Table of Contents

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

FORM 10-Q

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

For the Quarterly Period Ended March 31, 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 April 30, 2013, there were 85,801,664 shares of the registrant's Common Stock outstanding.

CADENCE PHARMACEUTICALS, INC.

INDEX

PART I. FINANCIAL INFORMATION

Item 1. ***Financial Statements***

CADENCE PHARMACEUTICALS, INC.

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

	March 31, 2013 (unaudited)	December 31, 2012
Assets		
Current assets:		
Cash and cash equivalents	$ 60,495	$ 58,327
Investments in marketable securities	3,745	3,745
Restricted cash	640	640
Accounts receivable, net	8,908	6,152
Inventory	6,083	6,498
Prepaid expenses	1,955	1,064
Other current assets	86	90
Total current assets	81,912	76,516
Property and equipment, net	1,905	1,967
Intangible assets, net	11,754	12,090
Other assets	90	7,106
Total assets	$ 95,661	$ 97,679
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,808	$ 5,796
Accrued liabilities	12,532	12,969
Deferred revenue	-	2,234
Current debt, less discount of $93 and $—, respectively	2,552	-
Total current liabilities	20,892	20,999
Long-term debt, less current portion and discount of $967 and $1,182, respectively	26,388	28,818
Other liabilities	233	51
Total liabilities	47,513	49,868
Commitments and contingencies (Note 11)		
Stockholders' equity :		
Common stock, $0.0001 par value; 200,000,000 shares authorized, 85,683,981 shares and 85,668,668 shares issued and outstanding at March 31, 2013 and December 31, 2012, respectively	9	9
Additional paid-in capital	497,158	495,458
Accumulated other comprehensive income	-	-
Accumulated deficit	(449,019)	(447,656)
Total stockholders' equity	48,148	47,811
Total liabilities and stockholders' equity	$ 95,661	$ 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 March 31,	
	2013	2012
Revenues:		
Product revenue, net	$23,612	$ 8,004
Total revenues	23,612	8,004
Costs and expenses:		
Cost of product sales	8,167	4,246
Amortization of patent license	336	336
Research and development	1,363	1,511
Selling, general and administrative	21,635	23,531
Other	50	-
Total costs and expenses	31,551	29,624
Loss from operations	(7,939)	(21,620)
Other (expense) income:		
Interest income	22	36
Interest expense	(1,100)	(1,099)
Other income	7,654	10
Total other income (expense), net	6,576	(1,053)
Net loss	$ (1,363)	$(22,673)
Basic and diluted net loss per share	$ (0.02)	$ (0.27)
Shares used to compute basic and diluted net loss per share	85,672	85,519

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 March 31,	
	2013	2012
Net loss	$(1,363)	$(22,673)
Other comprehensive income (loss):		
Net unrealized loss on securities available for sale	-	(1)
Other comprehensive income (loss)	-	(1)
Comprehensive loss	$(1,363)	$(22,674)

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

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

	Three Months Ended March 31,	
	2013	2012
Operating activities		
Net loss	$ (1,363)	$(22,673)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	89	411
(Gain) on disposal of assets	(7,654)	-
Inventory write-down	-	163
Stock-based compensation	1,647	2,870
Non-cash interest expense	4	7
Amortization of intangible assets	336	336
Amortization of discount on note payable	122	135
Amortization of premiums (accretion of discounts) on available-for-sale securities	(1)	(10)
Changes in operating assets and liabilities:		
Accounts receivable	(2,756)	(493)
Inventory	415	(1,336)
Prepaid expenses and other assets	(875)	(323)
Accounts payable	12	1,336
Deferred revenue	(2,234)	304
Accrued liabilities and other liabilities	(255)	1,028
Net cash used in operating activities	(12,513)	(18,245)
Investing activities		
Maturities and sales of marketable securities	-	22,050
Proceeds from the sale of Incline option and preferred shares	14,654	-
Purchases of property and equipment	(26)	(446)
Net cash provided by investing activities	14,628	21,604
Financing activities		
Proceeds from issuance of common stock, net	53	89
Net cash provided by financing activities	53	89
Net increase in cash and cash equivalents	2,168	3,448
Cash and cash equivalents at beginning of period	58,327	82,609
Cash and cash equivalents at end of period	$ 60,495	$ 86,057
Supplemental disclosures		
Property and equipment purchases in accounts payable and accrued expenses at period end	$ 338	$ 1,023
Unrealized loss on investment securities	$ -	$ (1)
Cash paid for interest and fees	$ 785	$ 641

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

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS

(Unaudited)

1. The Company

Cadence Pharmaceuticals, Inc. (the "Company") was incorporated in the state of Delaware in May 2004. The Company is a biopharmaceutical company focused on acquiring, in-licensing, developing and commercializing proprietary products principally for use in the hospital setting. In March 2006, the Company in-licensed the exclusive U.S. and Canadian rights to OFIRMEV® (acetaminophen) injection, an intravenous formulation of acetaminophen, from Bristol-Myers Squibb Company ("BMS"). In November 2010, the Food and Drug Administration ("FDA") approved the Company's New Drug Application ("NDA") for OFIRMEV for the management of mild to moderate pain, 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.

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 sale 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 during the three months ended March 31, 2013, to recognize revenue that had previously been deferred, resulting in additional net revenue of $2,616,000 and cost of sales of $919,000 during the period. 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 three months ended March 31, 2013. The per share net impact of the adjustment for the three months ended March 31, 2013, was a reduction in net loss of $0.02 per share.

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 through its wholesalers to these group purchasing organizations and accrues for the chargebacks it anticipates from its wholesalers for the difference between the current retail price and the reduced price paid by the members of the group purchasing organizations. An administrative service fee the Company incurs for these transactions is also recorded at the time of sale. The Company also provides government programs a predetermined discount that is recorded at the time of sale.

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

Accounts Receivable

The Company extends credit to its customers in the normal course of business based upon an evaluation of the customer's credit history, financial condition and other factors. Trade accounts receivable are recorded on gross sales to wholesalers, net of allowances for prompt payment and other discounts, 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 March 31, 2013 and December 31, 2012, the Company's allowance for uncollectible receivables was $13,000 and $56,000, respectively. During the three months ended March 31, 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 months ended March 31, 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 March 31,	
	2013	2012
Risk-free interest rates	1.1%	1.3%
Expected life in years	6.1 years	5.9 years
Expected dividend yield	0.0%	0.0%
Expected volatility	66.1%	70.6%

Compensation expense for stock-based payment awards is recognized using the straight-line method. Stock-based compensation expense recognized during the period is based on the value of the portion of awards that is ultimately expected to vest. Hence, the gross expense is reduced for estimated forfeitures and adjusted for the probability of achieving performance criteria, as applicable. If awards are forfeited prior to vesting, all previous expense recognized for unvested awards is recovered during the period in which the forfeiture occurs.

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

	Three Months Ended March 31,	
	2013	2012
Cost of product sales	$ 71	$ 110
Research and development	166	536
Selling, general and administrative	1,410	2,224
Total stock-based compensation expense included in loss from operations	$ 1,647	$ 2,870

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.

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

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 March 31, 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 March 31, 2013	Fair Value Measurements as of March 31, 2013		
		Level 1	Level 2	Level 3
Assets:				
Cash equivalents:				
Money market funds	$ 58,745	$ 58,745	$ -	$ -
Investments in marketable securities – short-term:				
Debt instruments – Corporate debt obligations	1,400	-	1,400	-
Debt instruments – Municipal debt obligations	1,345	-	1,345	-
Certificates of deposit	1,000	-	1,000	-
Assets at fair value	$ 62,490	$ 58,745	$ 3,745	$ -

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	$ -

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

3. Recent Accounting Pronouncements

In January 2013, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2013-01, *Clarifying the Scope of Disclosures About Offsetting Assets and Liabilities.* ASU 2013-01 clarifies which instruments and transactions are subject to the offsetting disclosure requirements established by ASU 2011-11, *Disclosures About Offsetting Assets and Liabilities.* Under ASC 2013-01, instruments or transactions subject to disclosure include recognized derivative instruments accounted for in accordance with ASC 815, *Derivative Hedging*, including bifurcated embedded derivatives, repurchase agreements and reverse repurchase agreements, and securities borrowing and securities lending transactions, to the extent they are offset in the financial statements or subject to an enforceable master netting agreement or similar agreement. Further, such disclosures are required irrespective of whether the transactions are offset in the statement of financial position. The Company applies the offsetting principle to certain assets and liabilities, however it does not hold instruments, and has not had transactions involving such instruments, which would be subject to the disclosure requirements. The guidance is effective for annual reporting periods beginning on or after January 1, 2013, and interim periods within those annual periods. The Company adopted this standard on January 1, 2013, which did not impact the Company's financial results or disclosures for the current period and is not expected to have an impact on the Company's annual financial results or disclosures.

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

In February 2013, the FASB issued ASU No. 2013-02, *Comprehensive Income (Topic 220): Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income*. Under ASU 2013-02, an entity is required to provide information about the amounts reclassified out of accumulated other comprehensive income ("AOCI") by component. In addition, an entity is required to present, either on the face of the financial statements or in the notes, significant amounts reclassified out of AOCI by the respective line items of net income, but only if the amount reclassified is required to be reclassified in its entirety in the same reporting period. For amounts that are not required to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures that provide additional details about those amounts. ASU 2013-02 does not change the current requirements for reporting net income or other comprehensive income in the financial statements. The guidance is effective for annual reporting periods beginning on or after January 1, 2013, and interim periods within those annual periods. The Company adopted this standard on January 1, 2013, which did not impact the Company's financial results or disclosures for the current period and is not expected to have an impact on the Company's annual financial results or disclosures.

4. Net Loss Per Share

Net loss per share is presented as basic and diluted net loss per share. Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, stock options, restricted stock units and warrants are considered to be common stock equivalents, 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 months ended March 31, 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 March 31, 2013 and 2012, stock options, restricted stock units, and warrants totaling 18,079,000 and 16,568,000 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):

	March 31, 2013	December 31, 2012
Inventory:		
Raw material	$ 83	$ 83
Finished goods	6,000	6,415
Total	$ 6,083	$ 6,498

During the three months ended March 31, 2012, the Company recorded a charge for inventory losses of $163,000 in cost of sales to write-down certain inventory manufactured to its estimated net realizable value. The product in question had been placed on indefinite hold due to an investigation into unidentified particulate matter observed during routine product stability testing. No similar charges were recorded in the three months ended March 31, 2013. See "Supply Agreements" in Note 11 below for further information.

6. Property and Equipment

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

	March 31, 2013	December 31, 2012
Property and equipment:		
Manufacturing equipment	$ 2,999	$ 2,999
Leasehold improvements	1,639	1,639
Computer equipment and software	1,496	1,489
Furniture and fixtures	478	478
Construction-in-process	744	724
	7,356	7,329
Less accumulated depreciation	(5,451)	(5,362)
Total	$ 1,905	$ 1,967

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

As of December 31, 2012, the Company impaired the value of its manufacturing equipment and construction-in-process due to the termination of its supply agreement with Baxter Healthcare Corporation ("Baxter"). These assets were reduced to their estimated fair market value and the Company stopped depreciating the manufacturing assets during the three months ended March 31, 2013. See "Supply Agreements" in Note 11 below for further information.

For the three months ended March 31, 2013 and 2012, the Company incurred depreciation expense of $89,000 and $411,000, 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 March 31, 2013 and December 31, 2012 consisted of the following (in thousands):

At March 31, 2013	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	$ 1,400	$ -	$ -	$ -	$ 1,400
Debt instruments – Municipal debt obligations	1,345	-	-	-	1,345
Certificates of deposit	1,000	-	-	-	1,000
	$ 3,745	$ -	$ -	$ -	$ 3,745

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):

	March 31, 2013		December 31, 2012	
	Cost	Fair Value	Cost	Fair Value
Due or callable in one year or less	$3,745	$ 3,745	$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 months ended March 31, 2013 and 2012. Further, as of March 31, 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 is developing IONSYS™ (fentanyl iontophoretic transdermal system), an investigational product candidate intended to provide patient-controlled analgesia for adult inpatients requiring opioids following surgery. As consideration for the Option, the Company paid Incline a $3,500,000 upfront option fee in June 2010 and made a second payment of $3,500,000 in September 2011. 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.

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

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 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 three months ended March 31, 2013. No similar gain was recorded during the three months ended March 31, 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 temporarily 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 commenced a restructuring of its workforce to focus its resources on the commercialization of OFIRMEV and reduce program costs not directly associated with such efforts. As a result of the 2011 restructuring, the Company recorded one-time employee termination charges of $1,142,000 in connection with the termination of 17 employees. The following table details the restructuring charges for severance-related costs and termination of contractual obligations for periods presented (in thousands):

	Three Months Ended March 31,	
	2013	2012
Beginning restructuring liability	$ -	$ 931
Severance and termination charges incurred	-	-
Severance and termination disbursements	-	(885)
Ending restructuring liability	$ -	$ 46

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 amends and restates 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.

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

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 2011 Amendment), the lenders may declare all outstanding amounts due and payable under the 2012 Amendment. As of March 31, 2013, the Company was in compliance with all covenants under the 2012 Amendment.

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 March 31, 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 a six-year 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. The lease will expire in December 2013 with no option to extend the term.

As security for the initial lease, a letter of credit in the initial amount of $1,581,000 was required by the landlord. The letter of credit is collateralized by a certificate of deposit in the same amount that is classified as restricted cash in the Company's balance sheet. The required amount subject to the letter of credit and corresponding certificate of deposit was eligible to be reduced by 22% on each of the first four anniversaries of the commencement of the lease and as of March 31, 2013, the letter of credit had been reduced by $1,391,000 in accordance with the agreement and the related restricted cash had been adjusted by a like amount. The value of the letter of credit and corresponding certificate of deposit, classified as restricted cash on the Company's balance sheet at March 31, 2013 and December 31, 2012, was $190,000.

The Company also leases certain office equipment under capital and operating leases. Its current capital lease has a term of four years and expires in 2016. As of March 31, 2013 and December 31, 2012, the assets under this current capital lease had a gross value of $56,000 and during the three months ended March 31, 2013, the Company recorded amortization expense of $4,000. No similar expense was recorded during the three months ended March 31, 2012. The remaining obligation under its capital lease at March 31, 2013 is recorded on the Company's balance sheet in accrued expenses and other long-term liabilities at $12,000 and $41,000, respectively.

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(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 March 31, 2013 and 2012 was $168,000 and $236,000, 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 March 31, 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 March 31, 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, 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 ("sNDA") to the FDA in the second half of 2013, seeking approval of the product to be manufactured by Grifols.

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

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 temporarily 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 has estimated will cost approximately $750,000. Accordingly, it has 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. No further charges were incurred during the three months ended March 31, 2013, for the retirement obligation, and the balance of the obligation on the Company's balance sheet in accrued liabilities at March 31, 2013, was $698,000. Also pursuant to the settlement, a previously accrued liability of $317,000 was canceled, which was recorded in cost of sales during the three months ended March 31, 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, as of March 31, 2013, 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 has incurred costs associated with these recalls, including administration costs, of approximately $300,000 through March 31, 2013, and the Company will continue to incur storage fees for the quarantined product until the time of its destruction. Through March 31, 2013, approximately 6,000 vials have been returned as a result of these recalls, and the Company believes that the potential number of additional vials that will be returned is minimal. The costs related to the recalls are being recognized as selling, general and administrative expenses on the Company's statement of operations as they are incurred. The charge to reduce the value of the inventory was recorded as a cost of product sales on the Company's statement of operations during the period in which the impairment was taken. As of March 31, 2013, $340,000 of the accrued destruction charges remained on the Company's balance sheet in accrued liabilities.

Additionally, 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. Additionally, 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 March 31, 2013.

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued
(Unaudited)

No reimbursements under the Amended Supply Agreement were made during the three months ended March 31, 2013, and 2012.

License Agreements and Acquired Development and Commercialization Rights

In March 2006, the Company in-licensed the technology and the exclusive development and commercialization rights to OFIRMEV in the U.S. and Canada from BMS. BMS sublicensed these rights to the Company under a license agreement with Pharmatop 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 November 2010, the Company entered into a data license agreement among Terumo Corporation ("Terumo"), the Company and SCR Pharmatop S.A. ("Pharmatop"). Under the data license agreement, the Company provided to Terumo certain data and information resulting from the Company's clinical development program for OFIRMEV for Terumo's use in obtaining regulatory approval for and commercializing the same intravenous formulation of acetaminophen in Japan. Further, the Company was to provide to Terumo, without charge, up to 500 hours of technical assistance and consulting services regarding the licensed technical information, data and know-how, as reasonably necessary to assist Terumo in obtaining regulatory approval and manufacturing capacity for the product candidate. In April 2011, the Company received an upfront payment of $5,329,000 under the terms of the data license agreement. If Terumo is successful in obtaining regulatory approval for and commercializing the product in Japan, the Company may also be entitled to an additional lump-sum payment upon the first commercial sale of the product candidate and royalty payments on any commercial sales of the product in Japan.

In accordance with multiple-element arrangement guidance, the Company determined both the data license and consulting service deliverables were separate units of accounting, each having value on a standalone basis. The Company estimated the fair value of the data license based upon similar proposals from third parties and internal costs incurred in developing the data and obtaining similar rights. The value of the consulting services was based on contracts the Company had engaged with third parties for similar services. The Company allocated the value of the payment received on a relative fair value basis and will recognize the consideration allocated to the data license upon delivery and the consideration allocated to the consulting services as such services are rendered. There is no right of return or similar refund provisions in the data license agreement. During 2011, the Company transferred the data and related information to Terumo and provided a portion of the consulting hours and in April 2011, the Company recognized $5,210,000 of licensing revenue pursuant to the agreement for the data transfer and consulting hours provided. As of December 31, 2012, the remaining balance of $119,000 had been recognized as licensing revenue. No licensing revenue was recognized for the three months ended March 31, 2013 and 2012. Any milestones or royalties received from potential sales of the product candidate will be recognized as revenue in the period earned.

Legal Matters

In August 2011, the Company and Pharmatop filed suit in the United States District Court for the District of Delaware against Paddock Laboratories, Inc., Perrigo Company and Paddock Laboratories, LLC, collectively 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 follows 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 alleges that Perrigo and Exela have 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 has filed an answer in the case that asserts, among other things, non-infringement and invalidity of the asserted patents, and has also filed counterclaims. A date for the bench trial in the case with Exela has been scheduled for May 2013.

