

ACORDA THERAPEUTICS INC

Form 10-Q

November 08, 2007

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

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**FORM 10-Q**

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

**For the quarterly period ended September 30, 2007**

**OR**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission File Number 000-50513**

**ACORDA THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State of incorporation)

**13-3831168**  
(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 ☒ No ☐

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

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☒

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

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

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Class

Outstanding at October 31, 2007

Common Stock, \$0.001 par value  
per share

28,578,831 shares

**ACORDA THERAPEUTICS, INC.**

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*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, 2006, 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, 2007	December 31, 2006
	(unaudited)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 20,626,272	\$ 18,100,908
Restricted cash	284,671	274,381
Short-term investments	84,507,306	35,655,524
Trade accounts receivable, net	3,765,172	4,316,099
Grant receivable	41,313	73,004
Prepaid expenses	2,264,442	1,406,024
Finished goods inventory held by the Company	5,475,410	4,701,025
Finished goods inventory held by others	1,702,538	1,520,064
Revenue interest milestone receivable		5,000,000
Other current assets	1,435,699	1,186,402
Total current assets	120,102,823	72,233,431
Property and equipment, net of accumulated depreciation	1,741,185	1,222,704
Intangible assets, net of accumulated amortization	14,333,231	10,177,592
Other assets	680,942	734,318
Total assets	\$ 136,858,181	\$ 84,368,045

**Liabilities and Stockholders' Equity**

Current liabilities:		
Accounts payable	\$ 7,809,124	\$ 3,315,391
Accrued expenses and other current liabilities	6,240,035	10,717,350
Deferred product revenue Zanaflex tablets	7,856,615	9,116,975
Deferred product revenue Zanaflex Capsules	11,715,884	11,324,161
Current portion of notes payable	463,377	1,044,167
Current portion of revenue interest liability	2,573,634	3,391,574
Total current liabilities	36,658,669	38,909,618
Long-term portion of notes payable		187,427
Put/call liability	362,500	350,000
Non current portion of revenue interest liability	18,164,025	19,744,454
Long-term convertible notes payable	6,654,383	6,507,827
Commitments and contingencies		
Stockholders' equity:		
Common stock, \$0.001 par value. Authorized 80,000,000 shares at September 30, 2007 and December 31, 2006; issued and outstanding 28,497,475 and 23,657,755 shares as of September 30, 2007 and December 31, 2006, respectively		
	28,497	23,658
Additional paid-in capital	331,069,496	250,693,024
Accumulated deficit	(256,306,196)	(232,061,303)
Other comprehensive income	226,807	13,340

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	September 30, 2007	December 31, 2006
Total stockholders' equity	75,018,604	18,668,719
Total liabilities and stockholders' equity	\$ 136,858,181	\$ 84,368,045

See accompanying Unaudited Notes to Consolidated Financial Statements

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARY

## Consolidated Statements of Operations

(unaudited)

	Three-month period ended September 30,	Three-month period ended September 30,	Nine-month period ended September 30,	Nine-month period ended September 30,
	2007	2006	2007	2006
Gross sales Zanaflex	\$ 11,506,696	\$ 6,537,576	\$ 30,810,390	\$ 18,303,614
Less: discounts and allowances	(1,067,668)	(380,610)	(2,576,340)	955,266
Net sales	10,439,028	6,156,966	28,234,050	19,258,880
Grant revenue	20,277	70,350	36,464	371,615
Total net revenue	10,459,305	6,227,316	28,270,514	19,630,495
Less: cost of sales	(2,181,565)	(1,652,281)	(5,746,485)	(4,037,405)
Gross profit	8,277,740	4,575,035	22,524,029	15,593,090
Operating expenses:				
Research and development	5,602,828	2,594,466	12,854,260	8,892,352
Sales and marketing	7,917,861	5,297,223	22,005,596	14,142,074
General and administrative	3,720,222	3,435,290	12,550,151	9,273,166
Total operating expenses	17,240,911	11,326,979	47,410,007	32,307,592
Operating loss	(8,963,171)	(6,751,944)	(24,885,978)	(16,714,502)
Other income (expense):				
Interest and amortization of debt discount expense	(1,008,244)	(766,669)	(2,208,650)	(1,674,203)
Interest income	1,440,559	280,626	2,804,679	853,504
Other income	(1,584)	68,321	45,057	71,173
Total other income (expense)	430,731	(417,722)	641,086	(749,526)
Cumulative effect of change in accounting principle				454,225
Net loss	(8,532,440)	(7,169,666)	(24,244,892)	(17,009,803)
Beneficial conversion feature, accretion of issuance costs, preferred dividends, and fair value of warrants issued to convertible preferred stockholders				(36,007,456)
Net loss allocable to common stockholders	\$ (8,532,440)	\$ (7,169,666)	\$ (24,244,892)	\$ (53,017,259)
Net loss per share basic and diluted	\$ (0.30)	\$ (0.37)	\$ (0.95)	\$ (3.17)
Weighted average common shares outstanding used in computing net loss per share basic and diluted	28,209,406	19,632,660	25,467,580	16,745,628

See accompanying Unaudited Notes to Consolidated Financial Statements





## ACORDA THERAPEUTICS, INC. AND SUBSIDIARY

## Consolidated Statements of Cash Flows

(unaudited)

