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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2006

OR

o **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 or organization)	(I.R.S. Employer Identification No.)

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

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

N/A
(Former name, former address and former fiscal year, if changed since last report)

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 o No ☑

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

Large accelerated filer o Accelerated filer o Non-accelerated filer ☑

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

As of November 20, 2006, there were 29,013,294 shares of the registrant's common stock ($0.0001 par value) outstanding.

CADENCE PHARMACEUTICALS, INC.
QUARTERLY REPORT ON FORM 10-Q
September 30, 2006

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2006 (unaudited)	December 31, 2005	Pro Forma September 30, 2006 (unaudited) (See Note 1)
Assets			
Current assets:			
Cash and cash equivalents	$ 38,186,823	$ 8,025,285	$ 95,412,823
Securities available-for-sale	—	7,000,000	—
Prepaid expenses and other current assets	605,556	526,173	605,556
Total current assets	38,792,379	15,551,458	96,018,379
Property and equipment, net	2,854,549	117,740	2,854,549
Restricted cash	1,581,130	—	1,581,130
Other assets	1,834,549	222,000	601,549
Total assets	$ 45,062,607	$ 15,891,198	$ 101,055,607
Liabilities and Stockholders' Equity			
Current liabilities:			
Accounts payable	$ 3,694,566	$ 715,781	$ 3,694,566
Accrued liabilities	5,068,886	430,220	5,068,886
Current portion of long-term debt	1,675,919	—	1,675,919
Total current liabilities	10,439,371	1,146,001	10,439,371
Deferred rent	1,516,629	—	1,516,629
Long-term debt, less current portion	5,324,081	—	5,324,081
Commitments			
Stockholders' equity :			
Preferred stock, $0.0001 par value:			
Series A-1 convertible preferred stock, 8,085,108 shares authorized, issued and outstanding at September 30, 2006 and December 31, 2005; aggregate liquidation preference of $7,600,002	809	809	—
Series A-2 convertible preferred stock, 18,060,347 shares and 17,675,347 shares authorized at September 30, 2006 and December 31, 2005, respectively; 17,675,347 shares issued and outstanding at September 30, 2006 and December 31, 2005; aggregate liquidation preference of $17,675,347	1,767	1,767	—
Series A-3 convertible preferred stock, 53,870,000 shares authorized issued and outstanding at September 30, 2006; aggregate liquidation preference of $53,870,000	5,387	—	—
Common stock, $0.0001 par value; 100,000,000 shares and 40,000,000 shares authorized at September 30, 2006 and December 31, 2005, respectively; 2,177,935 shares and 1,904,000 shares issued and outstanding at September 30, 2006 and December 31, 2005, respectively; 28,985,540 shares issued and outstanding pro forma	218	190	2,899
Additional paid-in capital	81,435,380	25,472,880	137,433,662
Stock subscription receivable	—	(187,600)	—
Accumulated other comprehensive income	104,540	—	104,540
Deficit accumulated during the development stage	(53,765,575)	(10,542,849)	(53,765,575)
Total stockholders' equity	27,782,526	14,745,197	83,775,526
Total liabilities and stockholders' equity	$ 45,062,607	$ 15,891,198	$ 101,055,607

See accompanying notes to unaudited financial statements.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)
STATEMENTS OF OPERATIONS
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from May 26, 2004 (Inception) Through September 30,
	2006	2005	2006	2005	2006
Operating expenses:					
Research and development	$ 6,387,623	$ 2,038,497	$ 40,051,593	$ 4,440,086	$ 48,061,176
Marketing	244,284	17,782	560,825	160,283	842,300
General and administrative	1,362,551	408,281	3,330,531	948,195	5,619,487
Total operating expenses	7,994,458	2,464,560	43,942,949	5,548,564	54,522,963
Loss from operations	(7,994,458)	(2,464,560)	(43,942,949)	(5,548,564)	(54,522,963)
Other income (expense):					
Interest income	479,500	102,851	1,032,001	116,847	1,297,166
Interest expense	(227,954)	—	(271,849)	—	(271,849)
Other expense	(39,929)	—	(39,929)	(183,000)	(267,929)
Total other income (expense)	211,617	102,851	720,223	(66,153)	757,388
Net loss	$(7,782,841)	$(2,361,709)	$(43,222,726)	$(5,614,717)	$(53,765,575)
Basic and diluted net loss per share	$ (6.01)	$ (2.04)	$ (34.27)	$ (4.92)	
Shares used to compute basic and diluted net loss per share	1,295,807	1,160,469	1,261,127	1,141,406	

See accompanying notes to unaudited financial statements.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)
STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,		Period from May 26, 2004 (Inception) Through September 30,
	2006	2005	2006
Operating activities			
Net loss	$ (43,222,726)	$ (5,614,717)	$ (53,765,575)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation	76,195	26,757	121,460
Loss on disposal of assets	39,929	—	39,929
Stock-based compensation	1,470,138	—	1,470,949
Non-cash interest expense and impairment charges	41,665	183,000	269,665
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(82,484)	(531,894)	(608,657)
Accounts payable, accrued liabilities and deferred rent	7,104,572	917,488	8,250,573
Net cash used in operating activities	(34,572,711)	(5,019,366)	(44,221,656)
Investing activities			
Purchases of marketable securities	—	(7,000,000)	(7,450,000)
Maturities of marketable securities	7,000,000	—	7,000,000
Restricted cash	(1,581,130)	—	(1,581,130)
Purchases of property and equipment	(1,662,403)	(43,385)	(1,825,408)
Net cash provided by (used in) investing activities	3,756,467	(7,043,385)	(3,856,538)
Financing activities			
Proceeds from issuance of common stock, net	202,769	109,000	331,269
Proceeds from sale of preferred stock, net	53,775,013	14,023,380	78,933,748
Borrowings under debt agreements	7,000,000	—	7,000,000
Net cash provided by financing activities	60,977,782	14,132,380	86,265,017
Net increase in cash and cash equivalents	30,161,538	2,069,629	38,186,823
Cash and cash equivalents at beginning of period	8,025,285	4,271,229	—
Cash and cash equivalents at end of period	$ 38,186,823	$ 6,340,858	$ 38,186,823

See accompanying notes to unaudited financial statements.

CADENCE PHARMACEUTICALS, INC.
(a development stage company)
NOTES TO UNAUDITED FINANCIAL STATEMENTS

1. The Company and Summary of Significant Accounting Policies

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 organizational activities, including recruiting personnel, establishing office facilities, conducting research and development, including clinical trials, and raising capital. To date, the Company has in-licensed rights to two Phase III product candidates. Since the Company has not begun principal operations of commercializing a product candidate, the Company is considered to be in the development stage.

Basis of Presentation

The Company has prepared the accompanying unaudited financial statements in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by generally accepted accounting principles for complete financial statements. In the opinion of our management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2006 are not necessarily indicative of the results that may be expected for the year ending December 31, 2006. For further information, see the financial statements and disclosures thereto for the year ended December 31, 2005 in our Final Prospectus dated October 24, 2006 and filed with the Securities and Exchange Commission in connection with the Company's initial public offering ("IPO").

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Stock Split

In October 2006, the Company's board of directors and stockholders approved a one-for-four reverse stock split of the Company's outstanding common stock. The accompanying financial statements and notes to the financial statements give retroactive effect to the reverse stock split for all periods presented.

Unaudited Pro Forma Balance Sheet

The unaudited pro forma balance sheet information in the accompanying balance sheet is provided as a result of a significant change in the Company's capital structure subsequent to the balance sheet date and assumes the following transactions that were completed subsequent to September 30, 2006 had occurred on September 30, 2006:

- On October 30, 2006, the Company completed an IPO whereby it sold 6,000,000 shares of common stock at $9.00 per share and received net proceeds of $48,460,000 (after underwriting discounts and offering costs);
- On October 19, 2006, the automatic conversion of the 79,630,455 outstanding shares of convertible preferred stock into 19,907,605 shares of common stock in connection with the Company's IPO; and
- On November 13, 2006, the Company completed the sale of 900,000 shares of common stock at $9.00 per share and received net proceeds of $7,500,000 (after underwriting discounts). The sale of these shares was the result of the underwriters' full exercise of the over-allotment option the Company granted them in connection with the Company's IPO.

Comprehensive Loss

The Company has applied SFAS No. 130, *Reporting Comprehensive Income*, which requires that all components of comprehensive income, including net income, be reported in the financial statements in the period in which they are recognized. Comprehensive income is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income and other comprehensive income, including foreign currency translation adjustments and unrealized gains and losses on investments, are reported, net of their related tax effect, to arrive at comprehensive income. The net loss and comprehensive loss were the same for all periods presented in 2005. The comprehensive loss was $104,540 less than the net loss for the three and nine months ended September 30, 2006 due to unrealized gains on investments.

Stock-Based Compensation

Effective January 1, 2006, the Company adopted the provisions of SFAS No. 123(R), *Share-Based Payment*, using the prospective transition method and therefore, prior period results will not be restated. SFAS No. 123(R) supersedes Accounting Principles Board ("APB") Opinion No. 25, *Accounting for Stock issued to Employees*, and related interpretations, and revises guidance in SFAS No. 123, *Accounting for Stock-Based Compensation.* Under this transition method, the compensation cost related to all equity instruments granted prior to, but not yet vested as of, the adoption date is recognized based on the grant-date fair value which is estimated in accordance with the original provisions of SFAS No. 123; however, those options issued prior to but unvested on January 1, 2006 and valued using the minimum value method are excluded from the options subject to SFAS No. 123(R). Compensation costs related to all equity instruments granted after January 1, 2006 are recognized at grant-date fair value of the awards in accordance with the provisions of SFAS No. 123(R). Additionally, under the provisions of SFAS No. 123(R), the Company is required to include an estimate of the number of the awards that will be forfeited in calculating compensation costs, which is recognized over the requisite service period of the awards on a straight-line basis.

Under SFAS No. 123(R), based on the department to which the associated employee reports, the Company has reported the following amounts of stock-based compensation expense in the statements of operations for the three and nine months ended September 30, 2006 and the period from May 26, 2004 (inception) through September 30, 2006:

	Three Months Ended September 30, 2006	Nine Months Ended September 30, 2006	Period from May 26, 2004 (Inception) Through September 30, 2006
Research and development	$ 280,077	$ 390,416	$ 390,416
Marketing	766	850	850
General and administrative	502,434	1,078,872	1,078,872
Total stock-based compensation	$ 783,277	$ 1,470,138	$ 1,470,138
Stock-based compensation per share, basic and diluted	$ 0.60	$ 1.17	

The following table shows the assumptions used to compute the stock-based compensation costs for the stock options granted during the three and nine months ended September 30, 2006 using the Black-Scholes option pricing model:

	Three Months Ended September 30, 2006	Nine Months Ended September 30, 2006
Employee Stock Options		
Risk-free interest rate	4.68 - 5.05%	4.36 - 5.08%
Dividend yield	0.00%	0.00%
Expected life of options (years)	5.81 - 6.08	5.81 - 6.08
Volatility	70.00%	70.00%

The risk-free interest rate assumption was based on the United States Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The assumed dividend yield was based on the Company's expectation of not paying dividends in the foreseeable future. The weighted average expected life of options was calculated using the simplified method as prescribed by Securities and Exchange Commission ("SEC") Staff Accounting Bulletin ("SAB") No. 107. This decision was based on the lack of relevant historical data due to the Company's limited historical experience. In addition, due to the Company's limited historical data, the estimated volatility also reflects the application of SAB No. 107, incorporating the historical volatility of comparable companies whose share prices are publicly available.

The weighted average grant-date fair values of stock options granted during the nine months ended September 30, 2006 was $5.97 per share.

As of September 30, 2006, the Company has approximately $9,000,000 of unrecognized stock-based compensation costs related to the non-vested balance of the 1,799,302 stock options granted during the nine months ended September 30, 2006 (211,006 of which have been early-exercised and remain unvested at September 30, 2006) and expects to recognize such compensation over a weighted average period of 3.43 years.

Prior to January 1, 2006, the Company applied the intrinsic-value-based method of accounting prescribed by APB Opinion No. 25, and related interpretations including Financial Accounting Standards Board ("FASB") Interpretation No. 44, *Accounting for Certain Transactions involving Stock Compensation — an interpretation of APB Opinion No. 25* , to account for its equity-based awards to employees and directors. Under this method, if the exercise price of the award equaled or exceeded the fair value of the underlying stock on the measurement date, no compensation expense was recognized. The measurement date was the date on which the final number of shares and exercise price were known and was generally the grant date for awards to employees and directors. If the exercise price of the award was below the fair value of the underlying stock on the measurement date, then compensation cost was recorded, using the intrinsic-value method, and was generally recognized in the statements of operations over the vesting period of the award.

The effect on net loss as if the fair-value-based method had been applied to all outstanding and unvested awards in each period would have been less than a $10,000 increase in the net loss for each period in the period from May 26, 2004 (inception) through December 31, 2005. For purposes of disclosures required by SFAS No. 123, the estimated fair value of the options was amortized on a straight-line basis over the vesting period. The fair value of these awards was estimated using the Minimum Value pricing model, with the following weighted-average assumptions for 2004 and 2005: risk-free interest rate of 3.53% and 4.17%, respectively; dividend yield of 0%; expected volatility of 0%; and a life of four years.

Equity instruments issued to non-employees are recorded at their fair value as determined in accordance with SFAS No. 123(R) and Emerging Issues Task Force ("EITF") 96-18, *Accounting for Equity Instruments That are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods and Services*, and are periodically revalued as the equity instruments vest and are recognized as expense over the related service period. Compensation expense related to the 2,500 stock options issued to a non-employee was $811 for both the period from May 26, 2004 (inception) through December 31, 2004 and the period from May 26, 2004 (inception) through September 30, 2006. The fair value of these stock options was estimated using the Black-Scholes pricing model, with the following weighted-average assumptions: risk-free interest rate of 4.19%; dividend yield of 0%; expected volatility of 70%; and a life of 10 years.

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, convertible preferred stock, stock options and warrants are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2006	2005	2006	2005
Historical				
Numerator:				
Net Loss	$ (7,782,841)	$(2,361,709)	$(43,222,726)	$(5,614,717)
Denominator:				
Weighted average common shares outstanding	2,166,576	1,442,500	2,027,432	1,276,758
Weighted average unvested common shares subject to repurchase	(870,769)	(282,031)	(766,304)	(135,353)
Weighted average common shares outstanding	1,295,807	1,160,469	1,261,128	1,141,405
Basic and diluted net loss per share	$ (6.01)	$ (2.04)	$ (34.27)	$ (4.92)
Historical outstanding anti-dilutive securities not included in diluted net loss per share				
Preferred stock (as converted)	19,907,605	6,440,107	19,907,605	6,440,107
Preferred stock warrants (as converted)	96,250	—	96,250	—
Common stock options	1,731,293	289,000	1,731,293	289,000
Common stock subject to repurchase	864,192	256,875	864,192	256,875
	22,599,340	6,985,982	22,599,340	6,985,982

Recent Accounting Pronouncements

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, which defines fair value, establishes a framework for measuring fair value in GAAP and expands disclosures about fair value measurements. This Statement is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company is currently assessing the impact to the Statement on its financial statements.

In September 2006, the SEC issued SAB No. 108, "*Considering the Effects on Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements.*" SAB No. 108 requires registrants to quantify errors using both the income statement method (i.e. iron curtain method) and the rollover method and requires adjustment if either method indicates a material error. If a correction in the current year relating to prior year errors is material to the current year, then the prior year financial information needs to be corrected. A correction to the prior year results that are not material to those years would not require a "restatement process" where prior financials would be amended. SAB No. 108 is effective for fiscal years ending after November 15, 2006. The Company does not anticipate that SAB No. 108 will have a material effect on its financial statements.

2. Composition of Certain Balance Sheet Items

Property and equipment are as follows:

	Useful Lives (in years)	September 30, 2006	December 31, 2005
Leasehold improvements	2 - 6	$ 1,518,781	$ 1,146
Computer equipment and software	3	289,326	63,972
Furniture and equipment	5	331,294	94,982
Manufacturing equipment	7	122,500	—
Construction in-process	—	680,192	—
		2,942,093	160,100
Less accumulated depreciation		(87,544)	(42,360)
Total		$ 2,854,549	$ 117,740

3. Commitments

Loan and Security Agreement

In February 2006, the Company entered into a $7,000,000 loan and security 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 loan and security agreement with Silicon Valley Bank and Oxford Finance Corporation and has no further credit available under this agreement. The Company will make interest only payments on growth capital advances until the first day of the month following the six month anniversary of each growth capital advance, at which date the Company will make the first of 30 equal monthly principal and interest payments. Interest accrues on all outstanding amounts at the fixed rate of 11.47%. The loans are collateralized by substantially all the assets of the Company (excluding intellectual property) and are subject to prepayment penalties. 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. 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.

In conjunction with the loan and security agreement, the Company issued fully exercisable warrants to the lenders to purchase an aggregate of 385,000 shares of the Company's Series A-2 preferred stock at an exercise price of $1.00 per share. Excluding certain mergers or acquisitions, the warrants expire upon the later of: (a) 10 years from issuance or (b) five years after the closing of an initial public offering of the Company's common stock. The $313,572 fair value of the warrants was determined using the Black-Scholes valuation model, recorded as debt issuance costs which are included as other long-term assets in the accompanying balance sheets, and 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 4.57%; dividend yield of 0%; expected volatility of 70%; and contractual term of 10 years.