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 Company, or Perrigo, has been 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 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 us. 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 has granted Perrigo the non-exclusive right to market a generic intravenous 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.

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

In September 2012, an unidentified third party filed with the 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 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. 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.

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 lacks standing to seek such relief. Exela also seeks declaratory judgment that the USPTO’s rules and regulations that allow for revival of abandoned, international patent applications under the “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. A decision by the Court of Appeals in favor of Exela could result in the invalidation of the ‘218 patent.

In January 2013, the Company filed suit in the United States District Court for the Southern District of California and the Northern District of Illinois against Fresenius Kabi USA, LLC, or Fresenius. The lawsuits follow a December 2012 notice by Fresenius concerning its filing of a New Drug Application, or NDA, containing a Paragraph IV patent certification with the FDA for a generic version of OFIRMEV. In the lawsuits, the Company alleges that Fresenius has infringed the ‘222 patent and the ‘218 patent by filing its NDA seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. Fresenius has filed an answer in the Southern District of California that asserts, among other things, non-infringement and invalidity of the asserted patents, and has also filed counterclaims.

In February 2013, the Company filed suit in the United States District Court for the Southern District of California and the District of New Jersey against Sandoz, Inc., or Sandoz. The lawsuits follow a December 2012 notice by Sandoz concerning its filing of an ANDA containing a Paragraph IV patent certification with the FDA for a generic version of OFIRMEV. In the lawsuits, the Company alleges that Sandoz has infringed the ‘222 patent and the ‘218 patent by filing its ANDA seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. Sandoz has filed an answer in the Southern District of California that asserts, among other things, non-infringement and invalidity of the asserted patents, and has also filed 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 courts may order.

Regardless of the outcome of any litigation, no NDA or ANDA relying in whole or in part on studies conducted by or for the Company can receive final approval from the FDA before expiration of the regulatory exclusivity period for OFIRMEV. Specifically, the FDA has granted OFIRMEV three years of regulatory exclusivity, which expires November 2, 2013. The Company intends to vigorously enforce its intellectual property rights relating to OFIRMEV to prevent the marketing of infringing generic products prior to the expiration of its patents. The ‘222 patent expires August 5, 2017 (or February 5, 2018 if pediatric exclusivity is granted) and the ‘218 patent expires June 6, 2021 (or December 6, 2021 if pediatric exclusivity is granted). However, given the unpredictability inherent in litigation, the Company cannot predict the outcome of 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.

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued

(Unaudited)

12. Stockholders' Equity

Authorized Shares

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

Private Placement

In February 2009, the Company issued 12,039,794 shares of its common stock at a purchase price of $7.13 per share pursuant to a private placement. In addition to the shares of the Company's common stock, warrants to purchase up to 6,019,897 additional shares of the Company's common stock were also issued as part of the transaction at a price of $0.125 per warrant. Each warrant is immediately exercisable and has a five-year term. The warrants may be exercised through either cash or net exercise for one share of common stock at a price of $7.84 and have been accounted for as permanent equity. As of March 31, 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 principally one segment. It sells its only product, OFIRMEV, primarily to established wholesale distributors in the pharmaceutical industry, including the nation's three leading wholesale pharmaceutical distributors: Cardinal Health, Inc., AmerisourceBergen Corporation and McKesson Corporation.

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

	Three Months Ended March 31,	
	2013	2012
AmerisourceBergen Corporation	34%	32%
Cardinal Health, Inc.	32%	35%
McKesson Corporation	27%	26%

Related receivables from customers representing 10% or more of total product revenue for each period are as follows (as a percentage of total gross trade receivables):

	Three Months Ended March 31,	
	2013	2012
AmerisourceBergen Corporation	33%	25%
Cardinal Health, Inc.	34%	43%
McKesson Corporation	26%	26%

CADENCE PHARMACEUTICALS, INC.

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued
(Unaudited)

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

Pursuant to Internal Revenue Code Sections 382 and 383, annual use of the Company's net operating loss and research and development credit carryforwards may be limited in the event of a cumulative change in ownership of more than 50% within a three-year period. The Company has not completed this analysis regarding the limitation and therefore has removed the (1) deferred tax assets for net operating losses of approximately $149,071,000 and (2) research and development credits of approximately $6,809,000 generated through 2012 from its deferred tax asset schedule. Further, the Company has recorded a corresponding decrease to its valuation allowance. When this analysis is finalized, the Company plans to update its deferred tax asset and valuation allowance accordingly. The Company expects to complete this analysis within the next three months and, as a result, the Company may have a change in the unrecognized tax benefits that are recorded. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact the Company's effective tax rate.

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

Introduction

This discussion may contain forward-looking statements that involve risks and uncertainties. As used herein, the terms "we," "us," or "our" refer to Cadence Pharmaceuticals, Inc., a Delaware corporation. Our actual results could differ materially from those anticipated in any forward-looking statements as a result of many factors, including those set forth below under the caption "Risk Factors." The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 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 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 initial focus during the launch of OFIRMEV was to ensure formulary adoption, which we believe was an important first step to obtain broad market acceptance for the product, and as of March 31, 2013, OFIRMEV had been successfully placed on formulary at approximately 2,200 institutions. Our current focus is educating doctors, pharmacists and other healthcare professionals on the appropriate use of OFIRMEV and effective approaches to utilizing multimodal analgesia. We continue to see a positive impact from this strategy as our revenue has consistently grown each quarter since launch. More specifically, the net product revenue we reported for the quarter ended March 31, 2013, was $23.6 million, which included the one-time recognition of $2.6 million in deferred revenue on previously shipped product. This recognition of previously deferred revenue had no impact on our cash balances. Excluding the recognition of previously deferred revenue, our net product revenue was $21.0 million for the quarter ended March 31, 2013, which represents an increase of more than 160% from the first quarter of 2012.

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 second half 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 temporarily suspended production of OFIRMEV by Baxter, and in March 2013, we and Baxter mutually agreed to terminate the supply agreement.

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 March 31, 2013, we have received total net proceeds of approximately $444.1 million from the sale of our preferred stock, common stock and warrants to purchase common stock. Additionally, we have entered into multiple loan and security agreements with Oxford Finance LLC, Silicon Valley Bank and General Electric Capital Corporation to provide us with growth capital, and as of March 31, 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 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 hospital 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 customers about OFIRMEV. As a result of these programs, over 4,000 unique accounts had ordered OFIRMEV as of March 31, 2013. Further, these customers have, on average, increased the average size of their orders. The impact of the continued growth in these metrics is evident in our net product revenue. Specifically, our net product revenue for the first quarter of 2013 was $23.6 million, which includes the one-time recognition of $2.6 million in deferred revenue on previously shipped product. Excluding the recognition of previously deferred revenue, our net product revenue for the three months ended March 31, 2013, was $21.0 million, which is approximately 160% more than the $8.0 million reported for the first quarter of 2012. See Critical Accounting Policies and Estimates — Revenue Recognition for further discussion of our revenue recognition policy and the change in our estimate for product returns.

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

Cost of Sales

Our cost of sales consists primarily of our third-party manufacturing fees, 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 take steps to reduce costs. We had also been incurring unabsorbed period costs related to our Baxter supply agreement, which we terminated in March 2013. As a result, our gross margin for the three months ended March 31, 2013, improved to 65%, as compared to 47% for the first quarter of 2012.

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 temporarily suspended production of OFIRMEV by Baxter, and in March 2013, we and Baxter mutually agreed to terminate our supply agreement for OFIRMEV. During the Baxter suspension, we continued to incur certain manufacturing costs, which were included in cost of sales for the year ended December 31, 2012, and we are obligated to pay the cost to remove our equipment located at Baxter's facility. We have estimated that this retirement obligation will cost approximately $0.7 million, which we recorded during the fourth quarter of 2012. Further, we placed certain inventory produced by Baxter on indefinite hold in February 2012, fully impairing the value of such inventory as of December 31, 2012. We decided to destroy this product and accrued $0.3 million for the destruction costs during the fourth quarter of 2012. Moreover, due to the termination of the supply agreement with Baxter, we reduced the carrying value of our manufacturing assets and manufacturing equipment and facility construction assets in process to their current estimated fair value as of December 31, 2012. See Critical Accounting Policies and Estimates — Long-Lived Assets for further discussion of this impairment.

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

License Fees and Patent Amortization

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

Research and Development Expenses

Our research and development expenses relate predominantly to the development of product candidates, including OFIRMEV. 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 began enrolling patients in an FDA-required post-approval clinical trial for OFIRMEV in pediatric patients under two years of age during the third quarter of 2012 and that trial is on-going. 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 incurred in relation to our medical affairs programs, including salaries, related employee benefits and costs incurred by our medical science liaisons; as well as the related professional fees for these functions, insurance and facility costs.

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

Interest and Other Income and Expense

Our interest income consists primarily of interest earned on our cash, cash equivalents and short-term investments. Interest expense consists of the interest we incur under our loan and security agreements and the amortization of debt issuance costs. Other income and expense includes gains or losses recognized on transactions denominated in foreign currencies and other transactions not related to our operations, including the waiver and termination of our option to purchase Incline and the sale of the Incline stock we held in January 2013.

Our current loan and security agreement had a principal balance of $30.0 million as of March 31, 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 stated interest rate of 10.9545% that is fixed 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.

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, substantial changes in our ownership may limit the amount of net operating loss carryforwards and development tax credit carryforwards that could be utilized annually in the future to offset taxable income. Any such annual limitation may significantly reduce the utilization of the net operating losses and tax credits before they expire. We have not completed a Section 382/383 study at this time to determine the impact ownership changes have had on our carryforwards but expect to complete the analysis within the next three months and, as a result, we may have a change in the unrecognized tax benefits that are recorded. In each period since our inception, we have recorded a valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As a result, we have not recognized any federal or state income tax benefit in our statement of operations and, due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact our effective tax rate.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the 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 the assessment of recoverability of long-lived assets, which primarily impacts operating expenses when we impair assets or accelerate depreciation. We review our estimates, judgments, and assumptions used in our accounting practices periodically and reflect the effects of revisions in the period in which they are deemed to be necessary. We believe that these estimates are reasonable, however, our actual results may differ from these estimates.

Revenue Recognition

We sell OFIRMEV to wholesalers and directly to hospitals and other end-user customers. Our primary distribution channel for OFIRMEV involves our third party logistics distributor, which distributes the product to independent wholesalers, which in turn distribute the product directly to hospitals and other end-user customers. We also sell the product directly to 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 during the three months ended March 31, 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. The corresponding impact of this one-time adjustment was a reduction of $1.7 million in both our loss from continuing operations and net loss for the three months ended March 31, 2013. The per share net impact of the adjustment for the three months ended March 31, 2013, was a reduction in net loss of $0.02 per share.

We record certain fees, sales reserves and allowances as a reduction to gross revenue and deferred revenue, as applicable. These reserves and allowances include distribution service fees, a prompt payment reserve, a group purchasing discount and administrative service fee, 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 government programs and certain customers a predetermined discount that is 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 downtime are recognized as expense in the period in which they are incurred.

In February 2012, we placed certain inventory produced by Baxter on indefinite hold and temporarily suspended production of OFIRMEV by Baxter. Production by Baxter remained suspended through December 31, 2012, and in March 2013, we and Baxter mutually agreed to terminate our supply agreement for OFIRMEV. We recorded charges of $5.6 million for the fourth quarter of 2011 and $0.2 million for the first quarter of 2012 in cost of sales to fully write-down the value of this inventory. Further, we decided to destroy this product as a result of a second voluntary recall of product manufactured by Baxter and have accrued for those costs as of December 31, 2012. During the suspension, we transitioned the supply of OFIRMEV to BMS Anagni, which is presently our sole supplier for the product. No supply shortages are anticipated as a result of the termination of our supply agreement with Baxter as we continue to distribute product manufactured by BMS Anagni.

Stock-Based Compensation

We account for stock-based compensation by calculating the fair value of the award on the date of grant for equity awards or, in the case of liability classified awards, we revalue the awards each reporting period until the awards are subsequently classified as equity awards, or otherwise vest. 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, we reduced the carrying value of our manufacturing assets and 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. The carrying value on our balance sheet of the manufacturing assets located at Baxter at March 31, 2013 and December 31, 2012 was $1.0 million, and the value of the manufacturing equipment and facility construction assets in process was $0.4 million. The balance of our accrued asset retirement obligation, included in accrued liabilities, at March 31, 2013 and December 31, 2012, was $0.7 million.

Results of Operations

Three-Month Periods Ended March 31, 2013 and 2012

Revenue

During the three months ended March 31, 2013, we recognized $23.6 million of net product revenue from the sale of OFIRMEV to hospitals and other end-users, which represents an increase of $15.6 million, or 195%, from the $8.0 million reported for the comparable period in 2012. Included in net revenue for the three months ended March 31, 2013, is $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 in 2013 is primarily attributable to the continued expansion of our end-user customer base and increased use of OFIRMEV in surgical settings. For example, unique end-user accounts increased to over 4,000 at March 31, 2013, from approximately 2,200 at January 1, 2012. Further, this growing customer base has increased the average frequency with which they order the product as well as their average order size. For example, the average order size for end-user customers for the first quarter of 2013 increased more than 28%, as compared to the average order size for the first quarter of 2012.

The net revenue reported for the three months ended March 31, 2013, was also positively impacted by price increases for OFIRMEV implemented in July 2012 and January 2013. The impact of the higher average net selling price during the three months ended March 31, 2013, as compared to the same period in 2012 was approximately $2.6 million 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 March 31, 2013, was $8.2 million, or 35% of net product revenue, compared to $4.2 million, or 53% of net product revenue, for the comparable period in 2012. The improvement in our costs of sales as a percentage of net product revenue during the first three months of 2013 was primarily due to higher freight costs incurred during the first quarter of 2012 as a result of a temporary supply disruption during that period that were not incurred in 2013. More specifically, 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, and we expedited certain shipments to our wholesalers during this period. We also sustained unabsorbed manufacturing costs due to fixed costs that we incurred during the temporary suspension of production by Baxter, and incurred a loss from an inventory write-down during the three months ended March 31, 2012. Our costs of product sales for the three months ended March 31, 2013 were impacted by a credit we recorded of $0.3 million during the period pursuant to the cancellation of a previously accrued liability with Baxter, which was partially offset by a $0.1 million charge we incurred for product that had spoiled during the period.

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 March 31, 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 $0.1 million, or 10%, for the three months ended March 31, 2013, to $1.4 million, compared to $1.5 million for the comparable period in 2012. This decrease was primarily due to lower personnel costs, mostly offset by costs incurred on our FDA-required post-approval clinical trial for OFIRMEV in pediatric patients under two years of age, which we began enrolling during the third quarter of 2012.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased $1.9 million, or 8%, for the three months ended March 31, 2013, to $21.6 million, compared to $23.5 million for the comparable period in 2012. This decrease was mostly attributable to the timing of educational and marketing programs during the year, as we had front-loaded the timing of these programs in 2012. Additionally, we incurred lower personnel costs for our hospital sales specialists during the first quarter of 2013, as compared to 2012. Partially offsetting these reductions, however, were higher legal expenses incurred during the first three months of 2013, as compared to the same period in 2012, related to our ongoing intellectual property litigation.

Other Income and Expenses, Net

Net other income for the three months ended March 31, 2013, was $6.6 million, representing an increase of $7.7 million from the net expense of $1.1 million incurred during the comparable period in 2012. This change is due to the $13.5 million we received from the waiver and termination of our Incline option and the $1.5 million we received from the sale of our Incline stock. 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 three months ended March 31, 2013. No similar gain was recorded during the same period in 2012.

Our interest expense during the three months ended March 31, 2013, of $1.1 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 $45.0 million in research and development costs through March 31, 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. 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, as of March 31, 2013, we had realized approximately $41.0 million in gross profit on sales of OFIRMEV and we continued to operate at a 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 for consideration of $13.1 million in cash. Additionally, we received $1.5 million for the shares of Incline stock we sold as part of the transaction.

Since inception, our operations have been financed primarily through the sale of equity securities, in both public and private offerings. From our inception through March 31, 2013, we have received net proceeds of approximately $444.1 million from the sale of our preferred stock, common stock and warrants to purchase common stock. Through March 31, 2013, the sales of shares of our preferred stock, common stock and warrants were as follows:

- from July 2004 to March 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 3,233,196 shares of common stock to our founders, employees, directors and consultants for aggregate net proceeds of $3.1 million;
- from July 2004 to August 2004, we issued and sold a total of 8,085,108 shares of Series A-1 preferred stock for aggregate net proceeds of $7.5 million;
- from June 2005 to September 2005, we issued and sold a total of 17,675,347 shares of Series A-2 preferred stock for aggregate net proceeds of $17.6 million;
- in March 2006, we issued and sold a total of 53,870,000 shares of Series A-3 preferred stock for aggregate net proceeds of $53.8 million;
- in the fourth quarter of 2006, we completed our initial public offering in which we issued and sold a total of 6,900,000 shares of our common stock for aggregate net proceeds of $55.9 million;
- in February 2008, we completed a registered direct offering pursuant to an effective shelf registration in which we issued and sold a total of 9,240,307 shares of our common stock for aggregate net proceeds of $49.1 million;
- in February 2009, we raised aggregate net proceeds of approximately $86.2 million through a private placement transaction in which we issued 12,039,794 shares of common stock and warrants to purchase up to 6,019,897 additional shares of common stock at a price of $7.84, all of which remain outstanding at December 31, 2011;
- 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 March 31, 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 March 31, 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 March 31, 2013 from our loan agreements.

Liquidity

As of March 31, 2013, we had $60.5 million in cash and cash equivalents, compared to $58.3 million at December 31, 2012. This $2.2 million increase in our cash and cash equivalent balance during the first quarter of 2013 was primarily due to the $13.1 million we received for the waiver and termination of our Incline option and the $1.5 million we received from the sale of our Incline stock, which was mostly offset by our use of cash in operations. During the three months ended March 31, 2013, this use of cash was $12.5 million, which represents a decrease of $5.7 million from the $18.2 million used in operations during the comparable period in 2012. The reduction in our use of cash from operations during the current period was mostly due to the increase in our revenue. However, the impact of our increased revenue was partially offset by an increase in our working capital requirements during the first quarter of 2013. More specifically, during the three months ended March 31, 2013, we used $0.9 million for prepaying certain expenses. Further, our accounts receivable balance increased $2.7 million during the three months ended March 31, 2013 to $8.9 million, from $6.2 million at December 31, 2012. Despite this increase in our accounts receivable balance, however, our collection period at March 31, 2013, remained relatively constant at approximately 32 days based on our calculation of days sales outstanding.

