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

FORM 10-Q

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

For the Quarterly Period Ended September 30, 2009

OR

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

For the Transition Period from to

Commission File Number 001-33103

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

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

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

(858) 436-1400
(Registrant's telephone number, including area code)

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

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

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

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

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

As of October 31, 2009, there were 50,451,528 shares of the registrant's Common Stock outstanding.

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CADENCE PHARMACEUTICALS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. ***Financial Statements***

CADENCE PHARMACEUTICALS, INC.
(a development stage company)
CONDENSED BALANCE SHEETS

	September 30, 2009 (unaudited)	December 31, 2008
Assets		
Current assets:		
Cash and cash equivalents	$ 85,810,760	$ 47,627,246
Investments in marketable securities	10,741,522	-
Restricted cash	1,695,696	2,195,696
Prepaid expenses	435,063	144,118
Other current assets	134,364	75,556
Total current assets	98,817,405	50,042,616
Property and equipment, net	6,826,161	4,477,020
Restricted cash	189,738	537,586
Other assets	25,082	90,792
Total assets	$ 105,858,386	$ 55,148,014
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,997,956	$ 4,877,854
Accrued liabilities	5,599,841	9,063,310
Current portion of long-term debt	6,229,049	7,694,173
Other current liabilities	22,048	22,048
Total current liabilities	14,848,894	21,657,385
Deferred rent	725,625	952,274
Long-term debt, less current portion and discount of $201,785 and $377,396, respectively	1,650,996	6,098,113
Total liabilities	17,225,515	28,707,772
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock, $0.0001 par value; 100,000,000 shares authorized, 50,442,805 shares and 38,363,985 shares issued and outstanding at September 30, 2009 and December 31, 2008, respectively	5,044	3,836
Additional paid-in capital	290,330,030	197,964,600
Accumulated other comprehensive income	4,540	-
Deficit accumulated during the development stage	(201,706,743)	(171,528,194)
Total stockholders' equity	88,632,871	26,440,242
Total liabilities and stockholders' equity	$ 105,858,386	$ 55,148,014

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

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

CONDENSED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from May 26, 2004 (Inception) through September 30, 2009
	2009	2008	2009	2008	
Operating expenses:					
Research and development	$ 4,924,778	$ 10,241,943	$ 15,144,099	$ 32,463,211	$ 152,780,004
Sales and marketing	2,608,441	664,143	4,330,695	2,175,120	11,272,085
General and administrative	3,762,851	2,754,064	9,549,203	8,323,996	37,517,197
Other	(944)	509	412,141	28,766	2,796,392
Total operating expenses	11,295,126	13,660,659	29,436,138	42,991,093	204,365,678
Loss from operations	(11,295,126)	(13,660,659)	(29,436,138)	(42,991,093)	(204,365,678)
Other (expense) income:					
Interest income	99,430	370,948	223,296	1,395,762	7,367,988
Interest expense	(243,124)	(459,262)	(924,298)	(1,463,146)	(4,205,754)
Other expense	(2,285)	(22)	(41,409)	(4,269)	(503,299)
Total other (expense) income, net	(145,979)	(88,336)	(742,411)	(71,653)	2,658,935
Loss before income tax	(11,441,105)	(13,748,995)	(30,178,549)	(43,062,746)	(201,706,743)
Net loss	$(11,441,105)	$(13,748,995)	$(30,178,549)	$(43,062,746)	$ (201,706,743)
Basic and diluted net loss per share[1]	$ (0.23)	$ (0.36)	$ (0.63)	$ (1.18)	
Shares used to compute basic and diluted net loss per share[1]	50,364,493	38,116,063	48,189,177	36,371,272	

(1) As a result of the issuance of 12,039,794 shares of common stock pursuant to a private placement in the first quarter of 2009 and 9,240,307 shares of common stock pursuant to an effective shelf registration in the first quarter of 2008, there is a lack of comparability in the per share amounts between the 2009 and 2008 periods presented. Please see Note 4 of the Notes to Financial statements for further discussion.

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

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,		Period from May 26, 2004 (Inception) through September 30,
	2009	2008	2009
Operating activities			
Net loss	$(30,178,549)	$(43,062,746)	$ (201,706,743)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	406,371	392,708	1,718,726
Loss on disposal of assets	-	28,766	68,123
Impairment of long-lived assets	-	-	2,353,162
Adjustment to estimate of impairment of long-lived assets	(180,926)	-	(180,926)
Impairment of available-for-sale securities	45,461	-	450,000
Stock-based compensation	6,071,300	4,475,117	18,484,972
Non-cash interest expense	20,249	24,929	67,515
Amortization of discount on note payable	175,611	198,551	630,662
Amortization of premiums on available-for-sale securities, net of accretion of discounts	53,650	-	53,650
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(402,037)	445,254	(714,306)
Accounts payable	(1,870,231)	2,310,425	2,851,552
Accrued liabilities and other liabilities	(4,572,813)	(3,736,206)	3,768,074
Net cash used in operating activities	(30,431,914)	(38,923,202)	(172,155,539)
Investing activities			
Purchases of marketable securities	(10,738,348)	-	(18,188,348)
Maturities of marketable securities	-	-	7,000,000
Restricted cash	847,848	134,000	(1,885,434)
Purchases of property and equipment	(1,607,808)	(1,212,692)	(8,119,320)
Proceeds from the sale of property and equipment	-	195	195
Net cash used in investing activities	(11,498,308)	(1,078,497)	(21,192,907)
Financing activities			
Proceeds from issuance of common stock, net	86,295,338	49,147,447	192,426,453
Disbursements from repurchase of common stock	-	-	(19,075)
Proceeds from sale of preferred stock, net	-	-	78,933,748
Borrowings under debt agreements	-	-	21,955,000
Payments under debt agreements	(6,181,602)	(3,475,806)	(14,136,920)
Net cash provided by financing activities	80,113,736	45,671,641	279,159,206
Net increase in cash and cash equivalents	38,183,514	5,669,942	85,810,760
Cash and cash equivalents at beginning of period	47,627,246	55,392,921	-
Cash and cash equivalents at end of period	$ 85,810,760	$ 61,062,863	$ 85,810,760
Supplemental disclosures			
Issuance of warrants in connection with loan and security agreement	$ -	$ -	$ 787,448
Assets acquired through lease concessions	$ -	$ -	$ 1,190,530
Property and equipment purchases in accounts payable and accrued expenses	$ 1,147,704	$ -	$ 1,147,704
Unrealized gain (loss) on investment securities	$ 4,540	$ (125,405)	$ 4,540
Cash paid for interest and fees	$ 671,424	$ 1,160,240	$ 3,187,055

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

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED FINANCIAL STATEMENTS
(Unaudited)

1. The Company

Cadence Pharmaceuticals, Inc. (the "Company") was incorporated in the state of Delaware in May 2004. The Company is a biopharmaceutical company focused on in-licensing, developing and commercializing proprietary product candidates principally for use in the hospital setting. The Company's primary activities since incorporation have been conducting research and development activities, including clinical trials, of the product candidates in its portfolio; organizational activities, including recruiting personnel, establishing office facilities; and raising capital to fund these activities. To date, the Company has in-licensed rights to two late-state product candidates, Acetavance™, an intravenous formulation of acetaminophen, and Omigard™, an omiganan pentahydrochloride 1% aqueous gel. In May 2009, the Company submitted a New Drug Application ("NDA"), for Acetavance, which was accepted for filing by the U.S. Food and Drug Administration ("FDA") and designated for priority review by the agency in July 2009. In March 2009, the Company announced that its Phase III clinical trial of Omigard did not meet its primary endpoint, and that it was discontinuing its development efforts for this product candidate because the results would not support an NDA submission. At the same time, the Company implemented cost reduction measures and restructured its operations to make additional resources available for its Acetavance development program and other operating activities. Since the Company has not begun principal operations of commercializing Acetavance, the Company is considered to be a development stage company.

The Company is currently evaluating alternative product names for intravenous acetaminophen because the FDA has rejected the initial proposed name, Acetavance. Although the Company has submitted alternative product names to the FDA for evaluation, this product candidate will continue to be referred to as Acetavance in this report.

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, 2008, as included in the Company's 2008 Annual Report on Form 10-K filed with the SEC on March 16, 2009.

The Company has evaluated subsequent events through November 5, 2009, which is the date these financial statements were issued, and does not believe there are any material subsequent events that would require further disclosure.

Stock-Based Compensation

Stock option awards. Stock options are currently valued using the Black-Scholes option pricing model on the date of grant. This option pricing model involves a number of estimates, including the expected lives of stock options, the Company's anticipated stock volatility and interest rates. The following table summarizes the weighted average estimates the Company used in the Black-Scholes option-pricing model during the three and nine months ended September 30, 2009 and 2008, to determine the fair value of employee and non-employee director stock options granted during each period:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Risk free interest rates	2.7%	3.2%	2.1%	2.9%
Expected life in years	6.1 years	6.0 years	6.0 years	6.0 years
Expected dividend yield	0.0%	0.0%	0.0%	0.0%
Expected volatility	71.8%	70.0%	71.8%	70.0%

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued
(Unaudited)

Restricted stock awards. Restricted stock units ("RSUs") are valued based on the fair market value of the Company's stock on the date of grant. In August 2009, the Company granted a total of 300,500 RSUs to certain officers and employees. One-half of the RSUs vest upon the approval by the FDA of the NDA for Acetavance, if such approval occurs prior to December 31, 2009. The remaining half vest upon the first anniversary of the approval by the FDA of the NDA for Acetavance.