	Nine-month period ended September 30, 2007	Nine-month period ended September 30, 2006
Cash flows from operating activities:		
Net loss	\$ (24,244,893)	\$ (17,009,803)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock compensation expense	5,927,181	2,906,869
Amortization of note discount		41,958
Amortization of net premiums and discounts on short-term investments	(1,916,724)	(34,560)
Cumulative effect of change in accounting principle		(454,225)
Amortization of revenue interest issuance cost	56,835	
Accretion of discount		34,525
Unrealized gain on warrants		58,478
Depreciation and amortization expense	1,464,063	1,284,079
Loss (gain) on put/call liability	12,500	(75,000)
(Gain) loss on disposal of property and equipment	(23,750)	587
Changes in assets and liabilities:		
Decrease (increase) in accounts receivable	550,927	(3,230,479)
Decrease in grant receivables	31,691	28,920
Decrease (increase) in prepaid expenses and other current assets	(1,107,715)	777,679
Increase in inventory held by the Company	(774,385)	(274,015)
Increase in inventory held by others	(182,474)	(110,667)
Decrease (increase) in other assets	(3,459)	24,083
Increase (decrease) in accounts payable, accrued expenses, other current liabilities	5,313,849	(6,817,727)
Decrease in returns liability		(1,831,211)
Decrease in deferred product revenue tablets	(1,260,360)	(2,905,033)
Increase in deferred product revenue Capsules	391,723	2,476,403
Restricted cash	(10,290)	(7,713)
Net cash used in operating activities	(15,775,281)	(25,116,852)
Cash flows from investing activities:		
Purchases of property and equipment	(1,114,433)	(300,350)
Purchases of intangible assets	(10,000,000)	
Purchases of short-term investments	(106,521,591)	(11,881,791)
Proceeds from maturities of short-term investments	59,800,000	7,486,000
Net cash (used in)/provided by investing activities	(57,836,024)	4,696,141
Cash flows from financing activities:		
Proceeds from issuance of common stock and option exercises	74,454,130	31,479,307
Proceeds from sale of revenue interest	5,000,000	
Repayments of revenue interest liability	(2,549,244)	(729,179)
Repayments of notes payable	(768,217)	(777,810)
Net cash provided by financing activities	76,136,669	29,972,318
Net increase in cash and cash equivalents	2,525,365	159,325
Cash and cash equivalents at beginning of period	18,100,908	11,761,299
Cash and cash equivalents at end of period	\$ 20,626,272	\$ 11,920,624

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	Nine-month period ended September 30, 2007	Nine-month period ended September 30, 2006
Supplemental disclosure:		
Cash paid for interest	1,898,504	1,026,785
Non-cash charges related to convertible preferred stock:		
Beneficial conversion feature		48,470,740
Preferred dividend		(12,734,009)
Accretion of issuance costs		270,725

See accompanying Unaudited Notes to 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 (MS), 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, 2006 included in the Company's Annual Report on Form 10-K for such year, as filed with the Securities and Exchange Commission (the "SEC").

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.

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 proceeds to the Company of approximately \$29.8 million, net of issuance costs.

The Company completed a secondary public offering in June 2007. As part of that offering, 3,626,960 shares of the Company's common stock were sold, resulting in proceeds of approximately \$62.7 million, net of issuance costs.

In July 2007, the underwriters of the June 2007 secondary public offering exercised their option to purchase an additional 562,500 shares of common stock, resulting in additional proceeds of approximately \$9.6 million, net of issuance costs.

In September 2007, the Company received a Paragraph IV Certification Notice from Apotex Inc. advising that Apotex Inc. had filed an Abbreviated New Drug Application (ANDA) with the FDA for generic versions of each of the three Zanaflex Capsules (tizanidine hydrochloride) dosage strengths marketed by the company. In response to the filing of the ANDA, in October 2007, the Company filed a lawsuit against Apotex Corp. and Apotex Inc. in the United States District Court for the District of New Jersey asserting infringement of the Company's U.S. Patent No. 6,455,557 relating to multiparticulate tizanidine compositions, including those sold by the Company as Zanaflex Capsules. The patent expires in 2021. If the FDA approves that ANDA and Apotex Corp. and Apotex Inc. are successful in challenging the validity of the patent, Apotex Corp. and Apotex Inc. might be permitted to sell a generic tizanidine hydrochloride capsule in competition with Zanaflex Capsules and Zanaflex tablets.

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 will be sufficient to fund operations and meet financial obligations through the first quarter of 2009 based on the Company's current projected revenue and spending levels. To the extent the Company's capital resources are insufficient to meet future operating requirements, the Company will need to raise additional capital, reduce planned expenditures, or incur indebtedness to fund its operations. The Company may be unable to obtain additional debt or equity financing on acceptable terms, if at all. If adequate funds are not available, the Company may be required to curtail its sales and marketing efforts, delay, reduce the scope of or eliminate some of its 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 it 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) and share-based compensation accounting, which are largely 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 among 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 has 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 was 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 expects to be able to apply a more traditional revenue recognition policy such that revenue is recognized upon shipment to the customer when it believes it has sufficient data to develop reasonable estimates of expected returns based upon historical returns.

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 are 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.

### ***Earnings per Share***

Net loss per share is computed in accordance with SFAS No. 128, *Earnings Per Share*, by dividing the net loss by the weighted average number of shares of common stock outstanding. The Company has certain stock options and restricted stock (see Note 3), which have not been used in the calculation of diluted net loss per share because to do so would be anti-dilutive. 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.

#### ***Recent Accounting Pronouncements***

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements*. 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.

In February 2007, the FASB issued Statement of Financial Account Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including Amendment of FASB Statement No. 115*. The new standard permits, but does not require, entities to measure certain financial instruments and other assets and liabilities at fair value on an instrument-by-instrument basis. Unrealized gains and losses on items for which the fair value option has been elected should be recognized in earnings at each subsequent reporting date. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company does not believe SFAS 159 will have a material impact on its results from operations or financial position.

In June 2007, the Emerging Issues Task Force (EITF) issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities*. EITF Issue No. 07-3 provides guidance concerning the accounting for non-refundable advance payments for goods and services that will be used in future R&D activities and requires that they be expensed when the research and development activity has been performed and not at the time of payment. The provisions of EITF Issue No. 07-3 are effective for the fiscal years beginning after December 15, 2007, with a cumulative-effect adjustment to Retained Earnings as of the beginning of the year of adoption. The Company is evaluating the potential impact of this consensus.

Refer to Footnote 4 with respect to the adoption of FIN 48.

#### ***Segment Information***

The Company is managed and operated as one business. The entire business is managed by a single management team that reports to the chief executive officer. The Company does not operate separate lines of business with respect to any of its product candidates. Accordingly, the Company does not prepare discrete financial information with respect to separate product candidates or by location and does not have separately reportable segments as defined by SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*.