We used less than $0.1 million of cash for purchases of property and equipment during the three months ended March 31, 2013, and our net property and equipment balance remained relatively constant at approximately $1.9 million. These assets, however, are mostly manufacturing-related assets, including machinery, construction-in-process assets and an asset retirement obligation, related to our supply agreement with Baxter that we terminated in March 2013. As of March 31, 2013, our manufacturing equipment remained in the Baxter facility and we are responsible for the removal of the equipment, which must occur within 180 days of the termination of the agreement. As of December 31, 2012, we had fully accrued for the estimated $0.7 million asset retirement obligation, and as of March 31, 2013, $0.7 million remained outstanding. Moreover, we accrued $0.3 million for the estimated destruction costs for inventory manufactured by Baxter as of December 31, 2012. As of March 31, 2013, a liability of $0.3 million remains on our balance sheet in accrued liabilities for this destruction.

We made no principal payments under our debt agreements during the first quarter of 2013 and our outstanding principal balance remained at $30.0 million as of March 31, 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;
- our capacity to manage our commercial infrastructure and related expenses, including our hired 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;
- 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;
- 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 the OFIRMEV and maintain our market exclusivity;
- costs associated with any product recall or investigation into quality concerns;
- our ability to successfully procure sufficient quantities of OFIRMEV and maintain adequate supply levels;

- regulatory developments affecting OFIRMEV or the products of our competitors; and
- the level of underlying hospital demand for OFIRMEV and our wholesalers' buying patterns.

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 March 31, 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 second half of 2013; our estimate of the cost to remove equipment from Baxter's facility and the destruction costs for the recalled lots of OFIRMEV manufactured by Baxter; 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 abbreviated new drug applications ("ANDAs") for generic versions of OFIRMEV; the potential that we may be required to continue intellectual property litigation for substantial lengths of time or file additional lawsuits to defend our patent rights from challenges by companies that have submitted ANDAs for generic versions of OFIRMEV, and the substantial costs associated with such lawsuits; the potential introduction of generic competition to OFIRMEV in the event we are unsuccessful in current or future intellectual property litigation; our dependence on our licensors for the maintenance and enforcement of our intellectual property rights; the potential product liability exposure associated with pharmaceutical products such as OFIRMEV and other products we may in-license or acquire; our ability to fully comply with numerous federal, state and local laws and regulatory requirements that apply to our commercial activities; public concern regarding the safety of drug products such as OFIRMEV, which could result in the implementation by regulatory agencies of new requirements 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 March 31, 2013, our cash equivalents and short-term investment holdings consisted of investments in money market funds, debt obligations of municipalities, commercial paper 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 March 31, 2013 (in thousands):

	Amortized Cost Basis	Fair Value
Cash equivalents	$ 58,745	$ 58,745
Available-for-sale marketable securities	$ 3,745	$ 3,745

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 March 31, 2013, was $30.0 million, and is collateralized by substantially all of our assets (excluding intellectual property). Under the terms of our current agreement, 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 believe we were in compliance with all such covenants under the agreement as of March 31, 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. As of January 1, 2013, we began to recognize revenue and estimate returns on sales of our product to wholesale customers. Prior to this time, we deferred the recognition of revenue until the time that the product had been sold by the wholesaler to a hospital or other end-user customer because the lack of historical product return data did not allow us to reasonably estimate returns on sales to the wholesalers. However, based upon product return history gathered since the commercial launch of our product in January 2011, we determined that we have sufficient data to reasonably estimate a return rate as of January 1, 2013. As a result, we changed our product return estimate and are now recognizing revenue on sales to wholesalers. The implementation of this change in our product return estimate resulted in the implementation of new controls, as well as changes to existing controls, systems and procedures that affect our internal control over financial reporting.

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

PART II. OTHER INFORMATION

Item 1. ***Legal Proceedings***

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 follows the notices that we 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, we allege that Perrigo and Exela have 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 has filed an answer in the case that asserts, among other things, non-infringement and invalidity of the asserted patents, and has also filed counterclaims. A date for the bench trial in the case with Exela has been scheduled for May 2013.

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 has been 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 have granted Perrigo the non-exclusive right to market a generic intravenous 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.

In September 2012, an unidentified third party 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. 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 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.

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 lacks standing to seek such relief. Exela also seeks declaratory judgment that the USPTO's rules and regulations that allow for revival of abandoned, international patent applications under the "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. A decision by the Court of Appeals in favor of Exela could result in the invalidation of the '218 patent.

In January 2013, we filed suit in the United States District Court for the Southern District of California and the Northern District of Illinois against Fresenius Kabi USA, LLC, or Fresenius. The lawsuits follow a December 2012 notice by Fresenius concerning its filing of a New Drug Application, or NDA, containing a Paragraph IV patent certification with the FDA for a generic version of OFIRMEV. In the lawsuits, we allege that Fresenius has infringed the '222 patent and the '218 patent by filing its NDA seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. Fresenius has filed an answer in the Southern District of California that asserts, among other things, non-infringement and invalidity of the asserted patents, and has also filed counterclaims.

In February 2013, we filed suit in the United States District Court for the Southern District of California and the District of New Jersey against Sandoz, Inc., or Sandoz. The lawsuits follow a December 2012 notice by Sandoz concerning its filing of an ANDA containing a Paragraph IV patent certification with the FDA for a generic version of OFIRMEV. In the lawsuits, we allege that Sandoz has infringed the ‘222 patent and the ‘218 patent by filing its ANDA seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. Sandoz has filed an answer in the Southern District of California that asserts, among other things, non-infringement and invalidity of the asserted patents, and has also filed 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 courts may order.

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

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

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

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

In March 2013, we 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 plastic bags. We plan to submit a supplemental NDA to the FDA in the second half 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.

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

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

For example, in February 2012, we announced a voluntary recall of a single lot of OFIRMEV that was manufactured by our previous contract manufacturer, Baxter Healthcare Corporation, or Baxter, and in July 2012, we announced a second voluntary recall of product manufactured at Baxter's facility due to the presence of unidentified, visible particles in a limited number of vials 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. As a result of the first recall, during the first quarter of 2012, some of our customers experienced short-term supply delays due to the temporary suspension of shipments from Baxter before we were able to expedite sufficient shipments of OFIRMEV from BMS Anagni. In addition, during that time we incurred higher freight costs to expedite shipments of OFIRMEV from BMS Anagni in order to meet demand for the product following the temporary suspension at Baxter's facility. We also continued to incur unabsorbed manufacturing costs due to fixed costs that accrued under our supply agreement with Baxter during the time that Baxter's manufacturing of the product was suspended.

As a result of the second recall, we decided to destroy the Baxter-manufactured finished product inventory that we previously placed on indefinite hold. We recorded charges of $5.8 million in relation to this product due to uncertainty as to the amount of time that would be required to complete the investigation and whether the product would have sufficient remaining shelf life or otherwise be saleable after the investigation was completed. In March 2013, we and Baxter mutually agreed to terminate our supply agreement for OFIRMEV. Under the termination agreement, we are 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. 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 certain manufacturing assets involved with the manufacture of OFIRMEV under the terminated development and supply agreement with Baxter.

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

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 intravenous acetaminophen for our targeted indications that do not directly infringe our in-licensed patent rights. The commercial opportunity for OFIRMEV could be significantly harmed if competitors are able to develop alternative formulations outside the scope of our in-licensed patents.

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 lawsuits to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of intravenous acetaminophen, such as our intellectual property litigation, including any such costs we may be required to expend if our licensors are unwilling or unable to do so.

Until we can generate a sufficient amount of revenue from sales of OFIRMEV, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, as well as through interest income earned on cash and investment balances. We have engaged in various financing activities in the past. In May 2011, for example, we established a universal shelf registration statement to permit us, from time to time, to offer and sell up to $150.0 million of equity or debt securities. In November 2011, we undertook a public offering of common stock using our universal shelf registration statement that raised net proceeds of approximately $77.3 million. In addition, 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.

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

OFIRMEV remains subject to ongoing FDA requirements with respect to manufacturing, labeling, packaging, storage, distribution, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. The FDA has the authority to regulate the claims we make in marketing OFIRMEV to ensure that such claims are true, not misleading, supported by scientific evidence and consistent with the approved label for the drug. In addition, the discovery of previously unknown problems with OFIRMEV, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, may result in the imposition of additional restrictions, including withdrawal of the product from the market.

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

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

- issue warning letters or untitled letters;
- impose consent decrees, which may include the imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- impose fines other civil or criminal penalties;
- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements;
- exclude us from participating in U.S. federal healthcare programs, including Medicaid or Medicare; or
- seize or detain products or require a product recall.

In addition to FDA restrictions, numerous other federal, state and local laws and regulations apply to the promotion and sale of pharmaceutical products, such as 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 will also be 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. Manufacturers will be required to begin data collection on August 1, 2013, and report such data to CMS by March 31, 2014, and by the 90th day of every 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 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 receive approval outside of the U.S. to commercialize OFIRMEV or any other products or product candidates we may acquire.

Our rights to OFIRMEV include Canada, as well as the U.S. In order to market OFIRMEV, and any other products or product candidates we may acquire, in Canada or other jurisdictions outside of the U.S., we must comply with numerous and varying regulatory requirements of other countries regarding non-clinical testing, manufacturing, clinical safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. For example, in July 2012, we filed a New Drug Submission for OFIRMEV with Health Canada which was accepted for review in August 2012. We are currently evaluating the commercial prospects and partnering opportunities for the product in Canada and anticipate that the product would not be approved by Canadian regulatory authorities for at least 18 months after this submission, if at all. The regulatory approval process in other countries may include all of the risks detailed above as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the U.S. As described above, such effects include the risks that OFIRMEV and any other products may not be approved for all indications requested, which could limit the uses of our products and have an adverse effect on product sales and potential royalties, and that any regulatory approvals we may obtain may be subject to limitations on the indicated uses for which our products may be marketed or require us to perform costly, post-marketing follow-up studies.

Public concern regarding the safety of drug products such as OFIRMEV could result in new requirements from regulatory agencies to include unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs.

In light of widely publicized events concerning the safety risk of certain drug products, the FDA, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and the establishment of risk management programs that may, for example, restrict distribution of drug products after approval. For example, in January 2011, the FDA issued a press release and posted on its website a drug safety communication asking manufacturers of prescription drug products containing combinations of acetaminophen and opioid medications to limit the amount of acetaminophen to no more than 325 milligrams (mg) in each dosage unit (i.e. each tablet or caplet). In the announcement, the FDA also requested manufacturers to update labels for such products to include a boxed warning highlighting the potential for severe acetaminophen-induced liver injury and a warning highlighting the potential for allergic reactions. The boxed warning required for affected products reaffirms previous statements made by the FDA that most cases of liver injury are associated with acetaminophen doses that exceed 4,000 mg per day. While the FDA has indicated that this communication does not apply to intravenous acetaminophen, it is possible that the FDA may apply similar labeling requirements to OFIRMEV in the future. We reaffirmed our dosing recommendations for OFIRMEV in July 2011 following a news release by a major manufacturer of over-the-counter acetaminophen products announcing its plan to lower the recommended maximum daily dose of some oral acetaminophen products in an effort to reduce the risk of accidental acetaminophen overdose among its customers in the over-the-counter setting.

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

In addition, the Food and Drug Administration Amendments Act of 2007, or FDAAA, granted significant expanded authority to the FDA, much of which is aimed at improving the safety of drug products before and after approval. In particular, the law authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. It also significantly expands the federal government’s clinical trial registry and results databank, which we expect will result in significantly increased government oversight of clinical trials. Under the FDAAA, companies that violate these and other provisions of that law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. Data from clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional preclinical studies or clinical trials.

If 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 March 31, 2013, we had approximately 204 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 intravenous 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 intravenous 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 issued 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 ANDA for a generic drug product containing acetaminophen and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that, in the opinion of that third party, the patent listed in the Orange Book for a branded product is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of the third party's generic drug product. A third party certification that the new product will not infringe the Orange Book-listed patents for OFIRMEV, or that such patents are invalid, is called a Paragraph IV patent certification. If the third party submits a Paragraph IV patent certification to the FDA, a notice of the Paragraph IV patent certification must also be sent to us once the third-party's ANDA is accepted for filing by the FDA. A lawsuit may then be initiated to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of the receipt of notice of a Paragraph IV patent certification automatically prevents the FDA from approving the ANDA until the earlier of the expiration of a 30-month period, the expiration of the patents, the entry of a settlement order stating that the patents are invalid or not infringed, a decision in the infringement case that is favorable to the ANDA applicant, or such shorter or longer period as the court may order. If a patent infringement lawsuit is not initiated within the required 45-day period, the third-party's ANDA will not be subject to the 30-month stay. Regardless of the outcome of any litigation, no ANDA or NDA relying in whole or in part on studies conducted by or for us can receive final approval from the FDA before expiration of the regulatory exclusivity period for OFIRMEV in November 2013.

In August 2011, we and Pharmatop filed suit in the United States District Court for the District of Delaware against Perrigo and Exela alleging that each has infringed the '222 and '218 patents, which are listed in the Orange Book for OFIRMEV, by filing their respective ANDA seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of these patents. The 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 Exela and/or Perrigo, or such shorter or longer period as the Court may order. Each of Perrigo and Exela filed an answer in the case that asserts, among other things, non-infringement and invalidity of the asserted patents, and has also filed counterclaims. A date for the bench trial in this case has been scheduled for May 2013.

We settled with Perrigo and the case against Perrigo was dismissed in November 2012. Under the settlement and license agreements with Perrigo, Perrigo has been 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. Additionally, we granted Perrigo the non-exclusive right to market a generic intravenous 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.

In January 2013, we and Pharmatop filed suit in the United States District Court for the Southern District of California and the Northern District of Illinois against Fresenius Kabi USA, LLC, or Fresenius. In February 2013, we filed suit in the United States District Court for the Southern District of California and the District of New Jersey against Sandoz, Inc., or Sandoz. In these cases, we have alleged that each of Fresenius and Sandoz has each infringed the '222 and '218 patents by filing their respective NDA, in the case of Fresenius, or ANDA, in the case of Sandoz, seeking approval from the FDA to market a generic version of OFIRMEV prior to the expiration of our patents for OFIRMEV. 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 courts may order. Fresenius and Sandoz have both filed answers in the Southern District of California that assert, among other things, non-infringement and invalidity of the asserted patents, and have also filed counterclaims.

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 lacks standing to seek such relief. Exela also seeks declaratory judgment that the USPTO's rules and regulations that allow for revival of abandoned, international patent applications under the "intentional" standard are invalid, and similar relief in connection with one or more counterclaims it has filed in the Delaware litigation. 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 court's decision to the Court of Appeals for the Federal Circuit. 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 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. 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, or canceled 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.

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 March 31, 2013, we had an accumulated deficit of $449.0 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, we have incurred increased commercialization and marketing expenses since that time in connection with our launch of OFIRMEV. Further, since the launch of OFIRMEV, we have also incurred significant increased sales, marketing and outsourced manufacturing expenses. In addition, we are required to pay a minimum annual royalty under our license agreement for OFIRMEV and we have minimum purchase obligations under our supply agreements with our contract manufacturers for OFIRMEV. If our sales of OFIRMEV are insufficient to meet our minimum annual royalty obligations, we will be required to make larger royalty payments than would have otherwise been required based on sales of OFIRMEV alone. As a result, we expect to continue to incur significant operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

We currently have a limited history of revenue and may never be profitable.

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

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

We have incurred and anticipate continuing to incur significant costs associated with our efforts to commercialize, market and sell OFIRMEV. We also do not anticipate that we will achieve profitability for a period of time after generating material revenues, if ever. If we are unable to generate sufficient revenues, we will not become profitable and may be unable to continue operations without continued funding.

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

We were incorporated in May 2004 and have only been conducting operations with respect to OFIRMEV since March 2006. Prior to 2011, our operations were limited to organizing and staffing our company, in-licensing and conducting product development activities, including clinical trials and manufacturing development activities, and preparing to commercialize OFIRMEV. In January 2011, we launched OFIRMEV and began generating revenues. 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;
- our capacity to manage our commercial infrastructure and related expenses, including our hired 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;
- 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;
- 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 the OFIRMEV and maintain our market exclusivity;
- costs associated with any product recall or investigation into quality concerns;
- 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; and
- the level of underlying hospital demand for OFIRMEV and wholesalers' buying patterns.

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

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

To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership will be diluted. 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 expect to complete an analysis as to whether such a change of ownership has occurred in the next three months, and in such an event, we may be limited to the amount of net operating loss carryforwards and research tax credits that could be utilized annually in the future to offset taxable income. Any such annual limitation may significantly reduce the utilization of the net operating loss carryforwards and research tax credits before they expire. In addition, certain states have suspended the use of net operating loss carryforwards for certain taxable years, and other states are considering similar measures. Currently, California allows companies to utilize their net operating losses, however, new legislation could suspend the use of those losses in the future. As a result, we may incur higher state income tax expense in the future. Depending on our future tax position, continued suspension of our ability to use net operating loss carryforwards in states in which we are subject to income tax could have an adverse impact on our operating results and financial condition.

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

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

Risks Relating to Securities Markets and Investment in Our Stock

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

The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has recently experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Continued volatility in the overall capital markets could reduce the market price of our common stock in spite of our operating performance. Further, high stock price volatility could result in higher stock-based compensation expense.

The trading prices for our common stock during the 52 weeks ending March 31, 2013 ranged from a high of $6.85 to a low of $2.56. The market price of our common stock is likely to continue to be highly volatile and may fluctuate substantially due to many factors, including:

- announcements concerning our operating results and the hospital formulary acceptance of OFIRMEV;
- market conditions in the pharmaceutical and biotechnology sectors or the economy as a whole;
- price and volume fluctuations in the overall stock market;
- the failure of OFIRMEV to achieve commercial success;
- announcements of the introduction of new products by us or our competitors;
- developments pertaining to the 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 potential products;
- actual fluctuations in our quarterly operating results, and concerns by investors that such fluctuations may occur in the future;
- deviations in our operating results from the estimates of securities analysts or other analyst comments;
- additions or departures of key personnel;

- health care reform legislation, including measures directed at controlling the pricing of pharmaceutical products and 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 March 31, 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.

