ACORDA THERAPEUTICS INC
Form 10-Q
November 14, 2006

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549**

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# FORM 10-Q

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

**For the quarterly period ended September 30, 2006**

**OR**

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

**For the transition period from to**

**Commission File Number 000-50513**

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# ACORDA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

| **Delaware** | **13-3831168** |
|---|---|
| (State of incorporation) | (I.R.S. Employer identification number) |

**15 Skyline Drive**
**Hawthorne, New York 10532**
(914) 347-4300

(Address, including zip code, and telephone number,
including area code, of registrant s principal executive offices)

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 x No o

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.

Large accelerated filer o Accelerated filer o Non-accelerated filer x

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

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practicable date.

| Class | **Outstanding at October 31, 2006** |
| --- | --- |
| Common Stock, $0.001 par value per share | 23,021,912 shares |

**ACORDA THERAPEUTICS, INC.**

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## PART I FINANCIAL INFORMATION

*This Quarterly Report on Form 10-Q contains forward-looking statements relating to future events and our future performance within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Stockholders are cautioned that such statements involve risks and uncertainties. These forward-looking statements are based on current expectations, estimates, forecasts and projections about the industry and markets in which we operate and management s beliefs and assumptions. All statements, other than statements of historical facts, included in this report regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. The words anticipates, believes, estimates, expects, intends, may, plans, projects, will, would, and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this report and in the Risk Factors section in our Annual Report on Form 10-K for the year ended December 31, 2005, Form 10-Q for the three-month period ended March 31, 2006, Form 10-Q for the three-month period ended June 30, 2006 and this report, particularly in the Risk Factors section, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make. We do not assume any obligation to update any forward-looking statements.*

**PART I**

**Item 1.** Financial Statements

**ACORDA THERAPEUTICS, INC. AND SUBSIDIARY**

**Consolidated Balance Sheets**

| | September 30, 2006 (unaudited) | December 31, 2005 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 11,920,624 | $ 11,761,299 |
| Restricted cash | 270,706 | 262,993 |
| Short-term investments | 6,439,560 | 2,001,175 |
| Trade accounts receivable, net | 3,819,731 | 589,252 |
| Grant receivable | 126,259 | 155,178 |
| Prepaid expenses | 1,717,814 | 2,224,042 |
| Finished goods inventory held by the Company | 5,860,857 | 5,586,842 |
| Finished goods inventory held by others | 1,281,270 | 1,170,603 |
| Other current assets | 1,441,099 | 1,712,550 |
| Total current assets | 32,877,920 | 25,463,934 |
| Property and equipment, net of accumulated depreciation | 1,277,073 | 1,707,104 |
| Intangible assets, net of accumulated amortization | 5,397,976 | 5,952,261 |
| Other assets | 764,448 | 788,531 |
| Total assets | $ 40,317,417 | $ 33,911,830 |
| **Liabilities, Mandatorily Redeemable Convertible Preferred Stock and Stockholders (Deficit)** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,161,550 | $ 4,133,611 |
| Accrued expenses and other current liabilities | 4,760,674 | 9,926,773 |
| Accrued product returns | | 1,831,211 |
| Deferred product revenue Zanaflex tablets | 8,604,565 | 11,509,598 |
| Deferred product revenue Zanaflex Capsules | 7,702,509 | 5,226,106 |
| Current portion of notes payable | 1,010,873 | 1,068,414 |
| Current portion of revenue interest liability | 3,202,795 | 2,162,160 |
| Total current liabilities | 27,442,966 | 35,857,873 |
| Long-term portion of notes payable | 461,211 | 1,146,956 |
| Other long-term liabilities | 532,501 | 549,023 |
| Non current portion of revenue interest liability | 11,321,859 | 12,913,519 |
| Long-term convertible notes payable principal amount, plus accrued interest less unamortized debt discount of $13,987 and $55,944 as of September 30, 2006 and December 31, 2005, respectively | 8,952,037 | 8,767,798 |
| Mandatorily Redeemable Convertible Preferred Stock: | | |
| Series E convertible preferred stock $0.001 par value. Authorized 7,472,612 shares at September 30, 2006 and December 31, 2005; issued and outstanding 0 and 7,472,612 at September 30, 2006 and December 31, 2005, respectively (Redemption and liquidation value of $0 as of September 30, 2006) | | 10,331,648 |

See accompanying Unaudited Notes to the Consolidated Financial Statements.

**ACORDA THERAPEUTICS, INC. AND SUBSIDIARY**

**Consolidated Balance Sheets (Continued)**

| | September 30, 2006 (unaudited) | December 31, 2005 |
|---|---|---|
| Series I convertible preferred stock $0.001 par value. Authorized 10,204,047 shares at September 30, 2006 and December 31, 2005; issued and outstanding 0 and 10,204,047 at September 30, 2006 and December 31, 2005, respectively (Redemption and liquidation value of $0 as of September 30, 2006) | | 20,369,508 |
| Series J convertible preferred stock $0.001 par value. Authorized 112,790,233 shares at September 30, 2006 and December 31, 2005; issued and outstanding 0 and 112,790,233 at September 30, 2006 and December 31, 2005, respectively (Redemption and liquidation value of $0 as of September 30, 2006) | | 47,355,590 |
| Series K convertible preferred stock $0.001 par value. Authorized 1,573,330 shares at September 30, 2006 and December 31, 2005; issued and outstanding 0 and 1,533,327 shares at September 30, 2006 and December 31, 2005, respectively (Redemption and liquidation value of $0 at September 30, 2006) | | 13,155,593 |
| Commitments and contingencies | | |
| Stockholders (deficit): | | |
| Series A convertible preferred stock, $0.001 par value. Authorized 1,646,068 shares at September 30, 2006 and December 31, 2005; issued and outstanding 0 and 1,306,068 shares at September 30, 2006 and December 31, 2005, respectively (liquidation value of $0 as of September 30, 2006) | | 1,306 |
| Series B convertible preferred stock, $0.001 par value. Authorized 2,250,000 shares at September 30, 2006 and December 31, 2005; issued and outstanding 0 and 900,000 shares at September 30, 2006 and December 31, 2005, respectively (liquidation value of $0 as of September 30, 2006) | | 900 |
| Series C convertible preferred stock, $0.001 par value. Authorized 333,333 shares at September 30, 2006 and December 31, 2005; issued and outstanding 0 and 333,333 at September 30, 2006 and December 31, 2005, respectively (liquidation value of $0 as of September 30, 2006) | | 333 |
| Series D convertible preferred stock, $0.001 par value. Authorized 400,000 shares at September 30, 2006 and December 31, 2005; issued and outstanding none | | |
| Series F convertible preferred stock, $0.001 par value. Authorized 2,300,000 shares at September 30, 2006 and December 31, 2005; issued and outstanding 0 and 2,300,000 at September 30, 2006 and December 31, 2005, respectively (liquidation value of $0 as of September 30, 2006) | | 2,300 |

See accompanying Unaudited Notes to the Consolidated Financial Statements.

**ACORDA THERAPEUTICS, INC. AND SUBSIDIARY**

**Consolidated Balance Sheets (Continued)**

| | September 30, 2006 (unaudited) | December 31, 2005 |
|---|---|---|
| Series G convertible preferred stock, $0.001 par value. Authorized 1,250,000 shares at September 30, 2006 and December 31, 2005; issued and outstanding none | | |
| Series H convertible preferred stock, $0.001 par value. Authorized 1,575,229 shares at September 30, 2006 and December 31, 2005; issued and outstanding 0 and 1,575,229 shares at September 30, 2006 and December 31, 2005, respectively (liquidation value of $0 as of September 30, 2006) | | 1,575 |
| Common stock, $0.001 par value. Authorized 260,000,000 and 200,000,000 shares at September 30, 2006 and December 31, 2005, respectively; issued and outstanding 19,630,636 and 208,732 shares as of September 30, 2006 and December 31, 2005, respectively | 19,635 | 209 |
| Additional paid-in capital | 216,632,468 | 91,501,190 |
| Accumulated deficit | (225,051,734) | (208,041,931) |
| Other comprehensive income (loss) | 6,474 | (1,560) |
| Total stockholders (deficit) | (8,393,157) | (116,535,678) |
| Total liabilities, mandatorily redeemable convertible preferred stock and stockholders (deficit) | $ 40,317,417 | $ 33,911,830 |

See accompanying Unaudited Notes to the Consolidated Financial Statements.

**ACORDA THERAPEUTICS, INC. AND SUBSIDIARY**
**Consolidated Statements of Operations**
**(unaudited)**

| | Three-month period ended September 30, 2006 | Three-month period ended September 30, 2005 | Nine-month period ended September 30, 2006 | Nine-month period ended September 30, 2005 |
|---|---|---|---|---|
| Gross sales Zanaflex | $ 6,537,576 | $ 2,760,908 | $ 18,303,614 | $ 3,239,091 |
| Less: discounts and allowances | (380,610) | (147,124) | 955,266 | (991,560) |
| Net sales | 6,156,966 | 2,613,784 | 19,258,880 | 2,247,531 |
| Grant revenue | 70,350 | 29,553 | 371,615 | 184,195 |
| Total net revenue | 6,227,316 | 2,643,337 | 19,630,495 | 2,431,726 |
| Less: cost of sales | (1,652,281) | (706,826) | (4,037,405) | (2,273,970) |
| Gross profit | 4,575,035 | 1,936,511 | 15,593,090 | 157,756 |
| Operating expenses: | | | | |
| Research and development | 2,594,466 | 2,509,551 | 8,892,352 | 9,652,543 |
| Sales and marketing | 5,297,223 | 4,288,373 | 14,142,074 | 9,657,233 |
| General and administrative | 3,435,290 | 2,405,627 | 9,273,166 | 6,338,716 |
| Total operating expenses | 11,326,979 | 9,203,551 | 32,307,592 | 25,648,492 |
| Operating loss | (6,751,944) | (7,267,040) | (16,714,502) | (25,490,736) |
| Other income (expense): | | | | |
| Interest and amortization of debt discount expense | (766,669) | (304,217) | (1,674,203) | (824,196) |
| Interest income | 280,626 | 89,413 | 853,504 | 347,352 |
| Other income | 68,321 | (39) | 71,173 | 989 |
| Total other income (expense) | (417,722) | (214,843) | (749,526) | (475,855) |
| Cumulative effect of change in accounting principle | | 2,805 | 454,225 | 2,805 |
| Net loss | (7,169,666) | (7,479,078) | (17,009,803) | (25,963,786) |
| Beneficial conversion feature, accretion of issuance costs, preferred dividends, and fair value of warrants issued to convertible preferred stockholders | | (6,426,937) | (36,007,456) | (18,636,443) |
| Net loss allocable to common stockholders | $ (7,169,666) | $ (13,906,015) | $ (53,017,259) | $ (44,600,229) |
| Net loss per share allocable to common stockholders basic and diluted | $ (0.37) | $ (66.62) | $ (3.17) | $ (221.17) |
| Weighted average common shares outstanding used in computing net loss per share allocable to common stockholders basic and diluted | 19,632,660 | 208,732 | 16,745,628 | 201,656 |