Compensation expense for all stock-based payment awards is recognized using the straight-line method. Stock-based compensation expense recognized during the period is based on the value of the portion of awards that is ultimately expected to vest. Hence, the gross expense is reduced for estimated forfeitures and adjusted for the probability of achieving performance criteria. More specifically, the performance conditions for the August 2009 RSU grants were considered probable of being achieved as of September 30, 2009, and therefore stock-based compensation expense of $789,187 related to the RSU grants was recognized during the three months ended September 30, 2009. The table below summarizes the total stock-based compensation expense included in the Company's statements of operations for the periods presented:

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from May 26, 2004 (Inception) through September 30,
	2009	2008	2009	2008	2009
Research and development	$1,132,762	$ 648,128	$2,159,261	$1,501,684	$ 5,930,668
Sales and marketing	161,335	15,077	230,967	46,042	326,065
General and administrative	1,554,112	970,392	3,681,072	2,927,391	12,228,240
Stock-based compensation expense included in operating expenses	2,848,209	1,633,597	6,071,300	4,475,117	18,484,973
Total stock-based compensation expense included in loss from operations	$2,848,209	$1,633,597	$6,071,300	$4,475,117	$ 18,484,973

Fair Value Reporting

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

Effective January 1, 2008, the Company adopted new authoritative guidance for fair value measurements. This new guidance defines fair value, establishes a framework for measuring fair value in accordance with GAAP, and expands disclosures about fair value measurements, but does not require any new fair value measurements. The valuation techniques included in the guidance are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect market assumptions and are classified into the following fair value hierarchy:

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

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

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

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued
(Unaudited)

The following table presents further detail of the financial instruments carried at fair value on the Company's balance sheet as of September 30, 2009. The table does not include assets and liabilities which are measured at historical cost or on any basis other than fair value:

Description	Total Carrying Value	Fair Value Measurements as of September 30, 2009			
		Level 1	Level 2	Level 3	Total Fair Value
Assets:					
Cash and cash equivalents:					
Money market funds	$84,130,072	$84,130,072	$ -	$ -	$ 84,130,072
Debt instruments – U.S. Government agencies	1,489,544	1,489,544	-	-	1,489,544
Investments in marketable securities – short-term:					
Debt instruments – U.S. Government agencies	10,741,522	10,741,522	-	-	10,741,522
Assets at fair value	$96,361,138	$96,361,138	$ -	$ -	$ 96,361,138

3. Recent Accounting Pronouncements

Effective January 1, 2009, the Company adopted the guidance for determining whether an equity-linked financial instrument (or embedded feature) is indexed to an entity's own stock. If it is determined that the instrument is linked to an entity's own stock, it would qualify as a scope exception for derivative accounting. The warrants issued by the Company in its February 2009 private placement were determined to be indexed to its own stock and therefore, and in accordance with other relevant guidance, were accounted for as permanent equity. See Note 11 for further discussion.

In May 2009, the Financial Accounting Standards Board ("FASB") issued guidance regarding subsequent events, which is intended to establish general standards of accounting for, and disclosure of, events that occur after the balance sheet date but before financial statements are issued or are available to be issued. Specifically, the guidance sets forth the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements, the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements, and the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. The guidance is effective for financial statements issued for interim and annual financial periods ending after June 15, 2009 and the Company adopted the provisions for the quarter ended June 30, 2009. This adoption of the guidance did not have a material effect on the Company's financial statements. See Note 2 for the Company's disclosure regarding its evaluation of subsequent events.

In June 2009, the FASB issued *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles*, which replaces the previous guidance, *The Hierarchy of Generally Accepted Accounting Principles*, and establishes only two levels of U.S. GAAP, authoritative and non-authoritative. Under the standard, the FASB Accounting Standards Codification (the "Codification") is the source of authoritative, non-governmental GAAP, except for rules and interpretive releases of the SEC, which are sources of authoritative GAAP for SEC registrants. All other non-grandfathered, non-SEC accounting literature not included in the Codification is non-authoritative. This standard is effective for financial statements issued for interim and annual financial periods ending after September 15, 2009 and the Company adopted the provisions for the quarter ended September 30, 2009. Adoption of the standard has not had a material impact on the Company's financial statements.

4. Net Loss Per Share

Net loss per share is presented as basic and diluted net loss per share. Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, stock options, restricted stock units and warrants are considered to be common stock equivalents and are not included in the calculations of diluted net loss per share as their effect is antidilutive. Additionally, the restricted stock units granted during the three months ended September 30, 2009 were excluded from the basic net loss calculation as these units do not include dividend rights and therefore are not considered to be participating securities.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued
(Unaudited)

The actual net loss per share amounts for the three and nine months ended September 30, 2009 and 2008 were computed based on the weighted average shares of common stock outstanding during the respective periods. The net loss per share for the three and nine months ended September 30, 2009 includes the effect of the (i) 12,039,794 common shares issued pursuant to a private placement in the first quarter of 2009 and (ii) 9,240,307 common shares issued pursuant to an effective shelf registration in the first quarter of 2008. The net loss per share for the three and nine months ended September 30, 2008 includes only the effect of the 9,240,307 common shares issued pursuant to an effective shelf registration in the first quarter of 2008. As a result of the issuance of these common shares, there is a lack of comparability in the basic and diluted net loss per share amounts for the periods presented.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2009	2008	2009	2008
Shares for basic and dilutive net loss per share:				
Weighted average common shares outstanding	50,430,608	38,357,478	48,297,103	36,669,055
Weighted average unvested common shares subject to repurchase	(66,115)	(241,415)	(107,926)	(297,783)
Denominator for basic and diluted earnings per share	50,364,493	38,116,063	48,189,177	36,371,272

At September 30, 2009 and 2008, stock options, restricted stock units, and warrants totaling 11,317,818 and 3,919,583 shares, respectively, were excluded from the calculations as their effect would have been antidilutive.

5. Comprehensive Income (Loss)

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

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from May 26, 2004 (Inception) through September 30,
	2009	2008	2009	2008	2009
Net loss	$(11,441,105)	$(13,748,995)	$(30,178,549)	$(43,062,746)	$ (201,706,743)
Other comprehensive income:					
Net unrealized gain (loss) on available-for-sale investments	4,540	(27,214)	4,540	(125,405)	4,540
Comprehensive loss	$(11,436,565)	$(13,776,209)	$(30,174,009)	$(43,188,151)	$ (201,702,203)

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued
(Unaudited)

6. Property and Equipment

Property and equipment for operations were as follows:

	September 30, 2009	December 31, 2008
Property and equipment:		
Leasehold improvements	$ 1,592,404	$ 1,592,404
Computer equipment and software	739,370	607,319
Furniture and fixtures	465,366	427,811
Construction-in-process	5,594,879	3,008,972
	8,392,019	5,636,506
Less accumulated depreciation	(1,565,858)	(1,159,486)
Total	$ 6,826,161	$ 4,477,020

For the three months ended September 30, 2009 and 2008, the Company incurred depreciation expense of $135,052 and $133,852, respectively. For the nine months ended September 30, 2009 and 2008, the Company incurred depreciation expense of $406,371 and $392,708, respectively. Since May 26, 2004 (inception) through September 30, 2009, the Company has incurred depreciation expense of $1,718,726.

7. Investments in Marketable Securities

The cost, gross unrealized holding gains, gross unrealized holding losses and fair value of available-for-sale investments by types and classes of security at September 30, 2009 and December 31, 2008 consisted of the following:

At September 30, 2009	Amortized Cost Basis	Other-than-temporary Impairments	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Available-for-sale:					
Debt instruments – U.S. Government agencies	$12,226,526	$ -	$ 4,540	$ -	$12,231,066
	$12,226,526	$ -	$ 4,540	$ -	$12,231,066

At December 31, 2008	Amortized Cost Basis	Other-than-temporary Impairments	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Fair Value
Available-for-sale:					
Equity securities	$ 450,000	$ (404,539)	$ -	$ -	$ 45,461
	$ 450,000	$ (404,539)	$ -	$ -	$ 45,461

Investments by contractual maturity are as follows:

	September 30, 2009		December 31, 2008	
	Cost	Fair Value	Cost	Fair Value
Due or callable in one year or less	$12,226,526	$12,231,066	$ -	$ -
Due after one year	$ -	$ -	$ -	$ -

Investments are considered to be impaired when a decline in fair value is judged to be other-than-temporary. The Company employs a methodology that reviews specific securities in evaluating potential impairment of its investments. In the event that the cost of an investment exceeds its fair value, the Company evaluates, among other factors, the Company's intent and ability to hold the investment and extent to which the fair value is less than cost; the financial health of and business outlook for the issuer; and

CADENCE PHARMACEUTICALS, INC.
(a development stage company)

NOTES TO CONDENSED FINANCIAL STATEMENTS - Continued
(Unaudited)

operational and financing cash flow factors. During the fourth quarter of 2008, the Company recorded an other-than-temporary impairment charge of $176,539 to reduce the book value of the Company's equity security position in its Migenix holding to the current fair value. In the first and second quarters of 2009, the Company recorded charges of $25,690 and $19,771, respectively, to impair the remaining balance of the security holding after the Company discontinued its Omigard program.

8. Omigard Restructuring Charges

In March 2009, the Company announced its decision to discontinue the development of its Omigard product candidate. This decision was due to the failure of the Company's Phase III clinical trial of Omigard to meet its primary endpoint and the Company's belief that the results of this clinical trial would not support an NDA submission. In connection with the discontinuation of the development of Omigard, the Company implemented a corporate restructuring in order to reduce, and eventually eliminate, costs associated with the Omigard program, including the termination of 11 employees. The Company recorded impairment charges in the fourth quarter of 2008 of $2,353,162 with respect to certain Omigard manufacturing equipment, and recorded restructuring charges of $650,786 in the first quarter of 2009 for severance-related costs and the termination of contractual obligations. During the second and third quarters of 2009, the Company recorded an adjustment to the impairment charge taken on the manufacturing equipment, reducing the charge by $180,699 and $227, respectively, as actual costs incurred in disposing of the assets were less than anticipated. Additionally, adjustments of $57,002 and $717, respectively, were recorded to the severance obligation in the second and third quarters of 2009. All of the charges and adjustments are included in the Company's "Other" operating expenses on the condensed statement of operations. As of September 30, 2009, a liability of $113,310, included in "Accrued liabilities" on the condensed balance sheet, remains for the unpaid portion of the restructuring liability for severance-related costs and termination of contractual obligations. There was no such liability at December 31, 2008.

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

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from May 26, 2004 (Inception) through September 30,
	2009	2008	2009	2008	2009
Beginning restructuring liability	$ 302,397	$ -	$ -	$ -	$ -
Severance and termination charges incurred	-	-	650,786	-	650,786
Adjustments to severance and termination charges	(717)	-	(57,719)	-	(57,719)
Severance and termination disbursements	(188,370)	-	(479,757)	-	(479,757)
Ending restructuring liability	$ 113,310	$ -	$ 113,310	$ -	$ 113,310

Further, on May 8, 2009, the Company notified Migenix, Inc. ("Migenix") of the termination of the license agreement for Omigard, and informed Solvay, S.A. ("Solvay") of its intention to terminate the long-term supply agreement and a related license agreement for the active ingredient in Omigard. The termination of the long-term supply agreement and related license agreement became effective on July 7, 2009. No charges were incurred from the termination of these agreements. See Note 10 for further discussion.

