

ACORDA THERAPEUTICS INC  
Form 10-Q  
May 11, 2009

Table of Contents

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

---

**FORM 10-Q**

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

**For the quarterly period ended March 31, 2009**

**OR**

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

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

---

**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 ý No o

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

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

## Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-Q

Large accelerated filer ☐

Accelerated filer ☐

Non-accelerated filer ☐ (Do not check if a smaller reporting company)

Smaller Reporting Company ☐

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

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

| Class                                        | Outstanding at April 30, 2009 |
|----------------------------------------------|-------------------------------|
| Common Stock, \$0.001 par value<br>per share | 38,011,594 shares             |

---

ACORDA THERAPEUTICS, INC.

TABLE OF CONTENTS

PART I FINANCIAL INFORMATION

|                 |                                                                                              |           |
|-----------------|----------------------------------------------------------------------------------------------|-----------|
| <u>Item 1.</u>  | <u>Financial Statements</u>                                                                  | <u>3</u>  |
|                 | <u>Consolidated Balance Sheets</u>                                                           | <u>3</u>  |
|                 | <u>March 31, 2009 (unaudited) and December 31, 2008</u>                                      | <u>3</u>  |
|                 | <u>Consolidated Statements of Operations (unaudited)</u>                                     | <u>4</u>  |
|                 | <u>Three-month periods ended March 31, 2009 and 2008</u>                                     | <u>4</u>  |
|                 | <u>Consolidated Statements of Cash Flows (unaudited)</u>                                     | <u>5</u>  |
|                 | <u>Three-month periods ended March 31, 2009 and 2008</u>                                     | <u>5</u>  |
|                 | <u>Notes to Consolidated Financial Statements (unaudited)</u>                                | <u>6</u>  |
| <u>Item 2.</u>  | <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> | <u>13</u> |
| <u>Item 3.</u>  | <u>Quantitative and Qualitative Disclosures About Market Risk</u>                            | <u>24</u> |
| <u>Item 4.</u>  | <u>Controls and Procedures</u>                                                               | <u>24</u> |
|                 | <b><u>PART II OTHER INFORMATION</u></b>                                                      |           |
| <u>Item 1.</u>  | <u>Legal Proceedings</u>                                                                     | <u>26</u> |
| <u>Item 1A.</u> | <u>Risk Factors</u>                                                                          | <u>26</u> |
| <u>Item 6.</u>  | <u>Exhibits</u>                                                                              | <u>27</u> |

Table of Contents

*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, 2008, 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.*

Table of Contents**PART I****Item 1. Financial Statements****ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES****Consolidated Balance Sheets**

|                                                                                                                                                                                                                         | <b>March 31,<br/>2009<br/>(unaudited)</b> | <b>December 31,<br/>2008</b> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------|------------------------------|
| <b>Assets</b>                                                                                                                                                                                                           |                                           |                              |
| Current assets:                                                                                                                                                                                                         |                                           |                              |
| Cash and cash equivalents                                                                                                                                                                                               | \$ 36,118,002                             | \$ 29,612,916                |
| Restricted cash                                                                                                                                                                                                         | 298,867                                   | 297,655                      |
| Short-term investments                                                                                                                                                                                                  | 189,833,975                               | 216,435,416                  |
| Trade accounts receivable, net                                                                                                                                                                                          | 4,603,410                                 | 4,622,486                    |
| Prepaid expenses                                                                                                                                                                                                        | 4,381,651                                 | 3,330,069                    |
| Finished goods inventory held by the Company                                                                                                                                                                            | 2,546,386                                 | 3,670,949                    |
| Finished goods inventory held by others                                                                                                                                                                                 | 2,517,920                                 | 2,472,692                    |
| Other current assets                                                                                                                                                                                                    | 1,840,274                                 | 1,605,572                    |
| <b>Total current assets</b>                                                                                                                                                                                             | <b>242,140,485</b>                        | <b>262,047,755</b>           |
| Property and equipment, net of accumulated depreciation                                                                                                                                                                 | 2,779,983                                 | 2,348,147                    |
| Intangible assets, net of accumulated amortization                                                                                                                                                                      | 16,244,782                                | 16,565,456                   |
| Other assets                                                                                                                                                                                                            | 500,589                                   | 539,328                      |
| <b>Total assets</b>                                                                                                                                                                                                     | <b>\$ 261,665,839</b>                     | <b>\$ 281,500,686</b>        |
| <b>Liabilities and Stockholders' Equity</b>                                                                                                                                                                             |                                           |                              |
| Current liabilities:                                                                                                                                                                                                    |                                           |                              |
| Accounts payable                                                                                                                                                                                                        | \$ 7,316,527                              | \$ 10,124,840                |
| Accrued expenses and other current liabilities                                                                                                                                                                          | 11,024,279                                | 13,993,753                   |
| Deferred product revenue Zanaflex tablets                                                                                                                                                                               | 8,051,892                                 | 7,867,046                    |
| Deferred product revenue Zanaflex Capsules                                                                                                                                                                              | 17,316,494                                | 16,436,474                   |
| Current portion of revenue interest liability                                                                                                                                                                           | 6,921,125                                 | 6,181,100                    |
| <b>Total current liabilities</b>                                                                                                                                                                                        | <b>50,630,318</b>                         | <b>54,603,213</b>            |
| Put/call liability                                                                                                                                                                                                      | 337,500                                   | 337,500                      |
| Non current portion of revenue interest liability                                                                                                                                                                       | 12,249,694                                | 12,497,745                   |
| Long-term convertible notes payable                                                                                                                                                                                     | 6,956,669                                 | 6,904,883                    |
| Commitments and contingencies                                                                                                                                                                                           |                                           |                              |
| Stockholders' equity:                                                                                                                                                                                                   |                                           |                              |
| Common stock, \$0.001 par value. Authorized 80,000,000 shares at March 31, 2009 and December 31, 2008; issued and outstanding 37,685,944 and 37,613,356 shares as of March 31, 2009 and December 31, 2008, respectively | 37,686                                    | 37,614                       |
| Additional paid-in capital                                                                                                                                                                                              | 554,353,297                               | 550,683,383                  |
| Accumulated deficit                                                                                                                                                                                                     | (363,084,554)                             | (344,376,410)                |
| Accumulated other comprehensive income                                                                                                                                                                                  | 185,230                                   | 812,758                      |
| <b>Total stockholders' equity</b>                                                                                                                                                                                       | <b>191,491,659</b>                        | <b>207,157,345</b>           |
| <b>Total liabilities and stockholders' equity</b>                                                                                                                                                                       | <b>\$ 261,665,839</b>                     | <b>\$ 281,500,686</b>        |



