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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, 2013

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, 2013, there were 86,087,199 shares of the registrant's Common Stock outstanding.

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CADENCE PHARMACEUTICALS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. ***Financial Statements***

CADENCE PHARMACEUTICALS, INC.

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

	September 30, 2013 (unaudited)	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 51,980	$ 58,327
Investments in marketable securities	2,326	3,745
Restricted cash	548	640
Accounts receivable, net	8,711	6,152
Inventory	6,094	6,498
Prepaid expenses	1,183	1,064
Other current assets	124	90
Total current assets	70,966	76,516
Property and equipment, net	1,801	1,967
Intangible assets, net	11,082	12,090
Restricted cash	92	-
Other assets	83	7,106
Total assets	$ 84,024	$ 97,679
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,473	$ 5,796
Accrued liabilities	15,379	12,969
Deferred revenue	-	2,234
Current portion of long-term debt, less discount of $221 and $—, respectively	7,937	-
Total current liabilities	27,789	20,999
Long-term debt, less current portion and discount of $591 and $1,182, respectively	21,251	28,818
Other liabilities	604	51
Total liabilities	49,644	49,868
Commitments and contingencies (Note 11)		
Stockholders' equity :		
Common stock, $0.0001 par value; 200,000,000 shares authorized, 86,085,324 shares and 85,668,668 shares issued and outstanding at September 30, 2013 and December 31, 2012, respectively	9	9
Additional paid-in capital	502,203	495,458
Accumulated other comprehensive income	-	-
Accumulated deficit	(467,832)	(447,656)
Total stockholders' equity	34,380	47,811
Total liabilities and stockholders' equity	$ 84,024	$ 97,679

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,	
	2013	2012	2013	2012
Revenues:				
Product revenue, net	$28,957	$ 13,898	$ 77,243	$ 32,977
License revenue	-	-	-	33
Total revenues	28,957	13,898	77,243	33,010
Costs and expenses:				
Cost of product sales	9,964	6,076	26,425	16,078
Amortization of patent license	336	336	1,008	1,008
Research and development	1,655	2,235	4,698	5,446
Selling, general and administrative	22,928	20,039	70,261	66,811
Other	(107)	13	(602)	14
Total costs and expenses	34,776	28,699	101,790	89,357
Loss from operations	(5,819)	(14,801)	(24,547)	(56,347)
Other (expense) income:				
Interest income	15	34	55	97
Interest expense	(1,122)	(1,122)	(3,333)	(3,331)
Other (expense) income	(12)	(1)	7,649	29
Total other (expense) income, net	(1,119)	(1,089)	4,371	(3,205)
Net loss	$ (6,938)	$(15,890)	$ (20,176)	$(59,552)
Basic and diluted net loss per share	$ (0.08)	$ (0.19)	$ (0.24)	$ (0.70)
Shares used to compute basic and diluted net loss per share	86,044	85,560	85,841	85,544

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,	
	2013	2012	2013	2012
Net loss	$(6,938)	$(15,890)	$(20,176)	$(59,552)
Other comprehensive income (loss):				
Net unrealized loss on securities available for sale	-	-	-	(2)
Other comprehensive loss	-	-	-	(2)
Comprehensive loss	$(6,938)	$(15,890)	$(20,176)	$(59,554)

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,	
	2013	2012
Operating activities		
Net loss	$(20,176)	$(59,552)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	169	1,226
(Gain) Loss on disposal of assets	(16)	14
Gain on sale of investment	(7,654)	-
Inventory write-down	-	163
Stock-based compensation	5,326	6,925
Non-cash interest expense	13	21
Amortization of intangible assets	1,008	1,008
Amortization of discount on note payable	371	409
Accretion of discounts on available-for-sale securities	(2)	(14)
Changes in operating assets and liabilities:		
Accounts receivable	(2,559)	(4,145)
Inventory	404	(3,649)
Prepaid expenses and other assets	(143)	425
Accounts payable	(1,323)	2,658
Deferred revenue	(2,234)	710
Accrued liabilities and other liabilities	2,976	2,459
Net cash used in operating activities	(23,840)	(51,342)
Investing activities		
Maturities and sales of marketable securities	1,420	40,860
Purchases of marketable securities	-	(1,396)
Proceeds from the sale of Incline option and preferred shares	14,654	-
Purchases of property and equipment	(80)	(1,460)
Proceeds from the sale of property and equipment	80	2
Net cash provided by investing activities	16,074	38,006
Financing activities		
Proceeds from issuance of common stock, net	1,419	97
Net cash provided by financing activities	1,419	97
Net increase in cash and cash equivalents	(6,347)	(13,239)
Cash and cash equivalents at beginning of period	58,327	82,609
Cash and cash equivalents at end of period	$ 51,980	$ 69,370
Supplemental disclosures		
Property and equipment purchases in accounts payable and accrued expenses at period end	$ 202	$ 109
Unrealized loss on investment securities	$ -	$ (2)
Cash paid for interest and fees	$ 2,428	$ 2,290

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 ("IV") 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, 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. 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, 2012, as included in the Company's 2012 Annual Report on Form 10-K filed with the SEC on March 8, 2013.

During the three months ended September 30, 2013, the Company identified selling, general and administrative expenses of $574,000 that should have been recorded in previously reported quarters of 2013. Of this amount, $252,000 related to the three months ended March 31, 2013, and $322,000 related to the three months ended June 30, 2013. The Company determined that the adjustments were immaterial to each of the previously reported interim periods based on a quantitative and qualitative analysis. As a result, the Company recorded the correction of these errors during the three months ended September 30, 2013. There is no impact on the Company's interim financial statements for the nine months ended September 30, 2013.

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 discounts to certain group purchasing organizations, end-user hospitals, and government 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.

OFIRMEV, which was launched in January 2011, is the Company's first and only commercially available product. Because the Company initially had limited product return data, it deferred the recognition of revenue on sales to wholesalers and, instead, recognized revenue at the time that product was sold by a wholesaler to an end-user customer. Shipments of product that were not recognized as revenue were treated as deferred revenue. However, as of January 1, 2013, the Company determined that it had obtained sufficient product return history to reasonably estimate future wholesaler returns. Since that time, the Company has recognized revenue at the time product is sold to a wholesaler. As a result of this change, the Company recorded a one-time adjustment to recognize revenue that had previously been deferred, resulting in additional net revenue of $2,616,000 and cost of sales of $919,000 for the nine months ended September 30, 2013. The corresponding impact of this one-time adjustment was a reduction of $1,697,000 in both the Company's loss from continuing operations and net loss for the nine months ended September 30, 2013, and the per share net impact of the adjustment was a reduction in net loss of $0.02 per share for the period. There was no similar impact on the reported revenue, cost of sales or loss per share for the three months ended September 30, 2013, or the three or nine months ended September 30, 2012.

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

The Company records certain sales reserves and allowances as a reduction to gross revenue. These reserves and allowances include distribution service fees, a prompt payment discount, a group purchasing discount and administrative service fee, discounts to certain end-user customers and governmental programs and a reserve for estimated product returns based on historical return rates, 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 Company offers a prompt payment discount to 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 from 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. Administrative service fees for these transactions are also recorded at the time of sale. The Company also provides predetermined discounts under certain government programs, which are recorded at the time of sale.

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, wholesaler fees, chargebacks and doubtful accounts. 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. At September 30, 2013 and December 31, 2012, the Company's allowance for uncollectible receivables was $16,000 and $56,000, respectively. During the three months ended September 30, 2013, charges of $2,000 were taken to reserve for past due accounts and no previously reserved accounts were written off. During the nine months ended September 30, 2013, past due accounts totaling $40,000 that were previously reserved were written off. No charges were incurred to reserve or write-off past due accounts during the three and nine months ended September 30, 2012.

Stock-Based Compensation

Stock option awards. Stock options are valued using the Black-Scholes option pricing model. The Company values option awards on the date of grant or, if the awards are classified as liability awards, it revalues the awards each reporting period using this model until the awards are subsequently classified as equity awards, or otherwise vest. The Black-Scholes option pricing model involves a number of estimates, including the expected lives of stock options, the Company's anticipated stock volatility and interest rates.

The following table summarizes the weighted average estimates the Company used in the Black-Scholes option-pricing model during the 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,	
	2013	2012	2013	2012
Risk free interest rates	1.8%	0.8%	1.2%	0.9%
Expected life in years	6.0 years	6.1 years	6.0 years	5.7 years
Expected dividend yield	0.0%	0.0%	0.0%	0.0%
Expected volatility	68.5%	69.6%	65.3%	72.0%

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.

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

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,	
	2013	2012	2013	2012
Cost of product sales	$ 68	$ 77	$ 207	$ 264
Research and development	190	597	552	1,483
Selling, general and administrative	1,569	1,500	4,567	5,178
Total stock-based compensation expense included in loss from operations	$ 1,827	$ 2,174	$ 5,326	$ 6,925

Fair Value Reporting

The Company's financial instruments consist of cash and cash equivalents, marketable securities, restricted cash, trade receivables and payables, 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 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, 2013 and December 31, 2012. 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, 2013	Fair Value Measurements as of September 30, 2013 Level 1	Level 2	Level 3
Assets:				
Cash equivalents:				
Money market funds	$ 46,672	$ 46,672	$ -	$ -
Investments in marketable securities – short-term:				
Debt instruments – Municipal debt obligations	1,326	-	1,326	-
Certificates of deposit	1,000	-	1,000	-
Assets at fair value	$ 48,998	$ 46,672	$ 2,326	$ -

Description	Balance at December 31, 2012	Fair Value Measurements as of December 31, 2012 Level 1	Level 2	Level 3
Assets:				
Cash equivalents:				
Money market funds	$ 55,736	$ 55,736	$ -	$ -
Investments in marketable securities – short-term:				
Debt instruments – Corporate debt obligations	1,398	-	1,398	-
Debt instruments – Municipal debt obligations	1,347	-	1,347	-
Certificates of deposit	1,000	-	1,000	-
Assets at fair value	$ 59,481	$ 55,736	$ 3,745	$ -

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

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.

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

3. Recent Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2013-11, *Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists*. ASU 2013-11 provides explicit guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. The guidance is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013, with an option for early adoption. The Company intends to adopt this guidance at the beginning of its first quarter of fiscal year 2014, and is currently evaluating the impact on its financial statements and 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, however, are not included in the calculations of diluted net loss per share for the periods presented as their effect would be anti-dilutive. Additionally, the unvested restricted stock units outstanding during 2012 and 2013 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, 2013 and 2012, were computed based on the weighted average shares of common stock outstanding during the respective periods. The Company incurred net losses for all periods presented and there were no reconciling items for potentially dilutive securities. More specifically, at September 30, 2013 and 2012, stock options, restricted stock units, and warrants totaling 17,950,000 and 16,790,000 shares, respectively, were excluded from the calculations as their effect would have been antidilutive.

5. Inventory

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

	September 30, 2013	December 31, 2012
Inventory:		
Raw material	$ 83	$ 83
Finished goods	6,011	6,415
Total	$ 6,094	$ 6,498

6. Property and Equipment

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

	September 30, 2013	December 31, 2012
Property and equipment:		
Manufacturing equipment	$ 2,801	$ 2,999
Leasehold improvements	1,639	1,639
Computer equipment and software	1,570	1,489
Furniture and fixtures	478	478
Construction-in-process	709	724
	7,197	7,329
Less accumulated depreciation	(5,396)	(5,362)
Total	$ 1,801	$ 1,967

As of December 31, 2012, the Company impaired the value of its manufacturing equipment and construction-in-process to their estimated fair market value due to the termination of the Company's supply agreement with Baxter Healthcare Corporation ("Baxter"). See "Supply Agreements" in Note 11 below for further information.