9. Loan and Security Agreement

In February 2006, the Company entered into a $7,000,000 Loan and Security Agreement (the "Agreement") with Silicon Valley Bank and Oxford Finance Corporation to provide growth capital to the Company. In June 2006, the Company drew down $7,000,000 under the Agreement at a fixed interest rate of 11.47% and in July 2009, the Company made the final payment to retire the obligation.

In November 2007, the Company amended the Agreement and entered into the Second Amendment to Loan and Security Agreement (the "Second Amendment") with the same parties and GE Business Financial Services Inc. (formerly known as Merrill Lynch Business Financial Services Inc.), to secure an additional $15,000,000 credit facility. In December 2007, the Company drew down $15,000,000 under the Second Amendment in two separate draws of $5,000,000 and $10,000,000 with fixed interest rates of

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7.83% and 7.74%, respectively, net of a $45,000 loan fee (the "loan fee"). In January 2008, the Company began making the first of six monthly interest-only payments on the $15,000,000 balance of the Second Amendment and in July 2008, began making the first of 30 equal monthly principal and interest payments.

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

As of September 30, 2009 and December 31, 2008, the aggregate principal balance of the loans, net of the loan discount, included on the Company's balance sheets was $7,880,045 and $13,792,286, respectively.

Warrants

In connection with the Second Amendment to the Agreement with Silicon Valley Bank, Oxford Finance Corporation and GE Business Financial Services Inc., the Company issued six fully exercisable warrants to the lenders to purchase an aggregate of 50,331 shares of the Company's common stock at an exercise price of $12.67 per share, expiring November 30, 2014. The Company determined the fair value of these warrants to be $473,876, using the Black-Scholes valuation model. The value of the warrants was recorded as a discount to the note payable, and will be amortized to interest expense over the expected term of the loan agreement. The warrants were valued using the following assumptions: risk-free interest rate of 3.64%; dividend yield of 0.0%; expected volatility of 70.0%; and a contractual term of seven years. As of September 30, 2009, all warrants related to the Second Amendment were outstanding.

10. Commitments and Contingencies

Leases

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

Rent expense, net of sublease rent income, for the three months ended September 30, 2009 and 2008 was $154,272 and $144,857, respectively. Rent expense, net of sublease rent income, for the nine months ended September 30, 2009 and 2008 was $438,764 and $423,950, respectively. Since May 26, 2004 (inception) through September 30, 2009, the Company has incurred total net rent expense of $2,560,004.

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Supply Agreements

Baxter Healthcare Corporation

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

The Supply Agreement also requires the Company to fund specified improvements at Baxter's manufacturing facility and purchase certain equipment for use by Baxter in manufacturing Acetavance. As of September 30, 2009, the Company has reimbursed Baxter for a portion of the facility improvements and has expensed the costs as they have been incurred. The equipment purchased for the manufacturing of Acetavance to which the Company retains title is being capitalized as it has alternative future uses and will be amortized over the life of the equipment. At the time of termination, the Supply Agreement requires the Company to reimburse Baxter for all reasonable costs for the de-installation of the Company's equipment and the restoration of Baxter's manufacturing facility to its pre-installation condition. The Company is not able to reasonably estimate the cost and the timing of these expenses at this time and therefore cannot reasonably estimate the fair value of the retirement obligation.

In anticipation of the execution of the Supply Agreement, the Company entered into an irrevocable standby letter of credit in favor of Baxter in January 2007. The letter of credit was for an initial amount of $3,268,000 and was based on anticipated costs to be incurred by Baxter for the improvements at Baxter's manufacturing facility and the purchase of equipment to be used by Baxter in the manufacturing of the finished drug product. Under the terms of the Supply Agreement, the amount of the letter of credit may be reduced on a quarterly basis following the execution of the Supply Agreement for the costs the Company has reimbursed Baxter to fund the specified facility improvements or equipment purchases. As of September 30, 2009, at the request of the Company and based upon the costs reimbursed to Baxter by the Company, the letter of credit had been reduced by $2,268,000 to $1,000,000. The letter of credit in favor of Baxter is collateralized by a certificate of deposit which may be drawn down in part or in whole by Baxter in the event the Company fails to perform its obligations to fund the specified facility improvements or equipment purchases. As of September 30, 2009, the certificate of deposit had been reduced to $1,000,000 in accordance with the reduction in the letter of credit.

Solvay SA

As a result of the discontinuation of the Company's development program for Omigard and the termination of its license agreement with Migenix for this product candidate, on May 8, 2009, the Company notified Solvay of its intention to terminate the long-term supply agreement for the active ingredient in Omigard and a related license agreement between the Company and Solvay. The termination of the long-term supply agreement and related license agreement became effective on July 7, 2009. No charges were incurred from the termination of these agreements.

License Agreements and Acquired Development and Commercialization Rights

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

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In July 2004, the Company in-licensed from Migenix the technology and the exclusive development and commercialization rights to its omiganan pentahydrochloride product candidate for the prevention and treatment of device-related, wound-related and burn-related infections in North America and Europe. As a result of the discontinuation of the Omigard development program, on May 8, 2009, the Company terminated the collaboration and license agreement between the Company and Migenix for this product candidate. No charges were incurred from the termination of this agreement. The Company has disclosed the final results of its Phase III clinical trial of Omigard in several scientific forums and intends to complete its other regulatory obligations related to the closure of this study.

11. Stockholder's Equity

Private Placement

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

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

Shelf Registration

On November 30, 2007, the Company filed a shelf registration statement (the "Common Stock Registration Statement") that was declared effective by the SEC on December 11, 2007. The Common Stock Registration Statement authorized the Company to sell shares of its common stock from time to time in one or more offerings, with an aggregate offering price of up to $100,000,000. In February 2008, the Company issued 9,240,307 shares of its common stock at a purchase price of $5.34 per share pursuant to a registered direct offering under the Common Stock Registration Statement. The registered direct offering raised proceeds, net of offering costs, of $49,139,017 and the purchasers in the offering consisted of new investors and existing stockholders, including executive officers and directors of the Company. On September 4, 2009, the Company filed a universal shelf registration statement (the "Universal Self Registration Statement") to allow the Company to sell up to $100,000,000 of debt securities, preferred stock, common stock, debt warrants and equity warrants. The Universal Shelf Registration Statement was subsequently declared effective on September 17, 2009 by the SEC and as a result, the Company filed an amendment to its Common Stock Registration Statement on the same day to deregister all of the remaining shares of common stock originally registered by the Common Stock Registration Statement. This amendment to deregister the remaining shares under the Common Stock Registration Statement was declared effective by the SEC on September 18, 2009.

12. Income Taxes

The Company is subject to taxation in the U.S. and various state jurisdictions. The Company's tax years for 2004 and forward are subject to examination by the Federal and California tax authorities due to the carryforward of unutilized net operating losses and research and development credits. The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrued interest and/or penalties related to income tax matters in the Company's condensed balance sheets at September 30, 2009 or December 31, 2008, and has recognized no interest and/or penalties in the Company's condensed statement of operations for the three and nine months ended September 30, 2009 and 2008, respectively. As of September 30, 2009, the Company had not recorded any unrecognized tax benefits.

The Company has not completed a Section 382/383 analysis regarding the limitation of net operating loss and research and development credit carryforwards. Until this analysis has been completed, the Company has removed the deferred tax assets for net operating losses from its deferred tax asset schedule and has recorded a corresponding decrease to its valuation allowance. When this analysis is finalized, the Company plans to update its unrecognized tax benefits. 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

The following discussion contains forward-looking statements, which involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various 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, 2008 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, 2008.

Overview

We are a biopharmaceutical company focused on in-licensing, developing and commercializing product candidates principally for use in the hospital setting. Since our inception in May 2004, we have in-licensed rights to two late-stage product candidates, Acetavance™, a proprietary intravenous formulation of acetaminophen, and Omigard™, or omiganan pentahydrochloride 1% aqueous gel. We in-licensed the exclusive United States, or U.S., and Canadian rights to Acetavance from Bristol-Myers Squibb Company, or BMS, which markets this product candidate in Europe and other markets for the treatment of acute pain and fever under the brand name Perfalgan®. We in-licensed the exclusive rights to commercialize Omigard in North America and Europe in July 2004, and we devoted substantial efforts to the development of this product candidate from that time until March 2009, when we announced the discontinuation of this program due to the failure of our Phase III clinical trial to meet its primary endpoint.

We submitted a New Drug Application, or NDA, for Acetavance in May 2009, which was accepted for filing by the U.S. Food and Drug Administration, or FDA, and designated for priority review by the agency in July 2009. We believe that Acetavance may fulfill significant unmet needs in the hospital setting. We also believe that the hospital pharmaceuticals market is both concentrated and underserved, which may enable us to build our own hospital-focused sales force if Acetavance achieves FDA approval. We intend to build a leading franchise in the hospital setting, continuing to focus on products that are in late stages of development, currently commercialized outside the U.S., or approved in the U.S. but with significant commercial potential for proprietary new uses or formulations.

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

The U.S. Patent and Trademark Office has issued a Notice of Allowance in connection with our intent-to-use trademark application for the mark Cadence™, and we have applied for U.S. trademark registration for Acetavance™. This report also contains trademarks of others, including Perfalgan®. We are currently evaluating alternative product names for intravenous acetaminophen because the FDA has rejected the initial proposed name, Acetavance. Although we have submitted alternative product names to the FDA for evaluation, this product candidate will continue to be referred to as Acetavance throughout this report.

Background

We are a biopharmaceutical company focused on in-licensing, developing and commercializing product candidates principally for use in the hospital setting. We were incorporated in May 2004 and during that year we focused on hiring our management team and initial operating employees. Since that time, we have in-licensed rights to two late-stage product candidates, Acetavance, a proprietary intravenous formulation of acetaminophen, and Omigard, or omiganan pentahydrochloride 1% aqueous gel. Substantial operations did not commence until September 2004. During 2005, we completed the special protocol assessment, or SPA, for Omigard, and initiated Phase III clinical trials for this product candidate. In March 2006, we in-licensed rights to Acetavance from BMS which currently markets the product in Europe and several other markets under the brand name Perfalgan. In October 2006, we initiated our Phase III clinical development program for this product candidate for the treatment of acute pain and fever in adults and children. We believe that Acetavance may fulfill significant unmet needs in the hospital setting. We also believe that the hospital pharmaceuticals market is both concentrated and underserved which may enable us to build our own hospital-focused sales force as Acetavance approaches potential FDA approval. We intend to build a leading franchise in the hospital setting, continuing to focus on products that are in late stages of development, currently commercialized outside the U.S., or approved in the U.S. but with significant commercial potential for proprietary new uses or formulations.