Table of Contents**ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES****Consolidated Statements of Operations****(unaudited)**

|                                                                                                   | <b>Three-month<br/>period ended<br/>March 31,<br/>2009</b> | <b>Three-month<br/>period ended<br/>March 31,<br/>2008</b> |
|---------------------------------------------------------------------------------------------------|------------------------------------------------------------|------------------------------------------------------------|
| Gross sales Zanaflex                                                                              | \$ 14,617,943                                              | \$ 12,676,509                                              |
| Less: discounts and allowances                                                                    | (2,148,865)                                                | (1,189,183)                                                |
| Net sales                                                                                         | 12,469,078                                                 | 11,487,326                                                 |
| Grant revenue                                                                                     |                                                            | 26,232                                                     |
| Total net revenue                                                                                 | 12,469,078                                                 | 11,513,558                                                 |
| Less: cost of sales                                                                               | (2,558,937)                                                | (2,986,392)                                                |
| Gross profit                                                                                      | 9,910,141                                                  | 8,527,166                                                  |
| Operating expenses:                                                                               |                                                            |                                                            |
| Research and development                                                                          | 7,916,936                                                  | 9,592,322                                                  |
| Sales and marketing                                                                               | 12,874,371                                                 | 10,196,634                                                 |
| General and administrative                                                                        | 7,147,333                                                  | 5,063,203                                                  |
| Total operating expenses                                                                          | 27,938,640                                                 | 24,852,159                                                 |
| Operating loss                                                                                    | (18,028,499)                                               | (16,324,993)                                               |
| Other expense (net):                                                                              |                                                            |                                                            |
| Interest and amortization of debt discount expense                                                | (1,492,264)                                                | (1,358,100)                                                |
| Interest income                                                                                   | 797,219                                                    | 1,212,638                                                  |
| Other income                                                                                      | 15,400                                                     | 39,580                                                     |
| Total other expense (net)                                                                         | (679,645)                                                  | (105,882)                                                  |
| Net loss                                                                                          | \$ (18,708,144)                                            | \$ (16,430,875)                                            |
| Net loss per share basic and diluted                                                              | \$ (0.50)                                                  | \$ (0.54)                                                  |
| Weighted average common shares outstanding used in computing net loss per share basic and diluted | 37,642,894                                                 | 30,343,950                                                 |

See accompanying Unaudited Notes to Consolidated Financial Statements

Table of Contents**ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES****Consolidated Statements of Cash Flows****(unaudited)**

|                                                                             | <b>Three-month<br/>period ended<br/>March 31,<br/>2009</b> | <b>Three-month<br/>period ended<br/>March 31,<br/>2008</b> |
|-----------------------------------------------------------------------------|------------------------------------------------------------|------------------------------------------------------------|
| Cash flows from operating activities:                                       |                                                            |                                                            |
| Net loss                                                                    | \$ (18,708,144)                                            | \$(16,430,875)                                             |
| Adjustments to reconcile net loss to net cash used in operating activities: |                                                            |                                                            |
| Acquired in-process research and development                                |                                                            | 2,685,900                                                  |
| Share-based compensation expense                                            | 2,718,140                                                  | 1,921,911                                                  |
| Amortization of net premiums and discounts on short-term investments        | 364,146                                                    | (689,707)                                                  |
| Amortization of revenue interest issuance cost                              | 31,915                                                     | 29,167                                                     |
| Depreciation and amortization expense                                       | 681,421                                                    | 835,727                                                    |
| Gain on disposal of property and equipment                                  | (15,400)                                                   |                                                            |
| Changes in assets and liabilities:                                          |                                                            |                                                            |
| Decrease in accounts receivable                                             | 19,076                                                     | 145,159                                                    |
| Increase in prepaid expenses and other current assets                       | (1,286,284)                                                | (179,128)                                                  |
| Decrease in inventory held by the Company                                   | 1,434,123                                                  | 1,125,460                                                  |
| Increase in inventory held by others                                        | (45,228)                                                   | (144,130)                                                  |
| Decrease (increase) in other assets                                         | 6,824                                                      | (5,738)                                                    |
| Decrease in accounts payable, accrued expenses, other current liabilities   | (5,791,285)                                                | (597,163)                                                  |
| Increase (decrease) in deferred product revenue Zanaflex tablets            | 184,846                                                    | (54,444)                                                   |
| Increase in deferred product revenue Zanaflex Capsules                      | 880,020                                                    | 1,708,930                                                  |
| Restricted cash                                                             | (1,212)                                                    | (2,769)                                                    |
| Net cash used in operating activities                                       | (19,527,042)                                               | (9,651,700)                                                |
| Cash flows from investing activities:                                       |                                                            |                                                            |
| Purchases of property and equipment                                         | (271,490)                                                  | (330,583)                                                  |
| Purchases of short-term investments                                         | (78,290,233)                                               | (49,877,516)                                               |
| Proceeds from maturities of short-term investments                          | 103,900,000                                                | 36,300,000                                                 |
| Net cash provided by (used in) investing activities                         | 25,338,277                                                 | (13,908,098)                                               |
| Cash flows from financing activities:                                       |                                                            |                                                            |
| Proceeds from issuance of common stock and option exercises                 | 951,846                                                    | 74,811,917                                                 |
| Repayments of revenue interest liability                                    | (257,995)                                                  | (440,044)                                                  |
| Repayments of notes payable                                                 |                                                            | (187,645)                                                  |
| Net cash provided by financing activities                                   | 693,851                                                    | 74,184,228                                                 |
| Net increase in cash and cash equivalents                                   | 6,505,086                                                  | 50,624,430                                                 |
| Cash and cash equivalents at beginning of period                            | 29,612,916                                                 | 16,810,415                                                 |
| Cash and cash equivalents at end of period                                  | \$ 36,118,002                                              | \$ 67,434,845                                              |
| Supplemental disclosure:                                                    |                                                            |                                                            |
| Cash paid for interest                                                      | 690,508                                                    | 540,496                                                    |
| Non-cash activities:                                                        |                                                            |                                                            |
| Accrued inventory                                                           | 309,560                                                    |                                                            |