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

For the three months ended September 30, 2013 and 2012, the Company incurred depreciation expense of $42,000 and $401,000, respectively. For the nine months ended September 30, 2013 and 2012, the Company incurred depreciation expense of $169,000 and $1,226,000, respectively.

7. Investments in Marketable Securities

In accordance with the Company's investment policy, it has invested funds 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, 2013 and December 31, 2012 consisted of the following (in thousands):

At September 30, 2013	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	$ 1,326	$ -	$ -	$ -	$ 1,326
Certificates of deposit	1,000	-	-	-	1,000
	$ 2,326	$ -	$ -	$ -	$ 2,326

At December 31, 2012	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	$ 1,398	$ -	$ -	$ -	$ 1,398
Debt instruments – Municipal debt obligations	1,347	-	-	-	1,347
Certificates of deposit	1,000	-	-	-	1,000
	$ 3,745	$ -	$ -	$ -	$ 3,745

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

	September 30, 2013		December 31, 2012	
	Cost	Fair Value	Cost	Fair Value
Due or callable in one year or less	$2,326	$ 2,326	$3,745	$ 3,745
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, 2013 and 2012. Further, as of September 30, 2013 and December 31, 2012, there were no investments in unrealized loss positions.

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 (the "Option") to acquire Incline, which was 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. Additionally, in consideration of the Company's expenditure of funds in connection with conducting its initial 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.

In December 2012, the Company and Incline entered into a Waiver, Consent and Option Termination Agreement (the "Waiver Agreement") pursuant to which the Company agreed to the buy-out and termination of its Option, contingent upon the closing of a separate agreement and plan of merger between Incline and The Medicines Company whereby The Medicines Company agreed to acquire Incline (the "Incline Acquisition"). In January 2013, The Medicines Company completed its acquisition of Incline. As consideration for entering into the Waiver Agreement and relinquishing its Option, the Company received a payment of $13,125,000 upon the closing of the Incline Acquisition. The Company also received an additional payment of $1,529,000 as consideration for the 500,000 shares of Incline Series A preferred stock held by the Company, and it could receive future milestone payments related to potential future licensing, regulatory approval and sales of the product candidate. Such milestones, if any, will be recorded as they are earned.

At the time the Option Agreement was entered into, the Company determined that Incline was a variable interest entity ("VIE"). However, because it would not absorb a disproportionate amount of Incline's expected losses or receive a disproportionate amount of Incline's expected residual returns, the Company was not the primary beneficiary of this entity. Further, the Company did not have

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

oversight of the day-to-day operations of Incline, nor did it have sufficient rights or voting representation to influence the operating or financial decisions of Incline, and the Company was not a founder of Incline and had no additional equity or funding requirements in future financings or otherwise. As such, the Company did not consolidate Incline into its financial statements. Alternatively, it valued its 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 with a carrying value of $7,000,000. No adjustments were made to the carrying value of these assets prior to the closing of the Incline Acquisition in January 2013, and, as a result, the Company recorded a gain of $7,654,000 in other income during the nine months ended September 30, 2013. No similar gains were recorded during the three months ended September 30, 2013, or during the three or nine months ended September 30, 2012.

9. Restructuring and Impairment Charges

In February 2012, the Company observed particulate matter during routine product stability testing of OFIRMEV that was manufactured at one of its third-party manufacturers, Baxter. As a result, the Company decided to suspend further production by Baxter. In March 2013, the Company and Baxter mutually agreed to terminate the supply agreement for OFIRMEV. As a result, the Company reduced the carrying value of its manufacturing assets and its manufacturing equipment and facility construction assets in process to their current estimated fair value as of December 31, 2012, resulting in an impairment charge of $6,973,000 during the year. The fair value of these assets was determined through a third-party valuation assessment based upon research of market prices for similar equipment and the Company's prior experience with asset disposals. The determination of the fair value of the manufacturing assets was considered a Level 3 measurement. The Company also fully impaired the retirement obligation asset related to the removal of the equipment as of December 31, 2012, resulting in a charge of $750,000 during the year. See "Supply Agreements" in Note 11 below for further information.

In November 2011, the Company restructured 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 the periods presented (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
Beginning restructuring liability	$ -	$ 13	$ -	$ 931
Severance and termination disbursements	-	(6)	-	(924)
Ending restructuring liability	$ -	$ 7	$ -	$ 7

10. Loan and Security Agreement

In December 2012, the Company entered into a First Amendment to Second Amended and Restated Loan and Security Agreement (the "2012 Amendment") with Oxford Finance LLC, Silicon Valley Bank and General Electric Capital Corporation (collectively, the "Lenders"), which amended and restated the Company's previous Second Amended and Restated Loan and Security Agreement entered into in December 2011 (the "2011 Amendment"). Pursuant to the terms of the 2012 Amendment, the Company will make interest-only payments through December 2013, and in January 2014, will begin to make equal monthly principal and interest payments to fully amortize the balance over the remaining 30-month term. The stated interest rate under the 2012 Amendment is 10.9545% and the Company will be required to make a final payment of 6% of the total advance at the termination of the loan.

At the time of closing the 2012 Amendment, the Company made a term loan final payment of $752,000 in accordance with the terms of the 2011 Amendment, which had been amortized over the term of the 2011 Amendment, and paid customary closing fees and expenses of $18,000 in connection with the closing of the 2012 Amendment. Additionally, the Company issued warrants to purchase 154,638 shares of the Company's common stock, as detailed below, to the Lenders in connection with the 2012 Amendment at an exercise price $3.88 per share. The warrants are 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. Further, 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 2012 Amendment, 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 prepayment penalties and certain financial and non-financial covenants, including the maintenance of minimum quarterly product revenue of at least $12,500,000. Upon the occurrence of an event of default, including a Material Adverse Change (as defined in the 2011 Amendment), the lenders may declare all outstanding amounts due and payable under the 2012 Amendment. As of September 30, 2013, the Company was in compliance with all covenants under the 2012 Amendment.

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The Company determined that the terms of the 2012 Amendment were not substantially different than the 2011 Amendment and has accounted for the transaction as a loan modification. As such, the fair value of the warrants issued in connection with the 2012 Amendment and the carrying value of the issuance costs and discount related to the 2011 Amendment were aggregated and are being amortized to interest expense throughout the life of the 2012 Amendment using an effective interest rate of 15.30%. Prior to the 2012 Amendment, the Company had been amortizing the 2011 Amendment using an effective interest rate of 15.31%.

Warrants

In connection with the establishment of the Company's credit facilities and related amendments, including the 2012 Amendment, the Company has issued warrants to the Lenders to purchase shares of the Company's common stock. The table below summarizes the issuances of such warrants currently outstanding, including the Black-Scholes valuation model assumptions used to determine the fair value of the warrants:

	Date of Issuance			
	December 2012	December 2011	June 2010	November 2007
Aggregate shares pursuant to warrants issued	154,638	158,311	254,793	50,331
Per share exercise price of warrants issued	$ 3.88	$ 3.79	$ 7.0645	$ 12.67
Fair value of warrants issued	$ 416,000	$ 390,000	$ 1,237,000	$ 474,000
Expiration date of warrants	December 9, 2019	December 22, 2018	June 18, 2017	November 30, 2014
Black-Scholes valuation inputs:				
Expected volatility	70.17%	72.40%	76.50%	70.00%
Risk-free interest rate	1.02%	1.40%	2.70%	3.64%
Dividend yield	0.00%	0.00%	0.00%	0.00%
Expected term	7 years	7 years	7 years	7 years

As of September 30, 2013, all of the aforementioned warrants to purchase 618,073 shares of the Company's common stock were outstanding.

11. Commitments and Contingencies

Leases

In May 2006, the Company entered into an operating lease for corporate 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 lease, returning space to the lessor. 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. In September 2013, the Company further amended the lease to extend the lease term until May 31, 2019, and to expand the rented space. The Company has the right to renew the lease for one additional five year term. The terms of the lease include a one-time tenant improvement allowance of up to $475,000, which the Company will record as the improvements are completed, and which will be amortized ratably over the shorter of the useful life or the remaining life of the lease. As of September 30, 2013, no such improvements had been completed.

As of September 30, 2013, the future minimum payments related to the operating lease for the Company's corporate office space were as follows (in thousands):

Remainder 2013	$ 192
2014	557
2015	983
2016	1,013
2017	1,043
Thereafter	1,535
Total	$5,323

As security for the initial lease, the landlord required a letter of credit, which is collateralized by a certificate of deposit in the same amount, and which the Company has classified as restricted cash on its balance sheet. As of September 30, 2013 and December 31, 2012, the amount of each of the letter of credit and the corresponding certificate of deposit was $190,000. The security deposit required by the landlord will be reduced to $92,000, effective January 1, 2014.

The Company also leases certain office equipment under capital and operating leases. Its current capital lease has an initial term of four years and expires in 2016. As of September 30, 2013 and December 31, 2012, the assets under this capital lease had a gross value of $56,000 and during the three and nine months ended September 30, 2013, the Company recorded amortization expense of $3,000 and $10,000, respectively. No similar expense was recorded during the three and nine months ended September 30, 2012. The remaining obligation under its capital lease at September 30, 2013 is recorded on the Company's balance sheet in accrued expenses and other long-term liabilities at $12,000 and $34,000, respectively.

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(Unaudited)

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 agreements for the three months ended September 30, 2013 and 2012 was $168,000 and $236,000, respectively. Rent expense under the Company's lease agreements for the nine months ended September 30, 2013 and 2012 was $504,000 and $709,000, 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 to $450,000 related to an increase in its credit limit. At September 30, 2013, the Company maintained the pledge agreement and the funds under the agreement are classified as restricted cash on the Company's balance sheet at September 30, 2013 and December 31, 2012.

Supply Agreements

Lawrence Laboratories

In February 2013, the Company entered into an Amended and Restated Supply Agreement (the "Supply Agreement") with Lawrence Laboratories, an operating division of Swords Laboratories, and a member of the BMS group of companies, which amended and restated the original agreement entered into between the parties in December 2010, for the manufacture of commercial supplies of the finished drug product for OFIRMEV packaged in vials (the "Product"), for sale and distribution by the Company in the United States and Canada. Bristol-Myers Squibb Srl ("BMS Anagni"), an indirect subsidiary of BMS located in Anagni, Italy, manufactures the Product on behalf of Lawrence Laboratories. BMS Anagni is currently the Company's sole supplier of OFIRMEV.

Pursuant to the terms of the Supply Agreement, the Company pays Lawrence Laboratories a set price for each unit of Product purchased, based upon the aggregate quantity of Product the Company has specified that it intends to order during a calendar year, and whether Lawrence Laboratories has implemented certain agreed-upon manufacturing capacity increase improvements. The Company is obligated to purchase a minimum number of units each year, or pay Lawrence Laboratories an amount equal to the shortfall between the minimum purchase requirement and the number of units of Product actually ordered during such year, multiplied by a pre-set amount that also varies depending upon whether Lawrence Laboratories has implemented certain agreed-upon manufacturing capacity increase improvements. The Company is obligated to purchase at least 75% of its annual Product requirements from Lawrence Laboratories each contract year. The Supply Agreement also requires the Company to pay Lawrence Laboratories for additional services requested by the Company at a specified hourly rate and for any validation batches that may be required by the Company, not to exceed a specified rate. All amounts payable under the Supply Agreement are paid in U.S. dollars.

The term of the Supply Agreement extends through December 31, 2018, unless extended by mutual agreement of the Company and Lawrence Laboratories, or unless the Supply Agreement is terminated sooner: (1) by the mutual agreement of the parties, (2) by either party for convenience following 24 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 Supply Agreement. In addition, either party may terminate the Supply Agreement: (a) within 60 days, after written notice in the event of a material uncured breach of the Supply 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.