We have completed our clinical development program for Acetavance and submitted an NDA to the FDA in May 2009, requesting marketing approval of Acetavance for the treatment of acute pain and fever in adults and children. Our NDA was accepted for filing by the FDA and designated for priority review in July 2009. Priority review is granted to those products that address significant unmet medical needs or have the potential to provide a significant improvement compared to marketed products and provides for a target review period of six months from the date of the NDA submission. As such, the FDA issued a goal date for completion of its review of the NDA of November 13, 2009 under the Prescription Drug User Fee Act, or PDUFA.

In March 2009, we announced that our Phase III clinical trial of Omigard did not meet its primary endpoint and discontinued our development efforts for this product candidate because we believe that the results of the study do not support applications for marketing approval. At the same time, we implemented cost reduction measures and restructured our operations to make additional resources available for our Acetavance development program and other operating activities.

We are a development stage company and we have incurred significant net losses since our inception. As of September 30, 2009, we had an accumulated deficit of $201.7 million. These losses have resulted principally from costs incurred in connection with research and development activities, including license fees, costs of clinical trial activities associated with our product candidates and general and administrative expenses. We expect to continue to incur operating losses for the next several years as we commercialize Acetavance, if approved by the FDA, and acquire or in-license additional products, technologies or businesses that are complementary to our own.

In October 2006, we completed an initial public offering in which we sold 6.0 million shares of our common stock at $9.00 per share and received aggregate net proceeds of $48.4 million (after underwriting discounts and offering costs). In November 2006, following exercise of the underwriters' over-allotment option, we sold 0.9 million shares of our common stock at $9.00 per share and received aggregate net proceeds of $7.5 million (after underwriting discounts). In February 2008, we completed a registered direct offering pursuant to an effective shelf registration statement under which we issued and sold 9.2 million shares of common stock at $5.34 per share and received aggregate net proceeds of approximately $49.1 million (after offering costs). In February 2009, we raised additional funds by completing a private placement of approximately 12.0 million shares of common stock at a price of $7.13 per share, and warrants to purchase up to approximately 6.0 million additional shares of common stock at a price of $0.125 per warrant, for aggregate net proceeds of $86.2 million (after offering costs). Each warrant has a five-year term and is exercisable in cash or by net exercise for one share of common stock at a price of $7.84. As of September 30, 2009, all of the warrants remain outstanding.

Revenues

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

Research and Development Expenses

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

Our historical research and development expenses relate predominantly to Acetavance and our discontinued product candidate, Omigard. We expense all research and development charges as they are incurred as the underlying technology associated with these expenditures relates to our research and development efforts and has no alternative future uses. We use external service providers and vendors to conduct our clinical trials, to manufacture our product candidates to be used in clinical trials and to provide various other research and development related products and services. A substantial portion of these external costs are tracked on a project basis. Our internal research and development resources are used in several projects and may not be attributable to a specific product candidate. For example, a substantial portion of our internal costs, including personnel and facility related costs, is not tracked on a project basis.

The following table summarizes our research and development expenses included in our statements of operations by project for the periods indicated. Costs that are not attributable to a specific product candidate, including salaries and related personnel costs, are included in the "other supporting costs" category (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from May 26, 2004 (Inception) through September 30,
	2009	2008	2009	2008	2009
Acetavance[1]	$ 1,555	$ 4,773	$ 4,651	$12,246	$ 62,044
Omigard[2][3]	61	2,512	1,596	12,844	57,392
Other supporting costs	3,309	2,957	8,897	7,373	33,344
	$ 4,925	$ 10,242	$15,144	$32,463	$ 152,780

(1) We paid an up-front license fee of $25.0 million in 2006 for Acetavance, which is included in the costs for the period from May 26, 2004 (inception) through September 30, 2009. We may be required to make future milestone payments totaling up to $40.0 million upon the achievement of various milestones related to regulatory and commercial events in addition to royalties on the sales of the licensed products, including payments totaling $15.0 million upon the approval of our NDA by the FDA.

(2) We paid an up-front license fee of $2.0 million in 2004 for Omigard, of which $1.5 million is included in the costs for the period from May 26, 2004 (inception) through September 30, 2009. As a result of the termination of our collaboration and license agreement with Migenix, Inc., or Migenix, on May 8, 2009, we will not be obligated to make any future milestone or royalty payments with respect to this product candidate.

(3) For the first quarter of 2009, we recorded restructuring charges of $0.7 million related to the discontinuation of our Omigard development program, and for the fourth quarter of 2008, we recorded an impairment charge of $2.4 million on our Omigard manufacturing equipment due to the discontinuation of the program. In the second quarter of 2009, we adjusted the impairment charge on the manufacturing equipment, reducing the charge by $0.2 million as actual costs incurred have been lower than anticipated. These charges and adjustments are presented separately on our statement of operations in "Other" operating expenses for the applicable periods and are not included in the research and development expenses presented in the table.

At this time, due to the risks inherent in the clinical trial and regulatory approval processes, we are unable to estimate with any certainty the costs we will incur in completing the development and obtaining approval from the FDA for the potential commercialization of Acetavance. Clinical development and regulatory approval timelines, the probability of success and development costs vary widely. We are currently focused on completing our product development program for Acetavance and obtaining marketing authorizations for this product candidate. We cannot forecast with any degree of certainty whether Acetavance will be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

We expect our development expenses to decrease over the next few years due to the completion of our clinical development program and the filing of our NDA for Acetavance, combined with the discontinuation of our development program for Omigard. However, we expect we will continue to incur development costs for Acetavance as we initiate additional clinical studies in children in an effort to obtain a six-month pediatric extension of market exclusivity for this product candidate.

Sales and Marketing Expenses

Our sales and marketing expenses consist primarily of market research studies and pre-launch marketing activities, fees related to the establishment of our commercial infrastructure, salaries, benefits and professional fees related to building our sales and marketing capabilities. We anticipate substantial increases in our sales and marketing expenses as we continue to develop and prepare for the potential commercialization of Acetavance, including the addition of marketing and hospital-focused sales personnel to market our products to physicians, nurses, group purchasing organizations and third-party payors.

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries, benefits and professional fees related to our administrative, finance, human resources, legal, business development and internal systems support functions, as well as insurance and facility costs. We anticipate increases in general and administrative expenses as we continue to build our corporate infrastructure in preparation for the potential commercialization of Acetavance.

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 is primarily the interest we have incurred under our amended loan and security agreement. Other expense includes charges we have incurred to recognize other-than-temporary declines in the market value of our available-for-sale securities, losses we have recognized on the disposal of equipment and the gains or losses recognized on transactions denominated in foreign currencies.

Income Taxes

A deferred tax asset is recognized for temporary differences that will result in deductible amounts in future years and for carryforwards. In addition, a valuation allowance is recognized if, based on existing facts and circumstances, it is more likely than not that some portion, or all, of the deferred tax asset will not be realized. As of December 31, 2008, we had both federal and state net operating loss carryforwards of approximately $131.9 million, and both federal and state research and development tax credit carryforwards of approximately $3.1 million and $1.3 million, respectively. If not utilized, the net operating loss carryforwards will begin expiring in 2024 for federal purposes and 2014 for state purposes. The federal tax credits will begin expiring in 2024 unless previously utilized and the state tax credits carryforward indefinitely. Under Section 382/383 of the Internal Revenue Code of 1986, as amended, 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. Until this analysis is completed, we have removed the deferred tax assets and research and development credits from our deferred tax asset schedule, and have recorded a corresponding decrease to our valuation allowance. When this analysis is completed, we plan to update the unrecognized tax benefits if it is more likely than not that some portion, or all, of the deferred tax asset will be realized. As of September 30, 2009, we have not recognized any federal or state income tax benefit in our statement of operations. We recognize the impact of an uncertain income tax position taken on our income tax return at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position is not recognized if it has less than a 50% likelihood of being sustained. As of September 30, 2009, we have not recorded any unrecognized tax benefits.

Critical Accounting Policies and Estimates

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

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

Research and Development Expenses

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

Stock-Based Compensation

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from May 26, 2004 (Inception) through September 30,
	2009	2008	2009	2008	2009
Research and development	$ 1,133	$ 648	$ 2,159	$ 1,502	$ 5,931
Sales and marketing	161	15	231	46	326
General and administrative	1,554	970	3,681	2,927	12,228
Stock-based compensation expense included in operating expenses	2,848	1,633	6,071	4,475	18,485
Total stock-based compensation expense included in loss from operations	$ 2,848	$ 1,633	$ 6,071	$ 4,475	$ 18,485

As of September 30, 2009, the total future compensation expense related to the current unvested stock options and RSUs is approximately $16.1 million.

Long-Lived Assets

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

Results of Operations

Three-Month Periods Ended September 30, 2009 and 2008

Operating expenses

Research and Development Expenses. Research and development expenses decreased $5.3 million to $4.9 million for the three months ended September 30, 2009, from $10.2 million for the comparable period in 2008. This reduction is primarily due to decreased clinical trial activity in 2009 as compared to 2008 as we completed our clinical development program and filed our NDA for Acetavance in May 2009. Further, in March 2009, we discontinued our development efforts for our Omigard product candidate as our Phase III clinical trial for this drug did not meet its primary endpoint and the results would not support an NDA submission. More specifically, the reduction in research and development expenses for the three months ended September 30, 2009, as compared to the three months ending September 30, 2008, can be attributed to the following:

- a decrease of $3.2 million in spending under our Acetavance program, primarily due to a reduction in clinical research expenses as we completed our development program in early 2009;

- a decrease of $2.5 million in spending under our Omigard program, primarily due to a reduction in spending related to the completion of enrollment in our CLIRS clinical trial in April 2008 and the subsequent discontinuation of our Omigard development program, and reduced expenses related to the discontinuation of our efforts to prepare for the commercial manufacturing of this product candidate; and

- an increase of $0.4 million in other supporting costs, primarily related to an additional $0.5 million in stock-based compensation charges from an increase in equity awards outstanding during the 2009 period which was partially offset by a reduction in other salary and related personnel costs.