Item 6. ***Exhibits***

Exhibit Number	Description of Exhibit
10.1	Amended and Restated Supply Agreement, dated February 22, 2013, by and between the Company and Lawrence Laboratories, 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 February 28, 2013
10.2±*	Settlement and Termination Agreement, dated March 5, 2013, by and between the Company and Baxter Healthcare Corporation
10.3±*	Manufacturing and Supply Agreement, dated March 4, 2013, by and between the Company and Laboratorios Grifols, S.A.
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.

* Confidential treatment has been requested as to certain portions of this exhibit, which portions have been omitted and filed separately with the Securities and Exchange Commission.

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

SIGNATURES

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

CADENCE PHARMACEUTICALS, INC.

Dated: May 3, 2013

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

Table of Contents

INDEX TO EXHIBITS

Exhibit Number	Description of Exhibit
10.1	Amended and Restated Supply Agreement, dated February 22, 2013, by and between the Company and Lawrence Laboratories, 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 February 28, 2013
10.2±*	Settlement and Termination Agreement, dated March 5, 2013, by and between the Company and Baxter Healthcare Corporation
10.3±*	Manufacturing and Supply Agreement, dated March 4, 2013, by and between the Company and Laboratorios Grifols, S.A.
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.

* Confidential treatment has been requested as to certain portions of this exhibit, which portions have been omitted and filed separately with the Securities and Exchange Commission.

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

Exhibit 10.2

CONFIDENTIAL

CERTAIN MATERIAL (INDICATED BY AN ASTERISK) HAS BEEN OMITTED FROM THIS DOCUMENT PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

SETTLEMENT AND TERMINATION AGREEMENT

This **SETTLEMENT AND TERMINATION AGREEMENT,** (this "Termination Agreement") is effective as of March 5, 2013 (the "Effective Date") by and between **CADENCE PHARMACEUTICALS, INC.,** a corporation organized and existing under the laws of the State of Delaware and having its principal office at 12481 High Bluff Drive, Suite 200, San Diego, California 92130 ("Cadence"), and **BAXTER HEALTHCARE CORPORATION**, a corporation organized and existing under the laws of the State of Delaware and having its principal office at One Baxter Parkway, Deerfield, Illinois 60015 ("Baxter"). All references to "Cadence" and "Baxter" will include their respective Affiliates. Baxter and Cadence are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

RECITALS

WHEREAS, Cadence and Baxter are parties to that certain Amended and Restated Development and Supply Agreement dated January 28, 2011 (the "Supply Agreement"), pursuant to which Baxter agreed to provide certain development and commercial supply services to Cadence;

WHEREAS, the development and commercial supply services rendered by Baxter under the Supply Agreement are subject to that certain Quality Agreement between the Parties, dated December 18, 2007, and amended by the First Amendment, dated November 7, 2009, the Second Amendment, dated September 21, 2010 and the Third Amendment, dated February 7, 2011 (collectively, the "Quality Agreement");

WHEREAS, the Parties now desire to, among other things, terminate the Supply Agreement and the Quality Agreement (the Supply Agreement and the Quality Agreement are collectively referred to as the "Contract Documents") and fully and finally settle and resolve all existing and potential claims and disputes arising out of the Contract Documents;

NOW, THEREFORE, in consideration of the foregoing and the premises and conditions set forth herein, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1.0 DEFINITIONS

Capitalized terms and phrases used herein and not otherwise defined or modified herein below shall have the respective meanings ascribed thereto in the Supply Agreement.

The term "Contract Documents" will have the meaning set forth in the Recitals.

The term "Effective Date" will have the meaning set forth in the Recitals.

The term "Cadence Documentation" will have the meaning set forth in Section 4.1.3 of this Termination Agreement.

The term "Quality Agreement" will have the meaning set forth in the Recitals.

The term "Supply Agreement" will have the meaning set forth in the Recitals.

The term "Termination Agreement" will have the meaning set forth in the first paragraph of this Termination Agreement.

The term "Valid Claim" means a claim of U.S. Patent Nos. 6,028,222 and 6,992,218, including all extensions, continuations, continuations-in-part, divisionals, reissues, or reexaminations thereof, in each case whether granted or allowed before, on, or after the Effective Date that: (i) has not been revoked, declared unenforceable or unpatentable, or held invalid by a court or other governmental agency of competent jurisdiction that is unappealable or unappealed within the time allowed for appeal, (ii) has not been admitted to be rendered invalid or unenforceable through reissue, disclaimer or otherwise, and (iii) has not been finally cancelled, withdrawn, abandoned, allowed to lapse, or rejected by any governmental agency of competent jurisdiction.

2.0 TERMINATION OF THE SUPPLY AGREEMENT

2.1 The Parties hereby mutually agree to terminate the Contract Documents as of the Effective Date and, as a result of such termination, the Parties hereby acknowledge and agree that, except as expressly provided for under this Termination Agreement, (a) their respective rights and obligations under the Contract Documents are hereby terminated as of the Effective Date, and (b) neither Party shall have any further liability to the other Party under the Contract Documents or with respect to the Contract Documents.

2.2 The Parties hereby mutually agree that, upon the Effective Date:

2.2.1 Notwithstanding anything to the contrary contained herein, the following sections of the Supply Agreement shall survive the termination of the Supply Agreement: Sections 5.3, 10.4, 10.5, 10.6, 12.3.5, 14.1, 14.2.2, 14.2.3, 14.3.2 (except any sublicenses to the Baxter License granted by Cadence to Third Parties other than the licensors of the Cadence Licensed Intellectual Property, and only to the extent used in connection with the manufacture of the Product), 14.4, 20.4, 20.6, and Sections 12.3.1, 12.3.2, 12.3.3, and 12.3.4 (only for purposes of indemnity claims made pursuant to Article 15), in addition to Articles 13.0, 15.0, 18.0, 21.0, 22.0 and 23.0, together with any definitions used therein or in this Termination Agreement, which shall survive such termination;

2.2.2 The Confidential Disclosure Agreement shall remain in full force and effect; and

2.2.3 Notwithstanding anything to the contrary contained herein, the following sections of the Quality Agreement shall survive the termination of the Quality Agreement: Sections 6.4, 7.2.2, 7.2.3, 7.5, 7.7, 7.8, 7.9 and 8.1.

3.0 RELEASES

3.1 Except as set forth in Section 3.3 of this Termination Agreement, each Party does for itself and its Affiliates, heirs, successors, assigns, and personal representatives hereby release, acquit and forever discharge the other Party and such other Party's Affiliates, predecessors, successors, heirs, assigns, agents, employees, officers, directors and attorneys of and from any and all claims, actions or causes of action, demands, damages (both actual and punitive) costs, judgments, expenses, liabilities, attorneys' fees and legal costs, injunctive or declaratory relief, whether known or unknown, whether in law or in equity, whether in tort or contract, of any kind or character including without limitation claims to recover damages for breach of contract, negligence, fraud, unfair trade practices, or any cause of action whatsoever, which they now have, or might otherwise have, against the persons or entities released herein, arising from any known or unknown act or omission, whether undertaken prior to or after the Effective Date in connection with the Contract Documents, relating to any claim that was brought, could have been brought, or may be brought by any Party arising from the Contract Documents.

3.2 This Termination Agreement shall not be construed to be an admission of liability or wrongdoing by any Party. The Parties further agree that neither this Termination Agreement, nor the terms hereof or negotiations relating thereto, shall be offered in evidence in any proceeding for any purpose whatsoever, except to enforce the terms hereof or in any proceeding in which the terms of this Termination Agreement are applicable. Each Party agrees that this Termination Agreement shall remain confidential and shall not be disclosed by it to any Third Party for any reason at any time; *provided*, *however*, that, subject to Article 13 of the Supply Agreement, (i) each Party may disclose, in confidence and on a need-to-know basis, this Termination Agreement to its attorneys, accountants, lenders and potential lenders, directors, officers, employees, consultants, insurers, the licensors of the Cadence Licensed Intellectual Property and, with respect to Cadence, existing or potential acquirors, and (ii) each Party may disclose the terms of this Agreement as required by law or governmental regulation, or by valid legal process.

3.3 Notwithstanding anything in Sections 3.1 and 3.2 of this Termination Agreement to the contrary, the releases set forth in this Article 3 shall not apply with respect to: (a) any breach by either Party of this Termination Agreement, (b) any breach by either Party of Sections 13.0 (Confidentiality) or 14.0 (Intellectual Property) of the Supply Agreement, (c) any breach by Baxter of Section 12.3.5 (Cadence Licensed Intellectual Property) or 20.8 (Baxter Non-Compete Obligation) of the Supply Agreement, (d) any breach by Baxter of Sections 6.4 and 7.5 of the Quality Agreement, or (e) either Party's right to seek indemnification, or defend against any claim for indemnification, under Section 15.0 (Indemnification) of the Supply Agreement.

4.0 TRANSITION MATTERS

4.1 Transition Activities by Baxter.

4.1.1 Baxter represents and warrants that the list of Cadence Owned Equipment and spare parts therefor attached hereto as **Exhibit A** is an accurate and complete listing of all Cadence Owned Equipment and spare parts therefor Within Baxter's Control as of the Effective Date, and that it will provide to Cadence within ninety (90) days following the Effective Date: (a) all such spare parts, and (b) accurate and complete copies of all operational manuals, instructions, software, schematics, maintenance records, qualification documentation, work orders and drawings related to the Cadence Owned Equipment. For the avoidance of doubt, the term, "Within Baxter's Control," as used in this Termination Agreement, is intended by the Parties to include, as applicable, all Product, Product test, stability and retention samples, API, Materials, Cadence Owned Equipment and spare parts, warranties, guarantees, maintenance or service agreements related thereto, whether held by Baxter or its Affiliates, or by any contractor, agent or employee of Baxter.

4.1.2 Within thirty (30) days following the Effective Date, Baxter shall provide Cadence with (a) a complete list of the manufacturer's name, location and part numbers for all Materials, and (b) all warranties, guarantees, maintenance or service agreements related to the Cadence Owned Equipment that are Within Baxter's Control as of such date. Cadence shall develop its own specifications for the Materials, but may use as a basis for such specifications those specifications listed on **Exhibit D**.

4.1.3 Baxter represents that, to the best of its knowledge following due inquiry, **Exhibit B** represents an accurate and complete listing of (a) all Reports (including API/Formulation Specifications and Baxter Development Deliverables), Original Product Data, and all other documentation owned by Cadence and required to be produced and maintained by Baxter under Section 14.2.1 the Supply Agreement, and (b) all documents and information required to be provided to Cadence under Sections 5.9.1, 6.5.1, 6.6.1, 7.1.1,7.2, and 7.3.1(3) of the Quality Agreement), (collectively, the "Cadence Documentation"). Within ninety (90) days following the Effective Date, Baxter shall provide Cadence with complete copies, on electronic media, of all Cadence Documentation.

4.1.4 Within thirty (30) days following the Effective Date, Baxter shall, at no cost to Cadence, provide a final stability report for Product batch number **[***]*****.

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

4.1.5 Baxter shall, at no cost to Cadence: (a) destroy all Product Within Baxter's Control within ninety (90) days following the Effective Date, (b) destroy all retain, stability and all other test samples of the Product, API and all other Materials Within Baxter's Control within thirty (30) days following the completion of the applicable retention period for such test samples, Product, API and other Materials as set forth under the Quality Agreement. Promptly following such destruction, Baxter shall provide Cadence with a certificate, signed by a duly authorized representative of Baxter, listing the items destroyed, attesting to the destruction of such retain samples, API and Materials, and stating that no additional Product, Product test, stability or retention samples, API or Materials, exist Within Baxter's Control.

4.1.6 While the Product, Product test, stability or retention samples, API and other Materials are Within Baxter's Control after the Effective Date, Baxter shall be responsible for complying with all applicable statutory and regulatory requirements of all Regulating Groups in the Territory, and environmental and health and safety laws of the Territory.

4.2 Transition Activities by Cadence.

Within one hundred eighty (180) days following the Effective Date, Cadence shall, at no cost to Baxter, remove all Cadence Owned Equipment listed in Exhibit A attached hereto, from the Facility in accordance with Sections 20.4 and 20.6 of the Supply Agreement. In connection therewith, Baxter shall reasonably cooperate with, and provide full access to Cadence and its contractors engaged in such removal activities, and shall not unreasonably impede or delay any such activities. The Parties will cooperate to ensure that all such removal activities shall be conducted in a manner that is not unreasonably disruptive to Baxter, and does not impose unreasonable burdens on Cadence, Cadence's contractors, Baxter or Baxter's operations at the Facility. Baxter shall provide Cadence with a written estimate of any fees, costs or expenses that Baxter anticipates it will incur in connection with Cadence's removal of the Cadence Owned Equipment, and will obtain prior written approval from Cadence prior to incurring any such fees, costs or expenses. Cadence shall reimburse Baxter for all such fees, costs or expenses within thirty (30) days of receipt of any invoice for such pre-approved fees, costs or expenses from Baxter. Additionally, in the event that Cadence or its contractors damage the Facility in the course of removing the Cadence Owned Equipment, Cadence will ensure that such damage is repaired to Baxter's reasonable satisfaction.

4.3 For the avoidance of doubt, and notwithstanding any provisions of the Supply Agreement or the Quality Agreement to the contrary, under no circumstances shall either Party have any obligations to the other Party under Sections 6.2 (Supply and Purchase Obligations), 6.4 (Purchase Orders; Firm Purchase Orders); 7.0 (Manufacturing Fee); 20.1 (Payments) or 20.3 (Disposal of API or Product), nor shall Cadence have any obligation to Baxter under Sections 20.2 (Non-cancelable Costs and Expenses), or 20.5 (Restoration Costs of the Facility) of the Supply Agreement.

4.4 **[***]*****

4.5 Each Party shall reasonably cooperate with the other Party for purpose of supporting the closure or resolution of 483 observations issued by the FDA that relate to the Product and the Parties' activities under the Contract Documents; *provided, however*, that the provisions of Section 5.3 of the Supply Agreement shall continue to apply to all such activities and Communications.

5.0 GENERAL CONDITIONS

5.1 Statement Regarding Termination Agreement. A mutually agreeable statement regarding the Termination Agreement is attached hereto as **Exhibit C**, and each Party hereby consents to the use of such statement by the other Party in a press release or other public filing made in connection with activities under the Contract Documents and the execution of this Termination Agreement.

5.2 Non-Disparagement. Each Party agrees that it, unless required to do so by legal process, shall not make any Disparaging Statement, either directly or indirectly, whether orally or in writing, to any Third Party regarding the other Party's products, services, operations or employees. As used in this paragraph, the term, "Disparaging Statement," refers to any communication that, if publicized to a Third Party, would cause or tend to cause the recipient of the communication to question the business condition, integrity, competence or product quality of the Party to whom the communication relates.

5.3 Mutual Representations and Warranties. Each Party hereby represents and warrants to the other Party that (a) such Party has the authority and right to enter into and perform this Termination Agreement, (b) this Termination Agreement is a legal and valid obligation binding up on such Party and is enforceable in accordance with its terms, subject to applicable limitations on such enforcement based on bankruptcy laws and other debtors' rights, and (c) such Party's execution, delivery and performance of this Termination Agreement will not conflict in any material fashion with the terms of any other agreement or instrument to which it is or becomes a party or by which it is or becomes bound.

5.4 Injunctive Relief. Either Party may seek immediate injunctive or other interim equitable relief as necessary to enforce the terms of this Termination Agreement, provided that such relief is sought exclusively from a court as provided in Section 5.4 hereof.

5.5 Jurisdiction. This Termination Agreement will be deemed to have been entered into in the State of New York and its interpretation and construction and the remedies for its enforcement or breach are to be applied pursuant to and in accordance with the laws of the State of New York without regard to the United Nations Convention on Contracts for the International Sale of Goods and without giving effect to any choice of laws rule that would cause the application of the laws of any jurisdiction other than the internal laws of the State of New York, to the rights and duties of the Parties.

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

5.6 Counterparts. This Termination Agreement may be executed in counterparts, each of which shall be deemed an original, but such counterparts, when taken together, shall constitute one agreement.

5.7 Binding Effect. This Termination Agreement shall inure to the benefit of, and shall be binding upon, the Parties hereto and their respective legal representatives, successors and assigns.

5.8 Further Assurances. Each of Cadence and Baxter hereby agree to execute such further documents or instruments as may be necessary or appropriate to carry out the intention of this Termination Agreement.

5.9 Severability. In the event that any one or more of the provisions contained in this Agreement should be held invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein will not in any way be affected or impaired thereby, unless the absence of the invalidated provision(s) adversely affect the substantive rights of the Parties. The Parties agree to replace any invalid provision or parts thereof by new provision(s) which closely approximate the economic and proprietary results intended by the Parties.

5.10 Voluntary Agreement; Review with Counsel. The Parties have read this Termination Agreement and reviewed same with its legal counsel, on the advice of such counsel, they have freely and voluntarily entered into this Termination Agreement. Accordingly, the rule of construction that any ambiguity in this Agreement is to be construed against the drafting Party will not apply.

5.11 Notices. All notices or other communications which are required or permitted under this Termination Agreement will be in writing and deemed delivered at the time they are personally delivered, or on the business day next following the date of confirmed transmission when sent by facsimile, or two (2) business days after being sent by a nationally recognized overnight courier, and addressed as follows:

If to Baxter:

Baxter Healthcare Corporation
BioPharma Solutions
One Baxter Parkway
Deerfield, Illinois 60015
Attention: General Manager

Fax No.: [***]***

With a copy to:
Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, Illinois 60015
Attention: General Counsel
Fax No.: **[***]**

If to Cadence:

Cadence Pharmaceuticals, Inc.
12481 High Bluff Drive, Suite 200
San Diego, CA 92130
Attention: Chief Commercial Officer
Fax No: **[***]**

With a copy to:
Cadence Pharmaceuticals, Inc.
12481 High Bluff Drive, Suite 200
San Diego, CA 92130
Attention: General Counsel
Fax No: **[***]**

5.12 Entire Agreement. Except as expressly set forth herein, this Termination Agreement sets forth the entire agreement between the Parties, and fully supersedes any and all prior written or oral negotiations, commitments and writings between the Parties pertaining to the subject matter hereof. No promises, representations, understandings, warranties and agreements have been made by any of the Parties hereto except as referred to herein; and all inducements to the making of this Termination Agreement relied upon by either Party hereto have been expressed herein. No change or modification of this Termination Agreement shall be valid unless the same is in writing and signed by the Parties.

5.13 Counterparts. This Termination Agreement may be executed in two counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

[Remainder of page intentionally left blank.]

