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

# FORM 10-Q

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

**For the Quarterly Period Ended March 31, 2007**

**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) | (I.R.S. Employer Identification No.) |

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

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

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

As of April 30, 2007, there were 29,129,295 shares of the Registrant's Common Stock outstanding.

**CADENCE PHARMACEUTICALS, INC.**

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## PART I. FINANCIAL INFORMATION



## PART II. OTHER INFORMATION

## PART I. FINANCIAL INFORMATION

**Item 1.** ***Financial Statements***

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

| | March 31, 2007 (unaudited) | December 31, 2006 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 77,442,626 | $ 86,825,526 |
| Prepaid expenses and other current assets | 1,177,718 | 1,168,160 |
| Total current assets | 78,620,344 | 87,993,686 |
| Property and equipment, net | 4,309,501 | 3,558,618 |
| Restricted cash | 2,867,281 | 1,233,281 |
| Other assets | 608,521 | 536,042 |
| Total assets | $ 86,405,647 | $ 93,321,627 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 3,226,431 | $ 2,073,726 |
| Accrued liabilities | 8,489,538 | 7,378,750 |
| Current portion of long-term debt | 2,612,168 | 2,338,010 |
| Total current liabilities | 14,328,137 | 11,790,486 |
| Deferred rent | 1,403,589 | 1,460,109 |
| Long-term debt, less current portion | 3,980,733 | 4,661,990 |
| Other long-term liabilities | 22,048 | — |
| Total liabilities | 19,734,507 | 17,912,585 |
| Commitments and contingencies (Note 6) | | |
| Stockholders' equity : | | |
| Common stock, $0.0001 par value; 100,000,000 shares authorized, 29,129,295 shares and 29,092,720 shares issued and outstanding at March 31, 2007 and December 31, 2006, respectively | 2,913 | 2,909 |
| Additional paid-in capital | 138,782,204 | 138,057,890 |
| Accumulated other comprehensive income | 161,511 | 64,033 |
| Deficit accumulated during the development stage | (72,275,488) | (62,715,790) |
| Total stockholders' equity | 66,671,140 | 75,409,042 |
| Total liabilities and stockholders' equity | $ 86,405,647 | $ 93,321,627 |

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

**CADENCE PHARMACEUTICALS, INC.**
**(a development stage company)**

**CONDENSED STATEMENTS OF OPERATIONS**
**(Unaudited)**

| | Three Months Ended March 31, | | Period from May 26, 2004 (Inception) through March 31, 2007 |
|---|---|---|---|
| | 2007 | 2006 | |
| Operating expenses: | | | |
| Research and development | $ 8,241,804 | $ 28,735,246 | $ 64,078,148 |
| Marketing | 302,183 | 95,758 | 1,393,973 |
| General and administrative | 1,827,592 | 537,349 | 9,062,669 |
| Total operating expenses | 10,371,579 | 29,368,353 | 74,534,790 |
| Loss from operations | (10,371,579) | (29,368,353) | (74,534,790) |
| Other income (expense): | | | |
| Interest income | 1,031,890 | 143,939 | 3,241,963 |
| Interest expense | (220,009) | (16,666) | (717,626) |
| Other expense | — | — | (265,035) |
| Total other income, net | 811,881 | 127,273 | 2,259,302 |
| Net loss | $ (9,559,698) | $ (29,241,080) | $ (72,275,488) |
| Basic and diluted net loss per share (1) | $ (0.34) | $ (23.84) | |
| Shares used to compute basic and diluted net loss per share (1) | 28,402,352 | 1,226,682 | |

(1) As a result of the issuance of 6,900,000 shares of common stock in the Company's initial public offering in the fourth quarter of 2006 and the conversion of the Company's preferred stock into 19,907,605 shares of common stock upon completion of the Company's initial public offering, there is a lack of comparability in the basic and diluted net loss per share amounts for the periods presented above. Please see Note 3 for further discussion.

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

**CADENCE PHARMACEUTICALS, INC.**
**(a development stage company)**

**CONDENSED STATEMENTS OF CASH FLOWS**
**(Unaudited)**

| | Three Months Ended March 31, | | Period from May 26, 2004 (Inception) to March 31, 2007 |
|---|---|---|---|
| | 2007 | 2006 | |
| **Operating activities** | | | |
| Net loss | $ (9,559,698) | $ (29,241,080) | $ (72,275,488) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation | 121,967 | 10,732 | 388,913 |
| Loss on disposal of assets | — | — | 37,034 |
| Stock-based compensation | 723,818 | — | 2,859,587 |
| Non-cash interest expense and impairment charges | 24,999 | 16,666 | 344,662 |
| Changes in operating assets and liabilities: | | | |
| Prepaid expenses and other current assets | (9,558) | (127,275) | (857,969) |
| Accounts payable, accrued liabilities and other liabilities | 2,229,021 | 1,002,511 | 11,672,603 |
| Net cash used in operating activities | (6,469,451) | (28,338,446) | (57,830,658) |
| **Investing activities** | | | |
| Purchases of marketable securities | — | — | (7,450,000) |
| Maturities of marketable securities | — | 7,000,000 | 7,000,000 |
| Restricted cash | (1,634,000) | — | (3,215,130) |
| Purchases of property and equipment | (872,850) | (47,803) | (3,544,918) |
| Net cash (used in) provided by investing activities | (2,506,850) | 6,952,197 | (7,210,048) |
| **Financing activities** | | | |
| Proceeds from issuance of common stock, net | 500 | 203,000 | 56,956,683 |
| Proceeds from sale of preferred stock, net | — | 53,775,013 | 78,933,748 |
| (Payments) borrowings under debt agreements | (407,099) | — | 6,592,901 |
| Net cash (used in) provided by financing activities | (406,599) | 53,978,013 | 142,483,332 |
| Net (decrease) increase in cash and cash equivalents | (9,382,900) | 32,591,764 | 77,442,626 |
| Cash and cash equivalents at beginning of period | 86,825,526 | 8,025,285 | — |
| Cash and cash equivalents at end of period | $ 77,442,626 | $ 40,617,049 | $ 77,442,626 |
| **Supplemental disclosures** | | | |
| Issuance of warrants in connection with loan and security agreement | $ — | $ — | $ 313,572 |
| Assets acquired through lease concessions | $ — | $ — | $ 1,190,530 |
| Unrealized gain on investment securities | $ 97,478 | $ — | $ 161,511 |

