

GILEAD SCIENCES INC  
Form 10-Q  
October 31, 2008  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
WASHINGTON, D.C. 20549

**FORM 10-Q**

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

**For the quarterly period ended September 30, 2008**

**or**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission File Number: 0-19731**

**GILEAD SCIENCES, INC.**

(Exact Name of Registrant as Specified in Its Charter)

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**Delaware**  
(State or Other Jurisdiction of

**94-3047598**  
(IRS Employer

**Incorporation or Organization)**

**Identification No.)**

**333 Lakeside Drive, Foster City, California**  
(Address of principal executive offices)

**94404**  
(Zip Code)

**650-574-3000**

**(Registrant's Telephone Number, Including Area Code)**

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

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

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

Number of shares outstanding of the issuer's common stock, par value \$0.001 per share, as of October 27, 2008: 910,509,730

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We own or have rights to various trademarks, copyrights and trade names used in our business, including the following: GILEAD SCIENCES®, TRUVADA®, VIREAD®, EMTRIVA®, HEPSERA®, AMBISOME®, VISTIDE®, LETAIRIS® and VOLIBRIS®. ATRIPLA® is a registered trademark belonging to Bristol-Myers Squibb & Gilead Sciences, LLC. MACUGEN® is a registered trademark belonging to OSI Pharmaceuticals, Inc. SUSTIVA® is a registered trademark of Bristol-Myers Squibb Company. TAMIFLU® is a registered trademark belonging to F. Hoffmann-La Roche Ltd. FLOLAN® is a registered trademark of GlaxoSmithKline Inc. This report also includes other trademarks, service marks and trade names of other companies.

**Table of Contents****PART I. FINANCIAL INFORMATION****ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS  
GILEAD SCIENCES, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS**

(in thousands, except per share amounts)

|   | September 30,<br>2008<br>(unaudited) | December 31,<br>2007<br>(1) |
|---|--------------------------------------|-----------------------------|
| <b>Assets</b>   |                                      |                             |
| Current assets:   |                                      |                             |
| Cash and cash equivalents   | \$ 1,209,424                         | \$ 968,086                  |
| Short-term marketable securities  | 709,870                              | 203,892                     |
| Accounts receivable, net  | 1,047,205                            | 795,127                     |
| Inventories   | 897,623                              | 599,966                     |
| Deferred tax assets   | 100,772                              | 152,533                     |
| Prepaid taxes   | 220,998                              | 216,909                     |
| Other current assets  | 140,791                              | 91,779                      |
| Total current assets  | 4,326,683                            | 3,028,292                   |
| Property, plant and equipment, net  | 512,281                              | 447,696                     |
| Noncurrent portion of prepaid royalties   | 267,994                              | 290,742                     |
| Noncurrent deferred tax assets  | 315,065                              | 297,359                     |
| Long-term marketable securities   | 1,336,968                            | 1,550,444                   |
| Other noncurrent assets   | 215,137                              | 220,183                     |
| Total assets  | \$ 6,974,128                         | \$ 5,834,716                |
| <b>Liabilities and Stockholders Equity</b>  |                                      |                             |
| Current liabilities:  |                                      |                             |
| Accounts payable  | \$ 631,525                           | \$ 290,333                  |
| Accrued government rebates  | 152,258                              | 115,495                     |
| Accrued compensation and employee benefits  | 102,974                              | 90,553                      |
| Income taxes payable  | 90,042                               |                             |
| Other accrued liabilities   | 236,075                              | 208,861                     |
| Deferred revenues   | 40,205                               | 30,747                      |
| Current portion of other long-term obligations  | 6,055                                | 286                         |
| Total current liabilities   | 1,259,134                            | 736,275                     |
| Long-term deferred revenues   | 56,153                               | 61,316                      |
| Convertible senior notes  | 1,299,854                            | 1,300,000                   |
| Long-term income taxes payable  | 44,074                               | 125,232                     |
| Other long-term obligations   | 21,367                               | 11,604                      |
| Minority interest   | 127,636                              | 140,299                     |
| Commitments and contingencies (Note 5)  |                                      |                             |
| Stockholders equity:  |                                      |                             |
| Preferred stock, par value \$0.001 per share; 5,000 shares authorized; none outstanding   |                                      |                             |
| Common stock, par value \$0.001 per share; 2,800,000 shares authorized; 920,744 and 932,484 shares issued and outstanding at September 30, 2008 and December 31, 2007, respectively | 921                                  | 932                         |
| Additional paid-in capital  | 3,616,798                            | 3,214,341                   |

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|   |                  |                  |
|---|------------------|------------------|
| Accumulated other comprehensive income (loss) | 17,190           | (4,363)          |
| Retained earnings                             | 531,001          | 249,080          |
| <b>Total stockholders' equity</b>             | <b>4,165,910</b> | <b>3,459,990</b> |
| Total liabilities and stockholders' equity    | \$ 6,974,128     | \$ 5,834,716     |

- (1) The condensed consolidated balance sheet at December 31, 2007 has been derived from audited consolidated financial statements at that date, but does not include all of the information and footnotes required by U.S. generally accepted accounting principles for complete financial statements.

See accompanying notes.

**Table of Contents****GILEAD SCIENCES, INC.****CONDENSED CONSOLIDATED STATEMENTS OF INCOME**

(unaudited)

(in thousands, except per share amounts)

|   | <b>Three Months Ended<br/>September 30,</b> |                   | <b>Nine Months Ended<br/>September 30,</b> |                     |
|---|---|-------------------|--|---------------------|
|   | <b>2008</b>                                 | <b>2007</b>       | <b>2008</b>                                | <b>2007</b>         |
| <b>Revenues:</b>                              |   |                   |  |                     |
| Product sales                                 | \$ 1,338,502                                | \$ 961,931        | \$ 3,697,024                               | \$ 2,707,214        |
| Royalty revenues                              | 25,161                                      | 91,003            | 185,221                                    | 407,212             |
| Contract and other revenues                   | 7,605                                       | 5,869             | 25,300                                     | 20,896              |
| <b>Total revenues</b>                         | <b>1,371,268</b>                            | <b>1,058,803</b>  | <b>3,907,545</b>                           | <b>3,135,322</b>    |
| <b>Costs and expenses:</b>                    |   |                   |  |                     |
| Cost of goods sold                            | 300,183                                     | 198,460           | 805,715                                    | 553,229             |
| Research and development                      | 188,062                                     | 140,357           | 519,905                                    | 406,378             |
| Selling, general and administrative           | 189,189                                     | 172,956           | 603,679                                    | 525,693             |
| Purchased in-process research and development |   |                   | 10,851                                     |                     |
| <b>Total costs and expenses</b>               | <b>677,434</b>                              | <b>511,773</b>    | <b>1,940,150</b>                           | <b>1,485,300</b>    |
| Income from operations                        | 693,834                                     | 547,030           | 1,967,395                                  | 1,650,022           |
| Interest and other income, net                | 3,637                                       | 29,502            | 40,363                                     | 80,295              |
| Interest expense                              | (2,951)                                     | (2,989)           | (9,230)                                    | (10,243)            |
| Minority interest                             | 2,160                                       | 2,478             | 6,195                                      | 7,032               |
| Income before provision for income taxes      | 696,680                                     | 576,021           | 2,004,723                                  | 1,727,106           |
| Provision for income taxes                    | 192,675                                     | 177,702           | 561,763                                    | 513,450             |
| <b>Net income</b>                             | <b>\$ 504,005</b>                           | <b>\$ 398,319</b> | <b>\$ 1,442,960</b>                        | <b>\$ 1,213,656</b> |
| <b>Net income per share basic</b>             | <b>\$ 0.55</b>                              | <b>\$ 0.43</b>    | <b>\$ 1.56</b>                             | <b>\$ 1.31</b>      |
| Shares used in per share calculation basic    | 920,807                                     | 926,963           | 923,894                                    | 928,519             |
| <b>Net income per share diluted</b>           | <b>\$ 0.52</b>                              | <b>\$ 0.42</b>    | <b>\$ 1.50</b>                             | <b>\$ 1.26</b>      |
| Shares used in per share calculation diluted  | 960,585                                     | 959,043           | 964,267                                    | 962,804             |

See accompanying notes.

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**GILEAD SCIENCES, INC.**

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**

(unaudited)

(in thousands)

**Nine Months Ended  
September 30,**

ese, or approximately 69%, remained active, with duration of treatment ranging over three years. Also, as of this same date, 214 patients from MS-F204 had been enr  
ely 86%, remained active, with a duration of treatment ranging up to 17 months. The total exposure to Fampridine-SR in our MS studies to that date, including both d  
-years. By contrast, in our controlled trials we have collected safety data on placebo treatment that totals to approximately 54 patient-years.

vents most commonly experienced in the MS-F203 and MS-F 204 studies were urinary tract infection, falls, insomnia, dizziness, headache, nausea, asthenia (weaknes  
, balance disorder and fatigue. The majority of these events were mild to moderate in intensity. Among these types of event, only insomnia, dizziness, headache, nau  
han double the frequency in the Fampridine-SR-treated than the placebo-treated patients in our controlled trials.

been reported in a small number of subjects over the course of the development program and have also been reported in cases of overdose with fampridine outside the  
ntial for seizure as a side effect, including the possibility of interaction with other drugs that are known to lower the threshold for seizure in susceptible subjects. The  
ll, the incidence of seizures at the current dose of 10 mg twice a day has been within the rates reported for placebo-treated groups in long-term, controlled studies of i  
nged up to 2% of patients in a two year study, or 1 seizure per 100 patient years. Incidence of seizures has been reported to be higher in actively treated groups in stud  
ear study or 2.5 seizures per 100 patient years. The proportion of patients treated with beta interferons in our studies of Fampridine-SR has been in the range of 40-45%

ded from our studies subjects known to be at risk for seizures because they have had seizures previously or because they have an abnormal electroencephalogram ind  
of interferon drugs. We have therefore also compared the incidence of seizure events in the open label extension studies with the expected incidence rates for a first s  
ical literature, and find these rates to be comparable for the 10 mg twice a day dose of Fampridine-SR. With our current knowledge, there are no means of determinin  
increased seizure risk when taking Fampridine-SR

dose, fampridine is known to block a wide range of potassium ion channels in cell membranes, which are potentially important not only in the nervous system but als  
initiated in September 2007 and favorable results from that study were released in January 2008. This study evaluated the potential to cause an increase in the electroc



both therapeutic and supratherapeutic doses, was found to be no different than placebo. In addition we have completed studies to examine the specific effects of the drug on the human ether-a-go-go related gene or hERG channel. These are standardized tests of the potential for a drug to cause a prolongation of the QT interval is believed to be a risk factor for triggering potentially fatal cardiac arrhythmias. These laboratory studies showed that fampridine blocks the hERG channel at clinically relevant concentrations. In another standard test, we have also performed studies on isolated dog cardiac Purkinje fibers. These showed that fampridine blocks the hERG channel at clinically relevant concentrations, including concentrations 100 times higher than the

weak levels in the blood of patients. Additional studies of cardiac safety in dogs showed no notable changes in cardiac electrical behavior or function, up to maximum t

***Development Programs***

***ation Programs***

tion programs include two distinct therapeutic approaches to stimulate repair of the damaged myelin sheath in MS, neuregulins/GGF2 and remyelinating antibodies. 7  
different and potentially complementary routes. Both programs require finalizing production of clinical-grade material and completion of preclinical toxicology tests be  
believe a therapy that could permanently repair myelin sheaths has the potential to restore substantial neurological function to those affected by demyelinating conditi

***ins/GGF2***

ns form a family of growth factors related to epidermal growth factor. These molecules bind to erbB receptors, which translate the growth factor signal to the cell and  
and gene expression. Neuregulins have been shown in published studies to have a range of effects in protection and repair of cells both in the nervous system and in th  
icals plc., or CeNeS, an exclusive worldwide license to its neuregulin patents and related technology, including GGF2, our lead molecule for the neuregulin family.

covered in the portfolio from CeNeS have a number of potential applications. Neuregulins and their erbB receptors are essential for cardiac development and have been  
that can lead to congestive heart failure, including myocardial infarction. Additionally, neuregulins have been shown to protect the heart and brain from the toxicity o  
agents, such as anthracyclines. Studies in mouse, rat and dog models of congestive heart failure have shown that neuregulins significantly improve cardiac function an  
remyelination in animal models of MS and to protect the brain in animal models of stroke. Therefore, the neuregulins offer us the potential for multiple CNS and card  
ive heart failure as well as protection from chemotherapy-induced damage. In 2008, we began to work with a contract manufacturer to develop production and purifica  
in preparation for a potential future IND application to support human clinical trials. We anticipate filing an IND in late 2009, subject to the results of ongoing toxic  
S.

***ating Antibodies Program***

ating antibodies program is based on research performed at Mayo Foundation for Medical Education and Research, or Mayo Clinic. Under a license agreement entered  
e have exclusive worldwide rights to patents and other intellectual property for these antibodies related to use and treatment of CNS disorders. Studies have demonstr  
ate repair of the myelin sheath in three different animal models of MS. In particular, these antibodies were found to react with molecules on the surface of the cells th  
number of ways, leading to increased remyelination activity. First identified in mice, similar antibodies were subsequently identified in human blood samples by the  
combinant human antibody that may be suitable for clinical development.

supported preclinical studies at Mayo Clinic to learn more about the ways the antibodies act to stimulate the myelin sheath-forming cells. In 2004, Mayo Clinic received clinical-grade material and progress the program towards clinical development. In May 2006, Mayo Clinic and the FDA had a pre-IND meeting to discuss the details of the program. We have been working with a contract manufacturer to produce rHIgM22, one of these antibodies, under cGMP, and had previously anticipated filing an IND in late 2009, but we have delayed our filing for bankruptcy in 2008.

#### *Chondroitinase Program*

We developed a program based on the concept of breaking down the matrix of scar tissue that develops as a result of an injury to the CNS. Published research has demonstrated that blocking the regeneration of nerve fibers in the CNS. A similar matrix exists even in uninjured parts of the CNS tissue and restricts plasticity, the ability to modify or re-grow. This matrix may also inhibit repair of the myelin sheath by restricting the movements of the myelinating cells into the area of damage.

Two components of these two forms of matrix are chondroitin sulfate proteoglycans, or CSPGs. Cell culture studies and a number of animal studies have shown that these CSPGs are key factors in the failure of the spinal cord or brain to regenerate and repair. Studies also have shown that bacterial enzymes called chondroitinases break down the CSPG matrix.

Our laboratories have published animal studies showing that application of chondroitinase results in recovery of function following injuries to various areas of the brain including forelimb grasping, sensation, and visual and bladder function. We have successfully tested the ability of one of these molecules, Chondroitinase ABC-I, to improve function. These studies were published in the Journal of Neurotrauma in February 2005. In these studies, rats that sustained a spinal cord injury were treated with either chondroitinase or vehicle over 10 weeks of recovery. Animals treated with chondroitinase showed significant improvements both in motor function of the limbs and in bladder function, compared to vehicle. We have also produced and successfully tested in animal models a recombinant version of naturally-occurring Chondroitinase ABC-I.

We are conducting a research program, which has been funded in part by federal and state grants, to develop second generation approaches to overcoming the proteoglycan matrix. We are exploring alternative approaches to blocking matrix formation. We are exploring the possibility of obtaining additional research grants from the NIH as well as potential partnership opportunities. We are conducting preclinical program in chondroitinase. In 2003, we obtained an exclusive worldwide license to certain patents and technology from Cambridge University Technical Services. We are also building our intellectual property position with respect to this technology with patent applications around uses of the known chondroitinase program.

ng

We established two sales channels for marketing Zanaflex Capsules: an internal, field-based specialty sales force and an external telesales group.

*Internal, Field-Based Specialty Sales Force.* We employ a team of highly experienced sales professionals to call on neurologists and other prescribers who specialize in the treatment of multiple sclerosis.

with conditions that involve spasticity. Our sales professionals have had an average of approximately 14 years of sales experience prior to joining us. Our specialty sales calls on neurologists, other specialists, and primary care prescribers treating patients with conditions that involve spasticity, and who are high volume prescribers of tizanidine. We plan to approximately double the size of our sales force in anticipation of the potential launch of Fampridine-SR, if approved.

*Internal Managed Care Team.* We employ an internal and field-based team responsible for payer strategy, as well as contracting and account management of managed care organizations, benefit managers, specialty pharmacies, wholesale drug distribution customers, the Veterans Affairs institutions and the Department of Defense.

*Contract Pharmaceutical Telesales Organization.* We have retained TMS Professional Markets Group, LLC (which purchased various telesales assets from Access Therapeutics, with whom we had previously contracted) to provide a small, dedicated sales force of pharmaceutical telesales professionals to contact primary care physicians and specialists to express their interest in receiving samples of Zanaflex Capsules or a visit from one of our sales representatives. TMS Professional Markets Group also contacts pharmacies to inform them that Zanaflex Capsules are not interchangeable with Zanaflex or tizanidine tablets.

In general, people with MS and SCI are knowledgeable about their conditions, actively seek new treatments, and directly influence their prescriber's evaluation of treatment options with the major advocacy groups that focus on MS and SCI. We provide regular scientific updates regarding our development programs and we sponsor or support a comprehensive series of educational and promotional programs to support Zanaflex Capsules. These include educational materials, a peer-to-peer speakers' program, patient assistance services, as well as a patient assistance program. At the request of the FDA, we have also implemented an educational program to inform pharmacists, prescribers and patients that the tablets are not therapeutically equivalent to Zanaflex Capsules and that, as a result, a prescription for Zanaflex Capsules should not be substituted with any tablet form.

For pharmaceutical companies, our principal customers are wholesale pharmaceutical distributors. We currently depend on three key customers. For the year ended December 31, 2008, Walgreens, AmerisourceBergen Corporation and AmerisourceBergen Corporation accounted for approximately 46.4%, 33.7% and 14.7% of our shipments, respectively.

The expertise we are developing through commercializing Zanaflex Capsules will provide a strong foundation for our marketing of Fampridine-SR, if approved, as well as other products for people with MS and SCI. As a result, we plan to promptly launch and market Fampridine-SR ourselves in the United States and possibly in Canada, if it is approved in both countries. We also have programs to educate consumers, physicians, and other healthcare professionals about the challenges of walking disability in the MS population. For example, in 2008, we sponsored the Multiple Sclerosis Society's Walk MS program. This sponsorship allowed us to engage thousands of people with MS, as well as their families, physicians and caregivers, in their lives. We will be a national sponsor once again in 2009 and in 2010.

**Medical Network**

Established advisory team and network of well-recognized scientists, clinicians and opinion leaders in the fields of MS and SCI. Depending on their expertise, these advisors conduct preclinical trials, keep us apprised of the latest scientific advances and help us identify and evaluate business development opportunities.

**License Agreements and License Agreements**

*etc*

In 1997, we licensed from Elan exclusive worldwide rights to Elan's sustained release formulation of fampridine, Fampridine-SR, for the treatment of SCI. In April 1998, we entered into a license agreement with Elan, Elan International Services, Ltd., or EIS, to develop Fampridine-SR for treatment of MS. At that time, MSRDC licensed from Elan exclusive worldwide rights to Elan's sustained release formulation of fampridine, Fampridine-SR, for the treatment of MS.

In 2003, we entered into a termination and assignment agreement with Elan, EIS and MSRDC pursuant to which MSRDC assigned to us its assets, including the license from Elan, for approximately \$11.5 million for all the assets and assumed liabilities of MSRDC. MSRDC distributed the purchase price to its shareholders according to their equity ownership. We received approximately \$9.5 million. We also purchased EIS's shares at par value, and own approximately 88% of MSRDC, which now has no assets or liabilities and is inactive.

In 2003, we entered into an amended and restated license with Elan, which replaced the two prior licenses for Fampridine-SR in oral sustained release dosage form. Under the license, we have the rights to Fampridine-SR for all indications, including SCI, MS and all other indications. We agreed to pay Elan milestone payments of up to \$15.0 million and royalties on net sales. We have not made any payments under this agreement through December 31, 2008.

Elan is supplying us with product for our clinical trials under this agreement.

We may terminate our license in countries in which we have a license, including the United States, if we fail to file regulatory approvals within a commercially reasonable time after the date of the license agreement. We may also lose our rights under the license agreement if we fail to launch the product in the applicable country within a commercially reasonable time after regulatory approval or if we fail to fulfill our payment obligations under the license agreement. If Elan terminates our license in any applicable country, Elan is entitled to the right to market the product in the applicable country, subject to royalty payments to us.

We have the right to terminate the Elan license at any time by written notice. In addition, the Elan license may be immediately terminated by either party following an incurable breach of the license agreement. The Elan license may also be terminated by either party following notice and a cure period with respect to an uncured breach by either party.

Notwithstanding the early termination provisions, the Elan license terminates on a country by country basis on the last to occur of fifteen years from the date of the agreement, the expiration of the patent for the product or the appearance of a competitive product in that country.

we entered into an Asset Purchase Agreement with Elan pursuant to which we acquired all of Elan's research, development, distribution, sales and marketing rights to Zanaflex in the United States. The assets acquired include the products' FDA registrations and FDA dossiers, proprietary product know-how, a patent and two related patent applications, clinical trial data, books and records. Elan also granted us a license allowing us to use the Zanaflex trademarks in the United States, with the right to buy the Zanaflex trademark for a nominal fee. No royalty payments were made. Those payments have been made, and we purchased and now own the trademarks. Elan also granted us an exclusive, perpetual and royalty-free license to use the technology contained in Zanaflex Capsules and Zanaflex tablets or used in the manufacture of Zanaflex Capsules, for use in connection with the sale and marketing of Zanaflex in the United States. We also acquired the right to develop new indications, formulations, dosage forms, delivery systems and process improvements of Zanaflex. Under the agreement, we are prohibited from market, distribute or sell any products containing tizanidine as an active pharmaceutical ingredient in the United States until the later of the end of our obligation to pay royalties to Elan pursuant to our agreement with Elan. In addition, we agreed not to directly or indirectly market, distribute or sell any products containing tizanidine as its active pharmaceutical ingredient in the United States.