Facility Leases

In 2004, the Company subleased its corporate headquarters under a non-cancelable operating lease that expired in September 2006. As of September 30, 2006, the sublessor held a security deposit of $50,685. 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, rent abatement and has an option to extend the lease for five years. Monthly rental payments are adjusted on an annual basis and the lease expires in September 2012. As security for the lease, the landlord required a letter of credit in the amount of $1,581,130. The letter of credit is collateralized by a certificate of deposit in the same amount that is classified as restricted cash in the accompanying balance sheet. The required amount subject to the letter of credit and corresponding certificate of deposit will be reduced by 22% on each of the first four anniversaries of the commencement of the lease. Rent expense was $293,514, $567,745, $50,684, $140,227 and $602,688 for the three and nine months ended September 30, 2006, the three and nine months ended September 30, 2005 and the period from May 26, 2004 (inception) through September 30, 2006, respectively. As of September 30, 2006, future minimum payments under the operating leases total $113,106, $1,009,000, $1,074,851, $1,112,206, $1,151,676, $1,191,851 and $917,676 for the years ending December 31, 2006, 2007, 2008, 2009, 2010, 2011 and 2012, respectively.

Severance Obligations

In September 2006, Kenneth R. Heilbrunn, M.D., the Company's former Senior Vice President, Clinical Development, resigned. In accordance with the terms of his employment agreement, the Company was obligated to pay Dr. Heilbrunn a lump-sum cash payment equal to his annual base salary and other benefits for 12 months following his date of termination. The employment agreement also allows for the acceleration of vesting for those options that would vest one year from the date of termination. The Company recorded a charge of $495,000 for the termination payments and accelerated vesting of options.

4. 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 IV APAP product candidate in the United States 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 $50,000,000 upon the achievement of various milestones related to regulatory or commercial events. The Company is also obligated to pay a royalty on net sales of the licensed product and has the right to grant sublicenses to third parties. The Company expects to initiate Phase III clinical trials for the licensed product in 2006 but does not expect FDA approval prior to 2008. Accordingly, all payments related to the BMS agreement have been recorded as research and development expense.

5. Stockholders' Equity

Stock Options

In 2004, the Company adopted the Cadence Pharmaceuticals, Inc. 2004 Equity Incentive Plan (the "2004 Plan"). The 2004 Plan allows for the grant of options, restricted stock awards, performance share awards, dividend equivalents, restricted stock units, stock payments and stock appreciation rights to employees, directors and consultants of the Company. As of September 30, 2006, the 2004 Plan had 2,875,000 shares of common stock reserved for issuance. Options granted under the 2004 Plan expire no later than 10 years from the date of grant. Options generally vest over a four-year period and may be immediately exercisable. After one year, the options generally vest 25%. Thereafter, options generally vest monthly in 36 equal installments. The exercise price of incentive stock options shall not be less than 100% of the fair value of the Company's common stock on the date of grant. The exercise price of any option granted to a 10% stockholder may be no less than 110% of the fair value of the Company's common stock on the date of grant. The fair value of the Company's common stock is established contemporaneously by the Company's board of directors all of whom are related parties. From May 26, 2004 (inception) through February 2006 the valuations were performed by the Company's board of directors who have experience in valuing early stage companies.

The Company has applied the guidance in the American Institute of Certified Public Accountants ("AICPA") Audit and Accounting Practice Aid Series, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, to determine the fair value of its common stock for purposes of setting the exercise prices of stock options granted to employees and others. This guidance emphasizes the importance of the operational development in determining the value of the enterprise. As a development stage enterprise, the Company is at an early stage of existence, primarily focused on product development with an unproven business model. To date, the Company has been funded primarily by venture capitalists with a history of funding start-up, high-risk entities with the potential for high returns in the event the investments are successful. Prior to the licensing of IV APAP in March 2006, the Company was considered to be in a very early stage of development as defined in the AICPA guidance where the preferences of the preferred stockholders, in particular the liquidation preferences, are very meaningful and the common stock was valued at $0.40 per share. Subsequent to the Company's licensing of IV APAP but prior to the initiation of the Company's initial public offering process on June 14, 2006, the Company allocated additional enterprise value to its common stock with an increase in the common stock valuation to $1.36 per share. Subsequent to the initiation of the initial public offering process, the Company increased its common stock valuation to $3.20 per share.

On June 14, 2006, the Company commenced the initial public offering process, and based on the preliminary valuation information presented by the underwriters, management reassessed the value of the common stock used to grant equity awards back to June 30, 2005. The reassessment of fair value was completed by management, all of whom are related parties, without the use of an unrelated valuation specialist. Management concluded that the stock options granted to employees and directors in May and June of 2006 were at prices below the reassessed values. The values of the common stock for May and June of 2006 were initially determined by the Company's board of directors. In the reassessment process, management concluded that the original valuations did not give enough consideration to the impact of an initial public offering on the value of the common stock. Accordingly, for the 1,124,057 options granted at $1.36 per share in May 2006, and for the 259,500 options granted in June 2006 at $3.20 per share, the reassessed fair values were determined to be $6.60 per share and $7.70 per share, respectively. The reassessed values were determined by using the low end of the estimated offering range of $11.00 per share, less a marketability discount of 40% and 30%, respectively, which reflects the estimated risk of not completing the initial public offering. The Company maintained the fair value of its common stock at $7.70 per share during the third quarter of 2006 since no events occurred that gave rise to a change in the assessment of fair value during the period.

At September 30, 2006, a total of 90,772 shares of common stock remained available for issuance under the 2004 Plan. A summary of the Company's stock option activity under the 2004 Plan and related information are as follows:

	Options Outstanding	Weighted Average Exercise Price
Balance at December 31, 2005	289,000	$0.40
Granted	1,799,302	$2.04
Exercised	(273,935)	$1.49
Cancelled	(83,074)	$0.96
Balance at September 30, 2006	1,731,293	$1.91

	September 30, 2006					
	Options Outstanding			Options Exercisable		
Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Remaining Contractual Life (in years)	Weighted Average Exercise Price
$0.40	219,614	8.45	$0.40	185,246	8.42	$0.40
$1.36	880,179	9.61	$1.36	842,004	9.61	$1.36
$3.20	631,500	9.80	$3.20	568,750	9.80	$3.20
	1,731,293	9.53	$1.91	1,596,000	9.54	$1.90

During the period from May 26, 2004 (inception) through December 31, 2004 and the quarterly periods ended March 31, 2005, June 30, 2005, September 30, 2005, December 31, 2005, March 31, 2006, June 30, 2006 and September 30, 2006 the Company granted options to purchase shares of the Company's common stock in the amount of 306,250, 162,500, 90,000, 47,750, 469,000, 3,750, 1,383,552, and 412,000, respectively. All such grants had both a fair value and exercise price of $0.40 for periods through March 31, 2006. During the quarterly period ended June 30, 2006, the exercise price of 1,124,053 and 259,500 option grants was $1.36 per share and $3.20 per share, respectively, and the fair value was $6.60 per share and $7.70 per share, respectively. During the quarterly period ended September 30, 2006, the exercise price of 412,000 option grants was $3.20 per share and the fair value was $7.70 per share.

As of September 30, 2006, 155,037 of the outstanding options under the 2004 plan were vested and 864,194 of the options exercised were subject to repurchase by the Company since they were unvested.

The aggregate grant date fair value of options that vested during the nine months ended September 30, 2006 was approximately $357,000. The aggregate intrinsic value of options exercised during the nine months ended September 30, 2006 was approximately $1,400,000.

The aggregate intrinsic value of options outstanding and options exercisable as of September 30, 2006 (based upon a $9.00 IPO price) was approximately $12,300,000 and $11,300,000, respectively.

Shares Reserved For Future Issuance

The following shares of common stock are reserved for future issuance at September 30, 2006:

Conversion of preferred stock	19,907,605
Common stock options granted and outstanding	1,731,293
Preferred stock warrants outstanding	96,250
Common stock options reserved for future issuance	90,772
	21,825,920

6. Subsequent Events

Stock Options

In connection with the Company's initial public offering which became effective on October 24, 2006, the 2006 Equity Incentive Award Plan (the "2006 Plan") became effective. The 2006 Plan initially has 2,100,000 shares of common stock reserved for issuance. The initial number of reserved shares will be increased by (i) the 90,772 shares of common stock that remained available for issuance under the 2004 Plan as of the effective date of the 2006 Plan and (ii) the number of shares under the 2004 Plan that are repurchased, forfeited, expired or cancelled on or after the effective date of the 2006 Plan.

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

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 Part II, Item 1A, "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, 2005 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Registration Statement on Form S-1, as amended.

Overview

Background

We are a biopharmaceutical company focused on in-licensing, developing and commercializing proprietary product candidates principally for use in the hospital setting. Since our inception in 2004, we have in-licensed rights to two Phase III product candidates, both of which have been studied in prior Phase III clinical trials conducted by our licensors. We have in-licensed the exclusive U.S. and Canadian rights to IV APAP, an intravenous formulation of acetaminophen that is currently marketed in Europe for the treatment of acute pain and fever by Bristol-Myers Squibb Company, or BMS. We believe that IV APAP is the only stable, pharmaceutically-acceptable intravenous formulation of acetaminophen. We have also in-licensed the exclusive North American and European rights to omiganan pentahydrochloride 1% aqueous gel, or Omigard™, for the prevention and treatment of device-related, surgical wound-related and burn-related infections.

We believe that the hospital setting is a concentrated, underserved market for pharmaceuticals and anticipate building our own, hospital-focused sales force as our product candidates approach potential U.S. Food and Drug Administration, or 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 United States, or approved in the United States but with significant commercial potential for proprietary new uses or formulations.

We were incorporated in May 2004. During 2004, we focused on hiring our management team and initial operating employees and on in-licensing our first product candidate, Omigard. 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 IV APAP from BMS. In October 2006, we initiated the Phase III clinical development program for IV APAP.

We are a development stage company. We have incurred significant net losses since our inception. As of September 30, 2006, we had an accumulated deficit of $53.8 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 current product candidates and general and administrative expenses. We expect to continue to incur operating losses for the next several years as we pursue the clinical development and market launch of our product candidates 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 whereby we sold 6.0 million shares of common stock at $9.00 per share and received net proceeds of $48.5 million (after underwriting discounts and offering costs). In November 2006, we sold 0.9 million shares of common stock at $9.00 per share and received net proceeds of $7.5 million (after underwriting discounts). The sale of these shares was the result of the underwriters' full exercise of the over-allotment option we granted them in connection with our initial public offering.

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 product candidates ourselves or execute a collaboration arrangement.

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, and costs associated with non-clinical activities, such as regulatory expenses. Our most significant costs are for license fees and clinical trials. The clinical trial expenses include payments to vendors such as CROs, investigators, clinical suppliers and related consultants. Our historical research and development expenses relate predominantly to the in-licensing of IV APAP and Omigard and clinical trials for Omigard. We charge all research and development expenses to operations as incurred because 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.

We use our internal research and development resources across several projects and many resources are not attributable to specific projects. A substantial portion of our internal costs, including personnel and facility related costs, are not tracked on a project basis and are included in the "other supporting costs" category in the table below.

The following summarizes our research and development expenses for the periods indicated:

	Three Months Ended September 30,		Nine Months Ended September 30,		Period from May 26, 2004 (Inception) Through September 30,
	2006	2005	2006	2005	2006
Product Candidate		(in thousands)			
IV APAP	$ 207	$ —	$ 25,905	$ —	$ 25,905
Omigard	4,008	1,689	10,246	3,539	16,699
Other supporting costs	2,173	349	3,901	901	5,457
	$ 6,388	$ 2,038	$ 40,052	$ 4,440	$ 48,061

At this time, due to the risks inherent in the clinical trial process and given the early stage of our product development programs, we are unable to estimate with any certainty the costs we will incur in the continued development of our product candidates for potential commercialization. Clinical development timelines, the probability of success and development costs vary widely. While we are currently focused on advancing each of our product development programs, our future research and development expenses will depend on the determinations we make as to the scientific and clinical success of each product candidate, as well as ongoing assessments as to each product candidate's commercial potential. In addition, we cannot forecast with any degree of certainty which product candidates 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 be substantial over the next few years as we continue the advancement of our product development programs. We initiated our Phase III clinical trial program for Omigard in August 2005, and we have not yet commenced our own Phase III clinical trials for IV APAP. We expect to receive results from the ongoing Omigard clinical trial in the second half of 2007. In the fourth quarter of 2006, we initiated the Phase III clinical development program for IV APAP for submission to the FDA and expect Phase III clinical trial results to be available in the first half of 2008. The lengthy process of completing clinical trials and seeking regulatory approval for our product candidates requires the expenditure of substantial resources. Any failure by us or delay in completing clinical trials, or in obtaining regulatory approvals, could cause our research and development expense to increase and, in turn, have a material adverse effect on our results of operations.

Marketing

Our marketing expenses consist primarily of market research studies, salaries, benefits and professional fees related to building our marketing capabilities. We anticipate increases in marketing expenses as we add personnel and continue to develop and prepare for the potential commercialization of our product candidates.

General and Administrative

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 add personnel, comply with the reporting obligations applicable to publicly-held companies, and continue to build our corporate infrastructure in support of our continued development and preparation for the potential commercialization of our product candidates.

Interest and Other Income

Interest and other income consist primarily of interest earned on our cash, cash equivalents and short-term investments and other-than-temporary declines in the market value of available-for-sale securities.

Income Taxes

As of December 31, 2005, we had both federal and state net operating loss carryforwards of approximately $8.7 million. If not utilized, the net operating loss carryforwards will begin expiring in 2024 for federal purposes and 2014 for state purposes. As of December 31, 2005, we had both federal and state research and development tax credit carryforwards of approximately $0.3 million and $0.1 million, respectively. The federal tax credits will begin expiring in 2024 unless previously utilized and the state tax credits carryforward indefinitely. Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, substantial changes in our ownership may limit the amount of net operating loss carryforwards 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 before they expire. In each period since our inception, we have recorded a valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As a result, we have not recorded any federal or state income tax benefit in our statement of operations.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in conformity with generally accepted accounting principles in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures. Actual results could differ from those estimates.

We believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

Research and Development Expenses

A substantial portion of our on-going research and development activities are performed under agreements we enter into with external service providers, including CROs, who 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, and no material adjustments to research and development expenses have been recognized. We expect to expand the level of research and development activity performed by external service providers in the future. As a result, we anticipate that our estimated accruals will be more material to our operations in future periods. Subsequent changes in estimates may result in a material change in our accruals, which could also materially affect our results of operations.

Stock-Based Compensation

Effective January 1, 2006, we adopted Statement of Financial Accounting Standards, or SFAS, No. 123(R), *Share-Based Payment,* which revises SFAS No. 123, *Accounting for Stock-Based Compensation* and supersedes Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees.* SFAS No. 123(R) requires that share-based payment transactions with employees be recognized in the financial statements based on their fair value and recognized as compensation expense over the vesting period. Prior to SFAS No. 123(R), we disclosed the pro forma effects of applying SFAS No. 123 under the minimum value method. We adopted SFAS No. 123(R) effective January 1, 2006, prospectively for new equity awards issued subsequent to December 31, 2005. The adoption of SFAS No. 123(R) in the first quarter of 2006 did not result in the recognition of additional stock-based compensation expense.

Under SFAS No. 123(R), we calculate the fair value of stock option grants using the Black-Scholes option-pricing model. The assumptions used in the Black-Scholes model were 5.81-6.08 years for the expected term, 70% for the expected

volatility, 4.36-5.08% for the risk free rate and 0% for dividend yield for the nine months ended September 30, 2006. Future expense amounts for any particular quarterly or annual period could be affected by changes in our assumptions.

The weighted average expected option term for 2006 reflects the application of the simplified method set out in SEC Staff Accounting Bulletin, or SAB, No. 107 which was issued in March 2005. The simplified method defines the life as the average of the contractual term of the options and the weighted average vesting period for all option tranches.

Estimated volatility for fiscal 2006 also reflects the application of SAB No. 107 interpretive guidance and, accordingly, incorporates historical volatility of similar public entities.

As of September 30, 2006, we had approximately $9.0 million of unrecognized share-based compensation costs related to nonvested equity awards. As of September 30, 2006, we had outstanding vested options to purchase 155,037 shares of our common stock and unvested options to purchase 1,576,256 shares of our common stock with an intrinsic value of $1.3 million and $10.0 million, respectively, based on our initial public offering price of $9.00 per share.

Prior to January 1, 2006, we applied the intrinsic-value-based method of accounting prescribed by APB Opinion No. 25 and related interpretations. Under this method, if the exercise price of the award equaled or exceeded the fair value of the underlying stock on the measurement date, no compensation expense was recognized. The measurement date was the date on which the final number of shares and exercise price were known and was generally the grant date for awards to employees and directors. If the exercise price of the award was below the fair value of the underlying stock on the measurement date, then compensation cost was recorded, using the intrinsic-value method, and was generally recognized in the statements of operations over the vesting period of the award.

The fair value of our common stock has been established by our board of directors. We have applied the guidance in the American Institute of Certified Public Accountants, or AICPA, Audit and Accounting Practice Aid Series, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, to determine the fair value of our common stock for purposes of setting the exercise prices of stock options granted to employees and others. This guidance emphasizes the importance of the operational development in determining the value of the enterprise. As a development stage enterprise, we are at an early stage of existence, primarily focused on development with an unproven business model. To date, we have been funded primarily by venture capitalists with a history of funding start-up, high-risk entities with the potential for high returns in the event the investments are successful.

Prior to the licensing of IV APAP in March 2006, we valued our common stock at the nominal amount of $0.40 per share when we were considered to be in a very early stage of development (stages 1 and 2) as defined in the AICPA guidance, where the preferences of the preferred stockholders, in particular the liquidation preferences, are very meaningful. We utilized an asset-based approach for enterprise value and allocated such value to preferred and common stock based on the current value method. The significant estimates used in the asset-based approach consisted of the valuation of our assets and liabilities, which we determined were substantially the same as their fair market values. Since the fair market value of our net assets, including Omigard development costs incurred, of $22.7 million was less than the $25.3 million liquidation value of our preferred stock, no significant value was assigned to our common stock under the current value method, which allocates value based on liquidation preferences. We did not obtain a contemporaneous independent valuation as we were focused on product development and fund raising and believed our board of directors, all of whom are related parties, had the requisite experience at valuing early stage companies.