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

**CADENCE PHARMACEUTICALS, INC.**
**(a development stage company)**

**NOTES TO CONDENSED FINANCIAL STATEMENTS**
(Unaudited)

## 1. The Company 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 conducting research and development activities, including clinical trials, of its product portfolio; organizational activities, including recruiting personnel, establishing office facilities; and raising capital to fund these activities. To date, the Company has in-licensed rights to IV APAP, an intravenous formulation of acetaminophen, and Omigard™, an omiganan pentahydrochloride 1% aqueous gel, both of which are Phase III product candidates. Since the Company has not begun principal operations of commercializing either of its product candidates, the Company is considered to be a development stage company as defined in Statement of Financial Accounting Standards ("SFAS") No. 7, *Accounting and Reporting by Development Stage Enterprises*.

***Basis of Presentation***

The Company has prepared the accompanying unaudited condensed financial statements in accordance with accounting principles generally accepted in the United States of America ("GAAP"). However, certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed, or omitted, pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC"). In addition, the preparation of financial statements in conformity with GAAP requires management to make estimates and judgments that affect the amounts reported in the financial statements and accompanying notes. In the opinion of the Company's management, all adjustments consisting of normal, recurring adjustments considered necessary for a fair presentation of the results of the interim periods presented have been included. These condensed financial statements should be read in conjunction with the audited financial statements of the Company for the fiscal year ended December 31, 2006, as included in the Company's 2006 Annual Report on Form 10-K as filed with the SEC on March 28, 2007.

***Stock-Based Compensation***

Effective January 1, 2006, the Company adopted the provisions of SFAS No. 123(R), *Share-Based Payment*, which requires the measurement and recognition of compensation expense for all stock-based payment awards made to employees and directors. In adopting SFAS No. 123(R), the Company has applied the modified prospective transition method and therefore, prior period results were not restated. 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). As such, the Company's condensed financial statements for the three months ended March 31, 2007 and 2006 reflect the impact of SFAS No. 123(R).

**CADENCE PHARMACEUTICALS, INC.**
**(a development stage company)**

**NOTES TO CONDENSED FINANCIAL STATEMENTS-Continued**
(Unaudited)

SFAS No. 123(R) requires companies to estimate the fair value of stock-based compensation on the date of grant using an option pricing model. The Company currently uses the Black-Scholes option pricing model to estimate the fair value of its stock-based awards. This option pricing model involves a number of estimates, including the expected lives of stock options, the Company's stock volatility and interest rates. Stock-based compensation expense recognized during the period is based on the value of the portion of awards that is ultimately expected to vest and thus the gross expense is reduced for estimated forfeitures. Compensation expense for all stock-based payment awards was recognized using the straight-line method. The following table summarizes the average estimates the Company used in the Black-Scholes option-pricing model during the three months ended March 31, 2007 and 2006, to determine the fair value of employee stock options granted during each period:

| | Three months ended March 31, | |
|---|---|---|
| | 2007 | 2006 |
| Risk free interest rates | 4.5% | 4.4% |
| Expected life in years | 6.1 years | 6.1 years |
| Expected dividend yield | 0.0% | 0.0% |
| Expected volatility | 66.0% | 70.0% |

Stock-based compensation expense recognized under SFAS No. 123(R) for the three months ended March 31, 2007 and 2006 was $723,818 and $61, respectively. Since May 26, 2004 (inception) the Company has incurred $2,858,777 of stock-based compensation expense. The table below summarizes the stock-based compensation expense for the three months ended March 31, 2007 and 2006, and for the period from May 26, 2004 (inception) through March 31, 2007:

| | Three Months Ended March 31, | | Period from May 26, 2004 (Inception) through March 31, 2007 |
|---|---|---|---|
| | 2007 | 2006 | |
| Research and development | $ 193,635 | $ 61 | $ 754,892 |
| Marketing | 865 | — | 2,036 |
| General and administrative | 529,318 | — | 2,101,849 |
| Stock-based compensation expense included in operating expenses | 723,818 | 61 | 2,858,777 |
| Total stock-based compensation expense included in loss from operations | $ 723,818 | $ 61 | $ 2,858,777 |

**2. Recent Accounting Pronouncements**

In September 2006, the Financial Accounting Standards Board ("FASB") issued SFAS No. 157, *Fair Value Measurement*. SFAS No. 157 defines fair value, establishes a framework for measuring fair value in accordance with GAAP, and expands disclosures about fair value measurements but does not require any new fair value measurements. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007 and interim periods within those fiscal years. The Company is currently assessing the effects of SFAS No. 157 on its financial statements and it is not expected to have a material impact on the Company's financial statements.

**CADENCE PHARMACEUTICALS, INC.**
**(a development stage company)**

**NOTES TO CONDENSED FINANCIAL STATEMENTS — Continued**
(Unaudited)

### 3. Net Loss Per Share

Net loss per share is presented as basic and diluted net loss per share. Basic net loss per share is calculated by dividing the net loss by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, 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.

The actual net loss per share amounts for the three months ended March 31, 2007 and 2006 were computed based on the shares of common stock outstanding during the respective periods. The net loss per share for the three months ended March 31, 2007 includes the full effect of the 6,900,000 common shares issued in the Company's initial public offering in the fourth quarter of 2006 and the conversion of the Company's preferred stock into 19,907,605 shares of common stock upon completion of the Company's initial public offering. As a result of the issuance of these common shares, there is a lack of comparability in the basic and diluted net loss per share amounts for the three months ended March 31, 2007 and 2006.