If the Supply Agreement is terminated by the Company for its convenience or by Lawrence Laboratories due to the Company's material breach of the Supply Agreement, the Company will reimburse Lawrence Laboratories for: (1) any Product ordered under a firm order and received by the Company, and (2) any inventory of materials used to manufacture the Product that are specific to the Product and that Lawrence Laboratories 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 Supply Agreement is terminated for any reason other than by the Company for its convenience or by Lawrence Laboratories due to the Company's material breach of the Supply Agreement, the Company will not be required to reimburse Lawrence Laboratories for any inventory of materials used to manufacture the Product, 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.

Grifols

In March 2013, the Company entered into an agreement with Laboratorios Grifols, S.A. ("Grifols"), a division of Grifols, S.A., a global healthcare company headquartered in Barcelona, Spain, for the development, manufacture and supply of commercial

quantities of OFIRMEV in flexible IV bags. Grifols has supplied IV acetaminophen in flexible plastic bags to BMS for distribution in certain markets outside of the U.S. and Canada since 2010. The Company plans to submit a supplemental NDA to the FDA in the fourth quarter of 2013 seeking approval of the product to be manufactured by Grifols.

Pursuant to the terms of the agreement, the Company will pay Grifols a set price for the OFIRMEV it purchases, which may be adjusted annually by Grifols, subject to specified limitations. In addition, the Company will be obligated to pay Grifols a reservation fee, in lieu of any minimum purchase commitment, calculated by multiplying the shortfall between the annual production capacity it has reserved with Grifols and the amount of product actually ordered during that year by a fixed amount. Pending review and subsequent approval of the submission by the FDA, the agreement will terminate on the sixth anniversary of the approval by the FDA of the product manufactured by Grifols, unless it is terminated sooner by the Company upon the termination of its license agreement for the product with BMS, or after 60 days' written notice following the discontinuation of the distribution of the product by the Company. In addition, either party may terminate the agreement after 60 days' written notice in the event of a material uncured breach of the agreement by the other party (or 30 days in the case of a payment default), or immediately upon an insolvency event.

Baxter Healthcare Corporation

In July 2007, the Company entered into a development and supply agreement (the "Baxter Supply Agreement") with 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. In January 2011, the Company amended and restated the Baxter Supply Agreement (the "Amended Supply Agreement") in connection with a plan to expand the manufacturing capacity for OFIRMEV at Baxter.

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 and decided to suspend further production by Baxter. 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 December 31, 2012. In March 2013, the Company and Baxter mutually agreed to terminate the Amended Supply Agreement for OFIRMEV. As part of the settlement and termination with Baxter, the Company agreed that it would be responsible for the removal of the equipment, which the Company estimated would cost approximately $750,000. Accordingly, it recorded this retirement obligation on its balance sheet at December 31, 2012 as the conditions existed under the terms of the Amended Supply Agreement at that time. Further, as of December 31, 2012, the Company fully impaired this retirement obligation asset and recognized a charge of $750,000 in its statement of operations for the year ended December 31, 2012. During the three months ended September 30, 2013, the Company completed the removal of the equipment and released the remaining balance of the accrued obligation, resulting in a gain of $136,000 during the three and nine months ended September 30, 2013, which was recorded in other operating expenses. No similar gain was recorded during the three and nine months ended September 30, 2012. Also pursuant to the settlement, a previously accrued liability of $317,000 was canceled, which was recorded in cost of sales during the first quarter of 2013.

As a result of the initial recall, the Company recorded charges of $5,574,000 for the fourth quarter of 2011 and $163,000 for the first quarter of 2012 to fully write-down the value of the inventory placed on hold. As a result of the second recall, the Company decided to destroy the product that was previously placed on hold and accrued for estimated destruction charges, recording $290,000 during the fourth quarter of 2012 and $50,000 during the first quarter of 2013 in other operating expenses for the respective periods. In addition, the Company incurred costs associated with these recalls, including administration costs, of approximately $300,000 through September 30, 2013. As of September 30, 2013, the recall had been substantially completed and future returns are expected to be minimal, if any. 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. As of September 30, 2013, no accrued destruction charges remained on the Company's balance sheet.

Due to the termination of the Amended Supply Agreement with Baxter, the Company reduced the carrying value of its manufacturing assets and its manufacturing equipment and facility construction assets in process to their current estimated fair value, resulting in an impairment charge of $6,973,000 for the year ended December 31, 2012. The fair value of these assets was determined through a third-party valuation assessment and market prices for similar assets. Further, in December 2012, the Company sold a construction-in-process asset resulting in a loss on the disposal of $858,000. As a result, the carrying value of the manufacturing assets on the Company's balance sheet at December 31, 2012, was $975,000, and the value of manufacturing equipment and facility construction assets in process was $357,000. These assets were classified as held and used at December 31, 2012, as a formal plan to sell the assets, or otherwise dispose of them, had not been implemented at that time. The Company continues to assess the classification of these assets and has determined that, based upon relevant guidance, the assets continue to be considered held and used at September 30, 2013.

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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 SCR Pharmatop S.A. ("Pharmatop") and the Company has the right to grant sublicenses to third parties. As consideration for the license, the Company paid a $25,000,000 up-front fee in March 2006 and, as a result of the approval of the Company's NDA for OFIRMEV in the fourth quarter of 2010, the Company paid an additional milestone payment of $15,000,000 in the fourth quarter of 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 which range 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 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 June 2013, Health Canada issued a Notice of Compliance that granted marketing approval for OFIRMEV in Canada. The Company has not determined the commercial feasibility of launching the product in Canada, either independently or in collaboration with a company with an existing Canadian commercial presence, because it has not yet received a pricing review from the Canadian Patented Medicine Prices Review Board ("PMPRB"). The Company submitted a pricing review application for OFIRMEV to the PMPRB in October 2013.

In November 2010, the Company entered into a data license agreement among Terumo Corporation ("Terumo"), the Company and 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 commercialization of, the same IV formulation of acetaminophen in Japan. Further, the Company provided technical assistance and consulting services to Terumo at no charge regarding the licensed technical information, data and know-how, 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. In June 2013, the Company was notified that Terumo received regulatory approval for its IV acetaminophen from the Japanese Ministry of Health, Labour & Welfare. The Company will be entitled to receive a lump-sum payment upon the first commercial sale of the product by Terumo, and royalty payments on commercial sales of the product in Japan, however, Terumo has not yet initiated 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 recognized the consideration allocated to the data license upon delivery and recognized the consideration allocated to the consulting services as such services were 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 license revenue pursuant to the agreement for the data transfer and consulting hours provided. As of December 31, 2012, the remaining balance of $119,000 had been recognized as license revenue. No license revenue was recognized for the three and nine months ended September 30, 2013. License revenue of $33,000 was recognized for the three and nine months ended September 30, 2012. Any milestones or royalties received from potential sales of the product will be recognized as revenue in the period earned.

Legal Matters

'222 and '218 Patent Litigation: Exela Pharma Sciences, LLC and Paddock Laboratories, Inc. (Perrigo Company)

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 referred to herein as Perrigo, and against Exela Pharma Sciences, LLC, Exela PharmaSci, Inc. and Exela Holdings, Inc., collectively referred to herein as Exela. The lawsuit followed the notices that the Company received in July 2011 from each of Perrigo 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 alleged that Perrigo and Exela each infringed the '222 patent and 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 patent infringement lawsuit was filed within 45 days of receipt of the pertinent notice

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letters, thereby triggering a stay of FDA approval of the Perrigo 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 Perrigo or Exela, or such shorter or longer period as the Court may order. Each of Perrigo and Exela filed an answer in the case asserting, among other things, non-infringement and invalidity of the asserted patents, as well as certain counterclaims.

The Company settled with Perrigo and the case against Perrigo was dismissed on November 30, 2012. In connection with the settlement and license agreements entered into in November 2012, Perrigo was granted the exclusive right of first refusal to negotiate an agreement with the Company to market an authorized generic version of OFIRMEV in the U.S. in the event that the Company elects to launch an authorized generic version of the product. The license agreement also provides that, if the Company enters into an agreement for Perrigo to market an authorized generic version of OFIRMEV during the license period, Perrigo would purchase the product exclusively from the Company. The Company would receive product costs plus an administrative fee, as well as a royalty payment based on the net profits achieved by Perrigo from the sale of the authorized generic product. Additionally, the Company granted Perrigo the non-exclusive right to market a generic IV acetaminophen product in the U.S. under Perrigo’s ANDA after December 6, 2020, or earlier under certain circumstances. The Federal Trade Commission, or FTC, or the Department of Justice, or DOJ, could seek to challenge the Company’s settlement with Perrigo, or a competitor, customer or other third-party could initiate a private action under antitrust or other laws challenging the Company’s settlement with Perrigo.

A bench trial for the lawsuit with Exela was held in May 2013, with one additional trial date held in early July 2013. Post-trial briefs have been submitted, but the court has not yet issued a decision in this case. The court may render its decision at any time before or after the expiration of the applicable 30-month stay. It is not possible to predict the outcome of this litigation, and an adverse outcome could result in the launch of one or more generic versions of OFIRMEV before the expiration of the last of the listed patents on June 6, 2021 (or December 6, 2021 if pediatric exclusivity is granted), which could adversely affect the Company’s ability to successfully maximize the value of OFIRMEV, and would negatively impact the Company’s financial condition and results of operations, including causing a significant decrease in the Company’s revenues and cash flows.

‘222 and ‘218 Patent Litigation: Fresenius Kabi USA, LLC and Sandoz, Inc.

In January 2013, the Company filed suit in the United States District Court for the Southern District of California against Fresenius Kabi USA, LLC, or Fresenius, following receipt of a December 2012 notice from Fresenius concerning its submission of an NDA containing a Paragraph IV patent certification with the FDA for a generic version of OFIRMEV. In February 2013, the Company filed suit in the United States District Court for the Southern District of California against Sandoz, Inc., or Sandoz, following receipt of a December 2012 notice from Sandoz concerning its submission of an ANDA containing a Paragraph IV patent certification with the FDA for a generic version of OFIRMEV. In October 2013, the Company filed a motion to amend the complaint against Sandoz to join Sandoz AG, Neogen International N.V., APC Pharmaceuticals, LLC, and DIACO, S.p.A. to the lawsuit against Sandoz due to the involvement of each of these companies in the preparation of the Sandoz ANDA and related matters.

In the lawsuits against Fresenius and Sandoz, which have been coordinated for purposes of discovery and other pretrial proceedings in the Southern District of California, the Company alleges that Fresenius and Sandoz have each infringed the ‘222 patent and the ‘218 patent by filing an NDA, in the case of Fresenius, or an ANDA, in the case of Sandoz, seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. Both Fresenius and Sandoz have filed answers in the Southern District of California asserting, among other things, non-infringement and invalidity of the asserted patents, as well as certain counterclaims. Both the Fresenius and Sandoz lawsuits were filed within 45 days of receipt of the respective notice letters, thereby triggering a stay of FDA approval of the Fresenius NDA and the Sandoz 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 Fresenius and/or Sandoz, or such shorter or longer period as the court may order. A claims construction hearing in the lawsuits against Fresenius and Sandoz was held on November 4, 2013, and the bench trial for each of these lawsuits is tentatively scheduled to commence on July 14, 2014.

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 these matters 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.