On June 14, 2006, we commenced the initial public offering process, and based on the preliminary valuation information presented by the underwriters for our initial public offering, we reassessed the value of the common stock used to grant equity awards back to June 30, 2005. The reassessment of fair value was completed by management, all of whom are related parties, without the use of an unrelated valuation specialist. Management concluded that the stock options granted to employees and directors in May and June of 2006 were at prices that were below the reassessed values. The values of the common stock for May and June of 2006 were initially determined by our board of directors. In the reassessment process, our management concluded that the original valuations did not give enough consideration to the impact of an initial public offering on the value of the common stock and we revised the estimate of fair value as discussed below. The reassessed fair values may not be reflective of fair market value that would result from the application of other valuation methods, including accepted valuation methods for tax purposes.

In late March 2006, we completed the licensing of IV APAP and completed the sale of our Series A-3 preferred stock of $53.9 million, which was used to acquire the rights to IV APAP and we expect to be used to fund the clinical trials for IV APAP. We believe that the in-license of rights to IV APAP was a significant milestone which resulted in an increase in value since it provided us with a second drug candidate and demonstrated that we could execute on our strategic initiative to have multiple products in clinical trials with the potential for significant future revenues. No other corporate milestones have

occurred in 2006 that would result in material changes to our enterprise value. Prior to licensing IV APAP, we did not believe we could enter the public equity markets.

As of March 31, 2006, our board of directors, all of whom are related parties, performed a contemporaneous valuation, which initially resulted in an increase of our common stock valuation to $1.36 per share from $0.40 per share. The valuation utilized a market-based approach for enterprise value and allocated such value to preferred and common stock based on an option pricing model. This approach is consistent with the AICPA guidance based on our stage of development following our in-licensing of rights to IV APAP. The determination of enterprise value was based on our Series A-3 preferred stock financing, in which greater than 50% of the investors consisted of new investors to our company. On May 9, 2006, we granted 1,124,057 stock options at $1.36 per share; however, in connection with our reassessment process, we concluded that with the proximity to the initiation of our initial public offering on June 14, 2006, the value of the options should give more consideration to the expected valuation in our initial public offering. Accordingly, we concluded that the revised fair value of the common stock should be the estimated low end of the preliminary price range for our initial public offering as of June 14, 2006 of $11.00 per share, less a discount for marketability of 40%, which reflects an estimate of the risk of not completing our initial public offering, or $6.60 per share.

On June 12, 2006, we granted 259,500 stock options at $3.20 per share based on a contemporaneous valuation performed by our board of directors. The valuation utilized a market-based approach for enterprise value and allocated such value to preferred and common stock based on an option pricing model. The determination of the enterprise value was based on equal weighting of Series A-3 preferred stock financing values and valuation ranges provided by the underwriters for our initial public offering, less a marketability discount of 40% determined based on a put option analysis and published data regarding marketability discounts in initial public offerings. However, in connection with our reassessment process and the proximity to the initiation of our initial public offering, management concluded that the value of the options should give more consideration to the expected valuation in our initial public offering. The valuation ranges initially provided by our underwriters were consistent with the estimates of value currently being contemplated for our initial public offering at that time. Accordingly, the revised fair value of the common stock was estimated to be the low end of the preliminary price range for our initial public offering as of June 14, 2006 of $11.00 per share, less a discount for marketability of 30%, which reflects an estimate of the risk of not completing our initial public offering, or $7.70 per share. We maintained the fair value of our common stock at $7.70 per share during the third quarter of 2006 since no events occurred that gave rise to a change in our assessment of fair value during that period.

Since we utilized an asset-based approach in our very early stage of development and moved to a market-based approach upon the in-licensing of IV APAP, the probability of successful development of our product candidates was not a specific variable used in our valuation approaches. However, this probability was considered in the price paid for our Series A-3 preferred stock and the valuation ranges provided by the underwriters, which are specific factors included in our valuation approaches.

Equity instruments issued to non-employees are recorded at their fair value as determined in accordance with SFAS No. 123(R) and Emerging Issues Task Force 96-18, *Accounting for Equity Instruments That are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods and Services*, and are periodically revalued as the equity instruments vest and are recognized as expense over the related service period.

Under SFAS No. 123(R), based on the department to which the associated employee reports, we have reported the following amounts of stock-based compensation expense in the statements of operations for the three and nine months ended September 30, 2006:

	Three Months Ended September 30, 2006	Nine Months Ended September 30, 2006
Research and development	$ 280,077	$ 390,416
Marketing	766	850
General and administrative	502,434	1,078,872
Total stock-based compensation	$ 783,277	$ 1,470,138

Results of Operations

Comparison of three months ended September 30, 2006 and 2005

Research and Development Expenses. Research and development expenses increased to $6.4 million for the three months ended September 30, 2006 from $2.0 million for the comparable period during 2005. This increase of $4.4 million primarily was due to:

- an increase of $0.2 million in our IV APAP program primarily as a result of increased clinical and regulatory spending in 2006 after we licensed the rights to the product in March 2006;
- an increase of $2.3 million in our Omigard program as a result of clinical trial and related costs for a Phase III clinical trial initiated in August 2005; and
- an increase of $1.9 million in other supporting costs as a result of increased salaries and related personnel costs from increased research and development staff to support our clinical and regulatory efforts related to both Omigard and IV APAP.

Marketing Expenses. Marketing expenses increased to $0.2 million for the three months ended September 30, 2006 from a nominal amount for the comparable period during 2005. This increase of $0.2 million primarily was due to higher market research and branding and personnel costs in 2006.

General and Administrative Expenses. General and administrative expenses increased to $1.4 million for the three months ended September 30, 2006 from $0.4 million for the comparable period during 2005. This increase of $1.0 million primarily was due to stock-based compensation and other personnel related charges, our new facility lease, other professional fees and consulting fees.

Interest Income. Interest income increased to $0.5 million for the three months ended September 30, 2006 from $0.1 million for the comparable period during 2005. This increase of $0.4 million primarily was due to the increase in average cash and investment balances as a result of preferred stock sales and higher interest rates in 2006.

Interest Expense. Interest expense increased to $0.2 million for the three months ended September 30, 2006 from zero for the comparable period during 2005. This increase of $0.2 million was primarily due to interest on the $7.0 million we borrowed from Silicon Valley Bank and Oxford Finance Corporation in June 2006.

Comparison of nine months ended September 30, 2006 and 2005

Research and Development Expenses. Research and development expenses increased to $40.0 million for the nine months ended September 30, 2006 from $4.4 million for the comparable period during 2005. This increase of $35.6 million primarily was due to:

- an increase of $25.9 million in our IV APAP program primarily as a result of a $25.0 million initial license fee which was immediately expensed as in-process research and development;
- an increase of $6.7 million in our Omigard program as a result of clinical trial and related costs for a Phase III clinical trial initiated in August 2005; and
- an increase of $3.0 million in other supporting costs as a result of increased salaries and related personnel costs from increased research and development staff to support our clinical and regulatory efforts related to both Omigard and IV APAP.

Marketing Expenses. Marketing expenses increased to $0.6 million for the nine months ended September 30, 2006 from $0.2 million for the comparable period during 2005. This increase of $0.4 million primarily was due to higher market research and branding and personnel costs in 2006.

General and Administrative Expenses. General and administrative expenses increased to $3.3 million for the nine months ended September 30, 2006 from $0.9 million for the comparable period during 2005. This increase of $2.4 million primarily was due to stock-based compensation charges and other personnel related charges, legal fees related to the IV APAP license agreement and our new facility lease, other professional fees and consulting fees.

Interest Income. Interest income increased to $1.0 million for the nine months ended September 30, 2006 from $0.1 million for the comparable period during 2005. This increase of $0.9 million primarily was due to the increase in average cash and investment balances as a result of preferred stock sales and higher interest rates in 2006.

Interest Expense. Interest expense increased to $0.3 million for the nine months ended September 30, 2006 from zero for the comparable period during 2005. This increase of $0.3 million was primarily due to interest on the $7.0 million we borrowed from Silicon Valley Bank and Oxford Finance Corporation in June 2006.

Other income (expense). Other income (expense) decreased to $40,000 for the nine months ended September 30, 2006 from $0.2 million for the comparable period during 2005. The 2006 other income (expense) consists of losses on the disposal of assets related to our facility move and the 2005 amounts consist of impairment charges due to declines in the market value of our Migenix holdings that were determined to be other-than-temporary.

Liquidity and Capital Resources

Since inception, our operations have been financed primarily through the private placement of equity securities. Through September 30, 2006, we received net proceeds of approximately $79.6 million from the sale of shares of our preferred and common stock as follows:

- from July 2004 to September 2006, we issued and sold a total of 2,177,935 shares of common stock for aggregate net proceeds of $0.7 million;

- from July 2004 to August 2004, we issued and sold a total of 8,085,108 shares of Series A-1 preferred stock for aggregate net proceeds of $7.5 million;
- from June 2005 to September 2005, we issued and sold 17,675,347 shares of Series A-2 preferred stock for aggregate net proceeds of $17.6 million; and
- 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 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 have no further credit available under this agreement. We are required to make interest only payments on the loan balance for the first six months of the loan, and beginning February 2007, we are required to make the first of 30 equal monthly principal and interest payments. Interest accrues on all outstanding amounts at the fixed rate of 11.47%. The loan is collateralized by substantially all of our assets other than intellectual property. We are subject to prepayment penalties. 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.

In conjunction with the loan and security agreement, we issued warrants to the lenders to purchase 385,000 shares of Series A-2 preferred stock at an exercise price of $1.00 per share.

In October 2006, we completed an initial public offering whereby we sold 6.0 million shares of common stock at $9.00 per share and received net proceeds of $48.5 million (after underwriting discounts and offering costs).

In November 2006, we sold 0.9 million shares of common stock at $9.00 per share and received net proceeds of $7.5 million (after underwriting discounts). The sale of these shares was the result of the underwriters' full exercise of the over-allotment option we granted them in connection with our initial public offering.

As of September 30, 2006, we had $38.2 million in cash and cash equivalents. We have invested a substantial portion of our available cash funds in money market funds placed with reputable financial institutions for which credit loss is not anticipated. We have established guidelines relating to diversification and maturities of our investments to preserve principal and maintain liquidity.

Our operating activities used net cash in the amount of $34.6 million and $5.0 million in the nine months ended September 30, 2006 and 2005, respectively. The increase in net cash used in operating activities from 2005 to 2006 primarily was due to an increase in our net loss as a result of increased expenses related to the license fee paid for IV APAP. We cannot be certain if, when or to what extent we will receive cash inflows from the commercialization of our product candidates. We expect our development expenses to be substantial and to increase over the next few years as we continue the advancement of our product development programs.

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 two product candidates, IV APAP and Omigard. Pursuant to these agreements, we obtained exclusive licenses to the patent rights and know-how for selected indications and territories. Under the IV APAP agreement, we paid to BMS a $25.0 million up-front fee and may be required to make future milestone payments totaling up to $50.0 million upon the achievement of various milestones related to regulatory or commercial events. Under the Omigard agreement, we paid to Migenix Inc. 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, and may be required to make future milestone payments totaling up to $27.0 million upon the achievement of various milestones related to regulatory or commercial events. Under both agreements, we are also obligated to pay royalties on any net sales of the licensed products.

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

- the progress of our clinical trials, including expenses to support the trials and milestone payments that may become payable to BMS or Migenix;
- our ability to establish and maintain strategic collaborations, including licensing and other arrangements;
- the costs involved in enforcing or defending patent claims or other intellectual property rights;
- the costs and timing of regulatory approvals;
- the costs of establishing sales or distribution capabilities;
- the success of the commercialization of our products; and
- the extent to which we in-license, acquire or invest in other indications, products, technologies and businesses.

We believe that our existing cash and cash equivalents, including the net proceeds from our initial public offering completed in the fourth quarter of 2006 will be sufficient to meet our projected operating requirements through at least December 31, 2008.

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 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 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. In addition, 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. 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.

Contractual Obligations and Commitments

The following table describes our long-term contractual obligations and commitments as of December 31, 2005:

	Payments Due by Period				
	Total	Less Than 1 Year	1 - 3 Years	4-5 Years	After 5 Years
			(In thousands)		
Long-term debt obligations(1)	$ —	$ —	$ —	$ —	$ —
Operating lease obligations(2)	147	147	—	—	—
License obligations(3)	—	—	—	—	—
Total	$ 147	$ 147	$ —	$ —	$ —

(1) Long-term debt obligations do not include $7.0 million of indebtedness incurred in June 2006 under our loan and security agreement with Silicon Valley Bank and Oxford Finance Corporation.

(2) In May 2006, we entered into a six-year operating lease for 23,494 square feet of office space. Operating lease obligations do not include $6.7 million of non-cancelable operating lease payments related to this lease. Future minimum payments under the operating lease total $0.2 million, $1.0 million, $1.1 million, $1.1 million, $1.2 million, $1.2 million and $0.9 million for the years ending December 31, 2006, 2007, 2008, 2009, 2010, 2011 and 2012, respectively.

(3) License obligations do not include additional payments of up to $77.0 million due upon the occurrence of certain milestones related to regulatory or commercial events. We may also be required to pay royalties on any net sales of the licensed products. License payments may be increased based on the timing of various milestones and the extent to which the licensed technologies are pursued for other indications. These milestone payments and royalty payments under our license agreements are not included in the table above because we cannot, at this time, determine when or if the related milestones will be achieved or the events triggering the commencement of payment obligations will occur.

We also enter into agreements with third parties to manufacture our product candidates, conduct our clinical trials and perform data collection and analysis. Our payment obligations under these agreements depend upon the progress of our development programs. Therefore, we are unable at this time to estimate with certainty the future costs we will incur under these agreements.

Caution on Forward-Looking Statements

Any statements in this report about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and are forward-looking statements. You can identify these forward-looking statements by the use of words or phrases such as “believe,” “may,” “could,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “seek,” “plan,” “expect,” “should” or “would.” Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties inherent in our business including, without limitation: the potential for IV APAP and Omigard to receive regulatory approval for one or more indications on a timely basis or at all; the results of pending clinical trials for Omigard; unexpected adverse side effects or inadequate therapeutic efficacy of IV APAP or Omigard that could delay or prevent regulatory approval or commercialization, or that could result in recalls or product liability claims; other difficulties or delays in development, testing, manufacturing and marketing of and obtaining regulatory approval for IV APAP or Omigard; the scope and validity of patent protection for IV APAP or Omigard; the market potential for pain, fever, local catheter site infections and other target markets, and our ability to compete; the potential to attract a strategic collaborator and terms of any related transaction; our ability to raise sufficient capital and the discussions set forth below in Part II, Item 1A. Risk Factors.

Although we believe that the expectations reflected in our forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievement. We undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Our cash and cash equivalents as of September 30, 2006 consisted primarily of cash and money market funds. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because the majority of our investments are in short-term marketable securities. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the value of the investment 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 our investment will probably decline. To minimize this risk, we intend to continue to maintain our portfolio of cash equivalents and short-term investments in a variety of securities including commercial paper, money market funds and government and non-government debt securities, all with various maturities. In general, money market funds are not subject to market risk because the interest paid on such funds fluctuates with the prevailing interest rate.

Item 4. Controls and Procedures.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the 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.

As required by 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 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.

There has been no change in our internal control over financial reporting during our most recent fiscal quarter 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.

None.

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, which has been updated since the filing of our registration statement on Form S-1, 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 largely dependent on the success of our only two product candidates, IV APAP and Omigard, and we cannot be certain that our planned clinical development programs will be sufficient to support NDA submissions or that either product candidate will receive regulatory approval or be successfully commercialized;*
- *delays in the commencement, enrollment or completion of clinical testing for either of our product candidates could result in increased costs to us and delay or limit our ability to obtain regulatory approval;*
- *even if our product candidates are approved by regulatory authorities, we expect intense competition in the hospital marketplace for our targeted indications;*
- *the patent rights that we have in-licensed covering IV APAP 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 will require substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our development programs and commercialization efforts.*

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.

Risks Related to Our Business and Industry

We are largely dependent on the success of our two product candidates, IV APAP and Omigard, and we cannot be certain that either of these product candidates will receive regulatory approval or be successfully commercialized.

We currently have no drug products for sale and we cannot guarantee that we will ever have marketable drug products. The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the U.S. Food and Drug Administration, or FDA, and other regulatory authorities in the United States and other countries, which regulations differ from country to country. We are not permitted to market our product candidates in the United States until we receive approval of a new drug application, or NDA, from the FDA. We have not submitted an NDA or received marketing approval for either of our product candidates. Obtaining approval of an NDA is a lengthy, expensive and uncertain process. We currently have only two product candidates, and our business success currently depends entirely on their successful development and commercialization.

We have not developed either of our product candidates independently. We recently in-licensed exclusive rights to IV APAP, an intravenous formulation of acetaminophen that is currently marketed in Europe for the treatment of acute pain and fever by Bristol-Myers Squibb Company, or BMS. We intend to conduct six clinical trials to provide the FDA with data to support multiple dose efficacy for soft tissue surgery, efficacy for fever and safety in adults and children, based on the preliminary feedback we received from the FDA in our meeting in August 2006. In July 2004, we in-licensed the rights to

our only other product candidate, omiganan pentahydrochloride 1% aqueous gel, or Omigard, which is currently being evaluated in a single Phase III clinical trial for the prevention of local catheter site infections, or LCSIs, and will require the successful completion of this Phase III clinical trial before we are able to submit an NDA to the FDA for approval. Our clinical development programs for IV APAP and Omigard may not lead to commercial products if we fail to demonstrate that the product candidates are safe and effective in clinical trials and we may therefore fail to obtain necessary approvals from the FDA and similar foreign regulatory agencies, or because we may have inadequate financial or other resources to advance these product candidates through the clinical trial process. Any failure to obtain approval of IV APAP or Omigard would have a material and adverse impact on our business.