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

| | Three Months Ended March 31, | |
|---|---|---|
| | 2007 | 2006 |
| Shares for basic and dilutive net loss per share: | | |
| Weighted average common shares outstanding | 29,094,933 | 1,931,983 |
| Weighted average unvested common shares subject to repurchase | (692,581) | (705,301) |
| Denominator for basic and diluted net loss per share | 28,402,352 | 1,226,682 |

For the three months ended March 31, 2007 and 2006, options and other exercisable convertible securities totaling 2,677,320 and 20,910,480 shares, respectively, were excluded from the calculation as their effect would have been antidilutive.

### 4. Comprehensive Loss

The Company has applied Statement of Financial Accounting Standards ("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 components of other comprehensive loss for the three months ended March 31, 2007 and 2006, and for the period from May 26, 2004 (inception) through March 31, 2007, were as follows:

**CADENCE PHARMACEUTICALS, INC.**
**(a development stage company)**

**NOTES TO CONDENSED FINANCIAL STATEMENTS — Continued**
(Unaudited)

| | Three Months Ended March 31, 2007 | Three Months Ended March 31, 2006 | Period from May 26, 2004 (Inception) through March 31, 2007 |
|---|---|---|---|
| Net loss | $ (9,559,698) | $ (29,241,080) | $ (72,275,488) |
| Other comprehensive income: | | | |
| Net unrealized gain on available for sale investments | 97,478 | — | 161,511 |
| Comprehensive loss | $ (9,462,220) | $ (29,241,080) | $ (72,113,977) |

**5. Property and Equipment**

Property and equipment for operations were as follows:

| | March 31, 2007 | December 31, 2006 |
|---|---|---|
| Leasehold improvements | $ 1,572,690 | $ 1,572,690 |
| Computer equipment and software | 453,238 | 373,502 |
| Furniture and fixtures | 418,366 | 399,480 |
| Manufacturing equipment | 123,303 | 122,500 |
| Construction in-process | 2,091,277 | 1,317,852 |
| | 4,658,874 | 3,786,024 |
| Less accumulated depreciation | (349,373) | (227,406) |
| Total | $ 4,309,501 | $ 3,558,618 |

For the three months ended March 31, 2007 and 2006, the Company incurred depreciation expense of $121,967 and $10,732, respectively. Since May 26, 2004 (inception), the Company has incurred $388,913 of depreciation expense.

**6. Commitments and Contingencies**

***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. In February 2007, the Company began making the first of 30 equal monthly principal and interest payments and as of March 31, 2007 had paid $407,099 of the principle balance. 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.

***Warrants***

In connection with the loan and security agreement with Silicon Valley Bank and Oxford Finance Corporation, the Company issued two 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. These warrants became exercisable for 96,250 shares of the Company's common stock, at an exercise price of $4.00 per share, upon the completion of the Company's initial public offering in October 2006. Excluding certain mergers or acquisitions, the warrants

**CADENCE PHARMACEUTICALS, INC.**
**(a development stage company)**

**NOTES TO CONDENSED FINANCIAL STATEMENTS — Continued**
(Unaudited)

expire in February 2016. 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. In November 2006, one warrant was exercised for 48,125 shares at $9.45, resulting in 27,754 shares issued. In March 2007, the remaining warrant was exercised for 48,125 shares at $15.04, resulting in 35,325 shares issued. There were no warrants outstanding as of March 31, 2007.

***Facility Leases***

In 2004, the Company subleased its corporate headquarters under a non-cancelable operating lease that expired in September 2006. In May 2006, the Company entered into a six-year operating lease for 23,494 square feet of office space. The Company received certain tenant improvement allowances and rent abatement and has an option to extend the lease for five years. 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.

The Company has entered into a sublease agreement for a portion of its unused office space, through the third quarter of 2010. Rent expense, net of sublease rent income, for the three months ended March 31, 2007 and 2006 was $163,006 and $50,684, respectively. Since May 26, 2004 (inception) the Company has incurred $1,139,989 of net rent expense.

***Letter of Credit***

In connection with the Company’s current negotiations with a supplier for commercial supply of the finished drug product for IV APAP, in January 2007 the Company entered into an irrevocable standby letter of credit (“letter of credit”) in the amount of $3,268,000. The letter of credit balance is based on anticipated costs to be incurred by the supplier to facilitate the manufacturing of the drug product. The letter of credit is collateralized by a certificate of deposit in the amount of $1,634,000.

**CADENCE PHARMACEUTICALS, INC.**
**(a development stage company)**

**NOTES TO CONDENSED FINANCIAL STATEMENTS — Continued**
(Unaudited)

**7. Stockholders' Equity**

***Preferred Stock Issuances***

In July and August 2004, the Company issued in a private placement an aggregate of 8,085,108 shares of Series A-1 preferred stock at a per share price of $0.94, for an aggregate consideration of $7,600,002. In June and September 2005, the Company issued in a private placement an aggregate of 17,675,347 shares of Series A-2 preferred stock at a per share price of $1.00, for an aggregate consideration of $17,675,347. In March 2006, the Company issued in a private placement an aggregate of 53,870,000 shares of Series A-3 preferred stock at a per share price of $1.00, for an aggregate consideration of $53,870,000. Upon the completion of the Company's initial public offering in October 2006, these preferred shares were converted into 19,907,605 shares of common stock.

***Initial Public Offering***

In the fourth quarter of 2006, the Company completed an initial public offering whereby the Company sold 6,900,000 shares of common stock at $9.00 per share and received net proceeds of $55,895,148 (after underwriting discounts and offering costs). In connection with the Company's initial public offering, the 79,630,455 outstanding shares of preferred stock converted into 19,907,605 shares of common stock.

**8. Income Taxes**

The Company adopted the provisions of FIN 48 on January 1, 2007. On the date of adoption of FIN 48, the Company had no unrecognized tax benefits and thus did not recognize an increase in the liability for unrecognized tax benefits. Further, there are no unrecognized tax benefits included in the Company's condensed balance sheet at December 31, 2006 or March 31, 2007 that would, if recognized, affect the effective tax rate.

The Company is subject to taxation in the U.S. and California. The Company is subject to examination by the U.S. and California tax authorities for 2004 and subsequent tax years. The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. The Company had no accrued interest and penalties on the Company's condensed balance sheets at December 31, 2006 and at March 31, 2007, and has recognized no interest and/or penalties in the Company's condensed statement of operations for the three months ended March 31, 2007.