‘222 Patent: Ex Parte Reexamination

In September 2012, an unidentified third party (subsequently identified as Exela) filed with the United States Patent and Trademark Office, or USPTO, a Request for Ex Parte Reexamination of the ‘222 patent. In December 2012, the Company received notice that the USPTO had granted the Request for Reexamination. The reexamination process is provided for by law and requires the

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USPTO to consider the scope and validity of the patent based on substantial new questions of patentability raised by a third party or the USPTO. In February 2013, Cadence and Pharmatop filed with the USPTO a patent owner's statement commenting on the reexamination request, and in April 2013, Exela filed comments in response to the patent owner's statement. In a non-final, initial office action issued by the USPTO on August 13, 2013, the USPTO rejected certain claims of the '222 patent. A response to the office action is due in November 2013. All of the claims of the '222 patent remain valid and in force during the reexamination proceedings. Because the Company and Pharmatop believe that the scope and validity of the patent claims in this patent are appropriate and that the USPTO's prior issuance of the patent was correct, the Company, in conjunction with Pharmatop, will vigorously defend this patent. The Company cannot predict whether it and Pharmatop ultimately will succeed in maintaining the scope and validity of the claims of this patent during reexamination. If any of the patent claims in this patent ultimately are narrowed during prosecution before the USPTO, the extent of the patent coverage afforded to OFIRMEV could be impaired, which could potentially harm the Company's business and operating results.

'218 Patent Litigation: Exela Pharma Sciences, LLC

In April 2012, Exela filed suit against David J. Kappos and the USPTO in the United States District Court for the Eastern District of Virginia for declaratory judgment seeking a reversal of the USPTO's decision not 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 lacked 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 "unintentional" standard are invalid, and similar relief in connection with one or more counterclaims it has filed in the Delaware litigation. The Company's motion to intervene in this lawsuit was granted in October 2012. In December 2012, the district court dismissed the case with prejudice as barred by the applicable statute of limitations. In February 2013, Exela appealed the district court's decision to the Court of Appeals for the Federal Circuit. In response to an opening brief in the appeal filed by Exela, the Company and Phamatop filed an opening brief on September 27, 2013. A decision by the Court of Appeals in favor of Exela could result in the invalidation of the '218 patent.

12. Stockholders' Equity

Private Placement

In February 2009, the Company issued 12,039,794 shares of its common stock at a purchase price of $7.13 per share pursuant to a private placement. In addition to the shares of the Company's common stock, warrants to purchase up to 6,019,897 additional shares of the Company's common stock were also issued as part of the transaction at a price of $0.125 per warrant. Each warrant is immediately exercisable and has a five-year term. The warrants may be exercised through either cash or net exercise for one share of common stock at a price of $7.84 and have been accounted for as permanent equity. As of September 30, 2013, 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 for 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. The Company operates and manages its business as 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.

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The Company had three major customers, each representing 10% or more of total gross product revenue for the periods presented as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2012	2013	2012
AmerisourceBergen Corporation	35%	34%	35%	33%
Cardinal Health, Inc.	32%	33%	32%	34%
McKesson Corporation	27%	26%	27%	26%

Receivables from these customers at September 30, 2013 and December 31, 2012, amounted to the following percentages of total gross accounts receivable:

	September 30, 2013	December 31, 2012
AmerisourceBergen Corporation	34%	32%
Cardinal Health, Inc.	31%	31%
McKesson Corporation	28%	31%

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, 2013 and December 31, 2012, and has recognized no interest and/or penalties in the Company's statement of operations for the three and nine months ended September 30, 2013 and 2012. Further, as of September 30, 2013, the Company had not recorded any unrecognized tax benefits.

Pursuant to Internal Revenue Code ("IRC") Sections 382 and 383, annual use of the Company's net operating loss and research and development credit carryforwards may be limited in the event of a cumulative change in ownership of more than 50% within a three-year period. During the second quarter of 2013, the Company completed an analysis under IRC Sections 382 and 383 through December 31, 2012, and determined that it experienced an ownership change in March 2006. However, this ownership change did not result in the forfeiture of any net operating losses or research and development credits. Therefore, the Company has reinstated the (1) deferred tax assets for net operating losses of approximately $149,071,000 and (2) research and development credits of approximately $6,809,000 generated through 2012 to its deferred tax asset schedule. Further, the Company has recorded a corresponding increase to its valuation allowance. The amount of the Company's deferred tax assets will be disclosed in the Company's Annual Report on Form 10-K for fiscal year ending December 31, 2013. The analysis did not have any impact on the Company's unrecognized tax benefits.

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, 2012 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, 2012 as filed with the Securities and Exchange Commission, or SEC, on March 8, 2013.

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 differentiated products with significant unmet commercial potential that are complementary to our current product, OFIRMEV® (acetaminophen) injection, and enable us to effectively leverage our commercial infrastructure.

In 2006, we in-licensed the exclusive U.S. and Canadian rights to OFIRMEV an intravenous, or IV, 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 focus for OFIRMEV is on educating doctors, pharmacists and other healthcare professionals on the appropriate use of OFIRMEV and effective approaches to utilizing multimodal analgesia. We believe this strategy is having a positive impact as our revenue has grown each quarter since launch. In addition, we seek opportunities to acquire or in-license products that will allow us to leverage our commercial and development capabilities.

We have established a sales force of hospital sales specialists who promote OFIRMEV through a variety of marketing programs, including direct-to-physician promotional materials, peer-to-peer educational programs, medical journal advertising, and participation in targeted medical convention programs. The manufacturing of the finished product, OFIRMEV, is outsourced to third-party manufacturers. Currently, OFIRMEV is supplied to us in glass vials by Lawrence Laboratories, an operating division of Swords Laboratories, and a member of the BMS group of companies. Bristol-Myers Squibb Srl, or BMS Anagni, an indirect subsidiary of BMS located in Anagni, Italy, manufactures the product on behalf of Lawrence Laboratories. We have also entered into an agreement with Laboratorios Grifols, S.A., or Grifols, a division of Grifols, S.A., for the development, manufacture and supply of commercial quantities of OFIRMEV in flexible IV bags. We plan to submit a supplemental New Drug Application, or NDA, to the FDA in the fourth quarter of 2013 seeking approval of the product to be manufactured by Grifols. Previously, Baxter Healthcare Corporation, or Baxter, also manufactured OFIRMEV for us, however, in February 2012, we suspended production of OFIRMEV by Baxter, and in March 2013, we and Baxter mutually agreed to terminate our supply agreement. We updated the prescribing information for OFIRMEV in October 2013 adding, among other changes, a boxed warning regarding the potential for dosing errors with OFIRMEV and the risk of liver injury associated with the administration of acetaminophen (by all routes of administration) at doses that exceed the recommended maximum daily limits.

In executing our business strategy, we have incurred significant net losses since our inception, and we continue to incur losses despite the growth in our revenue. We 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 in a public offering in the fourth quarter of 2011 and received aggregate net proceeds of approximately $77.3 million (after underwriting discounts and offering costs). From inception through September 30, 2013, we have received total net proceeds of approximately $445.5 million from the sale of our stock and warrants to purchase common stock, and through the exercise of warrants and stock options. 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, and as of September 30, 2013, the outstanding principal balance 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 Therapeutics, Inc., or 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, which we launched in the United States in January 2011. We sell the product to independent wholesalers, which in turn sell the product to hospitals and other end-user customers. Our initial focus for revenue growth during our launch was to promote rapid hospital formulary adoption of the product. During the second half of 2011, our sales force began placing additional emphasis on generating pull-through sales of OFIRMEV from these institutions, and we have continued this focus by actively promoting the product through a variety of marketing programs to inform end-user customers about OFIRMEV. Our goal is that these programs will lead to an increasing number of patients being treated with OFIRMEV, which, in turn, will lead to increased utilization of OFIRMEV. We believe these efforts have had a positive impact on our growth.

As a result of these increases in end-user customer demand and strategic price increases implemented for OFIRMEV, our net product revenue has grown each quarter since the product's launch. During the third quarter of 2013 we recognized $29.0 million of net product revenue, an increase of $15.1 million, or 109%, from the third quarter of 2012, and for the nine months ended September 30, 2013, we recognized $77.2 million of revenue, an increase of $44.2 million, or 134%, from the same period in 2012. Included in net revenue for the nine months ended September 30, 2013, was $2.6 million of net revenue recognized during the period on shipments of product that had previously been deferred as a result of a change in our accounting estimate for revenue recognition. We intend to continue our marketing strategies to promote OFIRMEV for the foreseeable future and believe there are substantial growth opportunities available through continued promotion of the product.

Additionally, we have licensed certain data, and provided consulting support, to Terumo for their use in seeking regulatory approval for, and commercializing, the same IV formulation of acetaminophen in Japan. We transferred this data to Terumo in 2010 and provided consulting support pursuant to the agreement through November 2012. In June 2013, Terumo received regulatory approval from the Japanese Ministry of Health, Labour & Welfare for the IV acetaminophen formulation licensed from us and Pharmatop, and Terumo has completed its pricing discussions with the Ministry's Economic Affairs Division. We will be entitled to receive a lump-sum payment upon the first commercial sale of the product in Japan and royalty payments on commercial sales in Japan, however, Terumo has not yet initiated commercial sales of the product in Japan.

Cost of Sales

OFIRMEV is currently supplied to us by BMS Anagni in glass vials and we have entered into an agreement with Grifols for the supply of commercial quantities of OFIRMEV in flexible IV bags, subject to approval by the FDA. Previously, Baxter also manufactured OFIRMEV for us, however, in February 2012, we suspended production of OFIRMEV by Baxter, and in March 2013, we and Baxter mutually agreed to terminate our supply agreement for OFIRMEV. Our cost of sales consists primarily of third-party manufacturing fees paid to suppliers, in addition to freight, indirect costs, and personnel overhead costs. 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 price variances, variances in freight costs, variances of our overhead costs and any inventory adjustment charges we may record. Our cost of sales as a percentage of net revenue has steadily decreased since the launch of OFIRMEV as we gain efficiencies from higher production volumes and ship the product to our third-party distribution facility under more cost effective means, resulting in higher gross margins. For example, we incurred expedited freight costs on certain shipments of OFIRMEV from BMS Anagni in order to meet demand for OFIRMEV following the suspension of manufacturing at Baxter's facility in February 2012. These expedited costs were included in the value of our inventory, which were recognized through the sale of the related inventory throughout 2012. Additionally, we expedited certain shipments to our wholesalers during the first quarter of 2012, which were recognized in cost of sales at the time of shipment. We have also incurred costs related to our Baxter supply agreement, however, we have taken actions to eliminate these costs since the termination of the agreement in March 2013. As a result of the increased production volumes, price increases, and cost reduction actions, our gross margin for the nine months ended September 30, 2013, improved to 66%, as compared to 51% for the same period in 2012.

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 relate predominantly to the development of product candidates, including OFIRMEV, and the ongoing regulatory compliance requirements for our commercialized products. Historically, these expenses have consisted of salaries and related employee benefits for our research and development team, license fees paid to our licensors prior to approval of our drug candidates, pre-commercialization manufacturing development activities, costs associated with clinical trials, and costs associated with non-clinical activities, such as expenses related to regulatory submissions. We have expensed these charges as the costs were incurred in developing, testing and seeking marketing approval of our product candidates. We received marketing approval for OFIRMEV from the FDA in November 2010 and have since reduced our research and development expenses. However, we expect to continue to incur research and development expenses related to OFIRMEV in future periods, although it is difficult to anticipate the scope and magnitude of our future research and development expenses. For example, we continue to incur costs in maintaining our regulatory compliance, and in the third quarter of 2012, we began enrolling patients in an ongoing FDA-required post-approval clinical trial for OFIRMEV in pediatric patients under two years of age. We may also conduct additional clinical studies to expand the indications for OFIRMEV. Moreover, any product candidates we may in-license or acquire in the future would likely require significant research and development resources. Therefore, we are unable to estimate with any certainty the costs we will incur in completing our development efforts for OFIRMEV or any other product candidate we might acquire or in-license.

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 to enforce our intellectual property rights; costs incurred related 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 began to incur additional legal costs in 2012 related to our intellectual property litigation and we continue to incur these costs as we enforce our intellectual property rights. We expect to continue to incur significant selling, general and administrative expenses as we execute our marketing and sales strategies for OFIRMEV, enforce our intellectual property rights and operate our business. However, we are unable to estimate with any certainty the level of selling, general and administrative expenses we will incur in supporting OFIRMEV or any other product or product candidate we may acquire or in-license in the future.