## Edgar Filing: ACORDA THERAPEUTICS INC - Form 10-Q

|                                    |         |           |
|------------------------------------|---------|-----------|
| Accrued property and equipment     | 514,185 | 124,254   |
| Accrued Zanaflex milestone payment |         | 5,000,000 |

See accompanying Unaudited Notes to Consolidated Financial Statements

Table of Contents

**ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES**

**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 (CNS).

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 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, 2008 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 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 2010 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 subsidiaries. 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

Table of Contents

**ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements (Continued)**

(unaudited)

**(2) Summary of Significant Accounting Policies (Continued)**

statements and the reported amounts of revenues and expenses during the period. Significant items subject to such estimates and assumptions include research and development and share-based compensation accounting, which are largely dependent on the fair value of the Company's equity securities. 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 Statement of Financial Accounting Standards (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 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

Table of Contents

**ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements (Continued)**

(unaudited)

**(2) Summary of Significant Accounting Policies (Continued)**

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 and accounts receivable. The Company maintains cash and cash equivalents and restricted cash with approved financial institutions. The Company is exposed to credit risks and liquidity 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 options and a convertible promissory note 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 for each year are equal.

***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*.

***Recent Accounting Pronouncements***

In November 2007, the EITF issued Issue No. 07-01 (EITF 07-01), *Accounting for Collaborative Arrangements*, which requires collaborators to present the results of activities for which they act as the principal on a gross basis and report any payments received from (made to) other collaborators based on other applicable generally accepted accounting principles or, in the absence of other applicable generally accepted accounting principles, based on analogy to authoritative accounting literature or a reasonable, rational and consistently applied accounting policy election. EITF 07-01 is effective for fiscal years beginning after December 15, 2008. The adoption of EITF 07-01 did not have an impact on the Company's consolidated financial statements.

In December 2007, the Financial Accounting Standards Board (FASB) issued SFAS No. 141R, *Business Combinations*. This statement is effective for fiscal years beginning on or after December 15, 2008 and generally applies to business acquisitions completed after December 31, 2008. Among other

Table of Contents

**ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements (Continued)**

**(unaudited)**

**(2) Summary of Significant Accounting Policies (Continued)**

things, the new standard requires that all acquisition-related costs be expensed as incurred, that acquired in-process research and development be recorded at fair value as an indefinite-lived asset at the acquisition date and that all restructuring costs related to acquired operations be expensed as incurred. This new standard also addresses the current and subsequent accounting for assets and liabilities arising from contingencies acquired or assumed and, for acquisitions both prior and subsequent to December 31, 2008, requires the acquirer to recognize changes in the amount of its deferred tax benefits that are recognizable because of a business combination either in income from continuing operations in the period of the combination or directly in contributed capital, depending on the circumstances. The adoption of SFAS No. 141R did not have an impact on the Company's consolidated financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements*. SFAS No. 160 changes the accounting for minority interests, which will be recharacterized as noncontrolling interests and classified by the parent company as a component of equity. This statement is effective for fiscal years beginning on or after December 15, 2008. Upon adoption, SFAS No. 160 requires retroactive adoption of the presentation and disclosure requirements for existing minority interests and prospective adoption for all other requirements. The adoption of SFAS No. 160 did not have an impact on the Company's consolidated financial statements.

In April 2008, the FASB issued Final FASB Staff Position (FSP), FAS 142-3, *Determination of the Useful Life of Intangible Assets*, which amended the factors to be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, *Goodwill and Other Intangible Assets*. This FSP is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. The adoption did not have an impact on our consolidated financial statements.

In December 2008, the FASB issued FSP FAS 157-2, *Effective Date of FASB Statement No. 157*, which defers the effective date of SFAS 157, *Fair Value Measurements* for nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), to fiscal years and interim periods within those fiscal years, beginning after November 15, 2008. The adoption of this Staff Position did not have an impact on our consolidated financial statements.

**(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 March 31, 2009 and 2008, the Company recognized share-based compensation expense of \$2.7 million and \$1.9 million, respectively. Activity in options and restricted stock during the three-month period ended March 31, 2009 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 March 31, 2009 and 2008 were approximately \$13.31 and \$13.63, respectively.

Table of Contents**ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****(unaudited)****(3) Share-based Compensation (Continued)**

A summary of share-based compensation activity for the three-month period ended March 31, 2009 is presented below:

***Stock Option Activity***

|                                                  | <b>Number of<br/>Shares</b> | <b>Weighted<br/>Average<br/>Exercise Price</b> | <b>Weighted<br/>Average<br/>Remaining<br/>Contractual<br/>Term</b> | <b>Intrinsic<br/>Value</b> |
|--------------------------------------------------|-----------------------------|------------------------------------------------|--------------------------------------------------------------------|----------------------------|
| Balance at January 1, 2009                       | 3,284,323                   | \$ 13.55                                       |                                                                    |                            |
| Granted                                          | 539,824                     | 20.80                                          |                                                                    |                            |
| Forfeited                                        | (138,778)                   | 16.42                                          |                                                                    |                            |
| Exercised                                        | (72,588)                    | 13.11                                          |                                                                    |                            |
| Balance at March 31, 2009                        | 3,612,781                   | \$ 14.53                                       | 7.4                                                                | \$21,851,304               |
| Vested and expected to vest at<br>March 31, 2009 | 3,502,805                   | \$ 14.34                                       | 7.4                                                                | \$21,754,088               |
| Vested and exercisable at<br>March 31, 2009      | 1,861,907                   | \$ 9.97                                        | 6.3                                                                | \$18,763,642               |

***Restricted Stock Activity***

| <b>Restricted Stock</b>      | <b>Number of<br/>Shares</b> |
|------------------------------|-----------------------------|
| Nonvested at January 1, 2009 | 150,163                     |
| Granted                      | 198,291                     |
| Vested                       |                             |
| Forfeited                    | (15,289)                    |
| Nonvested at March 31, 2009  | 333,165                     |

As of March 31, 2009, there was \$25.3 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 2.6 years.