The adoption of FIN 48 did not impact the Company's financial condition, results of operations or cash flows. At January 1, 2007, the Company had net deferred tax assets of $26.5 million. The deferred tax assets are primarily composed of federal and state tax net operating loss carryfowards and federal and state research and development ("R&D") credit carryforwards. Due to uncertainties surrounding the Company's ability to generate future taxable income to realize these assets, a full valuation allowance has been established to offset the Company's net deferred tax asset. Additionally, the future utilization of the Company's net operating loss and R&D credit carryforwards to offset future taxable income may be subject to a substantial annual limitation as a result of ownership changes that may have occurred previously or that could occur in the future. The Company has not yet determined whether such an ownership change has occurred, however, the Company plans to complete a Section 382/383 analysis regarding the limitation of the net operating losses and research and development credits. When this analysis is completed, the Company plans to update its unrecognized tax benefits under FIN No. 48. However, the Company does not expect this analysis to be completed within the next 12 months and therefore, the Company does not expect that the unrecognized tax benefits will change within 12 months of this reporting date. Any carryforwards that will expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance. Due to the existence of the valuation allowance, future changes in the Company's unrecognized tax benefits will not impact the Company's effective tax rate.

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

**Introduction**

*The following discussion contains forward-looking statements, which involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below under the caption "Risk Factors." The interim financial statements and this Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the financial statements and notes thereto for the year ended December 31, 2006 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2006.*

**Overview**

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 May 2004, we have in-licensed rights to two product candidates, both of which are currently being studied in Phase III clinical trials. 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 ("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 ("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 ("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 are incorporated under the laws of the State of Delaware in May 2004. Our principal executive offices are located at 12481 High Bluff Drive, Suite 200, San Diego, California 92130 and our telephone number at that location is (858) 436-1400. Information about the company is also available at our website at www.cadence.com, which includes links to reports we have filed with the Securities and Exchange Commission ("SEC"). The contents of our website are not incorporated by reference in this Quarterly Report on Form 10-Q.

*Background*

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 ("SPA") for Omigard, and initiated a Phase III clinical trial of this product candidate. In April 30, 2007, we announced our plans to discuss with the FDA a proposal to increase the number of patients to be enrolled in our ongoing Phase III clinical trial of Omigard. This proposal was prompted by our planned re-analysis of data from the initial Phase III clinical trial of Omigard, which was conducted by our licensor. Using a slightly different, stricter definition of local catheter site infections ("LCSIs"), the re-analysis indicated a statistically significant reduction in the number of LCSIs of approximately 42% in the Omigard treatment arm as compared to the povidone-iodine treatment arm, while the original analysis of data from this trial indicated a statistically significant reduction of LCSIs of approximately 49%. Because the target sample size for our ongoing Phase III clinical trial of Omigard is based, in part, upon the LCSI rate and treatment effect of the original Phase III clinical trial of this product candidate, we believe that adding patients is prudent in order to maintain the statistical power of the study. Additionally, improvements to hospital infection prevention practices since the commencement of our Phase III clinical trial of Omigard began may reduce catheter-related infection rates, which we believe further supports the planned increase in the number of patients. If our plan is approved by the FDA, we expect that increasing the enrollment in the Phase III clinical trial of Omigard may move the completion of enrollment in this study from the second half of 2007 to mid-2008.

In March 2006, we in-licensed rights to IV APAP from BMS. In October 2006, we initiated a pharmacokinetic study in adults to assess the pharmacokinetics of single and multiple doses of IV APAP compared to oral

acetaminophen in adults. The enrollment in this Phase I clinical trial was completed in December 2006. Also in December 2006, we initiated enrollment in a Phase III clinical trial of IV APAP for the treatment of post-operative pain following gynecological surgery. We have elected to divide our planned Phase III clinical trial comparing IV APAP to placebo and oral acetaminophen for the treatment of fever in adults into two separate trials, one to compare IV APAP against a placebo, and one to compare IV APAP against oral acetaminophen. We currently anticipate that this change will have minimal impact on the total number of patients to be enrolled in, and the total costs for these trials, and should not delay our clinical trial program for IV APAP. We plan to initiate all five additional clinical trials of IV APAP in 2007.

We are a development stage company. We have incurred significant net losses since our inception. As of March 31, 2007, we had an accumulated deficit of $72.3 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 in which we sold 6.0 million shares of our common stock at $9.00 per share and received net proceeds of $48.4 million (after underwriting discounts and offering costs). In November 2006, following exercise of the underwriters' over-allotment option, we sold 0.9 million shares of our common stock at $9.00 per share and received net proceeds of $7.5 million (after underwriting discounts).

***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 ("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 and IV APAP. 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 included in our condensed statements of operations for the three months ended March 31, 2007 and 2006, and for the period from May 26, 2004 (inception) through March 31, 2007 (in thousands):

| Product Candidate | Three Months Ended March 31, 2007 | Three Months Ended March 31, 2006 | Period from May 26, 2004 (Inception) through March 31, 2007 |
|---|---|---|---|
| IV APAP | $ 1,880 | $ 25,478 | $ 29,932 |
| Omigard | 4,681 | 2,785 | 25,477 |
| Other supporting costs | 1,681 | 472 | 8,669 |
| | $ 8,242 | $ 28,735 | $ 64,078 |

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 expect to complete enrollment in the study by mid-2008. In the fourth quarter of 2006, we initiated the Phase III clinical development program for IV APAP 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 January 1, 2007, we had both federal and state net operating loss carryforwards of approximately $32.1 million. If not utilized, the net operating loss carryforwards will begin expiring in 2024 for federal purposes and 2014 for state purposes. As of January 1, 2007, we had both federal and state research and development tax credit carryforwards of approximately $1.1 million and $0.3 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**

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

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

***Research and Development Expenses***

A substantial portion of our on-going research and development activities are performed under agreements we enter into with external service providers, including CROs, which conduct many of our research and development activities. We accrue for costs incurred under these contracts based on factors such as estimates of work performed, milestones achieved, patient enrollment and experience with similar contracts. As actual costs become known, we adjust our accruals. To date, our accruals have been within management's estimates, 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.* The methods of accounting for stock-based compensation involve a number of estimates about the expected lives of stock options, interest rates, stock volatility, and assumptions as well as the selection of a valuation model. We have elected to use the Black-Scholes option valuation model to value our stock-based compensation. A change in any of the estimates used in the model, or the selection of a different option pricing model, could have a material impact on our operations. For further discussion regarding the implementation of SFAS No. 123(R), see Note 1 of the Notes to Condensed Financial Statements.