See accompanying Unaudited Notes to the Consolidated Financial Statements

**ACORDA THERAPEUTICS, INC. AND SUBSIDIARY**
**Consolidated Statements of Cash Flows**
**(unaudited)**

| | Nine-month period ended September 30, 2006 | Nine-month period ended September 30, 2005 |
|---|---|---|
| Cash flows from operating activities: | | |
| Net loss | $ (17,009,803) | $ (25,963,786) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation expense | 2,906,869 | 3,464,928 |
| Amortization of note discount | 41,958 | 92,495 |
| Amortization of discount on short-term investments | (34,560) | 193,930 |
| Cumulative effect of change in accounting principle | (454,225) | |
| Accretion of discount | 34,525 | 251,373 |
| Unrealized loss on warrants | 58,478 | |
| Depreciation and amortization expense | 1,284,079 | 1,033,130 |
| Loss on disposal of property and equipment | 587 | |
| Gain on put/call liability | (75,000) | |
| Changes in assets and liabilities: | | |
| Decrease (increase) in accounts receivable | (3,230,479) | 1,193,027 |
| Decrease in grant receivables | 28,920 | 51,285 |
| Decrease (increase) in prepaid expenses and other current assets | 777,679 | (1,546,783) |
| Increase in inventory held by the Company | (274,015) | (3,659,983) |
| Increase in inventory held by others | (110,667) | (870,435) |
| Decrease in other assets | 24,083 | |
| Increase (decrease) in accounts payable, accrued expenses, other current liabilities | (6,817,727) | 2,746,766 |
| Decrease in returns liability | (1,831,211) | (2,115,567) |
| Increase in deferred product revenue tablets | (2,905,033) | 4,959,993 |
| Increase (decrease) in deferred product revenue Capsules | 2,476,403 | 4,017,369 |
| Decrease in milestone payable | | (750,000) |
| Restricted cash | (7,713) | (4,470) |
| Net cash used in operating activities | (25,116,852) | (16,906,728) |
| Cash flows from investing activities: | | |
| Purchases of property and equipment | (300,350) | (142,154) |
| Purchases of intangible assets | | (750,000) |
| Purchases of short-term investments | (11,881,791) | (11,520,820) |
| Proceeds from maturities of short-term investments | 7,486,000 | 15,580,000 |
| Net cash (used in)/provided by investing activities | (4,696,141) | 3,167,026 |
| Cash flows from financing activities: | | |
| Proceeds from issuance of common stock | 31,479,307 | 20,448 |
| Proceeds from issuance of notes payable | | 5,785,215 |
| Proceeds from issuance of warrants | | 214,785 |
| Repayments of revenue interest liability | (729,179) | |
| Repayments of notes payable | (777,810) | (429,245) |
| Net cash provided by financing activities | 29,972,318 | 5,591,203 |
| Net increase (decrease) in cash and cash equivalents | 159,325 | (8,148,499) |
| Cash and cash equivalents at beginning of period | 11,761,299 | 11,729,112 |
| Cash and cash equivalents at end of period | $ 11,920,624 | $ 3,580,613 |
| Supplemental disclosure: | | |
| Cash paid for interest | $ 1,026,785 | $ 374,535 |
| Non-cash charges related to convertible preferred stock: | | |
| Beneficial conversion feature | 48,470,740 | 14,549,194 |
| Accretion of issuance costs | 270,725 | 81,219 |
| Preferred dividend | (12,734,009) | 4,006,030 |
| Non-cash activities: | | |
| Accrued Zanaflex milestone payments | | 2,250,000 |
| Gain on put/call liability | 75,000 | |

See accompanying Unaudited Notes to the Consolidated Financial Statements.

**ACORDA THERAPEUTICS, INC. AND SUBSIDIARY**
**Notes to Consolidated Financial Statements**
**(unaudited)**

## (1) Organization and Business Activities

Acorda Therapeutics, Inc. ( Acorda or the Company ) is a commercial stage biopharmaceutical company dedicated to the identification, development and commercialization of novel therapies that improve neurological function in people with multiple sclerosis, spinal cord injury and other disorders of the central nervous system.

The management of the Company is responsible for the accompanying unaudited interim consolidated financial statements and the related information included in the notes to the consolidated financial statements. In the opinion of management, the unaudited interim consolidated financial statements reflect all adjustments, including normal recurring adjustments necessary for the fair presentation of the Company s financial position and results of operations and cash flows for the periods presented. Results of operations for interim periods are not necessarily indicative of the results to be expected for the entire year.

These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements of the Company as of and for the year ended December 31, 2005 included in the Company s Annual Report on Form 10-K for such year, as filed with the Securities and Exchange Commission (the SEC). We have made certain reclassifications to the 2005 financial statements to conform to the 2006 presentation.

The Company completed an initial public offering on February 9, 2006. As part of that offering, 6,075,614 shares of the Company s common stock were sold, resulting in net proceeds of approximately $31.5 million after deducting the underwriting discount and offering expenses payable by the Company.

Upon the closing of the initial public offering, all of the Company s convertible preferred stock and mandatorily redeemable convertible preferred stock was converted into 13,338,278 shares of common stock. This conversion resulting in the following: (a) recognition of the unamortized portion of a beneficial conversion charge of $48.5 million; (b) recognition of the unamortized portion of issuance costs relating to Series E, Series I, Series J and Series K preferred stock of $271,000; and (c) net reversal of accrued preferred dividends on Series J and Series K preferred stock of $12.7 million (see Note 4 to the consolidated financial statements).

The Company completed a private placement on October 6, 2006. As part of that offering, 3,230,769 shares of the Company s common stock were sold, resulting in net proceeds to the Company of approximately $29.8 million net of issuance costs. The impact of this offering is not reflected in the accompanying interim financial statements.

On September 18, 2005, the Company s Board of Directors approved a 1-for-1.3 reverse stock split, which became effective on January 11, 2006. All references to common stock, common shares outstanding, average number of common shares outstanding, per share amounts, options and warrants and notes payable in these financial statements and notes to financial statements have been restated to reflect the 1-for-1.3 common stock reverse split on a retroactive basis.

The Company is devoting substantially all of its efforts to promoting sales of Zanaflex Capsules, conducting clinical trials, pursuing regulatory approval for products under development, and engaging in preclinical development. The Company has begun to generate product revenues but has not achieved profitable operations or positive cash flows from operations. There is no assurance that profitable

operations, if ever achieved, could be sustained on a continuing basis. The Company s accumulated deficit since inception through September 30, 2006 was $225.1 million and the Company expects to continue to incur losses for the foreseeable future. Further, the Company s future operations are dependent on the success of the Company in commercializing Zanaflex Capsules, completing the clinical development of Fampridine-SR in MS and obtaining regulatory approval and market acceptance of this product candidate and advancing its preclinical programs.

The Company finances its operations through a combination of issuance of equity securities, revenues from Zanaflex Capsules, loans and, to a lesser extent, grants. There are no assurances that the Company will be successful in obtaining an adequate level of financing needed to fund its development and commercialization efforts. The Company believes that its current financial resources and sources of liquidity, including the proceeds from the October 2006 private placement, should be sufficient to fund operations and meet financial obligations through the first quarter of 2008 based on the Company s current projected revenue and spending levels. To the extent our capital resources are insufficient to meet future operating requirements, we will need to raise additional capital or incur indebtedness to fund our operations. We may be unable to obtain additional debt or equity financing on acceptable terms, if at all. If adequate funds are not available, we may be required to curtail our sales and marketing efforts, delay, reduce the scope of or eliminate some of our research and development programs or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently.

## (2) Summary of Significant Accounting Policies

***Principles of Consolidation***

The accompanying consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States of America and include the results of operations of the Company and its majority owned subsidiary. All intercompany accounts and transactions have been eliminated in consolidation.

***Use of Estimates***

The preparation of the consolidated financial statements requires management of the Company to make a number of estimates and assumptions relating to the reported amount of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the period. Significant items subject to such estimates and assumptions include research and development (clinical trial accrual), beneficial conversion charges, stock warrants and option accounting, which are all dependent on the fair value of the Company s equity security. In addition, the Company recognizes revenue based on estimated prescriptions filled. The Company adjusts its inventory value based on an estimate of inventory that may be returned. Actual results could differ from those estimates.

***Revenue Recognition***

The Company applies the revenue recognition guidance in SFAS No. 48, *Revenue Recognition When the Right of Return Exists*, which amongst other criteria requires that future returns can be reasonably estimated in order to recognize revenue. The amount of future tablet returns is uncertain due to generic competition and customer conversion to Zanaflex Capsules. Zanaflex Capsules are a new product with limited historical return data. Due to the uncertainty of returns for both products, the Company is accounting for these product shipments using a deferred revenue recognition model. Under the deferred revenue model, the Company does not recognize revenue upon product shipment. For these product shipments, the Company invoices the wholesaler, records deferred revenue at gross invoice sales price, and

classifies the cost basis of the product held by the wholesaler as a component of inventory. The Company recognizes revenue when prescribed to the end-user, on a first-in first-out (FIFO) basis. The Company s revenue to be recognized is based on (1) the estimated prescription demand based on pharmacy sales for its products, and (2) the Company s analysis of third-party information, including third-party market research data. The Company s estimates are subject to the inherent limitations of estimates that rely on third-party data, as certain third-party information is itself in the form of estimates, and reflect other limitations. The Company s sales and revenue recognition reflects the Company s estimates of actual product prescribed to the end-user.

The Company s net revenues represent total revenues less allowances for customer credits, including estimated discounts, rebates, and chargebacks. Product shipping and handling costs are included in cost of sales. These reserves are recorded in accordance with Emerging Issues Task Force (EITF) Issue No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer*, which states that cash consideration given by a vendor to a customer is presumed to be a reduction of the selling prices of the vendor s products or services and, therefore, should be characterized as a reduction of revenue when recognized in the vendor s income statement. At the time product is shipped to wholesalers, an adjustment is recorded for estimated chargebacks, rebates, and discounts. These reserves are established by management as its best estimate based on available information and is adjusted to reflect known changes in the factors that impact such reserves. Reserves for chargebacks, rebates and discounts are established based on the contractual terms with customers, analysis of historical levels of discounts, chargebacks and rebates, communications with customers and the levels of inventory remaining in the distribution channel, as well as expectations about the market for each product and anticipated introduction of competitive products. In addition, the Company records a charge to cost of goods sold for the cost basis of the estimated product returns the Company believes may ultimately be realized at the time of product shipment to wholesalers. The Company has recognized this charge at the date of shipment since it is probable that it will receive a level of returned products; upon the return of such product it will be unable to resell the product considering its expiration dating; and it can reasonably estimate a range of returns. This charge represents the cost basis for the low end of the range of the Company s estimated returns.

***Concentration of Risk***

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of investments in cash and cash equivalents, restricted cash, accounts receivable and debt securities. The Company maintains cash and cash equivalents, restricted cash and debt securities with approved financial institutions. The Company is exposed to credit risks in the event of default by the financial institutions or issuers of investments in excess of FDIC insured limits. The Company performs periodic evaluations of the relative credit standing of these financial institutions and limits the amount of credit exposure with any institution.

The Company is substantially dependent upon Elan for several activities related to the development and commercialization of Fampridine-SR. The Company will rely on Elan to complete the chemistry, manufacturing and controls section of the New Drug Application (NDA) for Fampridine-SR in multiple sclerosis. If Elan fails to provide these parts of the NDA in a complete and timely manner the Company could incur delays in filing of its NDA for Fampridine-SR in multiple sclerosis.

The Company relies on a single manufacturer, Elan, for the supply of Zanaflex Capsules and through February 2007 on another single manufacturer, Novartis, for the manufacture of Zanaflex tablets and for the supply of tizanidine, the active pharmaceutical ingredient, or API, in Zanaflex Capsules and Zanaflex tablets. If either Elan or Novartis experiences any disruption in their operations, a delay or interruption in the supply of the Company s products could result until the affected supplier cures the problem or the Company locates an alternative source of supply. The Company may not be able to enter into alternative supply arrangements on terms that are commercially favorable, if at all. Any new supplier would also be

required to qualify under applicable regulatory requirements. The Company could experience substantial delays before it is able to qualify any new supplier and transfer the required manufacturing technology to that supplier. Novartis has discontinued production of tizanidine and successfully transferred the methods of manufacturing tizanidine to Rohner, an API manufacturer in Pratteln, Switzerland. The Company verified this transfer and visited Rohner s manufacturing site in February 2006, following the commencement of Rohner s manufacture of tizanidine. The Company has also identified an alternate source for tizanidine in collaboration with Elan. However Rohner and any supplier would need to be approved by the FDA as a tizanidine manufacturer for Zanaflex Capsules and tablets in order for it to be used as an API supplier for the company. It is the responsibility of each of Novartis and Elan to procure the API required to meet their contractual obligations under their respective supply agreements with the Company. The Company does not anticipate an interruption in API supply, and any cost associated with validating API suppliers would be incurred by Novartis (prior to February 2007) or Elan. The Company has arranged with another company, Sharp Corporation, to bottle and package Zanaflex tablets.

The Company has agreed to purchase at least 75% of its Fampridine-SR product requirements from Elan, and must make compensatory payments if it does not purchase 100% of its requirements from Elan. The Company and Elan have agreed that the Company may purchase up to 25% of its annual Fampridine-SR requirements from Patheon, Inc., a qualified manufacturing source of Fampridine-SR, provided that the Company makes compensatory payments to Elan. In addition, the Company does not have direct contractual relationships with the suppliers of fampridine, the active pharmaceutical ingredient in Fampridine-SR, referred to as API. Currently, the Company is relying on Elan s contracts with third parties to supply API. If Elan or an alternative manufacturer is unable to obtain API from these suppliers for any reason, a new supplier would have to be identified by the Company. Although other potential sources of API are available, any new supplier would be required to qualify under applicable regulatory requirements. Any delays in obtaining API to manufacture Fampridine-SR could delay the clinical trials of Fampridine-SR.