We expect that our development expenses in 2009 will continue to be considerably lower than we have historically reported as we have completed or discontinued our existing clinical development programs. However, expenses related to the commercial launch of Acetavance are expected to continue to increase in 2009 and partially offset the decline in clinical development expenses.

Sales and Marketing Expenses. Sales and marketing expenses increased $1.9 million for the three months ended September 30, 2009, to $2.6 million, from $0.7 million for the comparable period in 2008. This increase was primarily due to the initiation of our commercial and supply operation functions during 2009, as we establish our commercial infrastructure in preparation for the potential commercialization of Acetavance. In addition, advertising, promotion and market research expenses for the 2009 period increased as we prepare for the potential commercial launch for Acetavance. This increase in spending under our Acetavance program more than offset a reduction in spending under our Omigard program and we anticipate our sales and marketing expenses will increase substantially in the future as we continue to prepare for the potential commercial launch of Acetavance.

General and Administrative Expenses. General and administrative expenses increased $1.0 million for the three months ended September 30, 2009 to $3.8 million, from $2.8 million for the comparable period in 2008. This increase was primarily due to increases in salaries and related personnel costs during the 2009 period, including an additional $0.6 million in stock-based compensation charges from additional equity awards outstanding during the 2009 period as compared to the same period in 2008.

Other income and expense net

Our net other expense for the three months ended September 30, 2009 was $ 0.1 million, an increase of less than $0.1 million as compared to the three months ended September 30, 2008. This change was primarily due to a lower average yield earned on our investments during the three months ended September 30, 2009 as compared to the same period in 2008, mostly offset by lower interest expense incurred during the 2009 period due to the principal payments we have been making on the outstanding balance under our loan and security agreement. The aggregate balance of the loans as of September 30, 2009 and December 31, 2008, net of the loan discount, included on our condensed balance sheets was $7.9 million and $13.8 million, respectively.

Nine-Month Periods Ended September 30, 2009 and 2008

Operating expenses

Research and Development Expenses. Research and development expenses decreased $17.3 million to $15.1 million for the nine months ended September 30, 2009, from $32.4 million for the comparable period in 2008. This reduction was primarily due to decreased clinical trial activity in 2009 as compared to 2008, as we completed our existing clinical development programs and filed our NDA for Acetavance in May 2009. Further, in March 2009, we discontinued our development efforts for our Omigard product candidate as our Phase III clinical trial for this drug did not meet its primary endpoint and the results would not support an NDA submission. More specifically, the reduction in research and development expenses for the nine months ended September 30, 2009, as compared to the nine months ending September 30, 2008, can be attributed to the following:

- a decrease of $11.2 million in spending under our Omigard program, primarily due to a reduction in spending related to the completion of enrollment in our CLIRS clinical trial in April 2008 and the subsequent discontinuation of our Omigard development program, and reduced expenses related to the discontinuation of our efforts to prepare for the commercial manufacturing of this product candidate;

- a decrease of $7.6 million in spending under our Acetavance program due to a reduction in clinical research expenses as we completed our development program for this product candidate in early 2009; and

- an increase of $1.5 million in other supporting costs, primarily related to additional salary and related personnel costs during the nine months ended September 30, 2009 as compared to the same period in 2008, including an additional $0.7 million in stock-based compensation charges from additional equity awards outstanding during the 2009 period as compared to the same period in 2008.

Sales and Marketing Expenses. Sales and marketing expenses increased $2.1 million for the nine months ended September 30, 2009, to $4.3 million, from $2.2 million for the comparable period in 2008. This increase was primarily due to development of our commercial and supply operation functions during 2009 as we establish our commercial infrastructure in preparation for the potential commercialization of Acetavance. Partially offsetting this increase is a decline in marketing spending under our Omigard program for the 2009 period as compared to the same period in 2008 as we discontinued the Omigard program.

General and Administrative Expenses. General and administrative expenses increased $1.2 million for the nine months ended September 30, 2009 to $9.5 million, from $8.3 million for the comparable period in 2008. This increase was primarily due to increases in salaries and related personnel costs during the nine months ended September 30, 2009 as compared to the same period in 2008, including an additional $0.8 million in stock-based compensation charges from additional equity awards outstanding during the 2009 period as compared to the same period in 2008.

Other Operating Expenses. During the nine months ended September 30, 2009, we recorded restructuring charges of $0.6 million related to the discontinuation of our Omigard development plan. These charges include severance costs associated with a reduction in force of 11 employees and other costs associated with the termination of contractual obligations related to the Omigard program. Additionally, we recorded an adjustment to the previously recorded impairment charge on our Omigard manufacturing equipment, reducing the charge by $0.2 million. During the nine months ended September 30, 2008, we recorded a loss on the disposal of assets of less than $0.1 million.

Other income and expense net

Our net other expense for the nine months ended September 30, 2009 increased $0.6 million to $0.7 million, from $0.1 million for the nine months ended September 30, 2008. This change was due to a lower average yield earned on our investments during the nine months ended September 30, 2009 as compared to the same period in 2008, partially offset by a higher average cash balance during the 2009 period as compared to the 2008 period. Interest expense decreased $0.6 million for the nine months ended September 30, 2009 to $0.9 million, from $1.5 million for the nine months ended September 30, 2008. This decrease was due to the principal payments we have been making on the outstanding balance under our loan and security agreement.

Liquidity and Capital Resources

As a biopharmaceutical company focused on in-licensing, developing and commercializing proprietary pharmaceutical product candidates, we have entered into license agreements to acquire the rights to develop and commercialize our only current product candidate, Acetavance. Pursuant to our license agreement, we obtained the exclusive patent rights and know-how for this product candidate for the U.S. and Canada. Under the Acetavance agreement, we paid to BMS a $25.0 million up-front fee and may be required to make future milestone payments totaling up to $40.0 million upon the achievement of various milestones related to regulatory and commercial events, including payments totaling $15.0 million upon the approval of our NDA for Acetavance. In addition, we are also obligated to pay royalties on any net sales of the licensed product. We had also previously entered into a license agreement for our former product candidate, Omigard, under which we paid to Migenix an aggregate of $2.0 million in the form of an up-front fee, including the purchase of 617,284 shares of Migenix common stock. In May 2009, we terminated our license agreement with Migenix, and we will not be required to make future milestone or royalty payments under this agreement.

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

- the potential for delays in our efforts to seek regulatory approval for Acetavance, and any costs associated with delays;

- the costs of establishing a commercial organization to sell, market and distribute Acetavance;

- the rate of progress and costs of our efforts to prepare for the submission of an NDA for any other product candidate that we may in-license or acquire, and the potential that we may need to conduct additional clinical trials to support applications for regulatory approval;

- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with Acetavance and any other product candidate we may license or acquire, including any such costs we may be required to expend if our licensors are unwilling or unable to do so;

- the costs and timing of securing sufficient supplies of Acetavance from our contract manufacturers in preparation for commercialization;

- the effect of competing technological and market developments;

- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish;

- if Acetavance is approved, the potential that we may be required to file a lawsuit to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of this product candidate; and

- the success of the commercialization of Acetavance.

As of September 30, 2009, we had $85.8 million in cash and cash equivalents, an increase of $38.2 million from the $47.6 million at December 31, 2008. This increase was primarily due to proceeds, net of offering costs, received from our private placement completed in February 2009 of approximately $86.2 million. In addition, during the nine months ended September 30, 2009 restrictions were relieved on $0.8 million of cash that had previously been classified as restricted. Partially offsetting this increase in cash and cash equivalents during the nine months ended September 30, 2009 was a reduction to our cash and cash equivalents from cash used in operations ($30.4 million), purchases of available-for-sale investment securities ($10.7 million), principal payments on our debt obligations ($6.2 million), and purchases of property and equipment ($1.6 million).

The $30.4 million of cash used in operations for the nine months ended September 30, 2009 represents a $8.5 million decrease from the $38.9 million of cash used in operations during the same period in 2008. The decrease in the use of cash during the 2009 period was primarily due to a reduction in the net loss reported for the nine months ending September 30, 2009, adjusted for non-cash expenses, as compared to the same period in 2008. This reduction was partially offset by increased payments on our outstanding accounts payable balances during the 2009 period as compared to the 2008 period. As of September 30, 2009, we had reduced our accounts payable and accrued liabilities balance by $5.3 million, to $8.6 million, from $13.9 million at December 31, 2008, primarily due to reduced operating costs.

During the nine months ended September 30, 2009, our net current and long-term debt balances decreased $5.9 million as compared to December 31, 2008. This decrease was due to $6.2 million of principal payments during the period, partially offset by the amortization of warrant costs issued in connection with the loan agreements and the accrual of the term loan final payment on our $15.0 million credit facility. In July 2009, we made the final payment on our $7.0 million credit facility to retire the obligation, and as of September 30, 2009, we had 15 equal monthly payments and the term loan final payment remaining under our $15.0 million credit facility.

As of September 30, 2009, our net property and equipment balance increased by $2.3 million to $6.8 million, from $4.5 million at December 31, 2008. This increase was due to $2.7 million of capital equipment expenditures to be used primarily for the potential commercial manufacturing of Acetavance, of which $1.1 million had not been paid for as of September 30, 2009 and was accounted for in accounts payable and accrued expenses. Partially offsetting the equipment purchases in 2009 was depreciation of $0.4 million on our assets in service during the nine months ended September 30, 2009.