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

IN WITNESS WHEREOF, the Parties have executed this Termination Agreement by their duly authorized representatives as of the date first set forth above.

CADENCE PHARMACEUTICALS, INC.

By: /s/ Theodore R. Schroeder
Name: Theodore R. Schroeder
Title: President and Chief Executive Officer
Date: March 5, 2013

BAXTER HEALTHCARE CORPORATION

By: /s/ Robert Felicelli
Name: Robert Felicelli
Title: GFN, BPS
Date: March 5, 2013

EXHIBIT A
Cadence Owned Equipment

[***]* 14 PAGES REDACTED**

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT B - Cadence Documentation

[***]* 22 PAGES REDACTED**

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT C

Statement Regarding Termination Agreement

On March 5, 2013, Cadence Pharmaceuticals, Inc., and Baxter Healthcare Corporation, mutually agreed to terminate the Amended and Restated Development and Supply Agreement for OFIRMEV, which was effective as of January 2011. Under the termination agreement, Cadence is required to remove its manufacturing equipment from Baxter's facility within 180 days, and reimburse Baxter for anticipated costs or expenses related to such removal. Cadence is not required to reimburse Baxter for any remaining materials purchased by Baxter in connection with its manufacture of OFIRMEV, or restore Baxter's manufacturing facility to its condition prior to the installation of OFIRMEV-related improvements. The termination agreement also contains customary mutual releases.

EXHIBIT D

Specifications (Section 4.1.2)

Item #	Baxter Spec #	Description
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]***	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]		
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

Exhibit 10.3
Confidential

CERTAIN MATERIAL (INDICATED BY AN ASTERISK) HAS BEEN OMITTED FROM THIS DOCUMENT PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

MANUFACTURING AND SUPPLY AGREEMENT

dated as of March 4, 2013
by and between

Laboratorios Grifols, S.A.
and
Cadence Pharmaceuticals, Inc.

TABLE OF CONTENTS

MANUFACTURING AND SUPPLY AGREEMENT

THIS MANUFACTURING AND SUPPLY AGREEMENT (the "Agreement") dated as of the 4th day of March, 2013 (the "Effective Date"), is made by and between Laboratorios Grifols, S.A. ("Grifols"), a corporation organized under the laws of Spain, having its principal office at Calle Can Guasch, no. 2, Parets del Valles, Barcelona, Spain, and Cadence Pharmaceuticals, Inc., a corporation organized under the laws of the State of Delaware, U.S.A., having its principal office at 12481 High Bluff Drive, Suite 200, San Diego, California, 92130 ("Cadence").

RECITALS

WHEREAS, Cadence is a biopharmaceutical company focused on acquiring, in-licensing, developing and commercializing proprietary products principally for use in the hospital setting;

WHEREAS, Grifols is a company engaged in the production of pharmaceutical, diagnostic and hospital products;

WHEREAS, Cadence holds certain license rights in intellectual property relating to the Product (as defined below) for the Territory (as defined below) pursuant to the IV APAP Agreement dated February, 2006, between BMS (as defined below) and Cadence, as amended (the "IV APAP Agreement"), which sublicenses to Cadence certain intellectual property rights with respect to the United States and Canada under the License Agreement dated December 23, 2002, between SCR Pharmatop (as defined below) and BMS (the "Pharmatop License Agreement") and licenses to Cadence certain rights to use patents and know-how of BMS in the same jurisdictions;

WHEREAS, Cadence desires to purchase, and Grifols desires to manufacture and supply to Cadence, certain quantities of the Product for sale in the Territory; and

WHEREAS, Grifols has expertise in manufacturing the Product by virtue of a separate supply agreement between BMS and Grifols;

NOW, THEREFORE, in consideration of the foregoing recitals, mutual covenants, agreements, representations and warranties contained herein, the Parties, intending to be legally bound, hereby agree as follows:

ARTICLE I
DEFINITIONS

"Adverse Event" shall have the meaning provided in Section 5.9.

"Affiliate" shall mean any person or entity that, directly or indirectly, through one or more intermediaries, Owns, is Owned by or is under common Ownership with, a Party, where "Own," "Owned" or "Ownership" refers to (i) direct or indirect possession of at least fifty percent (50%) of the outstanding voting securities of a corporation or a comparable ownership in any other type of entity; or (ii) the actual ability of an entity, person or group to control and direct the management of the person or entity, whether by contract or otherwise.

"Annual Production Capacity Requirement" shall have the meaning provided in Section 2.3(b) of this Agreement.

"Applicable Laws" shall mean any and all applicable local, municipal, provincial, federal and international laws, statutes, ordinances, rules, regulations or operating procedures now or hereafter enacted or promulgated by any Governmental Body, including the Regulatory Acts.

"Bristol Myers Squibb Company" or "BMS" is a corporation organized under the laws of the State of Delaware, U.S.A., having its head office's address at 345 Park Avenue, New York, New York 10154, U.S.A.

"Business Day" shall mean a day which is not a Saturday, a Sunday, or a state or national holiday, as applicable, in the United States or with respect to matters herein pertaining to the Facility, at Facility's (as defined below) location.

"Cadence Indemnitee" shall have the meaning provided in Section 10.1 of this Agreement.

"Cadence Confidential Information" shall have the meaning provided in Section 12.2 of this Agreement.

"Cadence Intellectual Property" shall mean any and all Intellectual Property (as defined below) relating to the Product that (i) was owned by, or licensed to, Cadence prior to the Effective Date, and (ii) is developed, acquired by, or licensed to, Cadence after the Effective Date.

"Cadence Licensors" shall mean BMS and SCR Pharmatop.

"Confidential Information" shall have the meaning provided in Section 12.3 of this Agreement.

"Consent" shall mean any material consent, authorization, permit, certificate, license or approval of, exemption by, or filing or registration with, any Governmental Body (as defined below) or other person.

"Contract Year" shall mean the twelve-month period beginning on the first day of the month following the date on which a Drug Application (as defined below) for the Product is approved by the FDA (as defined below), and each successive twelve (12) month period thereafter during the Term.

"Current Good Manufacturing Practices" or "cGMPs" shall mean all applicable standards relating to manufacturing practices at the Facility for finished pharmaceutical products to be sold in the Territory (i) promulgated by any Governmental Body having jurisdiction over the manufacture of the Products at such Facility, in the form of laws or regulations or (ii) promulgated by any Governmental Body having jurisdiction over the manufacture of the Products at such Facility, in the form of guidance documents (including but not limited to advisory opinions, compliance policy guides and guidelines), which guidance documents are broadly implemented within the pharmaceutical manufacturing industry for such Products. For the avoidance of doubt, cGMPs shall include, without limitation, current good manufacturing practices as described in Parts 210 and 211 of Title 21 of the United States' Code of Federal Regulations, as updated, amended and revised from time to time.

"Days" (whether or not the word is capitalized) shall mean, except where specified otherwise, calendar days.

"Delivery Date" shall mean the date which Product is picked up from the Facility by Cadence's designated freight provider.

"Drug Application" shall mean any new drug application or an abbreviated new drug application, including any amendments or supplements thereto, filed by Cadence with the FDA pursuant to the FDCA (as defined below), or any comparable filing with any Drug Regulatory Authority in Canada, and includes any Common Technical Document for the Registration of Pharmaceuticals for Human Use filed with the FDA or any other Drug Regulatory Authority (as defined below) in the Territory.

"Drug Regulatory Authority" shall mean any Governmental Body or instrumentality with responsibility for granting any licenses, approvals, authorizations or granting pricing and/or reimbursement approvals necessary for the marketing and sale of pharmaceutical products in any regulatory jurisdiction including, without limitation, the FDA (as defined below).

"Facility" shall mean Grifols' manufacturing and testing facilities located at Passeig Fluvial, 24, Parets del Valles, Barcelona, Spain and at c/Logística, 2, Parets del Vallès, Barcelona, Spain.

"FDA" shall mean the United States Food and Drug Administration, and any successor agency of the United States government.

"FDCA" shall mean the United States Federal Food, Drug & Cosmetics Act, 21 U.S.C. 321 et seq., any amendments or supplements thereto, or any regulations promulgated or adopted thereunder.

"Firm Orders" shall have the meaning provided in Section 2.2 of this Agreement.

"GAAP" means generally accepted accounting principles, as consistently applied in the Territory.

"Governmental Body" shall mean any nation or government, any state, province, or other political subdivision thereof or any entity with legal authority to exercise executive, legislative, judicial, regulatory or administrative functions.

"Grifols Confidential Information" shall have the meaning provided in Section 12.1 of this Agreement.

"Grifols Indemnitee" shall have the meaning provided in Section 10.2 of this Agreement.

"Grifols Intellectual Property" shall mean any and all Intellectual Property relating to the manufacture of pharmaceutical products generally that (i) was owned by, or licensed to, Grifols prior to the Effective Date, or (ii) is developed or acquired by Grifols without reference to, or use of, any Cadence Intellectual Property or Cadence Confidential Information, after the Effective Date.

"Health Canada" shall mean Health Canada, and any successor agency of the Canadian government.

"Indemnified Party" shall have the meaning provided in Section 10.3 of this Agreement.

"Indemnifying Party" shall have the meaning provided in Section 10.3 of this Agreement.

"Intellectual Property" shall mean (i) trademarks, trademark registrations, trademark applications, service marks, service mark registrations, service mark applications, business marks, brand names, trade names, trade dress, names, logos and slogans and all goodwill associated therewith; (ii) patents, patent rights, provisional patent applications, patent applications, designs, registered designs, registered design applications, industrial designs, industrial design applications and industrial design registrations, including any and all divisions, continuations, continuations-in-part, extensions, substitutions, renewals, registrations, revalidations, reexaminations, reissues or additions, including supplementary certificates of protection, of or to any of the foregoing items; (iii) copyrights, copyright registrations, copyright applications, original works of authorship fixed in any tangible medium of expression, including literary works (including all forms and types of computer software, including all source code, object code, firmware, development tools, files, records and data, and all documentation related to any of the foregoing), musical, dramatic, pictorial, graphic and sculptured works; (iv) trade secrets, technology, discoveries and improvements, know-how, proprietary rights, formulae, confidential and proprietary information, technical information, techniques, inventions, designs, drawings, procedures, processes, models, formulations, manuals and systems, whether or not patentable or copyrightable, including all biological, chemical, biochemical, toxicological, pharmacological and metabolic material and information and data relating thereto and formulation, clinical, analytical and stability information and data which have actual or potential commercial value and are not available in the public domain; and (v) all other intellectual property or proprietary rights, in each case whether or not subject to statutory registration or protection.

"Invention(s)" shall have the meaning provided in Section 7.1(c) of this Agreement.

"IV APAP Agreement" shall have the meaning provided in the Preamble of this Agreement.

"Laboratory" shall have the meaning provided in Section 5.6 of this Agreement.

"Losses" shall mean, collectively, any and all claims, liabilities, damages, reduction in value, costs, expenses, including reasonable fees and disbursements of counsel and any consultants or experts and expenses of investigation, obligations, liens, assessments, court costs, arbitration or mediation fees, judgments, fines and penalties imposed upon or incurred by an Indemnified Party.

"Materials" shall mean (i) all raw materials, components, work-in-process and other ingredients required to manufacture the Product, including, without limitation, the active pharmaceutical ingredient, paracetamol (acetaminophen), and (ii) all packaging materials used in the manufacture, storage and shipment of the Product.

"Materials Certification" shall have the meaning provided in Section 4.4(b) of this Agreement.

"Party" shall mean either Cadence or Grifols as the context dictates, and "Parties" shall mean both Cadence and Grifols.

"PDUFA Fees" shall have the meaning provided in Section 3.6(c) of this Agreement.

"Person" shall mean any individual or corporation, company, partnership, trust, incorporated or unincorporated association, joint venture or other entity of any kind.

"Pharmatop License Agreement" shall have the meaning provided in the Preamble to this Agreement.

"Purchase Order" shall have the meaning provided in Section 2.4 of this Agreement.

"Purchase Price" shall have the meaning provided in Section 3.1 of this Agreement.

"Product" shall mean a sterile, non-pyrogenic formulation of paracetamol (acetaminophen) intended for intravenous infusion, with a concentration of 10 mg/ml in 100 ml, packaged in flexible bags, as more particularly set forth in the Specifications (as defined below).

"Quality Agreement" shall have the meaning provided in Section 4.5 of this Agreement.

"Quarter" shall mean the consecutive three-month periods commencing on each January 1, April 1, July 1 and October 1, of each calendar year during the Term (as defined below).

"Quarterly Forecast" shall have the meaning provided in Section 2.2 of this Agreement.

"Regulatory Acts" shall mean, as applicable, the FDCA, the rules and regulations thereunder, and any Applicable Laws and regulations governing the approval, manufacture, sale or licensing of pharmaceutical products or ingredients for inclusion therein of any other jurisdiction for which Grifols is then producing products.

"Reservation Fee" shall have the meaning provided in section 2.3(c) of this Agreement.

"SCR Pharmatop" is a civil law partnership organized under the laws of France, having its head office's address at 10, Square St. Florentin, 78150 Le Chesnay, France, recorded with the Register of Commerce and Companies of Versailles under No. 407552702.

"Specifications" shall mean the compilation of all specifications for Materials, formula, manufacturing, analytical and testing procedures, release, packaging, labeling, artwork and other processes relating to the manufacture of the Product. The preliminary Specifications for the Product are set forth on Exhibit A, and may be amended from time to time in accordance with Section 4.2 hereof.

"Term" shall have the meaning provided in Section 13.1 of this Agreement.

"Territory" shall mean means the United States (including Puerto Rico and all U.S. possessions and territories) and Canada.

"Third Party" shall mean any person or entity other than the Parties or their respective Affiliates.

"Third Party Claim" shall have the meaning provided in Section 10.3 of this Agreement

"Units" shall mean individual dosage units of the Product.

ARTICLE II
PURCHASE AND SALE OF PRODUCTS

2.1 General. Subject to the terms and conditions of this Agreement, during the Term, Grifols agrees to manufacture and sell to Cadence, and Cadence agrees to purchase from Grifols, the Product. The Product shall be manufactured by Grifols at the Facility solely for sale to Cadence, Cadence's Affiliates and sublicensees. Grifols will not otherwise produce or sell the Product, except as expressly agreed to in writing by Cadence, or to BMS and BMS' Affiliates. Nothing herein shall limit or otherwise restrict Cadence's right to purchase the Product during the Term of this Agreement from one or more alternate suppliers in addition to Grifols.

2.2 Quarterly Forecasts. During the Term of this Agreement, Cadence shall provide to Grifols a projection (each, a "Quarterly Forecast") of the anticipated quantities of the Product to be ordered by Cadence pursuant to Section 2.4 below during the next twelve (12) months (or such shorter period as remains under the Term of this Agreement). Cadence shall forecast in amounts comprising full batch quantities. Each Quarterly Forecast shall be made by Cadence in good faith, taking into account reasonable projections of demand for Products, and allowing for reasonable safety stock. Each Quarterly Forecast, once delivered in accordance herewith, shall constitute a binding commitment (each, a "Firm Order") to purchase the quantities of the Product specified for the first Quarter of such Quarterly Forecast period. Except for the Firm Order portion thereof, each Quarterly Forecast shall otherwise constitute a non-binding estimate of Cadence's then-current intention to purchase the Product quantities specified for the remainder of such Quarterly Forecast period. Cadence shall provide the first Quarterly Forecast to Grifols within ninety (90) days following the submission of a Drug Application for the Product manufactured at the Facility, and subsequent Quarterly Forecasts shall be provided on or before the first day of each Quarter thereafter.

2.3 Annual Supply and Purchase Commitments.

(a) Supply Commitment. During the Term, Grifols shall be obligated to maintain the capability to provide to Cadence the greater of: (i) [***] during each Contract Year; (ii) [***]; or (iii) [***]. For the avoidance of doubt, Cadence hereby acknowledges and agrees that the [***]*** mentioned in Section 2.3 (iii), above, [***].

(b) Annual Production Capacity Requirement. Cadence shall provide Grifols with Cadence's annual production capacity requirement for the Product for each Contract Year during the Term (the "Annual Production Capacity Requirement"). Unless otherwise agreed between the Parties, the Annual Production Capacity Requirement for each Contract Year shall be at least [***]. The Annual Production Capacity Requirement for the first Contract Year will be provided to Grifols within [***] days following the submission to the FDA of the first Drug Application for the Product manufactured at the Facility, and subsequent Annual Production Capacity Requirements shall be provided [***] prior to the beginning of each remaining Contract Year during the Term. Subject to Section 2.3(c), below, Cadence shall not be required to purchase from Grifols the Annual Production Capacity Requirement for any Contract Year.

(c) Capacity Reservation Fee. In the event that, by the end of each Contract Year, Cadence has not purchased a quantity of Product equal to the Annual Production Capacity Requirement for such Contract Year, subject to the provisions of Section 2.3(c)(iv) of this Agreement, Cadence shall pay Grifols a capacity reservation fee (the "Reservation Fee"). The Reservation Fee for each Contract Year shall be calculated as follows:

[***]

(iv) The Reservation Fee shall be in lieu of any minimum purchase commitment by Cadence under this Agreement. Further, and irrespective of anything in this Agreement to the contrary:

(A) Cadence shall not be required to pay a Reservation Fee for any Contract Year for which Grifols has not demonstrated, to Cadence's reasonable satisfaction, the ability to timely provide the full amount of the Annual Production Capacity Requirement for such Contract Year for any reason whatsoever including, without limitation, due to a Force Majeure event; and

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

(B) Cadence shall not be required to pay Grifols the Reservation Fee if this Agreement is terminated by Cadence pursuant to Sections 13.2(a), 13(b) or 13(c) of this Agreement, or by Grifols in breach hereof.

2.4 Purchase Orders. From time to time during the Term (typically, on a monthly basis), Cadence shall deliver purchase orders (each, a "Purchase Order") to Grifols for Product to be purchased pursuant to this Agreement. Each Purchase Order shall specify the quantity of the Product ordered, the destination for delivery of the Product, the required Delivery Date for the Product and the desired method of shipping. The Purchase Orders may be delivered electronically or by other means to such location as Grifols shall designate. Except with the prior written consent of Grifols, Cadence shall deliver each Purchase Order to Grifols not less than [***] days prior to the Delivery Date specified in the Purchase Order, and the minimum size of any order placed by Cadence shall be a full batches (i.e., [***]), with larger orders being in whole number multiples of a batch. All Purchase Orders shall be subject to Grifols' written acceptance, which shall be provided to Cadence within [***]*** of Grifols' receipt of the Purchase Order. Grifols shall supply the Product in response to each Purchase Order placed in accordance with the terms of this Agreement by Cadence, provided, that each such Purchase Order shall be deemed to have been fully satisfied if the quantity of each of the Products supplied is not more than [***]% and not less than [***]% of the quantity of each of the Products ordered. The maximum delivery lead time for all Product purchased by Cadence shall be [***] days after Grifols' receipt of each Purchase Order.