Prior to our initial public offering in October 2006, the fair value of our common stock was established by our board of directors. We have 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 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 were at an early stage of existence, primarily focused on development with an unproven business model. Prior to our initial public offering, we had 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. 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, which 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. 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.

The table below summarizes the stock based compensation expense included in our condensed statements of operations for the three months ended March 31, 2007 and 2006, and for the period from May 26, 2004 (inception) through March 31, 2007:

| | Three Months Ended March 31, | | Period from May 26, 2004 (Inception) through March 31, 2007 |
|---|---|---|---|
| | 2007 | 2006 | |
| Research and development | $ 193,635 | $ 61 | $ 754,892 |
| Marketing | 865 | — | 2,036 |
| General and administrative | 529,318 | — | 2,101,849 |
| Stock-based compensation expense included in operating expenses | 723,818 | 61 | 2,858,777 |
| Total stock-based compensation expense included in loss from operations | $ 723,818 | $ 61 | $ 2,858,777 |

**Results of Operations**

***Three-Month Periods Ended March 31, 2007 and 2006***

***Operating expenses***

*Research and Development Expenses.* Research and development expenses decreased $20.5 million for the three months ended March 31, 2007 to $8.2 million, from $28.7 million for the comparable period during 2006. This decrease was primarily due to the $25.3 million initial license fee for IV APAP we incurred in March 2006, which was immediately expensed as in-process research and development. Excluding this license fee, our research and development expenses for the three months ended March 31, 2007 increased $4.8 million, which was primarily due to the following:

- an increase of $1.9 million in our Omigard program as a result of clinical trial and related costs for a Phase III clinical trial initiated in August 2005;
- an increase of $1.7 million in our IV APAP program, primarily as a result of costs related to the initiation of our clinical development program and a Phase III clinical trial during the fourth quarter of 2006; and
- an increase of $1.2 million in other supporting costs as a result of increased salaries and related personnel costs (including $0.2 million in stock-based compensation charges) 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 $0.2 million for the three months ended March 31, 2007 to $0.3 million, as compared to $0.1 million for the comparable period during 2006. This increase was primarily due to increased market research costs and related outside services.

*General and Administrative Expenses.* General and administrative expenses increased $1.3 million for the three months ended March 31, 2007 to $1.8 million, from $0.5 million for the comparable period during 2006. This increase was primarily due to increased salaries and related personnel costs (including a $0.5 million increase in stock-based compensation charges), facility rent, costs related to operating as a public company, and depreciation expense.

*Interest Income.* Interest income increased $0.9 million for the three months ended March 31, 2007 to $1.0 million, from $0.1 million for the comparable period during 2006. This increase was primarily was due to our increased average cash and cash equivalent balance as a result of the proceeds we received from the completion of our initial public offering in the fourth quarter of 2006.

*Interest Expense.* Interest expense increased to $0.2 million for the three months ended March 31, 2007 from a nominal amount for the comparable period during 2006. This increase was due to interest we incurred on the $7.0 million we borrowed from Silicon Valley Bank and Oxford Finance Corporation in June 2006.

**Liquidity and Capital Resources**

As of March 31, 2007, we had $77.4 million in cash and cash equivalents, a decrease of $9.4 million from the $86.8 million at December 31, 2006. This decrease was primarily due to cash used in operations ($6.5 million), cash deemed to be restricted ($1.6 million), purchases of property and equipment ($0.9 million) and payments on our debt obligations ($0.4 million).

The $6.5 million of cash used in operations for the first three months ended March 31, 2007 represents a $21.8 million decrease from the $28.3 million of cash used in operations during the comparable period in 2006. This decrease was primarily due to a decrease in the net loss we reported during the applicable period in 2007 ($9.6 million) as compared to 2006 ($29.2 million). The net loss during the first quarter of 2006 was largely due to a $25.3 million license fee expensed and paid during the quarter.

Our net loss reported for the three months ended March 31, 2007 ($9.6 million) includes non-cash charges for stock-based compensation ($0.7 million) and depreciation ($0.1 million). The increase in our accounts payable, accrued expenses and other liabilities ($2.2 million) also offset the cash flow from the net loss reported for the quarter. This increase in our accounts payable, accrued expenses and other liabilities was primarily due to the timing of payments.

At March 31, 2007 our net property, plant and equipment balance increased by $0.7 million to $4.3 million, from $3.6 million at December 31, 2006. This increase was primarily due to capital expenditures associated with equipment for the manufacturing of our IV APAP product.

*Sources of Liquidity*

Since inception, our operations have been financed primarily through the issuance of our equity securities, in both public and private offerings. From our inception through March 31, 2007, we have received net proceeds of approximately $135.6 million from the sale of shares of our preferred and common stock as follows:

- from July 2004 to December 2006 (excluding our initial public offering), we issued and sold a total of 2,285,115 shares of common stock for aggregate net proceeds of $0.8 million;
- from July 2004 to August 2004, we issued and sold a total of 8,085,108 shares of Series A-1 preferred stock for aggregate net proceeds of $7.5 million;
- from June 2005 to September 2005, we issued and sold a total of 17,675,347 shares of Series A-2 preferred stock for aggregate net proceeds of $17.6 million;
- in March 2006, we issued and sold a total of 53,870,000 shares of Series A-3 preferred stock for aggregate net proceeds of $53.9 million; and
- in the fourth quarter of 2006, we completed our initial public offering in which we issued and sold a total of 6,900,000 shares of our common stock for aggregate net proceeds of $55.9 million.