Sources of Liquidity

Since inception, our operations have been financed primarily through the issuance of equity securities, in both public and private offerings. From our inception through September 30, 2009, we have received net proceeds of approximately $271.0 million from the sale of shares of our preferred and common stock. Through September 30, 2009, the sales of shares of our preferred and common stock were as follows:

- from July 2004 to September 2009 (excluding our initial public offering, our February 2008 registered direct offering and our February 2009 private placement), we issued and sold a total of 2,292,020 shares of common stock to our founders, employees, directors and consultants for aggregate net proceeds of $0.9 million;

- from July 2004 to August 2004, we issued and sold a total of 8,085,108 shares of Series A-1 preferred stock for aggregate net proceeds of $7.5 million;

- from June 2005 to September 2005, we issued and sold a total of 17,675,347 shares of Series A-2 preferred stock for aggregate net proceeds of $17.6 million;

- in March 2006, we issued and sold a total of 53,870,000 shares of Series A-3 preferred stock for aggregate net proceeds of $53.8 million;
- in the fourth quarter of 2006, we completed our initial public offering in which we issued and sold a total of 6,900,000 shares of our common stock for aggregate net proceeds of $55.9 million;
- in February 2008, we completed a registered direct offering pursuant to an effective shelf registration in which we issued and sold a total of 9,240,307 shares of our common stock for aggregate net proceeds of $49.1 million; and
- in February 2009, we raised aggregate net proceeds of approximately $86.2 million through a private placement transaction in which we issued 12,039,794 shares of common stock and warrants to purchase up to 6,019,897 additional shares of common stock.

Additionally, in February 2006, we entered into a $7.0 million loan and security agreement with Silicon Valley Bank and Oxford Finance Corporation to provide us with growth capital. We drew down $7.0 million in June 2006 and in July 2009 we made the final payment to retire the $7.0 million obligation. In November 2007, we amended the $7.0 million loan and security agreement and entered into the Second Amendment to Loan and Security Agreement with the same parties and GE Business Financial Services Inc. (formerly known as Merrill Lynch Business Financial Services, Inc.), to secure an additional $15.0 million credit facility. In December 2007, we drew down $15.0 million under the Second Amendment in two separate draws of $5.0 million and $10.0 million with fixed interest rates of 7.83% and 7.74%, respectively, net of a loan fee of less than $0.1 million. In February 2007, we began making the first of 30 equal monthly principal and interest payments on the $7.0 million loan and in July 2008 we began making the first of 30 equal monthly principal and interest payments to fully amortize the balance on the $15.0 million credit facility. As of September 30, 2009, we had no further credit available under these agreements. In connection with each credit facility, we issued warrants to the lenders to purchase shares of our stock.

Capital Resources

Our cash, cash equivalent and short-term investment balances are currently our principal sources of liquidity. We believe these balances at September 30, 2009, will satisfy our requirements for projected working capital, capital expenditures and debt servicing, at a minimum, through the next nine months. We have based this estimate on assumptions that may prove to be wrong, and we could spend our available financial resources faster than we currently expect. Further, the spending of our available financial resources could be significantly delayed if our NDA for Acetavance does not receive approval in the fourth quarter of 2009.

Our future funding requirements will depend on many factors, including, but not limited to costs associated with:

- the acceleration of our activities to establish a commercial organization and related infrastructure to sell, market and distribute Acetavance as a result of the priority review status granted to our NDA for this product candidate;
- any requirements to conduct additional clinical trials or other studies to support applications for regulatory approval of Acetavance;
- our efforts to secure sufficient supplies of Acetavance from our contract manufacturers in preparation for commercialization; and
- our efforts to acquire or license and complete development programs for any new product candidates.

Until we can generate significant cash from our operations, we expect to continue to fund our operations with existing cash resources generated from the proceeds of offerings of our equity securities and our existing borrowings under our amended loan and security agreement. In addition, we may finance future cash needs through the sale of additional equity securities, strategic collaboration agreements and debt financing. However, we have drawn down all available amounts under our existing amended loan and security agreement, and we may not be successful in obtaining strategic collaboration agreements or in receiving milestone or royalty payments under those strategic collaboration agreements. To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership will be diluted.

We cannot be sure that our existing cash and investment resources will be adequate, that additional financing will be available when needed or that, if available, financing will be obtained on terms favorable to us or our stockholders. As a result of the recent volatility in the capital markets, the cost and availability of credit has been and may continue to be adversely affected by illiquid credit markets and wider credit spreads. Concern about the stability of the markets generally and the strength of counterparties specifically has led many lenders and institutional investors to reduce, and in some cases, cease to provide funding to borrowers. Continued turbulence in the U.S. and international markets and economies may adversely affect our ability to obtain additional financing on terms acceptable to us, or at all. If these market conditions continue, they may limit our ability to timely replace maturing liabilities and to access the capital markets to meet liquidity needs. Having insufficient funds may require us to delay, scale-back or eliminate some or all of our development programs, relinquish some or even all rights to product candidates at an earlier stage

of development 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. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result. If we raise additional funds by incurring additional debt financing, the terms of the debt may involve significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

We have invested a substantial portion of our available cash in money market funds placed with reputable financial institutions and debt instruments of agencies of the U.S. government for which credit loss is not anticipated. The capital markets have been highly volatile and there has been a lack of liquidity for certain financial instruments, especially those with exposure to mortgage-backed securities and auction rate securities. This lack of liquidity has made it difficult for the fair value of these types of instruments to be determined. As of September 30, 2009 our money market fund holdings were invested solely in U.S. government agency securities and U.S. treasuries where an actively traded market is observed and through which values are determined. These funds do not hold auction rate securities.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of September 30, 2009.

Recent Accounting Pronouncements

In June 2009, the Financial Accounting Standards Board, or FASB, issued *The FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles*, which replaces the previous guidance, *The Hierarchy of Generally Accepted Accounting Principles*, and establishes only two levels of accounting principles generally accepted in the United States of America, or GAAP, authoritative and non-authoritative. Under the standard, the FASB Accounting Standards Codification, or the Codification, is the source of authoritative, non-governmental GAAP, except for rules and interpretive releases of the Securities and Exchange Commission, or SEC, which are sources of authoritative GAAP for SEC registrants. All other non-grandfathered, non-SEC accounting literature not included in the Codification is non-authoritative. This standard is effective for financial statements issued for interim and annual financial periods ending after September 15, 2009 and we adopted the provisions for the quarter ended September 30, 2009. In accordance with the Codification, citations to accounting literature in this report are to the relevant topic of the Codification or are presented in plain English.

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

Caution on Forward-Looking Statements

This Quarterly Report on Form 10-Q, or Quarterly Report, includes forward-looking statements that are subject to risks and uncertainties, many of which are beyond our control. Forward-looking statements discuss matters that are not historical facts, and include, but are not limited to, discussions regarding our business, regulatory and commercialization strategies, growth strategy, competition, industry, regulatory environment, economic conditions, financial condition, liquidity and capital resources and results of operations. In this Quarterly Report, for example, we make forward-looking statements regarding: the potential for Acetavance™ to receive regulatory approval, and the potential timeframe in which any such approval might be received; our expectations as to whether the results of clinical trials, and other data and information provided in our NDA for Acetavance will be sufficient to support regulatory approval of Acetavance; our preparations for the commercialization of Acetavance; the scope and validity of patent protection for Acetavance, and our ability to commercialize this product candidate without infringing the patent rights of others; our expectations regarding competition, pricing and market acceptance of Acetavance; and projections regarding our anticipated financial position and operating requirements. Such statements include, but are not limited to, statements preceded by, followed by or that otherwise include the words, “believe,” “may,” “might,” “can,” “could,” “will,” “would,”, “should,” “estimate,” “continue,” “anticipate,” “intend,” “seek,” “plan,” “project,” “expect,” or similar expressions.

While we believe that the expectations reflected in this Quarterly Report are reasonable, the inclusion of any forward-looking statements should not be regarded as a representation that any of our plans will be achieved. Our actual results will differ from those anticipated in our forward looking statements as a result of various factors, including those set forth below under the caption “Part II, Item 1A – Risk Factors,” and the differences may be material. These risk factors include, but are not limited to: our dependence on the success of our only product candidate, Acetavance, and on our ability to obtain regulatory approval for, and successfully commercialize, this product candidate on a timely basis, or at all; the risk that the FDA may not complete its review of our NDA for Acetavance prior to the PDUFA goal date, or that the FDA determines that the clinical, non-clinical and other data we have submitted in our NDA is not adequate to support the safety and efficacy of Acetavance; the risk that the FDA’s rejection of our proposed brand name for intravenous acetaminophen (Acetavance) might limit or delay our ability to build brand equity for this product candidate; the

adequacy of the clinical trial and other data we plan to submit in our applications for regulatory approval to support the safety and efficacy of Acetavance; our reliance on our contract manufacturer to timely complete pre-commercialization manufacturing development activities, comply with stringent regulatory requirements and, if Acetavance is approved and commercialized, to produce Acetavance in the volumes that we require; the potential that Acetavance may be found to have undesirable side effects that could delay or prevent its regulatory approval or commercialization; the impact of public concern regarding the safety of certain drug products, which has resulted in heightened scrutiny by the FDA in the process of approving new drugs and which could delay any regulatory approvals we may obtain, or result in the inclusion of unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs; the impact of the intense competition we expect for Acetavance on its commercial potential, and whether any new products may emerge that provide different or better therapeutic alternatives for our targeted indications; the limitations of the patent rights covering Acetavance, and the possibility that our market opportunity for this product candidate may be limited by the lack of patent protection for the active ingredient; and our requirements for substantial additional funding and potential inability to raise capital when needed, which would force us to delay, reduce or eliminate our development programs and commercialization efforts. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in Section 21E of the Private Securities Litigation Reform Act of 1995. You should not rely unduly on these forward-looking statements, which speak only as of the date on which they were made. We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

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

Cash and Cash Equivalents

Our cash, cash equivalents and short-term investments as of September 30, 2009 consisted of cash, money market funds and debt instruments of agencies of the U.S. government. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. 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 investment securities available-for-sale 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 investment securities available-for-sale to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of that security will probably decline. To minimize this risk, we intend to maintain a portfolio which may include cash, cash equivalents and investment securities available-for-sale in a variety of securities which may include money market funds, government and non-government debt securities and commercial paper, all with various maturity dates. Based on our current investment portfolio, we do not believe that our results of operations would be materially impacted by an immediate change of 10% in interest rates.

Our cash is invested 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. 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. Our money market accounts are invested solely in U.S. government agency securities and U.S. treasuries. 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.

Debt

The loans under our amended loan and security agreement have fixed interest rates. Consequently, we do not have significant interest rate cash flow exposure on our debt. The aggregate principal balance of the loans, net of the loan discount, under the agreement at September 30, 2009 was $7.9 million, and is collateralized by substantially all of our assets (excluding intellectual property). Under the terms of the agreement, we are precluded from entering into certain financing and other transactions, including disposing of certain assets and paying dividends, and are subject to various non-financial covenants and prepayment penalties.

