to develop a pipeline of products and 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. For example, we signed an agreement in June 2010 granting us an option to acquire Incline. As part of our efforts to acquire businesses such as Incline, or to in-license products, we conduct technical, business and legal due diligence with the goal of identifying and evaluating material risks involved in such transactions, which may include:

- 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;
- effectiveness of the acquired business’s internal controls and procedures;
- 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.

Additionally, in connection with any such acquisition or in-licensing transaction, we must estimate the value of the transaction by making certain assumptions about, among other things, likelihood of regulatory approval for unapproved products and the market potential for marketed products and/or product candidates. Ultimately, our assumptions may prove to be incorrect, which could cause us to fail to realize the anticipated benefits of a transaction. Despite our efforts, we ultimately may be unsuccessful in ascertaining or evaluating all such risks and, as a result, we might not realize the intended advantages of the acquisition or in-licensing transaction. If we fail to realize the expected benefits from the transactions we have consummated or may consummate in the future, the results of our operations and financial condition could be adversely affected.

It cannot be assured that, following an acquisition, we will achieve revenues, specific net income or loss levels that justify the acquisition or that the acquisition will result in increased earnings, or reduced losses, for the combined company in any future period. Moreover, we may need to raise additional funds through public or private debt or equity financings to acquire any businesses, which would result in dilution for stockholders or the incurrence of indebtedness. We may not be able to operate acquired businesses profitably or otherwise implement our growth strategy successfully.

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.

We may not be able to exercise our option to acquire Incline and, even if we are able to, we may fail to realize the anticipated benefits of the transaction.

We signed an agreement in June 2010 granting us the option to acquire Incline, but we may not have sufficient capital to exercise this option. We are currently in the second of two option periods under this agreement, and if we elect to exercise the option, the payment of up to $228.0 million, plus up to $57.0 million upon FDA approval of IONSYS, would require us to raise additional funds to finance the acquisition. Raising such additional funds or paying up to 50% of the applicable option exercise payment in the form of our common stock would result in the incurrence of additional indebtedness or dilution for our stockholders.

We are relying on Incline to develop and obtain regulatory approval for IONSYS. Although Theodore R. Schroeder, our President and CEO, serves as our representative on Incline's board of directors, and we have formed a joint development committee to oversee the global development of, and pursuit of regulatory approval for, IONSYS, Incline will remain responsible for these activities unless and until we elect to acquire Incline. We do not control these development activities and therefore cannot be certain that they will be accomplished in a satisfactory manner. For example, Incline may breach one of the agreements under which it has licensed the rights to IONSYS, and lose the ability to continue to develop and commercialize this product candidate. In addition, Incline's efforts to develop improved patient safety features for IONSYS may be unsuccessful, or Incline may not develop a risk evaluation and management strategy, or REMS, for IONSYS that is acceptable to the FDA. Even if a REMS for IONSYS is approved by the FDA, the implementation of any such strategy may not be commercially feasible.

If we elect to acquire Incline, there will be a number of risks involved in the acquisition, including the potential for our management's attention to be diverted from, or for disruptions to affect, our ongoing business, and difficulties and expenses related to integrating the acquired business and retaining all or part of its personnel. In addition, there is the risk that our valuation assumptions for Incline may turn out to be erroneous or inappropriate, which could result in our having overvalued Incline, or that the contemplated benefits of acquiring Incline do not materialize as planned. We cannot assure you that, if we acquire Incline, the acquisition will result in increased earnings or reduced losses for the combined company in any future period. The individual or combined effects of these risks could have a material adverse effect on our business.

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 OFIRMEV 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.

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 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 is not available for the acetaminophen molecule itself in the territories licensed to us, which include the U.S. and Canada. 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, Pharmatop. We are the exclusive licensee of two U.S. patents and two issued Canadian patents owned by Pharmatop, under BMS's license to these patents from Pharmatop. U.S. Patent No. 6,028,222 (Canadian patent number 2,233,924) covers the formulation of OFIRMEV, and this patent expires in August 2017. U.S. Patent No. 6,992,218 (Canadian patent number 2,415,403) covers the process used to manufacture OFIRMEV, and this patent expires in June 2021. We plan to complete a pediatric clinical trial by August 2015 and, upon timely completion and the acceptance by the FDA of the data from this study, OFIRMEV will be eligible for an additional six months of marketing exclusivity in the U.S.