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, including the waiver and termination of our option to purchase Incline and the sale of our Incline stock in January 2013.

Our current loan and security agreement had a principal balance of $30.0 million as of September 30, 2013 and we are currently making interest-only payments on the outstanding balance of this facility, which will continue through December 2013. In January 2014, 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, stated interest rate of 10.9545% 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, 2012, we had federal and state net operating loss carryforwards of approximately $369.7 million and $374.2 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 $3.2 million, respectively. The federal tax credits will begin expiring in 2025 unless previously utilized and the state tax credits carryforward indefinitely. Further, 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 recently completed an analysis that examined our ownership changes through December 31, 2012, pursuant to Sections 382 and 383 and determined that we experienced an ownership change in March 2006. However, this ownership change did not result in the forfeiture of any net operating losses or research and development credits.

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. Further, the completion of the analysis pursuant to Sections 382 and 383 did not impact our recorded, unrecognized tax benefits.

Critical Accounting Policies and Estimates

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

Our most critical accounting estimates include the recognition of revenue; the valuation of our inventory, which impacts gross margin; stock-based compensation, which impacts operating expenses and inventory; 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 predominantly to wholesalers. 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 end-user customers, and we have contracted with group purchasing organizations.

Our wholesaler agreements provide selling prices that are fixed on the date of sale, although we offer discounts to certain group purchasing organizations, end-user hospitals and government 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.

OFIRMEV, which was launched in January 2011, is our first and only commercially available product. Because we initially had limited product return data, we deferred the recognition of revenue on sales to wholesalers and, instead, recognized revenue at the time that product was sold by a wholesaler to an end-user customer. Shipments of product that were not recognized as revenue were treated as deferred revenue. However, as of January 1, 2013, we determined that we had obtained sufficient product return history to reasonably estimate future wholesaler returns. Since that time, we have recognized revenue at the time product is sold to a wholesaler consistent with other companies with products at this stage of commercialization. As a result of this change, we recorded a one-time adjustment in January 2013 to recognize revenue that had previously been deferred, resulting in additional net revenue of $2.6 million and cost of sales of $0.9 million during the period.

We record certain fees, sales reserves and allowances as a reduction to gross revenue, as applicable. These reserves and allowances include distribution service fees, a prompt payment reserve, a group purchasing discount and administrative service fee, discounts to certain end-user hospitals and governmental programs, and a reserve for estimated product returns based on historical return rates, 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. 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 accrued at the time of sale. We also provide predetermined discounts under certain government programs, which are recorded at the time of sale.

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 other direct costs, if any. 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 down-time are recognized as expense in the period in which they are incurred.

Stock-Based Compensation

We account for stock-based compensation by calculating the fair value of equity awards on the date of grant. 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

We evaluate our 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 and planned use 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.

A substantial portion of our capital assets are associated with our previous supply agreement with Baxter. As part of the agreement, which was terminated in March 2013, we agreed to 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 accrued for costs incurred based on factors such as estimates of work performed, milestones achieved and experience with similar contracts. As actual costs became known, we adjusted our accruals accordingly. In February 2012, we suspended production of OFIRMEV by Baxter, and in March 2013, we and Baxter mutually terminated our supply agreement for OFIRMEV. As a result of the termination, we reduced the carrying value of our manufacturing assets, manufacturing equipment and facility construction assets in process to their current estimated fair value, resulting in an impairment charge of $7.0 million for the year ended December 31, 2012. Moreover, we fully impaired the retirement obligation asset associated with the supply agreement, resulting in a charge of $0.7 million as of December 31, 2012. In June 2013, we removed our equipment from Baxter's facility and transferred it to alternative locations as we seek appropriate buyers, alternative uses or other disposal methods for the equipment.

The carrying value on our balance sheet of these manufacturing assets at September 30, 2013 and December 31, 2012 was $0.9 million and $1.0 million respectively. The carrying value of the manufacturing equipment and facility construction assets in process was $0.3 million and $0.4 million at September 30, 2013 and December 31, 2012, respectively. During the third quarter of 2013, we completed the restoration of Baxter's facility following the removal of our equipment from Baxter's facility and we released the balance of the accrued obligation related to these assets,

resulting in a gain of $0.1 million for the three and nine months ended September 30, 2013, which was recorded in other operating expenses. The balance of this accrued asset retirement obligation, included in accrued liabilities, at December 31, 2012, was $0.7 million.

Results of Operations

Three-Month Periods Ended September 30, 2013 and 2012

Revenue

Net product revenue from the sale of OFIRMEV was $29.0 million during the three months ended September 30, 2013, an increase of $15.1 million, or 109%, from the $13.9 million recognized for the comparable period in 2012. This increase in our net product revenue was primarily attributable to the continued expansion of our end-user customer base, the increased use of OFIRMEV in surgical settings and the price increases we implemented in January 2013 and July 2013. For example, during the third quarter of 2013, the number of end-user accounts that purchased OFIRMEV, increased 33% as compared to the third quarter of 2012. Further, the average order frequency of our end-user customers increased by approximately 8% in the third quarter of 2013 compared to the third quarter of 2012; and the average order size of our end-user customers increased by 22% during the same period. Moreover, the price increases implemented in January 2013 and July 2013 raised the average net selling price in 2013 as compared to 2012. These price increases led to approximately $3.6 million in additional net product revenue during the three months ended September 30, 2013, as compared to the same period in 2012, based on the difference between the average net selling prices between the two periods.

Costs and Expenses

Cost of Product Sales. Our cost of product sales for the three months ended September 30, 2013, was $10.0 million, or 34% of net product revenue, compared to $6.1 million, or 44% of net product revenue, for the comparable period in 2012. The improvement in our cost of sales as a percentage of net product revenue during the third quarter of 2013 was primarily due to the average supply price of product sold during the third quarter of 2013 being lower than the average supply price of product sold during the third quarter of 2012. In addition, during the third quarter of 2012, we sustained unabsorbed manufacturing costs due to fixed costs that we incurred during the suspension of production by Baxter. These unabsorbed costs were not incurred during 2013.

Patent Amortization. As a result of the approval of our NDA for OFIRMEV in the fourth quarter of 2010, we made a milestone payment of $15.0 million in the fourth quarter of 2010, which we recorded as an intangible asset and are amortizing over the estimated useful life of the licensed patents. During each of the three months ended September 30, 2013 and 2012, we incurred $0.3 million of non-cash expense related to the amortization of this intangible asset.

Research and Development Expenses. Research and development expenses decreased $0.5 million, or 23%, for the three months ended September 30, 2013, to $1.7 million, from $2.2 million for the three months ended September 30, 2012. This decrease was primarily due to severance obligations related to the departure of two officers, which were incurred during 2012. Similar severance obligations were not incurred during 2013. Partially offsetting this decrease were additional costs incurred in 2013 associated with our ongoing FDA-required post-approval clinical trial for OFIRMEV in pediatric patients under two years of age.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $2.9 million, or 15%, for the three months ended September 30, 2013, to $22.9 million, compared to $20.0 million for the comparable period in 2012. This increase was primarily attributable to higher legal expenses incurred during the third quarter of 2013, as compared to the third quarter of 2012, related to our ongoing intellectual property litigation, an increase in marketing program costs during the third quarter of 2013 due to a shift in the timing of the execution of our marketing programs, and higher personnel costs.

Other. During the three months ended September 30, 2013, we completed the restoration of Baxter's facility following the removal of our equipment from Baxter's facility and we released the balance of the accrued obligation related to these assets, resulting in a gain of $0.1 million. No similar gain was recognized during the three months ended September 30, 2012.

Other Income and Expenses, Net

Net other expense for the three months ended September 30, 2013, was $1.1 million, which was consistent with the comparable period in 2012 as the outstanding principal balance on our debt remained constant at $30.0 million.

Nine-Month Periods Ended September 30, 2013 and 2012

Revenue

During the nine months ended September 30, 2013, we recognized $77.2 million of net product revenue from the sale of OFIRMEV, which represents an increase of $44.2 million, or 134%, from the $33.0 million recognized for the comparable period in

2012. Included in net revenue for the nine months ended September 30, 2013, was $2.6 million of net revenue recognized during the period on shipments of product that had previously been deferred as a result of a change in our accounting estimate for revenue recognition.

The increase in our net product revenue for the nine months ended September 30, 2013, as compared to the same period of 2012 was primarily attributable to the continued expansion of our end-user customer base, increased use of OFIRMEV in surgical settings and price increases we have implemented during the period, which raised average net selling prices. The price increases led to approximately $9.1 million in additional net product revenue during the nine months ended September 30, 2013, as compared to the same period in 2012, based on the difference between the average net selling prices between the two periods.

Costs and Expenses

Cost of Product Sales. Our cost of product sales for the nine months ended September 30, 2013, was $26.4 million, or 34% of net product revenue, compared to $16.1 million, or 49% of net product revenue, for the comparable period in 2012. This improvement in our cost of sales as a percentage of net product revenue during the nine months ended September 30, 2013, was primarily due to lower freight costs incurred on product sold in 2013 as compared to 2012, and a lower average supply price for product sold during the nine months ended September 30, 2013, as compared to the same period in 2012. Additionally, during 2012, we sustained unabsorbed manufacturing costs during the suspension of production by Baxter, which were recognized as period expenses. Similar unabsorbed costs were not incurred during 2013.

Patent Amortization. Patent amortization for each of the nine month periods ended September 30, 2013, and September 30, 2012, was $1.0 million, as we continued to amortize the $15.0 million license payment made in the fourth quarter of 2010 over the estimated life of the patent. As of September 30, 2013, the unamortized balance of our license payment was $11.1 million.

Research and Development Expenses. Research and development expenses decreased $0.7 million, or 13%, for the nine months ended September 30, 2013, to $4.7 million, compared to $5.4 million for the comparable period in 2012. This decrease was primarily due to lower personnel costs, which were mostly offset by costs incurred on our ongoing FDA-required post-approval clinical trial for OFIRMEV in pediatric patients under two years of age.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased $3.5 million, or 5%, for the nine months ended September 30, 2013, to $70.3 million, compared to $66.8 million for the comparable period in 2012. This increase was mostly attributable to higher legal expenses related to our ongoing intellectual property litigation, combined with additional corporate development activities, partially offset by lower costs incurred by our sales and marketing teams.

Other. During the nine months ended September 30, 2013, we recognized a gain of $0.6 million from an insurance claim on damaged product. Additionally, we completed the removal of our equipment from Baxter's facility and released the balance of the accrued obligation related to these assets, resulting in a gain of $0.1 million. No similar gain was recognized during the nine months ended September 30, 2012.

Other Income and Expenses, Net

Net other income for the nine months ended September 30, 2013, was $4.4 million, representing an increase of $7.6 million from the net expense of $3.2 million incurred during the comparable period in 2012. The other income reported during the nine month period ended September 30, 2013, was related to the $14.7 million we received from the waiver and termination of our Incline option and the sale of our Incline stock in January 2013. We had recorded these assets using the cost method with a combined value of $7.0 million, and as a result of the transaction, recorded a gain of $7.7 million during the nine months ended September 30, 2013. No similar gain was recorded during the same period in 2012.

Our interest expense during the nine months ended September 30, 2013, of $3.3 million was consistent with our interest expense for the comparable period in 2012 as the outstanding principal balance on our debt remained constant at $30.0 million.