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

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

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

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

PART II. OTHER INFORMATION

Item 1. ***Legal Proceedings***

Not applicable.

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

Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this report as well as our other public filings with the Securities and Exchange Commission.

In the near-term, the success of our business will depend on many factors, including the following risks:

- *We are dependent on the success of our only product candidate, Acetavance, and upon our ability to obtain regulatory approval for, and successfully commercialize, this product candidate on a timely basis, and we cannot be certain that this product candidate will receive regulatory approval or be successfully commercialized;*
- *The FDA may not complete its review of our NDA for Acetavance by the PDUFA goal date, or the FDA may not approve our NDA if it determines that the clinical, non-clinical or other data we have submitted in our NDA are not adequate to support the safety or efficacy of Acetavance;*
- *The FDA has rejected our proposed brand name for intravenous acetaminophen (Acetavance), and the agency may not approve an alternative brand name in time for the commercial launch of this product candidate, which could limit or delay our ability to build brand equity;*
- *Public concern regarding the safety of drug products such as Acetavance could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs;*
- *If our contract manufacturer for Acetavance fails to complete pre-commercialization manufacturing development activities for Acetavance on a timely basis or fails to comply with stringent regulatory requirements, we will face delays in our ability to obtain regulatory approval for, and to commercialize, this product candidate, and our costs will increase;*
- *If Acetavance is approved and our contract manufacturer fails to produce the product in the volumes that we require on a timely basis, or to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the commercialization of this product candidate or be unable to meet market demand, and may lose potential revenues;*
- *We expect intense competition from existing products, as well as any new products that may emerge that provide different or better therapeutic alternatives for our targeted indications, which could diminish the commercial potential of Acetavance;*
- *The patent rights that we have in-licensed covering Acetavance are limited to a specific intravenous formulation of acetaminophen, and our market opportunity for this product candidate may be limited by the lack of patent protection for the active ingredient itself and other formulations that may be developed by competitors; and*
- *We may require substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our commercialization efforts and result in the loss of substantial revenues.*

Each of these factors, as well as other factors that may impact our business, are described in more detail in the following discussion. Although the factors highlighted above are among the most significant, any of the following factors could materially adversely affect our business or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time, and you should consider all of the factors described when evaluating our business.

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, 2008.

Risks Related to Our Business and Industry

We are dependent on the success of our only product candidate, Acetavance, and we cannot be certain that this product candidate will receive regulatory approval or be successfully commercialized.*

We currently have no drug products for sale, and only one drug product candidate, and cannot guarantee that we will ever have marketable drug products. Our business success depends on our ability to obtain regulatory approval and successfully commercialize our only product candidate, Acetavance.

We have submitted an NDA but have not received marketing approval for Acetavance. If approved, we anticipate that our ability to generate revenues from Acetavance will depend on our ability to:

- create market demand for Acetavance through our own marketing and sales activities, and any other arrangements to promote this product candidate we may later establish;
- ensure our third party manufacturer produces sufficient quantities of Acetavance to meet commercial demand at launch and thereafter;
- establish and maintain agreements with wholesalers and distributors on commercially reasonable terms; and
- maintain patent protection and regulatory exclusivity for Acetavance.

Any failure or significant delay in obtaining approval of our product candidate may prevent or delay our efforts to commercialize and derive revenues from our product candidate, and have a substantial adverse impact on our business and financial condition.

We may not receive regulatory approval for Acetavance, or its approval may be delayed.*

The process for obtaining approval of an NDA is time consuming, subject to unanticipated delays and costs, and requires the commitment of substantial resources. The FDA accepted our NDA in July 2009, and designated this application for priority review.

The FDA is conducting an in-depth review of the submission to determine whether to approve Acetavance for commercial marketing for the indications we have proposed. If the FDA is not satisfied with the information we provide, the agency may refuse to approve our NDA or may require us to perform additional studies or provide other information in order to secure approval. The FDA may delay, limit or refuse to approve our NDA for many reasons, including:

- the information we submit may be insufficient to demonstrate that Acetavance is safe and effective;
- the FDA might not approve the processes or facilities that will be used for the commercial manufacture of Acetavance; or
- the FDA's interpretation of the nonclinical, clinical or manufacturing data we provided in our NDA, or of pharmacovigilance data from the use of this product candidate outside of the U.S., may differ from our own interpretation of such data.

In addition to data from our own clinical studies of Acetavance, our NDA included data from clinical trials that were performed by BMS in support of European regulatory approvals. While the data from the BMS studies were taken from databases that have been checked against original clinical study records, not all of the original medical records for these studies were made available to us, so not all of the data have been fully reconciled against the original medical records. If the FDA determines that the clinical trials of Acetavance that were submitted in support of our NDA were not conducted in full compliance with the applicable protocols for these studies, as well as with applicable regulations and standards, or if the agency does not agree with our interpretation of the results of such studies, the FDA may reject the data that resulted from such studies. The rejection of data from clinical trials required to support our NDA for Acetavance could negatively impact our ability to obtain marketing authorization for this product candidate and would have a material adverse effect on our business and financial condition.

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

Under goals set in accordance with the Prescription Drug User Fee Act of 1992, as amended, or PDUFA, the FDA reviews most NDAs within 10 months of submission. Priority NDAs have a six month review goal. The Acetavance NDA has been granted priority status, with a PDUFA goal date of November 13, 2009. The review process may be formally extended by three months or longer if the FDA requires additional time to review any additional information that the agency requests or that we elect to provide. If we are unable to timely respond to the FDA's requests for additional information in the course of its review of the NDA for Acetavance, the approval of the NDA would be delayed. In addition, other companies have announced that the FDA has notified them that their scheduled review dates were delayed due to the FDA's internal resource constraints. There can be no assurance that the FDA will not impose such delays on the continuing review of our NDA for Acetavance, and any failure or significant delay in obtaining the required approval would have a material adverse effect on our business and financial condition.

We must obtain FDA approval of a product name for intravenous acetaminophen, and any failure or delay associated with such approval may adversely impact our business.*

Any trade name that we intend to use for intravenous acetaminophen must be approved by the FDA irrespective of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office. The FDA conducts a rigorous review of proposed product names, and may reject a product name if it believes that the name inappropriately implies medical claims or if it poses the potential for confusion with other product names. For example, the FDA has rejected the proposed product name, "Acetavance," based on its assertion that the name is unacceptable from a promotional perspective, and we have submitted alternative product names to the agency for review. The use of an alternative product name for intravenous acetaminophen will mean that we will lose the benefit of any brand equity that may already have been developed for the name, "Acetavance," and the benefit of our existing trademark applications for that trade name. We have expended additional resources to identify a suitable alternative product name that will be acceptable to FDA, that will qualify under applicable trademark laws and that will not infringe the existing rights of third parties. If the FDA does not approve one of our proposed alternative product names prior to the NDA approval date, we may be required to launch this product candidate without a brand name, and our efforts to build a successful brand identity for this product candidate, and to commercialize this product candidate, may be adversely impacted.

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

We do not manufacture Acetavance, and do not currently plan to develop any capacity to do so. Instead, we have relied on a third-party manufacturer, Baxter Healthcare Corporation, or Baxter, to manufacture and perform important pre-commercialization manufacturing development activities for this product candidate. As part of the process for obtaining regulatory approval, we will need to demonstrate that the facilities, equipment and processes used to manufacture Acetavance are capable of consistently producing a product that meets all applicable quality criteria, and that is comparable to the product that was used in our clinical trials.

Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up initial production. These problems may include unanticipated failures of, or an inability to timely obtain, specialized production equipment, limited availability of critical materials, equipment and facilities, inadequate yields, shortages of qualified personnel, and quality control difficulties. In order to receive regulatory approval to commercialize this product candidate, we will need to provide the FDA with comprehensive information regarding the validation of the manufacturing facilities, equipment and processes of our third party manufacturer. Additionally, the FDA may conduct inspections of Baxter's facilities as part of its review of our marketing application for Acetavance. If Baxter is not in compliance with cGMP requirements, the approval of our marketing application may be delayed, existing product batches may be compromised, and we may experience delays in the availability of this product candidate for commercial distribution.

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

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

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

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

All manufacturers of Acetavance and any other product candidates we may license or acquire must comply with strictly enforced federal, state and foreign regulations, including cGMP requirements enforced by the FDA through its facilities inspection program, and we have little control over our manufacturers' compliance with these regulations. The FDA and comparable

international regulatory authorities must inspect and approve the facilities and processes of our contract manufacturers, and any delays in obtaining approval of our contract manufacturers could cause delays in the availability of our product candidates for commercial distribution. In addition, our contract manufacturers and their facilities will be subject to continual review and periodic inspections by the FDA. A failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval.

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

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

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

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

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

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

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

We relied on third parties to assist us with our clinical trials, regulatory submissions and other important aspects of our development program for Acetavance. If the performance of these third parties was substandard, or if they failed to carry out their contractual duties, the regulatory approval of Acetavance may be delayed or prevented.*

We relied extensively upon independent clinical investigators, medical institutions, contract laboratories, contract research organizations, and regulatory, statistical and other consultants, to perform important functions related to the conduct of our clinical trials, the collection and analysis of data, and the preparation of regulatory submissions for Acetavance. If the performance of any of these third parties was substandard, or if they are inspected by the FDA and are found not to be in compliance with our study protocols or with applicable regulations, including FDA guidelines for the conduct of clinical trials, we may be prevented from obtaining regulatory approval for this product candidate.

Even if Acetavance receives regulatory approval, it may still face future development and regulatory difficulties.

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. If any such restrictions or requirements are imposed on Acetavance, our potential revenues from this product candidate could be adversely affected. For example, the label ultimately approved for Acetavance or any other product candidate that we may license or acquire, if any, may include restrictions on how such products may be used, and may not include one or more of our intended indications.

Acetavance and any other product candidates we may license or acquire will also be subject to ongoing FDA requirements with respect to the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, it may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If Acetavance or any other product candidate we may license or acquire fails to comply with applicable regulatory requirements, such as current Good Manufacturing Practices, or cGMPs, a regulatory agency may:

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

Even if Acetavance receives regulatory approval in the U.S., we may never receive approval or commercialize it outside of the U.S.