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 OFIRMEV 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 directed to 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 directed to 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. The commercial opportunity for OFIRMEV could be significantly harmed if competitors are able to develop alternative formulations of acetaminophen outside the scope of our in-licensed patents.

Two third-parties have challenged, and additional third parties may challenge, the patents covering OFIRMEV, 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 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, in the opinion of that third party, the patent listed in the Orange Book for a branded product is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of the third party's generic drug product. A third party 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 patent certification. If the third party submits a Paragraph IV patent certification to the FDA, a notice of the Paragraph IV patent certification must also be sent to us once the third-party's ANDA is accepted for filing by the FDA. A lawsuit may then be initiated to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of the receipt of notice of a Paragraph IV patent certification automatically prevents the FDA from approving the ANDA until the earlier of the expiration of a 30-month period, the expiration of the patents, the entry of a settlement order stating that the patents are invalid or not infringed, a decision in the infringement case that is favorable to the ANDA applicant, or such shorter or longer period as the court may order. If a patent infringement lawsuit is not initiated within the required 45-day period, the third-party's ANDA will not be subject to the 30-month stay.

In August 2011, we and Pharmatop filed suit in the United States District Court for the District of Delaware against Paddock and Exela alleging that each has infringed the '222 and '218 patents, which are listed in the Orange Book for OFIRMEV, by filing their respective ANDA seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. The intellectual property lawsuit was filed within 45 days of receipt of the pertinent notice letters, thereby triggering a stay of FDA approval of the Paddock ANDA and the Exela ANDA. Regardless of the outcome of any litigation, no ANDA can receive final approval from the FDA before expiration of the regulatory exclusivity period for OFIRMEV. We intend to vigorously enforce our intellectual property rights relating to OFIRMEV to prevent the marketing of infringing generic products prior to the expiration of our patents. However, given the unpredictability inherent in litigation, we cannot predict the outcome of this matter or guarantee the outcome of any litigation.

Certain pharmaceutical companies' patent settlement agreements with generic pharmaceutical companies have been challenged by the U.S. Federal Trade Commission alleging a violation of Section 5(a) of the Federal Trade Commission Act, and any patent settlement agreement that we may enter into with any generic pharmaceutical company may be subject to similar challenges, which could be both expensive and time consuming and may render such settlement agreements unenforceable.

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. Any adverse outcome of such litigation could result in one or more generic versions of OFIRMEV being launched before the expiration of the patents we have in-licensed from BMS and its licensor, Pharmatop, which could adversely affect our ability to successfully execute our business strategy to increase sales of OFIRMEV and negatively impact our financial condition and results of operations.

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 devote 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, 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 Pharmatop devote on our behalf, or the priority they place on maintaining and enforcing our patent rights, and prosecuting patent applications to our advantage.

Pharmatop is under a contractual obligation to BMS to maintain the issued OFIRMEV patents in the U.S., and to diligently prosecute the patent applications and maintain any issued patents related to OFIRMEV in Canada. BMS has the opportunity to consult, review and comment on any patent office communications. We may not receive any patent from the applications in Canada, or if patents are issued they may be inadequate to protect our OFIRMEV product from competition.

For a third-party challenge to the validity or enforceability of the OFIRMEV patents, we will have some ability to participate in either Pharmatop's or BMS' defense thereof. In the event that neither Pharmatop nor BMS elects to defend the third-party challenge, we may have the opportunity to defend it. BMS has the first right to prosecute a third-party infringement of the OFIRMEV patents relating to OFIRMEV, and Pharmatop has the second right. We may not have the ability to cooperate with BMS or Pharmatop in any such third-party infringement suits. In certain instances, we may be allowed to pursue a third-party infringement claim ourselves.