#### **(3) Share-based Compensation**

The Company accounts for share-based compensation, including options and nonvested shares, according to the provisions of SFAS No. 123R, "Share Based Payment". During the three-month periods ended September 30, 2007 and 2006, the Company recognized share-based compensation

expense of \$1.9 million and \$962,000 respectively. During the nine-month periods ended September 30, 2007 and 2006, the Company recognized share-based compensation expense of \$5.9 million and \$2.9 million respectively. Activity in options and restricted stock during the nine-month period ended September 30, 2007 and related balances outstanding as of that date are reflected below. The weighted average fair value per share of options granted to employees for the three-month periods ended September 30, 2007 and 2006 amounted to approximately \$12.47 and \$4.78, respectively. The weighted average fair value per share of options granted to employees for the nine-month periods ended September 30, 2007 and 2006 amounted to approximately \$13.00 and \$3.86, respectively.

A summary of share-based compensation activity for the nine-month period ended September 30, 2007 is presented below:

#### Stock Option Activity

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Intrinsic Value
Balance at January 1, 2007	2,534,663	\$ 6.23		
Granted	1,021,083	19.14		
Forfeited	(155,215)	12.87		
Exercised	(326,437)	6.40		
Balance at September 30, 2007	3,074,094	\$ 10.16	7.9	\$ 26,593,656
Vested and expected to vest at September 30, 2007	2,983,018	\$ 10.04	7.9	\$ 26,140,329
Vested and exercisable at September 30, 2007	1,402,445	\$ 5.81	6.7	\$ 17,790,923

#### Restricted Stock Activity

Restricted Stock	Number of Shares
Nonvested at January 1, 2007	413,477
Granted	
Vested	(306,954)
Forfeited	(29,654)
Nonvested at September 30, 2007	76,869

As of September 30, 2007, there was \$15.3 million of total unrecognized compensation costs related to unvested options and restricted stock awards that the Company expects to recognize over a weighted average period of approximately 2.7 years.

#### (4) Income Taxes

In July 2006, the FASB issued FASB Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109, Accounting for Income Taxes*. In addition, in

May 2007, the FASB issued FASB Staff Position FIN 48-1 which provided guidance on how an enterprise should determine whether a tax position is effectively settled for the purpose of recognizing previously unrecognized tax benefits. The Interpretation and Staff Position 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 adopted FIN 48 as of January 1, 2007. The adoption of this Interpretation had no impact on the Company's results of operations or financial position. The Company has no reserves for uncertain tax positions.

The Company had available net operating loss carry-forwards ("NOL") of approximately \$169.6 million and \$144.7 million as of September 30, 2007 and December 31, 2006, 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 2026. The Company also has research and development tax credit carryforwards of approximately \$1.4 million and \$1.3 million as of September 30, 2007 and December 31, 2006 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, 2007 and December 31, 2006, the Company had a deferred tax asset of \$104.2 million and \$94.2 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, private placement in October 2006, and secondary public offering in June 2007. 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.

#### **(5) Elan Milestones**

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. 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. During the three-month period ended June 30, 2007, the Company reached the fourth cumulative product sale milestone threshold and accordingly, accrued a payment of \$5.0 million, which was made to Elan during the three-month period ended September 30, 2007. As of September 30, 2007, the Company has made or accrued a total of \$14.5 million of these milestone payments. The final remaining milestone payment of \$5.0 million will be due the quarterly period following the achievement of \$105.0 million in cumulative sales of all Zanaflex products.



**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 central nervous system (CNS). Our marketed drug, Zanaflex Capsules, is U.S. Food and Drug Administration (FDA)-approved for the management of spasticity. We announced positive results from a Phase 3 clinical trial of our lead product candidate, Fampridine-SR, for the improvement of walking ability in people with MS in September 2006.

In May 2007, we reached agreement with the FDA on a Special Protocol Assessment (SPA) for a second Phase 3 trial of Fampridine-SR in MS, MS-F204, and we initiated this trial in June 2007. The objective of this study is to show that individuals treated with Fampridine-SR are significantly more likely to have consistent improvements in their walking than those treated with placebo. Pending clinical results, the FDA has agreed that this trial, together with our first Phase 3 trial, MS-F203, would be adequate to support a New Drug Application (NDA) for Fampridine-SR. Data from that study are expected in the second quarter of 2008. A Thorough QT cardiac study was initiated in September 2007 and data from that study are expected in the first quarter of 2008. Our preclinical programs also target MS and SCI, as well as other CNS disorders, including stroke and traumatic brain injury.

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 we expect that they will 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.

Our U.S. patent on Zanaflex Capsules expires in 2021. In September 2007, we received a Paragraph IV Certification Notice from Apotex Inc. advising that it filed an ANDA with the FDA for generic versions of each of the three Zanaflex Capsules dosage strengths marketed by us. In response to the Notice, in October 2007, we filed a lawsuit against Apotex Corp. and Apotex Inc. asserting infringement of our U.S. patent on Zanaflex Capsules. If Apotex Corp. and Apotex Inc. are successful in challenging our patent, and if the FDA approves that ANDA, they will be, and other third parties who file ANDAs for which they receive FDA approval might be, permitted to sell a generic tizanidine hydrochloride capsule in competition with Zanaflex Capsules. This would likely cause significant declines in our revenue and profit margin from Zanaflex Capsules and Zanaflex tablets.

We have established our own specialty sales force in the United States, which consisted of 65 sales professionals as of September 30, 2007. 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 addition, we retain TMS Professional Markets Group, LLC to provide a small, dedicated sales force of pharmaceutical telesales professionals who contact primary care, specialist physicians and pharmacists.

## Results of Operations

### *Three-Month Period Ended September 30, 2007 Compared to September 30, 2006*

#### *Gross Sales*

We recognize product sales using a deferred revenue recognition model where shipments to wholesalers are recorded as deferred revenue and only recognized as revenue when end-user prescriptions of the product are reported. We recognized revenue from the sale of Zanaflex Capsules and Zanaflex tablets of \$11.5 million for the three-month period ended September 30, 2007, as compared to \$6.5 million for the three-month period ended September 30, 2006. The increase is the result of an increase in prescriptions written for our products that we believe is the result of our sales force expansion as well as a 10% price increase effective January 1, 2007. Also included in tablet gross sales recorded in the three-month period ended September 30, 2007 was \$462,000 of revenue from our 2mg tablet deferred revenue. In August 2007, the right to return this product expired, allowing us to recognize the remaining \$462,000 deferred revenue as gross sales.