Our agreement with Elan obligated us to pay a combination of sales-based milestone payments of up to \$19.5 million, all of which have been achieved and paid, and royalties on sales of Zanaflex. We have no further Zanaflex milestone payment obligations with Elan. We also agreed to use commercially reasonable efforts to commercialize Zanaflex Capsules.

As a result of our acquisition, we assumed certain of Elan's rights and obligations relating to Zanaflex under a license agreement with Novartis, to the extent that these rights and obligations were not assumed by Novartis. Under this agreement we obtained certain rights to market and sell tizanidine products and rights to product improvements developed by Novartis.

We are the sole manufacturer of Zanaflex Capsules for us and we are in contract negotiations with Patheon Inc. for the manufacture of Zanaflex tablets. See " Manufacturing."

In October 2005, we entered into a financing arrangement with Paul Royalty Fund, or PRF, pursuant to which we assigned PRF the right to receive a portion of our net revenues from the sale of Zanaflex products. This agreement was amended in November 2006 potentially to increase the total amount of royalty payments to which PRF is entitled and to provide for the flow of payments from us to PRF and from PRF to us. The arrangement covers all Zanaflex net revenues generated from October 1, 2005 through and including December 31, 2015, unless otherwise provided in our Management's Discussion and Analysis of Financial Condition and Results of Operations Liquidity and Capital Resources Financing Arrangements."

#### ***St. Luke's Medical Center***

We were licensed from Rush-Presbyterian St. Luke's Medical Center, or Rush, know-how relating to fampridine for the treatment of MS. We subsequently licensed this know-how to an agreement with Rush and Elan terminating the Rush license to Elan and providing for mutual releases. We also entered into a license agreement with Rush in 2005 to license to its know-how relating to

reatment of MS. Rush has also assigned to us its Orphan Drug Designation for fampridine for the relief of symptoms of MS.

pay Rush a license fee, milestone payments of up to \$850,000 and royalties based on net sales of the product for neurological indications. We have made an aggregate of up to \$850,000 through December 31, 2008. The Rush license may be terminated by either party following an uncured material breach by the other party and notice. The Rush license may also be terminated by either party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other party. The Rush license also includes provisions relating to the allocation of payments between us and Elan of certain payments to Rush under the Rush license. Subject to the early termination provisions, the Rush license includes royalty obligations, which expire fifteen years from the date of the agreement.

**Research Organization**

In 2003, we entered into an Amended and Restated License Agreement with the Canadian Spinal Research Organization (CSRO). Under this agreement we were granted an exclusive license to use the assets and know-how of CSRO relating to the use of fampridine in the reduction of chronic pain and spasticity in a spinal cord injured subject.

We are obligated to pay to CSRO royalties based on a percentage of net sales of any product incorporating the licensed rights, including royalties on the sale of Fampridine-SR for a period of 15 years from the date of the agreement.

We have the right to terminate the CSRO agreement at any time by written notice. In addition, the CSRO agreement may be terminated by either party following an uncured material breach by the other party. The CSRO agreement may also be terminated by either party upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other party. In such event, the CSRO agreement will expire upon the termination of all royalty or other payment obligations on a country-by-country basis, which will be no longer than the term of the licensed patent in such country or ten years from the date of the first commercial sale of the product in such country.

**Cornell Research Foundation, Inc.**

In 2003, we entered into a license agreement with Cornell Research Foundation, Inc., or Cornell, pursuant to which we were granted an exclusive license under a patent for the treatment of motor neuron cell diseases. In consideration for the license, we paid Cornell an upfront license fee and are required to make payments of up to \$150,000 to Cornell upon the successful reissuance or reexamination of the patents licensed to us and, the completion of a clinical trial testing the use of Fampridine-SR in amyotrophic lateral sclerosis. We are also obligated to pay Cornell an annual royalty on net sales of Fampridine-SR in any and all indications, which may be up to \$25,000.

Under the Cornell agreement, Cornell is responsible for all patent prosecution and maintenance activities relating to the licensed patent, and we are responsible for paying all fees in connection with the patent. We have the right under this agreement to enforce any patent rights within the licensed patents against infringement by third parties at our own expense.

right to terminate the Cornell agreement at any time by written notice. In addition, the Cornell agreement may be terminated by either party following an uncured material breach. In the event of termination provisions, the term of the Cornell agreement will continue until the expiration of the last to expire valid claim under the licensed patent.

***Cambridge University Technical Services Limited and King's College London***

In 2003, we entered into a license agreement with Cambridge University Technical Services Limited and King's College London, pursuant to which we were granted an exclusive license to sublicense, under a U.S. patent application and its foreign counterpart to develop and commercialize products related to enzymatic methods, including chondroitinase, under a non-exclusive worldwide license, including the right to sublicense, under the same U.S. and foreign patent applications to develop and commercialize products related to chondroitinase disorders.

In connection with these licenses, we paid an upfront license fee and are required to make payments of up to \$2.15 million upon the achievement of certain milestones. We have entered into a license agreement through December 31, 2008. We are also obligated to pay royalties on net sales and on any sublicense royalties that we receive.

The Cambridge University license may be terminated by any party following an uncured material breach by any other party. The King's College license may also be terminated by any party following a court of competent jurisdiction to be bankrupt or upon the appointment of a liquidator of that party. Subject to the early termination provisions, the King's College license will terminate upon the expiration of the last to expire valid claim under the licensed patent applications, at which time the licenses granted under the license agreement will automatically become irrevocable.

***Mayo Clinic for Medical Education and Research***

In 2000, we entered into a license agreement with Mayo Foundation for Education and Research, or Mayo Clinic, pursuant to which we were granted an exclusive worldwide license and property on remyelinating antibodies. Under this agreement, we have the right to develop, make, use and sell the remyelinating antibody products for the prevention, diagnosis and treatment of MS and SCI. We have worked closely with one of Mayo Clinic's research groups on developing and patenting this emerging technology in connection with the therapeutic use of these antibodies. Mayo Clinic has the right to continue researching the antibodies and, in the event it develops other applications related to the licensed patent, which are for the treatment of CNS disorders. Mayo Clinic is required to offer rights in these new applications to us before it offers such rights to a third party.

In connection with the Mayo Clinic agreement, we are obligated to make milestone payments of up to \$1.875 million. We also pay royalties based on net sales. We have not made any milestone payments through December 31, 2008. The Mayo Clinic agreement may be terminated by either party following an uncured material breach by the other party. We may terminate the license to Mayo Clinic. In addition, either party also has the right to terminate upon the insolvency of the other party, the filing of bankruptcy by or against the other party, or the death of either party by the other party. Unless otherwise terminated, this license agreement will terminate upon the expiration of the last licensed patent in any such licensed product.



supported preclinical studies at Mayo Clinic to learn more about the ways the antibodies act to stimulate the myelin sheath-forming cells. In 2004, Mayo Clinic received clinical-grade material and progress the program towards clinical development. A subsequent letter agreement between Mayo Clinic and us acknowledges that the work was done and pursuant to the Mayo Clinic agreement.

*Pharmaceuticals plc*

In 2002, we entered into two license agreements with CeNeS Pharmaceuticals plc, or CeNeS. The first agreement relates to an exclusive worldwide sublicense under certain patents to make, have made, use, import, offer for sale and sell protein products composed of GGF2 and non-protein products developed through the use of material covered by a valid claim of these patents and the right to sub-license these patents were granted to CeNeS by the Ludwig Institute for Cancer Research.

Our obligations to CeNeS include payment of an upfront license fee, royalties based on annual net sales of the product, if any, as well as payments of up to \$8.5 million upon development, testing and regulatory approval of any protein products. We have not made any payments under this agreement through December 31, 2008. We are obligated to pay a royalty on the third calendar year following the first commercial sale of any licensed product. If we fail to pay any minimum royalty, CeNeS will have the option to convert this agreement to a license. This agreement with CeNeS is effective until the later of November 12, 2017 or the expiration of the last-to-expire valid claim in the licensed patents. We may terminate this agreement with notice to CeNeS. In addition, this first agreement may be terminated by either party following an uncured material breach by the other party and if this agreement is terminated, the exclusive worldwide sublicense granted to us under this agreement, provided that we continue to pay royalties.

The second agreement relates to an exclusive worldwide sublicense to us under certain patents, patent applications and know-how to make and have made, use and have used, sell, offer for sale and import products composed of one or more proteins encoded by the growth factor gene nrg-2 and non-protein products developed through the use of material covered by a valid claim of these patents. The right to sub-license this patent was granted to CeNeS by the President and Fellows of Harvard College.

Our obligations to CeNeS include a timeline to achieve certain milestones relating to the research and development and the clinical testing and filing of regulatory approvals for the products. We are obligated to pay a license fee of \$5.93 million. If we are unable to meet a milestone, CeNeS has agreed to negotiate in good faith with us to agree for a reasonable extension of the time to achieve the milestone. CeNeS is also obligated to pay us a license fee and royalties based on a percentage of net sales of protein products and non-protein products covered under the agreement. We have made payments to CeNeS through December 31, 2008.

This agreement may be terminated by either party following an unremedied default of a material obligation by the other party. CeNeS may terminate this agreement upon our failure to maintain or to maintenance of insurance liability or our failure to meet certain milestones. Harvard may terminate the underlying Harvard license if CeNeS becomes insolvent, merges with or is acquired by another entity, or has a petition bankruptcy filed for or against it. In that case, Harvard is required, upon our written request, to enter into a direct license with us under the same terms as the original license. We reserve the right to terminate this agreement at any time.

reement upon written notice to CeNeS. The license granted to us pursuant to this agreement continues after the expiration of this agreement and may continue after the circumstances under which this agreement is terminated.

By termination provisions, this agreement remains effective until the last patent, patent application or claim included in the licensed patents has expired, been abandoned

In 2003, we entered into an agreement with Elan for the supply of Fampridine-SR. Under that agreement, we are required to purchase at least 75% of our annual requirements if Elan is unable or unwilling to meet our requirements. In addition, the agreement also obligates us to make compensatory payments if we do not purchase 100% of our requirements.

Under our agreement with Elan, we have designated Patheon, Inc. (Patheon) as a qualified second manufacturing source of Fampridine-SR. In connection with that designation, we transferred our manufacturing technology to Patheon. We and Elan have agreed that we may purchase up to 25% of our annual requirements from Patheon if we make compensatory payments to Elan for Fampridine-SR if Elan is unable or unwilling to meet our requirements.

We rely on Elan to supply us with Zanaflex Capsules. Zanaflex Capsules are manufactured using Elan's proprietary SODAS (spheroidal oral drug absorption system) manufacturing process. We provide Elan with monthly written 18-month forecasts, and with annual written two-year forecasts, of our supply requirements for Zanaflex Capsules. In each of the five years of the forecast, we are obligated to purchase the quantity specified in the forecast, even if our actual requirements are greater or less. Elan is not obligated to supply products if it is unable to do so. We will use commercially reasonable efforts to fulfill any such orders. The initial term of the agreement expires in 2009, with two automatic two-year renewal terms. Either party may terminate the agreement by giving the other party at least 12 months prior to the expiration of the initial term or any renewal term. In addition, either party may terminate the agreement if the other party fails to perform its obligations. If a failure to supply occurs under the agreement, other than a force majeure event, or if we terminate the supply agreement for cause, Elan must use commercially reasonable efforts to transfer production of Zanaflex Capsules to us or a third-party manufacturer, provided that such third party is not a technological competitor of Elan. If we need to transfer production of Zanaflex Capsules to us or a third-party manufacturer, we will provide a non-exclusive, non-transferable, non-sublicensable license of its manufacturing know-how and other information and rights related to the production of Zanaflex Capsules, including a license to use its SODAS technology. We will also sublicense this know-how to a third party manufacturer, provided that this third party is not a technological competitor of Elan. In the event of termination of the supply agreement, the agreement continues for more than three months, Elan has agreed to enter into negotiations with us to preserve the continuity of supply of products, including the possibility of transferring production to us or a third party manufacturer.

In 2007, we relied on a single manufacturer, Novartis, for the manufacture of Zanaflex tablets and for the supply of tizanidine, the active pharmaceutical ingredient (API).

and Zanaflex tablets. Novartis has discontinued production of tizanidine and will no longer supply tizanidine to Elan for the production of Zanaflex Capsules or to us. We recently received FDA approval to use the tizanidine manufactured by a new supplier, Farmak, as the active ingredient in the production of Zanaflex Capsules. However, we do not have a new supplier of the tizanidine needed for the production of Zanaflex tablets. Elan has agreed to supply us with Novartis-manufactured tizanidine for the manufacture of Zanaflex tablets through the first quarter of 2010. If we fail to gain FDA approval of a new tizanidine supplier for Zanaflex tablets prior to February 2010, we may experience an interruption in the supply of Zanaflex tablets.

As a result of our reliance on Patheon for the manufacture of Zanaflex tablets, and Patheon has agreed to manufacture Zanaflex tablets prior to the contract being finalized, any disruption in their operations, a delay or interruption in the supply of our Zanaflex products could result until the affected supplier cures the problem or we locate a new supplier. We may be required to enter into alternative supply arrangements on terms that are commercially favorable, if at all. Any new supplier would also be required to qualify under applicable regulatory requirements, which could result in substantial delays before we are able to qualify any new supplier and transfer the required manufacturing technology to that supplier.

As a result of our reliance on Patheon for the manufacture of Zanaflex tablets, and Patheon has agreed to manufacture Zanaflex tablets prior to the contract being finalized, any disruption in their operations, a delay or interruption in the supply of our Zanaflex products could result until the affected supplier cures the problem or we locate a new supplier. We may be required to enter into alternative supply arrangements on terms that are commercially favorable, if at all. Any new supplier would also be required to qualify under applicable regulatory requirements, which could result in substantial delays before we are able to qualify any new supplier and transfer the required manufacturing technology to that supplier.

As a result of our reliance on Patheon for the manufacture of Zanaflex tablets, and Patheon has agreed to manufacture Zanaflex tablets prior to the contract being finalized, any disruption in their operations, a delay or interruption in the supply of our Zanaflex products could result until the affected supplier cures the problem or we locate a new supplier. We may be required to enter into alternative supply arrangements on terms that are commercially favorable, if at all. Any new supplier would also be required to qualify under applicable regulatory requirements, which could result in substantial delays before we are able to qualify any new supplier and transfer the required manufacturing technology to that supplier.

We have established the internal capability to manufacture research quantities of antibody and protein product candidates and have contracted for testing and manufacturing development services from outside contractor. In March 2008, we signed a Master Services Agreement with CMC ICOS Biologics to develop methods to produce GGF2 under cGMPs.

**Intellectual Property**

As of December 31, 2009, our intellectual property portfolio included intellectual property rights to over 35 U.S. patents, over 110 foreign patents and over 100 pending patent applications. The primary subject matter in our patent portfolio: Fampridine-SR, Zanaflex, neuregulins, remyelinating antibodies, and chondroitinase. Our intellectual property also includes confidential information and trademarks, as well as a portfolio of trademarks.

Our fampridine patent portfolio with multifaceted coverage on fampridine-related subject matter. Overall, our fampridine intellectual property estate includes approximately 18 fampridine-related patents. A total of 54 fampridine-related patents are issued and are being maintained world-wide (six in the U.S., 38 in the European Union, and ten in other jurisdictions).

We have a non-exclusive, worldwide license from Elan to three U.S. patents, with over 20 corresponding foreign patents and pending applications in a number of foreign countries. These patents cover formulations of a family of aminopyridine compounds, including fampridine, and methods of treatment directed to classes of relevant neurological conditions. One of the two U.S. patents expire in 2013.

those Elan patents, we have two pending U.S. patent applications and corresponding applications in a number of foreign countries covering methods of using aminopyridines. None of the patents resulting from any of these applications would be expected to expire in 2025.

exclusive license from Cornell University for an issued U.S. patent that relates to the use of aminopyridine compositions, including fampridine, for the treatment of disease associated with multiple sclerosis, which is also known as Lou Gehrig's disease. This patent expires in 2016.

exclusive, worldwide license from the Canadian Spinal Research Association (CSRO) for one U.S. patent and over 20 foreign counterpart patents covering the use of fampridine for chronic pain in patients with SCI. The U.S. patent expires in 2013.

In 2008, we acquired certain assets of Neurorecovery, Inc. (NRI). This acquisition enabled us to broaden our intellectual property portfolio on fampridine, and explore additional uses for fampridine, as well as provide access to pre-clinical compounds that may have utility in nervous system disorders. Under the terms of the purchase agreement, we were assigned two patents relating to the use of aminopyridines in peripheral neuropathies and to two early stage development candidates. We also acquired NRI's pre-clinical and clinical data, regulatory filings, rights, trademarks and domain names relating to the three products. Two Phase 2 studies of the aminopyridine compound Ampydin® (IR) for the treatment of chronic pain in patients with Guillain-Barre Syndrome (GBS) have been completed. During the past year, we evaluated the technologies acquired from NRI. Based on this evaluation, we identified certain technologies and devices that were not sufficiently relevant to our goals or business interests, and have begun the requisite process for returning the intellectual property relating to those technologies to the University of Alabama. We will continue to retain intellectual property that includes an issued U.S. patent and corresponding foreign patents covering the use of mono-aminopyridines.

As a result of our purchase from Elan of the Zanaflex assets, we acquired one issued U.S. patent and two pending U.S. patent applications. Our issued patent is generally directed to certain methods of using tizanidine to reduce peak plasma concentrations in patients receiving tizanidine therapy. This issued patent expires in 2021. Our two pending U.S. patent applications are directed to certain methods of using tizanidine in other methods of using tizanidine.

We entered into a Supply Agreement with Elan as part of the acquisition, whereby Zanaflex Capsules are manufactured for us by Elan using Elan's proprietary SODAS technology. This proprietary technology is owned by Elan and, in the event Elan ceases to manufacture Zanaflex Capsules, Elan has agreed to grant us a royalty-free, fully paid-up license to use the technology and rights related to the production of Zanaflex Capsules, including a license to use its SODAS technology for specified purposes. We have the right to sublicense the technology to a third party as long as this third party is not a technological competitor of Elan.

We purchased the Zanaflex trademarks in the United States from Elan.

In 2007, we received a Paragraph IV Certification Notice from Apotex Inc. advising that it had submitted an Abbreviated New Drug Application (ANDA) to the FDA seeking approval to market Zanaflex Capsules. In October 2007, we filed a lawsuit against Apotex Corp. and Apotex Inc. (collectively, Apotex) for patent infringement in relation to the filing of

ex. The defendants have answered our complaint, asserting patent invalidity and non-infringement and counterclaiming, seeking a declaratory judgment of patent invalidity and counterclaims. In March 2008, Apotex filed a motion, which we opposed, for partial judgment on the pleadings dismissing the Company's request for relief on the grounds of 35 U.S.C. 1(e)(4) or 285. The court ruled in our favor and denied Apotex' motion in December 2008. We and Apotex are currently proceeding with discovery in the case. If the court rules in favor of Apotex in challenging the validity of the patent, Apotex could be permitted to sell a generic tizanidine hydrochloride capsule in competition with Zanaflex Capsules and Zanaflex Tablets.

Our patent portfolio contains over 20 pending applications, and over 80 Neuregulin-related issued patents.

We are an exclusive licensee under a license agreement with CeNeS Pharmaceuticals, plc, of a worldwide portfolio of patents, patent applications and IP rights related to products and methods of use, these patents claim the use of particular neuregulins to treat various pathophysiological conditions, particularly uses to stimulate myelinating cells in order to treat conditions of the nervous system that involve demyelination. These patents also claim a number of additional potential uses of neuregulins, including stimulation of growth in cardiac and mammary tissue, stroke, ischemic brain events, peripheral neuropathy and nerve injury.

We have obtained an issued patent which covers methods for eliciting muscle cell survival, cell division or development by use of neuregulins. In January 2009, we received a decision from the U.S. Patent and Trademark Office on our application to neuregulin subject matter, which we expect will issue in 2009. This allowed case covers using specified neuregulin sequences to treat a central or peripheral nervous system disorder.

#### **Antibodies**

We have approximately ten remyelinating antibody-related patent applications, along with 13 corresponding issued patents (two in the U.S. and 11 foreign). We are the exclusive licensee of these patents related to a series of remyelinating antibodies discovered in the laboratory of Dr. Moses Rodriguez at the Mayo Clinic for the treatment of CNS disorders. We have two issued patents in 2009 and is directed to antibody compositions that can induce remyelination, as well as several issued related foreign counterparts.

We have numerous pending U.S. and foreign pending applications in our portfolio. Work actively continues on this subject matter and the remyelinating antibodies patent portfolio. Additional filings expected throughout 2009.

We have several chondroitinase-related U.S. patents, obtained in 2008, an issued Australian patent, and over 50 pending chondroitinase patent applications.