It is possible that Pharmatop or BMS could take some action or fail to take some action that could harm the patents related to OFIRMEV. For example, if Pharmatop decides it no longer wants to maintain the OFIRMEV patents, to prosecute the patent applications related to OFIRMEV in Canada, or if Pharmatop or BMS decide not to defend the patents against third party challenges, we risk losing the benefit of all or some of those patent rights. Moreover, Pharmatop or BMS may experience serious difficulties related to their respective businesses or financial stability, and may be unwilling or unable to continue to expend the financial resources required to maintain and prosecute these patents and patent applications, or to defend the patents against third party challenges.

Our success will depend in part on our ability to obtain and maintain patent protection for OFIRMEV, both in the U.S. and Canada. While we intend to take actions reasonably necessary to enforce our patent rights, we depend on our licensors to protect a substantial portion of our 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.

We or our licensors may also be notified of alleged infringement and be sued for infringement of third-party patents or other proprietary rights. 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. 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 effect 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 products or 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 products, 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 products or 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 products or product candidates. In the event that a third party has also filed a U.S. patent application relating to our products or product candidates or a similar invention, we may have to participate in interference proceedings declared by the USPTO 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 products or product candidates. Even if patents are issued, 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 or 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 products or 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 effect 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 began generating revenues from the commercialization of OFIRMEV in January 2011. Prior to that time, we 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 $93.0 million, $56.6 million and $45.5 million for the

years ended December 31, 2011, 2010 and 2009, respectively. As of September 30, 2012, we had an accumulated deficit of $426.2 million. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and our working capital. For example, while our development expenses decreased in 2011 and 2010 due to the completion of our clinical development program for OFIRMEV and the discontinuation of our development program for our omiganan pentahydrochloride product candidate in 2009, we have incurred increased commercialization and marketing expenses since 2010 in connection with our launch of OFIRMEV. Further, since the launch of OFIRMEV, we have also incurred significant increased sales, marketing and outsourced manufacturing expenses. In addition, we are required to pay a minimum annual royalty under our license agreement for OFIRMEV and we have minimum purchase obligations under our supply agreements with our contract manufacturers for OFIRMEV. If our sales of OFIRMEV are insufficient to meet our minimum annual royalty obligations, we will be required to make larger royalty payments than would have otherwise been required based on sales of OFIRMEV alone. 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 a limited history of revenue and may never be profitable.*

Our ability to become profitable depends upon our ability to generate revenue. We began to market OFIRMEV in January 2011, and we had not generated any revenue prior to that time. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- effectively commercialize OFIRMEV;
- manufacture commercial quantities of OFIRMEV at acceptable cost levels;
- successfully manage our commercial organization and the supporting infrastructure required to successfully market and sell OFIRMEV; and
- obtain regulatory approval for any other product or product candidates that we may license or acquire.

We have incurred and anticipate continuing to incur significant costs associated with our efforts to commercialize, market and sell OFIRMEV. 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 sufficient 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. Prior to 2011, our operations were limited to organizing and staffing our company, in-licensing and conducting product development activities, including clinical trials and manufacturing development activities, and preparing to commercialize OFIRMEV. In January 2011, we launched OFIRMEV and began generating revenues. OFIRMEV is still in the early stages of commercialization, and we have not yet demonstrated an ability to successfully market and sell OFIRMEV or any other product. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully commercializing pharmaceutical products.

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:

- our ability to successfully market and sell OFIRMEV;
- our capacity to manage our commercial infrastructure and related expenses, including our sales and marketing personnel and our agreements 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 development programs for any future product candidates;

- costs associated with our ongoing intellectual property infringement lawsuits related to OFIRMEV, and any product liability or other litigation in which we may become involved;
- costs associated with any product recall or investigation into quality concerns;
- regulatory developments affecting OFIRMEV or the products or product candidates of our competitors;
- the level of underlying hospital demand for OFIRMEV and wholesalers' buying patterns; and
- any determination to acquire any other product or product candidates, including the exercise of our option to acquire Incline.

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. For example, we undertook a public offering of our common stock in November 2010 through which we issued a total of 12.5 million shares of common stock and raised net proceeds of $93.6 million, and in November 2011 we issued a total of 21.8 million shares of common stock in a public offering and raised net proceeds of $77.3 million. If we raise additional funds through alternative means such as 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 December 2011, we refinanced our $30.0 million secured credit facility with Oxford Finance LLC, Silicon Valley Bank and General Electric Capital Corporation. This secured credit facility 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 current 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 current 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 and potential foreclosure on the assets pledged to secure the 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.