**(4) Income Taxes**

The Company had available net operating loss carry-forwards (NOL) of approximately \$279.1 million and \$262.2 million as of March 31, 2009 and December 31, 2008, 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 2028. The Company also has research and development tax credit carryforwards of approximately \$1.6 million as of both March 31, 2009 and December 31, 2008, 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 March 31, 2009 and December 31, 2008, the Company had a deferred tax asset of \$125.6 million and \$119.5 million, respectively, offset by a full valuation allowance. Since inception, the



Table of Contents

**ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES**

**Notes to Consolidated Financial Statements (Continued)**

(unaudited)

**(4) Income Taxes (Continued)**

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. 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 gross deferred tax assets as of and for all periods presented. As of March 31, 2009, management believes that it is more likely than not that the gross deferred tax assets will not be realized based on future operations and reversal of deferred tax liabilities. Accordingly, the Company has provided a full valuation allowance against its gross deferred tax assets and no tax benefit has been recognized relative to its pretax losses.

**(5) Fair Value Measurements**

Effective January 1, 2008, the Company adopted SFAS No. 157, *Fair Value Measurements* (SFAS 157), as it relates to financial assets and financial liabilities. SFAS 157 establishes a framework for measuring fair value in generally accepted accounting principles and expands disclosures about fair value measurements. SFAS 157 applies under other previously issued accounting pronouncements that require or permit fair value measurements but does not require any new fair value measurements. The adoption of SFAS 157 did not have an impact on our consolidated financial statements.

Effective January 1, 2009, the Company adopted FASB Staff Position (FSP) No. SFAS 157-2, *Effective Date of FASB Statement No. 157* (FSP 157-2). FSP 157-2 defers the effective date of SFAS 157 for nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually), to fiscal years and interim periods within those fiscal years, beginning after November 15, 2008. The adoption of this FSP 157-2 did not have an impact on our consolidated financial statements.

SFAS 157 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. SFAS 157 establishes a fair value hierarchy which requires us to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. We primarily apply the market approach for recurring fair value measurements. The standard describes three levels of inputs that may be used to measure fair value:

Level 1 Quoted prices in active markets for identical assets or liabilities.

Level 2 Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Table of Contents**ACORDA THERAPEUTICS, INC. AND SUBSIDIARIES****Notes to Consolidated Financial Statements (Continued)****(unaudited)****(5) Fair Value Measurements (Continued)**

The following table presents information about our assets and liabilities measured at fair value on a recurring basis as of March 31, 2009 and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value.

|                                           | Level 1       | Level 2 | Level 3 |
|-------------------------------------------|---------------|---------|---------|
| <b>Assets Carried at Fair Value:</b>      |               |         |         |
| Cash equivalents                          | \$ 32,587,642 | \$      | \$      |
| Short-term investments                    | 189,833,975   |         |         |
| <b>Liabilities Carried at Fair Value:</b> |               |         |         |
| Put/call liability                        |               |         | 337,500 |

The following table presents additional information about assets and/or liabilities measured at fair value on a recurring basis and for which we utilize Level 3 inputs to determine fair value.

|                                           | Balance as of<br>December 31,<br>2008 | Realized<br>gains<br>(losses)<br>included<br>in net loss | Unrealized<br>losses included<br>in other<br>comprehensive<br>loss | Balance as<br>of<br>March 31,<br>2009 |
|-------------------------------------------|---------------------------------------|----------------------------------------------------------|--------------------------------------------------------------------|---------------------------------------|
| <b>Liabilities Carried at Fair Value:</b> |                                       |                                                          |                                                                    |                                       |
| Put/call liability                        | \$ 337,500                            | \$                                                       | \$                                                                 | \$ 337,500                            |

We evaluate fair value of positions classified within the Level 3 category based on revenue projections, business, general economic and market conditions that could be reasonably evaluated as of the valuation date.

Table of Contents

**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. A second Phase 3 trial of Fampridine-SR in MS, MS-F204, was initiated in June 2007 and favorable results from that study were released in June 2008. The objective of this study was to show that individuals treated with Fampridine-SR are significantly more likely to have consistent improvements in their walking than those treated with placebo. A Thorough QT cardiac study was initiated in September 2007 and favorable results from that study were released in January 2008. This study evaluated the potential of Fampridine-SR to cause an increase in the electrocardiographic QT interval. Fampridine-SR, at both therapeutic and supratherapeutic doses, was found to be no different than placebo.

On January 30, 2009, we announced the submission of a New Drug Application (NDA) to the FDA for Fampridine-SR. The Fampridine-SR NDA submission is based on data from a comprehensive development program assessing the safety and efficacy of Fampridine-SR, including two Phase 3 trials that involved 540 people with MS and were conducted under Special Protocol Assessments (SPAs) from the FDA. The safety and efficacy profile of Fampridine-SR was consistent across Phase 2 and Phase 3 trials. Overall, the NDA filing included more than 50 clinical studies of Fampridine-SR. The total exposure to Fampridine-SR in MS studies filed as part of the NDA was over 1,200 patient-years. Additionally, more than 450 people are currently enrolled in Fampridine-SR extension trials, with treatment duration ranging from seven months to almost five years.

We announced the receipt of a refuse to file letter (RTF) from the FDA on March 31, 2009 regarding our NDA for Fampridine-SR. The FDA raised what it termed "format issues" regarding the eCTD (electronic) submission, requesting that some of the data in the NDA be reformatted, as well as requesting that some additional supporting information and pharmacokinetic data from a fed/fasted study be included in the filing. The FDA did not request or recommend additional clinical or other studies.

We announced the resubmission of our NDA for Fampridine-SR to the FDA on April 23, 2009. On May 6, 2009, we announced that the FDA had accepted our NDA for filing, and had assigned it Priority Review and a Prescription Drug User Fee Act (PDUFA) date of October 22, 2009. The PDUFA date is the target date for the FDA to complete its review of the Fampridine-SR NDA.

We have also discussed Fampridine-SR with national regulatory authorities of four European Union member states and believe that the current data are sufficient to allow us to file a centralized Marketing Authorization Application (MAA) with the European Medicines Agency (EMA). We are in discussions with potential marketing partners regarding the commercialization of Fampridine-SR in the European Union and other non-U.S. markets. At the same time, we are preparing for the filing of a centralized MAA with the EMA and a New Drug Submission (NDS) with Health Canada. We plan to maintain our flexibility in the timing of such a filing in order to optimize our ex-U.S.

Table of Contents

commercialization pathway and availability to patients. We recently formed a subsidiary under the laws of the United Kingdom in order to meet EMEA requirements for filing a centralized MAA.