If clinical trials of our current or future product candidates do not produce results necessary to support regulatory approval in the United States or elsewhere, we will be unable to commercialize these products.

To receive regulatory approval for the commercial sale of IV APAP, Omigard or any other product candidates that we may in-license or acquire, we must conduct, at our own expense, adequate and well controlled clinical trials to demonstrate efficacy and safety in humans. Clinical testing is expensive, takes many years and has an uncertain outcome. Clinical failure can occur at any stage of the testing. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing. For example, Migenix Inc., or Migenix, the licensor for our Omigard product candidate, together with its former collaborator, Fujisawa Healthcare, Inc., or Fujisawa, completed enrollment in a Phase III trial in February 2003 that demonstrated statistically significant results for the secondary endpoints of the trial: the prevention of LCSIs and catheter colonization, which is the growth of microorganisms on the portion of the catheter below the skin surface. However, the trial did not show statistical significance for the primary endpoint, the prevention of catheter-related bloodstream infections, or CRBSIs.

After the termination of the collaboration between Migenix and Fujisawa in January 2004, we in-licensed the rights to Omigard from Migenix in July 2004 and subsequently reached an agreement under the special protocol assessment, or SPA, process with the FDA concerning the protocol for our own Phase III clinical trial for Omigard. In connection with the SPA for Omigard, the FDA agreed that a single confirmatory Phase III trial will be required for approval of Omigard and that the prevention of LCSIs will be the sole primary efficacy endpoint. However, we cannot be certain that our ongoing Phase III trial for Omigard will demonstrate statistical significance or otherwise demonstrate sufficient efficacy and safety to support the filing of an NDA or ultimately lead to regulatory approval. Furthermore, despite having completed the SPA process, the FDA's agreement with us on the trial protocol remains subject to future public health concerns unrecognized at the time of the FDA's protocol assessment.

Our failure to adequately demonstrate the efficacy and safety of IV APAP, Omigard or any other product candidates that we may in-license or acquire would prevent receipt of regulatory approval and, ultimately, the commercialization of that product candidate.

Because the results of earlier clinical trials are not necessarily predictive of future results, IV APAP, Omigard or any other product candidate we advance into clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Success in clinical testing and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of the investigational drug. A number of companies in the pharmaceutical industry, including those with greater resources and experience, have suffered significant setbacks in Phase III clinical trials, even after promising results in earlier clinical trials.

In March 2006, we in-licensed the rights to IV APAP from BMS, which is currently marketing IV APAP in Europe and other parts of the world under the brand name Perfalgan. BMS has completed nine clinical trials, mostly in Europe, primarily in support of European regulatory approvals for this product candidate. However, we do not know at this time what regulatory weight, if any, the U.S. and Canadian regulatory agencies will give to these clinical data in supplementing clinical data generated by us for potential regulatory approval of IV APAP in the United States and Canada. The FDA and foreign regulatory agencies may reject these clinical trial results if they determine that the clinical trials were not conducted in accordance with requisite regulatory standards and procedures. Furthermore, we have not audited or verified the accuracy of the primary clinical data provided by BMS and cannot determine their applicability to our regulatory filings. Even though BMS has obtained marketing approval in Europe and other territories for IV APAP, we must conduct additional adequate and well controlled clinical trials in the United States to demonstrate IV APAP's safety and efficacy in specific indications to gain regulatory approval in the United States. We may not be able to demonstrate the same safety and efficacy for IV APAP in our planned Phase III clinical trial as was demonstrated previously by BMS.

Our other product candidate, Omigard, is a novel antimicrobial peptide and is not yet approved in any jurisdiction. No antimicrobial peptide has been approved by the FDA, including two antimicrobial peptides with mechanisms of action similar to Omigard that were studied in Phase III clinical trials. Although Omigard has been studied in more than 750 patients, all of the patients studied were enrolled in trials conducted or sponsored by Migenix or Fujisawa. Since in-licensing rights to Omigard from Migenix in July 2004, we have initiated a Phase III clinical trial in which we are still seeking to enroll the target patient population. We do not expect to complete enrollment in this Phase III clinical trial until the second half of 2007. Similar to IV APAP, we have obtained electronic databases from the completed Phase III trials sponsored by Migenix and Fujisawa, and are currently analyzing these data. We have not audited or verified the accuracy of the primary clinical data provided by our licensor and its former collaborator and cannot determine their applicability to our regulatory filings. Although the Phase III clinical trial for Omigard conducted by Migenix and Fujisawa demonstrated favorable, statistically significant results for the prevention of LCSIs and catheter colonization, secondary endpoints in their trial, we may not observe similar results in our ongoing Phase III clinical trial. Furthermore, the earlier Phase III clinical trial failed to show statistical significance for the primary endpoint of that trial, the prevention of CRBSIs. While we will measure the prevention of CRBSIs as a secondary endpoint in our ongoing Phase III clinical trial for Omigard, our trial is not designed to demonstrate statistical significance for this secondary endpoint. Although we are targeting a different primary endpoint in our trial, the prevention of LCSIs, it is possible that we will experience similar, unexpected results. Failure to satisfy a primary endpoint in a Phase III clinical trial would generally mean that a product candidate would not receive regulatory approval without a further successful Phase III clinical trial.

The data collected from our clinical trials may not be adequate to support regulatory approval of IV APAP, Omigard or any other product candidates that we may in-license or acquire. Moreover, all clinical data reported is taken from databases that may not have been fully reconciled against medical records kept at the clinical sites. Despite the results reported by others in earlier clinical trials for our product candidates, we do not know whether any Phase III or other clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates.

Delays in the commencement or completion of clinical testing could result in increased costs to us and delay or limit our ability to obtain regulatory approval for our product candidates.

Delays in the commencement or completion of clinical testing could significantly affect our product development costs. We do not know whether planned clinical trials for IV APAP will begin on time or be completed on schedule, if at all. Similarly, we may not complete enrollment for our ongoing Phase III clinical trial for Omigard on schedule, or at all. The commencement and completion of clinical trials requires us to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs for the same indication as our product candidates or may not be eligible to participate in or may be required to withdraw from a clinical trial as a result of changing standards of care. The commencement and completion of clinical trials can be delayed for a variety of other reasons, including delays related to:

- reaching agreements on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining regulatory approval to commence a clinical trial;
- obtaining institutional review board approval to conduct a clinical trial at a prospective site;
- recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including competition from other clinical trial programs for the same indication as our product candidates; and
- retaining patients who have initiated a clinical trial but may be prone to withdraw due to the treatment protocol, lack of efficacy, personal issues, side effects from the therapy or who are lost to further follow-up.

In addition, a clinical trial may be suspended or terminated by us, the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues or any determination that a trial presents unacceptable health risks; or
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our CROs and other third parties.

Additionally, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to institutional review boards for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in the completion of, or if we terminate, our clinical trials, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a

delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Even if we are able to ultimately commercialize our product candidates, other therapies for the same indications may have been introduced to the market and established a competitive advantage.

We expect intense competition in the territories in which we have rights to our product candidates, 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 our product candidates from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. There can be no assurance that developments by others will not render our product candidates 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 our product candidates obsolete or noncompetitive.

We intend to develop IV APAP for the treatment of acute pain in the hospital setting, which will compete with well established injectable drugs for this and similar indications, including opioids such as morphine, fentanyl, meperidine and hydromorphone, each of which is available generically from several manufacturers, as well as an extended release injectable formulation of morphine, DepoDur, currently marketed by an affiliate of Endo Pharmaceuticals Holdings Inc. Ketorolac, an injectable non-steroidal anti-inflammatory drug, or NSAID, is also available generically from several manufacturers and used to treat acute pain. During the time that it will take us to obtain regulatory approval for IV APAP, 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.

We are also developing our Omigard product candidate for the prevention of intravascular catheter-related infections in the hospital setting. If approved, Omigard will compete with well established topical products that are currently used in practice to prevent these infections as well as BioPatch, a device marketed by Johnson & Johnson, which has been approved for wound dressing and prevention of catheter-related infections. Other competitive products may be under development.

In addition, competitors may seek to develop alternative formulations of our product candidates 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. Furthermore, there are third-party patents covering analogs of omiganan and Migenix has patented analogs of omiganan that are not licensed to us. The commercial opportunity for our product candidates 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 our product candidates. Our competitors may also develop drugs that are more effective, useful and less costly than ours and may also be more successful than us in manufacturing and marketing their products. We also expect to face similar competition in our efforts to identify appropriate collaborators or partners to help develop or commercialize our product candidates in markets outside the United States.

If any of our product candidates for which we receive regulatory approval do not achieve broad market acceptance, the revenues that we generate from their sales will be limited.

The commercial success of our product candidates for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon the acceptance of these products by the medical community and coverage and reimbursement of them by third-party payors, including government payors. The degree of market acceptance of any of our approved products 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 IV APAP that may be more restrictive than oral formulations of acetaminophen;
- changes in the standard of care for the targeted indications for either of our product candidates could reduce the marketing impact of any superiority claims that we could make following FDA approval;
- limitations inherent in the approved indication for either of our product candidates compared to more commonly-understood or addressed conditions, including, in the case of Omigard, the ability to promote Omigard to hospitals and physicians who may be more focused on an indication specifically for the prevention of CRBSIs compared to the prevention of LCSIs, the primary endpoint in our ongoing Phase III clinical trial; and
- potential advantages over, and availability of, alternative treatments, including, in the case of IV APAP, a number of products already used to treat acute pain in the hospital setting, and in the case of Omigard, a number of competitive topical products as well as a device that has been approved for wound dressing and prevention of catheter-related infections.

Our ability to effectively promote and sell our product candidates in the hospital marketplace will also depend on pricing and cost effectiveness, including our ability to produce a product at a competitive price and 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.

The decreasing use of the comparator product in our clinical trial for Omigard may limit our ability to complete the trial in a timely manner and hinder the competitive profile of this product candidate.

Over the last several years, many hospitals, particularly in the United States, have increased the use of another topical antiseptic, chlorhexidine, as the standard of care to sterilize catheter insertion sites. Although we believe 10% povidone-iodine continues to be used by a sufficient number of hospitals to support continued enrollment of patients in our Phase III clinical trial for Omigard, this changing standard of care limits the number of potential clinical trial sites available to us. Accordingly, it may be difficult for us to maintain the clinical trial sites that we have already retained for the Omigard trial if any of these institutions elects to replace our comparator product with chlorhexidine, and it may take us longer than anticipated to identify and reach terms with additional hospitals to serve as clinical trial sites for the trial. Delays in the completion of enrollment or clinical testing for our ongoing Phase III clinical trial for Omigard and any other studies we may conduct to compare Omigard to chlorhexidine or another topical antiseptic could significantly affect our product development costs, our prospects for regulatory approval and our ability to compete. Furthermore, the decreasing use of 10% povidone-iodine in favor of chlorhexidine could reduce the marketing impact of any superiority claims that we could make following FDA approval. For example, hospitals and physicians may be reluctant to adopt the use of Omigard as a single agent for the prevention of local catheter site infections. Even if Omigard is approved by the FDA, if this product candidate does not achieve an adequate level of acceptance by physicians, health care payors and patients, we may be unable to generate sufficient revenues to recover our development costs or otherwise sustain and grow our business.

Even if our product candidates receive regulatory approval, they 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. Any of these restrictions or requirements could adversely affect our potential product revenues. For example, the label ultimately approved for IV APAP, Omigard or any other product candidates that we may in-license or acquire, if any, may include a restriction on the term of its use, or it may not include one or more of our intended indications.

Our product candidates will also be subject to ongoing FDA requirements for the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information on the drug. In addition, approved products, manufacturers and manufacturers' facilities are subject to continual review and periodic inspections. 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, a regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If our product candidates fail 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 our product candidates receive regulatory approval in the United States, we may never receive approval or commercialize our products outside of the United States.

Our rights to IV APAP are limited to the United States and Canada, and our rights to Omigard are limited to North America and Europe. In order to market any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding 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 United States 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 United States. As described above, such effects include the risks that our product candidates may not be approved for all indications requested, which could limit the uses of our product candidates 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.

We have never marketed a drug before, and if we are unable to establish an effective sales and marketing infrastructure, we will not be able to successfully commercialize our product candidates.

In the United States, we plan to build our own sales force to market our products directly to physicians, nurses, hospitals, group purchasing organizations and third-party payors. We currently do not have significant internal sales, distribution and marketing capabilities. In order to commercialize any of our product candidates, we must either acquire or internally develop sales and marketing capabilities, or enter into collaborations with partners to perform these services for us. The acquisition or development of a hospital-focused sales and marketing infrastructure for our domestic operations will require substantial resources, will be expensive and time consuming and could negatively impact our commercialization efforts, including delay any product launch. Moreover, we may not be able to hire a sales force that is sufficient in size or has adequate expertise. If we are unable to establish our sales and marketing capability or any other capabilities necessary to commercialize any products we may develop, we will need to contract with third parties to market and sell our products. If we are unable to establish adequate sales and marketing capabilities, whether independently or with third parties, we may not be able to generate any product revenue, may generate increased expenses and may never become profitable.

Our product candidates may have undesirable side effects that could delay or prevent their regulatory approval or commercialization.

Undesirable side effects caused by our product candidates could interrupt, delay or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing our product candidates and generating revenues from their sale. For example, the adverse events related to IV APAP observed in clinical trials completed to date include transient liver enzyme evaluations, nausea or vomiting and pain or local skin reactions at the injection site. When used outside the current guidelines for administration, acetaminophen has the potential to cause liver toxicity. While administration of acetaminophen in intravenous form is not expected to 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 that the FDA will not require additional trials or impose more severe labeling restrictions due to liver toxicity or other concerns. Drug-related adverse events observed in clinical trials completed to date for Omigard have been limited to local skin reactions, including redness, swelling, bleeding, itching, bruising and pain. In addition, while these drug-related adverse events have all been related to the skin, including the catheter insertion site, we cannot be certain that other drug-related side effects will not be reported in clinical trials or thereafter.

If either of our product candidates receives marketing approval and we or others later identify undesirable side effects caused by the product:

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

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

If the government or third-party payors fail to provide coverage and adequate coverage and payment rates for our future products, 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, IV APAP, Omigard 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 the United States, we expect that there will continue to be federal and state proposals to implement similar governmental controls. For example, in December 2003, Congress enacted a limited prescription drug benefit for Medicare beneficiaries in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Under this program, drug prices for certain prescription drugs are negotiated by drug plans, with the goal to lower costs for Medicare beneficiaries. In some foreign markets, 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. Cost control initiatives could decrease the price that we would receive for any products in the future, which would limit our revenue and profitability. Accordingly, legislation and regulations affecting the pricing of pharmaceuticals might change before our product candidates are approved for marketing. Adoption of such legislation could further limit reimbursement for pharmaceuticals.

If we breach any of the agreements under which we license rights to our product candidates from others, we could lose the ability to continue the development and commercialization of our product candidates.

In March 2006, we entered into an exclusive license agreement with BMS relating to our IV APAP product candidate for the United States and Canada, and in July 2004, we entered into an exclusive license agreement with Migenix relating to our Omigard product candidate for North America and Europe. Because we have in-licensed the rights to our two product candidates from third parties, if there is any dispute between us and our licensors regarding our rights under these license agreements, our ability to develop and commercialize these product candidates may be adversely affected. Any uncured, material breach under these license agreements could result in our loss of exclusive rights to the related product candidate and may lead to a complete termination of our product development efforts for the related product candidate.

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

Our license for IV APAP 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 IV APAP. 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 IV APAP product candidate and may lead to a complete termination of our product development and any commercialization efforts for IV APAP.

We rely on third parties to conduct our clinical trials, including our Phase III clinical program for IV APAP and our ongoing Phase III clinical trial for Omigard. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates on our anticipated timeline or at all.

We intend to rely primarily on third-party CROs to oversee our clinical trials for our IV APAP and Omigard product candidates, and we depend on independent clinical investigators, medical institutions and contract laboratories to conduct our clinical trials. Although we rely on CROs to conduct our clinical trials, we are responsible for ensuring that each of our clinical trials is conducted in accordance with its investigational plan and protocol. Moreover, the FDA requires us to comply with regulations and standards, commonly referred to as good clinical practices, or GCPs, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. Our reliance on CROs does not relieve us of these responsibilities and requirements. CROs and investigators are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. If our CROs or independent investigators fail to devote sufficient time and resources to our drug development programs, or if their performance is substandard, it will delay the approval of our FDA applications and our introductions of new products. The CROs with which we contract for execution of our clinical trials play a significant role in the conduct of the trials and the subsequent collection and analysis of data. Failure of the CROs to meet their obligations could adversely affect clinical development of our product candidates. Moreover, these independent investigators and CROs may also have relationships with other commercial entities, some of which may have competitive products under development or currently marketed. If independent investigators and CROs assist our competitors, it could harm our competitive position. If any of these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the clinical data is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for IV APAP, Omigard or future product candidates.

If the manufacturers upon whom we rely fail to produce our product candidates 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 development and commercialization of, or be unable to meet demand for, our products and may lose potential revenues.