2.5 Accommodations. From time to time, due to significant unforeseen circumstances, Cadence may deliver to Grifols a Purchase Order for Product quantities in excess of those specified in the Firm Order portion of a Quarterly Forecast. Upon Cadence's written request, Grifols shall use its commercially reasonable efforts to provide Cadence with such excess Product quantities.

2.6 Notice of Anticipated Non-Performance. If at any time Grifols determines with reasonable certainty that it may not be able to satisfy fully the timing and/or amount of Cadence's Purchase Orders or the Firm Orders of the Quarterly Forecasts, Grifols shall promptly provide Cadence with written notice thereof.

2.7 Standard Forms; Conflicts. In ordering and delivering the Products pursuant hereto, Cadence and Grifols may use their standard forms (including, but not limited to, Purchase Orders and invoices), but nothing in those forms shall be construed to modify, amend or supplement the terms of this Agreement and, in case of any conflict herewith, the terms of this Agreement shall control, and any additional or modified terms contained in any such Purchase Order or other form shall be null and void and shall not be binding upon the receiving Party.

ARTICLE III
PURCHASE PRICE; SHIPMENT; PAYMENTS

3.1 Purchase Price. During the Term, Cadence shall pay Grifols for the Product in accordance with the applicable purchase price set forth in Exhibit B (the "Purchase Price"), subject to the price adjustments permitted in accordance with Exhibit B. The Purchase Price shall include [***]. Grifols shall obtain all Materials only from suppliers listed in Cadence's approved Drug Application for the Product, or approved by Cadence's authorized Quality Assurance representative in writing, and shall perform all testing of Materials required by such Drug Application or the Quality Agreement. Prior to the initial shipment of Product to Cadence, Cadence shall provide Grifols with a list of documentation required to be provided by Grifols with each shipment of the Product.

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

3.2 Invoices. Invoices for the Products shall be submitted by Grifols to Cadence at the address specified in Section 14.1 (or at such other address as Cadence shall direct from time to time in accordance with Section 14.1). Each invoice shall, at a minimum, identify all applicable Purchase Order numbers and provide the description, quantity, lot or batch number, and the Purchase Price for the Products covered thereby. Each invoice shall also separately itemize applicable sales, use, transfer, excise, value-added and similar taxes due with respect to the invoiced Products. Invoices shall be issued no earlier than the date Product is picked up from the Facility by Cadence's designated carrier.

3.3 Payment. Payments for Products invoiced under Section 3.2 above shall be due net [***]*** days from the date of Grifols' valid invoice. All payments shall be submitted by Cadence to Grifols at the address specified in Section 14.1 (or at such other address as Grifols shall direct from time to time in accordance with Section 14.1).

3.4 Payment Denominations. Payments made under this Agreement shall be made in Euros. All payments shall be made by wire transfer to such U.S. or non-U.S. bank account(s) as Grifols shall designate.

3.5 Shipment; Title; Transport.

(a) General. The Product shall be shipped EXW (as defined in INCOTERMS, 2010) Parets del Vallès, Barcelona, Spain, with title and risk of loss determined in accordance with Section 3.5(b) of this Agreement below. Shipping, insurance, and related charges consistent with this Section 3.5(a) will be included as separate line items in each invoice for the Product provided to Cadence. Grifols shall be responsible for contacting the freight provider designated by Cadence and coordinating with such freight provider the delivery of the Product on or before the Delivery Date and to the destination designated by Cadence. Grifols shall be responsible for loading the Product to be shipped with the designated freight provider and for customs export clearance. All Product, when delivered to the freight provider, shall be warranted as to comply with the Specifications.

(b) Title/Risk of Loss. Title to and risk of loss with respect to any Products shall pass from Grifols to Cadence when such Products are picked up by the freight provider specified by Cadence at the Facility. All Products delivered to Cadence shall be free and clear of any liens and encumbrances.

(c) Shelf Life. All Products sold to Cadence hereunder shall, as of the Delivery Date for each such Product, have a shelf-life [***].

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

3.6 Taxes.

(a) Cadence shall pay and otherwise be responsible for all applicable sales, Product, services, and transfer taxes in connection with any payment made by Cadence pursuant to this Agreement.

(a) Any income or other tax that one Party hereunder is required to withhold and pay on behalf of the other Party hereunder with respect to amounts payable under this Agreement shall be deducted from and offset against said amounts prior to payment to the other Party; provided, however, that in regard to any tax so deducted, the Party making the withholding shall give or cause to be given to the other Party such assistance as may reasonably be necessary to enable that other Party to claim exemption therefrom or credit therefore, and in each case shall furnish the Party on whose behalf amounts were withheld, proper evidence of the taxes paid on its behalf. Each Party shall comply with reasonable requests of the other Party to take any proper actions that may minimize any withholding obligation.

(b) PDUFA Fees: If applicable, Grifols shall comply with the Prescription Drug User Fee Act and shall reasonably cooperate with Cadence and reasonably assist Cadence in complying with same. Without limiting the generality of the foregoing, Grifols shall be responsible for the payment of any fees required under such act to be paid by Grifols, including without limitation with respect to (a) facilities to produce a finished dosage form of a human drug, (b) ownership, submission use or reference to a drug master file, and (c) to the extent resulting from changes to the manufacture or supply of the Product, prior approval supplements (the "PDUFA Fees"). Notwithstanding the foregoing, Cadence shall reimburse Grifols for that portion of any payments of PDUFA Fees made by Grifols that are directly related to the manufacture of the Product, but shall not be required to reimburse Grifols for (a) any PDUFA Fees related to changes to the manufacture or supply of Product proposed by Grifols, or (b) any PDUFA Fees, or portions thereof, related to the manufacture of products other than the Product.

ARTICLE IV
MANUFACTURE OF PRODUCT

4.1 Standards. Grifols shall procure all Materials, manufacture, test, package, store, label, release and deliver the Product in accordance with the Specifications, together with, as applicable, and in all material respects, the cGMPs, Applicable Laws and the Quality Agreement. Grifols shall at all times during the Term maintain the Facility in compliance with all Applicable Laws, rules and regulations, including but not limited to the cGMPs, and any environmental and health and safety laws. Grifols shall be responsible for all costs and expenses related to maintaining the Facility in compliance with such Applicable Laws.

4.2 Specification Changes.

(a) General. Cadence or Grifols may request a Specification change for the purpose of maintaining high standards for the Product, or for the purpose of complying with the Applicable Laws, in which event the Parties shall discuss in good faith the implementation of any such requested changes; provided, however, that no Specification change shall be made without the prior written consent of Cadence's authorized quality assurance representative.

(b) Procedure. If a Party feels that a Specification change is required, that Party shall provide a written notice of the required change to the other Party, which notice shall contain reasonably adequate details regarding the reasons for such change and the nature and extent of the requested change. Both Parties shall in good faith consider the merits of the requested change before deciding to pursue or not pursue the requested change. Once Cadence decides to implement a Specification change, both Parties will cooperate in effecting the Specification change on a timely basis in accordance with the procedures for such changes set forth in the Quality Agreement.

(c) Payment. If any Specification change can reasonably be demonstrated to materially increase or decrease Grifols' cost of producing any of the Products, then upon the mutual agreement of the Parties, the Purchase Price for the Product shall be increased or decreased by the amount of the demonstrated increase or decrease, as the case may be, in Grifols' cost of production.

(d) Labeling and Packaging. From time to time Cadence may require labeling or packaging changes that will affect the Products. These changes may either be initiated by Cadence, pursuant to this Section 4.2, or may be a requirement resulting from cGMP changes. Notwithstanding anything herein to the contrary, the prior, written approval of Cadence's authorized quality representative shall be required for the form and content of all such labeling or packaging changes prior to their implementation and use in connection with the Products, and thereafter Grifols shall be responsible for ensuring that all such changes are accurately reflected and/or incorporated in the labeling and packaging for the Products, in accordance with the procedures for such changes set forth in the Quality Agreement. The costs associated to any labeling and/or packaging change, as set forth in Exhibit C, shall be borne by Cadence, unless such changes are requested by Grifols.

4.3 Validations and Stability Studies. Grifols shall perform all validations and stability studies required by the Specifications, cGMPs, Applicable Laws, and the Quality Agreement in connection with the regular course of manufacturing the Products for commercial supply, subject to the prior written approval of Cadence's authorized quality assurance representative of all such studies, including the protocols and methodology therefor. Cadence shall pay Grifols reasonable fees for performing such studies in accordance with the schedule set forth in Exhibit C to this Agreement (the "Service Fees").

4.4 Materials.

(a) Finished Products Supply. During the Term, Grifols shall obtain such Materials, at such times, and in such amounts, as shall be necessary in order for Grifols to timely produce and deliver to Cadence in accordance herewith the quantities of the Products required by Cadence as reflected in the then current Quarterly Forecast including, without limitation, the active pharmaceutical ingredient (paracetamol, or acetaminophen). Grifols shall obtain the Materials for the Products produced under this Agreement only from suppliers named in the approved Drug Application or Specifications for the Product, where applicable, and all Materials shall comply with the applicable Specifications. Grifols shall perform all testing of Materials required by the applicable Materials Specifications.

(b) Materials Certifications. Grifols shall prepare or cause to be prepared by its suppliers, as the case may be, all certifications as to any Materials required by the Specifications, cGMPs, Regulatory Acts, Applicable Laws or the Quality Agreement (each, a "Materials Certification").

(c) Production Schedule. During the Term, Grifols shall manufacture the Products at such times, and in such amounts, as shall be necessary in order for Grifols to timely deliver to Cadence in accordance the Firm Order portion of each Quarterly Forecast.

4.5 Quality Agreement.

The Parties shall work together in good faith to develop and execute a mutually acceptable Quality Agreement for the Products within six (6) months following the Effective Date (the "Quality Agreement"). The terms contained in the Quality Agreement are intended to complement the terms of this Agreement, and they shall be interpreted as complementary to the extent possible. In the event of a conflict between the terms of the Quality Agreement and the terms of this Agreement, the terms of this Agreement shall control; provided, however, the inclusion of a particular term or level of detail in the Quality Agreement where such term or level of detail is absent from this Agreement shall not be deemed to constitute a conflict between the two agreements. Only where competing terms in the two agreements conflict in terms of the principal focus of an express prescription or prohibition in the agreements shall a conflict between the two agreements be deemed to exist.

ARTICLE V
QUALITY CONTROL, TESTING AND QUALITY ASSURANCE

5.1 Technology Transfer. Cadence shall assist Grifols with the transfer of the relevant manufacturing and analytical technology required to manufacture the Product at the Facility, to the extent such transfer is consistent with Cadence's legal obligations to any Third Parties. All costs related to the technology transfer shall be borne by Cadence in accordance with Exhibit E.

5.2 Testing. All Product testing required to be performed by Grifols hereunder shall be performed in accordance with the Specifications and the Quality Agreement. Grifols shall perform all quality control testing and evaluation of Materials, and Grifols shall promptly notify Cadence in writing of all formal Quality Assurance investigations undertaken with respect to the Product or any Materials used or intended to be used to manufacture the Product.

5.3 In-Process and Finished Product Testing. Grifols will perform in-process and finished Product testing, including sterility, using the approved Specifications and validated or otherwise qualified methods of analysis as provided in the approved Drug Application and the Quality Agreement.

5.4 Quality Assurance. Grifols is responsible for establishing and maintaining Product specific manufacturing and testing documentation and standard operating procedures.

5.5 Deviations and Investigations. Any deviations from the process during manufacture, including but not limited to, batch record execution, environmental monitoring excursions or aseptic processing procedures shall be documented. Any such deviation which may impact the safety, identity, strength, purity, or quality of the Products shall be promptly reported to Cadence and fully investigated as provided in the Quality Agreement.

5.6 Batch Disposition; Inspection; Returns. Cadence may, at its expense, inspect and test each shipment of the Product within [***]*** after receipt at Cadence's designated destination in the Territory. Cadence shall have the right to reject any shipment, if Cadence determines that (i) the Product does not conform to the Specifications or the Applicable Laws, or (ii) the related Manufacturing Batch Record does not demonstrate Product compliance with the cGMPs. Prior to any such return, Cadence shall request a return authorization from Grifols, which authorization shall not be unreasonably withheld or delayed, and the return of such Product shall be made in accordance with such authorization. Any Product that Cadence has not rejected within such [***] day-period shall be deemed accepted; provided, however, that if the discovery of any non-conformity of the Product could not reasonably have been discovered until after such [***] day-period, Cadence may reject the shipment, provided that such rejection occurs reasonably promptly following Cadence's discovery of such non-conformity. In the event that any Product is rejected by Cadence in accordance herewith:

(a) if Cadence has not paid for the rejected Product, Cadence shall not be required to pay Grifols for such Product; or

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

(b) if Cadence has paid Grifols for the rejected Product, at Cadence's election, Grifols shall either promptly refund the applicable Purchase Price to Cadence or use commercially reasonable efforts to promptly replace the rejected Product.

(c) Grifols shall be responsible for all expenses relating to the destruction or return of Products to the destination designated by Grifols.

If Grifols and Cadence do not agree on the return of Product, then either Party may refer the matter for final analysis to a specialized laboratory of recognized reputation acceptable to both Parties for the purpose of determining the results (the "Laboratory"). The determination of the Laboratory with respect to all or part of any Product shall be final and binding upon the Parties. The fees and expenses of the Laboratory making such determination shall be borne by Cadence if the Product is determined to be conforming, and Grifols if the Product is determined to be non-conforming, to the Specifications, Applicable Laws and/or Product warranty. For the avoidance of doubt, Product accepted by Grifols as not meeting the applicable Specifications, Applicable Laws and Product warranty, or which are determined by the Laboratory not to meet such Specifications, Applicable Laws and Product warranty, shall be destroyed by Cadence, at Grifols' expenses.

5.7 Product Recalls. If a Product recall results from: (i) the failure of any Product, packaging or labeling supplied hereunder to conform to the Specifications or to comply with the Applicable Laws, cGMP, the terms of this Agreement or the Quality Agreement, at the time such Product was delivered to the carrier, for any reason other than due to mishandling of such Product that occurred after delivery by Grifols to Cadence's designated carrier; (ii) any claim of failure by Grifols to comply in any material respects with Applicable Laws that apply to Grifols in relation to Grifols' activities under this Agreement; or (iii) any negligent, grossly negligent or willful act or omission by Grifols, including without limitation the negligent or grossly negligent manufacture of the Product by Grifols; then Grifols shall: (x) credit to Cadence an amount equal to the total purchase price paid by Cadence to Grifols for the Product so recalled, including all shipping costs, taxes, fees and duties; (y) reimburse Cadence for the reasonable expenses of conducting its recall action (e.g. advertising, mailing, Product shipment, administration, Product destruction, etc.); and (z) indemnify and hold harmless Cadence and each other Cadence Indemnitee from and against any and all Losses suffered by such Cadence Indemnitee arising from or related to such recall.

(a) If a Product recall results from: (i) a defect in the Product that is solely due to mishandling of such Product after delivery by Grifols to Cadence's designated carrier; (ii) the inadequate or misleading nature of any text specified by Cadence that appears on the packaging or labeling of the Product; or (iii) any negligent, grossly negligent or willful act or omission by Cadence; then Cadence shall indemnify, defend and hold harmless Grifols and each other Grifols Indemnitee from and against any and all Losses suffered by such Grifols Indemnitee arising from or related to such recall.

(b) The rights and remedies available to each Party under this Section 5.7 are not exclusive and shall be in addition to all other right and remedies available to such Party at law and in equity.

5.8 Product Complaints. It is expected that all Product complaints will be received by Cadence. However, if Grifols receives any Product complaints, Grifols shall promptly notify Cadence of any and all complaints of which Grifols becomes aware relating to any Product, and shall forward to Cadence's designated quality representative a copy of any such written complaint, or a written summary of any such oral complaint, received by Grifols. Cadence shall promptly inform Grifols of any and all complaints that Cadence receives which implicate Grifols' manufacturing or other processes at the Facility. Notification shall be given by email, with a facsimile confirmation immediately following. Grifols shall thoroughly and promptly investigate all complaints relating to the Product and provide Cadence's designated quality representative with all relevant information, data and conclusions regarding such investigation.

5.9 Adverse Events. For the purposes of this Agreement, "Adverse Event" shall mean any adverse event associated with the use of any Product in humans, whether or not considered drug-related, that is, or is thought by the reporter to be, serious or associated with relevant clinical signs or symptoms. Cadence shall be responsible for complying with all pharmacovigilance obligations related to the Product in the Territory, including the maintenance of a safety database, and for the collection, evaluation and reporting of safety data regarding the Product for the Territory as required under Applicable Law. However, if Grifols receives any Adverse Event notifications, Grifols shall notify Cadence promptly following Grifols' receipt of written information of an Adverse Event and shall disclose to Cadence any and all information it has regarding that Adverse Event. To the extent an Adverse Event of which Cadence becomes aware implicates Grifols' manufacturing or other processes at the Facility, Cadence shall inform Grifols of such Adverse Event and shall disclose to Grifols any information it has regarding that Adverse Event.

5.10 Retained Samples. Grifols shall retain samples from each batch of Products for the period specified by Cadence's authorized quality assurance representative, or such longer period required by the Applicable Laws for record keeping, testing and regulatory purposes. The costs associated with retained samples shall be borne by Cadence in accordance with Exhibit C.

ARTICLE VI
REGULATORY MATTERS

6.1 Manufacturing Consents. Grifols currently holds, and at all times during the Term shall hold, all Consents required by Grifols for the performance of its obligations under this Agreement.

6.2 Product Consents. Cadence shall, at its expense, obtain and maintain any Consents which may from time to time be required by any Governmental Body with respect to ownership of the Drug Applications, or with respect to the marketing, distribution, clinical investigation, import or export of the Products. Cadence shall be responsible for responding to all requests for information related to such Consents made by, and making all legally required filings relating to such Consents with, any Governmental Body having jurisdiction to make such requests or require such filings. In the event any Consent held by Cadence relating directly to any of the Products is hereafter suspended or revoked, Cadence shall promptly notify Grifols of the event and shall promptly inform Grifols of the impact on Cadence's purchases of the affected Product and Cadence's general intentions with respect to the affected Product.