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

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

In light of widely publicized events concerning the safety risk of certain drug products, the FDA, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and the establishment of risk management programs that may, for example, restrict distribution of drug products after approval. The Food and Drug Administration Amendments Act of 2007, or FDAAA, grants significant expanded authority to the FDA, much of which is aimed at improving the safety of drug products before and after approval. In particular, the new law authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. It also significantly expands the federal government's clinical trial registry and results databank, which we expect

will result in significantly increased government oversight of clinical trials. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of data from our clinical trials. Data from clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional preclinical studies or clinical trials. If the FDA requires us to conduct additional preclinical studies or clinical trials prior to approving Acetavance, our ability to obtain approval of this product candidate will be delayed. If the FDA requires us to provide additional clinical or preclinical data following the approval of Acetavance, the indications for which this product candidate is approved may be limited or there may be specific warnings or limitations on dosing, and our efforts to commercialize Acetavance may be otherwise adversely impacted.

We expect intense competition in the territories in which we have rights to Acetavance, and new products may emerge that provide different or better therapeutic alternatives for our targeted indications.*

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition in the development and marketing of Acetavance from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. There can be no assurance that developments by others will not render Acetavance 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 Acetavance obsolete or noncompetitive.

We intend to seek marketing authorization for Acetavance for the treatment of acute pain and fever in adults and children, which will compete with well-established products for this and similar indications. Competing products available for the treatment of pain include opioids such as morphine, fentanyl, meperidine and hydromorphone, each of which is available generically from several manufacturers, and several of which are available as proprietary products using novel delivery systems. Ketorolac, an injectable non-steroidal anti-inflammatory drug, or NSAID, is also available generically in the U.S. from several manufacturers, and Caldolor (ibuprofen for injection), an NSAID, was approved by the FDA in June 2009 for the treatment of acute pain and fever in adults. Competing products available for the treatment of fever in the hospital setting include acetaminophen administered orally and rectally, aspirin and NSAIDs, which may be administered orally, topically or intravenously. During the time that it will take us to obtain regulatory approval for Acetavance, if at all, we anticipate that several additional products may be developed for the treatment of acute pain, including other injectable NSAIDs, novel opioids, new formulations of currently available opioids, 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 this product candidate that address our targeted indications that do not directly infringe on our in-licensed patent rights. For example, we are aware of several U.S. and Canadian patents and patent applications covering various potential injectable formulations of acetaminophen, including intravenous formulations, as well as methods of making and using these potential formulations. The commercial opportunity for Acetavance could be significantly harmed if competitors are able to develop alternative formulations outside the scope of our in-licensed patents. Compared to us, many of our potential competitors have substantially greater:

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

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

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

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

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

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

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

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

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

We have retained third-party service providers to perform a variety of functions related to the sale and distribution of Acetavance, key aspects of which will be out of our direct control. These service providers will provide key services related to warehousing and inventory control, distribution, customer service, accounts receivable management and cash collection, and, as a result, most of our inventory will be stored at a single warehouse maintained by one such service provider. We will substantially rely on this provider as well as other third-party providers that perform services for us, including entrusting our inventories of products to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter physical or natural damage at their

facilities, our ability to deliver product to meet commercial demand would be significantly impaired. In addition, we have engaged third parties to perform various other services for us relating to adverse event reporting, safety database management, fulfillment of requests for medical information regarding our product candidate and related services. If the quality or accuracy of the data maintained by these service providers is insufficient, we could be subject to regulatory sanctions.

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

In both domestic and foreign markets, our sales of any future products will depend in part upon the availability of coverage and reimbursement from third-party payors. Such third-party payors include government health programs such as Medicare, managed care providers, private health insurers and other organizations. In particular, many U.S. hospitals receive a fixed reimbursement amount per procedure for certain surgeries and other treatment therapies they perform. Because this amount may not be based on the actual expenses the hospital incurs, hospitals may choose to use therapies which are less expensive when compared to our product candidates. Accordingly, Acetavance or any other product candidates that we may in-license or acquire, if approved, will face competition from other therapies and drugs for these limited hospital financial resources. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to the satisfaction of hospitals, other target customers and their third-party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Our future products might not ultimately be considered cost-effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

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

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

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

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

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

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

As of September 30, 2009, we had 68 full-time employees. We will need to substantially expand our managerial, commercial, financial and other personnel resources in order to manage our operations and prepare for the commercialization of Acetavance, if approved. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth, and we may not be able to recruit and retain qualified personnel in the future, particularly for sales and marketing positions, due to competition for personnel among pharmaceutical businesses, and the failure to do so could have a significant negative impact on our future product revenues and business results. Our need to effectively manage our operations, growth and various projects requires that we:

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

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

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

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

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

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

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

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

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;

- decreased demand for our product candidates;
- impairment of our business reputation;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues; and
- the inability to commercialize our product candidates.

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

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

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

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

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

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

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

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

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

Risks Related to Intellectual Property

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

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

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

If Acetavance is approved by the FDA, one or more third parties may challenge the patents covering this product candidate, which could result in the invalidation or unenforceability of some or all of the relevant patent claims. For example, if a third party files an Abbreviated New Drug Application, or ANDA, for a generic drug product containing acetaminophen and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA for Acetavance; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third party's generic drug product. A certification that the new product will not infringe the Orange Book-listed patents for Acetavance, or that such patents are invalid, is called a paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not

file a patent infringement lawsuit within the required 45-day period, the third party's ANDA will not be subject to the 30-month stay. Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could adversely impact our ability to prevent third parties from competing with our products.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Our Finances and Capital Requirements

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

We are a development stage company with a limited operating history. We have focused primarily on in-licensing and developing Acetavance and our former product candidate, Omigard, 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 $57.1 million, $51.7 million and $52.2 million for the years ended December 31, 2008, 2007 and 2006, respectively. As of September 30, 2009, we had an accumulated deficit of $201.7 million. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital. We expect our development expenses to decrease over the next few years due to the completion of our clinical development program for Acetavance, and the discontinuation of our development program for Omigard. However, we have incurred increased pre-commercialization expenses during 2009 as we prepare for the market launch of Acetavance. In addition, if we obtain regulatory approval for Acetavance, we expect to incur significant sales, marketing and outsourced manufacturing expenses, as well as continued development expenses. As a result, we expect to continue to incur significant operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all.

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

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

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

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

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

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

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

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

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

In February 2009, we completed a private placement of common stock and warrants to purchase common stock, raising aggregate gross proceeds of approximately $86.6 million. We believe that with our currently available cash and cash equivalent balance, we have sufficient funds to meet our projected operating requirements for, at a minimum, the next nine months. We have based this estimate on assumptions that may prove to be wrong and we could spend our available financial resources faster than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

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

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

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

Our quarterly operating results may fluctuate significantly.*

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

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

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

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

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

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

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

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. As a result, we are required to periodically perform an evaluation of our internal controls over financial reporting to allow management to report on the effectiveness of those controls, as required by Section 404 of the Sarbanes-Oxley Act. Additionally, our independent auditors are required to perform a similar evaluation and report on the effectiveness of our internal controls over financial reporting. These efforts to comply with Section 404 and related regulations have required, and continue to require, the commitment of significant financial and managerial resources. While we anticipate maintaining the integrity of our internal controls over financial reporting and all other aspects of Section 404, we cannot be certain that a material weakness will not be identified when we test the effectiveness of our control systems in the future. If a material weakness is identified, we could be subject to sanctions or investigations by NASDAQ, the SEC or other regulatory authorities, which would require additional financial and management resources, costly litigation or a loss of public confidence in our internal controls, which could have an adverse effect on the market price of our stock.

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

Our net operating loss carryforwards and research and development tax credits may expire and not be used. As of December 31, 2008, we have generated federal and state net operating loss carryforwards of approximately $131.9 million, and federal and state research and development tax credit carryforwards of approximately $3.1 million and $1.3 million, respectively. Our net operating loss carryforwards will begin expiring in 2024 for federal purposes and 2014 for state purposes if we have not used them prior to that time, and our federal tax credits will begin expiring in 2024 unless previously used. Our state tax credits carryforward indefinitely. Additionally, our ability to use any net operating loss and credit carryforwards to offset taxable income in the future will be limited under Internal Revenue Code Sections 382 and 383 if we have a cumulative change in ownership of more than 50% within a three-year period. We have not completed an analysis as to whether such a change of ownership has occurred, but in such an event, may be limited to the amount of net operating loss carryforwards and research tax credits that could be utilized annually in the future to offset taxable income. Any such annual limitation may significantly reduce the utilization of the net operating loss carryforwards and research tax credits before they expire.

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

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

Risks Relating to Securities Markets and Investment in Our Stock

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

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

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

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

The trading prices for our common stock during the 52 weeks ending September 30, 2009 ranged from a high of $12.68 to a low of $4.39. The market price of our common stock is likely to continue to be highly volatile and may fluctuate substantially due to many factors, including:

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

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

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

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

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

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

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

As of September 30, 2009, our executive officers and directors and their affiliates together controlled approximately 51.1% of our outstanding common stock. As a result, these stockholders will collectively be able to significantly influence all matters requiring approval of our stockholders, including the election of directors and approval of significant corporate transactions. The concentration of ownership may delay, prevent or deter a change in control of our company even when such a change may be in the best interests of all stockholders, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets, and might affect the prevailing market price of our common stock.

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

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

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

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

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

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

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

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

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

Not applicable.

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

Not applicable.

Item *4.* ***Submission of Matters to a Vote of Security Holders***

Not applicable.

Item 5. ***Other Information***

Not applicable.

Item 6. ***Exhibits***

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

± Included in this Report.

SIGNATURES

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

CADENCE PHARMACEUTICALS, INC.

Dated: November 5, 2009

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

INDEX TO EXHIBITS

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31.2±	Certification of Chief Financial Officer pursuant to Rule 13a – 14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32±	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002

± Included in this Report.

Exhibit 31.1

CERTIFICATION

I, Theodore R. Schroeder, certify that:

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

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

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

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

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

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

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

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

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

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

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

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

Date: November 5, 2009

Exhibit 31.2

CERTIFICATION

I, William R. LaRue, certify that:

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

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

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

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

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

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

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

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

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

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

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

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

Date: November 5, 2009

Exhibit 32

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

In connection with the filing of the Quarterly Report on Form 10-Q of Cadence Pharmaceuticals, Inc. ("Cadence") for the quarterly period ended September 30, 2009, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of Cadence, hereby certifies, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that, to our knowledge:

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

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

The undersigned have executed this Certification effective as of November 5, 2009.

/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.