We do not manufacture any of our product candidates, and we do not currently plan to develop any capacity to do so. We do not yet have agreements established regarding commercial supply of either of our product candidates and may not be able to establish or maintain commercial manufacturing arrangements on commercially reasonable terms for IV APAP, Omigard or any other product candidates that we may in-license or acquire. Any problems or delays we experience in preparing for commercial-scale manufacturing of a product candidate may result in a delay in FDA approval of the product candidate or may impair our ability to manufacture commercial quantities, which would adversely affect our business. For example, our manufacturers will need to produce specific batches of our product candidates to demonstrate acceptable stability under various conditions and for commercially viable lengths of time. We and our contract manufacturers will need to demonstrate to the FDA and other regulatory authorities this acceptable stability data for our product candidates, as well as validate methods and manufacturing processes, in order to receive regulatory approval to commercialize IV APAP, Omigard or any other product candidate. Furthermore, if our commercial manufacturers fail to deliver the required commercial quantities of bulk drug substance or finished product on a timely basis and at commercially reasonable prices, we would likely be unable to meet demand for our products and we would lose potential revenues.

We currently have what we believe are adequate clinical supplies of our Omigard product candidate. We entered into a clinical supply agreement with Lawrence Laboratories, an affiliate of BMS, under which Lawrence Laboratories has manufactured a single batch of clinical supplies of IV APAP and a single batch of placebo. With these batches, we believe we

will have adequate clinical supplies of our IV APAP product candidate and placebo. The term of the clinical supply agreement generally extends until the earlier of the receipt by us of regulatory approval for IV APAP or December 31, 2008. In addition, the clinical supply agreement could terminate upon mutual written consent of the parties, the termination of the IV APAP agreement or our dissolution. The clinical supply agreement may also be terminated by either party upon written notice to the other party of an uncured, material breach. We are currently negotiating with suppliers for the potential commercial supply of the finished drug product for IV APAP. We do not have any long-term commitments from our suppliers of clinical trial material or guaranteed prices for our product candidates or placebos. The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate and quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Our manufacturers may not perform as agreed. If our manufacturers were to encounter any of these difficulties, our ability to provide product candidates to patients in our clinical trials would be jeopardized.

In addition, all manufacturers of our product candidates must comply with cGMP requirements enforced by the FDA through its facilities inspection program. These requirements include quality control, quality assurance and the maintenance of records and documentation. Manufacturers of our product candidates may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. We have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements 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 safety of any quantities supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

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 each of our two current product candidates, IV APAP and Omigard, from third parties who conducted the initial development of each 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;
- 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.

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

As of September 30, 2006, we had 29 full-time employees. We will need to continue to expand our managerial, operational, financial and other resources in order to manage and fund our operations and clinical trials, continue our development activities and commercialize our product candidates. Our management, personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

- manage our clinical trials effectively, including our planned Phase III clinical program for IV APAP, which will be conducted at numerous clinical trial sites, and our ongoing Phase III clinical trial for Omigard, which is being conducted at numerous clinical sites;
- manage our internal development efforts effectively while carrying out our contractual obligations to 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 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, and William R. LaRue, our Senior Vice President, Chief Financial Officer, Treasurer and Secretary. If we lose one or more of these key employees, our ability to implement our business strategy successfully 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 and Mr. LaRue, 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 a product candidate and may have to limit its commercialization.

The use of our product candidates 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 $10 million annual aggregate coverage limit and additional amounts in selected foreign countries where we are conducting clinical trials. 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 candidates 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.

Recent proposed legislation may permit re-importation of drugs from foreign countries into the United States, including foreign countries where the drugs are sold at lower prices than in the United States, which could materially adversely affect our operating results and our overall financial condition.

Legislation has been introduced in Congress that, if enacted, would permit more widespread re-importation of drugs from foreign countries into the United States, which may include re-importation from foreign countries where the drugs are sold at lower prices than in the United States. Such legislation, or similar regulatory changes, could decrease the price we receive for any approved products which, in turn, could materially adversely affect our operating results and our overall financial condition. For example, BMS markets IV APAP in Europe and other countries principally under the brand name Perfalgan. Although Perfalgan is not labeled for sale in the United States and we have an exclusive license from BMS and its licensor to develop and sell our product candidate in the United States, it is possible that hospitals and other users may in the future seek to import Perfalgan rather than purchase IV APAP in the United States for cost-savings or other reasons. We would not receive any revenues from the importation and sale of Perfalgan into the United States.

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

Our third-party manufacturers' 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 candidates and other hazardous compounds. We and our manufacturers 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 or ongoing clinical trials for IV APAP or Omigard 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 candidates may be delayed.

Risks Related to Intellectual Property

The patent rights that we have in-licensed covering IV APAP 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 IV APAP is acetaminophen. There are currently no patents covering the acetaminophen molecule itself in the territories licensed to us, which include the United States and Canada. As a result, competitors who obtain the requisite regulatory approval can offer products with the same active ingredient as IV APAP 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 United States that claim methods of making acetaminophen. If a supplier of the active pharmaceutical ingredient, or API, for our IV APAP 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. In addition, Injectapap, a formulation of acetaminophen for intramuscular injection was approved by the FDA for the reduction of fever in adults in March 1986 but was withdrawn from the market by McNeil Pharmaceutical in July 1986. Although we are not aware of any announcement regarding the reasons for Injectapap's withdrawal, we believe it was likely withdrawn from the market due to product-related concerns either related to the intramuscular injection mode of administration or the sodium bisulfite in the formulation.

The number of patents and patent applications covering products in the same field as IV APAP 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 our IV APAP product candidate could be significantly harmed if competitors are able to develop an alternative formulation of acetaminophen outside the scope of our in-licensed patents.

The patent rights that we have in-licensed covering Omigard are limited in scope and limited to specific territories.

We have an exclusive license from Migenix for Omigard in North America and Europe for the licensed field, although currently there are issued patents only in the United States and certain European countries. Canadian applications are pending; however, the claims that ultimately issue in Canada may be narrower than the protection obtained in the United States and Europe or may simply not issue at all. In addition, no patent protection has been sought in Mexico. Accordingly, the manufacture, sale and use of Omigard in Mexico by a competitor cannot be prevented. Furthermore, there are third-party patents covering analogs of omiganan and Migenix has patented analogs of omiganan that are not licensed to us. It is possible that competitors having rights to these patents may develop competing products having the same, similar or better efficacy compared to Omigard.

Furthermore, our license agreement with Migenix may be construed to cover only the use of Omigard and other formulations of omiganan for the licensed field, which is the treatment of burn-related, surgical wound-related, or device-related infections. Thus, Migenix or third-party licensees of Migenix may be able to market Omigard for other uses, including treatment of non-surgery related wound infections. We may be unable to prevent physicians from using any such competitive Omigard product off-label for the field licensed to us.

We depend on our licensors for the maintenance and enforcement of our intellectual property and have limited control, if any, over the amount or timing of resources that our licensors devote on our behalf.

We depend on our licensors, BMS and Migenix, to protect the proprietary rights covering IV APAP and Omigard. Regarding IV APAP, either BMS or its licensor, SCR Pharmatop, depending on the patent or application, is responsible for maintaining issued patents and prosecuting patent applications. Regarding Omigard, Migenix is responsible for maintaining issued patents and prosecuting patent applications. We have limited, if any, control over the amount or timing of resources that our licensors devote on our behalf or the priority they place on maintaining these patent rights and prosecuting these patent applications to our advantage. 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. For patents and applications licensed from Migenix, Migenix is obligated to use commercially reasonable efforts to obtain and maintain patent rights covering Omigard in North America and Europe. If Migenix intends to abandon prosecution or maintenance of any patents or applications, they are obligated to notify us, and at that time, we will be granted an opportunity to maintain and prosecute the patents and applications. In such a case, Migenix is required to transfer all necessary rights and responsibilities to facilitate our maintenance and prosecution of the patents and applications. Similar to BMS, however, we cannot be certain that Migenix will perform its contractual obligations as required or that we will be able to adequately assume the prosecution or maintenance of the Omigard-related patents and applications.

As part of a financing transaction, Migenix has pledged as collateral to its lenders the patents and patent applications covering Omigard. While we believe our license agreement with Migenix would survive any foreclosure on these patents and patent applications, we cannot be sure that the lenders will have adequate expertise or resources to properly perform Migenix’s obligations to us under the license agreement, including maintaining and prosecuting the 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. In the case of the IV APAP patents, 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. In certain instances, we may be allowed to pursue the infringement claim ourselves. With respect to Omigard, we have the first right to prosecute a third-party for infringement of the in-licensed Migenix patents provided the infringing activities are in North America or Europe and relate primarily to the licensed field of use. Migenix is obligated to reasonably cooperate with any such suit.

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 United States 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. Finally, Migenix is not obligated to defend or assist in our defense of a third-party infringement suit relating to our Omigard product candidate; however, Migenix has the right to control the defense and settlement that relates to the validity and enforceability of claims in the in-licensed Migenix patents.

For a third-party challenge to the SCR Pharmatop in-licensed patents relating to IV APAP, we will have some ability to participate in either SCR Pharmatop's or BMS's defense thereof. In the case that neither party elects to defend the third-party challenge, then we may have the opportunity to defend it. For a third-party challenge to the in-licensed BMS patents relating to IV APAP, BMS has the sole right to defend such challenge. If it chooses not to, 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 IV APAP, Omigard or any other product candidates that we may in-license or acquire and the methods we use to manufacture them, as well as successfully defending these patents 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 United States. The patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States 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 United States 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 some of 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 United States. 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 drug 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 United States 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 IV APAP, Omigard or any other product candidate we may in-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 IV APAP, Omigard or any other product candidates that we may in-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 prevention of infections and cover the use of numerous compounds and formulations in our targeted markets. For instance, there is a patent in force in various European countries, with claims that, if valid, may be broad enough in scope to cover the formulation of our Omigard product candidate. It is possible that we may determine it prudent to seek a license to this European patent in order to avoid potential litigation and other disputes. We cannot be sure that a license would be available to us on commercially reasonable terms, or at all. Similarly, there is a patent application pending in the United States that corresponds to the European patent. Because this patent application has neither published nor issued, it is too early to tell if the claims of this application will present similar issues for Omigard in the United States. There is also a patent application pending in Canada that corresponds to the European patent. Because this patent application has not issued, it is too early to tell if the claims of this application will present similar issues for Omigard in Canada. However, similar to the European patent, if the U.S. or Canadian patent applications issue with a scope that is broad enough to cover our Omigard product candidate and we are unable to assert successful defenses to any patent claims, we may be unable to commercialize Omigard, or may be required to expend substantial sums to obtain a license to the other party's patent. While we believe there may be multiple grounds to challenge the validity of the European patent, and these grounds may be applicable to the U.S. and Canadian applications should they issue as patents, the outcome of any litigation relating to this European patent and the U.S. and Canadian patent applications, or any other patents or patent applications, is uncertain and participating in such litigation would be expensive, time-consuming and distracting to management. Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we and Migenix 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 IV APAP or Omigard may infringe. There could also be existing patents of which we are not aware that IV APAP or Omigard 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 is not 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 our two product candidates, IV APAP and Omigard, with the goal of supporting regulatory approval for these product candidates. We have financed our operations almost exclusively through private placements of preferred stock and have incurred losses in each year since our inception in May 2004. Net losses were $7.7 million in 2005 and $43.2 million for the first nine months of 2006. The net loss for the first nine months of 2006 was principally attributed to our expense related to the $25.0 million licensing fee for IV APAP paid to BMS and clinical trial and regulatory expenses. As of September 30, 2006, we had an accumulated deficit of $53.8 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 as well as clinical product manufacturing expenses to increase in connection with our ongoing and planned Phase III clinical trials for our product candidates. In addition, if we obtain regulatory approval for IV APAP or Omigard, 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 and increasing 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:

- successfully complete our ongoing and planned clinical trials for IV APAP and Omigard;
- obtain regulatory approval for either of our two product candidates;
- assuming these regulatory approvals are received, manufacture commercial quantities of our product candidates at acceptable cost levels; and
- successfully market and sell any approved products.

Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product. 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 our IV APAP product candidate since March 2006 and our Omigard product candidate since July 2004. Our operations to date have been limited to organizing and staffing our company, in-licensing our two product candidates and initiating product development activities for our two product candidates. 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 to conduct adequate and well-controlled clinical trials to provide clinical data to support regulatory approval of marketing applications;
- continue our development activities;
- qualify and outsource the commercial-scale manufacturing of our products under cGMP; and
- commercialize IV APAP, Omigard or any other product candidates that we may in-license or acquire, if any of these product candidates receive regulatory approval.

We believe that our existing cash and cash equivalents, including the net proceeds from our initial public offering completed in the fourth quarter of 2006, will be sufficient to meet our projected operating requirements through at least December 31, 2008. We have based this estimate on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

- the rate of progress and cost of our clinical trials and other product development programs for IV APAP, Omigard and any other product candidates that we may in-license or acquire;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates;
- the cost and timing of completion of an outsourced commercial manufacturing supply for each product candidate;
- the costs and timing of regulatory approval;
- the costs of establishing sales, marketing and distribution capabilities;
- the effect of competing technological and market developments; and
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish.

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:

- the timing of milestone payments required under our license agreements for IV APAP and Omigard;
- our execution of other collaborative, licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements;
- our addition or termination of clinical trials or funding support;
- variations in the level of expenses related to our two existing product candidates or future development programs;
- any intellectual property infringement lawsuit in which we may become involved;
- regulatory developments affecting our product candidates or those of our competitors; and
- if either of our product candidates receives regulatory approval, the level of underlying hospital demand for our product candidates and wholesalers' buying patterns.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly 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 which 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 the 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 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 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 will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC and the Nasdaq Global Market, have imposed various new requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these new compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to 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 requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, commencing in fiscal 2007, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management and our independent registered public accounting firm to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Our testing, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses. Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Moreover, if we are not able to comply with the requirements of Section 404 in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would require additional financial and management resources.

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 develop or 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. 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. 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. Since our initial public offering through November 20, 2006, the trading prices for our common stock ranged from a high of $12.00 to a low of $9.25.

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 will be able to sell in the public market in the near future. 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.

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, our directors and executive officers may in the future establish programmed selling plans under Rule 10b5-1 of the Securities Exchange Act 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.

We expect that the price of our common stock will fluctuate substantially.

The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including:

- the results from our clinical trial programs, including our planned Phase III clinical program for IV APAP and our ongoing Phase III clinical trial for Omigard;
- the results of clinical trial programs for IV APAP and Omigard being performed by others;
- FDA or international regulatory actions, including failure to receive regulatory approval for any of our product candidates;
- failure of any of our product candidates, if approved, to achieve commercial success;
- announcements of the introduction of new products by us or our competitors;
- market conditions in the pharmaceutical and biotechnology sectors;
- developments concerning product development results or intellectual property rights of others;
- litigation or public concern about the safety of our potential products;
- actual and anticipated fluctuations in our quarterly operating results;
- deviations in our operating results from the estimates of securities analysts or other analyst comments;
- additions or departures of key personnel;
- 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 management’s attention and resources, which could hurt our business, operating results and financial condition.

Our management team may invest or spend the proceeds from our initial public offering in ways in which our stockholders may not agree or in ways which may not yield a return.

We intend to use the net proceeds from our initial public offering:

- to fund clinical trials for IV APAP and Omigard and other research and development activities;
- to fund capital expenditures, primarily including equipment associated with the manufacturing of IV APAP; and
- to fund working capital and other general corporate purposes.

Our management and directors will, however, have broad discretion in the application of the net proceeds from the offering and could spend the proceeds in ways that do not necessarily improve our operating results or enhance the value of our common stock.. We may also use a portion of the net proceeds to in-license, acquire or invest in complementary businesses or products. We have no present understandings, commitments or agreements with respect to any such in-licenses, acquisitions or investments and no portion of the net proceeds has been allocated for any specific transaction. Until the net proceeds are used, they will be placed in investments that do not produce significant income or that lose value.

Our executive officers and directors and their affiliates will 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, 2006, including the impact of our initial public offering in October 2006, our executive officers and directors and their affiliates will together control approximately 56.8% 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, which became effective at the closing of our initial public offering, 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 loan and security agreement with Silicon Valley Bank and Oxford Finance Corporation restricts our ability to pay dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of 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

Recent Sales of Unregistered Securities

From July 1, 2006 to September 30, 2006, we granted stock options to purchase 412,000 shares of our common stock at an exercise price of $3.20 per share to our employees and directors under our 2004 Equity Incentive Plan. From July 1, 2006 to September 30, 2006, we issued and sold an aggregate of 40,000 shares of our common stock to our employees and directors at a price of $3.20 per share for an aggregate of $128,000 pursuant to exercises of options granted under our 2004 Equity Incentive Plan.

The sales and issuances of securities in the transactions described above were deemed to be exempt from registration under the Securities Act of 1933, as amended, in reliance upon Rule 701 promulgated under Section 3(b) of the Securities Act of 1933, as amended, as transactions pursuant to compensatory benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of securities in each transaction represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. All recipients had adequate access, through employment or other relationships, to information about us. All certificates representing the securities issued in these transactions included appropriate legends setting forth that the securities had not been offered or sold pursuant to a registration statement and describing the applicable restrictions on transfer of the securities. There were no underwriters employed in connection with any of the transactions set forth above.

Use of Proceeds

Our initial public offering of common stock was effected through a Registration Statement on Form S-1 (File No. 333-135821) that was declared effective by the Securities and Exchange Commission on October 24, 2006, which registered an aggregate of 6,900,000 shares of our common stock. On October 24, 2006, 6,000,000 shares of common stock were sold on our behalf at an initial public offering price of $9.00 per share, for an aggregate gross offering price of $54.0 million, managed by Merrill Lynch & Co., Deutsche Bank Securities, Pacific Growth Equities, LLC and JMP Securities. On November 13, 2006, in connection with the exercise of the underwriters' over-allotment option, 900,000 additional shares of common stock were sold on our behalf at the initial public offering price of $9.00 per share, for an aggregate gross offering price of $8.1 million. Following the sale of the 6,900,000 shares, the offering terminated.