In addition, in July 2010, the Dodd-Frank Wall Street Reform and Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access, and the SEC has since issued final rules implementing "say on pay" measures. Our efforts to comply with corporate governance and related requirements have resulted in, and are likely to continue to result in, an increase in expenses and a diversion of management's time from other business activities.

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, 2011, we had generated federal and state net operating loss carryforwards of approximately $306.5 million and $310.0 million, respectively. We also had federal and state research and development tax credit carryforwards of approximately $4.8 million and $2.8 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. Our federal tax credits will begin expiring in 2024 unless previously used and our state tax credits carryforward indefinitely. Additionally, under Internal Revenue Code Sections 382 and 383, the annual use of our net operating loss carryforwards and research tax credits will be limited in the event a cumulative change in our ownership occurs within a three-year period. We expect to complete an analysis as to whether such a change of ownership has occurred in the next six months, and in such an event, we 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, certain states have suspended the use of net operating loss carryforwards for certain taxable years, and other states are considering similar measures. Currently, California allows companies to utilize their net operating losses, however, new legislation could suspend the use of those losses in the future. 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 difficult residential real estate market in the U.S. have contributed to increased volatility and shifting expectations for the economy and the markets going forward. These factors, combined with volatile oil prices, fluctuating business and consumer confidence and continued unemployment concerns, have precipitated significant economic uncertainty. Domestic and international equity markets continue to experience heightened volatility and turmoil. These events and the continuing market changes may have an adverse effect on us. In the event of continuing market turbulence, 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 decline.

Risks Relating to Securities Markets and Investment in Our Stock

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 recently experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Continued volatility in the overall capital markets 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 September 30, 2012 ranged from a high of $6.99 to a low of $2.56. 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 our operating results and the hospital formulary acceptance of OFIRMEV;
- 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 to achieve commercial success;
- announcements of the introduction of new products by us or our competitors;
- developments pertaining to the ANDAs relating to OFIRMEV, including any future ANDA filings, and any other challenges to our patents and other intellectual property rights;
- developments concerning product development results or intellectual property rights of others;
- product recalls, quality concerns or manufacturing difficulties;
- 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, we undertook public offerings of our common stock through which we issued totals of 21.8 million shares of common stock in November 2011 and 12.5 million shares of common stock in November 2010, and in May 2009, we completed the registration of approximately 18.1 million 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. 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.

Furthermore, any future equity financing we may undertake, or the expectation of such financing, could reduce the market price of our common stock over dilution concerns. 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 September 30, 2012, our executive officers and directors and their affiliates together controlled approximately 30% 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 president or by a majority of the total number of 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 current loan and security agreement with Oxford Finance LLC, Silicon Valley Bank and General Electric Capital Corporation 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. ***Mine Safety Disclosures***

Not applicable.

Item 5. ***Other Information***

Not applicable.

Table of Contents

Item 6. ***Exhibits***

Exhibit Number	Description of Exhibit
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
101.INS±†	XBRL Instance Document
101.SCH±†	XBRL Taxonomy Extension Schema Document
101.CAL±†	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF±†	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB±†	XBRL Taxonomy Extension Label Linkbase Document
101.PRE±†	XBRL Taxonomy Extension Presentation Linkbase Document

± Included in this Report.

† Pursuant to Rule 406T of Regulation S-T, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Section 11 or 12 of the Securities Act, are deemed not filed for purposes of Section 18 of the Exchange Act, and otherwise are not subject to liability under these sections.

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: November 6, 2012

By: /S/ WILLIAM R. LARUE

William R. LaRue

Senior Vice President, Chief Financial Officer,
Treasurer and Assistant Secretary
(Principal Financial and Accounting Officer)

Table of Contents

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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(s) 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 its 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(s) 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: November 6, 2012

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(s) 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 its 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(s) 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: November 6, 2012

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 September 30, 2012, 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 November 6, 2012.

/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.