***Earnings per Share***

Net loss per share is computed in accordance with SFAS No. 128, *Earnings Per Share*, by dividing the net loss allocable to common stockholders by the weighted average number of shares of common stock outstanding. For the three and nine-month periods ended September 30, 2006 and September 30, 2005 all of the Company s common share equivalents would have been anti-dilutive and have not been used in the calculation of diluted net loss per share. As such, the numerator and the denominator used in computing both basic and diluted net loss per share allocable to common stockholders for each year are equal. The Company has reflected the beneficial conversion feature for Series E, Series I and Series J, accretion of issuance costs for Series E, Series I, Series J and Series K, and preferred dividend for Series J and Series K in the net loss allocable to common stockholders as set forth below.

| | **Beneficial conversion feature** | **Accretion of issuance costs** | **Preferred dividend** |
|---|---|---|---|
| For the three-month period ended September 30, 2006 | $ | $ | $ |
| For the three-month period ended September 30, 2005 | 4,849,731 | 27,073 | 1,335,348 |
| For the nine-month period ended September 30, 2006 | 48,470,740 | 270,725 | (12,734,009 ) |
| For the nine-month period ended September 30, 2005 | 14,549,194 | 81,219 | 4,006,030 |

***Stock-Based Compensation***

The Company has various stock-based employee and non-employee compensation plans, which are described more fully in Note 5.

Historically, the Company accounted for share-based compensation costs under the provisions of Statement of Financial Accounting Standards 123 (SFAS No. 123), Accounting for Stock-Based Compensation, using a fair-value-based method of accounting for stock-based employee compensation plans.

On January 1, 2006, the Company adopted the provisions of Statement of Financial Accounting Standards 123 (revised 2004), Share-Based Payment (SFAS No. 123R), which requires that the costs resulting from all share-based payment transactions be recognized in the financial statements at their fair values. The Company adopted SFAS No. 123R using the modified prospective application method under which the provisions of SFAS No. 123R apply to new awards and to awards modified, repurchased, or cancelled after the adoption date. Additionally, compensation cost for the portion of the awards for which the requisite service has not been rendered that are outstanding as of the adoption date is recognized in the Consolidated Statement of Operations over the remaining service period after the adoption date based on the award s original estimate of fair value. Results for prior periods have not been restated.

In connection with the adoption of SFAS No. 123R, the Company changed from recognizing the effect of forfeitures as they occur to estimating the number of outstanding instruments for which the requisite service is not expected to be rendered. Prior to the adoption of SFAS No. 123R, the Company recognized forfeitures associated with its share-based awards as they occurred rather than estimating forfeitures. Upon adoption of SFAS No. 123R, the Company recorded a cumulative effect of change in accounting principle of $454,225, calculated as the difference between compensation cost recognized through December 31, 2005 using actual forfeitures and the cost that would have been recognized to date using estimated forfeitures. The Company estimates that its future annual forfeiture rate will be approximately 5%.

The Company accounts for stock options granted to non-employees on a fair-value basis in accordance with EITF No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services,* and FASB Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans an Interpretation of APB Opinion No. 15 and 25.*

***Recently Issued Accounting Standards***

In July 2006, the FASB issued FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes , an interpretation of FASB Statement No. 109, Accounting for Income Taxes . The Interpretation establishes criteria for recognizing and measuring the financial statement tax effects of positions taken on a company s tax returns. A two-step process is prescribed whereby the threshold for recognition is a more-likely-than-not test that the tax position will be sustained upon examination and the tax position is measured at the largest amount of benefit that is greater than 50 percent likely of being realized upon ultimate settlement. The Company currently recognizes a tax position if it is probable of being sustained. The Interpretation is effective for the Company beginning January 1, 2007 and will be applicable to all tax positions upon initial adoption. Only tax positions that meet the more-likely-than-not recognition threshold at the effective date may continue to be recognized upon adoption of the Interpretation. The Company is evaluating the potential effects the Interpretation may have on its consolidated financial position or results of operations, but no material consequence is expected.

In September 2006, the Staff of the SEC provided guidance on the need to consider the effects of prior year misstatements in quantifying the materiality of current year misstatements - Staff Accounting Bulletin No. 108 (SAB 108). According to SAB 108, a registrant must consider both the current year effect of an accounting error as well as the earnings effect of adjusting the balance sheet for related previous errors that might individually have been immaterial but that would be material to the current year s earnings if corrected on a catch-up basis. SAB 108 permits adjustment for the cumulative effect of errors

relating to prior years in the carrying amount of assets and liabilities as of the beginning of the current fiscal year with an offsetting adjustment to the opening balance of retained earnings in the year of adoption. SAB 108 further requires the adjustment of any prior quarterly financial statements within the year of adoption for the effects of such errors on the quarters when the information is next presented. Such adjustments do not require reports previously filed with the SEC to be amended. SAB 108 is effective for annual financial statements covering fiscal years ending after November 15, 2006 for those registrants electing not to restate prior periods. The Company is in the process of evaluating SAB 108 but does not believe it will have a material effect on its consolidated financial statements or results of operations.

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, Fair Value Measurements (SFAS No. 157). The new standard provides guidance on the definition of and how to measure fair value and what sources of information are to be used in such measurements. It also prescribes expanded disclosures about fair value measurements contained in the financial statements. The Company is in the process of evaluating the new standard which is not expected to have any effect on its financial position or results of operations although financial statement disclosures will be revised to conform to the new guidance. The pronouncement, including the new disclosures, is effective for the Company as of the first quarter of 2008.

## (3) Beneficial Conversion Feature

In May 2003, the Company completed a private placement of 112,790,233 shares of Series J mandatorily redeemable convertible preferred stock at $0.49 per share for an aggregate purchase price of approximately $55,267,000.

As part of this financing, the original conversion price of the Series A through Series I preferred stock was reduced as a result of anti-dilution adjustments, which resulted in a beneficial conversion amounting to $80,730,286 in accordance with EITF No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios* and EITF No. 00-27, *Application of Issue No. 98-5 to Certain Convertible Instruments*. The beneficial conversion charge of $20,860,491 relating to Series A, Series B, Series C, Series F and Series H convertible preferred stock, which were not mandatorily redeemable and could be converted at any time at the option of the holders to common stock, was recorded as an immediate charge to additional paid-in capital. The remaining beneficial conversion amount of $59,869,795 related to Series E and Series I convertible preferred stock, which were mandatorily redeemable at any time on or after June 30, 2008, was being accreted ratably over the mandatory redemption period. Such accretion amounted to $29,058,676 and $8,722,382 for the nine-month periods ended September 30, 2006 and 2005, respectively, and is charged to additional paid-in capital. Upon completion of the company s initial public offering on February 9, 2006, the remaining beneficial conversion amount was fully accreted.

In addition, the issuance of Series J mandatorily redeemable convertible preferred stock resulted in a beneficial conversion amounting to $39,994,812 in accordance with EITF No. 98-5. The beneficial conversion is calculated based on the estimated fair value of the Company s common stock price per share at the date of issuance of Series J preferred stock of approximately $10.14 per share of common stock, which was calculated based on the estimated projected midpoint of the range of the Company s initial public offering price per common share, which was planned in the fourth calendar quarter of 2003, and the stock price appreciation in comparable public companies from May 2003 to August 2003. The beneficial conversion feature was being accreted ratably over the mandatory redemption period, with a charge to additional paid-in capital of $19,412,064 and $5,826,812 for the nine-month periods ended September 30, 2006 and 2005, respectively. Upon completion of the Company s initial public offering on February 9, 2006, the remaining beneficial conversion amount was fully accreted.

**(4)** Mandatorily Redeemable Convertible Preferred Stock and Convertible Preferred Stock

The board of directors of the Company had authorized 141,754,865 shares of convertible preferred stock, designated as Series A, B, C, D, E, F, G, H, I, J and K preferred stock (Series A, Series B, Series C, Series D, Series E, Series F, Series G, Series H, Series I, Series J and Series K; collectively, the Preferred Stock). Series E, Series I, Series J and Series K are mandatorily redeemable convertible preferred stock (Redeemable Preferred Stock). Upon the Company s initial public offering in February 2006, all the Company s outstanding Preferred Stock was converted into common stock.

The terms of the Preferred Stock were as follows:

***(a) Dividends***

The Preferred Stock (except Series J and Series K) were entitled to noncumulative dividends prior to and in preference to dividends declared or paid on the common stock, at the rate of $0.10 per share per annum for Series A through Series H and at the rate of $0.39 per share per annum for Series I when and if declared by the board of directors. Dividends on Series J and Series K were cumulative and accrued on each share of Series J Preferred Stock and Series K Preferred Stock commencing on the date of issuance, whether or not earned or declared at the rate of $0.0392 per share per annum for Series J and at the rate of $0.60 per share per annum for Series K, based on the original issue price of Series J Preferred Stock and Series K Preferred Stock, prior and in preference to any declaration or payment of any dividend on any other Series of Preferred Stock holders (Series A through Series I). Accrued dividends for Series J and K were $11.1 million and $1.7 million as of December 31, 2005. Upon the Company s initial public offering in February 2006, the total dividend accruals of $11.6 million and $1.8 million for Series J and K, respectively, were reversed. The net reversal of dividends for the nine-month period ended September 30, 2006 was $12.7 million, including accruals made from the beginning of the year up to the initial public offering.

***(b) Conversion***

The Preferred Stock automatically converted into common stock upon the completion of the Company s initial public offering on February 9, 2006.

| Preferred stock | Shares outstanding at February 9, 2006 | Conversion Price | Shares of Common Stock |
|---|---|---|---|
| Series A | 1,306,068 | $ 9.06 | 144,074 |
| Series B | 900,000 | 11.86 | 151,820 |
| Series C | 333,333 | 14.64 | 68,339 |
| Series D | | 11.86 | |
| Series E | 7,472,612 | 13.81 | 1,461,363 |
| Series F | 2,300,000 | 13.81 | 449,803 |
| Series G | | (1 ) | |
| Series H | 1,575,229 | 15.34 | 333,827 |
| Series I | 10,204,047 | 17.11 | 2,319,457 |
| Series J | 112,790,233 | 7.64 | 7,230,118 |
| Series K | 1,533,327 | 9.75 | 1,179,478 |

(1) The product of (x) the number of Series G Preferred Stock surrendered and (y) the number determined by dividing (i) the greater of $31.20 or 80% of the closing price per share of the most recently completed bona fide equity financing of the Company prior to the issuance of Series G Preferred Stock by (ii) the Series G conversion price in effect.

**(5)** Common Stock Options, Warrants and Restricted Stock

On June 18, 1999, the Company s board of directors approved the adoption of the Acorda Therapeutics, Inc. 1999 Employee Stock Option Plan (the 1999 Plan). All employees of the Company were eligible to participate in the 1999 Plan, including executive officers, as well as directors, independent contractors, and agents of the Company. The 1999 Plan also covers the issuance of restricted stock. The 1999 Plan is administered by the Compensation Committee of the Board of Directors, which selects the individuals to be granted options and stock appreciation rights, determines the time or times at which options and stock appreciation rights shall be granted under the 1999 Plan, determines the number of shares to be granted subject to any option or stock appreciation right under the 1999 Plan and the duration of each option and stock appreciation right, and makes any other determinations necessary, advisable, and/or appropriate to administer the 1999 Plan. Under the 1999 Plan, each option granted expires no later than the tenth anniversary of the date of its grant. Compensation expense is calculated using a Black-Scholes calculation with the expense being recognized over the vesting period. No option may be granted pursuant to the 1999 Plan more than ten years after the date on which the 1999 Plan was adopted by the board of directors and any option granted under the 1999 Plan shall, by its terms, not be exercisable more than ten years after the date of grant. The number of shares authorized for issuance under the 1999 Plan is 3,186,856.

On January 12, 2006, the Company s board of directors approved the adoption of the Acorda Therapeutics, Inc. 2006 Employee Incentive Plan (the 2006 Plan). This 2006 Plan shall serve as the successor to the Company s 1999 Plan, as amended, and no further option grants or stock issuances shall be made under the 1999 Plan after the effective date, as determined under Section 14 of the 2006 Plan. All employees of the Company are eligible to participate in the 2006 Plan, including executive officers, as well as directors, independent contractors, and agents of the Company. The 2006 Plan also covers the issuance of restricted stock. The 2006 Plan is administered by the Compensation Committee of the board of directors, which selects the individuals to be granted options and stock appreciation rights, determines the time or times at which options and stock appreciation rights shall be granted under the 2006 Plan, determines the number of shares to be granted subject to any option or stock appreciation right under the 2006 Plan and the duration of each option and stock appreciation right, and makes any other determinations necessary, advisable, and/or appropriate to administer the 2006 Plan. Under the 2006 Plan, each option granted expires no later than the tenth anniversary of the date of its grant. Compensation expense is calculated using a Black-Scholes calculation with the expense being recognized over the vesting period. No option may be granted pursuant to the 2006 Plan more than ten years after the date on which the 2006 Plan was adopted by the board of directors and any option granted under the 2006 Plan shall, by its terms, not be exercisable more than ten years after the date of grant. Subject to increase under Section 3(b) of the 2006 Plan and adjustment under Section 10 of the 2006 Plan, the number of shares of common stock reserved for issuance pursuant to awards made under the 2006 Plan shall not exceed 3,000,000 shares of stock. The total number of shares of common stock available for issuance under this 2006 Plan, including shares of common stock subject to the then outstanding awards, shall automatically increase on January 1 of each year during the term of this plan, beginning 2007, by a number of shares of common stock equal to 4% of the outstanding shares of common stock on that date, unless otherwise determined by the Board of Directors. Upon the exercise of options in the future, the Company intends to issue new shares.