#### *Discounts and Allowances*

We recorded discounts and allowances of \$1.1 million for the three-month period ended September 30, 2007 as compared to \$380,000 for the three-month period ended September 30, 2006. 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, 2007 consisted of \$480,000 in fees for services to wholesalers, \$313,000 in allowances for chargebacks and rebates and \$275,000 in cash discounts. Discounts and allowances for the three-month period ended September 30, 2006 consisted of \$208,000 in allowances for chargebacks and rebates and \$173,000 in cash discounts.

#### *Grant Revenue*

Grant revenue for the three-month period ended September 30, 2007 was \$20,000 compared to \$70,000 for the three-month period ended September 30, 2006. 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 \$2.2 million for the three-month period ended September 30, 2007 as compared to \$1.7 million for the three-month period ended September 30, 2006. The increase was primarily due to the increase in gross sales. Cost of sales for the three-month period ended September 30, 2007 consisted of \$990,000 in inventory costs related to recognized revenues, \$766,000 in royalty fees, based on net product shipments, \$389,000 in amortization of intangible assets, an amount unrelated to either the volume of shipments or the amount of revenue recognized, and \$36,000 in period costs related to freight, destruction and stability testing. 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. Payments to and interest expense related to our Paul Royalty Fund, or PRF, transaction discussed below in the section titled "Liquidity and Capital Resources" do not impact our cost of sales.

#### *Research and Development*

Research and development expenses for the three-month period ended September 30, 2007 were \$5.6 million as compared to \$2.6 million for the three-month period ended September 30, 2006, an increase of approximately \$3.0 million, or 116%. MS clinical development program expense increased

\$858,000 or 65% to \$2.2 million for the three-month period ended September 30, 2007 primarily due to the continuation of our second Phase 3 clinical trial of Fampridine-SR which began in June 2007. Other contract expenses increased \$429,000 or 1,116% to \$467,000 for the three-month period ended September 30, 2007 as a result of manufacturing and stability fees for Fampridine-SR.

Operating expenses for clinical development, preclinical research and development and regulatory were \$2.8 million for the three-month period ended September 30, 2007, compared to \$1.2 million for the three-month period ended September 30, 2006, an increase of \$1.6 million, or 139%. This increase was primarily attributable to an increase regulatory expenses of \$1.4 million, including \$1.0 million for the preparation of an NDA for Fampridine-SR and related consulting fees and approximately \$300,000 in increased salaries and benefits.

#### *Sales and Marketing*

Sales and marketing expenses for the three-month period ended September 30, 2007 were \$7.9 million compared to \$5.3 million for the three-month period ended September 30, 2006, an increase of approximately \$2.6 million or 49%. This increase was primarily attributable to an increase in salaries and benefits of \$1.6 million and other selling related expenses of \$1.0 million resulting from the expansion of our Zanaflex Capsules specialty sales force completed during the three-month period ended March 31, 2007.

#### *General and Administrative*

General and administrative expenses for the three-month period ended September 30, 2007 were \$3.7 million compared to \$3.4 million for the three-month period ended September 30, 2006, an increase of approximately \$285,000, or 8%. This increase was primarily the result of an increase in non-cash charges related to share-based compensation.

#### *Other Income (Expense)*

Other income was \$431,000 for the three-month period ended September 30, 2007 compared to other expense of \$418,000 for the three-month period ended September 30, 2006, an increase of approximately \$848,000 or 203%. This increase was largely due to a \$1.2 million increase in interest income as a result of the investment of net proceeds from our secondary public offering in June 2007, offset by an increase in interest expense of \$242,000 principally related to the PRF revenue interest agreement.

#### ***Nine-month Period Ended September 30, 2007 Compared to September 30, 2006***

##### *Gross Sales*

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. We recognized revenue from the sale of Zanaflex Capsules and Zanaflex tablets of \$30.8 million for the nine-month period ended September 30, 2007, as compared to \$18.3 million for the nine-month period ended September 30, 2006. The increase was due to an increase in prescriptions written for our products that we believe is the result of our sales force expansion as well as a 10% price increase effective January 1, 2007. Also included in tablet gross sales recorded in the nine-month period ended September 30, 2007 was \$462,000 of revenue from our 2mg tablet deferred revenue. In August 2007, the right to return this product expired, allowing us to recognize the remaining \$462,000 deferred revenue as gross sales.

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 in June 2006 the Company recognized the \$2.2 million deferred revenue balance as gross sales.

#### *Discounts and Allowances*

We recorded discounts and allowances of \$2.6 million for the nine-month period ended September 30, 2007 as compared to negative \$955,000 for the nine-month period ended September 30, 2006. As part of the 2004 Zanaflex acquisition, we agreed to accept Zanaflex tablets returns that were received subsequent to January 17, 2005, including returns of product originally sold by Elan. Product returns prior to that date were the responsibility of Elan. As a result of this agreement, we recorded a returns liability of \$4.1 million in December 2004 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. Based on the returns we accepted through June 2006, the net balance remaining on this liability was approximately \$1.8 million. We reversed this liability in June 2006 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, 2007 consisted of \$1.0 million for fees for services to wholesalers, \$856,000 in allowances for chargebacks and rebates and \$692,000 in cash discounts. Discounts and allowances for the nine-month period ended September 30, 2006, consisted of negative \$1.8 million due to the Elan product return liability reversal described above, \$440,000 in allowances for chargebacks and rebates, and \$405,000 in cash discounts.

#### *Grant Revenue*

Grant revenue for the nine-month period ended September 30, 2007 was \$36,000 compared to \$372,000 for the nine-month period ended September 30, 2006. 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 \$5.7 million for the nine-month period ended September 30, 2007 as compared to \$4.0 million for the nine-month period ended September 30, 2006. The increase was primarily due to the increase in gross sales. Cost of sales for the nine-month period ended September 30, 2007 consisted of \$2.7 million in inventory costs related to recognized revenues, \$2.0 million in royalty fees, based on net product shipments, \$844,000 in amortization of intangible assets, an amount unrelated to either the volume of shipments or the amount of revenue recognized, and \$194,000 in period costs related to freight, destruction and stability testing. Cost of sales for the nine-month period ended September 30, 2006 consisted of \$1.6 million in inventory costs related to recognized revenue, \$1.7 million in royalty fees, based on net product shipments, \$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.