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 commercial products and the right to develop and commercialize product candidates, which requires a significant amount of resources. Further, these agreements and related development programs may not result in commercially successful products that generate significant revenue and, for product candidates, even if a commercial product is developed, it could take a substantial amount of time to recover the investment in the program, if at all. 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 in addition to royalties on the net sales of

OFIRMEV. Further, in developing OFIRMEV, we have incurred approximately $47.2 million in research and development costs through September 30, 2013 specific to the product. However, our total investment in the OFIRMEV program is significantly more, as these costs exclude a substantial portion of our internal costs, such as salaries and related personnel costs, which are not tracked on a project basis, and the legal expenses we have incurred, and continue to incur, in defending the OFIRMEV patents. In January 2011, we commenced sales of OFIRMEV, however, we have yet to recover our investment in the drug product and development program. For example, since the launch of OFIRMEV through September 30, 2013, we had realized approximately $77.0 million in gross profit on sales of OFIRMEV and we continue to operate at a quarterly loss.

OFIRMEV is currently our only product and we have no ongoing development programs for other product candidates. If we acquire, in-license or develop other drug products or drug candidates, it will likely require substantial capital resources. We previously entered into an option agreement with Incline whereby we had the option to acquire Incline. However, in December 2012, we entered into a waiver, consent and option termination agreement with Incline pursuant to which we agreed to the buy-out and termination of our option. In January 2013, under the terms of the waiver agreement, we relinquished our option and, as part of the transaction, we also sold our shares of Incline stock for total consideration of $14.7 million in cash.

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, 2013, we have received net proceeds of approximately $445.5 million from the sale of our stock and warrants to purchase common stock, and through the exercise of warrants and stock options. Through September 30, 2013, the sales of shares of our preferred stock, common stock and warrants were as follows:

- from July 2004 to September 2013 (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 3,634,539 shares of common stock to our founders, employees, directors and consultants for aggregate net proceeds of $4.5 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;
- 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, 2013, the current secured credit facility with this syndicate had an outstanding principal balance of $30.0 million and we had no further available credit. We are currently making interest-only payments on the outstanding balance of this facility, which will continue through December 2013. In January 2014, 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, 2013, 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, 158,311 common shares at $3.79 per share and 154,638 common shares at $3.88 per share, remain outstanding at September 30, 2013 from our loan agreements.

Liquidity

As of September 30, 2013, we had $52.0 million in cash and cash equivalents, compared to $58.3 million at December 31, 2012. This $6.3 million decrease in our cash and cash equivalent balance during the nine months ended September 30, 2013, was primarily due to the $23.8 million of cash used in operations, partially offset by the $14.7 million we received for the waiver and termination of our Incline option and the sale of our Incline stock. We also received $1.4 million from the maturity of marketable securities and $1.4 million from the exercise of stock options.

Our use of cash in operations of $23.8 million for the nine months ended September 30, 2013 was $27.5 million less than the $51.3 million we used during the same period in 2012. This reduction was mostly due to the increase in our revenue and improved gross margin during 2013. For example, during the first nine months of 2013, we realized a gross margin of $50.8 million, an increase of $33.9 million from our gross margin of $16.9 million for the first nine months of 2012. However, the impact of our increased gross margin was partially offset by an increase in our working capital requirements during the nine months ended September 30, 2013. More specifically, our accounts receivable balance increased $2.5 million during the nine months ended September 30, 2013 to $8.7 million, from $6.2 million at December 31, 2012, as a result of our increased revenue. Despite this increase in our accounts receivable balance, however, our collection period at September 30, 2013, remained relatively constant at less than 30 days, based on our calculation of days sales outstanding.

We made no principal payments under our debt agreements during the nine months ended September 30, 2013, and our outstanding principal balance remained at $30.0 million as of September 30, 2013. Pursuant to the terms of our amended credit facility, we are currently making interest-only payments through December 31, 2013.

Capital Resources

Our cash, cash equivalents and short-term investment balances are our primary source of liquidity and currently the only sources available to us. We believe we have sufficient financial resources to fund our operations, 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;
- the level of underlying hospital demand for OFIRMEV and our wholesalers' buying patterns;
- our capacity to manage our commercial infrastructure and related expenses, including our sales and marketing personnel, and costs incurred under 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;
- 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;
- our ability to successfully defend the patents for OFIRMEV and maintain our market exclusivity;
- our ability to successfully procure sufficient quantities of OFIRMEV and maintain adequate supply levels;
- regulatory developments affecting OFIRMEV or the products or product candidates of our competitors;
- costs associated with any product recalls or investigations into quality concerns; and
- variations in the level of expenses related to our development programs for any future product candidates and any further development costs associated with OFIRMEV, including our ongoing pediatric clinical trial.

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. Additional 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, which 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, 2013.

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: our plans to submit a supplemental NDA to the FDA for OFIRMEV in flexible plastic bags in the fourth quarter of 2013; the potential for us to receive milestone and royalty payments from Terumo and Incline; our belief that there are substantial growth opportunities available through continued promotion of OFIRMEV; our expectations regarding the sufficiency of our capital resources to fund our operations; the potential for us to acquire 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; 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 NDAs or abbreviated new drug applications, or 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 NDAs or 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, and its potential impact on the sales and pricing of the product; 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, and the potential implementation by regulatory agencies of new requirements to include 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***

As of September 30, 2013, our cash equivalents and short-term investment holdings consisted of investments in money market funds, 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 cash, cash equivalents and investment securities are held at fair value. The following table shows the fair value of our cash equivalents and investment securities as of September 30, 2013 (in thousands):

	Amortized Cost Basis	Fair Value
Cash equivalents	$ 46,672	$ 46,672
Available-for-sale marketable securities	$ 2,326	$ 2,326

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 outstanding principal balance of the loan and security agreement at September 30, 2013, was $30.0 million and we are making monthly interest-only payments at the stated interest rate of 10.9545%. Pursuant to the terms of our agreement, the debt is collateralized by substantially all of our assets (excluding intellectual property) and we must maintain minimum quarterly product revenue of at least $12.5 million, are precluded from entering into certain financing and other transactions, including disposing of certain assets and paying dividends, and are subject to prepayment penalties and various non-financial covenants. We were in compliance with all covenants under the agreement as of September 30, 2013.

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***

‘222 and ‘218 Patent Litigation: Exela Pharma Sciences, LLC and Paddock Laboratories, Inc. (Perrigo Company)

In August 2011, we 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 referred to herein as Perrigo, and against Exela Pharma Sciences, LLC, Exela PharmaSci, Inc. and Exela Holdings, Inc., collectively referred to herein as Exela. The lawsuit followed the notices that we received in July 2011 from each of Perrigo and Exela concerning their filings of ANDAs containing a “Paragraph IV” patent certification with the FDA for a generic version of OFIRMEV. In the lawsuit, we alleged that Perrigo and Exela each infringed the ‘222 patent and 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 patent infringement lawsuit was filed within 45 days of receipt of the pertinent notice letters, thereby triggering a stay of FDA approval of the Perrigo 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 Perrigo or Exela, or such shorter or longer period as the Court may order. Each of Perrigo and Exela filed an answer in the case asserting, among other things, non-infringement and invalidity of the asserted patents, as well as certain counterclaims.

We settled with Perrigo and the case against Perrigo was dismissed on November 30, 2012. In connection with the settlement and license agreements entered into in November 2012, Perrigo was granted the exclusive right of first refusal to negotiate an agreement with us to market an authorized generic version of OFIRMEV in the U.S. in the event that we elect to launch an authorized generic version of the product. The license agreement also provides that, if we enter into an agreement for Perrigo to market an authorized generic version of OFIRMEV during the license period, Perrigo would purchase the product exclusively from us. We would receive product costs plus an administrative fee, as well as a royalty payment based on the net profits achieved by Perrigo from the sale of the authorized generic product. Additionally, we granted Perrigo the non-exclusive right to market a generic IV acetaminophen product in the U.S. under Perrigo’s ANDA after December 6, 2020, or earlier under certain circumstances. The Federal Trade Commission, or FTC, or the Department of Justice, or DOJ, could seek to challenge our settlement with Perrigo, or a competitor, customer or other third-party could initiate a private action under antitrust or other laws challenging our settlement with Perrigo.

A bench trial for the lawsuit with Exela was held in May 2013, with one additional trial date held in early July 2013. Post-trial briefs have been submitted, but the court has not yet issued a decision in this case. The court may render its decision at any time before or after the expiration of the applicable 30-month stay. It is not possible to predict the outcome of this litigation, and an adverse outcome could result in the launch of one or more generic versions of OFIRMEV before the expiration of the last of the listed patents in June 6, 2021 (or December 6, 2021 if pediatric exclusivity is granted), which could adversely affect our ability to successfully maximize the value of OFIRMEV, and would negatively impact our financial condition and results of operations, including causing a significant decrease in our revenues and cash flows.

‘222 and ‘218 Patent Litigation: Fresenius Kabi USA, LLC and Sandoz, Inc.

In January 2013, we filed suit in the United States District Court for the Southern District of California against Fresenius Kabi USA, LLC, or Fresenius, following receipt of a December 2012 notice from Fresenius concerning its submission of a New Drug Application, or NDA, containing a Paragraph IV patent certification with the FDA for a generic version of OFIRMEV. In February 2013, we filed suit in the United States District Court for the Southern District of California against Sandoz, Inc., or Sandoz, following receipt of a December 2012 notice from Sandoz concerning its submission of an ANDA containing a Paragraph IV patent certification with the FDA for a generic version of OFIRMEV. In October 2013, we filed a motion to amend our complaint against Sandoz to join Sandoz AG, Neogen International N.V., APC Pharmaceuticals, LLC, and DIACO S.p.A. to the lawsuit against Sandoz due to the involvement of each of these companies with the preparation of the Sandoz ANDA and related matters.

In the lawsuits against Fresenius and Sandoz, which have been coordinated for purposes of discovery and other pretrial proceedings in the Southern District of California, we allege that Fresenius and Sandoz have each infringed the ‘222 patent and the ‘218 patent by filing an NDA, in the case of Fresenius, or an ANDA, in the case of Sandoz, seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. Both Fresenius and Sandoz have filed answers in the Southern District of California asserting, among other things, non-infringement and invalidity of the asserted patents, as well as certain counterclaims. Both the Fresenius and Sandoz lawsuits were filed within 45 days of receipt of the respective notice letters, thereby triggering a stay of FDA approval of the Fresenius NDA and the Sandoz 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 Fresenius and/or Sandoz, or such shorter or longer period as the court may order. A claims construction hearing in the lawsuits against Fresenius and Sandoz was held on November 4, 2013, and the bench trial for each of these lawsuits is tentatively scheduled to commence on July 14, 2014.

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 these matters or any other litigation. 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.

‘222 Patent: Ex Parte Reexamination

In September 2012, an unidentified third party (subsequently identified as Exela) filed with the United States Patent and Trademark Office, or USPTO, a Request for Ex Parte Reexamination of the ‘222 patent. In December 2012, we received notice that the USPTO had granted the Request for Reexamination. The reexamination process is provided for by law and requires the USPTO to consider the scope and validity of the patent based on substantial new questions of patentability raised by a third party or the USPTO. In February 2013, we and Pharmatop filed with the USPTO a patent owner’s statement commenting on the reexamination request, and in April 2013, Exela filed comments in response to the patent owner’s statement. In a non-final, initial office action issued by the USPTO on August 14, 2013, the USPTO rejected certain claims of the ‘222 patent. A response to the office action is due on November 10, 2013. All of the claims of the ‘222 patent remain valid and in force during the reexamination proceedings. Because we and Pharmatop believe that the scope and validity of the patent claims in this patent are appropriate and that the USPTO’s prior issuance of the patent was correct, we, in conjunction with Pharmatop, will vigorously defend this patent. We cannot predict whether we and Pharmatop ultimately will succeed in maintaining the scope and validity of the claims of this patent during reexamination. If any of the patent claims in this patent ultimately are narrowed during prosecution before the USPTO, the extent of the patent coverage afforded to OFIRMEV could be impaired, which could potentially harm our business and operating results.