The effects of applying SFAS No. 123R in a particular year, may not be representative of the effects on reported net income or loss for future years. The fair value of each option granted is estimated on the date of grant using an option-pricing model with the following weighted average assumptions:

| | Three-month period ended September 30 | | Nine-month period ended September 30, | |
|---|---|---|---|---|
| | 2006 | 2005 | 2006 | 2005 |
| Employees and directors: | | | | |
| Estimated volatility | 70.8 % | 78.1 % | 72.3 % | 78.4 % |
| Expected life in years | 5.4 | 5.0 | 5.4 | 5.0 |
| Risk free interest rate | 4.9 % | 4.1 % | 4.7 % | 4.1 % |
| Dividend yield | | | | |

The Company estimated volatility for purposes of computing compensation expense on its employee and non-employee options using the volatility of public companies that the Company considered comparable. The expected life used to estimate the fair value of non-employee options is equal to the contractual life of the option granted, which is 10 years. The expected life used to estimate the fair value of employee options is 5.4 years. The Company based this assumption on the 50th percentile of 10 peer companies choices for expected life for their valuations.

The weighted average fair value per share of options granted to employees and directors for the three-month periods ended September 30, 2006 and 2005 amounted to approximately $4.78 and $4.10 respectively. The weighted average fair value per share of options granted to employees and directors for the nine-month periods ended September 30, 2006 and 2005 amounted to approximately $3.86 and $4.16 respectively. No options were granted to non-employees for the nine-month periods ended September 30, 2006 and 2005.

During the three-month period ended September 30, 2006, the Company granted 60,600 stock options to employees under the 2006 Plan. During the nine-month period ended September 30, 2006, the Company granted 844,340 stock options to employees and directors under the 2006 Plan. The stock options were issued with a weighted average exercise price of $6.10 per share. 100 of these options vested immediately, 32,698 of these options will vest over a three-year vesting schedule, and 811,542 will vest over a four-year vesting schedule. As a result of these grants the total compensation charge to be recognized over the service period is $2,877,572, of which $422,936 was recognized during the nine-month period ended September 30, 2006.

Compensation costs for options and restricted stock granted to employees and directors amounted to $962,425 and $1,489,865 for the three-month periods ended September 30, 2006 and 2005, respectively. Compensation costs for options and restricted stock granted to employees and directors amounted to $2,905,670 and $3,464,128 for the nine-month periods ended September 30, 2006 and 2005, respectively. There were no compensation costs capitalized in our inventory balances. Compensation expense for options and restricted stock granted to employees and directors are classified between research and development, sales and marketing and general and administrative expense based on employee job function. Compensation costs recognized during the nine-month period ended September 30, 2006 were $312,445 less than would have been recorded had the Company not adopted SFAS No. 123R and it continued to apply the fair value provisions of SFAS No. 123.

Options granted to non-employees vest immediately or over a one to four year period based upon future service requirements. Compensation cost for options granted to non-employees amounted to $1,199 and $800 for the nine-month periods ended September 30, 2006 and 2005, respectively. The amount of compensation cost to be recorded in the future for options granted to non-employees is subject to change each reporting period based upon changes in the estimated fair value of the Company s common stock,

estimated volatility and risk free interest rate until the non-employee completed performance under the option agreement.

A summary of share-based compensation activity for the nine-month period ended September 30, 2006 is presented below:

***Stock Option Activity***

| | Number of Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term | Intrinsic Value |
|---|---|---|---|---|
| Balance at January 1, 2006 | 1,770,494 | $ 3.44 | | |
| Granted | 844,340 | 6.10 | | |
| Forfeited | (37,293) | 6.00 | | |
| Exercised | (13,460) | 1.56 | | |
| Balance at September 30, 2006 | 2,564,081 | $ 4.29 | 8.0 | $ 10,140,921 |
| Vested and expected to vest at September 30, 2006 | 2,442,082 | $ 4.48 | 7.9 | $ 9,836,416 |
| Exercisable at September 30, 2006 | 1,394,882 | $ 3.88 | 7.0 | $ 7,428,565 |

| Nonvested stock options | Number of Shares | Weighted Average Grant Date Fair Value |
|---|---|---|
| Nonvested at January 1, 2006 | 556,460 | $ 10.91 |
| Granted | 844,340 | 6.10 |
| Vested | (206,473) | 7.25 |
| Forfeited | (25,128) | 7.84 |
| Nonvested at September 30, 2006 | 1,169,199 | $ 8.15 |

| Range of exercise price | Options Outstanding Outstanding as of September 30, 2006 | Weighted-average remaining contractual life | Weighted-average exercise price | Options Exercisable Exercisable as of September 30, 2006 | Weighted-average exercise price |
|---|---|---|---|---|---|
| $1.56-$ 4.81 | 1,125,050 | 6.72 | $ 2.66 | 1,057,069 | $ 2.59 |
| $5.85-$12.48 | 1,434,961 | 8.95 | 7.20 | 333,743 | 7.75 |
| $23.40 | 4,070 | 4.94 | 23.40 | 4,070 | 23.40 |
| | 2,564,081 | 7.96 | $ 5.23 | 1,394,882 | $ 3.88 |

Unrecognized compensation costs for unvested awards as of September 30, 2006 totaled $5.4 million and is expected to be recognized over a weighted average period of approximately 1.6 years.

***Restricted Stock Activity***

| Restricted Stock | Number of Shares | Average grant date fair value |
|---|---|---|
| Nonvested at January 1, 2006 | 755,083 | $ 9.73 |
| Granted | | |
| Vested | | |
| Forfeited | (846) | 9.75 |
| Nonvested at September 30, 2006 | 754,237 | $ 9.73 |

Unrecognized compensation costs for restricted stock as of September 30, 2006 totaled $2.3 million and is expected to be recognized over a weighted average period of approximately 0.9 years.



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## (6) Product Returns

As part of the terms of the Zanaflex asset purchase agreement, any product returned within six months of acquisition date was the obligation of Elan. Beginning in January 2005, such returns became a liability of the Company. Through June 30, 2006, the Company accepted $4.7 million in total product returns, of which $2.3 million was for product not sold by the Company. The Company accepts product returned up to twelve months subsequent to its expiration date. The Company recorded a charge to discounts and allowances of $4.1 million in the year ending December 31, 2004 to record an estimated liability for returns of Zanaflex tablets sold by Elan. The Company continued to receive returns of the product sold by Elan through June 2006 at which point the right of return expired and the remaining $1.8 million accrual balance was reversed through discounts and allowances.

As part of the Zanaflex acquisition, the Company purchased certain tablet inventory from Elan that expired within one year. The majority of this product was sold by the Company during July 2004 through March 2005. The Company received returns of the product sold by Elan through June 2006 at which point the right of return expired and the company recognized the $2.2 million deferred revenue balance as gross sales.

## (7) Income Taxes

The Company had available net operating loss carryforwards (NOL) of approximately $148.3 million and $130.0 million as of September 30, 2006 and December 31, 2005 respectively, for federal and state income tax purposes, which are available to offset future federal and state taxable income, if any, and expire between 2010 and 2025. The Company also has research and development tax credit carryforwards of approximately $1.3 million and $1.2 million as of September 30, 2006 and December 31, 2005, respectively, for federal income tax reporting purposes that are available to reduce federal income taxes, if any, and expire in future years beginning in 2018.

At September 30, 2006 and December 31, 2005, the Company had a deferred tax asset of $91.4 million and $84.4 million, respectively, offset by a full valuation allowance. Since inception, the Company has incurred substantial losses and expects to incur substantial losses in future periods. The Tax Reform Act of 1986 (the Act ) provides for a limitation of the annual use of NOL and research and development tax credit carryforwards (following certain ownership changes, as defined by the Act) that could significantly limit the Company s ability to utilize these carryforwards. The Company has experienced various ownership changes, as a result of past financings and its initial public offering in February 2006. Accordingly, the Company s ability to utilize the aforementioned carryforwards may be limited. Additionally, because U.S. tax laws limit the time during which these carryforwards may be applied against future taxes, the Company may not be able to take full advantage of these attributes for federal income tax purposes. Because of the above mentioned factors, the Company has not recognized its net deferred tax assets as of and for all periods presented. Accordingly, the Company has provided a full valuation allowance against its net deferred tax assets and no tax benefit has been recognized relative to its pretax losses.

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

The following discussion and analysis of our consolidated financial condition and results of operations should be read in conjunction with our unaudited consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q.

**Background**

Since we commenced operations in 1995, we have devoted substantially all of our resources to the identification, development and commercialization of novel therapies that improve neurological function in people with Multiple Sclerosis (MS), Spinal Cord Injury (SCI) and other disorders of the CNS. Our marketed drug, Zanaflex Capsules, is FDA-approved for the management of spasticity. Our preclinical programs also target MS and SCI, as well as other CNS disorders, including stroke and traumatic brain injury.

From 1995 until mid-2004, we were engaged almost exclusively in the in-licensing of compounds and the preclinical and clinical development of these compounds. We licensed the rights to Fampridine-SR from Elan for the treatment of SCI in 1997. In September 2003 we entered into an amended license agreement with Elan that granted us exclusive worldwide rights to Fampridine-SR in return for the payment of royalties and milestones. In addition, we entered into a supply agreement under which Elan provides Fampridine-SR based upon an agreed upon price schedule.

We have expended a significant portion of our funds on a number of clinical trials for Fampridine-SR, our most advanced product candidate, including two Phase 3 clinical trials of Fampridine-SR in SCI and a Phase 2 clinical trial in MS, the results of which were announced in March 2004. An earlier Phase 2 clinical trial in MS was completed in 2001. In mid-2004, we decided to put our clinical trials of Fampridine-SR in SCI on hold, and refocused our efforts on our ongoing Fampridine-SR in MS program, leading to our current Phase 3 clinical trial of Fampridine-SR for improvement of walking ability in people with MS. We may resume our clinical development of Fampridine-SR for SCI in the future.

In September 2006 we announced positive results from the Phase 3 clinical trial of our lead product candidate, Fampridine-SR in MS. Statistical significance was achieved on all three efficacy criteria defined in the Special Protocol Assessment (SPA) by the FDA. A significantly greater proportion of people taking Fampridine-SR were responders, that is, had a consistent improvement in walking speed, the study s primary outcome, compared to people taking placebo (34.8 percent vs. 8.3 percent) as measured by the Timed 25-Foot Walk ($p<0.001$). In addition, the effect was maintained in this study throughout the 14-week treatment period ($p<0.001$) and there was a statistically significant improvement in the 12-Item MS Walking Scale (MSWS-12) for walking responders vs. non-responders ($p<0.001$).

The average increase in walking speed over the treatment period compared to baseline was 25.2 percent for the drug responder group vs. 4.7 percent for the placebo group. Increased response rate on the Timed 25-Foot Walk was seen across all four major types of MS. In addition, statistically significant increases in leg strength were seen in both the Fampridine-SR Timed Walk responders ($p<0.001$) and the Fampridine-SR Timed Walk non-responders ($p=0.046$) compared to placebo. The Company intends to discuss the results from the trial with the FDA to determine the next steps.

In July 2004, we acquired all of Elan s research, development, distribution, sales and marketing rights to Zanaflex Capsules and Zanaflex tablets in the United States. These products are FDA-approved for the management of spasticity. We made an upfront payment to Elan of $2.0 million and are obligated to pay royalties on sales and to make milestone payments upon achievement of specified sales levels. To date, we have achieved two milestones, the first triggering payment of $1.5 million, 50% of which was paid in the first quarter of 2005 and 50% of which was paid in the first quarter of 2006, and the second payment of $3.0 million in the first quarter of 2006. We expect to reach the third milestone level in the fourth quarter of 2006 which would trigger a $5.0 million payment that would be payable in the first quarter 2007. There

are additional future milestones that could result in payments by us to Elan of $10.0 million. As part of our Zanaflex acquisition, we entered into a long-term supply agreement with Elan under which Elan provides us with Zanaflex Capsules. Elan also assigned us its rights under an agreement with Novartis for the supply of tizanidine and Zanaflex tablets.