6.3 Drug Application Documentation. Cadence shall be responsible for submitting a Drug Application to the FDA and to Health Canada, with respect to the addition of the Facility as a source for the Product. Grifols shall provide all documents, information, data and technical assistance required by Cadence to complete and obtain approval for such Drug Applications.

6.4 Regulatory Changes. The Parties shall promptly notify each other of any material revisions or amendment of or additions to cGMPs and confer with each other with respect to the best means to comply with such requirements.

6.5 Regulatory Inspections. If either Party is notified that any Product or Facility will be subject to an inspection by any Governmental Body, such Party shall promptly notify the other Party of its receipt of such notification, and both Parties shall thereafter cooperate fully with any such inspection to the extent required by Applicable Laws.

6.6 Debarment. In the event that during the Term of this Agreement Grifols becomes debarred under the provisions of the Generic Drug Enforcement Act of 1992, 21 U.S.C. § 335(a) and (b), or receives notice of an action or threat of an action with respect to its debarment, Grifols shall immediately notify Cadence thereof.

6.7 Product Release to the Market. Following its acceptance of the Product and all documentation required to be provided by Grifols under the Quality Agreement (including, without limitation, a certificate of compliance from Grifols), Cadence or its designee shall be responsible for releasing batches of the Product for commercial sale in the Territory.

ARTICLE VI
IINTELLECTUAL PROPERTY

7.1 Grant of Licenses; Ownership of Inventions.

(a) From Cadence to Grifols. Subject to the terms and conditions of this Agreement, Cadence hereby grants to Grifols a non-exclusive, royalty-free license, with no right to sublicense, to make the Product during the Term, under the Cadence Intellectual Property, solely to the extent necessary for Grifols to perform Grifols' obligations to manufacture the Product for Cadence, Cadence's Affiliates and sublicensees, under this Agreement. Such license shall be subject and subordinate to the IV APAP Agreement and the Pharmatop License Agreement. BMS shall be an express third party beneficiary of Grifols' obligations under the license granted herein that relate to compliance with the terms and conditions of the IV APAP Agreement, with the express right to enforce the same directly against Grifols. The license granted herein shall terminate immediately upon the first to terminate of this Agreement, the IV APAP Agreement, or the Pharmatop License Agreement.

(b) From Grifols to Cadence. Subject to the terms and conditions of this Agreement, Grifols hereby grants to Cadence a nonexclusive, royalty-free license, with a right to sublicense to Cadence's Affiliates and sublicensees, to make, have made, use, sell, offer for sell and import the Product under Grifols Intellectual Property, to the extent that such Grifols Intellectual Property is used in the manufacture of the Product under this Agreement. The license granted herein shall terminate immediately upon the termination of this Agreement. Notwithstanding the foregoing, the Grifols License shall survive if this Agreement is terminated by Cadence pursuant to Sections 13.2 (b) or 13.2(c) of this Agreement.

(c) Ownership of Inventions. Cadence shall be the sole owner of any proprietary technology, know-how or other proprietary rights developed by Grifols in the course of its activities under this Agreement, whether developed solely by Grifols or jointly between Grifols and Cadence ("Inventions"), and Cadence shall be entitled to apply for patent protection for such Inventions at Cadence's expense and risk. Grifols shall fully cooperate with Cadence in completing any patent applications relating to Inventions, and executing and delivering any instrument required to assign, convey or transfer to Cadence such interests in the Inventions. All employees, consultants, subcontractors and agents performing services for Grifols under this Agreement shall have assigned in writing to Grifols all of their right, title and interest in, to and under any and all such Inventions so as to effectuate the provisions of this Section 7.1(c), and Grifols shall be responsible for any compensation required to be paid to such employees, consultants, subcontractors or agents as a consequence thereof.

(d) No right or license under any Cadence Intellectual Property or Grifols Intellectual Property or any Product Trademark or other mark is granted or shall be granted by implication as a result of the respective rights of the Parties under this Agreement. All such rights or licenses are or shall be granted only as expressly provided in this Agreement

ARTICLE VIII
INFORMATION; ACCESS; AUDIT RIGHTS

8.1 Provision of Information. From time to time during the Term, Grifols shall provide Cadence with such information as Cadence shall reasonably request, including copies (in electronic or hard-copy form, as requested by Cadence) of all data and reports, relative to Grifols' purchase of the Materials and the manufacture and supply of the Product pursuant to this Agreement, including but not limited to (a) all Product data in its control, including testing and release results, Product complaint test results and all investigations, and (b) Product inventory reports detailing (i) Grifols' raw materials inventory, (ii) work-in-progress, and (iii) scrapped goods.

8.2 Audit and Inspection Rights. Subject to the confidentially obligations of Article XII, Cadence and the Cadence Licensors shall have the right to audit and inspect the Facility including, without limitation, all inventory of Products and Materials located at the Facility. Such audits or inspections shall occur during business hours and shall be scheduled by Cadence, at least, ten (10) Business Days in advance of Cadence's written notice thereof; provided, however, that in the event of an Adverse Event or Product complaint that implicates Grifols' manufacturing or other processes at the applicable Facility or any proposed or actual inspection by the FDA or other Governmental Body, at a Facility, Cadence shall have the right during normal business hours upon prior oral or written notice to Grifols of five (5) Business Days to conduct an audit or inspection hereunder of the Facility. Cadence's audit and inspection rights under this Section 8.2 shall not extend to any portions of any Facility, documents, records or other information that do not relate to the Products or Materials. Grifols may redact confidential information relating to Third Parties and their products or materials from any documents deliverable to Cadence in connection with Cadence's exercise of its audit and inspection rights hereunder.

8.3 Documentation. Each Party shall maintain, in accordance with and for the period required under cGMPs, all other Applicable Laws, rules and regulations, and the Quality Agreement, complete and adequate records pertaining to the methods and facilities used for the manufacture, processing, testing, packing, labeling, holding and distribution of the Products.

ARTICLE IX
REPRESENTATIONS AND WARRANTIES

9.1 Representations and Warranties of Grifols. Grifols represents and warrants to Cadence that:

(a) Organization and Authority. Grifols is a duly organized, validly existing and in good standing under the laws of Spain. Grifols has full corporate power and authority to execute and deliver this Agreement and effect the transactions contemplated hereby and has duly authorized the execution, delivery and performance of this Agreement and the transactions or documents contemplated hereby by all necessary corporate action. Grifols has all corporate power and authority necessary to own its assets and carry on its business as it is now conducted. Grifols is duly licensed or qualified to do business and is in good standing in Spain and each other jurisdiction in which its operations or ownership of assets in connection with this Agreement requires such licensing or qualification, except where the failure to obtain such license or qualification would not have a material impact on Grifols' operations or business. This Agreement is the valid and legally binding obligation of Grifols, enforceable against it in accordance with its terms, subject to applicable bankruptcy moratorium, reorganization, insolvency and similar laws of general application relating to or affecting the rights and remedies of creditors generally and to general equitable principles (regardless of whether in equity or at law).

(b) Consents; No Violations. The execution, delivery and performance by Grifols of this Agreement and the consummation by Grifols of the transactions contemplated hereby will not require any notice to, filing with, or the consent, approval or authorization of, any Person or Government Body, except as has already been obtained by Grifols. Neither the execution and delivery of this Agreement nor the consummation of the transactions contemplated hereby will (i) violate or result in a breach or result in the acceleration or termination of, or the creation in any Third Party of the right to accelerate, terminate, modify or cancel, any material indenture, contract, lease, sublease, loan agreement, note or other obligation or liability to which Grifols is a party or by which Grifols is bound or to which any of the Grifols Intellectual Property is subject, (ii) conflict with, violate or result in a breach of any provision of the organizational documents of Grifols, or (iii) conflict with or violate, in any material respect, any Applicable Law.

(c) Litigation. There are no lawsuits, claims or any civil, administrative or criminal actions, suits, or proceedings or governmental investigations existing, pending, or to the knowledge of Grifols, threatened, with respect to the Grifols Intellectual Property or with respect to this Agreement or the transactions contemplated hereby. To Grifols' knowledge, Grifols is not subject to any decree or order of any Government Body that would impair or delay its ability to perform its obligations under this Agreement.

(d) Debarment. Neither Grifols nor any of its officers, employees, or consultants has been convicted of an offense under (i) either a federal or state law that is cited in 21 U.S.C. § 335(a) as a ground for debarment, denial of approval, or suspension, or (ii) any other law cited in any comparable Regulatory Act as a ground for debarment, denial of approval or suspension.

(e) Regulatory Consents. Grifols has all material government approvals, permits and licenses necessary for the performance of its obligations hereunder. All such approvals, permits and licenses are in full force and effect.

(f) Compliance. Grifols shall, in connection with its performance under this Agreement, comply with all Applicable Laws, including, without limitation, the United States Foreign Corrupt Practices Act. Further, the manufacture, generation, processing, distribution, transport, treatment, storage, disposal and other handling of any Materials or Products by Grifols until delivery to a carrier or freight forwarder shall be in accordance with and conform to the Specifications, and, as applicable, in all materials respects, cGMPs and all Applicable Laws.

(g) Intellectual Property. Grifols acknowledges and agrees that (i) it has been informed that the Product is to be made subject to the IV APAP Agreement, (ii) it will only use the Cadence Intellectual Property for the benefit of Cadence and its Affiliates, and (iii) it will not manufacture the Product for marketing, sale or distribution in the Territory by any Third Party. Further, Grifols agrees that it shall not take any act or step impairing Cadence's Intellectual Property, or do anything that may otherwise adversely affect the Cadence Intellectual Property.

(h) Warranty Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED HEREIN, GRIFOLS MAKES NO WARRANTIES IN THIS AGREEMENT OR THE QUALITY AGREEMENT, EXPRESS OR IMPLIED, WITH RESPECT TO THE PRODUCTS, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF NON-INFRINGEMENT, WARRANTY OF MERCHANTABILITY OR WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE.

9.2 Representations and Warranties of Cadence. Cadence represents and warrants to Grifols that:

(a) Organization and Authority. Cadence is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware. Cadence has full corporate power and authority to execute and deliver this Agreement and effect the transactions contemplated hereby and has duly authorized the execution, delivery and performance of this Agreement and the transactions or documents contemplated hereby by all necessary corporate action. Cadence has all corporate power and authority necessary to own its assets and carry on its business as it is now conducted. Cadence is duly licensed or qualified to do business and is in good standing in each other jurisdiction in which its operations or ownership of assets in connection with this Agreement requires such licensing or qualification. This Agreement is the valid and legally binding obligation of Cadence, enforceable against it in accordance with their terms, subject to applicable bankruptcy moratorium, reorganization, insolvency and similar laws of general application relating to or affecting the rights and remedies of creditors generally and to general equitable principles (regardless of whether in equity or at law).

(b) Consents; No Violations. The execution, delivery and performance by Cadence of this Agreement and the consummation by Cadence of the transactions contemplated hereby will not require any notice to, filing with, or the consent, approval or authorization of, any Person or Government Body, except as has already been obtained by Cadence. Neither the execution and delivery of this Agreement nor the consummation of the transactions contemplated hereby will (i) violate or result in a breach or result in the acceleration or termination of, or the creation in any Third Party of the right to accelerate, terminate, modify or cancel, any indenture, contract, lease, sublease, loan agreement, note or other obligation or liability to which Cadence is a party or by which Cadence is bound or to which any of the Cadence Intellectual Property is subject, (ii) conflict with, violate or result in a breach of any provision of the organizational documents of Cadence, or (iii) conflict with or violate any Applicable Laws.

(c) Litigation. There are no lawsuits, claims or any civil, administrative or criminal actions, suits, or proceedings or governmental investigations existing, pending, or to the knowledge of Cadence, threatened, with respect to the Cadence Intellectual Property or with respect to this Agreement or the transactions contemplated hereby. Cadence is not subject to any decree or order of any Government Body that would impair or delay its ability to perform its obligations under this Agreement.

(d) Regulatory Consents. Cadence has all government approvals, permits and licenses necessary for the performance of its obligations hereunder. All such approvals, permits and licenses are in full force and effect.

(e) Compliance. Cadence shall, in connection with its performance under this Agreement, comply with all Applicable Laws, including, without limitation, the United States Foreign Corrupt Practices Act.

ARTICLE X
LIABILITY AND INDEMNIFICATION

10.1 Indemnity by Grifols. Grifols shall indemnify, defend and hold Cadence and its Affiliates, and each of their respective directors, officers, employees and agents (each, a "Cadence Indemnitee") harmless from and against all Losses suffered by the Cadence Indemnitees or sublicensees to the extent such Losses arise from, are based upon, or are caused by: (a) any breach or nonperformance of any of Grifols' covenants, obligations, representations or warranties under this Agreement; (b) Grifols' failure to obtain, maintain or comply in any respect with any of its Consents which are required to perform any of its obligations hereunder or under the Regulatory Acts or other Applicable Laws; (c) any violation of Applicable Laws by Grifols in the performance of its obligations hereunder; or (d) any actual or alleged infringement or misappropriation of any Intellectual Property rights of any Third Party relating to the manufacturing processes or equipment used by Grifols to manufacture the Product. The foregoing indemnification obligations shall not apply to the extent any particular Loss is a direct result of (i) the negligence, gross negligence or intentional misconduct of a Cadence Indemnitee or sublicensee; or (ii) any matter for which Cadence is obligated to indemnify Grifols pursuant to Section 10.2 of this Agreement.

10.2 Indemnity by Cadence. Cadence shall indemnify, defend and hold Grifols and each Grifols Affiliate and their respective directors, officers, employees and agents (each a "Grifols Indemnitee") harmless from and against all Losses suffered by the Grifols Indemnitees to the extent that such Losses arise from, are based upon, or are caused by: (a) Cadence's failure to obtain, maintain or comply in any respect with any of its Consents that are required to perform any of its obligations hereunder, or under the Regulatory Acts or other Applicable Laws; (b) any breach or non-performance of any of Cadence's covenants, obligations, representations or warranties under this Agreement; (c) any product liability claims arising from Product or its use, or allegedly caused by the Product; or (d) any actual or alleged infringement or misappropriation of any Intellectual Property rights of any Third Party concerning the Product. The foregoing indemnification obligations shall not apply in each case to the extent any particular Loss is a direct result of (i) the negligence, gross negligence or intentional misconduct of a Grifols Indemnitee or (ii) any matter for which Grifols is obligated to indemnify Cadence pursuant to Section 10.1 of this Agreement.

10.3 Procedures. Any indemnification of Grifols, Grifols Affiliates, Cadence, or Cadence Affiliates hereunder shall include and extend to the benefit of their respective shareholders, directors, officers and employees. Any person that may be entitled to indemnification under this Agreement (an "Indemnified Party") shall give written notice to the Person obligated to indemnify it (an "Indemnifying Party") with reasonable promptness upon becoming aware of any facts upon which a claim for indemnification will be based; the notice shall set forth such information with respect thereto as is then reasonably available to the Indemnified Party. The Indemnifying Party shall have the right to undertake the defense of any claim, demand, suit, action or proceeding by any Third Party (a "Third Party Claim") with counsel reasonably satisfactory to the Indemnified Party and the Indemnified Party shall cooperate in such defense and make available all records, materials and witnesses reasonably requested by the Indemnifying Party in connection therewith at the Indemnifying Party's expense. If the Indemnifying Party shall have assumed the defense of the Third-Party Claim with counsel reasonably satisfactory to the Indemnified Party, the Indemnifying Party shall not be liable to the Indemnified Party for any legal or other expenses (other than for reasonable costs of investigation) subsequently incurred by the Indemnified Party in connection with the defense thereof. The Indemnifying Party shall not be liable for any Third-Party Claim settled without its consent, which consent shall not be unreasonably withheld or delayed. The Indemnifying Party shall obtain the written consent of the Indemnified Party prior to ceasing to defend, settling or otherwise disposing of any Third-Party Claim if as a result thereof the Indemnified Party would become subject to injunctive or other equitable relief or if the Indemnified Party may reasonably object to such disposition of such Third-Party Claim based on a continuing adverse effect on the Indemnified Party.

ARTICLE XI
INSURANCE

11.1 Insurance Requirements. Each Party shall at all times maintain in full force and effect, with financially sound and reputable carriers reasonably satisfactory to the other Party, insurance policies in such amounts and with such scope of coverage as are set forth on Exhibit D. Each Party shall provide the other Party with evidence of such insurance from time to time upon the other Party's request. Neither Party shall terminate such insurance or otherwise allow such insurance to lapse without providing the other Party with at least [***]*** prior written notice of such termination or expiration.

ARTICLE XII
CONFIDENTIALITY

12.1 Definition of "Grifols Confidential Information". As used herein, the term "Grifols Confidential Information" shall mean all confidential business and technical communications, documents and other information, whether in written, oral or other form, of Grifols or a Grifols Affiliate (whether relating to Grifols, a Grifols Affiliate or any Third Party to which Grifols has an obligation of confidentiality) that are disclosed or furnished to Cadence or a Cadence Affiliate by Grifols or a Grifols Affiliate, or of which Cadence or a Cadence Affiliate otherwise learn in connection with the negotiation or performance of this Agreement.

12.2 Definition of "Cadence Confidential Information". As used herein, the term "Cadence Confidential Information" shall mean all confidential business and technical communications, documents or other information, whether in written, oral or other form, of Cadence, BMS, SCR Pharmatop or a Cadence Affiliate (whether relating to Cadence, BMS, SCR Pharmatop, a Cadence Affiliate, or any Third Party to which Cadence has an obligation of confidentiality) that are disclosed or furnished to Grifols or a Grifols Affiliate by Cadence or a Cadence Affiliate, or of which Grifols or a Grifols Affiliate otherwise learn in connection with the negotiation or performance of this Agreement.

12.3 Treatment of Confidential Information. Both during the Term of this Agreement and thereafter, Cadence shall treat all Grifols Confidential Information and Grifols shall treat all Cadence Confidential Information in accordance with the requirements of this Article XII. For convenience, Grifols Confidential Information and Cadence Confidential Information are both referred to herein as "Confidential Information" for purposes of establishing the obligations of each Party with regard to the other Party's Confidential Information.