#### *Research and Development*

Research and development expenses for the nine-month period ended September 30, 2007 were \$12.9 million as compared to \$8.9 million for the nine-month period ended September 30, 2006, an increase of approximately \$4.0 million, or 45%. Other contract expense increased \$899,000 or 228% to \$1.3 million for the nine-month period ended September 30, 2007 as a result of manufacturing and stability fees for Fampridine-SR.

Operating expenses for clinical development, preclinical research and development and regulatory were \$6.4 million for the nine-month period ended September 30, 2007, compared to \$3.3 million for the nine-month period ended September 30, 2006, an increase of \$3.1 million, or 96%. This increase is primarily attributable to regulatory expenses of \$2.1 million including \$1.0 million for the preparation of an NDA for Fampridine-SR and related consulting fees and \$742,000 in increased salaries and benefits.

#### *Sales and Marketing*

Sales and marketing expenses for the nine-month period ended September 30, 2007, were \$22.0 million compared to \$14.1 million for the nine-month period ended September 30, 2006, an increase of approximately \$7.9 million or 56%. This increase was primarily attributable to an increase in salaries and benefits of \$5.6 million and other selling related expenses of \$2.3 million resulting from the expansion of our Zanaflex Capsules specialty sales force completed during the three-month period ended March 31, 2007.

#### *General and Administrative*

General and administrative expenses for the nine-month period ended September 30, 2007, were \$12.6 million compared to \$9.3 million for the nine-month period ended September 30, 2006, an increase of approximately \$3.3 million, or 35%. This increase is primarily attributable to a \$1.2 million increase in non-cash charges related to share-based compensation, an increase in general and administrative compensation expense of \$670,000 due to employee headcount and salary increases, other third party services of \$428,000 resulting from costs associated with compliance activities from being a publicly traded company and medical affairs expenses of \$880,000 including \$615,000 of Zanaflex study and medical educational program expense.

#### *Other Income (Expense)*

Other income was \$641,000 for the nine-month period ended September 30, 2007 compared to other expense of \$750,000 for the nine-month period ended September 30, 2006, an increase of approximately \$1.4 million or 187%. This increase was largely due to an increase of \$2.0 million in interest income as a result of the investment of the net proceeds from our secondary public offering in June 2007, offset by an increase in interest expense of \$534,000 principally related to the PRF revenue interest agreement.

#### *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 had not been rendered that were 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. 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 which was recognized in the nine-month period ended September 30, 2006. The cumulative effect adjustment represented 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 decreased from \$36.0 million for the nine-month period ended September 30, 2006 to no charge for the nine-month period ended September 30, 2007, due to the recognition of the remaining unamortized portion of beneficial conversion charges and issuance costs and reversal of the cumulative preferred dividend upon the completion of our initial public offering of our common stock in February 2006. No further charges are necessary.

**Liquidity and Capital Resources**

We have incurred annual operating losses since inception and, as of September 30, 2007, we had an accumulated deficit of approximately \$256.3 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 issuances of our common stock.

Our initial public offering in February 2006 resulted in the issuance of approximately 6.1 million shares of our common stock and the conversion of all of our outstanding convertible and mandatorily convertible preferred stock. In connection with the offering of common shares, we raised approximately \$31.5 million, net of issuance costs.

We completed a private placement in October 2006 in which approximately 3.2 million shares of our common stock were sold, resulting in proceeds to us of approximately \$29.8 million, net of issuance costs.

We completed a secondary public offering in June 2007 in which approximately 3.6 million shares of our common stock were sold, resulting in proceeds to us of approximately \$62.7 million, net of issuance costs.

In July 2007, the underwriters of our June secondary offering exercised their option to purchase an additional 562,500 shares of our common stock, resulting in proceeds to us of approximately \$9.6 million, net of issuance costs.

On November 6, 2007, we filed a shelf registration statement on Form S-3 with the SEC covering the issuance of up to \$150,000,000 of securities including common stock, preferred stock, debt securities and/or warrants to purchase common stock, preferred stock and/or debt securities. No securities have been issued under this registration statement. We may publicly offer securities from time to time at prices and terms to be determined at the time of the offering.

*Financing Arrangements*

Since our inception and through September 30, 2007, we have raised aggregate net proceeds of \$189.0 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, of which \$5.0 million was outstanding as of September 30, 2007. 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 \$463,000 was outstanding as of September 30, 2007.

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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. To secure our obligations to PRF, we also granted PRF a security interest in substantially all of our assets related to Zanaflex. Our agreement with PRF covers all Zanaflex net revenues generated from October 1, 2005 through and including December 31, 2015, unless the agreement terminates earlier. In November 2006, we entered into an amendment to the revenue interests assignment agreement with PRF. Under the terms of the amendment, PRF paid us \$5.0 million in November 2006 and an additional \$5.0 million in February 2007 as our net revenues during the fiscal year 2006 exceeded \$25.0 million. This milestone receivable was reflected in our 2006 financial statements. Under the terms of the amendment, we are required to pay PRF \$5.0 million on December 1, 2009 and an additional \$5.0 million on December 1, 2010.

Under the agreement and the amendment, PRF is entitled to the following portion of Zanaflex net revenues:

with respect to Zanaflex net revenues up to and including \$30.0 million for each fiscal year during the term of the agreement, 15% of such net revenues;

with respect to Zanaflex net revenues in excess of \$30.0 million but less than and including \$60.0 million for each fiscal year during the term of the agreement, 6% of such net revenues; and

with respect to Zanaflex net revenues in excess of \$60.0 million for each fiscal year during the term of the agreement, 1% of such net revenues.

Notwithstanding the foregoing, once PRF has received and retained payments under the agreement that are at least 2.1 times the aggregate amount PRF has paid us under the agreement, PRF will only be entitled to 1% of Zanaflex net revenues. In connection with the transaction, we have a liability recorded, referred to as the revenue interest liability, of approximately \$20.7 million in accordance with EITF 88-18, *Sales of Future Revenues*. We impute interest expense associated with this liability using the effective interest rate method and record a corresponding accrued interest liability. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the life of the arrangement. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including the level of Zanaflex sales. We currently estimate that the imputed interest rate associated with this liability will be approximately 4.4%. Payments made to PRF as a result of Zanaflex sales levels reduce the accrued interest liability and the principal amount of the revenue interest liability.