Our marketing efforts are focused on Zanaflex Capsules, which we launched in April 2005. Zanaflex tablets lost compound patent protection in 2002 and both Zanaflex Capsules and Zanaflex tablets compete with 12 generic tizanidine products. Although we currently distribute Zanaflex tablets, we do not, and do not intend to, actively promote Zanaflex tablets. As a result, prescriptions for Zanaflex tablets have declined and may continue to decline. Our goal is to convert as many sales of Zanaflex tablets and generic tizanidine tablets to sales of Zanaflex Capsules as possible. We believe that sales of Zanaflex Capsules will constitute a significant portion of our total revenue for the foreseeable future.

In late 2004, we began establishing our own specialist sales force in the United States, which consisted of 32 sales professionals as of September 30, 2006. This sales force has targeted neurologists and other prescribers who specialize in treating people with conditions that involve spasticity. Members of this sales force also call on managed care organizations, pharmacists and distribution customers. In August 2005, we entered into an agreement with Cardinal Health, under which it provided approximately 160 sales representatives to market Zanaflex Capsules, on a non-exclusive basis, to primary care physicians in the United States. Sales in the primary care market did not reach the targets specified in our agreement. We terminated the agreement with Cardinal Health and made a payment of $125,000 in connection with that termination during the three month period ended September 30, 2006.

In May 2005 we retained Access Worldwide Communications, Inc. (Access) to provide a small, dedicated sales force of pharmaceutical telesales professionals to contact primary care, specialty physicians and pharmacists. In February 2006 we expanded the scope of the arrangement with Access and transferred some of the primary care physician contacts previously covered by Cardinal Health to Access. In addition, we initiated a pilot program with Innovex Inc. that provided six part-time representatives making exclusive calls promoting Zanaflex Capsules to primary care physicians, focusing on some of the contacts previously covered by Cardinal Health. In October 2006 we gave notice to Innovex Inc. of termination of the parties contract sales force agreement and announced that we will expand our sales force to 65 people, including 52 area business managers who will call on specialists as well as primary care physicians who are high-volume prescribers.

In September 2003, we entered into a collaboration agreement with Teva to jointly develop and promote in the United States products containing valrocemide, pursuant to which we made an initial payment to Teva of $2.0 million. We and Teva amicably terminated this collaboration agreement in June 2005 and in connection with the termination we paid Teva approximately $3.1 million. We and Teva have no further obligations to each other under this collaboration agreement.

In December 2005, we entered into a revenue interests assignment agreement with Paul Royalty Fund (PRF) pursuant to which we assigned PRF the right to receive a portion of our net revenues (as defined in the agreement, which definition is different from our net revenues as determined in accordance with generally accepted accounting principles) from Zanaflex Capsules, Zanaflex tablets and any future Zanaflex products. The agreement covers all such Zanaflex net revenues generated from October 1, 2005 through and including December 31, 2015, unless the agreement is terminated earlier. In consideration for the assignment, PRF paid us $15.0 million at signing. We used approximately $3.0 million of that payment to repay a portion of the amount we owe to GE Capital, $200,000 of that payment for expenses associated with such repayment and $500,000 of that payment to reimburse PRF for expenses it incurred in the transaction. Under our agreement with PRF, we are required to use the remainder of the amount we received at signing and any other amounts we receive under the agreement to support commercialization, sales, marketing, clinical and regulatory activities and other financial obligations related specifically and

solely to our Zanaflex operations. If our Zanaflex net revenues in 2005 had equaled or exceeded $11.0 million and our Zanaflex net revenues in the first six months of 2006 had equaled or exceeded $16.0 million, at our election, PRF would also have been required to loan us an additional $5.0 million. We did not meet this milestone. If our Zanaflex net revenues in 2006 equal or exceed $33.5 million, at our discretion, PRF would be required to loan us an additional $5.0 million. If we meet this milestone and decide to borrow these additional funds, we would be required to pay PRF $5.0 million on December 1, 2010. For more information regarding our agreement with PRF, see Liquidity and Capital Resources Financing Arrangements.

The Company completed an initial public offering on February 9, 2006. As part of that offering, 6,075,614 shares of the Company s common stock were sold, resulting in net proceeds of approximately $31.5 million after deducting the underwriting discount and offering expenses payable by the Company.

Upon the closing of the initial public offering, all of the Company s convertible preferred stock and mandatorily redeemable convertible preferred stock was converted into 13,338,278 shares of common stock. This conversion resulted in the following: (a) recognition of the unamortized portion of a beneficial conversion charge of $48.5 million; (b) recognition of the unamortized portion of issuance costs relating to Series E, Series I, Series J and Series K preferred stock of $271,000; and (c) reversal of accrued preferred dividends on Series J and Series K preferred stock of $12.7 million.

The Company completed a private placement on October 6, 2006. As part of that offering, 3,230,769 shares of the Company s common stock were sold, resulting in net proceeds to the Company of approximately $29.8 million net of issuance costs.

**Results of Operations**

***Three-Month Period Ended September 30, 2006 Compared to September 30, 2005***

*Gross Sales*

We recognized revenue from the sale of Zanaflex Capsules and Zanaflex tablets of $6.5 million for the three-month period ended September 30, 2006, as compared to $2.8 million for the three-month period ended September 30, 2005. The increase was due to an increase in prescriptions primarily related to our increased sales force. We recognize product sales using a deferred revenue recognition model meaning that shipments to wholesalers are recorded as deferred revenue and only recognized as revenue when end-user prescriptions of the product are reported.

*Discounts and Allowances*

We recorded discounts and allowances of $381,000 for the three-month period ended September 30, 2006 as compared to $147,000 for the three-month period ended September 30, 2005. Discounts and allowances are recorded when Zanaflex Capsules and Zanaflex tablets are shipped to wholesalers. Discounts and allowances for the three-month period ended September 30, 2006 consisted of $173,000 in cash discounts and $208,000 in allowances for chargebacks and rebates. Discounts and allowances for the three-month period ended September 30, 2005, consisted of $86,000 in cash discounts and allowances of $61,000 for chargebacks and rebates.

*Grant Revenue*

Grant revenue for the three-month period ended September 30, 2006 was $70,000 compared to $30,000 for the three-month period ended September 30, 2005. Grant revenue is recognized when the related research expenses are incurred and our performance obligations under the terms of the respective contract are satisfied.

*Cost of Sales*

We recorded cost of sales of $1.7 million for the three-month period ended September 30, 2006 as compared to $707,000 for the three-month period ended September 30, 2005. The increase was due to the increase in gross sales. Cost of sales for the three-month period ended September 30, 2006 consisted of $629,000 in inventory costs related to recognized revenue, $810,000 in royalty fees, based on net product shipments, $185,000 in amortization of intangible assets, an amount unrelated to either the volume of shipments or the amount of revenue recognized, and $29,000 in period costs related to packaging, freight, and stability testing. Cost of sales for the three-month period ended September 30, 2005 consisted of $355,000 in inventory costs related to recognized revenue, $193,000 in royalty fees, $83,000 in amortization of intangible assets and $76,000 in costs related to packaging, freight, and stability testing. Payments to and interest expense related to our Paul Royalty Fund transaction discussed below in the section entitled Liquidity and Capital Resources does not impact our cost of sales.

*Research and Development*

Research and development expenses for the three-month period ended September 30, 2006 were $2.6 million as compared to $2.5 million for the three-month period ended September 30, 2005, an increase of approximately $100,000, or 3%. The MS clinical development program expense increased $70,000 or 6% to $1.3 million for the three-month period ended September 30, 2006, due to the continuation of increased activity in our Phase 3 clinical trial program.

Other contract expenses decreased to $38,000 in the three-month period ended September 30, 2006, from $136,000 in the three-month period ended September 30, 2005, a decrease of $98,000 or 72%. Operating expenses for clinical development and preclinical research and development was $1.2 million for the three-month period ended September 30, 2006, compared to $1.1 million in the three-month period ended September 30, 2005, an increase of $100,000 or 4%.

*Sales and Marketing*

Sales and marketing expenses for the three-month period ended September 30, 2006 were $5.3 million compared to $4.3 million for the three-month period ended September 30, 2005, an increase of $1.0 million or 24%. This increase was primarily attributable to an increase in salaries and benefits of $774,000 and other selling related expenses of $280,000 resulting from the expansion of our Zanaflex Capsules specialist sales force. In addition, marketing and distribution and sales administration expense related to the launch of Zanaflex Capsules and the distribution of Zanaflex tablets decreased by $44,000.

*General and Administrative*

General and administrative expenses for the three-month period ended September 30, 2006 were $3.4 million compared to $2.4 million for the three-month period ended September 30, 2005, an increase of approximately $1.0 million or 43%. The increase was primarily attributable to the addition of a Medical and Regulatory Affairs department with $440,000 of related expenses. General and administrative staff and salaries increased $200,000, insurance expense increased by approximately $234,000 and other third party services increased by $155,000 resulting from our initial public offering.

*Other Income (Expense)*

Other income (expense) was an expense of $418,000 for the three-month period ended September 30, 2006 compared to expense of $215,000 for the three-month period ended September 30, 2005. Interest expense increased by $462,000 principally due to interest expense related to the Paul Royalty Fund revenue interest agreement, partially offset by a $191,000 increase in interest income due to an increase in

cash balances resulting from the completion of our initial public offering of common stock in February 2006 and a $69,000 increase in other income primarily due to a New York State tax refund.

*Beneficial Conversion Feature, Accretion of Issuance Costs, Preferred Dividends and Fair Value of Warrants Issued to Convertible Preferred Stockholders*

Charges related to preferred stock decreased from $6.2 million for the three-month period ended September 30, 2005, to no charge for the three-month period ended September 30, 2006, due to the recognition of the remaining unamortized portion of beneficial conversion charges and issuance costs and reversal of the cumulative preferred dividend upon our completion of our initial public offering of our common stock in February 2006. No further charges are necessary.

***Nine-Month Period Ended September 30, 2006 Compared to September 30, 2005***

*Gross Sales*

We recognized revenue from the sale of Zanaflex Capsules and Zanaflex tablets of $18.3 million for the nine-month period ended September 30, 2006, as compared to $3.2 million for the nine-month period ended September 30, 2005. The increase was due to an increase in prescriptions primarily related to our increased sales force. We recognize product sales using a deferred revenue recognition model meaning that shipments to wholesalers are recorded as deferred revenue and only recognized as revenue when end-user prescriptions of the product are reported. During the nine-month period ended September 30, 2006, we adopted IMS Heath data as the prescription data source used as the basis for recognizing shipments of Zanaflex product as revenue.

As part of the Zanaflex acquisition, the Company purchased certain tablet inventory from Elan that expired within one year. The majority of this product was sold by the Company during July 2004 through March 2005. The Company deferred revenue for this product due to the uncertainty of future returns. The Company received returns of the product sold by Elan through June 2006 at which point the right of return expired and the Company recognized the $2.2 million deferred revenue balance as gross sales.

Gross sales in the nine-month period ended September 30, 2005 consisted of Zanaflex tablet revenue recognized based on gross prescription data which we began receiving in March 2005, which is when we began receiving prescription data for tablets containing a code clearly identifying these prescriptions as having been filled with product we sold. We did not recognize revenue from Zanaflex Capsules prescription data until after our launch of the product in April 2005.

*Discounts and Allowances*

We recorded negative discounts and allowances of $955,000 for the nine-month period ended September 30, 2006 as compared to $992,000 for the nine-month period ended September 30, 2005. As part of the Zanaflex acquisition in 2004, we agreed to accept any returns of Zanaflex tablets that were returned subsequent to January 17, 2005, including returns of product that was originally sold by Elan. Product returns prior to that date were the responsibility of Elan. As a result of this agreement, in December 2004 we recorded a return liability of $4.1 million which was our best estimate of the Zanaflex tablet returns for which we could potentially become liable. Our obligation to continue to accept these returns ended in June 2006. As a result of the returns we accepted since 2004, the net balance remaining on this liability was approximately $1.8 million. We reversed this liability in June which resulted in a reduction in discounts and allowances of $1.8 million and a corresponding reduction of the product return liability on our balance sheet.

Discounts and allowances are recorded when Zanaflex Capsules and Zanaflex tablets are shipped to wholesalers. Discounts and allowances for the nine-month period ended September 30, 2006 consisted of a negative $1.8 million due to the Elan product return liability reversal described above, $405,000 in cash

discounts and $440,000 in allowances for chargebacks and rebates. Discounts and allowances for the nine-month period ended September 30, 2005, consisted of $684,000 in cash discounts and allowances of $308,000 for chargebacks and rebates.