We have a pending U.S. application and its foreign counterpart from King's College and University of Cambridge directed to treatment of CNS damage. We have filed a number of other counterparts directed to chondroitinase enzymes and methods of use and preparation. In particular, we have filed U.S. applications and foreign equivalents relating to chondroitinase, chimeric proteins including

tion mutants and certain methods relating to chondroitinase. One of the issued U.S. patents covers chondroitinase ABCI mutant enzymes and related methods of use, positions.

patents, our intellectual property portfolio includes trademarks. The marks "Acorda Therapeutics," and our stylized Acorda Therapeutics logo are registered trademarks. "Zanaflex" and "Zanaflex Capsules" in the U.S. Our trademark portfolio also includes several pending trademark applications for potential product names and for dis

r developing and marketing pharmaceutical products is highly competitive. We are aware of many biotechnology and pharmaceutical companies that are engaged in d road range of CNS conditions. Many of our competitors have substantially greater financial, research and development, human and other resources than we do. Further more experience than we do in preclinical testing, human clinical trials, regulatory approval procedures and sales and marketing.

e management approaches to MS are classified either as relapse management or disease course management approaches. For relapse management, the majority of neu day course of intravenous high-dose corticosteroids. Many of these corticosteroids are available generically. For disease course management, there are a number of I immune system. These treatments attempt to reduce the frequency and severity of exacerbations or slow the accumulation of physical disability for people with certai on are not known. These products include Avonex from Biogen-IDEC, Betaseron from Schering AG, Copaxone from Teva Pharmaceutical Industries, Ltd., Rebif from Elan.

nology and pharmaceutical companies, as well as academic laboratories, are involved in research and/or product development for various neurological diseases, incl is developing a sodium/potassium channel blocker, HP 184, with a potential indication in SCI, MS and other conditions. We believe that HP 184 is in clinical trials f s, any resulting product might compete with Fampridine-SR. We also believe that EUSA Pharma is developing a 3,4-diaminopyridine compound that is in clinical de this product were successfully developed and approved, physicians might prescribe it instead of Fampridine-SR even if it were not approved for MS. In certain circum mulating certain drug compounds to fill prescriptions on an individual patient basis. We are aware that at present compounded fampridine is used by some people wit substantially if Fampridine-SR is approved, it is possible that some people will continue to use compounded fampridine. Several companies are engaged in developin roaches and cell transplant approaches to remyelination for the treatment of people with MS. These programs are in early stages of development and may compete w es in the future.

product candidate, Fampridine-SR, is the first product to our knowledge that acts to improve the function of nerve fibers in subjects with MS. We are not aware of other compounds that specifically address improvement of walking ability in subjects with MS. As a result of its focus on improving function, we believe that Fampridine-SR may be complementary to disease course management therapies that are commercially available. Nonetheless, Fampridine-SR may compete for market acceptance with these current treatments being prescribed to people with MS by physicians.

The active pharmaceutical ingredient in Zanaflex Capsules, Zanaflex tablets and generic tizanidine tablets, is one of the two leading FDA-approved treatments for spasticity. Zanaflex tablets were approved by the FDA in 1996 and lost compound patent protection in 2002. Twelve generic manufacturers of tizanidine are distributing their products. We are currently in litigation with Apotex with regard to its filing of an ANDA for the approval of a purported generic version of Zanaflex Capsules and certification against the CBO. We have reported that they are working on potential new delivery formulations of tizanidine. Baclofen, which is also available generically, is the other leading drug for the treatment of spasticity. The side effects and associated effects of baclofen are different from those of tizanidine. Due to the different pharmacokinetic profile of Zanaflex Capsules, Zanaflex tablets and generic Zanaflex Capsules.

## Information

### *Product Approval*

Comparable regulatory agencies in state and local jurisdictions and in foreign countries impose substantial requirements upon the preclinical testing, clinical development and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, distribution, record keeping, approval, advertising, sale, promotion, import and export of our products and product candidates.

In the United States, Zanaflex tablets, Zanaflex Capsules, and some of our product candidates, including Fampridine-SR, are regulated by the FDA as drugs. Other of our product candidates are biological products. Drugs are subject to the Federal Food, Drug, and Cosmetic Act, as amended, and the regulations of the FDA, as well as to other federal, state, and local laws. Biological products are regulated under both the Federal Food, Drug, and Cosmetic Act, as amended, and the Public Health Service Act, as amended. Violations of regulatory requirements at any point in the development process, including the FDA's and other health authorities' delay in approving or refusal to approve a product. Violations of regulatory requirements also may result in enforcement actions, such as restrictions, seizure of products, fines, injunctions and/or civil or criminal penalties. Similar civil or criminal penalties could be imposed by other government agencies if our products are manufactured, sold or distributed.

The regulatory requirements required by the FDA under these laws before our product candidates may be marketed in the United States generally involves the following:

preclinical laboratory and animal tests;

submission to the FDA of an IND, an application which must become effective before clinical trials may begin;

completion of two adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed pharmaceutical in our intended use(s);

FDA review of whether the facility in which the product is manufactured, processed, packed or held meets standards designed to assure the product's continued quality;

submission to the FDA of an NDA in the case of a drug, or a Biologics License Application, or BLA, in the case of a biologic, that must be approved containing precise labeling and information to demonstrate that the product will be manufactured to appropriate standards.

The development and approval process requires substantial time, effort, and financial resources and we cannot be certain that any approval will be granted on a timely or certain basis.

Our clinical studies include laboratory evaluation of the product candidate, its chemistry, formulation and stability, as well as animal studies to assess its safety and potential efficacy. We submit together with manufacturing information, analytical data and any available clinical data or literature to the FDA as part of an IND application, which must become effective 30 days after the FDA filing, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial. The FDA must resolve any outstanding concerns before the clinical trial can begin. Further, an independent Institutional Review Board charged with protecting the welfare of human subjects at the medical center proposing to conduct the clinical trials must review and approve any clinical trial before it commences at that center. Study subjects must provide informed consent to participate in the research study.

Clinical trials are typically conducted in three sequential phases, which may overlap:

*Phase 1.* The drug is initially administered into healthy human subjects or subjects with the target condition and tested for safety, dosage tolerance, absorption, metabolism, and excretion.

*Phase 2.* The drug is administered to a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific indications, and to determine dosage tolerance and optimal dosage.

*Phase 3.* When Phase 2 evaluations demonstrate that a dosage range of the drug is effective and has an acceptable safety profile, Phase 3 clinical trials are undertaken to confirm the results from Phase 2 and to further test for safety in an expanded population at geographically dispersed clinical trial sites.

For product candidates for severe or life-threatening diseases such as MS, the initial human testing is often conducted in affected patients rather than in healthy volunteers. In these cases, these clinical trials may provide initial evidence of efficacy traditionally obtained in Phase 2 clinical trials and thus these clinical trials are frequently referred to as Phase 1/2 studies.

In addition to Phase 1/2 studies, sponsors may seek a written agreement from the FDA regarding the design, size, and conduct of a clinical trial. This is known as an SPA. Three types of SPAs are: (1) Phase 1/2 studies, (2) final product stability studies and (3) clinical studies for pivotal Phase 3 studies whose data will form the primary basis to establish a new drug or biologic.



Where the FDA agrees to an SPA, the agreement may not be changed by either the sponsor or the FDA except if the sponsor and the FDA agree to a change, or an important scientific issue essential to determining the safety or effectiveness of the product was identified after the testing began. SPAs thus help establish up front agreement on the design of a clinical trial to support a regulatory approval, but the agreement is not binding if new circumstances arise. In addition, even if an SPA remains in place and the sponsor complies with its terms, the FDA could determine that the overall balance of risks and benefits for the product candidate is not adequate to support approval, or only justifies approval for limited distribution or other burdensome post-approval requirements or limitations. There is thus no guarantee that a study will ultimately be adequate to support an approval.

The FDCA requires the submission of registry and results information for most clinical trials. These requirements do not apply to Phase 1 clinical trials. Many of the federal requirements have not yet been implemented and will be phased-in over time. Once fully implemented, the federal requirements will preempt similar requirements adopted by state law.

The FDCA requires that studies conducted to support approval for product marketing be "adequate and well controlled." In general, this means that either a placebo or a product already marketed in the United States under study must be used as a reference control. Studies must also be conducted in compliance with good clinical practice, or GCP, requirements.

We cannot guarantee that we will successfully complete Phase 1, Phase 2 or Phase 3 testing of our product candidates within any specific time period, if at all. Furthermore, the FDA may suspend or may prevent clinical trials from beginning or may place clinical trials on hold or terminate them at any point in this process if, among other reasons, they conclude that the potential benefits of the product candidate do not justify an unacceptable health risk.

The results of product development, preclinical studies and clinical trials must be submitted to the FDA for review and approval prior to marketing and commercial shipment. If a product candidate is regulated as a drug, an NDA must be submitted and approved before commercial marketing may begin. If the product candidate, such as an antibody, is regulated as a biological product, a BLA must be submitted and approved before commercial marketing may begin. The NDA or BLA must include a substantial amount of data and other information concerning the safety and effectiveness of the compound from laboratory, animal and clinical testing, as well as data and information on manufacturing, product stability, and proposed product labeling.

Manufacturing facilities, including any contract manufacturers we may decide to use, must be listed in the NDA or BLA and must be registered with the FDA. We cannot begin marketing until the FDA conducts a manufacturing inspection, approves the applicable manufacturing process for the drug or biological product, and determines that the facilities are suitable for manufacturing. If the manufacturing facilities and processes fail to pass the FDA inspection, we will not receive approval to market these products. The FDA may also inspect clinical trial sites to ensure that the clinical studies have been conducted in compliance with GCP.

Under the Prescription Drug User Fee Act, as amended, the FDA receives fees for reviewing a BLA or NDA and supplements thereto, as well as annual fees for commercial manufacturing. These fees can be significant. For the FDA's fiscal year

BLA review fee alone is \$1,247,200, although certain limited deferrals, waivers and reductions may be available.

Under the laws and FDA regulations, each NDA or BLA submitted for FDA approval is usually reviewed for administrative completeness and reviewability within 45 to 60 days. If the application is found to be complete, the FDA will "file" the NDA or BLA, thereby triggering substantive review of the application. The FDA can refuse to file any NDA or BLA that it deems incomplete. If the FDA refuses to file an application, the FDA will retain 25% of the user fee as a penalty. The FDA has established performance goals for the review of NDAs and BLAs. The average review time for NDAs is 12 months for regular applications. However, the FDA is not legally required to complete its review within these periods and these performance goals may change over time. An approval is generally favorable, typically is not an actual approval but an "action letter" that describes additional work that must be done before the application can be approved. The FDA may also require review and recommendations by an independent FDA advisory committee.

The FDA may deny an NDA or BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data. Even if such data is submitted, the FDA may ultimately deny approval. If the FDA approves a product, it may limit the approved therapeutic uses for the product as described in the product labeling, require that controls be implemented in the product labeling, require that additional studies or clinical trials be conducted following approval as a condition of the approval, impose restrictions and conditions on the product in the form of a risk management plan or risk evaluation and mitigation strategy (REMS), or otherwise limit the scope of any approval or post-approval, or limit the use of the product. Significant restrictions on distribution and use of a marketed product, may require the distribution of medication guides, patient labeling and/or communication plans, and may require periodic assessments of the effectiveness of a REMS. Once issued, the FDA may withdraw product approval if compliance with regulatory standards is not maintained or if problems are identified. The FDA may also impose a REMS post-approval if it becomes aware of new safety information that it believes necessitates a REMS. In addition, the FDA may require testing of approved products which have been commercialized, and the agency has the power to prevent or limit further marketing of a product based on the results of these tests.

The time to receive FDA approval under the above FDA requirements or similar requirements of state, local and foreign regulatory agencies typically takes several years or more and the actual time required may vary depending on the complexity and novelty of the pharmaceutical product candidate. Government regulation may delay or prevent marketing of potential products for a considerable period of time. The time spent on our activities. We cannot be certain that the FDA or any other regulatory agency will grant approval for any of our product candidates on a timely basis, or on a commercial basis. The completion of pre-clinical or early stage clinical trials does not assure success in later stage clinical trials. Data obtained from preclinical and clinical activities is not always conclusive or appropriate, and there may be conflicting interpretations which could delay, limit or prevent regulatory approval. Even if a product candidate receives regulatory approval, the approval may be significantly limited. If regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal. Delays, denials, or failures to obtain regulatory approvals would have a material adverse effect on our business. Marketing our product candidates abroad will require similar regulatory approvals.

predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

manufactured or distributed by us pursuant to FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA, including record-keeping requirements, labeling, other reporting, advertising and promotion restrictions. The FDA's rules for advertising and promotion require, among other things, that we not promote our products unless the claims are fairly balanced and adequately substantiated by clinical studies. We must also submit appropriate new and supplemental applications and obtain FDA approval for changes to our labeling or manufacturing process. On its own initiative, FDA may require safety labeling changes to the labeling of an approved drug if it becomes aware of new safety information not included in the approved drug's labeling. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies. Inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party suppliers, our present or future suppliers will be able to comply with the cGMP and other FDA regulatory requirements. The FDA also enforces the requirements of the Prescription Drug Marketing Act, among other things, imposes various requirements in connection with the distribution of product samples to physicians. Similar provisions exist at the state level.

In addition to inspections related to manufacturing, we are subject to periodic unannounced inspections by the FDA and other regulatory bodies related to the other regulatory requirements for products manufactured or distributed by us. The FDA also may conduct periodic inspections regarding our review and reporting of adverse events, or related to compliance with the requirements for the distribution of product samples. When the FDA conducts an inspection, the inspectors will identify any deficiencies they believe exist in the form of a notice of inspectional observations, which may be more or less significant. If we receive a notice of inspectional observations, we likely will be required to respond in writing, and may be required to undertake corrective actions to address the FDA's concerns. For example, the FDA conducted an inspection in February 2009. This was the first FDA inspection we have had since a previous inspection the FDA conducted in 2007. The FDA 483 regarding our reporting of adverse events for marketed products. Although the 2009 inspection showed that we had resolved issues from the previous inspection, the inspection identified inspectional observations. The observations cited the failure to submit NDA field alert reports for Zanaflex Capsules in a timely manner, the failure to review adequately the late submission of NDA annual reports, and inadequate written procedures for our quality control unit, NDA field alert reporting, and the training of our personnel. We have taken corrective actions in order to address the FDA's concerns cited in the Form FDA 483. However, we cannot assure you that the FDA will find our remedial actions to be adequate and that there will be no additional deficiencies in subsequent inspections.

Our product candidates are also subject to a variety of state laws and regulations in those states or localities where they are or will be marketed. Any applicable state or local laws and regulations may affect our product candidates in those states or localities.

Regulatory requirements may change and additional government regulations may be enacted which could prevent or delay regulatory approval of our product candidates. Moreover, increasing regulatory requirements in the United States and in foreign markets could result in new government regulations which could have a material adverse effect on our business. We

likelihood, nature or extent of adverse governmental regulation which might arise from future legislative or administrative action, either in the United States or abroad.

Under the Orphan Drug Act, special incentives exist for sponsors to develop products for rare diseases or conditions, which are defined to include those diseases or conditions that affect fewer than 200,000 persons in the United States. Orphan drug designation must be submitted before the submission of an NDA or BLA. We have received orphan drug designation for Fampridine-SR for the treatment of spinal cord injury.

Orphan drugs are eligible for special grant funding for research and development, FDA assistance with the review of clinical trial protocols, potential tax credits, and priority review. If a product that has an orphan drug designation is the first such product to receive FDA approval for the disease for which it has such designation, the product is eligible for orphan drug exclusivity. This means that, subsequent to approval, the FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, for example, if the application is for a different drug or different use, or if FDA determines that the subsequent product is clinically superior. Orphan drug approval cannot assure the availability of sufficient quantities of the drug to meet the public's need. If the FDA approves someone else's application for the same drug, the competing drug could be prescribed by physicians outside its FDA approval for the orphan use, notwithstanding the existence of orphan exclusivity. A grant of orphan drug exclusivity will be approved. If a sponsor receives orphan drug exclusivity upon approval, there can be no assurance that the exclusivity will prevent another person from receiving the same or other uses.

### ***Ratings and Pharmacy Substitution***

Generic drugs are approved through an abbreviated process, which differs in important ways from the process followed for innovative products. Generally an abbreviated new drug application (ANDA) must seek approval of a product candidate that has the same active ingredient(s), dosage form, strength, route of administration, and conditions of use (labeling) as the reference listed drug. An ANDA is not an NDA with full supporting data to establish safety and effectiveness. Only limited exceptions exist to this ANDA sameness requirement, including certain limited exceptions for combination products and biologics. The ANDA also generally contains clinical data to demonstrate that the product covered by the ANDA is absorbed in the body at the same rate and extent as the reference listed drug. This is known as bioequivalence. In addition, the ANDA must contain information regarding the manufacturing processes and facilities that will be used to ensure the quality of the product. The ANDA must also list the facilities listed with the FDA for the reference listed drug.

State laws may require or permit pharmacists to substitute generic equivalents for brand-name prescriptions unless the physician has prohibited substitution. Managed care organizations may also require or permit substitution of generic equivalents, and to authorize substitution, as a means of controlling costs of prescriptions. They also may require lower copayments as an incentive to patients to use generic drugs.

The determination of substitutability is one of state law, most states look to the FDA to determine whether a generic is substitutable. FDA lists therapeutic equivalence ratings in a table. In general, a generic drug that is listed in the

therapeutically equivalent to the branded product will be substitutable under state law and, conversely, a generic drug that is not so listed will not be substitutable. To be a generic drug must first be a pharmaceutical equivalent of the branded drug. This means that the generic has the same active ingredient, dosage form, strength or concentration. Tablets and capsules are presently considered different dosage forms that are pharmaceutical alternatives and not substitutable pharmaceutical equivalents.

Being pharmaceutical equivalents, therapeutic equivalents must be bioequivalent to their branded counterparts. Bioequivalence for this purpose is defined in the same way as a showing of comparable rate and extent of absorption in a small human study.

Generic drug products generally are rated "AB" in the Orange Book if they are considered therapeutic equivalents. If bioequivalence has been adequately demonstrated,

### ***Marketing and Product Approval***

In the United States, our ability to market a product candidate is contingent upon receiving a marketing authorization from the appropriate regulatory authorities. The requirements for marketing authorization, pricing and reimbursement vary widely from country to country. At present, foreign marketing authorizations are applied for at a national level, and marketing registration procedures are available to companies wishing to market a product in the entire European Economic Area (EEA) or in more than one individual EC member state. Marketing involves all of the risks associated with FDA approval discussed above.

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

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

***d Pricing Controls***

markets where we or our collaborative partners would commercialize a product following regulatory approval, the prices of pharmaceutical products are subject to different programs with varying price control mechanisms.

In the United States, there has been an increased focus on drug pricing in recent years. Although there are currently no direct government price controls over private sector purchases of pharmaceutical products, pharmaceutical manufacturers pay prescribed rebates on certain drugs to enable them to be eligible for reimbursement under certain public health care programs such as Medicaid and otherwise that seek to control drug prices, including by disfavoring certain higher priced drugs and by seeking supplemental rebates. These programs are a potent force in the market place that increases downward pressure on the prices of pharmaceutical products. Federal legislation, enacted in December 2003, has altered the reimbursement methodology for certain drugs covered by Medicare. Under the new reimbursement methodology, physicians are reimbursed based on a product's "average sales price," or ASP. This new methodology has resulted in higher reimbursement levels. The new federal legislation also added an outpatient prescription drug benefit to Medicare, effective January 2006. This benefit is provided through a program that requires pharmaceutical manufacturers to negotiate price concessions from pharmaceutical manufacturers.

Private health care payers control costs and influence drug pricing through a variety of mechanisms, including through negotiating discounts with the manufacturers and through other mechanisms that provide preferential access to certain drugs over others within a therapeutic class. Payors also set other criteria to govern the uses of a drug that will be reimbursed or otherwise covered. In particular, many public and private health care payers limit reimbursement and coverage to the uses of a drug that are either included in a restricted drug compendium. Drug compendia are publications that summarize the available medical evidence for particular drug products and identify which uses of a drug are covered, whether or not such uses have been approved by the FDA. For example, in the case of Medicare coverage for physician-administered oncology drugs, the Omnibus Budget Reconciliation Act of 1990, with certain exceptions, provides for Medicare coverage of unapproved uses of an FDA-approved drug if the unapproved use is reasonable and necessary and is supported by the National Formulary Service Drug Information, the national Comprehensive Cancer Network Drugs and Biologics Compendium, Thompson Micromedex, DrugDex, or Clinical Drug Data System Compendium, for example under Medicaid, is the DrugDex Information System.

Similar pricing and reimbursement schemes exist in other countries. For example, in the European Union, governments influence the price of pharmaceutical products through their national health care systems that fund a large part of the cost of such products to consumers. The approach taken varies from member state to member state. Some jurisdictions require that products may only be marketed once a reimbursement price has been agreed. Other member states allow companies to fix their own prices for medicines, but may limit or restrict reimbursement. The downward pressure on health care costs in general, particularly prescription drugs, has become very intense. As a result, in many countries, the introduction of new products, as exemplified by the National Institute for Clinical Excellence in the UK which evaluates the data supporting new medicines and passes reimbursement decisions, and in some countries cross-border imports from low-priced markets (parallel imports) exert a commercial pressure on pricing within a country.

As of December 31, 2009, we had 174 employees. Of the 174 employees, 42 perform research and development activities, including preclinical programs, clinical trials, regulatory and medical affairs, business development, manufacturing and communications, and 34 perform general and administrative tasks.

## FORMATION

Incorporated in 1995 as a Delaware corporation. Our principal executive offices are located at 15 Skyline Drive, Hawthorne, New York 10532. Our telephone number is (914) 486-7000.

## FORMATION AND WHERE TO FIND IT

Our annual report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available on our website (<http://www.acorda.com> under the "SEC Filings" caption) as soon as reasonably practicable after we electronically file such material with, or furnish to, the Securities and Exchange Commission (SEC).