We believe Fampridine-SR is the first potential therapy in late-stage clinical development for MS that seeks to improve the function of damaged nerve fibers and, if approved, could be complementary to existing drugs used to treat MS. To our knowledge, there are no current therapies indicated to improve walking ability in people with MS.

We have three preclinical programs focused on novel approaches to repair damaged components of the CNS. We believe all of our preclinical programs neuregulins, remyelinating antibodies and chondroitinase have broad applicability and have the potential to be first-in-class therapies. While these programs have initially been focused on MS and SCI, we believe they may be applicable across a number of CNS disorders, including stroke and traumatic brain injury, because many of the mechanisms of tissue damage and repair are similar. In addition, we believe that these programs may have applicability beyond the nervous system, including in such fields as cardiology, oncology, orthopedics and ophthalmology. In 2008, we began to work with a contract manufacturer to develop larger scale manufacturing and purification processes for one of the neuregulins, GGF2, under good manufacturing practices (cGMP) in preparation for a potential future Investigational New Drug (IND) application to support human clinical trials. We expect to file such an IND in late 2009, pending the successful completion of animal toxicology and other preclinical activities. If we are able to establish a proof of concept through human clinical studies, we believe that this may enable us to enter into a partnership with a cardiovascular-focused company, and that such a partnership, if achieved, could more efficiently move GGF2 forward in a cardiac indication, while potentially providing Acorda the capital to support our work on GGF2 in neurological indications. We have also begun work with contract manufacturers to scale up manufacturing and purification processes for one of the remyelinating antibodies (rHIgM22) under cGMPs for preparation for a future IND application.

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 until we begin to generate sales of Fampridine-SR, if approved. Zanaflex Capsules and tablets commercial operations were cash flow positive in 2008 and are expected to be cash flow positive in 2009, with Zanaflex Capsules revenue expected to grow modestly during this period. We are conducting prelaunch activities to prepare for the commercialization of Fampridine-SR, if approved.

We also are conducting activities to provide disease state education and awareness programs to health-care providers and consumers about mobility and walking impairment issues for people with MS.

In September 2007, we received a Paragraph IV Certification Notice from Apotex Inc. advising that it 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 us. In response to the filing of the ANDA, in October 2007, we filed a lawsuit against Apotex Corp. and Apotex Inc. (collectively, Apotex) 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. The patent expires in 2021. The defendants have answered our complaint, asserting patent invalidity and non-infringement and counterclaiming, seeking a declaratory judgment of patent invalidity and non-infringement. We have denied those counterclaims. If the ANDA were approved by the FDA and Apotex were successful in challenging the validity of the

Table of Contents

patent, Apotex could be permitted to sell a generic tizanidine hydrochloride capsule in competition with Zanaflex Capsules.

In March 2008, Apotex filed a motion, which we opposed, for partial judgment on the pleadings dismissing our request for relief on the ground that the case is "exceptional" under U.S.C. §§ 271(e)(4) or 285. The court ruled in our favor and denied Apotex's motion in December 2008. We and Apotex are currently proceeding with discovery in the case. The court has also determined that a Markman hearing on the construction of the claims of the patent will be held, and has set a schedule for the exchange of materials and briefs relating to the hearing. The hearing date has not been set.

We have established our own specialty sales force in the United States, which consisted of 61 sales professionals as of March 31, 2009. This sales force has targeted neurologists and other prescribers who specialize in treating people with conditions that involve spasticity. We also employ an internal and field-based team who 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. We expect to further increase our sales force, approximately doubling it, in anticipation of and in time for the launch of Fampridine-SR, if approved.

**Results of Operations**

***Three-Month Period Ended March 31, 2009 Compared to March 31, 2008***

*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 \$14.6 million for the three-month period ended March 31, 2009, as compared to \$12.7 million for the three-month period ended March 31, 2008. The increase was due to an increase in prescriptions written for our products that we believe is the result of our continued sales and marketing efforts as well as a 10% price increase effective January 1, 2009.

*Discounts and Allowances*

We recorded discounts and allowances of \$2.1 million for the three-month period ended March 31, 2009 as compared to \$1.2 million for the three-month period ended March 31, 2008. Discounts and allowances are recorded when Zanaflex Capsules and Zanaflex tablets are shipped to wholesalers. Discounts and allowances for the three-month period ended March 31, 2009 consisted of \$1.3 million in allowances for chargebacks and rebates which includes an adjustment of \$823,000, \$165,000 related to the first quarter of 2009 and \$658,000 related to 2008. This adjustment resulted from a Department of Defense (DOD) regulation finalized during the three-month period ended March 31, 2009 which purports to require manufacturers to pay rebates to DOD on utilization distributed to TriCare beneficiaries through retail pharmacies retroactive to January 28, 2008. Discounts and allowances for the three-month period ended March 31, 2009 also consisted of \$453,000 in fees for services payable to wholesalers and \$366,000 in cash discounts and patient program rebates. The application of the regulation is currently being challenged in court by a coalition representing a number of manufacturers. Discounts and allowances for the three-month period ended March 31, 2008 consisted of \$456,000 in allowances for chargebacks and rebates, \$385,000 for fees for services payable to wholesalers and \$344,000 in cash discounts and patient program rebates.

Table of Contents

*Grant Revenue*

Grant revenue for the three-month period ended March 31, 2009 was zero compared to \$26,000 for the three-month period ended March 31, 2008. 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 \$2.6 million for the three-month period ended March 31, 2009 as compared to \$3.0 million for the three-month period ended March 31, 2008. The decrease was primarily due to a decrease in amortization of intangible assets as our Zanaflex trademarks were fully amortized as of December 31, 2008. Cost of sales for the three-month period ended March 31, 2009 consisted of \$1.3 million in inventory costs related to recognized revenues, \$921,000 in royalty fees based on net product shipments, \$321,000 in amortization of intangible assets, which is unrelated to either the volume of shipments or the amount of revenue recognized, and \$42,000 in period costs related to freight and stability testing. Cost of sales for the three-month period ended March 31, 2008 consisted of \$1.4 million in inventory costs related to recognized revenue, \$921,000 in royalty fees based on net product shipments, \$596,000 in amortization of intangible assets, which is unrelated to either the volume of shipments or the amount of revenue recognized, and \$58,000 in period costs related to packaging, freight, destruction, and stability testing. Payments to and interest expense related to our Paul Royalty Fund (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 March 31, 2009 were \$7.9 million as compared to \$9.6 million for the three-month period ended March 31, 2008, a decrease of approximately \$1.7 million, or 17%. The decrease was primarily attributable to the Company's acquisition of certain in-process research and development assets of Neurorecovery, Inc. (NRI) during the three-month period ended March 31, 2008, resulting in a non-cash expense of approximately \$2.7 million in accordance with SFAS No. 2 *Accounting for Research and Development Expenses*. In addition, MS clinical development program expense decreased \$1.3 million or 50% to \$1.2 million for the three-month period ended March 31, 2009 primarily due to the conclusion of one of our Phase 3 clinical trials of Fampridine-SR in 2008.