‘218 Patent Litigation: Exela Pharma Sciences, LLC

In April 2012, Exela filed suit against David J. Kappos and the USPTO in the United States District Court for the Eastern District of Virginia for declaratory judgment seeking a reversal of the USPTO’s decision not 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 lacked 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 “unintentional” standard are invalid, and similar relief in connection with one or more counterclaims it has filed in the Delaware litigation. Our motion to intervene in this lawsuit was granted in October 2012. In December 2012, the district court dismissed the case with prejudice as barred by the applicable statute of limitations. In February 2013, Exela appealed the district court’s decision to the Court of Appeals for the Federal Circuit. In response to an opening brief in the appeal filed by Exela, we and Pharmatop filed our opening brief on September 27, 2013. A decision by the Court of Appeals in favor of Exela could result in the invalidation of the ‘218 patent.

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, 2012.

Risks Related to Our Business and Industry

Our success depends on the commercial success of our only product, OFIRMEV.*

Our success depends on the continued success of our efforts to 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 maintain and increase revenues from sales of OFIRMEV will depend on several factors, including:

- our ability to increase 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 continue to procure a supply of OFIRMEV from our sole source third-party manufacturer in sufficient quantities and at acceptable quality and pricing levels in order to meet commercial demand;
- the performance of our third-party manufacturer and our ability to ensure that our supply chain for OFIRMEV efficiently and consistently delivers OFIRMEV to our customers;
- our ability to continue to deploy and support a qualified sales force;
- our ability to maintain fees and discounts payable to the wholesalers and distributors who distribute OFIRMEV, as well as to group purchasing organizations, at commercially reasonable levels;
- whether the FTC, DOJ or third parties seek to challenge and are successful in challenging our settlement agreement with Perrigo;
- warnings or limitations that we may be required to add to OFIRMEV's FDA-approved labeling;
- the occurrence of adverse side effects or inadequate therapeutic efficacy of OFIRMEV, and any resulting product liability claims or product recalls; and
- our ability to achieve hospital formulary acceptance for OFIRMEV, and to the extent third-party payors separately cover and reimburse for OFIRMEV, the availability of adequate levels of reimbursement 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.

The continued success of our commercialization of OFIRMEV is subject to many internal and external challenges and if we cannot overcome these challenges in a timely manner, our 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 provide effective promotional materials to our sales force and medical and scientific support materials for our medical affairs staff for their use in communicating about 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. The effectiveness of our promotional and medical communication materials about OFIRMEV is critically important to our efforts to inform and educate potential customers about the benefits and risks of OFIRMEV and its proper administration, and the continued success of our commercialization activities for the product.

In addition to extensive internal efforts, the continued successful commercialization of OFIRMEV requires many third parties, over whom we have no control, to decide to utilize OFIRMEV and to make it readily available at the point of care throughout their hospitals. 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, either initially or later, when the increasing use of OFIRMEV within their institution begins to significantly impact their budgets. 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 maintain and grow hospital sales of OFIRMEV.

We have no manufacturing capabilities and depend entirely upon our sole source contract manufacturer to produce OFIRMEV. If our contract manufacturer fails to meet our requirements for OFIRMEV, or fails 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 contract manufacturers as our source for OFIRMEV.

In February 2013, we amended our supply agreement with Lawrence Laboratories, an operating division of Swords Laboratories and a member of the BMS group of companies, under which 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. Any termination or disruption of our relationship with BMS Anagni, which is currently our sole source for OFIRMEV, may materially harm our business and financial condition and adversely impact our commercialization and sales efforts with respect to the product.

We also 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. If our contract manufacturer or API supplier, or any other supplier of critical components for OFIRMEV, becomes unable to meet our supply requirements, the process of changing or adding a new contract manufacturer or critical component supplier 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.

In March 2013, we entered into an agreement with Grifols for the development, manufacture and supply of commercial quantities of OFIRMEV in flexible plastic bags. We plan to submit a supplemental NDA to the FDA in the fourth quarter of 2013 seeking approval of the product to be manufactured by Grifols, but Grifols will not be able to supply us with OFIRMEV until FDA approval is granted, if ever.

Our contract manufacturers must comply with strictly enforced federal, state and foreign regulations, including GMP regulations. The FDA will inspect our contract manufacturers' facilities from time to time and, in the event that any such inspection reveals that the 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.

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 short sales track record for OFIRMEV.

For example, in 2012, we announced two voluntary recalls of OFIRMEV manufactured by Baxter, our previous contract manufacturer, due to the presence of unidentified, visible particles in a limited number of vials of the product, which were detected during routine stability testing. Although we received no adverse event reports associated with the particulate matter or product complaints involving similar particulate matter, as a precautionary measure we suspended production by Baxter in connection with the initial recall and decided to recall all remaining lots of OFIRMEV manufactured by Baxter in connection with the second recall. Additionally, following the first recall, some of our customers experienced short-term supply delays due to the suspension of shipments from Baxter until we were able to expedite sufficient shipments of OFIRMEV from BMS Anagni, and we incurred higher freight costs associated with the expedited product shipments. We also incurred unabsorbed manufacturing costs during the time that Baxter's manufacturing of the product was suspended. As a result of the second recall, we destroyed the Baxter-manufactured finished product inventory that we previously placed on indefinite hold, and recorded charges of $5.8 million in relation to this product. In March 2013, we and Baxter mutually agreed to terminate our supply agreement for OFIRMEV. Under the termination agreement, we were required to remove our manufacturing equipment from Baxter's facility within 180 days and pay Baxter for any pre-approved costs or expenses related to such removal. As a result, we incurred impairment charges of $7.7 million and a loss on the sale of equipment of $0.9 million during the fourth quarter of 2012 in relation to the assets involved with the manufacture of OFIRMEV under the terminated development and supply agreement with Baxter.

In addition, in July 2013, we voluntarily issued a letter to our customers requesting that they inspect their inventories of OFIRMEV to ensure that each vial includes a lot number and expiration date, following our receipt of a small number of customer reports of vials where such information was missing. We have received no reports of adverse events associated with this issue, and have notified FDA of our voluntary notification to our customers. Corrective actions have been implemented by our contract manufacturer to prevent a reoccurrence.

Any future recalls of OFIRMEV 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 and equipment.

If OFIRMEV does not achieve sufficient 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 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 and children 17 years of age and older. 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 IV 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.

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.

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;
- 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; or
- acquire or in-license additional 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 or maintain lawsuits to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of IV acetaminophen, such as our ongoing 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, we have refinanced our $30.0 million secured credit facility with Oxford Finance LLC, Silicon Valley Bank and General Electric Capital Corporation on various occasions, including most recently in December 2012. 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 participation in 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.

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. 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.

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 from all routes of administration. Similarly, after discussions with the FDA, we added a boxed warning to the prescribing information for OFIRMEV in October 2013 regarding the potential for dosing errors with OFIRMEV and the risk of liver injury associated with the administration of acetaminophen (by all routes of administration) at doses that exceed the recommended maximum daily limits. A boxed warning is the strongest type of warning that the FDA can require for a drug and is generally reserved for situations where prescribers should be aware of the potential for adverse drug reactions that can cause serious injury or death. Products with boxed warnings are subject to more restrictive advertising regulations than products without such warnings. We cannot predict whether the FDA will require additional warnings, or place any additional limitations on our ability to advertise and promote OFIRMEV, which could negatively impact our sales of OFIRMEV. The OFIRMEV prescribing information was also updated in accordance with a drug safety communication issued by the FDA in August 2013 requiring a warning that acetaminophen has been associated with a risk of rare but serious skin reactions, such as Stevens-Johnson Syndrome, toxic epidermal necroylsis and acute generalized exanthematous pustulosis, which can be fatal. The FDA indicated that it will require that this warning be added to the labels of all prescription drug products containing acetaminophen to address this risk, and will request or encourage manufacturers of over-the-counter acetaminophen drug products to do the same. Similar warnings are also required for other medications used to treat pain or fever, including NSAIDs.

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, FDAAA 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 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.

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, concerns regarding a product’s safety, the discovery of previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where a product is manufactured, may result in the imposition of additional restrictions, including

withdrawal of the product from the market. For example, after discussions with the FDA, we added a boxed warning to the prescribing information for OFIRMEV in October 2013 regarding the potential for dosing errors with OFIRMEV and the risk of liver injury associated with the administration of acetaminophen (by all routes of administration) at doses that exceed the recommended maximum daily limits.

In addition, 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 the federal anti-kickback statute and false claims laws and regulations. The federal 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. 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. There are also federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. 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 statute 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, results of operations and growth prospects. Further, the recently enacted Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or PPACA, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity can now be found guilty of fraud or false claims under PPACA without actual knowledge of the statute or specific intent to violate it. In addition, the PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the false claims statutes. Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare, Medicaid and other government programs and forfeiture of amounts collected in violation of such prohibitions. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

The PPACA also imposes new reporting and disclosure requirements on device and drug manufacturers for any "transfer of value" made or distributed to prescribers and other healthcare providers. In addition, device and drug manufacturers are now required to report and disclose any 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 of up to an aggregate of $150,000 per year (and up to an aggregate of $1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests not reported in an annual submission. Also, as of August 1, 2013, manufacturers are required to begin data collection and will be required to report such data to CMS by March 31, 2014, and by the 90th day of every subsequent calendar year for the reporting period of the previous year.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing. Some states, such as California, Massachusetts and Vermont, mandate implementation of compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians. The shifting commercial compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and/or reporting requirements in multiple jurisdictions increase the costs associated with implementing and maintain such systems, and the possibility that a healthcare company may run afoul of one or more of the requirements.

The scope and enforcement of these laws is uncertain and subject to change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. We cannot predict the impact on our business of any changes in these laws. Federal or state regulatory authorities may challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations, and financial condition. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming.

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 PPACA became law and made 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. The PPACA seeks to expand health care coverage to the uninsured through private health insurance reforms and an expansion of Medicaid. The PPACA also imposes 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 promotes programs that increase the federal government's comparative effectiveness research, which may be used to evaluate the selection of medical services by clinicians and others. In addition, PPACA implements payment system reforms such as a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models, and creates an independent payment advisory board that will submit recommendations to reduce Medicare spending if projections of such spending exceed a specified growth rate.

Other legislative changes have been proposed and adopted since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable

to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. On March 1, 2013, the President signed an executive order implementing sequestration, and on April 1, 2013, the 2% Medicare payment reductions went into effect. The ATRA, among other things, also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws, as well as legislative and regulatory proposals that may be adopted from time to time in the future, may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations. 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.

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.

We may never be successful in our efforts to commercialize OFIRMEV in Canada.*

Our rights to OFIRMEV include Canada, as well as the United States. In June 2013, Health Canada issued a Notice of Compliance that granted marketing approval for OFIRMEV in Canada, and we initiated a pricing review for the product with the Canadian Patented Medicine Prices Review Board in October 2013. Following the completion of the pricing review process, we will assess the commercial feasibility of launching the product in Canada, either independently or in collaboration with a company with an existing Canadian commercial presence. Additionally, in order to market OFIRMEV in Canada, we must comply with numerous and varying Canadian regulatory requirements regarding non-clinical testing, manufacturing, clinical safety, efficacy and marketing. Our ability to successfully commercialize OFIRMEV in Canada will depend significantly on the price we are able to charge for the product and our ability to establish cost-effective marketing and sales capabilities and distribution channels for Canada. If the pricing for the product is not sufficient, we may elect to not market OFIRMEV in Canada, or if we do market the product, any profits we generate may be limited.

If our hospital customers fail to receive adequate reimbursement from the government or third-party payors 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 reimbursement rates our customers receive for OFIRMEV. 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, including government health programs such as Medicare, managed care providers and commercial 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.