We paid to the underwriters underwriting discounts totaling approximately $4.3 million in connection with the offering. In addition, we incurred additional expenses of approximately $1.8 million in connection with the offering, which when added to the underwriting discounts paid by us, amounts to total expenses of approximately $6.1 million. Thus, the net offering proceeds to us, after deducting underwriting discounts and offering expenses, were approximately $56.0 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

As of November 20, 2006, we had invested the $56.0 million in net proceeds from the offering in money market funds. Through November 20, 2006, we have not used the net proceeds from the offering. We intend to use the proceeds to fund clinical trials for IV APAP and Omigard and other research and development activities, to fund capital expenditures, primarily including equipment associated with the manufacturing of IV APAP and to fund working capital and other general corporate purposes. We may also use a portion of the net proceeds to in-license, acquire or invest in complementary businesses or products. We cannot specify with certainty all of the particular uses for the net proceeds from our initial public offering. The amount and timing of our expenditures will depend on several factors, including the progress of our clinical trials and commercialization efforts as well as the amount of cash used in our operations. Accordingly, our management will have broad discretion in the application of the net proceeds.

Item 3. Defaults Upon Senior Securities

None.

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

In August 2006, our stockholders acted by written consent to approve the following:

- effective immediately,
    - an amendment to our restated certificate of incorporation which increased the size of our Board of Directors to nine persons;

- appointment of Samuel L. Barker, Ph.D. as a director;
- amendment of our voting agreement to reflect Dr. Barker's appointment as a director;
- amendment of our amended and restated bylaws to authorize consent by electronic transmission with respect to actions taken by our Board of Directors without a meeting; and
- the implementation of indemnification agreements for our officers and directors.

- contingent upon the closing of our initial public offering,
  - filing of an amended and restated certificate of incorporation to provide for, among other things, authorized capital stock of 100,000,000 shares of common stock and 10,000,000 shares of undesignated preferred stock;
  - adoption of amended and restated bylaws;
  - classification of our Board of Directors into three classes; and
  - adoption of our 2006 equity incentive award plan.
- effective on the public trading date, adoption of a director compensation policy.

Stockholders holding an aggregate of 75,681,313 shares approved each of the above matters and stockholders holding approximately 12,660,882 shares did not vote with respect to such matters. Other than the authorized capital stock set forth in our amended and restated certificate of incorporation, the share numbers reported above do not reflect the reverse stock split of our outstanding common stock effected in October 2006.

Item 5. Other Information

None.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of the Registrant
3.2	Amended and Restated Bylaws of the Registrant
4.1	Form of the Registrant's Common Stock Certificate
4.2 (1)	Amended and Restated Investor Rights Agreement dated February 21, 2006
4.3 (1)	Warrant issued by Registrant in February 2006 to Silicon Valley Bank
4.4 (1)	Warrant issued by Registrant in February 2006 to Oxford Finance Corporation
31.1 *	Certification of Chief Executive Officer Pursuant to Rule 13a-14 and Rule 15d-14 of the Securities Exchange Act of 1934, as amended
31.2 *	Certification of the Chief Financial Officer Pursuant to Rule 13a-14 and Rule 15d-14 of the Securities Exchange Act of 1934, as amended
32.1 *	Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

(1) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (No. 333-135821) filed with the Securities and Exchange Commission on July 17, 2006.

* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934 and are not to be incorporated by reference into any filing of Cadence Pharmaceuticals, Inc., whether made before or after the date hereof, regardless of any general incorporation language in such filing.

SIGNATURES

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

CADENCE PHARMACEUTICALS, INC.

Date: November 30, 2006

By: /s/ William R. LaRue
William R. LaRue
Senior Vice President, Chief Financial Officer, Treasurer and Secretary
(Duly Authorized Officer and Principal Financial Officer)

EXHIBIT 3.1

AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
CADENCE PHARMACEUTICALS, INC.

(the "Corporation"), a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the "DGCL"), DOES HEREBY CERTIFY:

1. The name of the Corporation is Cadence Pharmaceuticals, Inc. The Corporation's original Certificate of Incorporation was filed on May 26, 2004 under the name Strata Pharmaceuticals, Inc.

2. That by action taken by the Board of Directors at a meeting held on August 23, 2006, resolutions were duly adopted setting forth a proposed amendment and restatement of the Certificate of Incorporation of the Corporation, declaring said amendment and restatement to be advisable and directing its officers to submit said amendment and restatement to the stockholders of the Corporation for consideration thereof. The resolution setting forth the proposed amendment and restatement is as follows:

"THEREFORE, BE IT RESOLVED, that the Certificate of Incorporation of the Corporation is hereby amended to read in its entirety as follows, subject to the required consent of the stockholders of the Corporation:

FIRST: The name of the Corporation (hereinafter the "Corporation") is Cadence Pharmaceuticals, Inc.

SECOND: The address, including street, number, city and county, of the registered office of the Corporation in the State of Delaware is 2711 Centerville Road, Suite 400, in the City of Wilmington, County of New Castle; and the name of the Registered Agent of the Corporation at such address is Corporation Service Company.

THIRD: The nature of the business or purposes to be conducted or promoted is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware (the "DGCL").

FOURTH: The Corporation is authorized to issue two classes of stock to be designated, respectively, Common Stock, par value $0.0001 per share ("Common Stock") and Preferred Stock, par value $0.0001 per share ("Preferred Stock"). The total number of shares the Corporation shall have the authority to issue is one hundred ten million (110,000,000) shares, one hundred million (100,000,000) shares of which shall be Common Stock and ten million (10,000,000) shares of which shall be Preferred Stock.

(1) Common Stock. The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights of the holders of the Preferred Stock of any series as may be designated by the Board of Directors upon any issuance of the Preferred Stock or any series. The holders of the Common Stock are entitled to one vote for each share held at all meetings of stockholders. There shall be no cumulative voting. Dividends may be declared and paid on the Common Stock from funds lawfully available therefor as and when determined by the Board of Directors and subject to any preferential dividend rights of any then outstanding Preferred Stock. Upon the dissolution or liquidation of the Corporation, whether voluntary or involuntary, holders of the

Corporation will be entitled to receive ratably all assets of the Corporation available for distribution to stockholders, subject to any preferential rights of any then outstanding Preferred Stock.

(2) Preferred Stock. Shares of Preferred Stock may be issued from time to time in one or more series, each of such series to have such terms as stated in the resolution or resolutions providing for the establishment of such series adopted by the Board of Directors of the Corporation as hereinafter provided. Authority is hereby expressly granted to the Board of Directors of the Corporation to issue, from time to time, shares of Preferred Stock in one or more series, and, in connection with the establishment of any such series by resolution or resolutions, to determine and fix such voting powers, full or limited, or no voting powers, and such other powers, designations, preferences and relative, participating, optional and other special rights, and the qualifications, limitations and restrictions thereof, if any, including, without limitation, dividend rights, conversion rights, redemption privileges and liquidation preferences, as shall be stated in such resolution or resolutions, all to the fullest extent permitted by the DGCL. Without limiting the generality of the foregoing, the resolution or resolutions providing for the establishment of any series of Preferred Stock may, to the extent permitted by law, provide that such series shall be superior to, rank equally with or be junior to the Preferred Stock of any other series. The powers, preferences and relative, participating, optional and other special rights of each series of Preferred Stock, and the qualifications, limitations or restrictions thereof, if any, may be different from those of any and all other series at any time outstanding. Except as otherwise expressly provided in the resolution or resolutions providing for the establishment of any series of Preferred Stock, no vote of the holders of shares of Preferred Stock or Common Stock shall be a prerequisite to the issuance of any shares of any series of the Preferred Stock authorized by and complying with the conditions of this Certificate of Incorporation.

FIFTH: (1) The business and affairs of the Corporation shall be managed by or under the direction of a Board of Directors having that number of directors set out in the Bylaws of the Corporation as adopted or as set forth from time to time by a duly adopted amendment thereto by the Board of Directors or stockholders of the Corporation.

(2) No director (other than directors elected by one or more series of Preferred Stock) may be removed from office by the stockholders except for cause and, in addition to any other vote required by law, upon the affirmative vote of not less than 66 2/3% of the total voting power of all outstanding securities of the Corporation then entitled to vote generally in the election of directors, voting together as a single class.

(3) The directors of the Corporation, other than directors elected by one or more series of Preferred Stock, shall be divided into three classes, designated Class I, Class II and Class III. Each class shall consist, as nearly as may be possible, of one-third of the total number of directors (other than directors elected by one or more series of Preferred Stock) constituting the entire Board of Directors. Each director (other than directors elected by one or more series of Preferred Stock) shall serve for a term ending on the date of the third annual meeting of stockholders next following the annual meeting at which such director was elected, provided that directors initially designated as Class I directors shall serve for a term ending on the date of the 2007 annual meeting, directors initially designated as Class II directors shall serve for a term ending on the date of the 2008 annual meeting and directors initially designated as Class III directors shall serve for a term ending on the date of the 2009 annual meeting. Notwithstanding the foregoing, each director shall hold office until such director's successor shall have been duly elected and qualified or until such director's earlier death, resignation or removal. If the number of directors (other than directors elected by one or more series of Preferred Stock) is changed, any increase or decrease shall be apportioned among the classes so as to maintain the number of directors in each class as nearly equal as possible, but in no event will a decrease in the number of directors shorten the term of any incumbent director. Vacancies on the Board of Directors resulting from death, resignation,

removal or otherwise and newly created directorships resulting from any increase in the number of directors (other than directors elected by one or more series of Preferred Stock) may be filled solely by a vote of a majority of the directors then in office (although less than a quorum) or by a sole remaining director, and each director so elected shall hold office for a term that shall coincide with the remaining term of the class to which such director shall have been elected. Whenever the holders of one or more classes or series of Preferred Stock shall have the right, voting separately as a class or series, to elect directors, the nomination, election, term of office, filling of vacancies, removal and other features of such directorships shall not be governed by this Article FIFTH unless otherwise provided for in the certificate of designation for such classes or series.

SIXTH: The Corporation is to have perpetual existence.

SEVENTH: The following provisions are inserted for the management of the business and the conduct of the affairs of the Corporation and for the further definition of the powers of the Corporation and its directors and stockholders:

(1) The Board of Directors is expressly authorized to make, adopt, amend, alter, rescind or repeal the Bylaws of the Corporation. Notwithstanding the foregoing, the stockholders may adopt, amend, alter, rescind or repeal the Bylaws with, in addition to any other vote required by law, the affirmative vote of the holders of not less than 66$^{2}/_{3}$% of the total voting power of all outstanding securities of the Corporation then entitled to vote generally in the election of directors, voting together as a single class.

(2) Elections of directors need not be by written ballot unless the Bylaws of the Corporation so provide.

(3) Any action required or permitted to be taken at any annual or special meeting of stockholders may be taken only upon the vote of stockholders at an annual or special meeting duly noticed and called in accordance with the DGCL and may not be taken by written consent of stockholders without a meeting.

(4) Special meetings of the stockholders of the Corporation for any purpose or purposes may be called at any time by the Chairman of the Board of Directors or the President or at the written request of a majority of the members of the Board of Directors and may not be called by any other person; provided, however, that if and to the extent that any special meeting of stockholders may be called by any other person or persons specified in any provisions of the Certificate of Incorporation or any amendment thereto or any certificate filed under Section 151(g) of the DGCL, then such special meeting may also be called by the person or persons, in the manner, at the times and for the purposes so specified.

EIGHTH: (a) Subject to Article EIGHTH (c), the Corporation shall indemnify and hold harmless any person who is or was a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the Corporation) by reason of the fact that he or she is or was a director or officer of the Corporation, or is or was serving at the request of the Corporation as a director or officer of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him or her in connection with such action, suit or proceeding if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the Corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction or upon a plea of *nolo contendere* or its equivalent, shall not, of itself, create a presumption that the person did not act in good faith and in a manner which he or she reasonably

believed to be in or not opposed to the best interests of the Corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that his or her conduct was unlawful.

(b) Subject to Article EIGHTH (c), the Corporation shall indemnify and hold harmless any person who is or was a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the Corporation to procure a judgment in its favor by reason of the fact that he or she is or was a director or officer of the Corporation, or is or was serving at the request of the Corporation as a director or officer of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by him or her in connection with the defense or settlement of such action or suit if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the Corporation; except that no indemnification shall be made in respect of any claim, issue or matter as to which such person shall have been adjudged to be liable to the Corporation unless and only to the extent that the Court of Chancery of the State of Delaware or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery of the State of Delaware or such other court shall deem proper.

(c) Any indemnification under this Article EIGHTH (unless ordered by a court) shall be made by the Corporation only as authorized in the specific case upon a determination that indemnification of the director or officer or other person entitled to indemnification under this Article EIGHTH is proper in the circumstances because he or she has met the applicable standard of conduct set forth in Article EIGHTH (a) or Article EIGHTH (b), as the case may be. Such determination shall be made, with respect to an officer or director, (i) by the Board of Directors by a majority vote of directors who were not parties to such action, suit or proceeding, even if constituting less than a quorum, (ii) by a committee of directors who were not parties to such action, suit or proceeding even if constituting less than a quorum, (iii) if there are no such directors, or if such directors so direct, by independent legal counsel in a written opinion or (iv) by the stockholders. To the extent, however, that a present or former director or officer of the Corporation has been successful on the merits or otherwise in defense of any action, suit or proceeding referred to in Article EIGHTH (a) or Article EIGHTH (b), or in defense of any claim, issue or matter therein, he or she shall be indemnified against expenses (including attorneys' fees) actually and reasonably incurred by him or her in connection therewith, without the necessity of authorization in the specific case.

(d) Notwithstanding any contrary determination in the specific case under Article EIGHTH (c), and notwithstanding the absence of any determination thereunder, any present or former director or officer of the Corporation may apply to the Court of Chancery of the State of Delaware for indemnification to the extent otherwise permissible under Article EIGHTH (a) and Article EIGHTH (b). The basis of such indemnification by a court shall be a determination by such court that indemnification of such person is proper in the circumstances because he or she has met the applicable standards of conduct set forth in Article EIGHTH (a) or Article EIGHTH (b), as the case may be. Neither a contrary determination in the specific case under Article EIGHTH (c) nor the absence of any determination thereunder shall be a defense to such application or create a presumption that such person seeking indemnification has not met any applicable standard of conduct. Notice of any application for indemnification pursuant to this Article EIGHTH (d) shall be given to the Corporation promptly upon the filing of such application. If successful, in whole or in part, such person seeking indemnification in the Court of Chancery of the State of Delaware shall also be entitled to be paid the expense of prosecuting such application.

(e) Expenses incurred by a person who is or was a director or officer of the Corporation in defending or investigating a threatened or pending action, suit or proceeding shall be paid

by the Corporation in advance of the final disposition of such action, suit or proceeding upon receipt of an undertaking by or on behalf of such person to repay such amount if it shall ultimately be determined that he or she is not entitled to be indemnified by the Corporation as authorized in this Article EIGHTH.

(f) The indemnification and advancement of expenses provided by or granted pursuant to this Article EIGHTH shall not be deemed exclusive of any other rights to which those seeking indemnification or advancement of expenses may be entitled under any bylaw, agreement, contract, vote of stockholders or disinterested directors or pursuant to the direction (howsoever embodied) of any court of competent jurisdiction or otherwise, both as to action in his or her official capacity and as to action in another capacity while holding such office, it being the policy of the Corporation that indemnification of the persons specified in Article EIGHTH (a) and Article EIGHTH (b) shall be made to the fullest extent permitted by law. The provisions of this Article EIGHTH shall not be deemed to preclude the indemnification of any person who is not specified in Article EIGHTH (a) or Article EIGHTH (b) but whom the Corporation has the power or obligation to indemnify under the provisions of the DGCL or otherwise.

(g) The Corporation may purchase and maintain insurance on behalf of any person who is or was a director or officer of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise against any liability asserted against him or her and incurred by him or her in any such capacity, or arising out of his or her status as such, whether or not the Corporation would have the power or the obligation to indemnify him or her against such liability under the provisions of this Article EIGHTH or Section 145 of the DGCL.

(h) For purposes of this Article EIGHTH, references to “the Corporation” shall include, in addition to the resulting corporation, any constituent corporation (including any constituent of a constituent) absorbed in a consolidation or merger which, if its separate existence had continued, would have had the power and authority to indemnify its directors or officers, so that any person who is or was a director or officer of such constituent corporation, or is or was serving at the request of such constituent corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise, shall stand in the same position under the provisions of this Article EIGHTH with respect to the resulting or surviving corporation as he or she would have with respect to such constituent corporation if its separate existence had continued. For purposes of this Article EIGHTH, references to “fines” shall include any excise taxes assessed on a person with respect to an employee benefit plan; and references to “serving at the request of the Corporation” shall include any service as a director, officer, employee or agent of the Corporation which imposes duties on, or involves services by, such person with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner he or she reasonably believed to be in the interest of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner “not opposed to the best interests of the Corporation” as referred to in this Article EIGHTH. For purposes of any determination under Article EIGHTH (c), a person shall be deemed to have acted in good faith in a manner he or she reasonably believed to be in or not opposed to the best interests of the Corporation, or, with respect to any criminal action or proceeding, to have had no reasonable cause to believe his or her conduct was unlawful, if his or her action is based on the records or books of account of the Corporation or another enterprise, or on information supplied to him or her by the officers of the Corporation or another enterprise in the course of their duties, or on the advice of legal counsel for the Corporation or another enterprise or on information or records given or reports made to the Corporation or another enterprise by an independent certified public accountant or by an appraiser or other expert selected with reasonable care by the Corporation or another enterprise. The term “another enterprise” as used in this Article EIGHTH (h) shall mean any other corporation or any partnership, joint venture, trust, employee benefit plan or other enterprise of which such person is or was serving at the request of the Corporation as a director, officer, employee or agent. The provisions of this Article

EIGHTH (h) shall not be deemed to be exclusive, or to limit in any way, the circumstances in which a person may be deemed to have met the applicable standard of conduct set forth in Article EIGHTH (a) or (b), as the case may be.