## Risk Factors.

*Investment in our common stock involves a high degree of risk. You should consider carefully the following risk factors and the other information contained in this prospectus and our annual report on Form 10-K before you decide to purchase our common stock. Additional risks that are not currently known or foreseeable to us may materialize at a future date. Our business and financial results may be materially adversely affected in a material way if any of these risks or uncertainties occur and you might lose all or part of your investment.*

## Our business

*We have a history of operating losses and we expect to continue to incur losses and may never be profitable.*

As of December 31, 2008, we had an accumulated deficit of approximately \$344.4 million. We had net losses of \$74.3 million, \$38.0 million, and \$60.0 million for the years ended December 31, 2008, 2007, and 2006, respectively. We have had operating losses since inception as a result of our significant clinical development, research and development, general and administrative, sales and marketing expenses, and we expect to incur losses for at least the next several years as we expand our sales and marketing capabilities, prepare for the potential launch of Fampridine-SR, and continue our research and development activities.

Our success in achieving profitability will depend primarily on how successful we are in executing our business plan to:

• obtain FDA approval for and commercialize Fampridine-SR;

• increase sales of Zanaflex Capsules;

• continue to develop our preclinical product candidates and advance them into clinical trials; and

• evaluate and act on appropriate opportunities for increasing shareholder value.

If we are not successful in executing our business plan, we may never achieve or may not sustain profitability.

*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 bus*

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 pur  
at our NDA is incomplete or otherwise not adequate to support review, it will refuse to accept the NDA for filing and will not proceed to further review. If the FDA a  
is a new substantial scientific issue regarding walking in the MS population or Fampridine-SR, the FDA may alter its opinion expressed in the prior SPAs regarding  
the FDA or the regulatory authorities in the European Union or other markets where we may apply for approval may also determine that the risks and benefits shown by  
approval, or support only a limited approval, or an approval conditioned on burdensome post-approval commitments.

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 2  
ed 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 toxicolog  
uded 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  
al 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 w  
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 consultan  
gnal 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  
e results may differ.

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 a  
ridine-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  
ulatory approval of Fampridine-SR could be seriously delayed or impaired, in which case our business prospects will be materially adversely affected.

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 demonstrate  
d under the criteria for Fast Track designation. We presented additional information on the ways in which Fampridine-SR improves walking ability in patients with M  
es as part of our request for reconsideration of that decision, but the FDA did not change its decision. We did not apply for Priority Review, and our NDA is therefore  
me under the Prescription Drug User Fee Act, rather than an expedited review time of six months.

ng 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  
ow set of uses or approval with restricted distribution or other burdensome post-approval requirements and limitations. Subjects taking Fampridine-SR have experie  
on, insomnia,



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 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 commitments, or if the Fampridine-SR program is terminated, our business prospects will be materially adversely affected.

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 MS. However, we cannot predict whether future clinical trials of Fampridine-SR in SCI will achieve their primary endpoints, how long they will last, or whether they will be

***materially dependent on sales of one product, Zanaflex Capsules, to generate revenue for the foreseeable future.***

derive substantially all of our revenue from the sale of Zanaflex Capsules and Zanaflex tablets, which are our only FDA-approved products. Although we currently do not actively promote Zanaflex tablets, we do not intend to, actively promote Zanaflex tablets. As a result, prescriptions for Zanaflex tablets have declined and our sales of Zanaflex tablets have decreased. Our goal is to convert sales of Zanaflex tablets and generic tizanidine tablets to sales of Zanaflex Capsules. We believe that sales of Zanaflex Capsules will constitute a significant portion of our revenue. If we are unable to convert tablet sales to capsule sales or are otherwise unable to increase our revenue from the sale of Zanaflex Capsules, our business prospects and results of operations could be materially adversely affected.

***Our sales force in anticipation of the possible launch of Fampridine-SR and sales of Zanaflex Capsules may not grow sufficiently, or Fampridine-SR may not be approved, which could be associated with this expansion.***

Our sales force has increased to 61 people as part of our strategy to increase sales of Zanaflex Capsules, which increased our fixed expenses significantly. We expect to continue to increase our sales force, in anticipation of the possible launch of Fampridine-SR, if approved. If we expand our sales force and an NDA is not approved by the FDA, or, if approved, we are unable to generate sales of Zanaflex Capsules and Fampridine-SR, our cash flow and our prospects for achieving profitability will be adversely affected. In addition, we may not be able to hire, train, and manage our sales personnel, in a timely manner or at all, or integrate and manage our larger sales and marketing organization.

There are currently 12 companies with generic versions of tizanidine tablets on the market and they are significantly cheaper than either Zanaflex Capsules or Zanaflex tablets. As a result, generic tizanidine tablets constituted approximately 93% of tizanidine sales in the United States. Although Zanaflex Capsules have a different pharmacokinetic profile when compared to Zanaflex tablets and their generic equivalents, we may be unsuccessful in convincing prescribers, patients and third-party payers, such as government health administration, private health insurers and other such organizations that these differences justify the higher price of Zanaflex Capsules. Despite our increased investment in sales and marketing, we may not be able to convert an additional number of current users of Zanaflex tablets or generic tizanidine tablets to Zanaflex Capsules. If that is the case, our ability to continue to generate meaningful revenue from the sale of Zanaflex Capsules will be adversely affected.

***Obtain regulatory approval in foreign jurisdictions where we seek to market our products.***

To market our products in the European Union and many other foreign jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying requirements in different countries and can involve additional clinical testing. The time required to obtain approval may differ from that required to obtain FDA approval. We may fail to obtain approval in some countries at all. In addition, individual countries, within the European Union or elsewhere, may require additional steps after regulatory approval to gain access to national markets and other agencies, that may affect our ability to market and sell our products outside the United States. Approval by the FDA does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We may not be able to file for, and may not receive, regulatory approval in any foreign market, which could adversely affect our business prospects.

We have met with national regulatory authorities in four European Union member states regarding Fampridine-SR and we believe, based on these discussions, that our current MAA with the EMEA. The EMEA may determine that such an MAA cannot be filed centrally, in which case we would be required to seek approval separately from each of the member states for Fampridine-SR through the European Union's decentralized or mutual recognition procedures. The EMEA may also determine that the data we submit are not sufficient to support the marketing of Fampridine-SR, which could lead to additional information requirements, including the submission of data from supplemental clinical trials other than those that we have submitted. Additional or supplemental trials would add to the cost of developing our product candidates. Additional or supplemental trials could also produce findings that are not consistent with those submitted to the FDA, in which case we would be obligated to report those findings to the FDA.

***Product candidates must undergo rigorous clinical testing, the results of which are uncertain and could substantially delay or prevent us from bringing them to market.***

To obtain regulatory approval for a product candidate, we must undertake extensive clinical testing in humans to demonstrate safety and efficacy to the satisfaction of regulatory authorities. Clinical trials of new product candidates sufficient to obtain regulatory marketing approval are expensive and take years to complete, and the outcome of such trials is uncertain.

The development of any product candidate that we determine to take into clinical trials may be curtailed, redirected, delayed or eliminated at any time for some or all of the following reasons:

• negative or ambiguous results regarding the efficacy of the product candidate;

• occurrence of undesirable side effects that delay or extend the trials, or other unforeseen or undesirable safety issues that make the product candidate not medically or commercially viable;

• inability to locate, recruit and qualify a sufficient number of patients for our trials;

• difficulty in determining meaningful end points or other measurements of success in our clinical trials;

• regulatory delays or other regulatory actions, including changes in regulatory requirements;

difficulties in obtaining sufficient quantities of our product candidates manufactured under current good manufacturing practices;

delays, suspension or termination of the trials imposed by us, an independent institutional review board for a clinical trial site, or clinical holds placed upon the trials;

FDA approval of new drugs that are more effective than our product candidates;

change in the focus of our development efforts or a re-evaluation of our clinical development strategy; and

a change in our financial position.

Termination of any of our clinical development programs could have an adverse effect on our business.

***Development programs are in early stages of development and may never be commercialized.***

Development programs other than Fampridine-SR are in the preclinical phase. Our future success depends, in part, on our ability to select successful product candidates, develop product candidates and advance them to clinical trials. These product candidates will require significant development, preclinical studies and clinical trials, regulatory clearances and approvals before they can be commercialized.

Our development programs may not lead to commercially viable products for several reasons. For example, we may fail to identify promising product candidates, our product candidates may fail in preclinical tests or clinical trials, or we may have inadequate financial or other resources to pursue discovery and development efforts for new product candidates. In addition, we may focus on product candidates that we believe are the most promising. As a result, we may delay or forego pursuit of opportunities with other product candidates. From time to time, we may change our development goals for our product candidates and programs; however, given the complex nature of the drug discovery and development process, it is difficult to predict our development goals. For example, the contract manufacturer with whom we had begun work to produce rHIgM22, one of our antibodies, under cGMP, filed for bankruptcy in 2008, and we were unsuccessful in advancing our preclinical programs into clinical testing or in obtaining regulatory approval, our long-term business prospects will be harmed.

***Our industry is subject to stringent regulation and failure to obtain regulatory approval will prevent commercialization of our product candidates.***

Our development, preclinical and clinical trial activities, as well as the manufacture and marketing of any products that we may successfully develop, are subject to an extensive regulatory process by regulatory agencies abroad. The process of obtaining required regulatory approvals for drugs is lengthy, expensive and uncertain, and any regulatory approvals may be limited, subject to drug, distribution restrictions or may be conditioned on burdensome post-approval study or other requirements, including the requirement that we institute and follow up on potential safety issues, all of which may eliminate or reduce the drug's market potential. Post-market evaluation of a product could result in marketing restrictions or withdrawal of the product.

Adverse events that could impact commercial success, or even continued regulatory approval, might emerge with more extensive post-approval patient use. Of the large number of

nt, only a small percentage result in the submission of an NDA to the FDA and even fewer are approved for commercialization.

duct clinical trials to obtain FDA approval to commercialize any product candidate, an IND application must first be submitted to the FDA and must become effective. An IND must be submitted to the FDA, including the results of adequate and well-controlled clinical trials demonstrating, among other things, that the product candidate is safe for the intended use. In addition, the manufacturing facilities used to produce the products must comply with current good manufacturing practices and must pass a pre-approval inspection. Preclinical and clinical trial data are required to demonstrate the safety, efficacy, potency and purity for each intended use. The FDA may refuse to accept our regulatory

are subject to oversight by institutional review boards and the FDA to ensure compliance with the FDA's good clinical practice requirements, as well as other requirements. We depend, in part, on third-party laboratories and medical institutions to conduct preclinical studies and clinical trials for our products and other third-party organizations that must maintain both good laboratory and good clinical practices required by regulators. If any such standards are not complied with in our clinical trials, the results may be suspended by an institutional review board or the FDA may suspend or terminate such trial, which would severely delay our development and possibly end the development of such product. Third-party manufacturers of our products to qualify for FDA approval and to comply with good manufacturing practices required by regulators. We cannot be certain that our third-party manufacturers comply with current good manufacturing practices. The failure to comply with good manufacturing practices may result in the termination of clinical studies, restrictions on the sale of our products in the market. Compliance by third parties with these standards and practices is outside of our direct control. For example, in January 2007, we and other pharmaceutical companies expressed concerns with the reliability of certain study analyses conducted by MDS Pharma Services, or MDS Pharma, at its St. Laurent (Montreal) and Blainville facilities. MDS Pharma helped conduct the studies submitted to FDA for the approval of Zanaflex Capsules. The MDS Pharma facility involved was in Ireland, not Canada, and we are unable to perform the types of analyses that the FDA identified in its recent notice as being of concern. Nonetheless, if the FDA's concerns extend to other MDS Pharma facilities that MDS Pharma assisted on for Zanaflex Capsules could be called into question, and we might have to confirm or repeat the studies.

are subject to regulation under other state and federal laws, including requirements regarding occupational safety, laboratory practices, environmental protection and other local, state, federal and foreign regulations. We cannot predict the impact of such regulations on us, although it could impose significant restrictions on our business operations and other regulations.

***Product candidates may not gain market acceptance among physicians, patients and the medical community, thereby limiting our potential to generate revenue.***

Success of our products and product candidates will depend on the benefits of our products in terms of safety, efficacy, convenience, ease of administration and cost effectiveness. Market acceptance also depends on the pricing of our products and the reimbursement policies of government and third-party payors. Physicians

our products, and patients may determine, for any reason, that our products are not useful to them. For example, physicians may not believe that the benefits of Zanaflex capsules or generic tizanidine tablets. The failure of any of our products or product candidates, once approved, to achieve market acceptance would limit our ability to affect our results of operations.

*Products may not be commercially viable if we fail to obtain an adequate level of reimbursement for these products by Medicaid, Medicare or other third-party payers.*

Our commercial success will depend in part on third-party payers, such as government health administrative authorities, including Medicaid and Medicare, private health insurers and other third-party payers, who will pay for the cost of our products. Significant uncertainty exists as to the reimbursement status of newly-approved healthcare products. Our business would be materially adversely affected if the Medicare program or other third-party payers were to deny reimbursement for our products or provide reimbursement only on unfavorable terms. Our business could also be adversely affected if the Medicare program or other reimbursing bodies or payers limit the indications for which our products will be reimbursed to a smaller set of indications than we believe.

Third-party payers frequently require that drug companies negotiate agreements with them that provide discounts or rebates from list prices. Although we do not have any such agreements with government payors, as sales of Zanaflex Capsules continue to increase, we expect increasing pressure to offer larger discounts or rebates to maintain acceptable reimbursement levels. If we were required to negotiate such agreements, there is no guarantee that we would be able to negotiate them at prices that would allow us to maintain acceptable reimbursement levels. If we were required to negotiate such agreements, there is no guarantee that we would be able to negotiate them at prices that would allow us to maintain acceptable reimbursement levels. Third-party payers now also require prior authorization for, or even refuse to provide, reimbursement for Zanaflex Capsules, and others may do so in the future. If we are unable to negotiate such agreements at acceptable levels, our business will be adversely affected. In addition, if our competitors reduce the prices of their products, or otherwise demonstrate that their products, this may result in a greater level of reimbursement for their products relative to our products, which would reduce our sales and adversely affect our results of operations.

The Medicare Prescription Drug, Improvement and Modernization Act of 2003, enacted in December 2003 added an outpatient prescription drug benefit to Medicare. The benefit is provided primarily through private entities, which attempt to negotiate with drug manufacturers. These negotiations increase pressure to lower prescription drug prices. While the law specifically prohibits the U.S. government from interfering in price negotiations between Medicare drug plan sponsors and drug manufacturers, some members of Congress are pursuing legislation that would permit the U.S. government to use its enormous purchasing power to negotiate with drug manufacturers, thereby creating de facto price controls on prescription drugs. In addition, the law contains triggers for Congressional consideration of cost containment measures if drug costs exceed a certain level. These cost containment measures could include limitations on prescription drug prices. This Medicare prescription drug coverage legislation, which may be enacted at a future date, could reduce our sales and adversely affect our results of operations.

*develop and market products that are more effective, safer or more convenient than our approved products, or obtain marketing approval before we obtain approval. Our revenue and market share will be reduced or eliminated.*

The competition in the pharmaceutical and biotechnology industries is intense and is expected to increase. Many biotechnology and pharmaceutical companies, as well as academic laboratories, are developing products for various neurological diseases, including MS and SCI. We are aware of a company developing a sodium/potassium channel blocker and of another Company developing a product, which may compete with Fampridine-SR, if approved. In certain circumstances, pharmacists are not prohibited from formulating certain drug compounds that are not commercially available. We are aware that at present compounded fampridine is used by some people with MS or SCI and it is possible that some people will want to continue to use compounded fampridine if approved. Several companies are engaged in developing products that include novel immune system approaches and cell transplant approaches to remyelination for MS. These products are in early stages of development and may compete in the future with Fampridine-SR or our preclinical candidates.

Our patents on tizanidine, the active ingredient in Zanaflex Capsules and Zanaflex tablets, expired in 2002. As of January 1, 2009, there were 12 companies with patents on tizanidine. To the extent that we are not able to differentiate Zanaflex Capsules from Zanaflex tablets and generic tizanidine tablets and/or pharmacists improperly substitute generic tizanidine tablets for Zanaflex Capsules, we may be unable to convert additional sales of Zanaflex tablets and generic tizanidine tablets to Zanaflex Capsules and our ability to generate additional sales may be reduced. Although no other FDA-approved capsule formulation of tizanidine exists, another company could develop a capsule or other formulation of tizanidine that competes with Zanaflex Capsules. A company advised us in August 2007 that it had submitted an Abbreviated New Drug Application (ANDA) to the FDA seeking marketing approval for generic versions of Zanaflex Capsules. We intend to maintain, and, if necessary, enforce our intellectual property", below). If a generic tizanidine hydrochloride capsule were approved and commercialized by any other company, we would face competition, which would likely cause significant declines in our revenue from this product, which is currently our only marketed product, and in our profit margin. Should we face generic competition, we might have to write off a portion of the intangible assets associated with Zanaflex Capsules and Zanaflex.

Our competitors may succeed in developing products that are more effective, safer or more convenient than our products or the ones we have under development or that render our products competitive or obsolete. In addition, our competitors may achieve product commercialization before we do. If any of our competitors develops a product that is more effective than our products or able to obtain FDA approval for commercialization before we do, we may not be able to achieve market acceptance for our products, which would adversely affect our revenue. The initial development costs we have incurred and will continue to incur.

Our products may be subject to competition from lower-priced versions of such products and competing products imported into the United States from Canada, Mexico and other countries. Tariffs, import controls or other market dynamics that make the products lower priced.

*ould be curtailed if we are unable to obtain any necessary additional financing on favorable terms or at all.*

er 31, 2008, we had approximately \$246.0 million in cash, cash equivalents and short-term investments. Although we anticipate this will be sufficient to fund our operations through 2010 based on our current projected revenue and spending levels, we have several product candidates in various stages of development, and all will require significant regulatory approval prior to commercialization. We will need to seek additional equity or debt financing or strategic collaborations to complete our product development and to commercialize any products that we successfully develop. We may not be able to raise additional capital on favorable terms or at all. To the extent that we are able to raise additional capital through the issuance of securities, the issuance of those securities would result in dilution to our stockholders. Holders of such new equity securities may also have rights, preference or privileges that are not available to our common stock. In addition, if financing is raised through the incurrence of indebtedness, we may become subject to various restrictions and covenants that could limit our ability to respond to market conditions or take advantage of business opportunities. To the extent funding is raised through collaborations or intellectual property-based financings, we may be required to grant intellectual property to one or more of our products, product candidates or preclinical programs. If we are unable to obtain sufficient financing on favorable terms when and if needed, we may be unable to continue one or more of our product development programs or devote less resources to marketing Zanaflex Capsules and Fampridine-SR, if approved.

*ing arrangement with the Paul Royalty Fund, or PRF, upon the occurrence of certain events, PRF may require us to repurchase the right to receive revenues that are secured by assets that secure our obligations to PRF. Any exercise by PRF of its right to cause us to repurchase the assigned right or any foreclosure by PRF could adversely affect our operations.*

On November 23, 2005, we entered into a revenue interest assignment agreement with PRF, which was amended on November 28, 2006, pursuant to which we assigned to PRF the right to receive revenues 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.

Under the assignment agreement with PRF, upon the occurrence of certain events, including if we experience a change of control, undergo certain bankruptcy events, transfer any of our intellectual property rights (including any agreement, development, commercialization, co-promotion, collaboration, partnering or similar agreement), transfer all or substantially all of our assets, or breach certain covenants or warranties under the revenue interest assignment agreement, PRF may (i) require us to repurchase the rights we assigned to it at the "put/call price" in effect on the date of the event, (ii) cause us to repurchase the rights we assigned to it, or (iii) foreclose on the Zanaflex assets that secure our obligations to PRF. Except in the case of certain bankruptcy events, if PRF exercises its right to cause us to repurchase the rights we assigned to it, we may fail to pay the put/call price as required. The put/call price on a given date is the greater of (i) 150% of all payments made by PRF to us as of such date, less all payments made by us to PRF as of such date, and (ii) the amount that would generate an internal rate of return to PRF of 25% on all payments made by PRF to us as of such date, taking into account the amount and timing of such payments.

exercise its right to cause us to repurchase the right we assigned to it, we cannot assure you that we would have sufficient funds available to pay the put/call price if available, we may have to use funds that we planned to use for other purposes and our results of operations and financial condition could be adversely affected. If PRF were to exercise its obligations to PRF, our results of operations and financial condition could also be adversely affected. Because PRF's right to cause us to repurchase the rights we assigned in control, transfer of any of our interests in Zanaflex (other than pursuant to a license agreement, development, commercialization, co-promotion, collaboration, partnership or joint venture) would result in the loss of substantially all of our assets, the existence of that right could discourage us or a potential acquirer from entering into a business transaction that would result in the occurrence of the events described above.

***Our dependence on our management and scientific personnel may hinder our ability to execute our business plan.***

Our success depends on the continuing contributions of our management team and scientific personnel, and maintaining relationships with our scientific and medical network and the institutions that conducts our clinical trials. We are highly dependent on the services of Dr. Ron Cohen, our President and Chief Executive Officer, as well as the other principal members of our management team. Our success depends in large part upon our ability to attract and retain highly qualified personnel. We face intense competition in our hiring efforts with other pharmaceutical companies and nonprofit research organizations, and we may have to pay higher salaries to attract and retain qualified personnel. With the exception of Dr. Ron Cohen, we do not have long-term employment contracts in the lives of our officers, directors or employees. The loss of one or more of our key employees, or our inability to attract additional qualified personnel, could substantially hinder our business plan.