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 and accordingly, we may be unable 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 hospital formularies, 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 sell 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 sell 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 commercial efforts.

If BMS breaches the underlying agreement under which we sublicense the rights to OFIRMEV, we could lose the ability to sell 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 commercial efforts for OFIRMEV.

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

As of September 30, 2013, we had approximately 211 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. 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. As part of our efforts to acquire businesses 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.

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 IV formulation of acetaminophen. As a result, our market opportunity for this product may be limited by the lack of patent protection for the active ingredient itself and other formulations of IV acetaminophen 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 Canadian patents owned by Pharmatop, under BMS's license to these patents from Pharmatop. U.S. Patent No. 6,028,222, or the '222 patent (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, or the '218 patent (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 of OFIRMEV within the period agreed on with the FDA, which is August 2015, and, upon timely completion and the acceptance by the FDA of the data from this study, we expect that OFIRMEV will be eligible for an additional six months of marketing exclusivity in the U.S.

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. We are also 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.

Four 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. If a third party files an NDA or ANDA for a generic drug product containing acetaminophen and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that, 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 NDA or 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 NDA or 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 NDA or 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 NDA or ANDA will not be subject to the 30-month stay.

For example, in August 2011, we and Pharmatop filed suit in the United States District Court for the District of Delaware against Perrigo and Exela. The lawsuit followed the notices that we received in July 2011 from each of Perrigo and Exela concerning their filings of ANDAs containing a "Paragraph IV" patent certification with the FDA for a generic version of OFIRMEV. In the lawsuit, we alleged that Perrigo and Exela each infringed the '222 patent and 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 patent infringement lawsuit was filed within 45 days of receipt of the pertinent notice letters, thereby triggering a stay of FDA approval of the Perrigo 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 Perrigo or Exela, or such shorter or longer period as the Court may order. Each of Perrigo and Exela filed an answer in the case asserting, among other things, non-infringement and invalidity of the asserted patents, as well as certain counterclaims. We settled with Perrigo and the case against Perrigo was dismissed on November 30, 2012. In connection with the settlement and license agreements entered into in November 2012, Perrigo was granted the exclusive right of first refusal to negotiate an agreement with us to market an authorized generic version of OFIRMEV in the U.S. in the event that we elect to launch an authorized generic version of the product. The license agreement also provides that, if we enter into an agreement for Perrigo to market an authorized generic version of OFIRMEV during the license period, Perrigo would purchase the product exclusively from us. We would receive product costs plus an administrative fee, as well as a royalty payment based on the net profits achieved by Perrigo from the sale of the authorized generic product. Additionally, we granted Perrigo the non-exclusive right to market a generic IV acetaminophen product in the U.S. under Perrigo's ANDA after December 6, 2020, or earlier under certain circumstances. The FTC or the DOJ could seek to challenge our settlement with Perrigo, or a competitor, customer or other third-party could initiate a private action under antitrust or other laws challenging our settlement with Perrigo. Any such challenge could be both expensive and time consuming and may render the settlement agreement unenforceable.

A bench trial for the lawsuit with Exela was held in May 2013, with one additional trial date held in early July 2013. Post-trial briefs have been submitted, but the court has not yet issued a decision in this case. The court may render its decision at any time before or after the expiration of the applicable 30-month stay. It is not possible to predict the outcome of this litigation, and an adverse outcome could result in the launch of one or more generic versions of OFIRMEV before the expiration of the last of the listed patents in June 6, 2021 (or December 6, 2021 if pediatric exclusivity is granted), which could adversely affect our ability to successfully maximize the value of OFIRMEV, and would negatively impact our financial condition and results of operations, including causing a significant decrease in our revenues and cash flows.

In addition, in January 2013, we filed suit in the United States District Court for the Southern District of California against Fresenius Kabi USA, LLC, or Fresenius, following receipt of a December 2012 notice from Fresenius concerning its submission of an NDA containing a Paragraph IV patent certification with the FDA for a generic version of OFIRMEV. In February 2013, we filed suit in the United States District Court for the Southern District of California against Sandoz, Inc., or Sandoz, following receipt of a December 2012 notice from Sandoz concerning its submission of an ANDA containing a Paragraph IV patent certification with the FDA for a generic version of OFIRMEV. In October 2013, we filed a motion to amend our complaint against Sandoz to join Sandoz AG, Neogen International N.V., APC Pharmaceuticals, LLC, and DIACO S.p.A. to the lawsuit against Sandoz due to the involvement of each of these companies with the preparation of the Sandoz ANDA and related matters. In the lawsuits against Fresenius and Sandoz, which have been coordinated for purposes of discovery and other pretrial proceedings in the Southern District of California, we allege that Fresenius and Sandoz have

each infringed the ‘222 patent and the ‘218 patent by filing an NDA, in the case of Fresenius, or an ANDA, in the case of Sandoz, seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. Both Fresenius and Sandoz have filed answers in the Southern District of California asserting, among other things, non-infringement and invalidity of the asserted patents, as well as certain counterclaims. Both the Fresenius and Sandoz lawsuits were filed within 45 days of receipt of the respective notice letters, thereby triggering a stay of FDA approval of the Fresenius NDA and the Sandoz 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 Fresenius and/or Sandoz, or such shorter or longer period as the court may order. A claims construction hearing in the lawsuits against Fresenius and Sandoz is currently scheduled to take place on November 4, 2013, and the bench trial in each of these lawsuits is tentatively scheduled to commence on July 14, 2014.

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 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 or guarantee the outcome of these matters or any other litigation. Regardless of how these matters are ultimately resolved, these matters may be costly, time-consuming and distracting to our management, which could have a material adverse effect on our business.

The protection of our intellectual property rights is critical to our success and any failure on our part to adequately secure such rights would materially affect our business.*

Our commercial success depends on maintaining patent protection and trade secret protection for OFIRMEV, as well as for any other products or product candidates that we may license or acquire, and 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.

For example, in April 2012, Exela filed suit against David J. Kappos and the USPTO in the United States District Court for the Eastern District of Virginia for declaratory judgment seeking a reversal of the USPTO’s decision not 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 lacked 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 “unintentional” standard are invalid, and similar relief in connection with one or more counterclaims it has filed in the Delaware litigation. Our motion to intervene in this lawsuit was granted in October 2012. In December 2012, the district court dismissed the case with prejudice as barred by the applicable statute of limitations. In February 2013, Exela appealed the district court’s decision to the Court of Appeals for the Federal Circuit. In response to an opening brief in the appeal filed by Exela, we and Pharmatop filed our opening brief on September 27, 2013. A decision by the Court of Appeals in favor of Exela could result in the invalidation of the ‘218 patent.

Additionally, in September 2012, an unidentified third party (subsequently identified as Exela) filed with the USPTO a Request for Ex Parte Reexamination of the ‘222 patent. In December 2012, we received notice that the USPTO had granted the Request for Reexamination. The reexamination process is provided for by law and requires the USPTO to consider the scope and validity of the patent based on substantial new questions of patentability raised by a third party or the USPTO. In February 2013, we and Pharmatop filed with the USPTO a patent owner’s statement commenting on the reexamination request, and in April 2013, Exela filed comments in response to the patent owner’s statement. In a non-final, initial office action issued by the USPTO on August 13, 2013, the USPTO rejected certain claims of the ‘222 patent. A response to the office action is due in November 2013. All of the claims of the ‘222 patent remain valid and in force during the reexamination proceedings. Because we and Pharmatop believe that the scope and validity of the patent claims in this patent are appropriate and that the USPTO’s prior issuance of the patent was correct, we, in conjunction with Pharmatop, will vigorously defend this patent. We cannot predict whether we and Pharmatop ultimately will succeed in maintaining the scope and validity of the claims of this patent during reexamination. If any of the patent claims in this patent ultimately are narrowed during prosecution before the USPTO, the extent of the patent coverage afforded to OFIRMEV could be impaired, which could potentially harm our business and operating results.

On November 4, 2013, we submitted a citizen petition to the FDA requesting that the FDA refrain from approving any new acetaminophen product for parenteral use that does not have an identical inactive ingredient profile as OFIRMEV without nonclinical studies and adequate and well-controlled clinical trials demonstrating the product is as safe and effective as OFIRMEV. The FDA is required by statute to issue a response to our citizen petition within 150 days, or no later than April 3, 2014; however, we cannot predict when or if the FDA will issue a final response to, or otherwise take any other action with respect to, our petition.

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.

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.

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 $81.0 million, $93.0 million and $56.6 million for the years ended December 31, 2012, 2011 and 2010, respectively. As of September 30, 2013, we had an accumulated deficit of $467.8 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 have decreased since 2010 due to the completion of our clinical development program for OFIRMEV, our sales, marketing, manufacturing and legal expenses have increased significantly since that time in connection with the commercialization OFIRMEV. In addition, we are required to pay a royalty on net sales of OFIRMEV, which includes minimum obligations, and we may be required to make future milestone payments upon the achievement of certain net sales levels of OFIRMEV. We also have minimum purchase obligations under our supply agreements with our contract manufacturers for OFIRMEV. As a result, we expect to continue to incur operating losses until we are able to generate sufficient revenues to operate profitably. Because of the numerous risks and uncertainties associated with developing and marketing 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 or procure 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, and we are not generating sufficient revenues to operate profitably. 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. The revenues we have generated from OFIRMEV have changed significantly since launch, and we anticipate that they will continue to change. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a longer history of marketing OFIRMEV or other 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;
- the level of underlying hospital demand for OFIRMEV and wholesalers' buying patterns;
- our capacity to manage our commercial infrastructure and related expenses, including our sales and marketing personnel, and costs incurred under 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;
- 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;
- our ability to successfully defend the patents for OFIRMEV and maintain our market exclusivity;
- our ability to successfully procure sufficient quantities of OFIRMEV and maintain adequate supply levels;
- regulatory developments affecting OFIRMEV or the products or product candidates of our competitors;
- costs associated with any product recalls or investigations into quality concerns; and
- variations in the level of expenses related to our development programs for any future product candidates and any further development costs associated with OFIRMEV, including our ongoing pediatric clinical trial.

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, we have refinanced our $30.0 million secured credit facility with Oxford Finance LLC, Silicon Valley Bank and General Electric Capital Corporation on various occasions, including most recently in December 2012. This secured credit facility contains a variety of affirmative and negative covenants, including minimum quarterly product revenue requirements, 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, 2012, we had generated federal and state net operating loss carryforwards of approximately $369.7 million and $374.2 million, respectively. We also had federal and state research and development tax credit carryforwards of approximately $4.8 million and $3.2 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 2025 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 recently completed an analysis through December 31, 2012, and determined that we experienced an ownership change in March 2006. However, this ownership change did not result in the forfeiture of any net operating loss carryforwards or research tax credits. We continue to monitor changes in our ownership as any future ownership changes 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 commodity 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, 2013 ranged from a high of $8.26 to a low of $2.88. 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;

- 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 intellectual property lawsuits relating to OFIRMEV, including any future lawsuits, 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 products or potential products, including concerns about the boxed warning in the prescribing information for OFIRMEV;
- 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 the amount of reimbursement received by our customers;
- 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, 2013, our executive officers and directors and their affiliates together controlled approximately 28% 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.

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Item 6. ***Exhibits***

Exhibit Number	Description of Exhibit
10.1	Third Amendment to Lease, dated September 24, 2013, by and among the Company and PRII High Bluffs LLC and Collins Corporate Center Partners, LLC, incorporated herein by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K (File No. 001-33103) as filed with the SEC on September 27, 2013
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.

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, 2013

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

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± Included in this Report.

Exhibit 31.1

CERTIFICATION

I, Theodore R. Schroeder, certify that:

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

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

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

4. The registrant's other certifying officer(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, 2013

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, 2013

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, 2013, 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, 2013.

/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.