### *Investment Activities*

At September 30, 2007, cash and cash equivalents and short-term investments were approximately \$105.1 million, as compared to \$53.8 million at December 31, 2006. 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. As of September 30, 2007, our cash and cash equivalents were \$20.6 million, as compared to \$18.1 million as of December 31, 2006. Our short-term investments consist of corporate debt securities with remaining maturities greater than three months and less than one year. The balance of these investments was \$84.5 million as of September 30, 2007, as compared to \$35.7 million as of December 31, 2006.

### *Inventory*

During the three-month period ended June 30, 2007, results from stability testing performed on Zanaflex Capsules by our manufacturing partner, Elan, supported an increase in Zanaflex Capsules expiration dating from 36 months to 48 months. The ultimate outcome of this testing was the addition of 12 months onto our Zanaflex Capsules product expiration dating which extends the shelf life of the product by 12 months.

### *Net Cash Used in Operations*

Net cash used in operations was \$15.8 million and \$25.1 million for the nine-month period ended September 30, 2007 and 2006, respectively. Cash used in operations for the nine-month period ended September 30, 2007 was primarily attributable to a net loss of \$24.2 million, amortization of the discount on short-term investments of \$1.9 million, a decrease in Zanaflex tablets deferred product revenues of \$1.3 million, an increase in prepaid expenses and other current assets of \$1.1 million and an increase in inventory of \$774,000. Cash used in operations for the nine-month period ended September 30, 2007, was partially offset by a non-cash share-based compensation expense of \$5.9 million, an increase in accounts payable, accrued expenses, and other current liabilities of \$5.3 million, depreciation and amortization of \$1.5 million, a decrease in accounts receivable of \$551,000 due to decreased shipments during that period compared to accelerated wholesaler ordering during the three-month period ended December 31, 2006 in expectation of a price increase at the beginning of 2007, and an increase in Zanaflex Capsules deferred product revenues of \$392,000. Cash used in 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 Zanaflex tablets deferred product revenue of \$2.9 million, a decrease in returns liability of \$1.8 million, and a cumulative effect of a change in accounting principle of \$454,000. Cash used in operations for the nine-month period ended September 30, 2006 was partially offset by non-cash share-based compensation expense of \$2.9 million, an increase in Zanaflex Capsules deferred product revenue of \$2.5 million, depreciation and amortization expense of \$1.3 million and a decrease in prepaid expenses and other current assets of \$778,000.

### *Net Cash Used in/Provided by Investing*

Net cash used in investing activities for the nine-month period ended September 30, 2007 was \$57.9 million, primarily due to \$106.5 million in net purchases of short-term investments, offset by \$59.8 million in proceeds from maturities of short-term investments and \$10.0 million for the purchase of intangible assets due to milestone payments relating to Zanaflex Capsules.

### *Net Cash Used in/Provided by Financing*

Net cash provided by financing activities for the nine-month period ended September 30, 2007 was \$76.1 million, primarily due to \$74.5 million in net proceeds from the issuance of common stock and option exercises and \$5.0 million received from the PRF transaction which was offset by \$2.5 million in repayments to PRF and \$768,000 for 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 support our sales and marketing infrastructure and increase our marketing efforts to support the commercialization of Zanaflex Capsules, continue our clinical development and pre-launch planning for Fampridine-SR, and advance our preclinical programs.

The Company believes that its current financial resources and sources of liquidity will be sufficient to fund operations and meet financial obligations through the first quarter of 2009 based on the Company's current projected revenue and spending levels. In addition, based on our current projections, we expect our Zanaflex commercial operations to be cash flow neutral by the end of 2007 and cash flow positive in 2008.

To the extent the Company's capital resources are insufficient to meet future operating requirements, the Company will need to raise additional capital, reduce planned expenditures, or incur indebtedness to fund its operations. The Company may be unable to obtain additional debt or equity financing on acceptable terms, if at all. If adequate funds are not available, the Company may be required to curtail its sales and marketing efforts, delay, reduce the scope of or eliminate some of its 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 it 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.

In January 1997, EIS loaned us an aggregate of \$7.5 million pursuant to two convertible promissory notes. 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 was non-interest bearing. On December 23, 2005, EIS transferred these promissory notes to funds affiliated with Saints Capital. In December 2006, Saints Capital exercised the conversion option of the \$2.5 million convertible promissory note at an exercise price of \$11.856 per share and received 210,863 shares of common stock. The remaining \$5.0 million convertible promissory note is convertible into 67,476 shares of common stock. Principal and interest are repayable, if not converted, ratably over a seven-year period, beginning one year after we receive regulatory approval for certain products to be developed, subject to limitations related to gross margin on product sales. If we and Saints Capital determine that regulatory approval will not likely occur, the \$5.0 million promissory note will automatically convert into the underlying common stock unless Saints Capital elects to have the amount due on the note cancelled. If our license and supply agreements with Elan are terminated for any other reason, the principal and interest is repayable ratably over 15 years. The \$5.0 million promissory note restricts our ability to incur indebtedness that is senior to the note, subject to certain exceptions, including for our revenue interests assignment arrangement with PRF.

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. 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 of September 30, 2007, we have made \$14.5 million of these milestone payments, including a \$5.0 million payment in the three-month period ended September 30, 2007. The final remaining milestone payment of \$5.0 million will be due upon the achievement of \$105.0 million in cumulative sales.

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 required to order 100% of the forecast required quantities for each five-month period immediately following each monthly forecast report. At September 30, 2007, the forecast requirement for the five-month period following September 30, 2007 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. We have not made any payments under this agreement to date. In addition, under our various other research, license and collaboration agreements with other parties we are obligated to make milestone payments of up to an aggregate of approximately \$16.8 million over the life of the contracts.

In December 2005, we entered into a revenue interests assignment agreement with 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. Under our agreement with PRF, we are required to use the net proceeds to support commercialization, sales, marketing, clinical and regulatory activities and other financial obligations related specifically and solely to our Zanaflex operations.