*Grant Revenue*

Grant revenue for the nine-month period ended September 30, 2006 was $372,000 compared to $184,000 for the nine-month period ended September 30, 2005. Grant revenue is recognized when the related research expenses are incurred and our performance obligations under the terms of the respective contract are satisfied.

*Cost of Sales*

We recorded cost of sales of $4.0 million for the nine-month period ended September 30, 2006 as compared to $2.3 million for the nine-month period ended September 30, 2005. The increase was due to the increase in gross sales. Cost of sales for the nine-month period ended September 30, 2006 consisted of $1.7 million in royalty fees, based on net product shipments, $1.6 million in inventory costs related to recognized revenue, $554,000 in amortization of intangible assets, an amount unrelated to either the volume of shipments or the amount of revenue recognized, and $166,000 in period costs related to packaging, freight, and stability testing. Cost of sales for the nine-month period ended September 30, 2005 consisted of $1.2 million in royalty fees, $561,000 in inventory costs related to recognized revenue, $275,000 in costs related to packaging, freight, and stability testing and $249,000 in amortization of intangible assets. Payments to and interest expense related to our Paul Royalty Fund transaction discussed below in the section entitled Liquidity and Capital Resources does not impact our cost of sales.

*Research and Development*

Research and development expenses for the nine-month period ended September 30, 2006 were $8.9 million as compared to $9.7 million for the nine-month period ended September 30, 2005, a decrease of approximately $760,000, or 8%. The decrease in research and development expenses was primarily due to a decrease in expenses related to the termination of the valrocemide collaboration agreement in June 2005. The MS clinical development program expense increased from $2.3 million for the nine-month period ended September 30, 2005 to $5.1 million for the nine-month period ended September 30, 2006, an increase of $2.8 million or 123%, due to the continuation of increased activity in our Phase 3 clinical trial program.

Other contract expenses decreased to $395,000 in the nine-month period ended September 30, 2006, from $3.7 million in the nine-month period ended September 30, 2005, a decrease of $3.3 million or 89%. This decrease was primarily due to a decrease in expenses related to the termination of the valrocemide collaboration agreement in June 2005. Operating expenses for clinical development and preclinical research and development was $3.3 million for the nine-month period ended September 30, 2006, compared to $3.5 million in the nine-month period ended September 30, 2005, a decrease of $208,000 or 6%.

*Sales and Marketing*

Sales and marketing expenses for the nine-month period ended September 30, 2006 were $14.1 million compared to $9.7 million for the nine-month period ended September 30, 2005, an increase of $4.4 million or 46%. This increase was primarily attributable to a $2.1 million increase in salaries and benefits related to the expansion of the sales force, a $1.2 million increase in marketing and distribution and sales administration expense related to the launch of Zanaflex Capsules and the distribution of Zanaflex tablets and a $1.2 million increase in other selling related expenses resulting from the expansion of our Zanaflex Capsules specialist sales force. Sales and marketing expenses are expected to trend higher over the remainder of the year.

*General and Administrative*

General and administrative expenses for the nine-month period ended September 30, 2006 were $9.3 million compared to $6.3 million for the nine-month period ended September 30, 2005, an increase of approximately $3.0 million or 46%. The increase was primarily attributable to the addition of a Medical and Regulatory Affairs department with $1.7 million of related expenses. Insurance expense increased by approximately $627,000 and general and administrative staff and salaries increased $643,000 resulting from our initial public offering.

*Other Income (Expense)*

Other income (expense) was an expense of $750,000 for the nine-month period ended September 30, 2006 compared to expense of $476,000 for the nine-month period ended September 30, 2005. Interest expense increased by $850,000 principally due to interest expense related to the Paul Royalty Fund revenue interest agreement, partially offset by a $506,000 increase in interest income due to an increase in cash balances resulting from the completion of our initial public offering of common stock in February 2006 and a $71,000 increase in other income primarily due to a New York State tax refund.

*Cumulative effect of change in accounting principle*

On January 1, 2006, we adopted the provisions of Statement of Financial Accounting Standards 123 (revised 2004), Share-Based Payment (SFAS 123R), which requires that the costs resulting from all share-based payment transactions be recognized in the financial statements at their fair values. We adopted SFAS 123R using the modified prospective application method under which the provisions of SFAS 123R apply to new awards and to awards modified, repurchased, or cancelled after the adoption date. Additionally, compensation cost for the portion of the awards for which the requisite service has not been rendered that are outstanding as of the adoption date is recognized in the consolidated statement of operations over the remaining service period after the adoption date based on the award s original estimate of fair value. Results for prior periods have not been restated. In connection with the adoption of SFAS No. 123R, the Company changed its method of recognizing the number of outstanding instruments for which the requisite service is not expected to be rendered from an actual basis to an estimate. This change resulted in the recognition of a cumulative effect of change in accounting principle as of January 1, 2006 of $454,000 compared to none for the nine-month period ended September 30, 2005. The cumulative effect adjustment represents the difference between compensation cost recognized through the date of adoption using actual forfeitures and the cost that would have been recognized to date using estimated forfeitures.

*Beneficial Conversion Feature, Accretion of Issuance Costs, Preferred Dividends and Fair Value of Warrants Issued to Convertible Preferred Stockholders*

Charges related to preferred stock increased from $18.6 million for the nine-month period ended September 30, 2005, to $36.0 million for the nine-month period ended September 30, 2006, due to the recognition of the remaining unamortized portion of beneficial conversion charges of $48.5 million and issuance costs of $271,000 upon our completion of our initial public offering of our common stock in February 2006. These charges primarily comprised accretion of issuance costs on Series E, Series I and Series J mandatorily redeemable convertible preferred stock, accrual of preferred dividend of on Series J and Series K mandatorily redeemable convertible preferred stock, accretion of beneficial conversion feature on Series A through Series I preferred stock for reset in conversion price, accretion of beneficial conversion feature on Series J preferred stock (see Notes 3 and 4 to our consolidated financial statements). These charges were partially offset by the reversal of the cumulative preferred dividends of $12.7 million on Series J and Series K mandatorily redeemable convertible preferred stock during the nine-month

period ended September 30, 2006 as they have been forfeited through completion of the initial public offering.

**Liquidity and Capital Resources**

We have incurred annual operating losses since inception, and, as of September 30, 2006, we had an accumulated deficit of approximately $225.1 million. We have financed our operations primarily through private placements of our securities, and, to a lesser extent, from loans, government grants and, more recently, our financing arrangement with PRF and the completion of our initial public offering of our common stock in February 2006.

Our initial public offering resulted in the issuance of approximately 6.1 million shares of our common stock and the conversion of all our outstanding convertible and mandatorily convertible preferred stock. In connection with the offering of common shares, we raised approximately $31.5 million, net of underwriter and other offering fees.

We completed a private placement on October 6, 2006. As part of that offering, 3,230,769 shares of our common stock were sold, resulting in net proceeds to us of approximately $29.8 million net of issuance costs. The impact of this offering is not reflected in the September 30, 2006 interim financial statements.

*Financing Arrangements*

Since our inception and through September 30, 2006, we have raised aggregate net proceeds of $159.2 million through private placements of equity securities. In January 1997, Elan International Services, Ltd. (EIS) loaned us an aggregate of $7.5 million pursuant to two convertible promissory notes to partly fund our research and development activities, all of which was outstanding as of September 30, 2006. In August and September 2002, we financed certain of our fixed assets through two financing agreements with General Electric Capital Corporation, or GE Capital, in the aggregate amount of approximately $1.2 million, of which no balance was outstanding as of September 30, 2006. In January 2005, we entered into a $6.0 million senior secured term loan, which is collateralized by all of our personal property and fixtures, other than the property that secures our revenue interests assignment arrangement with PRF, of which $1.5 million was outstanding as of September 30, 2006. On December 23, 2005, we entered into a revenue interests assignment agreement with PRF, a dedicated healthcare investment fund, pursuant to which we assigned to PRF the right to a portion of our net revenues (as defined in the agreement) from Zanaflex Capsules, Zanaflex tablets and any future Zanaflex products.

*Investment Activities*

At September 30, 2006, cash and cash equivalents and short-term investments were approximately $18.3 million, as compared to $13.8 million at December 31, 2005. Our cash and cash equivalents consist of highly liquid investments with original maturities of three months or less at date of purchase and consist of time deposits and investments in money market funds with commercial banks and financial institutions and high-quality government and investment grade corporate bonds. Also, we maintain cash balances with financial institutions in excess of insured limits. We do not anticipate any losses with respect to such cash balances. Our short-term investments consist of corporate debt securities with original maturities greater than three months and less than one year. Our balance in these investments was $6.4 million as of September 30, 2006, as compared to $2.0 million as of December 31, 2005. As of September 30, 2006, our cash and cash equivalents were $11.9 million, as compared to $11.8 million as of December 31, 2005.

*Net Cash Used by Operations*

Net cash used by operations was $25.1 million and $16.9 million for the nine-month periods ended September 30, 2006 and 2005, respectively. Cash used by operations for the nine-month period ended

September 30, 2006 was primarily attributable to a net loss of $17.0 million, a decrease in accounts payable, accrued expenses and other current liabilities of $6.8 million, an increase in accounts receivable of $3.2 million, a decrease in tablet deferred product revenue of $2.9 million and a decrease in returns liability of $1.8 million. Cash used in operations for the nine-month period ended September 30, 2006, was partially offset by non-cash stock compensation expense of $2.9 million, an increase in capsule deferred product revenue of $2.5 million and depreciation and amortization expense of $1.3 million. Cash used by operations for the nine-month period ended September 30, 2005 was primarily attributable to a net loss of $26.0 million, an increase in inventory held by the company of $3.7 million, a decrease in returns liability of $2.1 million and an increase in prepaid expenses and other current assets of $1.5 million. Cash used in operations for the nine-month period ended September 30, 2005, was partially offset by an increase in tablet deferred product revenue of $5.0 million, an increase in capsule deferred product revenue of $4.0 million, non-cash stock compensation expense of $3.5 million, an increase in accounts payable, accrued expenses and other current liabilities of $2.7 million and a decrease in accounts receivable of $1.2 million.

*Net Cash Used in/Provided by Investing*

Net cash used in investing activities for the nine-month period ended September 30, 2006, was $4.7 million, primarily due to purchases of short term investments of $11.9 million partially offset by $7.5 million in net proceeds received from maturities of short-term investments. In addition, we purchased property and equipment of approximately $300,000 in the nine-month period ended September 30, 2006. Net cash provided by investing activities for the nine-month period ended September 30, 2005, was $3.2 million, primarily due to purchases of short-term investments of $11.5 million partially offset by $15.6 million in net proceeds received from maturities of short-term investments. In addition, we purchased property and equipment of approximately $142,000 and intangible assets of $750,000 in the nine-month period ended September 30, 2005.

*Net Cash Used in/Provided by Financing*

Net cash provided by financing activities for the nine-month period ended September 30, 2006, was $30.0 million, primarily due to $31.5 of initial public offering proceeds, net of issuance costs, offset by $729,000 in repayments of revenue interest liability and $778,000 in repayments of notes payable. Net cash provided by financing activities for the nine-month period ended September 30, 2005, was $5.6 million, primarily due to $5.8 million from the issuance of notes payable and $215,000 from the issuance of warrants, offset by $429,000 in repayments of notes payable.

*Future Capital Needs*

Our future capital requirements will depend on a number of factors, including the amount of revenue generated from sales of Zanaflex Capsules, the continued progress of our research and development activities, the timing and outcome of regulatory approvals, the amount and timing of milestone or other payments made under collaborative agreements, the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims and other intellectual property rights and the acquisition of licenses to new products or compounds. We expect to incur losses from operations for at least the next several years as we continue to expand our sales and marketing infrastructure and increase our marketing efforts to support the commercialization of Zanaflex Capsules, continue our clinical development of Fampridine-SR and advance our preclinical programs.

We believe our existing cash and cash equivalents and short-term investment, together with the net proceeds from our October 2006 private placement, will be sufficient to fund our operations and meet financial obligations through the first quarter of 2008 based on our current projected revenue and spending levels. To the extent our capital resources are insufficient to meet future operating requirements, we will

need to raise additional capital or incur indebtedness to fund our operations. We may be unable to obtain additional debt or equity financing on acceptable terms, if at all. If adequate funds are not available, we may be required to curtail our sales and marketing efforts, delay, reduce the scope of or eliminate some of our research and development programs or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently.