***Our potential risk of liability in the event that the use or misuse of our products results in personal injury or death.***

If the use or misuse of Zanaflex Capsules or any other FDA-approved products we may sell in the future harms people, we may be subject to costly and damaging product liability claims from patients, health care providers, pharmaceutical companies, third-party payers or others. The use of our product candidates in clinical trials could also expose us to product liability claims. We currently have a product liability insurance policy that includes coverage of our clinical trials. This insurance policy has a \$10 million per claim limit and the aggregate amount of claims under the policy is limited to \$10 million. We do not have adequate marketed product liability coverage. We cannot predict all of the possible harms or side effects that may result from the use of our products or the testing of product candidates. The coverage we currently have may not be adequate to cover all liabilities or defense costs we might incur. A product liability claim or series of claims brought against us could exceed our resources. Even if claims are not successful, the costs of defending such claims and potential adverse publicity could be harmful to our business.

***Our potential risk of various federal and state laws regulating the marketing of Zanaflex Capsules and, if we do not comply with these regulations, we could face substantial penalties.***

Our promotion and other activities related to Zanaflex Capsules, or any of our other products under development following their regulatory approval, are subject to regulatory requirements of the FDA, including the Federal Trade Commission, the



ce, and state and local governments. We are subject to various federal and state laws pertaining to health care "fraud and abuse," including both federal and state anti-prescription drug manufacturer to solicit, offer, receive or pay any remuneration as an inducement for the referral of business, including the use, recommendation, purchase or sale of services. The federal government has published regulations that identify "safe harbors" or exemptions for certain payment arrangements that do not violate the anti-kickback statute. It is possible that our practices, or those of our contract sales force, might be challenged under anti-kickback or similar laws. Violations of fraud and abuse laws may result in civil fines and civil monetary penalties, and future exclusion from participation in government healthcare programs.

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

for which we currently have or may obtain marketing approval, along with the associated manufacturing processes, any post-approval clinical data that we might be required to submit, and promotional activities for the product, are subject to continual recordkeeping and reporting requirements, review and periodic inspections by the FDA and other regulatory agencies. We are also subject to limitations on the indicated uses for which the product may be marketed or to other restrictive conditions of approval that limit our ability to promote, sell or distribute the product. We are also subject to certain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. For example, we are required to inform the FDA of certain packaging of our commercialized products. In December 2007, we filed a field alert with the FDA notifying them that two bottles of Zanaflex Capsules were packaged incorrectly and contained no information on their labels. We worked with the packager of Zanaflex Capsules to identify and correct any issues that could have caused this, but there can be no assurance that the capsules will be labeled properly or that other similar issues will not occur. Additionally, in December 2008, we filed a field alert with the FDA notifying them that we had received a complaint that a Zanaflex Capsule that she had received from her physician did not appear to contain any drug substance. We worked closely with the manufacturer and packager to investigate the complaint, but we cannot assure you that this investigation uncovered all of the relevant information, that there will not be similar product complaints in the future, or that the complaint is adequate or that the complaint does not reflect a broader issue with our manufacturing or quality assurance systems.

Our ongoing FDA commitment, inherited from Elan, to provide an assessment of the safety and effectiveness of Zanaflex Capsules in pediatric patients. This commitment, which was to be satisfied by February 2007.

We submitted retrospective pediatric safety data to the FDA in April 2007. However, we were not able to complete the pediatric pharmacokinetic study by the February 2007 deadline. We are currently obtaining Institutional Review Board approvals. The study was completed and the final report submitted to the FDA in April 2008. The FDA reviewed our response to the comments on the new standards set out in the 2007 FDA Amendments Act and found that it does not fulfill them. We have withdrawn our submission and plan to meet with the FDA to discuss compliance with the revised standards. This could include conducting additional studies. Such additional studies could be more extensive and more costly than the current studies. Penalties for non-compliance with PREA, including a court-imposed injunction to conduct studies.

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

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

Our inability to adapt, or we may not be able to adapt, to changes in existing regulatory requirements or adoption of new legal or regulatory requirements or policies. Later discovered defects in our products, manufacturing processes, or failure to comply with regulatory requirements, may result in:

voluntary or mandatory recalls;

voluntary or mandatory patient or physician notification;

withdrawal of product approvals;

product seizures;

restrictions on, or prohibitions against, marketing our products;

restrictions on importation of our product candidates;

fines and injunctions;

civil and criminal penalties;

exclusion from participation in government programs; and

suspension of review or refusal to approve pending applications.

The FDA or another regulatory agency may conduct periodic unannounced inspections. If they determine that we or any of our manufacturing or other partners are not in compliance, they may issue a notice of inspectional observations. If the observations are significant, we may have to devote significant resources to respond and undertake appropriate corrective actions that may adversely affect our business prospects.

*and marketing compliance and reporting requirements may expose us to regulatory and legal action by state governments or other government authorities.*

several states, including California, Maine, Massachusetts, Minnesota, New Mexico, Nevada, New Hampshire, Texas, Vermont and West Virginia, and the District of Columbia, require pharmaceutical companies to establish marketing compliance programs and file periodic reports with the state on sales, marketing, pricing and other activities. For example, California requires pharmaceutical companies to adopt a comprehensive compliance program that is in accordance with the Office of Inspector General of the Department of Health and Human Services for Pharmaceutical Manufacturers. This compliance program must include policies for compliance with the Pharmaceutical Research and Manufacturers of America's Code of Ethics, as well as a specific annual dollar limit on gifts or other items given to individual healthcare professionals in California. The law requires posting policies on a public website as a condition of compliance.

Maine, Massachusetts, Minnesota, New Mexico, Nevada, New Hampshire, Texas, Vermont and West Virginia have also enacted laws of varying scope that require pharmaceutical companies pertaining to drug pricing and payments and costs associated with pharmaceutical marketing, advertising and promotional activities. Other than California, various pharmaceutical sales and marketing activities, and new legislation is being considered in many states. Many of the state law requirements are new and unclear. We are not aware of any companies against which fines or penalties have been assessed under these state reporting and disclosure laws to date. We are currently in the process of developing infrastructure and standard operating procedures to comply with such laws. Unless we are in full compliance with these laws, we could face enforcement action and reputational damage to our public image.

Proposed legislation may impose additional requirements. For example, in January 2009, Senators Grassley and Kohl introduced a federal physician payment disclosure bill, H.R. 1733, which, if enacted, will require pharmaceutical manufacturers to report certain gifts and payments to physicians, which will then be placed on a public database. Failure to comply with the bill could result in significant financial penalties.

*and hazardous materials in a manner that causes injury, we may be liable for damages.*

Our research and development activities involve the controlled use of potentially harmful biological materials, hazardous materials and chemicals that are subject to federal, state and local laws regarding the storage, handling and disposal. These materials include ketamine, buprenorphine, sodium pentobarbital, ether, acetonitrile, hexanes, chloroform, xylene, dehydrated formaldehyde. We cannot completely eliminate the risk of accidental contamination or injury from the use, storage, handling or disposal of these materials. If we fail to comply with applicable laws, we could be subject to criminal sanctions and/or substantial liability for any damages that result, and any substantial liability could exceed our resources.

We maintain a general liability insurance policy that has a \$2 million per claim limit and also caps aggregate claims at \$2 million. In addition, we have an umbrella insurance policy that provides coverage in excess of the general liability policy's \$2 million limit. This amount of insurance coverage may not be adequate to cover all liabilities or defense costs we

tion, the cost of compliance with environmental and health and safety regulations may be substantial.

*ations pursuant to compliance with the Sarbanes-Oxley Act of 2002 is expensive and time consuming.*

Oxley Act of 2002 requires that we maintain certain corporate governance practices and adhere to a variety of reporting requirements, including with respect to internal controls. Compliance with these requirements has increased our general and administrative costs. In addition, these requirements could make it more difficult and more expensive for us to attract and retain qualified members of our board of directors, particularly independent directors, or qualified executive officers.

**our dependence on third parties**

*no manufacturing capabilities and are substantially dependent upon Elan and other third party suppliers to manufacture Zanaflex Capsules, Zanaflex tablets and*

n or operate, and currently do not plan to own or operate, facilities for production and packaging of Zanaflex Capsules, Zanaflex tablets or Fampridine-SR. We rely on Elan for the production and packaging of our commercial products and clinical trial materials.

single manufacturer, Elan, for the supply of Zanaflex Capsules. Zanaflex Capsules are manufactured using Elan's proprietary SODAS multiparticulate drug delivery technology. We have agreed with Elan to supply Zanaflex Capsules, to use commercially reasonable efforts to assist us in either producing Zanaflex Capsules ourselves or in transferring production of Zanaflex Capsules to a third party. We have agreed that such third-party manufacturer is not a technological competitor of Elan. In the event production is transferred to a third party, the FDA may require us to demonstrate to the FDA through laboratory testing that the product made by the new supplier is equivalent to the current Zanaflex Capsules before we could distribute products from that supplier. The process of obtaining FDA approval for a new supplier could take a year or more.

supply agreement with Elan, we provide Elan with monthly written 18-month forecasts and with annual written two-year forecasts for our supply requirements of Zanaflex Capsules. Upon the submission of our written 18-month forecast we are obligated to purchase the quantity specified in the forecast, even if our actual requirements are greater or less than the forecasted amounts, in excess of our forecasted amounts, although it has agreed to use commercially reasonable efforts to do so. If our forecasts of our supply requirements are inaccurate, we may be required to purchase Zanaflex Capsules.

In 2007, we relied on a single manufacturer, Novartis, for the manufacture of Zanaflex tablets and for the supply of tizanidine, the active pharmaceutical ingredient in Zanaflex tablets. Novartis has discontinued production of tizanidine and will no longer supply tizanidine to Elan for the production of Zanaflex Capsules or to us for the production of Zanaflex tablets. We have agreed to use the tizanidine manufactured by a new supplier, Farmak, as the active ingredient in the production of Zanaflex Capsules. However, we are still required to obtain FDA approval for the production of Zanaflex tablets. Elan has agreed to supply us with Novartis-manufactured tizanidine for the manufacture of Zanaflex tablets to satisfy supply

tain FDA approval of a new tizanidine supplier for Zanaflex tablets prior to February 2010, we may experience an interruption in our supply. Beginning in May 2007, Novartis-manufactured tizanidine must be retested within 30 days of each manufacturing run. If Elan's tizanidine inventory fails its retest prior to FDA approval of a new supplier, our supply of our Zanaflex tablets could result.

ly in contract negotiations with Patheon regarding the manufacture of Zanaflex tablets, and Patheon has agreed to manufacture Zanaflex tablets prior to the contract being signed. In the event of any disruption in their operations, a delay or interruption in the supply of our Zanaflex products could result until the affected supplier cures the problem or we locate an alternative supplier. We may be required to enter into alternative supply arrangements on terms that are commercially favorable, if at all. Any new supplier would also be required to qualify under applicable regulatory requirements, which could result in substantial delays before we are able to qualify any new supplier and transfer the required manufacturing technology to that supplier.

May 2007, the chemical stability of Elan's inventory of Novartis-manufactured tizanidine must be retested within 30 days of each manufacturing run. If Elan's tizanidine inventory fails its retest prior to FDA approval of a new supplier for Zanaflex tablets, a delay or interruption in our supply of our Zanaflex tablets could result.

exclusively on Elan to supply us with our requirements for Fampridine-SR. We and Elan rely on a single third-party manufacturer to supply fampridine, the active pharmaceutical ingredient in our supply agreement with Elan, we are obligated to purchase at least 75% of our yearly supply of Fampridine-SR from Elan, and we are required to make competitive offers to purchase our requirements from Elan, subject to certain exceptions. We and Elan have agreed that we may purchase up to 25% of our annual requirements from Patheon, a mutual supplier, with compensatory payment.

dependence on others to manufacture our marketed products and clinical trial materials may adversely affect our ability to develop and commercialize our products on a timely basis.

***Contract research organizations do not perform in an acceptable and timely manner, our preclinical testing or clinical trials could be delayed or unsuccessful.***

Our ability to conduct all aspects of our preclinical testing or clinical trials ourselves. We rely and will continue to rely on clinical investigators, third-party contract manufacturers, and other vendors to perform some or all of the functions associated with preclinical testing and clinical trials. The failure of any of these vendors to perform in an acceptable and timely manner could result in our inability to comply with applicable regulatory requirements, such as good clinical and laboratory practices, or preclinical testing or clinical trial protocols, could cause a delay or other adverse effect on the timely advancement of our development programs. For example, the contract manufacturer that we were working with to produce rHlgM22 under our IND filing that we had targeted for late 2009.

**our intellectual property**

*to obtain, maintain and, if necessary, enforce our intellectual property, our ability to develop and commercialize our products will be severely limited.*

Our success will depend in part on our and our licensors' ability to obtain, maintain and enforce patent protection for the technologies, compounds and products, if any, resulting from our research and development. If we do not obtain adequate patent protection for the intellectual property we use or intend to use, other companies could offer substantially identical products for sale without incurring the sizable costs that we have incurred. Our ability to recover these expenditures and realize profits upon the sale of products could be diminished.

Our patents, in-licensed or are the assignee of over 35 U.S. patents, over 110 foreign patents and over 100 patent applications pending worldwide for technologies we invented, developed, in-licensed or are the assignee of. Obtaining, maintaining and enforcing patents can be time consuming and expensive with no certainty of success. Even if we spend the necessary time and money, a patent may not issue, it may not issue in a timely manner, or it may not provide the same level of protection as we expect. Our ability to obtain adequate patent protection for the particular technology it was intended to protect or to provide us with any commercial advantage. We may never be certain that we were the first to develop a particular technology or that our patent application for the particular technology because patent applications are confidential until they are published, and publications in the scientific or patent literature may disclose our technology. Our ability to obtain adequate patent protection for our proprietary rights will remain uncertain if our pending patent applications are not allowed or issued for any reason or if we are unable to develop additional patents. Furthermore, third parties may independently develop similar or alternative technologies, duplicate some or all of our technologies, design around our patented technologies, or otherwise circumvent our patents or our licensors' patents.

In the course of our actions to protect our intellectual property and in any litigation in which our patents or our licensors' patents are asserted, a court may determine that the patents are invalid or that the enforceability of these patents is upheld by a court, a court may not prevent alleged infringement on the grounds that such activity is not covered by the patent claims. In addition, patent rights may be unavailable or limited in some foreign countries for a variety of legal and public policy reasons. From time to time we may receive notices from third parties claiming that we have infringed their patent rights. Any litigation, whether to enforce our rights to use our or our licensors' patents or to defend against allegations that we infringe third party rights, would be costly and could divert resources away from other important tasks.

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

Our success is dependent on our business on trade secrets, know-how and other proprietary information. We seek to protect this information, in part, through the use of confidentiality agreements with our employees, consultants, collaborators, key

third parties apply technological information independently developed by them or by others to our proposed products, joint ownership may result, which could under disputes may arise as to the proprietary rights to such information which may not be resolved in our favor. The risk that other parties may breach confidentiality agreements independently discovered by competitors, could adversely affect us by enabling our competitors, who may have greater experience and financial resources, to copy or information in the advancement of their products, methods or technologies. Policing unauthorized use of our or our licensors' intellectual property is difficult, expensive and to the extent of any unauthorized use. Adequate remedies may not exist in the event of unauthorized use or disclosure.

In 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 products. 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 Columbia. U.S. Patent No. 6,455,557 relating to methods of reducing drowsiness in patients with immediate release multiparticulate tizanidine formulations, including those sold under the name Zanaflex.

In 2007, Apotex filed an answer to our complaint, asserting affirmative defenses of invalidity and non-infringement of U.S. Patent No. 6,455,557, and also filed counterclaims for patent infringement. Apotex' defenses or counterclaims may change during the course of the litigation and its arguments and/or the underlying bases for its arguments may change. We have opposed, for partial judgment on the pleadings dismissing the Company's request for relief on the ground that the case is "exceptional" under U.S.C. §§ 271(e)(2)(B) and (2)(C). Apotex' motion in December 2008. We and Apotex are currently proceeding with discovery in the case. Although we intend to vigorously defend our intellectual property rights, we can provide no assurance that we will prevail or that the ANDA filed by Apotex will not be approved by the FDA. The resolution of this patent litigation could be lengthy and at such time, we may absorb significant management time, all of which may materially and adversely affect our financial position and results of operations. In addition, if Apotex is successful in obtaining approval of that ANDA, it could be permitted to sell a generic tizanidine hydrochloride capsule. Further, other third parties may bring similar claims. We would face significant competition for the sale of Zanaflex capsules, which would cause significant declines in our revenue and profit margin. If a generic tizanidine hydrochloride capsule were approved and marketed, it would cause significant competition, which would likely cause significant declines in our revenue from this product, which is currently our only marketed product. Should sales of Zanaflex capsules decline, we might have to write off a portion of the intangible assets associated with Zanaflex Capsules and Zanaflex.

*Successfully claim that we infringed their patents or proprietary rights, our ability to continue to develop and successfully commercialize our product candidates could be significantly impaired.*

We may claim that we or our licensors or suppliers are infringing their patents or are misappropriating their proprietary information. In the event of a successful claim against us, we may be required to:

pay substantial damages;

stop using our technologies;

stop certain research and development efforts;

significantly delay product commercialization activities;

develop non-infringing products or methods, which may not be feasible; and

obtain one or more licenses from third parties.

From time to time, we may become aware of third parties who have, or claim to have, intellectual property rights covering matters such as methods for doing business, or manufacturing medications that are alleged to be broadly applicable across sectors of the industry, and we may receive assertions that these rights apply to us. The existence of such rights could be material to our business.

Our rights under any patents or proprietary rights held by a third party may not be available to us, or may not be available on acceptable terms. If we or our licensors or suppliers experience substantial delays in, or be prohibited from developing, manufacturing and commercializing our product candidates and advancing our preclinical or clinical programs. This could be time consuming, and might distract management from other important tasks.

*Our license agreements and if we fail to meet our obligations under these license agreements, or our agreements are terminated for any reason, we may lose our rights to certain intellectual property.*

We have entered into license agreements for intellectual property related to Zanaflex, Fampridine-SR and all of our preclinical programs. Our failure to meet any of our obligations under these license agreements could result in the loss of our rights to this intellectual property. If we lose our rights under any of these license agreements, we may be unable to commercialize a product that uses licensed intellectual property.

Our rights to Fampridine-SR under our license agreement with Elan in countries in which we have a license, if we fail to file regulatory approvals within a commercially reasonable period of time or receipt of positive data from all preclinical and clinical studies required for the NDA-equivalent. We could also lose our rights under our license agreement with Elan if we fail to obtain regulatory approval in the United States, within 180 days of NDA or equivalent approval. Elan could also terminate our license agreement if we fail to make payments due under the license agreement. Our prospects for generating revenue and recovering our substantial investment in the development of this product would be materially harmed.

#### **Our common stock**

*Our common stock may be volatile and you may lose all or a part of your investment.*

Since our initial public offering in February 2006, you could not buy or sell our common stock publicly. While our common stock is listed on the Nasdaq Global Market, an active market for our common stock has not been sustained. You may not be able to sell your shares quickly or at the current market price if trading in our stock is not active. Our stock price could fluctuate significantly.

Our stock price could be affected by the achievement or rejection of regulatory approvals by us or by our competitors;

changes in our stock price due to publicity regarding actual or potential clinical trial results or updates relating to products under development by us or our competitors;



announcements of new corporate partnerships, alliances, financings or other transactions, or of technological innovations or new commercial products by our competitors;

developments concerning proprietary rights, including patents;

developments concerning our collaborations;

economic or other crises or other external factors;

conditions or trends in the pharmaceutical or biotechnology industries;

litigation and other developments relating to our patents or other proprietary rights or those of our competitors;

governmental regulation and legislation in the United States and foreign countries;

changes in securities analysts' estimates of our performance or our failure to meet analysts' expectations;

sales of substantial amounts of our stock;

delay or failure in initiating, completing or analyzing pre-clinical trials or unsatisfactory design or result of these trials;

variations in product revenue and profitability;

variations in our anticipated or actual operating results; and

delays in completing Phase IV trials if required by the FDA.

These factors are beyond our control, and we believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance. If our operating results do not meet expectations, we may not be able to adjust our expenditures in that period, which could cause our operating results to suffer. If our operating results in any period do not meet securities analysts' estimates or investors' expectations, our stock price may fall by a significant amount.

The stock markets in general, and the Nasdaq Global Market and the market for biopharmaceutical companies in particular, have experienced extreme price and volume volatility that have been unrelated or disproportionate to the operating performance of these companies. These broad market and industry factors may adversely affect the market price of our common stock and our actual operating performance.

***Our common stock could cause our stock price to decline.***

If a large number of our stockholders sell a large number of shares of our common stock, or the public market perceives that existing stockholders might sell shares of common stock, the market price of our common stock may decline significantly. Sales of substantial amounts of shares of our common stock in the public market by our executive officers, directors, 5% or greater stockholders or other stockholders may also significantly affect the market price of our common stock. As of February 13, 2009, we have outstanding 37,774,711 shares of voting common stock. We have registered 6,625,000 shares of common stock for issuance under our equity compensation plans, including outstanding options to acquire 3,181,056 shares of common stock outstanding as of February 13, 2009, exercisable through 2011. To the extent that option holders exercise outstanding options, there may be further dilution and the sales of shares issued upon such exercises could cause our stock price to decline.



*directors and largest stockholders choose to act together, they may be able to control the outcome of stockholder vote.*

As of December 31, 2008, our officers, directors and holders of 5% or more of our outstanding common stock beneficially own approximately 45.9% of our common stock. As a result, they are able to significantly influence all matters requiring approval by our stockholders, including the election of directors and the approval of mergers or other business combinations. Our stockholders may not always coincide with the interests of other stockholders, and they may act in a manner that advances their best interests and not necessarily those of our stockholders.