Additionally, in February 2006, we entered into a $7.0 million loan and security agreement with Silicon Valley Bank and Oxford Finance Corporation to provide us with growth capital. We drew down $7.0 million in June 2006 and 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 in February 2007, we began making 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 connection with the loan and security agreement with Silicon Valley Bank and Oxford Finance Corporation, we issued two warrants to the lenders to purchase 385,000 shares of Series A-2 preferred stock at an exercise price of $1.00 per share. These warrants became exercisable for 96,250 shares of our common stock, at an exercise price of $4.00 per share, upon the completion of our initial public offering in October 2006. Excluding certain mergers or acquisitions, the warrants expire in February 2016. The 0.3 million 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. In November 2006, one warrant was exercised for 48,125 shares at $9.45, resulting in 27,754 shares issued. In March 2007, the remaining warrant was exercised for 48,125 shares at $15.04, resulting in 35,325 shares issued. As of March 31, 2007, there were no warrants remaining.

*Capital Resources*

As a biopharmaceutical company focused on in-licensing, developing and commercializing proprietary pharmaceutical product candidates, we have entered into license agreements to acquire the rights to develop and commercialize our 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 and timing of regulatory approvals;
- the costs involved in enforcing or defending patent claims or other intellectual property rights;
- 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.

Our current cash and cash equivalent balances are currently our principal sources of liquidity and we believe these will satisfy our projected working capital, capital expenditure, debt servicing and possible investment needs, at a minimum, through the third quarter of 2008. We have based this estimate on assumptions that may prove to be wrong, and we could spend our available financial resources faster than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to the 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. 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. To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership will be diluted. 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 and have established guidelines relating to diversification and maturities of our securities available-for-sale to preserve principal and maintain liquidity. 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.

**Recent Accounting Pronouncements**

See Note 2 of the Notes to Condensed Financial Statements for a discussion of recent accounting pronouncements.

**Caution on Forward-Looking Statements**

This Quarterly Report on Form 10-Q, or Quarterly Report, includes forward-looking statements that are subject to risks and uncertainties, many of which are beyond our control. Our actual results will differ from those anticipated in these forward looking statements as a result of various factors, including those set forth below under the caption "Part II., Item 1A. — Risk Factors" and the differences may be material. Forward-looking statements discuss matters that are not historical facts. Forward-looking statements include, but are not limited to, discussions regarding our operating strategy, growth strategy, acquisition strategy, cost savings initiatives, industry, economic conditions, financial condition, liquidity and capital resources and results of operations. In this Quarterly Report, for example, we make forward-looking statements regarding the potential for IV APAP and Omigard to receive regulatory approval for one or more indications on a timely basis or at all; the progress and results of pending clinical trials for IV APAP and Omigard, including any delays in commencing or completing enrollment for our ongoing clinical trials; 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; intense competition if

either of IV APAP or Omigard is ever commercialized; and our ability to raise sufficient capital when needed, or at all. Such statements include, but are not limited to, statements preceded by, followed by or that otherwise include the words “believes,” “expects,” “anticipates,” “intends,” “estimates,” “projects,” “can,” “could,” “may,” “will,” “would” or similar expressions. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in Section 21E of the Private Securities Litigation Reform Act of 1995. You should not rely unduly on these forward-looking statements, which speak only as of the date on which they were made. We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

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

**Cash and Cash Equivalents**

Our cash and cash equivalents as of March 31, 2007 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. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive without significantly increasing risk. Some of the investment securities available-for-sale that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the value of the investment securities available-for-sale to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of that security will probably decline. To minimize this risk, we intend to continue to maintain our portfolio of cash equivalents and investment securities available-for-sale 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 and we do not believe that our results of operations would be materially impacted by an immediate 10% change in interest rates.

**Debt**

Our $7.0 million loan and security agreement with Silicon Valley Bank and Oxford Finance Corporation has a fixed rate equal to 11.47% and consequently we did not have significant interest rate cash flow exposure on our long-term debt. The agreement is collateralized by substantially all the assets of the Company (excluding intellectual property) and 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.

**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.

*Evaluation of disclosure 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.

*Changes in internal control over financial reporting.* There was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## PART II. OTHER INFORMATION

**Item 1.** ***Legal Proceedings***

Not applicable.

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

*Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, which has been updated since the filing of our Annual Report on Form 10-K, 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 ongoing and 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;*
- *delays or quality issues with respect to the manufacturing of our product candidates could result in increased costs to us and delay or limit our ability to obtain regulatory approval;*
- *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;*
- *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; and*
- *whether we are able to maintain patent protection for our products and to commercialize our products without infringing the patent rights of others.*

*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. In March 2006, we 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. Based on the preliminary feedback we received from the FDA in our meeting in August 2006, we have completed one pharmacokinetic clinical trial in adults, initiated a Phase III clinical trial for the treatment of acute pain in adults, and intend to conduct five additional clinical trials in adults and children to provide the FDA with data to support multiple dose efficacy for acute pain, efficacy for fever and safety in adults and children. 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 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. In April 2007, we announced our plans to discuss with the FDA a proposal to increase the number of patients to be enrolled in our ongoing Phase III clinical trial of Omigard, which we expect will delay the completion of enrollment in this trial from the second half of 2007 to mid-2008 and require greater financial resources than originally anticipated. 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 of Omigard. In connection with the SPA for Omigard, the FDA agreed that a single confirmatory Phase III trial will be required for approval for Omigard and that the prevention of LCSIs will be the sole primary efficacy endpoint, and we initiated this clinical trial in August 2005. In April 2007, we announced our plans to discuss with the FDA a proposal to increase the number of patients to be enrolled in our ongoing Phase III clinical trial of Omigard. This proposal was prompted by our planned re-analysis of data from the initial Phase III clinical trial of Omigard. Using a slightly different, stricter definition of LCSIs, the re-analysis indicated a statistically significant reduction in the number of LCSIs of approximately 42% in the Omigard treatment arm as compared to the povidone-iodine treatment arm, while the original analysis of data from this trial indicated a statistically significant reduction of LCSIs of approximately 49%. Because the target sample size for our ongoing Phase III clinical trial of Omigard is based, in part, upon the LCSI rate and treatment effect of the original Phase III clinical trial of this product candidate, we believe that adding patients is prudent in order to maintain the statistical power of the study. Additionally, improvements to hospital infection prevention practices since our Phase III clinical trial of Omigard began may reduce catheter-related infection rates, which we believe further supports the planned increase in the number of patients. If our plan is approved by the FDA, we expect that increasing the enrollment in the Omigard