(i) The indemnification and advancement of expenses provided by, or granted pursuant to, this Article EIGHTH shall, unless otherwise provided when authorized or ratified, continue as to a person who has ceased to be a director or officer of the Corporation and shall inure to the benefit of the heirs, executors and administrators of such a person.

(j) Notwithstanding anything contained in this Article EIGHTH to the contrary, except for proceedings to enforce rights to indemnification (which shall be governed by Article EIGHTH (d)), the Corporation shall not be obligated to indemnify any person in connection with a proceeding (or part, thereof) initiated by such person unless such proceeding (or part thereof) was authorized or consented to by the Board of Directors of the Corporation.

(k) The Corporation may, to the extent authorized from time to time by the Board of Directors, provide rights to indemnification and to the advancement of expenses to employees and agents of the Corporation similar to those conferred in this Article EIGHTH to directors and officers of the Corporation.

NINTH: A director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, provided that this Article shall not eliminate or limit the liability of a director (i) for any breach of his or her duty of loyalty to the Corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of the law, (iii) under Section 174 of the DGCL or (iv) for any transaction from which the director derives an improper personal benefit.

If the DGCL is hereafter amended to authorize corporate action further limiting or eliminating the personal liability of directors, then the liability of the director to the Corporation shall be limited or eliminated to the fullest extent permitted by the DGCL, as so amended from time to time. Any amendment, repeal or modification of this Article shall be prospective only, and shall not adversely affect any right or protection of a director of the Corporation under this Article NINTH in respect of any act or omission occurring prior to the time of such amendment, repeal or modification.

TENTH: Each reference in this Certificate of Incorporation to any provision of the DGCL refers to the specified provision of the DGCL, as the same now exists or as it may hereafter be amended or superseded.

ELEVENTH: The Corporation reserves the right at any time and from time to time to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by the laws of the State of Delaware; and all rights conferred on stockholders, directors or any other persons herein are granted subject to this reservation; provided, however, that no amendment, alteration, change or repeal may be made to Article FIFTH, SEVENTH, EIGHTH, NINTH or ELEVENTH without the affirmative vote of the holders of at least $66^{2}/_{3}\%$ of the outstanding voting stock of the corporation, voting together as a single class."

3. That said Amended and Restated Certificate of Incorporation has been consented to and authorized by the holders of a majority of the issued and outstanding stock entitled to vote in accordance with the provisions of Section 228 of the DGCL.

4. That said Amended and Restated Certificate of Incorporation was duly adopted in accordance with the applicable provisions of Sections 242 and 245 of the DGCL.

IN WITNESS WHEREOF, Cadence Pharmaceuticals, Inc. has caused this Certificate to be signed by Theodore R. Schroeder, its President and Chief Executive Officer and William R. LaRue, its Senior Vice President, Chief Financial Officer, Treasurer and Secretary, this 30th day of October, 2006.

Cadence Pharmaceuticals, Inc.,
a Delaware corporation

By: /s/ William R. LaRue
Name: William R. LaRue
Title: Senior Vice President, Chief Financial Officer, Treasurer and Secretary

ATTEST

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

EXHIBIT 3.2

AMENDED AND RESTATED

BYLAWS

OF

CADENCE PHARMACEUTICALS, INC.

TABLE OF CONTENTS

AMENDED AND RESTATED
BYLAWS
OF
CADENCE PHARMACEUTICALS, INC.

ARTICLE I.
OFFICES

Section 1. REGISTERED OFFICES. The registered office shall be in the City of Wilmington, County of New Castle, State of Delaware.

Section 2. OTHER OFFICES. The corporation may also have offices at such other places both within and without the State of Delaware as the Board of Directors (the "Board") may from time to time determine or the business of the corporation may require.

ARTICLE II.
MEETINGS OF STOCKHOLDERS

Section 1. PLACE OF MEETINGS. Meetings of stockholders shall be held at any place within or outside the State of Delaware designated by the Board. In the absence of any such designation, stockholders' meetings shall be held at the principal executive office of the corporation.

Section 2. ANNUAL MEETING OF STOCKHOLDERS. The annual meeting of stockholders shall be held each year on a date and time designated by the Board. At each annual meeting directors shall be elected, and any other proper business may be transacted.

Section 3. QUORUM; ADJOURNED MEETINGS AND NOTICE THEREOF. A majority of the stock issued and outstanding and entitled to vote at any meeting of stockholders, the holders of which are present in person or represented by proxy, shall constitute a quorum for the transaction of business except as otherwise provided by law, by the Certificate of Incorporation or by these Bylaws. A quorum, once established, shall not be broken by the withdrawal of enough votes to leave less than a quorum, and the votes present may continue to transact business until adjournment. If, however, such quorum shall not be present or represented at any meeting of the stockholders, a majority of the voting stock represented in person or by proxy may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum shall be present or represented. At such adjourned meeting at which a quorum shall be present or represented, any business may be transacted which might have been transacted at the meeting as originally notified. If the adjournment is for more than thirty days, or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote thereat.

Section 4. VOTING. When a quorum is present at any meeting, in all matters other than the election of directors, the vote of the holders of a majority of the stock having voting power present in person or represented by proxy and entitled to vote on a particular question shall decide such question brought before such meeting, unless the question is one upon which by express provision of the statutes, the Certificate of Incorporation or these Bylaws, a different

vote is required in which case such express provision shall govern and control the decision of such question. Directors shall be elected by a plurality of the votes of the stock present in person or represented by proxy at the meeting and entitled to vote on the election of directors.

Section 5. PROXIES. At each meeting of the stockholders, each stockholder having the right to vote may vote in person or may authorize another person or persons to act for him or her by proxy appointed by an instrument in writing subscribed by such stockholder and bearing a date not more than three years prior to said meeting, unless said instrument provides for a longer period. All proxies must be filed with the Secretary of the corporation at the beginning of each meeting in order to be counted in any vote at the meeting. Each stockholder shall have one vote for each share of stock having voting power, registered in his name on the books of the corporation on the record date set by the Board as provided in Article II, Section 8 hereof.

Section 6. SPECIAL MEETINGS. Special meetings of the stockholders, for any purpose or purposes, unless otherwise prescribed by statute or by the Certificate of Incorporation, may be called by the Chairman of the Board or the President and shall be called by the President or the Secretary at the request in writing of a majority of the members of the Board. Business transacted at any special meeting of stockholders shall be limited to the purposes stated in the notice.

Section 7. NOTICE OF STOCKHOLDERS' MEETINGS. Whenever stockholders are required or permitted to take any action at a meeting, a written notice of the meeting shall be given, which notice shall state the place, date and hour of the meeting, and, in the case of a special meeting, the purpose or purposes for which the meeting is called. The written notice of any meeting shall be given to each stockholder entitled to vote at such meeting not less than ten nor more than sixty days before the date of the meeting. If mailed, notice is deemed given when deposited in the United States mail, postage prepaid, directed to the stockholder at his address as it appears on the records of the corporation.

Section 8. FIXING DATE FOR DETERMINATION OF STOCKHOLDERS OF RECORD. In order that the corporation may determine the stockholders entitled to notice of, or to vote at, any meeting of stockholders or any adjournment thereof, or entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board, and which record date: (a) in the case of determination of stockholders entitled to vote at any meeting of stockholders or adjournment thereof, shall, unless otherwise required by law, not be more than sixty nor less than ten days before the date of such meeting; and (b) in the case of any other action, shall not be more than sixty days prior to such other action. If no record date is fixed: (i) the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held; and (ii) the record date for determining stockholders for any other purpose shall be at the close of business on the day on which the Board adopts the resolution relating thereto. A determination of stockholders of record entitled to notice of, or to vote at, a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board may fix a new record date for the adjourned meeting.

Section 9. NOTICE OF STOCKHOLDER BUSINESS AND NOMINATIONS.

(a) Nominations of persons for election to the Board of the corporation and the proposal of business to be considered by the stockholders may be made at an annual meeting of stockholders (i) pursuant to the corporation's notice of meeting (or any supplement thereto), (ii) by or at the direction of the Board or (iii) by any stockholder of the corporation who was a stockholder of record at the time notice provided for in this Section 9 is given to the Secretary of the corporation, who is entitled to vote at the meeting and who complies with the notice procedures in this Section 9.

(b) For nominations or other business to be properly brought before an annual meeting by a stockholder pursuant to clause (iii) of paragraph (a) of this Section 9, the stockholder must have given timely notice thereof in writing to the Secretary of the corporation, and any such proposed business other than the nominations of persons for election to the Board must constitute a proper matter for stockholder action. To be timely, a stockholder's notice shall be delivered to the Secretary at the principal executive offices of the corporation not later than the close of business on the ninetieth day nor earlier than the close of business on the one hundred twentieth day prior to the first anniversary of the preceding year's annual meeting; provided, however, that in the event that the date of the annual meeting is more than thirty days before or more than sixty days after such anniversary date, notice by the stockholder to be timely must be so delivered not earlier than the close of business on the one hundred twentieth day prior to such annual meeting and not later than the close of business on the later of the ninetieth day prior to such annual meeting or the tenth day following the earlier of (i) the day on which notice of the meeting was mailed or (ii) the date public announcement of the date of such meeting is first made by the corporation. In no event shall the public announcement of an adjournment or postponement of an annual meeting commence a new time period (or extend any time period) for the giving of a stockholder's notice as described above. Such stockholder's notice shall set forth:

(A) as to each person whom the stockholder proposes to nominate for election or re-election as a director, all information relating to such person that is required to be disclosed in solicitations of proxies for election of directors in an election contest, or is otherwise required, in each case pursuant to Regulation 14A under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Rule 14a-101 thereunder (including such person's written consent to being named in the proxy statement as a nominee and to serving as a director if elected); (B) as to any other business that the stockholder proposes to bring before the meeting, a brief description of the business desired to be brought before the meeting, the text of the proposal or business (including the text of any resolutions proposed for consideration and, in the event that such business includes a proposal to amend the Bylaws, the language of the proposed amendment), the reasons for conducting such business at the meeting and any material interest in such business of such stockholder and the beneficial owner, if any, on whose behalf the nomination or proposal is made; and (C) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination or proposal is made, (I) the name and address of such stockholder and of such beneficial owner, as they appear on the corporation's books, (II) the class and number of shares of capital stock of the corporation which are owned beneficially and of record by such stockholder and such beneficial owner, (III) a representation that the stockholder is a holder of record of stock of the corporation entitled to vote at such meeting and intends to appear in person or by proxy at the meeting to propose such business or nomination and (IV) a representation whether the stockholder or the beneficial owner, if any, intends or is part of a group which intends (y) to deliver a proxy statement and/or form of proxy to holders of at least the percentage of the corporation's outstanding capital stock required to approve or adopt the proposal or elect the nominee and/or (z) otherwise to solicit proxies from stockholders in support of such proposal or nomination. The foregoing notice requirements shall be deemed satisfied by a stockholder if the stockholder has notified the corporation of his or her intention to present a proposal at an annual meeting in compliance with Rule 14a-8 (or any successor thereof) promulgated under the Exchange Act and such stockholder's proposal has been included in a proxy statement that has been prepared by the corporation to solicit proxies for such annual meeting. The corporation may require any proposed nominee to furnish such other information as it may reasonably require to determine the eligibility of such proposed nominee to serve as a director of the corporation.

(c) Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting pursuant to the corporation's notice of meeting. Nominations of persons for election to the Board may be made at a special meeting of stockholders at which directors are to be elected pursuant to the corporation's notice of meeting (i) by or at the direction of the Board or (ii) provided that the Board has determined that directors shall be elected at such meeting, by any stockholder of the corporation who is a stockholder of record at the time the notice provided for in this Section 9 is delivered to the Secretary of the corporation, who is entitled to vote at the meeting and who complies with the notice procedures set forth in this Section 9. In the event the corporation calls a special meeting of stockholders for the purpose of electing one or more directors to the Board, any such stockholder entitled to vote in such election of directors may nominate a person or persons (as the case may be) for election to such position(s) as specified in the corporation's notice of meeting, if the stockholder's notice required by paragraph (b) of this Section 9 shall be delivered to the Secretary at the principal executive offices of the corporation not earlier than the close of business on the one hundred twentieth day prior to such special meeting and not later than the close of business on the later of

(i) the ninetieth day prior to such special meeting or (ii) the tenth day following the day on which public announcement is first made of the date of the special meeting and of the nominees proposed by the Board to be elected at such meeting. In no event shall the public announcement of an adjournment or postponement of a special meeting commence a new time period (or extend any time period) for the giving of a stockholder's notice as described above.

(d) (i) Only such persons who are nominated in accordance with the procedures set forth in this Section 9 shall be eligible to be elected at an annual or special meeting of stockholders of the corporation to serve as directors, and only such business shall be conducted at a meeting of stockholders as shall have been brought before the meeting in accordance with the procedures set forth in this Section 9. Except as otherwise provided by law, the chairman of the meeting shall have the power and duty (A) to determine whether a nomination or any business proposed to be brought before the meeting was made or proposed, as the case may be, in accordance with the procedures set forth in this Section 9 (including whether the stockholder or beneficial owner, if any, on whose behalf the nomination or proposal is made solicited (or is part of a group which solicited) or did not so solicit, as the case may be, proxies in support of such stockholder's nominee or proposal in compliance with such stockholder's representation as required by paragraph (b) of this Section 9) and (B) if any proposed nomination or business was not made or proposed in compliance with this Section 9, to declare that such nomination shall be disregarded or that such proposed business shall not be transacted. Notwithstanding the foregoing provisions of this Section 9, if the stockholder (or a qualified representative of the stockholder) does not appear at the annual or special meeting of stockholders of the corporation to present a nomination or business, such nomination shall be disregarded and such proposed business shall not be transacted, notwithstanding that proxies in respect of such vote may have been received by the corporation.

(ii) For purposes of this Section 9, "public announcement" shall include disclosure in a press release reported by PRNewswire, Business Wire, the Dow Jones News Service, Associated Press or comparable national news service or in a document publicly filed by the corporation with the Securities and Exchange Commission pursuant to Section 13, 14 or 15(d) of the Exchange Act.

(iii) Notwithstanding the foregoing provisions of this Section 9, a stockholder shall also comply with all applicable requirements of the Exchange Act and the rules and regulations promulgated thereunder with respect to the matters set forth in this Section 9. Nothing in this Section 9 shall be deemed to affect any rights (A) of stockholders to request inclusion of proposals in the corporation's proxy statement pursuant to Rule 14a-8 under the Exchange Act or (B) of the holders of any series of preferred stock of the corporation to elect directors pursuant to any applicable provisions of the Certificate of Incorporation.

Section 10. MAINTENANCE AND INSPECTION OF STOCKHOLDER LIST. The officer who has charge of the stock ledger of the corporation shall prepare and make, at least ten days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting, arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting, during ordinary business hours, for a period of at least ten days prior to the meeting, either at a place within the city where the meeting is to be held, which place shall be specified in the notice of the meeting, or, if not so specified, at the place where the meeting is to be held. The list shall also be produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present.

Section 11. STOCKHOLDER ACTION BY WRITTEN CONSENT WITHOUT A MEETING. Unless otherwise provided in the Certificate of Incorporation, any action required to be taken at any annual or special meeting of stockholders of the corporation, or any action which may be taken at any annual or special meeting of such stockholders, may not be taken without a meeting.

ARTICLE III.
DIRECTORS

Section 1. THE NUMBER OF DIRECTORS. The number of directors which shall constitute the whole Board shall be not less than three nor more than fifteen. The actual number of directors shall be fixed from time to time solely by resolution adopted by the affirmative vote of a majority of the directors. The directors need not be stockholders. The directors shall be elected at the annual meeting of the stockholders, except as provided in Section 2 of this Article, and each director elected shall hold office until his successor is elected and qualified; provided, however, that unless otherwise restricted by the Certificate of Incorporation or by law, any director or the entire Board may be removed, for cause, from the Board at any meeting of stockholders by not less than 66 2/3% of the outstanding stock of the Corporation.

Section 2. VACANCIES. Vacancies on the Board by reason of death, resignation, retirement, disqualification, removal from office or otherwise, and newly created directorships resulting from any increase in the authorized number of directors may be filled solely by a vote of a majority of the directors then in office, although less than a quorum, or by a sole remaining director, and each director so elected shall hold office for a term that shall coincide with the remaining term of the class to which such director shall have been elected. If there are no directors in office, then an election of directors may be held in the manner provided by statute. If, at the time of filling any vacancy or any newly created directorship, the directors then in office shall constitute less than a majority of the whole Board (as constituted immediately prior to any such increase), the Court of Chancery may, upon application of any stockholder or stockholders holding at least ten percent of the total number of the shares at the time outstanding having the right to vote for such directors, summarily order an election to be held to fill any such vacancies or newly created directorships, or to replace the directors chosen by the directors then in office.

Section 3. POWERS. The property and business of the corporation shall be managed by or under the direction of its Board. In addition to the powers and authorities by these Bylaws expressly conferred upon them, the Board may exercise all such powers of the corporation and do all such lawful acts and things as are not by statute, by the Certificate of Incorporation or by these Bylaws directed or required to be exercised or done by the stockholders.

Section 4. PLACE OF DIRECTORS' MEETINGS. The directors may hold their meetings, have one or more offices and keep the books of the corporation outside of the State of Delaware.

Section 5. REGULAR MEETINGS. Regular meetings of the Board may be held without notice at such time and place as shall from time to time be determined by the Board.