*Under Delaware law, our certificate of incorporation and our bylaws may delay or prevent an acquisition of us that stockholders may consider favorable or may prevent us from pursuing business opportunities or our management, which could decrease the value of your shares.*

Our certificate of incorporation and bylaws contain provisions that could make it more difficult for a third party to acquire us, and may have the effect of preventing or hindering an acquisition of us by our stockholders or directors or officers. These provisions include:

Our board of directors has the right to elect directors to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director. This right may prevent our stockholders from being able to fill vacancies on our board of directors.

Our board of directors may issue, without stockholder approval, shares of preferred stock with rights, preferences and privileges determined by the board of directors. The issuance of preferred stock with voting or other rights or preferences makes it possible for our board of directors to issue preferred stock with super voting, special approval, dividend rights and other features on a discriminatory basis that could impede the success of any attempt to acquire us.

Our board of directors is divided into three classes, each with staggered three-year terms. As a result, only one class of directors will be elected at each annual meeting. The other two other classes of directors will continue to serve for the remainder of their respective three-year terms, limiting the ability of stockholders to reconstitute the board of directors.

The vote of the holders of 75% of the outstanding shares of our common stock is required in order to take certain actions, including amendment of our bylaws, removal of directors or officers, and certain amendments to our certificate of incorporation.

Under Delaware law, as a corporation, we are also subject to certain anti-takeover provisions of Delaware law. Under Delaware law, a corporation may not engage in a business combination with an acquirer unless the holders of the common stock have held the stock for three years or, among other things, the board of directors has approved the transaction. Our board of directors could rely on Delaware law to prevent such a business combination, which could have the effect of reducing your ability to receive a premium on your common stock.

*If we do not intend to pay dividends in the foreseeable future, you will benefit from an investment in our common stock only if it appreciates in value.*

We have not paid cash dividends on any of our classes of capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. We do not intend to pay cash dividends in the foreseeable future. The success of your investment in our common stock will depend entirely upon any future appreciation.

ee that our common stock will appreciate in value or even maintain the price at which you purchased your shares.

**Involved Staff Comments.**

**ies.**

executive offices are located in an approximately 46,103 square foot facility in Hawthorne, NY, which houses offices and laboratory space. The current annual rent for the facility is \$1,200,000. We believe that our facility is currently adequate for our purposes however there may be a need to rent additional space in the future depending upon the possible growth of our business through December 2012.

**Proceedings.**

On July 17, 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 Zantac products. 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 York. U.S. Patent No. 6,455,557 relating to methods of reducing drowsiness in patients with immediate release multiparticulate tizanidine formulations, including those so described. Apotex answered our complaint, asserting patent invalidity and non-infringement and counterclaiming, seeking a declaratory judgment of patent invalidity and non-infringement.

On December 11, 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 Rule 12(c)(2)(B) of the Federal Rules of Civil Procedure. The court granted Apotex's motion in favor and denied Apotex' motion in December 2008. We and Apotex are currently proceeding with discovery in the case.

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

On December 11, 2008, we submitted to a vote of security holders during the fourth quarter of 2008.

## PART II

**for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.**

Stock has been quoted on the NASDAQ Global Market under the symbol ACOR since our initial public offering on February 9, 2006. Prior to that date, there was no public market for our common stock. The following table sets forth, for the periods indicated, the high and low bid prices per share of our common stock as reported on the NASDAQ Global Market.

|  | <b>High</b> | <b>Low</b> |
|--|-------------|------------|
| <b>Fiscal Year Ended December 31, 2008</b> |             |            |
| Fourth Quarter                             | \$24.03     | \$14.42    |
| Third Quarter                              | \$35.65     | \$23.03    |
| Second Quarter                             | \$33.70     | \$17.74    |
| First Quarter                              | \$28.14     | \$17.03    |

|  | <b>High</b> | <b>Low</b> |
|--|-------------|------------|
| <b>Fiscal Year Ended December 31, 2007</b> |             |            |
| Fourth Quarter                             | \$23.40     | \$16.84    |
| Third Quarter                              | \$21.41     | \$15.80    |
| Second Quarter                             | \$26.58     | \$16.69    |
| First Quarter                              | \$25.88     | \$15.06    |

Transfer Company is the transfer agent and registrar for our common stock. As of February 13, 2009, we had approximately 42 registered holders of record of our common stock.

**Performance Graph**

This graph compares the cumulative 34-month total return attained by stockholders on Acorda Therapeutics, Inc's common stock relative to the cumulative total returns of the NASDAQ Composite Index and the NASDAQ Biotechnology index. An investment of \$100 is assumed to have been made in our common stock and in each of the indexes on 2/10/2006 and its relative performance is shown through 12/31/2008.

**COMPARISON OF 34 MONTH CUMULATIVE TOTAL RETURN\***

Among Acorda Therapeutics, Inc, The NASDAQ Composite Index  
And The NASDAQ Biotechnology Index

\* \$100 invested on 2/10/06 in stock & 1/31/06 in index including reinvestment of dividends. Fiscal year ending December 31.

|                          | 2/06   | 2/06   | 3/06   | 4/06   | 5/06  | 6/06  | 7/06  | 8/06  | 9/06   | 10/06  | 11/06  |
|--------------------------|--------|--------|--------|--------|-------|-------|-------|-------|--------|--------|--------|
| Acorda Therapeutics, Inc | 100.00 | 92.26  | 77.68  | 72.92  | 57.29 | 62.05 | 47.62 | 43.45 | 136.16 | 264.73 | 288.10 |
| NASDAQ Composite         | 100.00 | 98.94  | 101.92 | 101.51 | 95.35 | 95.19 | 92.07 | 96.20 | 99.30  | 104.20 | 107.17 |
| NASDAQ Biotechnology     | 100.00 | 103.61 | 101.75 | 95.72  | 92.16 | 91.09 | 92.89 | 93.37 | 95.18  | 100.89 | 99.74  |

|                          | 2/07   | 3/07   | 4/07   | 5/07   | 6/07   | 7/07   | 8/07   | 9/07   | 10/07  | 11/07  | 12/07  |
|--------------------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
| Acorda Therapeutics, Inc | 323.07 | 288.99 | 368.75 | 296.13 | 253.87 | 249.70 | 267.71 | 273.07 | 301.64 | 278.42 | 326.79 |
| NASDAQ Composite         | 106.93 | 107.36 | 111.33 | 114.98 | 114.93 | 112.53 | 114.32 | 119.77 | 126.45 | 117.37 | 116.69 |
| NASDAQ Biotechnology     | 97.23  | 94.38  | 102.67 | 101.43 | 98.70  | 97.27  | 98.85  | 104.54 | 109.02 | 105.77 | 99.24  |

|                          | 3/08   | 4/08   | 5/08   | 6/08   | 7/08   | 8/08   | 9/08   | 10/08  | 11/08  | 12/08  |
|--------------------------|--------|--------|--------|--------|--------|--------|--------|--------|--------|--------|
| Acorda Therapeutics, Inc | 267.11 | 313.24 | 320.83 | 488.54 | 488.24 | 418.90 | 354.91 | 303.57 | 269.64 | 305.21 |
| NASDAQ Composite         | 100.28 | 106.34 | 111.15 | 101.31 | 101.24 | 102.63 | 89.90  | 73.71  | 65.99  | 67.98  |
| NASDAQ Biotechnology     | 96.08  | 96.75  | 98.85  | 97.19  | 110.37 | 107.25 | 100.80 | 91.94  | 85.49  | 91.64  |

*Relative performance included in this graph is not necessarily indicative of future stock price performance.*

declared or paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our capital stock in the foreseeable future. We currently intend to use our cash and cash equivalents to fund the development and growth of our business.

**Financial Data.**

Unaudited selected consolidated financial data for each of the five years in the period ended December 31, 2008 are derived from our audited consolidated financial statements with our audited consolidated financial statements and related notes that are included elsewhere in this Annual Report on Form 10-K and with "Management's Discussion of Operations" included in Item 7 below.

|  | <b>Year Ended December 31,</b>               |             |             |             |             |
|--|--|-------------|-------------|-------------|-------------|
|  | <b>2008</b>                                  | <b>2007</b> | <b>2006</b> | <b>2005</b> | <b>2004</b> |
|  | <b>(in thousands, except per share data)</b> |             |             |             |             |
| <b>Statement of Operations Data:</b>   |  |             |             |             |             |
| Gross sales Zanaflex   | \$ 53,398                                    | \$ 43,586   | \$ 26,548   | \$ 5,923    | \$          |
| Less: discounts and allowances   | (5,670)                                      | (4,160)     | 396         | (1,114)     | (4,417)     |
| Net sales  | 47,728                                       | 39,426      | 26,944      | 4,809       | (4,417)     |
| Grant revenue  | 99   | 60          | 407         | 336         | 479         |
| Total net revenue  | 47,827                                       | 39,486      | 27,351      | 5,145       | (3,938)     |
| Less: cost of sales  | (11,355)                                     | (8,356)     | (7,123)     | (5,132)     | (885)       |
| Gross profit   | 36,472                                       | 31,130      | 20,228      | 13          | (4,823)     |
| <b>Operating expenses:</b>   |  |             |             |             |             |
| Research and development   | 36,604                                       | 22,410      | 12,055      | 12,890      | 21,999      |
| Sales and marketing  | 49,070                                       | 30,737      | 19,079      | 13,099      | 4,662       |
| General and administrative   | 24,237                                       | 17,431      | 12,561      | 8,435       | 13,283      |
| Total operating expenses   | 109,911                                      | 70,578      | 43,695      | 34,424      | 39,944      |
| Operating loss   | (73,439)                                     | (39,448)    | (23,467)    | (34,411)    | (44,767)    |
| <b>Other income (expense):</b>   |  |             |             |             |             |
| Interest and amortization of debt discount expense   | (5,591)                                      | (2,664)     | (2,553)     | (1,526)     | (385)       |
| Interest income  | 4,682  | 4,087       | 1,471       | 402         | 409         |
| Other income   | 8  | 51          | 76          | 1           | 2           |
| Total other income (expense)   | (901)  | 1,474       | (1,006)     | (1,123)     | 26          |
| Cumulative effect of change in accounting principle(3)   |  |             | 454         | 3           |             |
| Net loss   | (74,340)                                     | (37,974)    | (24,019)    | (35,531)    | (44,741)    |
| Beneficial conversion feature, accretion of issuance costs, preferred dividends, and fair value of warrants issued to convertible preferred stockholders |  |             | (36,008)    | (24,849)    | (24,746)    |
| Net loss allocable to common stockholders  | (74,340)                                     | (37,974)    | \$(60,027)  | \$(60,380)  | \$(69,487)  |
| Net loss per share allocable to common stockholders basic & diluted  | \$ (2.19)                                    | \$ (1.45)   | \$ (3.27)   | \$(295.27)  | \$(351.76)  |



|   |        |        |        |    |        |    |        |
|---|--------|--------|--------|----|--------|----|--------|
| Pro forma net loss per share allocable to common stockholders basic & diluted (unaudited)(1)  |        |        |        | \$ | (.79)  | \$ | (9.63) |
| Weighted average shares of common stock outstanding used in computing net loss per share allocable to common stockholders basic & diluted                             | 33,939 | 26,237 | 18,346 |    | 204    |    | 198    |
| Weighted average shares of common stock outstanding used in computing pro forma net loss per share allocable to common stockholders basic & diluted (unaudited)(1)(2) |        |        |        |    | 13,547 |    | 13,536 |

Pro forma net loss per share and weighted average shares of common stock used in computing pro forma net loss per share allocable to common stockholders for the year ended December 31, 2005 and 2004, respectively, are calculated as if all our convertible preferred stock and mandatorily redeemable convertible preferred stock were converted into common stock as of the beginning of the year ended December 31, 2004 or from their respective dates of issuance, if issued after December 31, 2004. The pro forma net loss per share allocable to common stockholders for the year ended December 31, 2004 was computed as follows:

was completed at the beginning of the fiscal year presented and has been adjusted to give effect to the following: (a) recognition of the automatic conversion charge of \$67.9 million; (b) recognition of the unamortized portion of issuance costs relating to Series E, Series I, Series J and Series K preferred stock of \$379,000; and (c) reversal of accrued preferred dividends on Series J and Series K preferred stock of \$7.4 million. The pro forma net loss per share for common stockholders for the year ended December 31, 2005 reflects the reversal of the accrued preferred dividend of \$5.3 million, amortized issuance cost of \$4 million and amortized issuance cost of \$108,000 assuming that the automatic conversion occurred as of the beginning of the fiscal year. For our initial public offering in February 2006, all the preferred stock was converted into common stock.

Weighted average shares of our common stock outstanding used in computing the pro forma net loss per share allocable to common stockholders includes Series A through Series J equivalent shares of common stock from the beginning of the fiscal year; and (b) Series K equivalent shares of common stock from the date of issuance of the Series K preferred stock.

On January 1, 2006, we adopted the provisions of Statement of Financial Accounting Standards 123 (revised 2004), "Share-Based Payment" (SFAS No. 123R), which requires that the costs resulting from all share-based payment transactions be recognized in the financial statements at their fair values. We adopted the modified prospective application method under which the provisions of SFAS No. 123R apply to new awards and to awards modified, repurchased or forfeited on the adoption date. Additionally, compensation cost for the portion of the awards for which the requisite service has not been rendered that are outstanding on the adoption date is recognized in the Consolidated Statement of Operations over the remaining service period after the adoption date based on the straight-line method. Results for prior periods have not been restated. Upon adoption of SFAS No. 123R, we recorded a cumulative effect of change in accounting principle of \$1.5 million during the three-month period ended March 31, 2006, calculated as the difference between compensation cost recognized to date using the straight-line method and the amount that would have been recognized to date using estimated forfeitures.

|                                   | <b>As of December 31,</b> |             |             |             |             |
|-----------------------------------|---------------------------|-------------|-------------|-------------|-------------|
|                                   | <b>2008</b>               | <b>2007</b> | <b>2006</b> | <b>2005</b> | <b>2004</b> |
|                                   | <b>(in thousands)</b>     |             |             |             |             |
| <b>Consolidated Balance Sheet</b> |                           |             |             |             |             |
| and cash equivalents              | \$ 29,613                 | \$ 16,810   | \$18,101    | \$ 11,761   | \$ 11,729   |
| Term investments                  | 216,435                   | 78,310      | 35,656      | 2,001       | 9,397       |
| Working capital                   | 207,445                   | 71,770      | 33,324      | (10,394)    | 9,067       |
| Assets                            | 281,501                   | 127,306     | 84,368      | 33,912      | 30,982      |
| Completed product                 |                           |             |             |             |             |
| Zanaflex tablets                  | 7,867                     | 7,914       | 9,117       | 11,510      | 6,668       |
| Completed product                 |                           |             |             |             |             |
| Zanaflex Capsules                 | 16,436                    | 13,924      | 11,324      | 5,226       |             |
| Current portion of notes payable  |                           | 188         | 1,044       | 1,068       | 302         |
| Current portion of notes          |                           |             |             |             |             |
| Payable                           |                           |             | 187         | 1,147       | 145         |
| Current portion of revenue        |                           |             |             |             |             |
| Liability PRF transaction         | 6,181                     | 1,785       | 3,392       | 2,162       |             |
| Option liability PRF transaction  | 338                       | 463         | 350         | 400         |             |
| Current portion of revenue        |                           |             |             |             |             |
| Liability PRF transaction         | 12,498                    | 17,444      | 19,744      | 12,914      |             |
| Term convertible notes            |                           |             |             |             |             |
| Payable                           | 6,905                     | 6,703       | 6,508       | 8,768       | 8,422       |
| Historically redeemable           |                           |             |             |             |             |
| Preferred stock                   |                           |             |             | 91,214      | 66,364      |
|                                   | 207,157                   | 63,433      | 18,669      | (116,536)   | (60,571)    |

stockholders' equity

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

Management's discussion and analysis of our consolidated financial condition and results of operations should be read in conjunction with our audited consolidated financial statements included in our Annual Report on Form 10-K.

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 the management of other disorders of the CNS. Our marketed drug, Zanaflex Capsules, is FDA-approved for the management of spasticity.

In 2008, we received 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 2008. A Phase 3 clinical trial for 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 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 were released in September 2008. This study evaluated the potential to cause an increase in the electrocardiographic QT interval. Fampridine-SR, at both therapeutic and suprathreshold doses, did not cause a clinically significant increase in QT interval. On July 30, 2009, we submitted a New Drug Application to the FDA for Fampridine-SR. We have also discussed Fampridine-SR with national regulatory authorities of four countries. Our current data are sufficient to file a centralized MAA with the European Medicines Agency. We are in discussions with potential marketing partners regarding the commercialization of Fampridine-SR in Europe and other non-U.S. markets. At the same time, we are preparing for the filing of a centralized MAA with the EMEA. We plan to maintain our flexibility in the timing of our U.S. commercialization pathway and availability to patients. We believe Fampridine-SR is the first potential therapy in late-stage clinical development for MS that seeks to improve walking ability. If approved, it could be complementary to existing drugs used to treat MS. To our knowledge, there are no current therapies indicated to improve walking ability in MS.

In 2008, the Company acquired certain assets of Neurorecovery, Inc. (NRI). These assets will enable Acorda to explore additional therapeutic indications for its investigational products, as well as gain access to pre-clinical compounds that may have utility in nervous system disorders. Under the terms of the purchase agreement, Acorda was assigned two products for development: one to the use of aminopyridines in peripheral neuropathies and two early stage development candidates. Acorda also acquired NRI's pre-clinical and clinical data, regulatory filings, patents, copyrights, trademarks and domain names relating to the three products. Acorda issued 100,000 shares of its Common Stock as the purchase price for these assets and the transaction was accounted for as an acquisition of in-process research and development assets and, as such, resulted in a non-cash expense in the first quarter of 2008 of \$2,680,000.

Our preclinical programs focused on novel approaches to repair damaged components of the CNS. We believe all of our preclinical programs — neuregulins, remyelinating agents, and others — 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 other CNS conditions, such as traumatic brain injury, because many of the mechanisms of tissue damage and repair are similar. In addition, we believe

have applicability beyond the nervous system, including in such fields as cardiology, oncology, orthopedics and ophthalmology. Our preclinical programs also target including stroke and traumatic brain injury.

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

We funded a significant portion of our funds on a number of clinical trials for Fampridine-SR, our most advanced product candidate, including two Phase 3 clinical trials of Fampridine-SR in SCI, the results of which were announced in April 2004 and the Phase 3 clinical trials for MS described above.

The Phase 2 clinical trial in MS was completed in 2001. In mid-2004, we decided to put our clinical trials of Fampridine-SR in SCI on hold, and refocused our efforts on our Phase 3 clinical trial of Fampridine-SR for improvement of walking ability in people with MS. We may resume our clinical development of Fampridine-SR in SCI.

We acquired all of Elan's research, development, distribution, sales and marketing rights to Zanaflex Capsules and Zanaflex tablets in the United States. These products are used to treat spasticity. We made an upfront payment to Elan of \$2.0 million and we will also be obligated to pay royalties upon the achievement of specified sales levels. Through December 2008, we have achieved milestones totaling \$19.5 million in the aggregate, based on the achievement of specified levels of sales. As part of our Zanaflex acquisition, we entered into a long-term supply agreement that provides us with Zanaflex Capsules. Elan also assigned us its rights under an agreement with Novartis for the supply of tizanidine and Zanaflex tablets.

Our current efforts are focused on Zanaflex Capsules, which we launched in April 2005 and pre-launch activities associated with the commercialization of Fampridine-SR, if approved. Zanaflex Capsules received FDA approval in 2002 and both Zanaflex Capsules and Zanaflex tablets compete with 12 generic tizanidine products. Although we currently distribute Zanaflex tablets, we expect sales of Zanaflex tablets to decline. 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 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 significant sales of 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 be a significant portion of our total revenue.

We began establishing our own specialty sales force in the U.S., which consisted of 61 sales professionals as of December 31, 2008. This sales force has targeted neurologists treating people with conditions that involve spasticity. We also employ an internal and field-based team who call on managed care organizations, pharmacists and distributors. We have also employed a Regional Markets Group, LLC to provide a small, dedicated sales force of pharmaceutical telesales professionals who contact primary care, specialist physicians and pharmacists.

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 from our net revenues as determined in accordance with GAAP) from Zanaflex Capsules, Zanaflex tablets and any future Zanaflex products. The agreement covers the period from October 1, 2005 through and including December 31, 2015, unless the agreement is terminated earlier. Under the agreement, PRF is entitled to a royalty consisting of certain percentages of net revenues, based upon the level of net revenues. The agreement provides that the royalty rate will drop to 1% upon PRF's receipt of 2.1 times the aggregate amount PRF has received under the terms of the agreement, we are required to pay PRF \$5.0 million on December 1, 2009 and an additional \$5.0 million on December 1, 2010. For more information on our financing arrangements, see "Capital Resources - Financing Arrangements."

Our initial public offering in February 2006, in which we sold 6,075,614 shares of our common stock, resulting in net proceeds of approximately \$31.5 million. Since our initial public offering, we have completed the placement of our common stock in October 2006 and three follow-on common stock offerings, raising an aggregate of approximately \$273.4 million, in July 2007, August 2007, and February 2008.

In October 2007, we received a Paragraph IV Certification Notice from Apotex Inc. advising that it had filed an ANDA with the FDA for generic versions of each of the three Zanaflex 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 Superior Court 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. Apotex answered our complaint, asserting patent invalidity and non-infringement and counterclaiming, seeking a declaratory judgment of patent invalidity and non-infringement. In October 2008, the ANDA were approved by the FDA and Apotex were successful in challenging the validity of the patent, Apotex could be permitted to sell a generic tizanidine hydrochloride capsules.

In November 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 the Federal Circuit's standard for summary judgment and denied Apotex' motion in December 2008. We and Apotex are currently proceeding with discovery in the case.