In November 2006, we entered into an amendment to the revenue interests assignment agreement with PRF. Under the amendment, PRF is entitled to a royalty consisting of certain specified percentages of Zanaflex net revenues, based upon the level of net revenues. Previously, once PRF had received and retained payments under the agreement that are at least twice the aggregate amount PRF paid us under the Agreement, the royalty rate would drop to 1% of Zanaflex net revenues. The amendment provides that the royalty rate will drop to 1% upon PRF's receipt of 2.1 times the aggregate amount PRF has paid us under the agreement, as amended. Under the terms of the amendment, PRF paid us \$5.0 million in November 2006 and agreed that we would be entitled to an additional \$5.0 million is due if our net revenues during the fiscal year 2006 equaled or exceeded \$25.0 million. This milestone has been met and the receivable is reflected in our December 31, 2006 financial statements. This milestone payment was received in February 2007. Under the terms of the amendment, we are required to pay PRF \$5.0 million on December 1, 2009 and an additional \$5.0 million on December 1, 2010.

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 an amount equal to (i) the base salary the chief executive officer would have received during the 15-month period immediately following the date of termination, plus (ii) the last annual bonus received by the chief executive officer multiplied by a fraction, the numerator of which is the number of days in the calendar year elapsed as of the termination date and the denominator of which is 365.

On May 10, 2007, we executed amendments to the employment agreements of our chief executive officer, Dr. Ron Cohen, our chief scientific officer, Dr. Andrew Blight, our chief operating officer, Mary Fisher, our chief financial officer, David Lawrence and our general counsel, Jane Wasman. On July 19, 2007 our chief operating officer, Mary Fisher resigned and is no longer with the company.

Under the terms of Dr. Cohen's employment agreement, in the event that we terminate the agreement with Dr. Cohen without cause, or if Dr. Cohen voluntarily terminates the agreement with good reason, we are obligated to make severance payments equal to 15 months' base annual salary and

COBRA premium payments for the severance period plus a bonus equal to his prior year's bonus pro rated for the number of days worked prior to termination. This amount would be paid in a lump sum within 30 days after such termination. In such event, all of Dr. Cohen's stock awards will become immediately vested, with all options and stock appreciation rights exercisable for 48 months following termination.

If Dr. Cohen's employment terminates for death or disability, we are obligated to pay his base salary for three months and COBRA premiums for the COBRA coverage period and 65% of his outstanding options will become immediately vested and remain exercisable for 48 months following such termination or for a lesser period, to the extent necessary to comply with U.S. tax law.

If Dr. Cohen voluntarily terminates his employment without good reason following a "change in control" (as defined in his employment agreement), we are obligated to make severance payments equal to 12 months' base annual salary and COBRA premium payments for the severance period and he is entitled to receive a bonus equal to his prior year's bonus pro rated for the number of days worked prior to termination. In addition, following implementation of the amendment to Dr. Cohen's employment and award agreement(s) as described above, if the "change in control" constitutes a "reorganization event" (as defined in the Company's 2006 Employee Incentive Plan), 100% of his outstanding options, restricted stock and any other awards will become immediately vested; otherwise not less than 50% of the unvested awards will become immediately and fully vested. Furthermore, all vested options will remain exercisable for 48 months following termination. Following his termination of employment, Dr. Cohen will remain subject to confidentiality, non-competition and non-solicitation covenants for one year in the case of non-competition and non-solicitation and five years in the case of confidentiality.

In the event we terminate our employment agreement with Dr. Blight, 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 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, or for a lesser period, to the extent necessary to comply with U.S. tax law. All unvested options, stock appreciation rights awards and stock awards will be cancelled on the date of termination.

If Dr. Blight, Mr. Lawrence or Ms. Wasman voluntarily terminates his or her employment with good reason or if we terminate his or her employment without cause within 18 months after a "change in control" (as defined in their employment agreements), we are obligated to make severance payments equal to one year's base annual salary, in the case of Dr. Blight, 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 a 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 addition, upon implementation of the amendment to each executive officer's employment and award agreement(s) as described above, if the "change in control" constitutes a "reorganization event" (as defined in the Company's 2006 Employee Incentive Plan), 100% of the outstanding options and restricted stock and any other awards then held by each such executive officer will become immediately vested; otherwise, not less than 50% of the unvested awards will become immediately and full vested. Furthermore, all vested options will remain exercisable for 18 months following such date, or for a lesser period, to the extent necessary to comply with U.S. tax law. 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. 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. At a future point in time, 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 sometimes 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 for both Zanaflex tablets and Zanaflex Capsules. Gross sales data reported in the financial statements in this filing are based on three months of actual prescription data. The method for estimating prescriptions is 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 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.

### 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 three or nine-month periods ended September 30, 2007 and 2006. 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, 2007.

As of September 30, 2007, we had available net operating loss carry-forwards of approximately \$169.6 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 2026 and research and development tax credit carry-forwards of approximately \$1.4 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.

### Share based Compensation

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.

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.

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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*.

### Recent Accounting Pronouncements

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157, *Fair Value Measurements*. 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.

In February 2007, the FASB issued Statement of Financial Account Standards No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including Amendment of FASB Statement No. 115*. The new standard permits, but does not require, entities to measure certain financial instruments and other assets and liabilities at fair value on an instrument-by-instrument basis. Unrealized gains and losses on items for which the fair value option has been elected should be recognized in earnings at each subsequent reporting date. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007. The Company does not believe SFAS 159 will have a material impact on its results from operations or financial position.

In July 2006, the FASB issued FASB Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109, Accounting for Income Taxes*. In addition, in May 2007, the FASB issued FASB Staff Position FIN 48-1 which provided guidance on how an enterprise should determine whether a tax position is effectively settled for the purpose of recognizing previously unrecognized tax benefits. The Interpretation and Staff Position 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 adopted FIN 48 as of January 1, 2007. The adoption of this Interpretation had no impact on the Company's results of operations or financial position. The Company has no reserves for uncertain tax positions.

In June 2007, the Emerging Issues Task Force (EITF) issued EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities*. EITF Issue No. 07-3 provides guidance concerning the accounting for non-refundable advance payments for goods and services that will be used in future R&D activities and requires that they be expensed when the research and development activity has been performed and not at the time of payment. The provisions of EITF Issue No. 07-3 are effective for the fiscal years beginning after December 15, 2007, with a cumulative-effect adjustment to Retained Earnings as of the beginning of the year of adoption. The Company is evaluating the potential impact of this consensus.