Section 6. SPECIAL MEETINGS. Special meetings of the Board may be called by the Chairman of the Board or the President on forty-eight hours' notice to each director, either personally, by mail, electronic mail or by telegram; special meetings shall be called by the President or the Secretary in like manner and on like notice on the written request of two directors, unless the Board consists of only one director, in which case special meetings shall be called by the President or Secretary in like manner or on like notice on the written request of the sole director.

Section 7. QUORUM. At all meetings of the Board a majority of the authorized number of directors shall be necessary and sufficient to constitute a quorum for the transaction of business, and the vote of a majority of the directors present at any meeting at which there is a quorum shall be the act of the Board, except as may be otherwise specifically provided by statute, by the Certificate of Incorporation or by these Bylaws. If a quorum shall not be present at any meeting of the Board, the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum shall be present. If only one director is authorized, such sole director shall constitute a quorum.

Section 8. ACTION WITHOUT MEETING. Unless otherwise restricted by the Certificate of Incorporation or these Bylaws, any action required or permitted to be taken at any meeting of the Board, or of any committee thereof, may be taken without a meeting, if all members of the Board or committee, as the case may be, consent thereto in writing, and the writing or writings are filed with the minutes of proceedings of the Board or committee.

Section 9. TELEPHONIC MEETINGS. Unless otherwise restricted by the Certificate of Incorporation or these Bylaws, members of the Board, or any committee designated by the Board, may participate in a meeting of the Board, or any committee, by means of conference telephone or similar communications equipment by means of which all persons participating in the meeting can hear each other, and such participation in a meeting shall constitute presence in person at such meeting.

Section 10. COMMITTEES OF DIRECTORS. The Board may, by resolution passed by a majority of the whole Board, designate one or more committees, each such committee to consist of one or more of the directors of the corporation. The Board may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not he, she or they constitute a quorum, may unanimously appoint another member of the Board to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the Board, shall have and may exercise all the powers and authority of the Board in the management of the business and affairs of the corporation and may authorize the seal of the corporation to be affixed to all papers which may require it; but no such committee shall have the power or authority in reference to amending the Certificate of Incorporation, adopting an agreement of merger or consolidation, recommending to the stockholders the sale, lease or exchange of all or substantially all of the corporation's property and assets, recommending to the stockholders a dissolution of the corporation or a revocation of a dissolution, or amending the Bylaws of the corporation; and, unless the resolution or the Certificate of Incorporation expressly so provide, no such committee shall have the power or authority to declare a dividend or to authorize the issuance of stock.

Section 11. MINUTES OF COMMITTEE MEETINGS. Each committee shall keep regular minutes of its meetings and report the same to the Board when required.

Section 12. COMPENSATION OF DIRECTORS. Unless otherwise restricted by the Certificate of Incorporation or these Bylaws, the Board shall have the authority to fix the compensation of directors. The directors may be paid their expenses, if any, of attendance at each meeting of the Board and may be paid a fixed sum for attendance at each meeting of the Board or a stated salary as director. No such payment shall preclude any director from serving the corporation in any other capacity and receiving compensation therefor. Members of special or standing committees may be allowed like compensation for attending committee meetings.

ARTICLE IV.
OFFICERS

Section 1. OFFICERS. The officers of this corporation shall be chosen by the Board and shall include a President, a Secretary and a Chief Financial Officer or Treasurer. The corporation may also have at the discretion of the Board such other officers as are desired, including one or more Vice Presidents, one or more Assistant Secretaries and Assistant Treasurers and such other officers as may be appointed in accordance with the provisions of Section 3 hereof. In the event there are two or more Vice Presidents, then one or more may be

designated as Executive Vice President, Senior Vice President or other similar or dissimilar title. At the time of the election of officers, the directors may by resolution determine the order of their rank. Any number of offices may be held by the same person, unless the Certificate of Incorporation or these Bylaws otherwise provide.

Section 2. ELECTION OF OFFICERS. The Board, at its first meeting after each annual meeting of stockholders, shall choose the officers of the corporation.

Section 3. SUBORDINATE OFFICERS. The Board may appoint such other officers and agents as it shall deem necessary who shall hold their offices for such terms and shall exercise such powers and perform such duties as shall be determined from time to time by the Board.

Section 4. COMPENSATION OF OFFICERS. The salaries of all officers and agents of the corporation shall be fixed by the Board.

Section 5. TERM OF OFFICE; REMOVAL AND VACANCIES. The officers of the corporation shall hold office until their successors are chosen and qualify in their stead. Any officer elected or appointed by the Board may be removed at any time by the affirmative vote of a majority of the Board. If the office of any officer or officers becomes vacant for any reason, the vacancy shall be filled by the Board.

Section 6. POWERS AND DUTIES OF OFFICERS. The officers of the corporation shall have such powers and duties in the management of the corporation as may be prescribed in a resolution by the Board and, to the extent not so provided, as generally pertain to their respective offices, subject to the control of the Board.

ARTICLE V.
INDEMNIFICATION OF EMPLOYEES AND AGENTS

The corporation may indemnify every person who is or was a party or is or was threatened to be made a party to any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he or she is or was an employee or agent of the corporation or, while an employee or agent of the corporation, is or was serving at the request of the corporation as an employee or agent or trustee of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise, against expenses (including counsel fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him or her in connection with such action, suit or proceeding, to the extent permitted by applicable law.

ARTICLE VI.
CERTIFICATES OF STOCK

Section 1. CERTIFICATES. Every holder of stock of the corporation shall be entitled to have a certificate signed by, or in the name of the corporation by, the President or a Vice President and by the Secretary or an Assistant Secretary, or the Treasurer or an Assistant Treasurer of the corporation, certifying the number of shares represented by the certificate owned by such stockholder in the corporation.

Section 2. SIGNATURES ON CERTIFICATES. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the corporation with the same effect as if he or she were such officer, transfer agent or registrar at the date of issue.

Section 3. STATEMENT OF STOCK RIGHTS, PREFERENCES, PRIVILEGES. If the corporation shall be authorized to issue more than one class of stock or more than one series of any class, the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualification, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of the certificate which the corporation shall issue to represent such class or series of stock, provided that, except as otherwise provided in section 202 of the General Corporation Law of Delaware, in lieu of the foregoing requirements, there may be set forth on the face or back of the certificate which the corporation shall issue to represent such class or series of stock, a statement that the corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

Section 4. LOST CERTIFICATES. The Board may direct a new certificate or certificates to be issued in place of any certificate or certificates theretofore issued by the corporation alleged to have been lost, stolen or destroyed, upon the making of an affidavit of that fact by the person claiming the certificate of stock to be lost, stolen or destroyed. When authorizing such issue of a new certificate or certificates, the Board may, in its discretion and as a condition precedent to the issuance thereof, require the owner of such lost, stolen or destroyed certificate or certificates, or his legal representative, to advertise the same in such manner as it shall require and/or to give the corporation a bond in such sum as it may direct as indemnity against any claim that may be made against the corporation with respect to the certificate alleged to have been lost, stolen or destroyed.

Section 5. TRANSFERS OF STOCK. Upon surrender to the corporation, or the transfer agent of the corporation, of a certificate for shares duly endorsed or accompanied by proper evidence of succession, assignation or authority to transfer, it shall be the duty of the corporation to issue a new certificate to the person entitled thereto, cancel the old certificate and record the transaction upon its books.

Section 6. REGISTERED STOCKHOLDERS. The corporation shall be entitled to treat the holder of record of any share or shares of stock as the holder in fact thereof and accordingly shall not be bound to recognize any equitable or other claim or interest in such share on the part of any other person, whether or not it shall have express or other notice thereof, except as expressly provided by the laws of the State of Delaware.

ARTICLE VII.
GENERAL PROVISIONS

Section 1. CHECKS. All checks or demands for money and notes of the corporation shall be signed by such officer or officers as the Board may from time to time designate.

Section 2. FISCAL YEAR. The fiscal year of the corporation shall be fixed by resolution of the Board.

Section 3. CORPORATE SEAL. The corporate seal shall have inscribed thereon the name of the corporation and shall be in such form as may be approved from time to time by the Board.

Section 4. MANNER OF GIVING NOTICE. Whenever, under the law, the Certificate of Incorporation or these Bylaws, notice is required to be given to any director or stockholder, it shall not be construed to mean personal notice, but such notice may be given in writing, by mail, addressed to such director or stockholder, at his address as it appears on the records of the corporation, with postage thereon prepaid, and such notice shall be deemed to be given at the time when the same shall be deposited in the United States mail. Notice to directors may also be given by telegram, telecopier or other means of communication permitted by law.

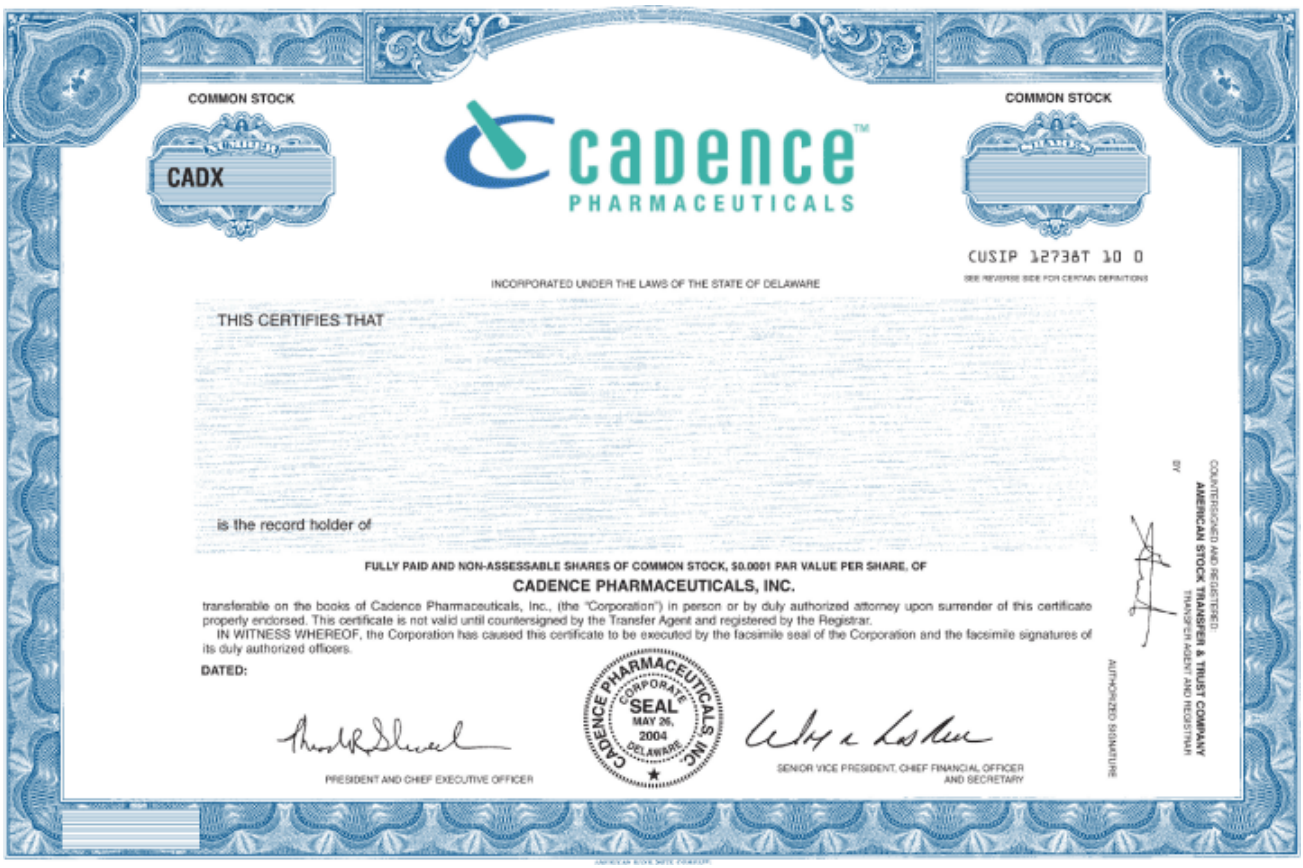
Section 5. WAIVER OF NOTICE. Whenever any notice is required to be given under the law, the Certificate of Incorporation or these Bylaws, a waiver thereof via electronic mail or in writing, signed by the person or persons entitled to said notice, whether before or after the time stated therein, shall be deemed equivalent thereto. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at nor the purpose of any regular or special meeting of the stockholders, directors or members of a committee of directors need be specified in any written waiver of notice.

ARTICLE VIII.
AMENDMENTS

These Bylaws may be altered, amended or repealed or new Bylaws may be adopted by the stockholders or by the Board in accordance with the terms of the Certificate of Incorporation. If the power to adopt, amend or repeal Bylaws is conferred upon the Board by the Certificate of Incorporation, it shall not divest or limit the power of the stockholders to adopt, amend or repeal Bylaws.

* * * * *

EXHIBIT 4.1


COMMON STOCK
CADX
cadence™
PHARMACEUTICALS
COMMON STOCK
CUSIP 12738T 10 0
SEE REVERSE SIDE FOR CERTAIN DEFINITIONS
INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE
THIS CERTIFIES THAT
is the record holder of
FULLY PAID AND NON-ASSESSABLE SHARES OF COMMON STOCK, $0.0001 PAR VALUE PER SHARE, OF
CADENCE PHARMACEUTICALS, INC.
transferable on the books of Cadence Pharmaceuticals, Inc., (the "Corporation") in person or by duly authorized attorney upon surrender of this certificate properly endorsed. This certificate is not valid until countersigned by the Transfer Agent and registered by the Registrar.
IN WITNESS WHEREOF, the Corporation has caused this certificate to be executed by the facsimile seal of the Corporation and the facsimile signatures of its duly authorized officers.
DATED:
CADENCE PHARMACEUTICALS INC
CORPORATE SEAL
MAY 26, 2004
DELAWARE
PRESIDENT AND CHIEF EXECUTIVE OFFICER
SENIOR VICE PRESIDENT, CHIEF FINANCIAL OFFICER AND SECRETARY
COUNTERSIGNED AND REGISTERED
AMERICAN STOCK TRANSFER & TRUST COMPANY
TRANSFER AGENT AND REGISTRAR
BY
AUTHORIZED SIGNATURE

CADENCE PHARMACEUTICALS, INC.

The Corporation is authorized to issue more than one class of stock. The Corporation shall furnish without charge to each stockholder who so requests the powers, designations, preferences and relative, participating, optional, or other special rights of each class of stock of the Corporation or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Such requests shall be made to the Corporation's Secretary at the principal office of the Corporation.

The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations:

TEN COM—as tenants in common
TEN ENT —as tenants by the entireties
JT TEN —as joint tenants with right of Survivorship and not as tenants in common

UNIF GIFT MIN ACT — _____ Custodian _____
(Cust) (Minor)
under Uniform Gifts to Minors Act _____
(State)

UNIF TRF MIN ACT — _____ Custodian (until age _____)
(Minor)
To Minors Act _____
(State)

Additional abbreviations may also be used though not in the above list.

For Value Received _____ hereby sell, assign and transfer unto

PLEASE INSERT SOCIAL SECURITY OR OTHER IDENTIFYING NUMBER OF ASSIGNEE

_____

PLEASE PRINT OR TYPEWRITE NAME AND ADDRESS, INCLUDING ZIP CODE, OF ASSIGNEE

_____

_____

_____

Of the _____Stock represented by the within Certificate, and do(es) hereby irrevocably constitute and appoint

_____Attorney

To transfer the said stock on the books of the within named Corporation with full power of substitution in the premises.

Dated _____

X_____

X_____

NOTICE: THE SIGNATURE(S) TO THIS ASSIGNMENT MUST CORRESPOND WITH THE NAME(S) AS WRITTEN UPON THE FACE OF THE CERTIFICATE IN EVERY PARTICULAR, WITHOUT ALTERATION OR ENLARGEMENT OR ANY CHANGE WHATEVER.

Signature(s) Guaranteed:

By _____

THE SIGNATURE(S) MUST BE GUARANTEED BY AN ELIGIBLE GUARANTOR INSTITUTION (BANKS, STOCKBROKERS, SAVINGS AND LOAN ASSOCIATIONS AND CREDIT UNIONS WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUARANTEE MEDALLION PROGRAM), PURSUANT TO S.E.C. RULE 17Ad-15.

KEEP THIS CERTIFICATE IN A SAFE PLACE. IF IT IS LOST, STOLEN OR DESTROYED, THE CORPORATION WILL REQUIRE A BOND OF INDEMNITY AS A CONDITION TO THE ISSUANCE OF A REPLACEMENT CERTIFICATE.

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

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)) 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) 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

c) 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.

Date: November 30, 2006

/s/ Theodore R. Schroeder
Theodore R. Schroeder
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

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)) 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) 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

c) 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.

Date: November 30, 2006

/s/ William R. LaRue
William R. LaRue
Senior Vice President, Chief Financial Officer, Treasurer and Secretary

Exhibit 32.1

Certifications
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

In connection with the Quarterly Report of Cadence Pharmaceuticals, Inc., a Delaware corporation (the "Company"), on Form 10-Q for the period ended September 30, 2006, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Theodore R. Schroeder, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or Section 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 the Company.

Dated: November 30, 2006

/s/ Theodore R. Schroeder
Theodore R. Schroeder
President and Chief Executive Officer
(principal executive officer of the registrant)

In connection with the Report, I, William R. LaRue, Senior Vice President, Chief Financial Officer, Treasurer and Secretary of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or Section 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 the Company.

Dated: November 30, 2006

/s/ William R. LaRue
William R. LaRue
Senior Vice President, Chief Financial Officer, Treasurer
and Secretary
(principal financial and accounting officer of the registrant)