These decreases were offset by an increase in research and development expense of \$2.2 million related to work on one of our preclinical pipeline products, GGF2, including an increase in staff and compensation to support this initiative. This overall increase in expense was primarily associated with animal toxicology expenses and the development of larger scale manufacturing and purification processes for GGF2, under cGMP, in preparation for a potential future IND application to support human clinical trials in late 2009.

*Sales and Marketing*

Sales and marketing expenses for the three-month period ended March 31, 2009 were \$12.9 million compared to \$10.2 million for the three-month period ended March 31, 2008, an increase of approximately \$2.7 million or 26%. This increase was primarily attributable to an increase of \$2.5 million in disease state education and awareness programs and pre-launch activities associated with the possible commercialization of Fampridine-SR, if approved, an increase in sales and marketing staff and compensation of \$448,000 to support the promotion of Zanaflex Capsules and Fampridine-SR pre-launch activities, and an increase of \$123,000 in Zanaflex Capsules sales and marketing initiatives offset by a decrease in other selling related expenses of \$345,000.

Table of Contents

*General and Administrative*

General and administrative expenses for the three-month period ended March 31, 2009 were \$7.1 million compared to \$5.1 million for the three-month period ended March 31, 2008, an increase of approximately \$2.0 million, or 41%. This increase was the result of an increase in staff and compensation and other expenses of \$1.2 million related to supporting the growth of the overall organization, an increase in legal fees of \$549,000 and an increase in costs associated with medical affairs research and educational programs of \$370,000.

*Other Expense*

Other expense was \$680,000 for the three-month period ended March 31, 2009 compared to other expense of \$106,000 for the three-month period ended March 31, 2008, an increase of approximately \$574,000 or 542%. This change was largely due to a decrease in investment interest income of \$415,000 in addition to a \$134,000 increase in interest expense under the PRF revenue interest agreement based on increased shipments.

**Liquidity and Capital Resources**

We have incurred annual operating losses since inception and, as of March 31, 2009, we had an accumulated deficit of approximately \$363.1 million. We have financed our operations primarily through private placements of our securities, public offerings of our common stock, and, to a lesser extent, from loans, government grants and our financing arrangement with PRF.

*Financing Arrangements*

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. On December 23, 2005, EIS transferred these promissory notes to funds affiliated with Saints Capital. As of March 31, 2009, \$5.0 million of these promissory notes were outstanding.

On December 23, 2005, we entered into a revenue interest 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 interest 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. 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.

Table of Contents

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 \$19.2 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 6.1%. 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 March 31, 2009, cash and cash equivalents and short-term investments were approximately \$226.0 million, as compared to \$246.0 million at December 31, 2008. As of March 2009, 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 a Treasury money market fund and high-quality government 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 March 31, 2009, our cash and cash equivalents were \$36.1 million, as compared to \$29.6 million as of December 31, 2008. Our short-term investments consist of US Treasury bonds and commercial paper securities with original maturities greater than three months and less than one year. The balance of these investments was \$189.9 million as of March 31, 2009, as compared to \$216.4 million as of December 31, 2008.

*Net Cash Used in Operations*

Net cash used in operations was \$19.5 million and \$9.7 million for the three-month period ended March 31, 2009 and 2008, respectively. Cash used in operations for the three-month period ended March 31, 2009 was primarily attributable to a net loss of \$18.7 million, a decrease in accounts payable, accrued expenses, and other current liabilities of \$5.8 million, and an increase in prepaid expenses and other current assets of \$1.3 million. Cash used in operations for the three-month period ended March 31, 2009, was partially offset by a non-cash share-based compensation expense of \$2.7 million, a decrease in inventory held by the Company of \$1.4 million, an increase in Zanaflex Capsules deferred product revenues of \$880,000, depreciation and amortization of \$681,000, and amortization of net premiums and discounts on short-term investments of \$364,000. Cash used in operations for the three-month period ended March 31, 2008 was primarily attributable to a net loss of \$16.4 million, amortization of net premiums and discounts on short-term investments of \$690,000, a decrease in accounts payable, accrued expenses, and other current liabilities of \$597,000, and an increase in prepaid expenses and other current assets of \$179,000. Cash used in operations for the three-month period ended March 31, 2008, was partially offset by a non-cash expense for the acquisition of NRI assets of \$2.7 million, a non-cash share-based compensation expense of \$1.9 million, an increase in Zanaflex Capsules deferred product revenues of \$1.7 million, a decrease in inventory held by the Company of \$1.1 million, and depreciation and amortization of \$836,000.

*Net Cash Used in/Provided by Investing*

Net cash provided by investing activities for the three-month period ended March 31, 2009 was \$25.3 million, primarily due to \$103.9 million in proceeds from maturities of short-term investments

Table of Contents

which was offset by \$78.3 million in purchases of short-term investments and \$272,000 in purchases of property and equipment.

*Net Cash Provided by Financing*

Net cash provided by financing activities for the three-month period ended March 31, 2009 was \$694,000 due to \$952,000 in proceeds from option exercises which was offset by \$258,000 in repayments to PRF.

*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, revenue from Fampridine-SR, if approved, 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 for the commercialization of Zanaflex Capsules, increase our efforts to support pre-launch activities for Fampridine-SR and its commercialization, if approved, and continue our clinical development and advance our preclinical programs.

We believe our year-end 2009 cash, cash equivalents and investment balances will be in excess of \$150.0 million and that our current financial resources and sources of liquidity will be sufficient to fund operations and meet financial obligations through 2010 based on our current projected revenue and spending levels. To the extent our capital resources are insufficient to meet future operating requirements we will need to raise additional capital, reduce planned expenditures, or incur indebtedness to fund our operations. We may be unable to obtain additional debt or equity financing on acceptable terms, if at all. If adequate funds are not available, we may be required to curtail our sales and marketing efforts, delay, reduce the scope of or eliminate some of our research and development programs or obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently.