12.4 Nondisclosure. Confidential Information of the other Party shall be kept strictly confidential by the receiving Party and, except as expressly permitted herein, shall not be disclosed to any Third Party by the receiving Party in any manner whatsoever including without limitation, any Affiliate, in whole or in part, without first obtaining the other Party's prior written consent to such disclosure. The standard of care required of each Party in protecting the confidentiality of the other Party's Confidential Information shall be, at least, the same standard of care that the receiving Party uses in protecting its own confidential and trade secret information, but in no event shall either Party use less than a reasonable standard of care. Confidential Information may be used by the receiving Party only for the purpose of performing under this Agreement.

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

12.5 Permitted Exceptions. Each Party may disclose the other Party's Confidential Information (i) to its employees or outside advisors and financing sources in connection with this Agreement who reasonably need to know such information for the purpose of advising or assisting it in connection with this Agreement (each, a "Representative"), and (ii) to any Parties required under operation of law. Prior to disclosing any Confidential Information to any Representative pursuant to this Section 12.5, the receiving Party will inform such Representative of the proprietary nature of the Confidential Information and will require such Representative to agree in writing (except in the case of outside legal advisors or auditors engaged to prepare a Party's financial statements, who may orally agree) to be bound by the requirements of this Article XII and not to use or disclose the Confidential Information except as permitted herein, or are bound by confidentiality obligations no less restrictive than those set forth in this Article XII.

12.6 Use By the Receiving Party. Confidential Information of the other Party shall not be utilized by a receiving Party except as expressly permitted herein, without first obtaining the other Party's prior written consent to such utilization and without first entering into a separate agreement duly executed by authorized representatives of the Parties hereto.

12.7 Excluded Information. Notwithstanding any provision herein to the contrary, the requirements of this Article XII shall not apply to any information of either Party which:

(a) at the time of disclosure hereunder is generally available to the public;

(b) after disclosure hereunder becomes generally available to the public, except through breach of this Article XII by the receiving Party or its Representatives;

(c) was not acquired directly or indirectly from the disclosing Party or its Affiliates and which the receiving Party lawfully had in its possession prior to disclosure by the disclosing Party;

(d) is independently developed by employees or agents of the receiving Party without the use of the Confidential Information of the disclosing Party; or

(e) becomes available to the receiving Party from a Third Party that is not legally prohibited from disclosing such Confidential Information, provided, to the knowledge of the receiving Party, such information was not acquired directly or indirectly from the disclosing Party or its Affiliates.

12.8 Notification of Mandatory Disclosure.

(a) Procedures. In the event that either Party is required by Applicable Law or regulation or by judicial or administrative process to disclose any part of the other Party's Confidential Information, such Party shall (i) promptly notify the other Party of each such requirement and identify the documents so required thereby, so that the other Party may seek an appropriate protective order or other remedy and/or waive compliance by the first Party with the provisions of this Article XII, (ii) consult with the other Party on the advisability of taking legally available steps to resist or narrow the scope of such requirement, (iii) assist the other Party, at its expense, in seeking a protective order or equivalent, and (iv) comply with any applicable protective order or equivalent.

(b) Limitations. If, in the absence of such a protective order or such a waiver by the other Party of the provisions of this Article XII, the first Party is nonetheless required by mandatory Applicable Law to disclose any part of the other Party's Confidential Information, the first Party may disclose such of the other Party's Confidential Information without liability under this Agreement, except that the first Party shall furnish only that portion of the other Party's Confidential Information which is legally required.

12.9 Publicity. Neither Party shall issue any press release or otherwise make any public statement, advertisement or disclosure with respect to this Agreement without the prior written consent of the other Party, such consent not to be unreasonably withheld; provided, however, that either Party shall be entitled to make a public announcement of this Agreement after giving prior written notice to the other Party hereto, if, in the opinion of the disclosing Party's legal counsel, such announcement is required by Applicable Laws.

12.10 Return of Confidential Information. At any time upon the request of the other Party, to the extent such Confidential Information is not reasonably necessary to enable a Party to perform its obligations under this Agreement, the receiving Party shall promptly return to the other Party or destroy the other Party's Confidential Information, and shall destroy all copies thereof, together with all notes, drawings, abstracts and other information relating to the other Party's Confidential Information prepared by the receiving Party or any of its Representatives, regardless of the medium in which such information is stored; provided, however, that the receiving Party may maintain a single archival copy of the other Party's Confidential Information in its files for purposes of establishing the extent of disclosures by the other Party under this Agreement. At either Party's written request, such Party's Confidential Information that is otherwise required to be returned to it shall be destroyed by the receiving Party and such destruction shall be certified in writing by an authorized officer of the receiving Party. The return and/or destruction of such Confidential Information as provided above shall not relieve the receiving Party of its other obligations under this Article XII.

ARTICLE XIII
TERM; TERMINATION; REMEDIES

13.1 Term. This term of this Agreement shall commence on the Effective Date and continue until the sixth anniversary of the date on which the first Drug Application for the Product is approved by the FDA, unless earlier terminated in accordance with the terms of Section 13.2 of this Agreement. The period, commencing on the Effective Date and continuing through the date on which this Agreement is terminated in accordance herewith, is herein referred to as the "Term".

13.2 Termination.

(a) Termination of the IV APAP Agreement. Cadence may terminate this Agreement effective immediately upon any termination or expiration of the IV APAP Agreement or the Pharmatop License Agreement.

(b) Material Breach. Either Party may terminate this Agreement effective upon sixty (60) days prior written notice (or thirty (30) days prior written notice in the case of a payment default) to the other Party, if the other Party commits a material breach of this Agreement and fails to cure such breach by the end of such sixty (60) day period (or thirty (30) day period in the case of a payment default).

(c) Bankruptcy. Either Party may terminate this Agreement effective upon written notice to the other Party, 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, trustee or other court officer appointed for its properties or assets.

(d) Discontinuance of Products. Cadence may terminate this Agreement at any time in its sole discretion upon sixty (60) days prior written notice to Grifols in the event that Cadence elects to discontinue distribution of all or substantially all of the Products.

(e) Post-Termination Obligations; Closing Inventory. In the event this Agreement is terminated for any reason, or otherwise expires at the conclusion of its Term, Grifols shall promptly cease production of the Product and shall make no further expenditures either for Materials or relative to the production of the Product. Within thirty (30) days following the effective date of the termination or expiration hereof, Grifols shall then provide Cadence with a closing inventory of the Product in its possession, including a Materials inventory, a work-in-process inventory, and a finished goods inventory. Cadence shall have thirty (30) days following its receipt of the closing inventory to either accept or reject the closing inventory as presented. If Cadence rejects the closing inventory as presented and the Parties are unable to amicably resolve their differences regarding the closing inventory, then the Parties shall agree upon and engage an independent Third Party to prepare a substitute closing inventory. Once the closing inventory (or the substitute closing inventory, as the case may be) has been finalized in accordance herewith, Cadence shall, within thirty (30) days thereof, pay Grifols a final inventory settlement payment in an amount equal to the Purchase Price for all Product manufactured pursuant to a Firm Order from Cadence, and Grifol's cost for all unused Materials purchased by Grifols to manufacture Product for the six-month period immediately following the termination date, provided that the total quantity of such Materials is consistent with the last forecast provided by Cadence, and provided further, that orders for such Materials cannot be canceled or used by Grifols to manufacture other pharmaceutical products. Notwithstanding anything in this Agreement to the contrary, under no circumstances shall Cadence be obligated to purchase any Product or Materials that fail to fully comply with all applicable Specifications and Applicable Laws.

(f) Remedies; Injunctive Relief. Except as expressly set forth in this Agreement, none of the remedies set forth in this Agreement are intended to be exclusive, and each Party shall have available to it all remedies available under law or in equity. In the event that either Cadence or Grifols breaches or threatens to breach any provision of Article VII or Article XII of this Agreement, the Parties agree that irreparable harm to the other Party should be presumed and the damage to such Party would probably be very difficult to ascertain and would be inadequate. Accordingly, in the event of such circumstances, each of Cadence and Grifols agree that, in addition to any other right and remedies available at law or in equity, the other Party shall have the right to seek injunctive relief from any court of competent jurisdiction.

ARTICLE XIV
MISCELLANEOUS

14.1 Notices. In addition to the other specific procedures for notification required herein, all notices, demands, requests and other communications made hereunder shall be in writing and shall be given either by personal delivery, by nationally recognized overnight courier (with charges prepaid), by electronic transmission (provided such transmission shall include information from which it can be determined that it was authorized by a Party hereto and the receipt of such transmission is confirmed by telephone) or by facsimile transmission (with telephone confirmation), and shall be deemed to have been given or made: (i) if personally delivered, on the day of such delivery; (ii) if sent by overnight courier, on the day following the date deposited with such overnight courier service; (iii) if by electronic transmission, on the date transmitted on such electronic medium; or (iv) if by facsimile transmission, on the date transmitted to receiving facsimile machine and confirmed by telephone, in each case pending the designation of another address, addressed as follows:

If to Grifols:
Laboratorios Grifols, S.A.
Polígono Industrial Sector Z
C/ Logística, 2
08150 – Parets del Vallès – SPAIN
Attention: President
Tel. [***]***
Fax: [***]

With a copy (which shall not constitute notice) to:
Grifols International, S.A.
Avda. Generalitat, 152-158
Polígono Can San Joan
08174 – Sant Cugat del Vallès- SPAIN
Attention: Marketing Manager IV Therapy
Tel. [***]
Fax: [***]

If to Cadence:
Cadence Pharmaceuticals, Inc.
12481 High Bluff Drive, Suite 200
San Diego, CA 92130
Attention: Chief Commercial Officer
Facsimile: [***]

With a copy (which shall not constitute notice) to:
Cadence Pharmaceuticals, Inc.
12481 High Bluff Drive, Suite 200
San Diego, CA 92130
Attention: General Counsel
Facsimile: [***]

14.2 Independent Contractors. In the exercise of its obligations and in respect of its rights and entitlements hereunder or in respect hereof, Cadence and Grifols are and shall in all respects be treated as independent contractors with respect to each other. Neither Party shall be deemed to be a co-venturer or partner of the other. Neither Party is an employee or a legal representative of the other Party for any purpose. Neither Party shall have the authority to enter into any contracts in the name of or on behalf of the other Party.

14.3 Entire Understanding. This Agreement, including the Exhibits hereto, and any other document identified herein, represents the entire understanding and agreement between the Parties hereto with respect to the subject matter hereof, and supersedes all prior and contemporaneous agreements and understandings between the Parties with respect to such subject matter, which are hereby expressly terminated.

14.4 Transferability; Binding Effect. Neither this Agreement, nor any of the rights or obligations of a Party may be directly or indirectly assigned, sold, delegated or otherwise disposed of without the prior written consent of the other Party, which consent may not be unreasonably withheld; provided, however, that either Party may assign this Agreement to an Affiliate or to a successor by merger, acquisition, or sale of all or substantially all of such Party's business assets in the field to which this Agreement relates, without the other Party's consent.

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

14.5 Dispute Resolution. If the Parties fail to resolve any claim, dispute, or controversy of whatever nature arising out of or relating to this Agreement, including any question regarding its existence, validity, breach or termination (a "Claim"), either Party may refer the dispute, by notice to the other Party, to their respective officers designated below or such other officers as the Parties may designate in writing from time to time, for attempted resolution by good faith negotiations within thirty (30) days after that notice is received. The designated officers are as follows:

For Grifols: President
For Cadence: Chief Commercial Officer

If such dispute is not solved by the end of the thirty (30) day period, the dispute shall be settled by arbitration at the London Court of International Arbitration in accordance with the UNCITRAL Arbitration Rules ("UNCITRAL Rules") then in effect, which rules are deemed to be incorporated by reference into this Section 14.4, subject to the following:

(a) the arbitration tribunal shall consist of three arbitrators to be appointed according to the UNCITRAL Rules;

(b) the language of the arbitration shall be English; and

(c) the decision of the arbitrators shall be final, binding, and conclusive upon the Parties.

14.6 Amendment. Notwithstanding anything herein to the contrary, any amendment, modification or supplement of or to any provision of this Agreement, including the Exhibits and Schedules hereto, shall be effective only by written agreement of the Parties.

14.7 Severability. If and to the extent that any court of competent jurisdiction holds any provision (or any part thereof) of this Agreement to be invalid or unenforceable, such holding shall in no way affect the validity or enforceability of the remainder of this Agreement, and the invalid or unenforceable provision shall be fully severed from this Agreement and there shall automatically be added in lieu thereof a provision as similar in terms and intent to such severed provision as may be legal, valid and enforceable.

14.8 Waiver. Any failure of Cadence or Grifols to comply with any obligation, covenant, agreement or condition herein contained may be expressly waived, in writing only, by the other Party hereto and such waiver shall be effective only in the specific instance and for the specific purpose for which made or given.

14.9 Survival. Articles 10, 11, 12, and 14, and Sections 5.6 – 5.10, 7.1(b), 7.1(c), 8.3, 13.2(e), 13.2(f), and any other provision which by its terms specifically shall so state, together with any obligation to make accrued but unpaid payments due hereunder, shall survive the termination or expiration of this Agreement.

14.10 Headings; Exhibits and Schedules; Counterparts.

(a) Headings. The headings of the Sections of this Agreement are for reference purposes only, are not part of this Agreement and shall not in any way affect the meaning or interpretation of this Agreement.

(b) Exhibits and Schedules. All Exhibits and Schedules delivered pursuant to this Agreement shall be deemed part of this Agreement and incorporated herein by reference, as if fully set forth herein. All provisions contained in any Exhibit or Schedule delivered by or on behalf of the Parties hereto, or in connection with the transactions contemplated hereby, are an integral part of this Agreement.

(c) Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original but all of which together shall constitute one and the same instrument.

14.11 Governing Law. This Agreement shall, for all purposes, be governed by, construed and enforced in accordance with the laws of England and Wales, without giving effect to any conflict of law rules. Neither the UNCITRAL Convention for the International Sale of Goods, nor any other unified laws relating to the conclusion and implementation of contracts for the international sale of goods, shall apply.

14.12 Enforceability. Anything in this Agreement to the contrary notwithstanding, this Agreement shall not have any force or effect unless and until the Purchase Agreement shall have been validly executed and delivered by all of the Parties thereto and have taken effect.

14.13 Force Majeure. Neither Party shall be liable for any failure to deliver or receive or any delay in delivery or receipt when such failure or delay shall be caused (directly or indirectly) by any contingency beyond such Party's reasonable control, including act of God (including fire, flood, earthquake or other natural disaster); accident; explosion; equipment or machinery breakdown; sabotage; strike, or any labor disturbance (regardless of the reasonableness of the demands of labor); civil commotions; riots; invasions; terrorist acts, wars (present or future); acts, restraints, requisitions, regulations, or directions of any Governmental Body; voluntary or mandatory compliance with any request of any Governmental Body; or voluntary or mandatory compliance with any request for material represented to be for purposes of (directly or indirectly) producing articles for national defense or national defense facilities.

14.14 Overdue Amounts. Any payments not made within the specified period of time for payment hereunder shall incur an interest charge at the rate of one percent (1%) per month, excluding any amounts that are subject to a bona fide dispute between the Parties.

14.15 Limitation of Liability. NOTWITHSTANDING ANYTHING HEREIN TO THE CONTRARY, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY, WHETHER FOR BREACH OF CONTRACT, IN TORT, NEGLIGENCE, BREACH OF WARRANTY, STRICT LIABILITY, OR UNDER ANY OTHER LEGAL THEORY, FOR ANY CONSEQUENTIAL OR PUNITIVE DAMAGES.

[Signature page follows]

IN WITNESS WHEREOF, each of the Parties hereto has caused this Agreement to be duly executed as of the date first written above.

Laboratorios Grifols, S.A.

By: /s/ José Antonio García García
Name: José Antonio García García
Title: President

Cadence Pharmaceuticals, Inc.

By: /s/ Theodore R. Schroeder
Name: Theodore R. Schroeder
Title: President and Chief Executive Officer

[Signature page to Manufacturing and Supply Agreement]

EXHIBIT A
Specifications

Confidential/Trade Secret/Proprietary Information of Cadence Pharmaceuticals, Inc.

Acetaminophen Injection, 10 mg/ml [***] (OFIRMEV®)

[***]	**[***]**	**[***]**	**[***]**
[***]	[***]***	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]			

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT B

Purchase Price

Table B

Purchase Price (Euros; per Unit based on 50 Units per case)	Quantity Purchased
[***]	[***]
[***]***	[***]

1. The Purchase Price set forth in Table B, above, shall be fixed for the first Contract Year. Thereafter, no more frequently than [***], Grifols may adjust the Purchase Price by delivering to Cadence not later than [***] days prior to the beginning of each Contract Year, a revised Exhibit B, containing a proposal for a revised Purchase Price in accordance with subsection (2) of this Exhibit B. Grifols shall simultaneously provide to Cadence such information and documentation as are reasonably sufficient to substantiate the proposed Purchase Price adjustment. Upon the approval of same by both parties, any such adjusted Purchase Price shall be effective for Product manufactured in the upcoming Contract Year only.
2. Adjustments to the Purchase Price may only be made as a result of: (a) [***] and (b) [***].
3. In the event that extraordinary circumstances outside of Grifols' control result in an increase in Materials costs incurred by Grifols, and as a result Grifols wishes to propose an increase in the Purchase Price beyond the limits set forth in paragraph (2) of this Exhibit B, the Parties may agree to negotiate in good faith a temporary additional adjustment to the Purchase Price.
4. Notwithstanding anything in this Exhibit B to the contrary, under no circumstances shall adjustments to the Purchase Price be effective unless mutually agreed upon by both Parties in writing.

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT C
Additional Fees

Technology Services

[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

Labeling / Packaging Changes*

[***]	[***]
[***]***	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT D
Insurance Requirements

Comprehensive or Commercial General Liability in an amount not less than (a) [***]***, and (b) [***].

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT E
Technology Transfer Costs

Acetaminophen 10 mg/ml injection Cadence in 100 ml flexible bag [***] for US market.

Item No.	Description	
[***]	[***]	
[***]	[***]***	
[***]	[***]	
[***]	[***]	
[***]	[***]	
[***]	[***]	
[***]	[***]	
[***]	[***]	
[***]	[***]	
[***]	[***]	
[***]	[***]	
[***]	[***]	
[***]	[***]	
TOTAL		[***]

General remarks:

This quotation applies to [***].

[***]

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

PROJECT TIMELINE

[***]*

[***] [***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

[***]

*** Certain information on this page has been omitted and filed separately with the Commission. Confidential treatment has been requested with respect to the omitted portions.

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: May 3, 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: May 3, 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 March 31, 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 May 3, 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.