Phase III clinical trial will delay the completion of enrollment in this study from the second half of 2007 to mid-2008 and require greater financial resources than originally anticipated. However, we cannot be certain that our ongoing Phase III clinical trial of Omigard will be able to enroll an adequate number of patients in the trial or ultimately demonstrate statistical significance or otherwise demonstrate sufficient efficacy and safety to support the filing of an NDA or ultimately lead to regulatory approval. We also cannot be certain that the FDA will not apply a statistical penalty to this clinical trial, which could mean that we will need to add even more patients. Furthermore, despite having completed the SPA process, the FDA's agreement with us on the trial protocol remains subject to future advances in the field or future public health concerns unrecognized at the time of the FDA's protocol assessment, and any changes we may propose to the protocol, such as increasing the number of patients to be enrolled, remains subject to the FDA's approval. We may not be able to obtain the FDA's agreement to increase enrollment in our ongoing Phase III clinical trial of Omigard on a timely basis, or at all.

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 and ongoing Phase III clinical trials 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. Similar to IV APAP, we have obtained electronic databases from the completed Phase III trials sponsored by Migenix and Fujisawa, and we are currently re-analyzing these data using a slightly different, stricter definition of LCSIs. In April 2007, we announced that our re-analysis indicated a statistically significant reduction in the number of LCSIs of approximately 42% in the Omigard treatment arm as compared to the povidone-iodine treatment arm, while the original analysis indicated a statistically significant reduction of LCSIs of approximately 49%. Because the target sample size for our own Phase III clinical trial of Omigard, is based, in part, upon the LCSI rate and treatment effect of the original Phase III clinical trial of this product candidate, we believe that adding patients is prudent in order to maintain the statistical power of the study. As a result, we have initiated discussions with the FDA regarding a proposal to increase the number of patients to be enrolled in our ongoing Phase III clinical trial of Omigard, which is expected to delay the completion of enrollment in this study from the second half of 2007 to mid-2008 and require greater financial resources than originally anticipated. Our audit and verification of the accuracy of the primary clinical data provided by our licensor and its former collaborator are continuing, and we cannot determine their applicability to our regulatory filings. Although the Phase III clinical trial of 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 of 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. As a result of auditing the data from these earlier clinical trials and completing the extensive re-analyses that we will need to perform as part of our standard procedures for preparing final reports of these studies, the previously reported results may change, which may negatively impact our ongoing Phase III clinical trials, or the suitability of earlier clinical trials for inclusion in applications for marketing authorization of our IV APAP and Omigard product candidates. As a result, 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 enrollment in our ongoing clinical trial of IV APAP for the treatment of post-operative pain following gynecological surgery will be completed on time, or whether our five additional planned clinical trials for IV APAP will be initiated or completed on schedule, if at all. In April 2007, we announced an estimated delay in the completion of enrollment for our ongoing Phase III clinical trial of Omigard from the second half of 2007 to mid-2008, because of our proposal to increase the number of patients to be enrolled, and we do not know if this clinical trial will be completed 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. For example, we believe that improvements to hospital infection prevention practices since we commenced enrollment in our Phase III clinical trial of Omigard may reduce catheter-related infection rates, which may result in the occurrence of an insufficient number of infections to demonstrate statistical significance in this clinical trial or require an even larger number of patients to be enrolled in order to demonstrate a statistically significant effect. Although we plan to increase the number of patients to be enrolled in our ongoing Phase III clinical trial of Omigard, we may not obtain the FDA's concurrence to do so, we may be unable to enroll an adequate number of patients and, even if we enroll our target number of additional patients, we may still be unable to demonstrate statistical significance or otherwise demonstrate sufficient efficacy and safety to support the filing of an NDA for Omigard. 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;
- new information suggesting unacceptable risk to subjects, or unforeseen safety issues or any determination that a trial presents unacceptable health risks;
- new information suggesting that the target condition occurs too infrequently for the product candidate to demonstrate efficacy; 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, or new information concerning the product candidate or the target medical condition may emerge, and we may need to perform additional, unanticipated non-clinical testing of our product candidates or amend clinical trial protocols to reflect these developments. Additional non-clinical testing would add costs and could delay or result in the denial of regulatory approval for a product candidate. 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 products for this and similar indications, including opioids such as morphine, fentanyl, meperidine and hydromorphone, each of which is available generically from several manufacturers, and several of which are available as proprietary products using novel delivery systems, as well as an extended release injectable (epidural) formulation of morphine, DepoDur. Ketorolac, an injectable non-steroidal anti-inflammatory drug, or NSAID, is also available generically in the U.S. 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 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 for 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 for 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 of Omigard and improvements in hospital infection control practices that lower catheter infection rates 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 a particular antiseptic, chlorhexidine, as their 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 of 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 of 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 for Omigard in combination with chlorhexadine antisepsis for the prevention of LCSIs. Additionally, we believe that improvements to hospital infection control practices since we commenced enrollment in our ongoing Phase III clinical trial of Omigard may reduce catheter-related infection rates, which may result in the occurrence of an insufficient number of infections to demonstrate statistical significance in this clinical trial or require an even larger number of patients to be enrolled in order to demonstrate a statistically significant effect. 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 non-clinical testing, manufacturing, safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the 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, allergic reactions, and pain or local skin reactions at the injection site. When used in excess of the current guidelines for administration, acetaminophen has an increased potential to cause liver toxicity. While 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 primarily limited to local skin reactions, including redness, swelling, bleeding, itching, bruising and pain. In addition, while these drug-related adverse events have generally 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 suspend or withdraw their approval of the product, or require it to be removed from the market;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product; 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 ongoing Phase III clinical program for IV APAP and our ongoing Phase III clinical trial of 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 manage the execution of 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 manage the execution of our clinical trials, we are responsible for oversight and 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 care, 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, at commercially reasonable prices, that meet all applicable quality standards, 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 and IV APAP product candidates. We are currently negotiating with suppliers for the commercial supply of the active pharmaceutical ingrediate, or API, and finished drug product for IV APAP and commercial supply of API and finished drug product for Omigard. 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 April 30, 2007, we had 38 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 ongoing Phase III clinical program for IV APAP, which will be conducted at numerous clinical trial sites, and our ongoing Phase III clinical trial of Omigard, which is being conducted at numerous clinical sites in the U.S. and Europe;
- 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 Assistant 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. Patent protection for the acetaminophen molecule itself in the territories licensed to us, which include the United States and Canada, is not available. 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. For example, Injectapap, a liquid formulation of acetaminophen for intramuscular injection was approved by the FDA for the reduction of fever in adults in March 1986, although it was subsequently withdrawn from the market by McNeil Pharmaceutical in July 1986.