**Contractual Obligations and Commitments**

In January 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 interest assignment arrangement with PRF.

Table of Contents

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 March 31, 2009, the forecast requirement for the five-month period following March 31, 2009 amounted to approximately \$3.8 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. The first milestone payment is due to Elan 90 days following the FDA's approval of a NDA for Fampridine-SR's use for the first indication and further milestone amounts are payable in connection with additional indications.

In December 2005, we entered into a revenue interest 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 interest 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 if our net revenues during the fiscal year 2006 equaled or exceeded \$25.0 million. This milestone was met and the 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. In such event, all of Dr. Cohen's options will become immediately exercisable and shall remain exercisable for 48 months following the termination date or for a lesser period, to the extent necessary to comply with U.S. tax law.

If Dr. Cohen's employment terminates for death or disability, we are obligated to pay his base salary for three months and his COBRA premiums for the COBRA coverage period. This amount would be paid, in case of death, within thirty days after death and, in case of disability, in a lump sum in the seventh month after such termination. In either such event, 65% of his outstanding options will

Table of Contents

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. This amount would be paid in a lump sum in the seventh month after such termination. In addition, 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 issued under the 2006 Employee Incentive Plan will become immediately vested; otherwise only 65% of his unvested awards will become immediately vested. If the "change in control" constitutes a "Change in Control" (as defined in the Company's 1999 Employee Stock Option Plan), 100% of his outstanding options, restricted stock and any other awards issued under the 1999 Employee Stock Option Plan will become immediately vested. All vested options will remain exercisable for 48 months following termination or for a lesser period, to the extent necessary to comply with U.S. tax law. 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.

Under the terms of the employment agreements with our chief scientific officer, Andrew Blight, our chief financial officer, David Lawrence and our general counsel, Jane Wasman, we are obligated to pay severance under certain circumstances. In the event we terminate our employment agreements 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. 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, 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 the prior year's bonus pro rated for the number of days worked prior to termination. We are also obligated to pay salary earned but not paid, vacation and sick leave days that have accrued, and reimbursable business expenses incurred through the date of termination. In such event, not less than 50% of the unvested options, stock appreciation rights and restricted or other stock awards shall become immediately and full vested and shall remain exercisable for 18 months following such date. All options that have vested as of the termination date shall remain exercisable for 90 days following such date. All unvested options, stock appreciation rights awards and stock awards will be cancelled on the date of termination.

**Critical Accounting Policies and Estimates**

The following discussion of critical accounting policies identifies the accounting policies that require application of management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. It is not intended to be a comprehensive list of all of our significant accounting policies. 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.

Table of Contents

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, which could be in a number of years, when we are able to reasonably estimate product returns 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 use the number of units of product prescribed to record gross sales. We then reduce deferred revenue and record cost of goods sold. We began receiving end-user prescription data in March 2005 which enabled us to begin recognizing revenue from Zanaflex tablet sales. We began marketing Zanaflex Capsules in April 2005 and began receiving prescription data and recognizing revenue in the same month.

In addition to the prescription data we purchase, we also receive data that we use to monitor trends in sales from wholesalers to their customers. We receive this data from an outside vendor on a monthly basis. This data includes the number of bottles shipped from certain wholesalers to their customers. We also compare our shipments to wholesalers to prescription reports to further assess inventory in the distribution channel on a monthly basis. We use the wholesaler sales trend data and the wholesaler vs. prescription comparison to better understand market conditions, but not as a basis for recognizing revenue.

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

**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, clinical trial vendors, contract manufacturing for our preclinical program, and regulatory consulting to support our NDA filing. 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. 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

Table of Contents

affect our results of operations. All research and development costs are expensed as incurred except where EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities* applies. In these cases, non-refundable advance payments for goods and services that will be used in future research and development activities are capitalized at the time of payment and expensed when the research and development activity has been performed.

**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-month periods ended March 31, 2009 and 2008. We have provided a valuation allowance for the full amount of our gross deferred tax assets since realization of any future benefit from deductible temporary differences and net operating loss carry-forwards cannot be sufficiently assured at March 31, 2009.

As of March 31, 2009, we had available net operating loss carry-forwards of approximately \$279.1 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 2028 and research and development tax credit carry-forwards of approximately \$1.6 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**

We account for stock options and restricted stock granted to employees according to the provisions of SFAS No. 123R, *Share Based Payment*, which requires that the costs resulting from all share-based payment transactions be recognized in the financial statements at their fair values. We estimate the fair value of each option on the date of grant using the Black-Scholes closed-form option-pricing model based on assumptions for the expected term of the stock options, expected volatility of our common stock, prevailing interest rates, and an estimated forfeiture rate.

Table of Contents

We have based our current assumptions on the following:

| <b>Assumption</b>                  | <b>Method of estimating</b>                                                                                                                 |
|------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------|
| Estimated expected term of options | Based on the 50 <sup>th</sup> percentile of our peer companies                                                                              |
| Expected volatility                | Combination of historic volatility of our common stock since October 1, 2006 and the historic volatility of the stock of our peer companies |
| Risk-free interest rate            | Yields of U.S. Treasury securities corresponding with the expected life of option grants                                                    |
| Forfeiture rates                   | Historical forfeiture data                                                                                                                  |

Of these assumptions, the expected term of the option and expected volatility of our common stock are the most difficult to estimate since they are based on the exercise behavior of the employees and expected performance of our common stock. Increases in the term and the volatility of our common stock will generally cause an increase in compensation expense.

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

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

Our financial instruments consist of cash equivalents, short-term investments, grants 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 March 31, 2009.

We have cash equivalents and short-term investments at March 31, 2009, 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, US Treasury bonds and commercial paper, the carrying value of our cash equivalents and short-term investments approximate their fair value at March 31, 2009. At March 31, 2009, we held \$226.0 million in cash and cash equivalents and short-term investments which had an average interest rate of approximately 0.3%.

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

**Item 4. Controls and Procedures**

*Evaluation of disclosure controls and procedures*

As required by Rule 13a-15 under the Exchange Act we carried out an evaluation of the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e)

Table of Contents

under the Exchange Act, as of the end of the period covered by this report. 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 March 31, 2009, our disclosure controls and procedures were effective.