**Contractual Obligations and Commitments**

In January 2005, we entered into a $6.0 million senior secured term loan with GE Capital. In December 2005, we used a portion of the initial payment we received under our revenue interest assignment arrangement with PRF to repay approximately $3.0 million of this loan. We are required to pay monthly installments until February 2008, with interest-only payments for the first six months followed by principal and interest payments for the remaining 29 months. Interest is fixed at the rate of 9.93% per annum. The loan is secured by all of our personal property and fixtures, other than the property that secures our arrangement with PRF. The aggregate principal payments required subsequent to September 30, 2006 are $1.5 million.

In 2002, we entered into two financing agreements with GE Capital for an aggregate amount of approximately $1.2 million, to finance the purchase of certain property and equipment. One note is for $766,781 and bears an annual fixed interest rate of 8.88%. The second note is for $386,731 and bears an annual fixed interest rate of 8.57%. These financing arrangements are secured by certain of our property and equipment and do not include any debt covenants. There are no further principal payments required subsequent to September 30, 2006.

In January 1997, Elan loaned us an aggregate of $7.5 million pursuant to two convertible promissory notes. On December 23, 2005, Elan transferred these promissory notes to funds affiliated with Saints Capital. One promissory note in the principal amount of $5.0 million bears interest at a rate of 3% which began on the first anniversary of the note. The other promissory note in the amount of $2.5 million is non-interest bearing. The unpaid principal of $5.0 million note is convertible into 67,476 shares of our common stock. The $2.5 million promissory note is convertible into 210,863 shares of our common stock. The notes contain repayment and conversion provisions which are triggered based upon the regulatory status of certain products and termination of the license agreement with Elan. Both promissory notes restrict our ability to incur indebtedness that is senior to the notes, subject to certain exceptions, including our revenue interests assignment arrangement with PRF.

Under our Zanaflex purchase agreement with Elan, we are obligated to make milestone payments to Elan of up to $19.5 million based on cumulative gross sales of Zanaflex tablets and Zanaflex Capsules as defined in the agreement. As of September 30, 2006, we have made or accrued $4.5 million of these milestone payments in the consolidated financial statements. We expect to reach the third milestone level in the fourth quarter 2006 which would trigger a $5.0 million payment that would be payable in the first quarter 2007. There are additional future milestones that could result in payments by us to Elan of $10.0 million. Under our Zanaflex supply agreement with Elan, we are required to provide to Elan an 18-month rolling forecast at the beginning of each month and a two-year forecast not later than July 1 of each year. We are bound to order one hundred percent of the forecast required quantities for each five month period immediately following each monthly forecast report. At September 30, 2006, the forecast requirement for the five month period following September 30, 2006 amounted to approximately $1.8 million.

Under our Fampridine-SR license agreement with Elan, we are obligated to make milestone payments to Elan of up to $15.0 million over the life of the contract and royalty payments as a percentage of product sales. Combined obligations of royalties and costs of goods as defined in the Fampridine-SR

license agreement is approximately 20%. In addition, under our various other research, license and collaboration agreements we are obligated to make milestone payments of up to an aggregate of approximately $16.8 million over the life of the contracts.

Under the terms of the employment agreement with our chief executive officer, Ron Cohen, we are obligated to pay severance under certain circumstances. If the employment agreement is terminated by us or by our chief executive officer for reasons other than for cause, we must pay (i) an amount equal to the base salary the chief executive officer would have received during the fifteen month period immediately following the date of termination, plus (ii) bonus equal to last annual bonus received by chief executive officer multiplied by a fraction, the numerator of which shall be the number of days in the calendar year elapsed as of the termination date and the denominator of which shall be 365.

Under the terms of the employment agreements with our chief scientific officer, Andrew Blight, our chief operating officer, Mary Fisher, our chief financial officer, David Lawrence and our general counsel, Jane Wasman, we are obligated to pay severance under certain circumstances. In the event we terminate our employment agreement with Dr. Blight, Ms. Fisher, Mr. Lawrence or Ms. Wasman without cause, or if one of them voluntarily terminates his or her agreements with good reason, we are obligated to make severance payments equal to nine months base annual salary, in the case of Dr. Blight and Ms. Fisher, and seven months base annual salary, in the case of Mr. Lawrence and Ms. Wasman, as well as COBRA premium payments for the severance period. In such event, all options, stock appreciation rights awards and restricted stock awards that have vested as of the termination date shall remain exercisable for 90 days following such date. All unvested options, stock appreciation rights awards and stock awards will be cancelled on the date of termination. If Dr. Blight, Ms. Fisher, Mr. Lawrence or Ms. Wasman voluntarily terminates his or her employment without good reason or if we terminate his or her employment without cause within 18 months after a change in control, we are obligated to make severance payments equal to one year s base annual salary, in the case of Dr. Blight and Ms. Fisher, and nine months base annual salary, in the case of Mr. Lawrence and Ms. Wasman, in each case paid in a lump sum within 30 days after termination, as well as COBRA premium payments for the severance period plus a bonus equal to the prior year s bonus pro rated for the number of days worked prior to termination. We are also obligated to pay salary earned but not paid, vacation and sick leave days that have accrued, and reimbursable business expenses incurred through the date of termination. In such event, not less than 50% of the unvested options, stock appreciation rights and restricted or other stock awards shall become immediately and fully vested and shall remain exercisable for 18 months following such date. All options that have vested as of the termination date shall remain exercisable for 90 days following such date. All unvested options, stock appreciation rights awards and stock awards will be cancelled on the date of termination.

**Critical Accounting Policies and Estimates**

The following discussion of critical accounting policies identifies the accounting policies that require application of management s most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. It is not intended to be a comprehensive list of all of our significant accounting policies, which are more fully described in Note 2 of the notes to the consolidated financial statements. In many cases, the accounting treatment of a particular transaction is specifically dictated by generally accepted accounting principles, with no need for management s judgment in their application. There are also areas in which the selection of an available alternative policy would not produce a materially different result. We have identified the following as our areas of critical accounting policies: sales revenue recognition, research and development, income taxes, and stock-based compensation.

**Revenue Recognition**

We apply the revenue recognition guidance in SFAS No. 48, *Revenue Recognition When the Right of Return Exists*, which among other criteria requires that future returns can be reasonably estimated in order to recognize revenue. Under SFAS No. 48 we are not permitted to recognize revenue until we can reasonably estimate the likely return rate for our products. Since we have only limited sales history with Zanaflex Capsules and due to generic competition and customer conversion from Zanaflex tablets to Zanaflex Capsules, we do not believe we can reasonably determine a return rate. As a result, we account for sales of these products using a deferred revenue recognition model. In the near future we expect to be able to reasonably estimate product returns, at which point we believe we will begin to recognize revenue based on shipments of product to our wholesale drug distributors.

Under our deferred revenue model, we do not recognize revenue upon shipment of product to our wholesale drug distributors. Instead, we record deferred revenue at gross invoice sales price, and classify the cost basis of the inventory shipped as inventory held by others. We recognize revenue when prescriptions are filled to an end-user because once a prescription is filled the product cannot be returned. We use monthly prescription data that we purchase to determine the amount of revenue to be recognized. We estimate prescription sales until the data becomes available, at which time adjustments are made to revenue and cost of sales to account for any differences between our estimates and the actual data. To date such differences have been minimal. The estimated prescription sales are based on average previous two month s prescriptions. Gross sales data reported in the financial statements in this filing are based on five months of actual prescription data and one month of estimated prescription data. The method for estimating prescriptions will be reevaluated as more prescription data becomes available. When we receive the prescription data, we use the number of units of product prescribed to record gross sales. We then reduce deferred revenue and record cost of goods sold. We began receiving end-user prescription data in March 2005 which enabled us to begin recognizing revenue from Zanaflex tablet sales. We began marketing Zanaflex Capsules in April 2005 and began receiving prescription data and recognizing revenue in the same month.

During the three-month period ended June 30, 2006 we adopted IMS Health data as the prescription data source used as the basis for recognizing shipments of Zanaflex product as revenue in lieu of a former prescription data provider. In addition to the prescription data we receive from IMS, we also receive data that we use to monitor trends in sales from wholesalers to their customers. We receive this data from an outside vendor on a monthly basis. This data includes the number of bottles shipped from certain wholesalers to their customers. We also compare our shipments to wholesalers to prescription reports to further assess inventory in the distribution channel on a monthly basis. We use the wholesaler sales trend data and the wholesaler vs. prescription comparison to better understand market conditions, but not as a basis for recognizing revenue.

We accept returns of products for six months prior to and 12 months after their expiration date. Returns of products sold by us are charged directly against deferred revenue, reducing the amount of deferred revenue that we may recognize.

*Sale of Zanaflex Tablet Inventory Acquired From Elan*

When we acquired Zanaflex from Elan, we also acquired Elan s inventory of Zanaflex tablets. This inventory included partial lots with expiration dating of less than 12 months and full lots with expiration dating greater than 12 months. We deferred recognition of any revenue from sales of the partial lot inventory until the return period for this product expired in June 2006, and recognized revenue only to the extent that deferred revenues exceeded returns. We could not use prescription data to recognize revenue associated with the partial lot inventory acquired from Elan because we cannot determine whether the

prescription was filled with product that Elan sold prior to our acquisition of Zanaflex or with product we sold.

All Zanaflex tablet partial lot inventory that we acquired from Elan had either been sold or is no longer being sold by us. As a result, after the return period expired in June 2006, there was no longer be deferred revenue associated with the Zanaflex tablet partial lot inventory acquired from Elan.

In July 2005 we began to recognize revenue from the full lots based on prescriptions filled for Zanaflex tablets. All of the Zanaflex tablet inventory sold by Elan prior to our acquisition reached expiration in June 2005, therefore any prescriptions filled for Zanaflex tablets subsequent to June 2005 must be from the full inventory lots acquired by and sold by us.

We were uncertain about the amount of returns that we may have received on these products, for a number of reasons including our limited historical returns experience. Returns of Zanaflex tablet inventory acquired from Elan and sold by us was charged against deferred revenue, reducing the amount of deferred revenue that we ultimately recognized during the three-month period ended June 30, 2006.

At September 30, 2006 we had deferred revenue from Zanaflex tablets of $8.6 million. At December 31, 2005 we had deferred revenue from Zanaflex tablets of $11.5 million, of which $2.3 million was related to product acquired from Elan that had an expiration date of less than 12 months at the time it was sold during 2004. The Company received returns of the product sold by Elan through June 2006 at which point the right of return expired and the company recognized the $2.2 million deferred revenue balance as gross sales.

*Returns of Zanaflex Tablets sold by Elan*

As part of the acquisition of Zanaflex, we agreed to accept any returns of Zanaflex tablets that were returned subsequent to January 17, 2005, including returns of product that was originally sold by Elan. Product returns prior to January 17, 2005, were the responsibility of Elan. We recorded a charge of $4.1 million in the year ended December 31, 2004, for the estimated returns of Zanaflex tablets sold by Elan. The Company continued to receive returns of the product sold by Elan through June 2006 at which point the right of return expired and the remaining $1.8 million accrual balance was reversed through discounts and allowances.

**Research and Development**

Research and development expenses include the costs associated with our internal research and development activities including, salaries and benefits, occupancy costs, and research and development conducted for us by third parties, such as sponsored university-based research, and clinical trial vendors. We account for our clinical study costs by estimating the patient cost per visit in each clinical trial and recognizing this cost as visits occur, beginning when the patient enrolls in the trial. This estimated cost includes payments to the trial site and patient-related costs, including laboratory costs related to the conduct of the trial. Cost per patient varies based on the type of clinical trial, the site of the clinical trial, and the length of the treatment period for each patient. As actual costs become known to us, we adjust our accrual; such changes in estimate may be a material change in our clinical study accrual, which could also materially affect our results of operations. In addition, research and development expenses include expenses related to grant revenue and the cost of clinical trial drug supply shipped to our clinical study vendors.

**Income Taxes**

As part of the process of preparing our financial statements we are required to estimate our income taxes in each of the jurisdictions in which we operate. We account for income taxes by the asset and liability method. Under this method, deferred income taxes are recognized for tax consequences in future

years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end, based on enacted laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are provided if, based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

We have not recorded any tax provision or benefit for the nine-month periods ended September 30, 2006 and 2005. We have provided a valuation allowance for the full amount of our net deferred tax assets since realization of any future benefit from deductible temporary differences and net operating loss carry-forwards cannot be sufficiently assured at September 30, 2006.

As of September 30, 2006, we had available net operating loss carry-forwards of approximately $148.3 million for federal and state income tax purposes, which are available to offset future federal and state taxable income, if any, and expire between 2010 and 2025 and research and development tax credit carry-forwards of approximately $1.3 million for federal income tax reporting purposes which are available to reduce federal income taxes, if any, through 2018. Since our inception, we have incurred substantial losses and expect to incur substantial and recurring losses in future periods. The Internal Revenue Code of 1986, as amended, the Code, provides for a limitation of the annual use of net operating loss and research and development tax credit carry forwards (following certain ownership changes, as defined by the Code) that could significantly limit our ability to utilize these carry-forwards. We have experienced various ownership changes, as defined by the Code, as a result of past financings. Accordingly, our ability to utilize the aforementioned carry-forwards may be limited. Additionally, because U.S. tax laws limit the time during which these carry forwards may be applied against future taxes we may not be able to take full advantage of these attributes for federal income tax purposes.