### 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, and put/call liability. The estimated fair values of all of our financial instruments approximate their carrying amounts at September 30, 2007.

We have cash equivalents and short-term investments at September 30, 2007, 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, 2007.

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 4T. 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, 2007, 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. There have been no changes in our internal controls over financial reporting (as defined in Rules 13a-15(b) and 15(d)-15(f) under the Exchange Act) or in other factors that has materially affected or is reasonably likely to materially affect internal controls over financial reporting.

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, 2007 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.

In September 2007, the Company received a Paragraph IV Certification Notice from Apotex Inc. advising that Apotex Inc. had filed an Abbreviated New Drug Application (ANDA) with the FDA for generic versions of each of the three Zanaflex Capsules dosage strengths. In response to the Notice, in October 2007, the Company filed a lawsuit against Apotex Corp. and Apotex Inc. in the United States District Court for the District of New Jersey asserting infringement of the Company's U.S. Patent No. 6,455,557 relating to multiparticulate tizanidine compositions, including those sold by the Company as Zanaflex Capsules. The patent expires in 2021. We intend to vigorously defend our intellectual property rights related to Zanaflex Capsules.

### 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, 2006, all of which could materially affect our business, financial condition or future results. Other than the revisions to the following risk factor set forth below, there have been no material changes from the risk factors referred to in the previous sentence. The risks described in the Annual Report 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.

*If we cannot protect our intellectual property, our ability to develop and commercialize our products will be severely limited.*

Our success will depend in part on our and our licensors' ability to obtain, maintain and enforce patent protection for the technologies, compounds and products, if any, resulting from our licenses and development programs. Without protection for the intellectual property we use, other companies could offer substantially identical products for sale without incurring the sizable discovery, development and licensing costs that we have incurred. Our ability to recover these expenditures and realize profits upon the sale of products could be diminished.

We have in-licensed or are the assignee of over 25 U.S. patents, over 60 foreign patents and over 65 patent applications pending in the United States or abroad for our own technologies and for technologies from our in-licensed programs. The process of obtaining patents can be time consuming and expensive with no certainty of success. Even if we spend the necessary time and money, a patent may not issue or it may not have sufficient scope or strength to protect the technology it was intended to protect or to provide us with any commercial advantage. We may never be certain that we were the first to develop the technology or that we were the first to file a patent application for the particular technology because U.S. patent applications are confidential until they are published, and publications in the scientific or patent literature lag behind actual discoveries. The degree of future protection for our proprietary rights will remain uncertain if our pending patent applications are not approved for any reason or if we are unable to develop additional proprietary technologies that are patentable. Furthermore, third parties may independently develop similar or alternative technologies, duplicate some or all of our technologies, design around our patented technologies or challenge our issued patents or the patents of our licensors.

We may initiate actions to protect our intellectual property and in any litigation in which our patents or our licensors' patents are asserted, a court may determine that the patents are invalid or unenforceable. Even if the validity or enforceability of these patents is upheld by a court, a court may not prevent alleged infringement on the grounds that such activity is not covered by the patent claims. In addition, effective intellectual property enforcement may be unavailable or limited in some foreign



countries. Any litigation, whether to enforce our rights to use our or our licensors' patents or to defend against allegations that we infringe third party rights, would be costly, time consuming, and may distract management from other important tasks.

As is commonplace in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. To the extent our employees are involved in research areas that are similar to those areas in which they were involved at their former employers, we may be subject to claims that such employees and/or we have inadvertently or otherwise used or disclosed the alleged trade secrets or other proprietary information of the former employers. Litigation may be necessary to defend against such claims, which could result in substantial costs and be a distraction to management and which could have an adverse effect on us, even if we are successful in defending such claims.

We also rely in our business on trade secrets, know-how and other proprietary information. We seek to protect this information, in part, through the use of confidentiality agreements with employees, consultants, advisors and others. Nonetheless, those agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information and prevent their unauthorized use or disclosure. To the extent that consultants, key employees or other third parties apply technological information independently developed by them or by others to our proposed products, disputes may arise as to the proprietary rights to such information which may not be resolved in our favor. The risk that other parties may breach confidentiality agreements or that our trade secrets become known or independently discovered by competitors, could adversely affect us by enabling our competitors, who may have greater experience and financial resources, to copy or use our trade secrets and other proprietary information in the advancement of their products, methods or technologies. Policing unauthorized use of our or our licensors' intellectual property is difficult, expensive and time-consuming, and we may be unable to determine the extent of any unauthorized use. Adequate remedies may not exist in the event of unauthorized use or disclosure.

In September 2007, we received a Paragraph IV Certification Notice from Apotex Inc. advising that it filed an ANDA with the FDA for generic versions of each of the three Zanaflex Capsules dosage strengths marketed by us. In response to that Notice, in October 2007, we filed a lawsuit against Apotex Corp. and Apotex Inc. in the United States District Court for the District of New Jersey asserting infringement of our U.S. Patent No. 6,455,557 relating to multiparticulate tizanidine compositions, including those sold by us as Zanaflex Capsules, which patent expires in 2021. Although we intend to vigorously defend our intellectual property rights related to Zanaflex Capsules, there is no assurance that we will win the litigation or that the ANDA filed by Apotex Inc. will not be approved by the FDA. In addition, if Apotex Corp. and Apotex Inc. are successful in challenging our patent, and if the FDA approves that ANDA, they will be, and other third parties who file ANDAs for which they receive FDA approval might be, permitted to sell a generic tizanidine hydrochloride capsule. The Company would face significant competition from any generic tizanidine hydrochloride capsule, which would likely cause significant declines in our revenue and profit margin from the sale of Zanaflex Capsules and Zanaflex tablets.

#### **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, in the State of New York, on this 8th day of November 2007.

**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	President, Chief Executive Officer and Director (Principal Executive Officer)	November 8, 2007
Ron Cohen, M.D.		
/s/ DAVID LAWRENCE	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	November 8, 2007
David Lawrence, M.B.A.		

**Exhibit Index**

<b>Exhibit No.</b>	<b>Description</b>
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PART I. FINANCIAL INFORMATION

PART I

ACORDA THERAPEUTICS, INC. AND SUBSIDIARY Consolidated Balance Sheets

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

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

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

PART II. OTHER INFORMATION

SIGNATURES

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