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***

In connection with the evaluation required by Exchange Act Rule 13a-15(d), our management, including our chief executive officer and chief financial officer, concluded that there were no changes in our internal control over financial reporting during the quarter ended March 31, 2009 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.

Table of Contents

**PART II OTHER INFORMATION**

**Item 1. Legal Proceedings**

In August 2007, we received a Paragraph IV Certification Notice from Apotex Inc. advising that it filed an ANDA with the FDA to market 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. (collectively, Apotex) 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 methods of reducing drowsiness in patients with immediate release multiparticulate tizanidine formulations, including those sold by us as Zanaflex Capsules. The defendants have answered our complaint, asserting patent invalidity and non-infringement and counterclaiming, seeking a declaratory judgment of patent invalidity and non-infringement. We have denied those counterclaims.

In March 2008, Apotex filed a motion, which we opposed, for partial judgment on the pleadings dismissing our request for relief on the ground that the case is "exceptional" under U.S.C. §§ 271(e)(4) or 285. The court ruled in our favor and denied Apotex's motion in December 2008. We and Apotex are currently proceeding with discovery in the case. The court has also determined that a Markman hearing on the construction of the claims of the patent will be held, and has set a schedule for the exchange of materials and briefs relating to the hearing. The hearing date has not been set.

**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, 2008, all of which could materially affect our business, financial condition or future results. Other than the revised 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 are unable to obtain regulatory approval for Fampridine-SR in the U.S., the European Union, or other markets, or any approval is unduly limited in scope or delayed, our business prospects will be materially adversely affected.*

In late January 2009, we submitted to the FDA an NDA for approval of Fampridine-SR for the improvement of walking in patients with MS, based on positive results from two Phase 3 clinical trials conducted pursuant to SPAs from the FDA. On March 31, 2009, we announced the receipt of a refuse to file (RTF) letter from the FDA regarding our NDA for Fampridine-SR. The FDA raised what it termed "format issues" regarding the eCTD (electronic) submission, requesting that some of the data in the NDA be reformatted, as well as requesting that some additional supporting information and pharmacokinetic data from a fed/fasted study be included in the filing. On April 22, 2009, we resubmitted our NDA for Fampridine-SR to the FDA in response to the issues raised in the RTF letter and, on May 6, 2009, we announced that the FDA accepted our NDA for filing and granted our NDA Priority Review. Notwithstanding the acceptance of the NDA and the granting of Priority Review, in the course of its review of the NDA, the FDA could determine that there is a new substantial scientific issue regarding walking in the MS population or Fampridine-SR. In such case, the FDA could alter its opinion expressed in the prior SPAs regarding the adequacy of the design of the Phase 3 studies. The FDA or the regulatory authorities in the European Union or other markets where we may apply for approval could also determine that the risks and benefits shown by the data that we have submitted do not support approval, or support only a limited approval, or an approval conditioned on burdensome post-approval commitments.

Table of Contents

The FDA may identify a need for further studies in order to confirm efficacy or to examine safety or other properties or characteristics of Fampridine-SR. For example, in October 2007, we met with the FDA to discuss the completed preclinical studies proposed for the NDA for Fampridine-SR and the FDA asked us to complete a series of bridging studies to bring our older preclinical toxicology studies to current scientific standards. This included a requirement to complete new studies to fully characterize the toxicokinetics of fampridine in the blood of experimental animals given doses that were used in the full range of our previously performed preclinical toxicology studies, so the FDA can evaluate the suitability of those doses and routes of administration of drug in its evaluation of safety. These additional studies were completed before the submission of our NDA in January 2009. The FDA also required us to execute a Thorough QT study of cardiac safety which was completed in January 2008. Although our QT consultants concluded that this study showed no safety signal for a risk of cardiac QT prolongation with Fampridine-SR at a therapeutic or supra-therapeutic dose, the FDA will make its own evaluation of the data as part of the NDA review and its interpretation of the results may differ.

We may also determine, on our own, to conduct additional studies from time to time to support our filing of an NDA or regulatory filings in other markets or to otherwise provide additional data regarding the safety or efficacy of Fampridine-SR. If the studies that we are required to conduct, or any studies that we determine, on our own, to conduct, cause us to incur unanticipated expenses or delays, or yield unfavorable results, our ability to obtain regulatory approval of Fampridine-SR could be seriously delayed or impaired, in which case our business prospects will be materially adversely affected.

In June 2008, we submitted a request to the FDA for Fast Track designation for Fampridine-SR. The FDA did not grant our request, stating that we had not at that time demonstrated that Fampridine-SR addresses an unmet medical need under the criteria for Fast Track designation. We presented additional information on the ways in which Fampridine-SR improves walking ability in patients with MS and differs in its effects from existing MS therapies as part of our request for reconsideration of that decision, but the FDA did not change its decision.

Notwithstanding the results of our clinical trials and pre-clinical studies, the FDA could determine that the overall balance of risks and benefits for Fampridine-SR is not adequate to support approval, or only justifies approval for a narrow set of uses or approval with restricted distribution or other burdensome post-approval requirements and limitations. Subjects taking Fampridine-SR have experienced adverse events, including falls, urinary tract infection, insomnia, dizziness, asthenia, headache, fatigue, nausea and balance disorder. A small number of subjects have also experienced seizures while taking Fampridine-SR, and there is a possibility that additional seizures will occur even at low doses of the drug. If the FDA denies approval of Fampridine-SR in MS, if FDA approval is substantially delayed, if approval is granted on a narrow basis or with restricted distribution or other burdensome post-approval requirements, or if the Fampridine-SR program is terminated, our business prospects will be materially adversely affected.

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

**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.

Table of Contents

**SIGNATURES**

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

**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         |
|-----------------------------------------------------|-------------------------------------------------------------------------------------------|--------------|
| <u>/s/ RON COHEN</u><br>Ron Cohen, M.D.             | President, Chief Executive Officer and Director<br>(Principal Executive Officer)          | May 11, 2009 |
| <u>/s/ DAVID LAWRENCE</u><br>David Lawrence, M.B.A. | Chief Financial Officer (Principal Financial Officer<br>and Principal Accounting Officer) | May 11, 2009 |

Table of Contents

**Exhibit Index**

| <b>Exhibit No.</b> | <b>Description</b>                                                                                                    |
|--------------------|-----------------------------------------------------------------------------------------------------------------------|
| 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. |