The number of patents and patent applications covering products in the same field as 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 topical administration to a burn or a surgical wound site for the treatment of burn-related, surgical wound-related infections and the topical administration to a device or the site around the device for the treatment of 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, SCR Pharmatop, 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 at our expense. 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' 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. It is possible that SCR Pharmatop or BMS could take

some action or fail to take some action that could harm the SCR Pharmatop patents. In certain instances, we may be allowed to pursue the infringement claim ourselves. 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, 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 $52.2 million and $7.7 million for the years ended December 31, 2006 and 2005, respectively. As of March 31, 2007, we had an accumulated deficit of $72.3 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, at a minimum, through the end of the third quarter of 2008. We have based this estimate on assumptions that may prove to be wrong, and we could spend our available financial resources faster than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

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

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

To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership will be diluted. If we raise additional funds through licensing arrangements, it may be necessary to relinquish potentially valuable rights to our potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. Any debt financing we enter into may involve covenants that restrict our operations. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. For example, in February 2006, we entered into a $7.0 million loan and security agreement with Silicon Valley Bank and Oxford Finance Corporation 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 continue to incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.***

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

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. 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 in October 2006 through March 31, 2007, the trading prices for our common stock ranged from a high of $16.92 to a low of $8.25.

***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 beginning 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 ongoing Phase III clinical program for IV APAP and our ongoing Phase III clinical trial of 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 executive officers and directors and their affiliates may exercise control over stockholder voting matters in a manner that may not be in the best interests of all of our stockholders.***

As of March 31, 2007, our executive officers and directors and their affiliates will together control approximately 53% of our outstanding common stock. As a result, these stockholders will collectively be able to significantly influence all matters requiring approval of our stockholders, including the election of directors and approval of significant corporate transactions. The concentration of ownership may delay, prevent or deter a change in control of our company even when such a change may be in the best interests of all stockholders, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock.

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

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

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

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

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

We have paid no cash dividends on any of our classes of capital stock to date and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Furthermore, our 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**

Not applicable.

**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 $1.9 million in connection with the offering, which when added to the underwriting discounts paid by us, amounts to total expenses of $6.2 million. Thus, the net offering proceeds to us, after deducting underwriting discounts and offering costs, were $55.9 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 March 31, 2007, we had used approximately $8.5 million of the net proceeds we received from our initial public offering to fund (1) clinical trials for IV APAP and Omigard and other research and development activities; (2) capital expenditures, primarily including equipment associated with the manufacturing of IV APAP; and (3) 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***

Not applicable.

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

Not applicable.

**Item 5.** ***Other Information***

Not applicable.

**Item 6.** ***Exhibits***

| | |
|---|---|
| 3.1(1) | Amended and Restated Certificate of Incorporation of the Registrant |
| 3.2(1) | Amended and Restated Bylaws of the Registrant |
| 4.1(1) | Form of the Registrant's Common Stock Certificate |
| 4.2(2) | Amended and Restated Investor Rights Agreement dated February 21, 2006 |
| 31.1± | Certification of Chief Executive Officer pursuant to Rule 13a – 14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 31.2± | Certification of Chief Financial Officer pursuant to Rule 13a – 14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 |
| 32± | Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18.U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002 |

(1) Incorporated herein by reference to the corresponding exhibit to the Registrant's Quarterly Report on Form 10-Q (File No. 001-33103) for the period ended September 30, 2006 as filed with the SEC on November 30, 2006.

(2) Incorporated herein by reference to the corresponding exhibit to the Registrant's Registration Statement on Form S-1 (File No. 333-135821) as filed with the SEC on July 17, 2006.

± Included in this Report.

**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.

Dated: May 15, 2007

By: /s/ WILLIAM R. LARUE

William R. LaRue

*Senior Vice President, Chief Financial Officer, Treasurer and Assistant Secretary*

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## INDEX TO EXHIBITS

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± Included in this Report.

**Exhibit 31.1**

**CERTIFICATION**

I, Theodore R. Schroeder, certify that:

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

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

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

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

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

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

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

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

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

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

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

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

Date: May 15, 2007

**Exhibit 31.2**

**CERTIFICATION**

I, William R. LaRue, certify that:

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

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

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

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

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

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

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

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

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

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

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

/s/ WILLIAM R. LARUE

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

Date: May 15, 2007

**Exhibit 32**

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

In connection with the filing of the Quarterly Report on Form 10-Q of Cadence Pharmaceuticals, Inc. ("Cadence") for the quarterly period ended March 31, 2007, as filed with the Securities and Exchange Commission on the date hereof ("the Report"), each of the undersigned officers of Cadence, hereby certifies, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that:

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

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

The undersigned have executed this Certification effective as of May 15, 2007.

/s/ THEODORE R. SCHROEDER

Theodore R. Schroeder
President, Chief Executive Officer and Director
(Principal Executive Officer)

/s/ WILLIAM R. LARUE

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