#### **Deferred Revenue**

Our revenue consists of sales of Zanaflex Capsules and Zanaflex tablets. Under SFAS 48, *Revenue Recognition When the Right of Return Exists*, we are not permitted to recognize revenue until we can 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 capsules to tablets, we cannot reasonably determine a return rate. As a result, we account for sales of these products using a deferred revenue recognition model. At a future point in time, we expect to recognize revenue and will then 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 value until the inventory held by the wholesaler as a component of inventory. We recognize revenue when prescriptions are filled to end-users because once prescriptions are filled

be returned. We use monthly prescription data that we purchase to determine the amount of revenue to be recognized. When we receive the prescription data, we use it to calculate 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. We began marketing Zanaflex Capsules in April 2005 and began receiving prescription data and recognizing revenue in the same month.

Revenue interest assignment agreement with PRF, as amended in November 2006, PRF is entitled to a portion of our net revenues from Zanaflex Capsules, Zanaflex tablets and Zanaflex oral suspension. The agreement covers all Zanaflex net revenues (as defined in the agreement) generated from October 1, 2005 through and including December 31, 2015, unless the agreement is terminated. PRF is entitled to a certain portion of such Zanaflex net revenues. For more information regarding our agreement with PRF, see "Liquidity and Capital Resources - Financing Activities."

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 net revenue. Returns are not a significant component of our revenue.

#### *Allowances*

Wholesaler fees for services, cash discounts, Medicaid and patient program rebates and chargebacks have been established. At the time product is shipped to wholesaler, the appropriate reserves are credited. These allowances are established by management as its best estimate of historical experience adjusted to reflect known changes in market conditions. Reserves for wholesaler fees for services, chargebacks, rebates and discounts are established based on contractual terms with customers and analyses of historical usage of drug products.

Intangible assets are recognized when the related research expenses are incurred and our performance obligations under the terms of the respective contract are satisfied. To the extent that the cost of an intangible asset is deferred and amortized over the shorter of its useful life or the life of the related contract.

Our cost of sales consists of cost of inventory, expense due to inventory reserves, royalty expense, milestone amortization of intangible assets associated with the Zanaflex acquisition, and stability testing costs. Our inventory costs, royalty obligations and milestone obligations are set forth in the agreements entered into in connection with our Zanaflex acquisition. Our cost of sales in connection with the revenue interest assignment transaction entered into in December 2005 will not constitute royalty expense or otherwise affect our cost of sales. See "Liquidity and Capital Resources - Financing Arrangements."

#### *Development Expenses*

Development expenses consist primarily of employee compensation and benefits, fees paid to professional service providers for independently monitoring our clinical trials, costs of contract manufacturing services, costs of materials used in clinical trials and research and development and depreciation of capital assets.

develop our products. Share-based compensation is classified between clinical development and preclinical research and development based on employee job function. as incurred.

table summarizes our research and development expenses for the years ended December 31, 2008, 2007 and 2006. Clinical development contract expense MS consisting largely of clinical trial and research services provided by outside laboratories and vendors in connection with each product candidate in clinical development primarily consists of costs associated with Fampridine-SR manufacturing development. Preclinical research and development research contracts consists of our external laboratories and vendors in connection with each product candidate in all preclinical programs as a group. Our internal research and development costs, which are in costs, related benefits and share-based compensation, that are not attributable to any individual project because we use these resources across several development projects. Total costs related to the preparation of the Fampridine-SR NDA and regulatory support for Fampridine-SR clinical studies and pre-clinical research and development.

|   | <b>Year Ended<br/>December 31,</b> |                 |                 |
|---|------------------------------------|-----------------|-----------------|
|   | <b>2008</b>                        | <b>2007</b>     | <b>2006</b>     |
| <b>Clinical development:</b>                      |                                    |                 |                 |
| Contract expense MS                               | \$ 8,887                           | \$ 10,823       | \$ 6,004        |
| Other contract expense                            | 2,120                              | 1,368           | 751             |
| NRI acquisition                                   | 2,687                              |                 |                 |
| Operating expense                                 | 5,290                              | 3,496           | 1,553           |
| <b>Total clinical development</b>                 | <b>18,984</b>                      | <b>15,687</b>   | <b>8,308</b>    |
| <b>Preclinical research and development:</b>      |                                    |                 |                 |
| Research contracts                                | 6,425                              | 681             | 153             |
| Operating expense                                 | 3,018                              | 2,406           | 3,057           |
| <b>Total preclinical research and development</b> | <b>9,443</b>                       | <b>3,087</b>    | <b>3,210</b>    |
| <b>Regulatory affairs</b>                         | <b>8,177</b>                       | <b>3,636</b>    | <b>537</b>      |
| <b>Total</b>                                      | <b>\$36,604</b>                    | <b>\$22,410</b> | <b>\$12,055</b> |

**Marketing Expenses**

Marketing expenses include personnel costs, related benefits and share-based compensation for our sales and marketing personnel and the cost of Zanaflex sales and marketing with the possible commercialization of Fampridine-SR.

**Administrative Expenses**

Administrative expenses consist primarily of personnel costs, related benefits and share-based compensation for personnel serving executive, finance, medical affairs, biology and human resource functions. Other costs include facility costs not otherwise included in research and development or sales and marketing expense and professional



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e consists of income earned on our cash, cash equivalents and short-term investments. Interest expense consists of interest expense related to our revenue interest liab

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**ber 31, 2008 Compared to Year Ended December 31, 2007**

l gross sales from the sale of Zanaflex Capsules and Zanaflex tablets of \$53.4 million for the year ended December 31, 2008, as compared to \$43.6 million for the year ended December 31, 2007, an increase of approximately \$9.8 million, or 23%. The increase was due to an increase in prescriptions written for our products that we believe is the result of expanding our sales force and increasing the number of physicians. We have not increased products' prices since a 10% increase effective January 1, 2007. We recognize product sales using a deferred revenue recognition model meaning that we recognize revenue when end-user prescriptions of the product are reported.

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discounts and allowances of \$5.7 million for the year ended December 31, 2008 as compared to a \$4.2 million for the year ended December 31, 2007, an increase of approximately \$1.5 million. The increase in discounts and allowances was the result of a higher level of Zanaflex revenues and related shipments. Discounts and allowances are recorded when Zanaflex Capsules are shipped.

allowances for the year ended December 31, 2008, consisted of \$2.3 million for fees for services payable to wholesalers, \$1.9 million for chargebacks and rebates and \$1.5 million for chargebacks and rebates. Discounts and allowances for the year ended December 31, 2007 consisted of \$1.6 million for fees for services payable to wholesalers, \$1.5 million for chargebacks and rebates and \$1.1 million for chargebacks and rebates.

for the year ended December 31, 2008 was \$99,000 compared to \$60,000 for the year ended December 31, 2007, an increase of approximately \$39,000, or 65%. Grant income is recognized when the performance obligations are incurred and our performance obligations under the terms of the respective contract are satisfied.

cost of sales of \$11.4 million for the year ended December 31, 2008 as compared to \$8.4 million for the year ended December 31, 2007, an increase of approximately \$3.0 million. The increase in cost of sales is primarily due to the increase in gross sales and the amortization of the Zanaflex intangible asset achieved in the beginning of 2008. Cost of sales for the year ended December 31, 2008 consisted of \$3.0 million in royalty fees, \$2.4 million in amortization of intangible assets, which is unrelated to either the volume of shipments or the amount of revenue recognized, \$3.9 million in inventory costs, \$1.2 million in amortization of intangible assets and stability testing. Cost of sales for the year ended December 31, 2007 consisted of \$3.0 million in royalty fees, \$3.9 million in inventory costs, \$1.2 million in amortization of intangible assets and stability testing.

related to either the volume of shipments or the amount of revenue recognized, and \$222,000 in costs related to packaging, freight and stability testing.

*Development*

Development expenses for the year ended December 31, 2008 were \$36.6 million as compared to \$22.4 million for the year ended December 31, 2007, an increase of \$14.2 million. An increase in research and development expenses was primarily due to an increase of \$5.8 million from \$602,000 to \$6.4 million for the development of our preclinical pipeline for these products and the Company's acquisition of certain in-process research and development assets of NRI resulted in a non-cash expense of approximately \$2.7 million. *For Research and Development Expenses.*

These expenses were partially offset by a decrease in MS clinical development program expense of \$1.9 million or 18% to \$8.9 million. This decrease was primarily due to an initial phase I study of Fampridine-SR during 2007 and the Thorough QT cardiac study which was conducted during the second half of 2007.

Expenses for clinical development, pre-clinical research and development and regulatory were \$16.5 million for the year ended December 31, 2008, compared to \$9.5 million for the year ended December 31, 2007, an increase of \$7.0 million, or 74%. This increase was primarily attributable to an increase in regulatory expenses of \$4.4 million for the preparation of an NDA for Fampridine-SR, an increase in research and development staff and compensation of approximately \$2.8 million to support pre-clinical research and development, Fampridine-SR clinical studies and regulatory expenses.

Manufacturing and stability fees increased to \$2.2 million for the year ended December 31, 2008, from \$1.4 million for the year ended December 31, 2007, an increase of \$800,000 or 55%. This increase was primarily due to an increase of \$753,000 for manufacturing and stability fees related to Fampridine-SR.

Marketing expenses for the year ended December 31, 2008 were \$49.1 million compared to \$30.7 million for the year ended December 31, 2007, an increase of approximately \$18.4 million. This increase was primarily attributable to an increase of \$12.4 million for pre-launch activities associated with the possible commercialization of Fampridine-SR, if approved. In addition, we incurred an increase in compensation of \$4.4 million to support promotion of Zanaflex Capsules and Fampridine-SR pre-launch activities, an increase in other selling related expenses of \$7.0 million for separate communications of \$550,000 and an increase in Zanaflex Capsules marketing expenses of \$211,000.

*Administrative*

Administrative expenses for the year ended December 31, 2008 were \$24.2 million compared to \$17.4 million for the year ended December 31, 2007, an increase of \$6.8 million. This increase was primarily the result of an increase in staff and compensation and other expenses related of \$3.4 million to supporting the growth of the overall organization, an increase in legal fees related to patent infringement litigation and an increase in costs associated with medical affairs research and educational programs of \$1.1 million.

marketing and general and administrative expenses are expected to increase in 2009 and 2010 primarily due to an increase in our expected pre-launch activities and an increase in our sales force in anticipation of the potential launch of Fampridine-SR, if approved.

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was \$901,000 in expense for the year ended December 31, 2008 compared to other income of \$1.5 million for the year ended December 31, 2007, a decrease of approximately \$2.4 million, primarily due to an increase in interest expense of \$2.9 million. This increase in interest expense was the result of a \$1.5 million increase in interest expense under the 2006 amended revenue interests assignment agreement with PRF. This out-of-period adjustment did not increase the total interest expense associated with this agreement by a \$500,000 increase in interest income as a result of the investment of net proceeds from our follow-on public offerings in February and August 2008.

**Year Ended December 31, 2007 Compared to Year Ended December 31, 2006**

Gross sales from the sale of Zanaflex Capsules and Zanaflex tablets of \$43.6 million for the year ended December 31, 2007, as compared to \$26.5 million for the year ended December 31, 2006, or 64%. The increase was due to an increase in prescriptions written for our products that we believe was the result of our sales force expansion in 2007. Also included in gross sales for the year ended December 31, 2007 was \$462,000 of revenue recognized associated with our 2mg tablet deferred revenue. In 2006, we recognized the remaining \$462,000 deferred revenue as gross sales. We recognize product sales using a deferred revenue recognition model meaning that revenue is only recognized as revenue when end-user prescriptions of the product are reported.

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discounts and allowances of \$4.2 million for the year ended December 31, 2007 as compared to a negative \$396,000 for the year ended December 31, 2006, an increase of \$4.6 million. In connection with our Zanaflex acquisition in 2004, we agreed to accept any returns of Zanaflex tablets that were returned subsequent to January 17, 2005, including returns of product that was shipped to wholesalers prior to that date were the responsibility of Elan. As a result of this agreement, in December 2004 we recorded a return liability of \$4.1 million which was our best estimate of the amount that would eventually become liable. Our obligation to continue to accept these returns ended in June 2006. As a result of the returns we accepted since 2004, the net balance remaining of this liability was \$1.8 million as of December 31, 2006. We reversed this liability in June 2006, which resulted in a reduction in discounts and allowances of \$1.8 million and a corresponding reduction of the product return liability. Contributing to the increase in discounts and allowances in 2007 versus 2006 was the higher level of Zanaflex revenues and related shipments.

allowances are recorded when Zanaflex Capsules and Zanaflex tablets are shipped to wholesalers. Discounts and allowances for the year ended December 31, 2007, included \$1.5 million for chargebacks and rebates and \$1.1 million in cash discounts and allowances. Discounts and allowances for the year ended December 31, 2006, included \$1.1 million for chargebacks and rebates and \$1.1 million for the Elan product return liability reversal described above, \$664,000 in cash discounts and \$742,000 in allowances for chargebacks and rebates.

for the year ended December 31, 2007 was \$60,000 compared to \$407,000 for the year ended December 31, 2006, a decrease of approximately \$347,000, or 85%. Gross expenses are incurred and our performance obligations under the terms of the respective contract are satisfied.

cost of sales of \$8.4 million for the year ended December 31, 2007 as compared to \$7.1 million for the year ended December 31, 2006, an increase of approximately \$1.3 million. For the year ended December 31, 2007 consisted of \$3.0 million in royalty fees, \$3.9 million in inventory costs, \$1.2 million in amortization of intangible assets, and \$222,000 in costs related to packaging, freight and stability testing. For the year ended December 31, 2006 consisted of \$2.9 million in royalty fees, \$2.6 million in inventory costs, \$775,000 in amortization of intangible assets, and \$1,000,000 in costs related to packaging, freight and stability testing. The charges for excess inventory were taken in 2006 due to lower than anticipated sales of Zanaflex Capsules. The expiration of Zanaflex Capsules had 36 month dating at the time. During the three-month period ended June 30, 2007, results from stability testing performed on Zanaflex Capsules by our manufacturer resulted in an extension of Zanaflex Capsules expiration dating from 36 months to 48 months.

*Development*

Research and development expenses for the year ended December 31, 2007 were \$22.4 million as compared to \$12.1 million for the year ended December 31, 2006, an increase of \$10.3 million, or 85%. The increase in research and development expenses was primarily due to the initiation of our second Phase 3 trial for Fampridine-SR and expenses related to our Thorough QT cardiac study. The Thorough QT cardiac program expense increased to \$10.8 million for the year ended December 31, 2007 from \$6.0 million for the year ended December 31, 2006, an increase of \$4.8 million, or 80%. This increase was primarily due to our second Phase 3 clinical trial of Fampridine-SR which began in June 2007 and the Thorough QT cardiac study which was conducted during the second half of 2007 and the first half of January 2008.

Expenses for clinical development, preclinical research and development and regulatory were \$9.5 million for the year ended December 31, 2007, compared to \$5.1 million for the year ended December 31, 2006, an increase of \$4.4 million, or 85%. This increase was primarily attributable to an increase in regulatory expenses of \$3.1 million for the preparation of an NDA for Fampridine-SR, an increase in charges related to share-based compensation and benefits and consulting fees and approximately \$854,000 in increased salaries, non-cash charges related to share-based compensation and expenses for preclinical research and development.

Manufacturing and stability fees related to Fampridine-SR and an increase of \$482,000 for preclinical programs related primarily to antibody development with the Mayo Clinic.

Marketing expenses for the year ended December 31, 2007 were \$30.7 million compared to \$19.1 million for the year ended December 31, 2006, an increase of approximately \$11.6 million, or 61%.

%. This increase was primarily attributable to an increase in salaries and benefits of \$5.8 million, other selling related expenses of \$2.0 million resulting from the expense, that was completed during the three-month period ended March 31, 2007, an increase in marketing expenses of \$2.3 million of which \$829,000 was related to pre-launch commercialization of Fampridine-SR, if approved and an increase of \$1.5 million in non-cash charges related to share-based compensation.

*Administrative*

Administrative expenses for the year ended December 31, 2007 were \$17.4 million compared to \$12.6 million for the year ended December 31, 2006, an increase of approximately \$4.8 million, primarily attributable to a \$1.8 million increase in non-cash charges related to share-based compensation, an increase in medical affairs expenses of \$791,000, an increase in research expenses of \$599,000 due to employee headcount and salary increases, an increase in other third party services of \$364,000 resulting from costs associated with compliance, an increase in business development expenses of \$211,000, an increase of \$206,000 in patent prosecution and defense expenses, an increase in depreciation primarily related to equipment of \$171,000 and an increase in the loss related to the PRF put/call valuation of \$163,000.

*Interest*

(expense) was \$1.5 million in income for the year ended December 31, 2007 compared to an expense of \$1.0 million for the year ended December 31, 2006, an increase of \$0.5 million. This increase was largely due to an increase of \$2.6 million in interest income as a result of the investment of the net proceeds from our follow-on public offering completed in 2006, less an expense of \$2.1 million, of which \$110,000 principally related to the PRF revenue interest agreement.

*Effect of change in accounting principle*

In 2006, we adopted the provisions of Statement of Financial Accounting Standards 123 (revised 2004), *Share-Based Payment* (SFAS No. 123R), which requires that all share-based payment transactions be recognized in the financial statements at their fair values. We adopted SFAS No. 123R using the modified prospective application method under which only new awards and to awards modified, repurchased, or cancelled after the adoption date. Additionally, compensation cost for the portion of the awards for which the recognition is outstanding as of the adoption date is recognized in the consolidated statement of operations over the remaining service period after the adoption date based on the award's remaining service periods have not been restated. In connection with the adoption of SFAS No. 123R, we changed our method of recognizing the number of outstanding instruments for which the recognition is outstanding from an actual basis to an estimate. This change resulted in the recognition of a cumulative effect of change in accounting principle for the twelve-months ending December 31, 2006, or the year ended December 31, 2007. The cumulative effect adjustment represents the difference between compensation cost recognized through the date of adoption and the amount that would have been recognized to date using estimated forfeitures.

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

to preferred stock decreased from \$36.0 million for the twelve-month period ended December 31, 2006 to no charge for the twelve-month period ended December 31, 2007. The amortized portion of beneficial conversion charges and issuance costs and reversal of the cumulative preferred dividend upon the completion of our initial public offering. No further charges are necessary.

**Capital Resources**

Since our inception, we have incurred annual operating losses since inception and, as of December 31, 2008, we had an accumulated deficit of approximately \$344.4 million. We have financed our operations through the sale of common stock, private placements of our securities, our financing arrangement with PRF and, to a lesser extent, from loans and government grants.

In February 2008, we completed a follow-on public offering in February 2008 in which approximately 3.7 million shares of our common stock were sold, resulting in proceeds of approximately \$74.0 million.

In August 2008, we completed a follow-on public offering in August 2008 in which approximately 4.6 million shares of our common stock were sold, resulting in proceeds of approximately \$126.0 million.

*Commitments*

In January 2007, 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. We assigned these promissory notes to funds affiliated with Saints Capital. As of December 31, 2008, \$5.0 million of these promissory notes were outstanding. In January 2009, we repaid the loan which was repaid during the three-month period ended March 31, 2008.

In October 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 receive (the "Assignment 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 our assets. The Assignment Agreement with PRF covers all Zanaflex net revenues generated from October 1, 2005 through and including December 31, 2015, unless the agreement terminates earlier. Pursuant 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 November 2007. If our 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 Assignment 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;

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.

ing 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 of future revenues. In connection with the transaction, we recorded a liability as of December 31, 2008, referred to as the revenue interest liability, of approximately \$18.7 million. We impute interest expense associated with this liability using the effective interest rate method and record a corresponding accrued interest liability at 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 dependent on Zanaflex sales. We currently estimate that the imputed interest rate associated with this liability will be approximately 6.2%. Payments made to PRF as a result of this liability and the principal amount of the revenue interest liability.

occurrence of certain events, including if we experience a change of control, undergo certain bankruptcy events, transfer any of our interests in Zanaflex (other than pursuant to a commercialization, co-promotion, collaboration, partnering or similar agreement), transfer all or substantially all of our assets, or breach certain of the covenants, represented in the agreement, PRF may (i) require us to repurchase the rights we sold them at the "put/call price" in effect on the date such right is exercised or (ii) foreclose on the Zanaflex assets. In the event of certain bankruptcy events, if PRF exercises its right, which we refer to as PRF's put option, to cause us to repurchase the rights we assigned to it, PRF may not be required to pay the "put/call price" in effect on the date such right is exercised. If we experience a change of control we have the right, which we refer to as our call option, to repurchase the rights we sold to PRF at the "put/call price" in effect on the date such right is exercised. The "put/call price" on a given date is the greater of (i) all payments made by PRF to us as of such date, less all payments received by PRF from us as of such date, and (ii) an amount equal to PRF of 25% on all payments made by PRF to us as of such date, taking into account the amount and timing of all payments received by PRF from us as of such date. If our call option meet the criteria to be considered an embedded derivative and should be accounted for as such. Therefore, we recorded a net liability of \$337,500 as of December 31, 2008, to reflect its current estimated fair value, in accordance with SFAS No. 133, *Accounting for Derivatives Instruments and Hedging Activities*. This liability is revalued at the end of each reporting period and any gain or loss resulting from the revaluation is recorded in earnings.

period during which PRF has the right to receive 15% of Zanaflex net revenues (as defined in the agreement), then 8% of the first \$30.0 million in payments from Zanaflex are distributed to PRF on a daily basis. Following the end of each fiscal quarter, if the aggregate amount actually received by PRF during such quarter exceeds the amount of net revenues we are entitled to receive, we will remit such excess to us. If the amount of net revenues PRF was entitled to receive during such quarter exceeds the aggregate amount actually received by PRF during such quarter, we will remit such excess to PRF.