**Stock-Based Compensation**

Historically, the Company accounted for share-based compensation costs under the provisions of Statement of Financial Accounting Standards 123 (SFAS No. 123), Accounting for Stock-Based Compensation, using a fair-value-based method of accounting for stock-based employee compensation plans.

On January 1, 2006, the Company adopted the provisions of Statement of Financial Accounting Standards 123 (revised 2004), Share-Based Payment (SFAS No. 123R), which requires that the costs resulting from all share-based payment transactions be recognized in the financial statements at their fair values. The Company adopted SFAS No. 123R using the modified prospective application method under which the provisions of SFAS No. 123R apply to new awards and to awards modified, repurchased, or cancelled after the adoption date. Additionally, compensation cost for the portion of the awards for which the requisite service has not been rendered that are outstanding as of the adoption date is recognized in the Consolidated Statement of Operations over the remaining service period after the adoption date based on the award s original estimate of fair value. Results for prior periods have not been restated.

In connection with the adoption of SFAS No. 123R, the Company changed from recognizing the effect of forfeitures as they occur to estimating the number of outstanding instruments for which the requisite service is not expected to be rendered. Prior to the adoption of SFAS No. 123R, the Company recognized forfeitures associated with its share-based awards as they occurred rather than estimating forfeitures. Upon adoption of SFAS No. 123R, the Company recorded a cumulative effect of change in accounting principle of $454,225 during the three-month period ended March 31, 2006, calculated as the difference between compensation cost recognized to date using actual forfeitures and the cost that would have been recognized to date using estimated forfeitures. The Company estimates that its future annual forfeiture rate will be 5%.

The Company accounts for stock options granted to non-employees on a fair-value basis in accordance with EITF No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services, and FASB Interpretation No. 28, Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans an Interpretation of APB Opinion No. 15 and 25.*

## Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our financial instruments consist of cash and cash equivalents, short-term investments, grant receivable, notes payable, convertible notes payable, accounts payable, warrant liability, and put/call liability. The estimated fair values of all of our financial instruments, excluding convertible notes payable to Saints Capital, approximate their carrying amounts at September 30, 2006.

We have cash equivalents and short-term investments at September 30, 2006, which are exposed to the impact of interest rate changes and our interest income fluctuates as our interest rates change. Due to the short-term nature of our investments in money market funds and corporate debt securities, the carrying value of our cash equivalents and short-term investments approximate their fair value at September 30, 2006.

We maintain an investment portfolio in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain proper liquidity to meet operating needs and maximize yields. Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or type of investment. Our investments are also subject to interest rate risk and will decrease in value if market interest rates increase. However, due to the conservative nature of our investments and relatively short duration, interest rate risk is mitigated. We do not own derivative financial instruments. Accordingly, we do not believe that there is any material market risk exposure with respect to derivative or other financial instruments.

## Item 4. Controls and Procedures.

***Evaluation of disclosure controls and procedures***

As required by Rule 13a-15 under the Exchange Act, within 90 days prior to filing this report, we carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. This evaluation was carried out under the supervision and with the participation of our management, including our chief executive officer and our chief financial officer. Based on that evaluation, these officers have concluded that, as of September 30, 2006, our disclosure controls and procedures were effective and designed to ensure that material information relating to us required to be included in our reports filed under the Exchange Act would be made known to them.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and regulations. Disclosure controls and procedures include controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our chief executive officer and chief financial officer as appropriate, to allow timely decisions regarding disclosure.

***Change in internal control over financial reporting***

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2006 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

***Limitations on the effectiveness of controls***

Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected.

**PART II OTHER INFORMATION**

**Item 1.** Legal Proceedings.

We are not currently a party to any material legal proceedings.

**Item 1A.** Risk Factors

In addition to the other information set forth in this report, you should carefully consider the risk factors discussed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2005, as well as those discussed in Part II, Item 1A. Risk Factors in our Form 10-Q for the three-month period ended March 31, 2006, Form 10-Q for the three-month period ended June 30, 2006, and this report, all of which could materially affect our business, financial condition or future results. The risks described in the Annual Report, as updated by our quarterly reports on Form 10-Q, are not the only risks facing our Company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results. Please note that the risk factors set forth below replace in their entirety the risk factors with the same or similar titles contained in our previously filed reports.

***Our company has limited sales and marketing experience and we may not be successful in building an effective sales and marketing organization to market Zanaflex Capsules to physicians.***

As a company, we have limited sales and marketing experience, having only launched Zanaflex Capsules in April 2005. In order to successfully commercialize Zanaflex Capsules or any other products that we may bring to market, we will need to have adequate sales, marketing and distribution capabilities. Although we intend to increase our sales force from 32 to 65 persons, we may not be able to attract, train and retain skilled sales and marketing personnel, in a timely manner or at all, or integrate and manage a growing sales and marketing organization. In addition, we may not succeed in increasing our sales of Zanaflex Capsules sufficiently to justify the expense associated with our expanded sales force, which would adversely affect our cash flow and our prospects for achieving profitability.

We had initially planned to target potential high-prescribing primary care physicians through contract sales representatives. However, we have terminated two agreements with contract sales representative companies, Cardinal Health PTS, LLC and Innovex Inc., that had been hired to provide sales representatives targeting the primary care market. We now intend to address that market through our expanded sales force. There can be no assurances that our sales force will be effective in reaching the primary care market.

***If any additional studies are required by the FDA, we are unable to obtain regulatory approval for Fampridine-SR, or any approval is unduly limited in scope or delayed, our business prospectus will be adversely affected.***

In September 2006, we announced results of a successful Phase 3 clinical trial of Fampridine-SR for the improvement of walking ability in patients with MS, which was performed under a Special Protocol Assessment, or SPA, from the FDA. Although statistical significance was achieved on all three efficacy criteria defined in the SPA, typically, positive results from at least one other clinical trial would be needed to support the filing of an NDA with the FDA. We cannot predict how long a second trial, or any additional trial that might be required by the FDA, would take or what the cost would be. In addition, if the FDA determines that a new substantial scientific issue regarding safety or efficacy of Fampridine-SR is identified, the FDA may alter its conclusion, expressed in the SPA, regarding the adequacy of the Phase 3 protocol. The FDA also may identify a need for studies in addition to a second study to confirm efficacy that would examine other properties or characteristics of the drug.

Notwithstanding the results of our clinical trials, the FDA could determine that the overall balance of risks and benefits for Fampridine-SR is not adequate to support approval, or only justifies approval for a

narrow set of uses or approval with restricted distribution or other burdensome post-approval requirements and limitations. If the FDA denies approval of Fampridine-SR in MS, FDA approval is substantially delayed, approval is granted on a narrow basis or with restricted distribution or other burdensome post-approval requirements, or the Fampridine-SR program is terminated, our business prospects will be adversely affected.

In March 2004, we completed two Phase 3 clinical trials of Fampridine-SR in SCI in which our results failed to reach their primary endpoints. We expect to resume development of Fampridine-SR for SCI after we have completed further development of the drug for MS. We cannot predict whether future clinical trials of Fampridine-SR in SCI will achieve their primary endpoints, how long these clinical trials will take or how much they will cost.

***We may be subject to penalties if we fail to comply with post-approval legal and regulatory requirements and our products could be subject to restrictions or withdrawal from the market.***

Any product for which we currently have or may obtain marketing approval, along with the associated manufacturing processes, any post-approval clinical data that we might be required to collect and the advertising and promotional activities for the product, are subject to continual recordkeeping and reporting requirements, review and periodic inspections by the FDA and other regulatory bodies. Regulatory approval of a product may be subject to limitations on the indicated uses for which the product may be marketed or to other restrictive conditions of approval that limit our ability to promote, sell or distribute a product. Furthermore, any approval may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product.

We have an outstanding FDA commitment, inherited from Elan, to provide an assessment of the safety and effectiveness of Zanaflex Capsules in pediatric patients. This commitment is included in the NDA approval for Zanaflex Capsules. The requirement was deferred by the FDA to December 31, 2005. However, with enactment of the Pediatric Research Equity Act, or PREA we believe that the date of this commitment was further deferred to February 2007, although we have not confirmed with the FDA that the date has been deferred.

We have submitted protocols to initiate a pediatric pharmacokinetic study and a retrospective safety study to the FDA. The FDA s prescribed 30-day period for review of these protocols has passed and we are proceeding with these studies. However, the FDA can still comment on or halt an ongoing study at any time. Depending on the outcome of these studies and whether the FDA considers them adequate to satisfy our PREA commitment, we may be required to conduct additional studies. Such additional studies could be more extensive and more costly than the currently-planned studies.

The retrospective pediatric safety data should be available for FDA review during February 2007. However, due to unexpected delays in investigator recruitment, we have not yet initiated the pediatric pharmacokinetic study and, therefore, will not be able to complete it by the February 2007 deadline, which may subject us to penalties for non-compliance with PREA.

Our advertising and promotion are subject to stringent FDA rules and oversight. In particular, the claims in our promotional materials and activities must be consistent with the FDA approvals for our products, and must be appropriately substantiated and fairly balanced with information on the safety risks and limitations of the products. Any free samples we distribute to physicians must be carefully monitored and controlled, and must otherwise comply with the requirements of the Prescription Drug Marketing Act, as amended, and FDA regulations. We must continually review adverse event information that we receive concerning our drugs and make expedited and periodic adverse event reports to the FDA and other regulatory authorities.

In addition, the research, manufacturing, distribution, sale and promotion of drug and biological products are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services, other divisions of the U.S. Department of Health and Human Services, the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-kickback and fraud and abuse provisions of the Social Security Act, as amended, the False Claims Act, as amended, the privacy provisions of the Health Insurance Portability and Accountability Act and similar state laws. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990, as amended, and the Veterans Health Care Act of 1992, as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. All of these activities are also potentially subject to federal and state consumer protection and unfair competition laws.

We may be slow to adapt, or we may not be able to adapt, to changes in existing regulatory requirements or adoption of new legal or regulatory requirements or policies. Later discovery of previously unknown problems with our products, manufacturing processes, or failure to comply with regulatory requirements, may result in:

- voluntary or mandatory recalls;
- voluntary or mandatory patient or physician notification;
- withdrawal of product approvals;
- product seizures;
- restrictions on, or prohibitions against, marketing our products;
- restrictions on importation of our product candidates;
- fines and injunctions;
- civil and criminal penalties;
- exclusion from participation in government programs; and
- suspension of review or refusal to approve pending applications.

In addition, the FDA or another regulatory agency may conduct periodic unannounced inspections. If they determine that we are not in compliance with applicable requirements, they may issue a notice of inspectional observations. If the observations are significant, we may have to devote significant resources to respond and undertake appropriate corrective and preventive actions, which could adversely affect our business prospects. For example, the FDA recently completed an inspection relating to our adverse event and product complaint handling and reporting for Zanaflex. The FDA has issued to us a Form 483, Inspectional Observations, with five observations. We have completed or expect to complete shortly all necessary corrective actions. The cost of the corrective actions is not expected to be material.

**Item 6.** Exhibits

| | |
|---|---|
| 31.1 | Certification by the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934. |
| 31.2 | Certification by the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934. |
| 32.1 | Certification pursuant to 18 USC. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, Acorda Therapeutics, Inc. has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, State of New York, on this 14th day of November 2006.

**ACORDA THERAPEUTICS, INC.**
By: /s/ RON COHEN
Ron Cohen
*President and Chief Executive Officer*

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

| Signature | Title | Date |
|---|---|---|
| /s/ RON COHEN<br>Ron Cohen, M.D. | President, Chief Executive Officer and Director (Principal Executive Officer) | November 14, 2006 |
| /s/ DAVID LAWRENCE<br>David Lawrence, M.B.A. | Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) | November 14, 2006 |

**Exhibit Index**

| Exhibit No. | **Description** |
|---|---|
| 10.44 | Securities Purchase Agreement, dated as of Oct 3, 2006, by and among the Registrant and the purchasers listed on Exhibit A thereto. Incorporated herein by reference to Exhibit 10.44 of the Registrant s Current Report on Form 8-K filed on October 5, 2006. |
| 31.1 | Certification by the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934. |
| 31.2 | Certification by the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934. |
| 32.1 | Certification pursuant to 18 USC. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. |