As of December 31, 2008, cash and cash equivalents and short-term investments were approximately \$246.0 million, as compared to \$95.1 million at December 31, 2007. Our cash and cash equivalents consist of 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 securities with financial institutions in excess of insured limits. We do not anticipate any losses with respect to such cash balances. As of December 31, 2008, our cash and cash equivalents compared to

December 31, 2007. Our short-term investments consist of US Treasury bonds, and commercial paper securities with original maturities greater than three months and cash. Cash and short-term investments as of December 31, 2008, was \$216.4 million as of December 31, 2008, as compared to \$78.3 million as of December 31, 2007.

*Operations*

Cash used in operations was \$49.2 million and \$25.7 million for the years ended December 31, 2008 and 2007, respectively. Cash used in operations for the year ended December 31, 2008 was primarily due to a loss of \$74.3 million, amortization of the discount on short-term investments of \$3.1 million, an increase in prepaid expenses and other current assets of \$1.3 million, and an increase in accounts receivable of \$357,000. Cash used in operations for the year ended December 31, 2008 was partially offset by an increase in accounts payable of \$8.8 million, a non-cash share-based compensation expense of \$9.8 million, depreciation and amortization of \$3.5 million, a non-cash expense for the acquisition of Zanaflex Capsules deferred product revenue of \$2.5 million and a decrease in inventory of \$3.3 million. Cash used in operations for the year ended December 31, 2007 was primarily due to amortization of the discount on short-term investments of \$3.0 million, a decrease in Zanaflex tablets deferred product revenue of \$1.2 million and an increase in prepaid expenses and other current assets of \$1.2 million. Cash used in operations for the year ended December 31, 2007 was partially offset by a non-cash share-based compensation expense of \$7.8 million, an increase in accounts payable of \$4.6 million, depreciation and amortization of \$2.3 million, and an increase in Zanaflex Capsules deferred product revenue of \$2.6 million.

*Investing*

Cash used in investing activities for the year ended December 31, 2008 was \$141.3 million, primarily due to \$326.0 million in purchases of short-term investments, a \$5.0 million payment for the final Elan Zanaflex milestone, and purchases of property and equipment of \$1.8 million, offset by \$191.6 million in proceeds from maturities and sales of short-term investments.

*by Financing*

Cash provided by financing activities for the year ended December 31, 2008 was \$203.2 million, primarily due to \$205.1 million in net proceeds from the issuance of common stock, offset by \$1.6 million in repayments to PRF and \$188,000 for notes payable.

*Risks*

Our future financial 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, development activities, the timing and outcome of regulatory approvals, the amount and timing of milestone or other payments made under collaborative agreements, the cost of maintaining, defending and enforcing patent claims and other intellectual property rights and the acquisition of licenses to new products or compounds. We expect to increase our capital expenditures over 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, and continue to invest in research and development.



its commercialization, if approved, and continue our clinical development and advance our preclinical programs.

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 meet our 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 may reduce planned expenditures, or incur indebtedness to fund its operations. We may be unable to obtain additional debt or equity financing on acceptable terms, if at all. 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 other means that may require us to relinquish rights to certain product candidates that we might otherwise seek to develop or commercialize independently.

#### Contingencies and Commitments

In 2007, 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 8% per year 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 Saints Capital. 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 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 in 2008, 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 be obtained, the 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 agreement with Elan, 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 a first lien assignment arrangement with PRF.

We have acquired all of Elan's research and development, distribution, and sales and marketing rights to Zanaflex Capsules and Zanaflex tablets in the United States. Under our license agreement, we are obligated to make milestone payments to Elan of up to \$19.5 million based on cumulative gross sales of Zanaflex tablets and Zanaflex Capsules. As of December 31, 2008, we have made \$14.5 million of milestone payments. The final \$5.0 million milestone was reached in January 2008 and was paid in the three-month period ended June 30, 2008. Under our Zanaflex supply agreement with Elan, we are required to submit a 12-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 quantity immediately following each monthly forecast report. At December 31, 2008, the forecast requirement for the five-month period following December 31, 2008 amounted to 1.5 million capsules.

Under our bupropion-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 on sales. 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 \$10.0 million over the life of the agreements.

within 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 ad

In 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) from our net revenues as determined in accordance with GAAP) from Zanaflex Capsules, Zanaflex tablets and any future Zanaflex products. The agreement covers the period 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 million at signing and we are required to use the remainder of the amount we received at signing and any other amounts we receive under the agreement to support commercialization, sales, marketing, and other obligations related specifically and solely to our Zanaflex operations.

In 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 percentage of net revenues 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 to us, 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 to us. 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 drop to 1% of Zanaflex net revenues. This milestone was met and the receivable was reflected in our December 31, 2006 financial statements. This milestone payment was received in February 2007. We are required to pay PRF \$5.0 million on December 1, 2009 and an additional \$5.0 million on December 1, 2010.

The following table summarizes our minimum contractual obligations as of December 31, 2008. This table does not include certain contingent payments as to which we cannot reasonably estimate the amount. We have included the \$5.0 million aggregate principal amount of convertible notes payable to Saints Capital or milestone payments under our license agreements as these amounts should be read in conjunction with the accompanying notes to our consolidated financial statements:

|  | <b>Payments due by period</b> |                         |                  |                  |
|--|-------------------------------|-------------------------|------------------|------------------|
|  | <b>Total</b>                  | <b>Less than 1 year</b> | <b>1-3 years</b> | <b>3-5 years</b> |
| PRF Payments(1)                                  | \$ 10,000                     | \$ 5,000                | \$ 5,000         | \$ -             |
| Accrued Interest on Convertible Notes Payable(2) | 1,128                         | 207                     | 446              | 475              |
| Operating Lease                                  | 4,000                         | 1,000                   | 2,000            | 1,000            |
| Inventory Purchase Commitment                    | 3,800                         | 3,800                   | -                | -                |
| <b>Total</b>                                     | <b>\$ 18,928</b>              | <b>\$ 10,007</b>        | <b>\$ 7,446</b>  | <b>\$ 1,475</b>  |

Payments represent the two \$5 million payments due to PRF on December 1, 2009 and December 1, 2010 and exclude principal and interest payments, due to uncertainty in the timing of these payments.

Accrued interest on the convertible note on the assumption that it remains outstanding during these periods. The table does not reflect the repayment of principal, due to uncertainty in the timing of the repayment and the timing thereof.

... 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 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 in which the termination occurs, 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 date of termination and the denominator of which is 365.

... of the employment agreements with our chief scientific officer, Andrew Blight, our chief financial officer, David Lawrence and our general counsel, Jane Wasman, under certain circumstances. In the event we terminate our employment agreement with Dr. Blight, Mr. Lawrence or Ms. Wasman without cause, or if one of them voluntarily terminates his or her employment, 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, 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 18 months 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 for 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 nine months 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 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 pay 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 stock awards shall remain exercisable for 18 months following such date. All options that have vested as of the termination date shall remain exercisable for 18 months following such date. All unvested options, stock appreciation rights awards and stock awards will be cancelled on the date of termination.

... assets are cash, cash equivalents and short-term investments. Because of their liquidity, these assets are not directly affected by inflation. Because we intend to retain certain property and fixtures and leasehold improvements, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. Our operating expenses, primarily employee compensation and contract services, which could increase our level of expenses.

#### **Accounting Policies and Estimates**

... discussion of critical accounting policies identifies the accounting policies that require application of management's most difficult, subjective or complex judgments, and 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. For a complete discussion of our accounting policies, see Note 2 of the notes to the consolidated financial statements included in this prospectus. In many cases, the accounting treatment of a particular transaction is specifically

need for management's judgment in their application. There are also areas in which the selection of an available alternative policy would not produce a materially different result. Areas of critical accounting policies: sales revenue recognition, research and development, income taxes, and share-based compensation.

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. Under SFAS 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 and 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 revenue 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 from our wholesale drug distributors.

Under the 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 less estimated returns. 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 the number of units of product prescribed to record gross sales. We then reduce deferred revenue based on the number of units returned. We received end-user prescription data in March 2005 which enabled us to begin recognizing revenue from Zanaflex tablet sales. We began marketing Zanaflex Capsules in March 2005 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 that provides 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 levels. 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.

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 revenue. Returns are estimated to be 1% of sales.

#### Development

Research and development expenses include the costs associated with our internal research and development activities including, salaries and benefits, occupancy costs, and research materials. Such as sponsored university-based research, clinical trial vendors, contract manufacturing for our preclinical program, and regulatory consulting to support our NDAs. 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 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 expenses throughout the duration of the trial. Cost per patient varies based on the type of clinical trial,

al 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 and also materially affect our results of operations. All research and development costs are expensed as incurred except where EITF Issue No. 07-3, *Accounting for Non-refundable Advance Payments 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 periods are capitalized at the time of payment and expensed when the research and development activity has been performed.

In 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 using the liability 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 bases. Valuation allowances are provided if, based upon the facts and circumstances, it is more likely than not that some or all of the deferred tax assets will not be realized.

We recorded no tax provision or benefit for the years ended December 31, 2008 and 2007. We have provided a valuation allowance for the full amount of our gross deferred tax assets from deductible temporary differences and net operating loss carry-forwards cannot be sufficiently assured at December 31, 2008.

As of December 31, 2008, we had available net operating loss carry-forwards of approximately \$262.2 million for federal and state income tax purposes, which are available to offset future taxable income 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 expire 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 imposes 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) on 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 carry-forwards is 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 the carry-forwards.

#### **Compensation**

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 the grant be recognized in the financial statements at their fair values. We adopted SFAS No. 123R using the modified prospective application method under which the provisions of SFAS No. 123R were modified, repurchased, or cancelled after the adoption date of January 1, 2006.

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 option, the risk-free interest rates, and an estimated forfeiture rate.

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 2007 and 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 the grants  |
| Forfeiture rates                   | Historical forfeiture data   |

ptions, 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 our common stock. Increases in the term and the volatility of our common stock will generally cause an increase in compensation expense.

r 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, 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 Accounting Principles*.

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

struments consist of cash and cash equivalents, short-term investments, grants receivable, notes payable, convertible notes payable, accounts payable, and put/call liabilities. Instruments approximate their carrying amounts at December 31, 2008.

equivalents and short-term investments at December 31, 2008, which are exposed to the impact of interest rate changes and our interest income fluctuates as our interest rate changes. Our investments in money market funds, US Treasury bonds and corporate debt securities, the carrying value of our cash equivalents and short-term investments approximate their carrying amounts at December 31, 2008.

an investment portfolio in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain proper liquidity and generate income. 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. 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 investment portfolio, the 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 our investment portfolio.

**Financial Statements and Supplementary Data.**

ed financial statements required pursuant to this item are included in Item 15 of this report and are presented beginning on page F-1.

**Conflicts of Interest and Disagreements With Accountants on Accounting and Financial Disclosure.**

**Internal Controls and Procedures.**

*Disclosure controls and procedures*

Under Rule 13a-15 under the Exchange Act, within 90 days prior to filing this report, we carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). This evaluation was carried out under the supervision and with the participation of our management, including our chief executive officer and chief financial officer. Based on that evaluation, these officers have concluded that, as of December 31, 2008, our disclosure controls and procedures were effective and designed to ensure that information required to be included in our reports filed under the Exchange Act would be made known to them. There have been no changes in our internal controls over financial reporting (as defined in Rule 15(d)-15(f) under the Exchange Act) or in other factors that has materially affected or is reasonably likely to materially affect internal controls over financial reporting.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is 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 reported 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, in a timely manner.

*Control over financial reporting*

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

*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, controls can provide absolute assurance that all control issues, if any, within a company have been detected.

**Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) of the Exchange Act).

Under the supervision of and with the participation of our chief executive officer and our chief financial officer, our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the framework and criteria established in Internal Control - Integrated Framework, issued by the Committee of Sponsoring Organizations of the Treadway Commission. Our management concluded that, as of December 31, 2008, our internal control over financial reporting was effective.

Our independent registered public accounting firm that audits our consolidated financial statements, has issued its attestation report on the Company's internal control over financial reporting. This attestation report appears below.

**dent Registered Public Accounting Firm**

tors and Stockholders  
s, Inc.:

ed Acorda Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2008, based on criteria established in *Internal Control - Integrated Framework* of the Treadway Commission (COSO). Acorda Therapeutics, Inc.'s management is responsible for maintaining effective internal control over financial reporting. Our audit of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on internal control over financial reporting based on our audit.

our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing other procedures that we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to support the preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that the control may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Acorda Therapeutics, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2008, based on criteria established by the Committee of Sponsoring Organizations of the Treadway Commission.



audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Acorda Therapeutic and 2007, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the years in the three-year period ended 2009 expressed an unqualified opinion on those consolidated financial statements.

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**Information.**

**PART III**

**Directors and Executive Officers of the Registrant.**

Information required by this item will be contained in our 2009 Proxy Statement under the captions "Discussion of Proposals," "Information About Corporate Governance," "Information About Our Directors" and "Other Information" and is incorporated herein by this reference.

We have adopted a code of business conduct and ethics applicable to all of our directors and employees, including our principal executive officer, principal financial officer and principal accounting officer. This code of ethics is available on the corporate governance section of "Investor Relations" of our website, *www.acorda.com*.

Any waiver of the code of business conduct and ethics for directors or executive officers, or any amendment to the code that applies to directors or executive officers, may only be made if it meets the disclosure requirement under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this code of ethics by posting such information on our website. To date, no such waivers have been requested or granted.

**Director and Executive Compensation.**

Information required by this item will be contained in our 2009 Proxy Statement under the captions "Corporate Governance," "Information About Our Executive Officers" and "Information About Our Directors" and is incorporated herein by this reference.

**Beneficial Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

Information required by this item will be contained in our 2009 Proxy Statement under the captions "Information About Our Executive Officers" and "Other Information" and is incorporated herein by this reference.

**Related Party Relationships and Related Transactions.**

Information required by this item will be contained in our 2009 Proxy Statement under the caption "Information About Our Executive Officers" and is incorporated herein by this reference.

**Independent Auditor's Fees and Services.**

Information required by this item will be contained in our 2009 Proxy Statement under the caption "Discussion of Proposals" and is incorporated herein by this reference.

**PART IV**

**ts and Financial Statement Schedules.**

**Documents are being filed as part of this report:**

The following financial statements of the Company and the Report of Independent Registered Public Accounting Firm are included in this Annual Report on Form 1

s of Acorda Therapeutics, Inc. and Subsidiary:

LLP, Independent Registered Public Accounting Firm

s of December 31, 2008 and 2007

erations for the years ended December 31, 2008, 2007 and 2006

anges in Stockholders' Equity for the years ended December 31, 2008,

sh Flows for the years ended December 31, 2008, 2007 and 2006

l Statements

**INDEX TO FINANCIAL STATEMENTS**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

tors and Stockholders  
s, Inc.:

ed the accompanying consolidated balance sheets of Acorda Therapeutics, Inc. and subsidiary (the Company) as of December 31, 2008 and 2007, and the related con  
ders' equity, and cash flows for each of the years in the three-year period ended December 31, 2008. These consolidated financial statements are the responsibility of  
express an opinion on these consolidated financial statements based on our audits.

our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform th  
ether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the  
he accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our a

the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Acorda Therapeutics, Inc. and subsidiary as of  
operations and their cash flows for each of the years in the three-year period ended December 31, 2008, in conformity with U.S. generally accepted accounting princip

audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting  
ed in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated Ma  
on the effectiveness of the Company's internal control over financial reporting.

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## ACORDA THERAPEUTICS, INC. AND SUBSIDIARY

## Consolidated Balance Sheets

|  | <b>December 31,</b>   |                       |
|--|-----------------------|-----------------------|
|  | <b>2008</b>           | <b>2007</b>           |
| <b>Assets</b>  |                       |                       |
| Current assets:  |                       |                       |
| Cash and cash equivalents  | \$ 29,612,916         | \$ 16,810,415         |
| Restricted cash  | 297,655               | 288,194               |
| Short-term investments   | 216,435,416           | 78,310,241            |
| Trade accounts receivable, net   | 4,622,486             | 4,265,581             |
| Prepaid expenses   | 3,330,069             | 2,341,585             |
| Finished goods inventory held by the Company   | 3,670,949             | 5,849,929             |
| Finished goods inventory held by others  | 2,472,692             | 1,874,405             |
| Other current assets   | 1,605,572             | 1,293,496             |
| <b>Total current assets</b>  | <b>262,047,755</b>    | <b>111,033,846</b>    |
| Property and equipment, net of accumulated depreciation  | 2,348,147             | 1,651,739             |
| Intangible assets, net of accumulated amortization   | 16,565,456            | 13,943,888            |
| Other assets   | 539,328               | 676,993               |
| <b>Total assets</b>  | <b>\$ 281,500,686</b> | <b>\$ 127,306,466</b> |
| <b>Liabilities and Stockholders' Equity</b>  |                       |                       |
| Current liabilities:   |                       |                       |
| Accounts payable   | \$ 10,124,840         | \$ 6,675,894          |
| Accrued expenses and other current liabilities   | 13,993,753            | 8,777,645             |
| Deferred product revenue Zanaflex tablets  | 7,867,046             | 7,913,776             |
| Deferred product revenue Zanaflex Capsules   | 16,436,474            | 13,923,781            |
| Current portion of notes payable   |                       | 187,645               |
| Current portion of revenue interest liability  | 6,181,100             | 1,785,018             |
| <b>Total current liabilities</b>   | <b>54,603,213</b>     | <b>39,263,759</b>     |
| Put/call liability   | 337,500               | 462,500               |
| Non current portion of revenue interest liability  | 12,497,745            | 17,444,324            |
| Long-term convertible notes payable  | 6,904,883             | 6,703,235             |
| Commitments and contingencies  |                       |                       |
| Stockholders' equity:  |                       |                       |
| Common stock, \$0.001 par value. Authorized 80,000,000 shares at December 31, 2008 and 2007 respectively; issued and outstanding 37,613,356 and 28,574,678 shares as of December 31, 2008 and 2007, respectively | 37,614                | 28,575                |
| Additional paid-in capital   | 550,683,383           | 333,144,050           |
| Accumulated deficit  | (344,376,410)         | (270,035,770)         |
| Accumulated other comprehensive income   | 812,758               | 295,793               |
| <b>Total stockholders' equity</b>  | <b>207,157,345</b>    | <b>63,432,648</b>     |
| <b>Total liabilities and stockholders' equity</b>  | <b>\$ 281,500,686</b> | <b>\$ 127,306,466</b> |

See accompanying Notes to Consolidated Financial Statements

## ACORDA THERAPEUTICS, INC. AND SUBSIDIARY

## Consolidated Statements of Operations

|  | Year ended<br>December 31,<br>2008 | Year ended<br>December 31,<br>2007 | Year ended<br>December 31,<br>2006 |
|--|------------------------------------|------------------------------------|------------------------------------|
| Gross sales Zanaflex   | \$ 53,397,999                      | \$ 43,586,367                      | \$ 26,548,264                      |
| Discounts and allowances   | (5,670,048)                        | (4,160,356)                        | 395,517                            |
| Net sales  | 47,727,951                         | 39,426,011                         | 26,943,781                         |
| Grant revenue  | 98,846                             | 59,880                             | 407,165                            |
| Total net revenue  | 47,826,797                         | 39,485,891                         | 27,350,946                         |
| Less: cost of sales  | (11,354,912)                       | (8,355,858)                        | (7,122,833)                        |
| Gross profit   | 36,471,885                         | 31,130,033                         | 20,228,113                         |
| Operating expenses:  |                                    |                                    |                                    |
| Research and development   | 36,604,478                         | 22,410,279                         | 12,054,780                         |
| Sales and marketing  | 49,069,841                         | 30,736,544                         | 19,079,013                         |
| General and administrative   | 24,236,920                         | 17,430,561                         | 12,561,245                         |
| Total operating expenses   | 109,911,239                        | 70,577,384                         | 43,695,038                         |
| Operating loss   | (73,439,354)                       | (39,447,351)                       | (23,466,925)                       |
| Other income (expense):  |                                    |                                    |                                    |
| Interest and amortization of debt discount expense   | (5,591,426)                        | (2,664,390)                        | (2,553,443)                        |
| Interest income  | 4,682,055                          | 4,086,521                          | 1,471,334                          |
| Other income   | 8,085                              | 50,753                             | 75,437                             |
| Total other income (expense)   | (901,286)                          | 1,472,884                          | (1,006,672)                        |
| Cumulative effect of change in accounting principle  |                                    |                                    | 454,225                            |
| Net loss   | (74,340,640)                       | (37,974,467)                       | (24,019,372)                       |
| Beneficial conversion feature, accretion of issuance costs, preferred dividends, and fair value of warrants issued to convertible preferred stockholders |                                    |                                    | (36,007,456)                       |
| Net loss allocable to common stockholders  | \$ (74,340,640)                    | \$ (37,974,467)                    | \$ (60,026,828)                    |
| Net loss per share allocable to common stockholders basic and diluted  | \$ (2.19)                          | \$ (1.45)                          | \$ (3.27)                          |
| Weighted average common shares outstanding used in computing net loss per share allocable to common stockholders basic and diluted                       | 33,938,980                         | 26,236,781                         | 18,345,543                         |

See accompanying Notes to Consolidated Financial Statements

ACORDA THERAPEUTICS, INC. AND SUBSIDIARY  
 Consolidated Statements of Changes in Stockholders' Equity

| Series A<br>convertible<br>preferred<br>stock | Series B<br>convertible<br>preferred<br>stock |              | Stockholders' equity   |              |                        | Series F<br>convertible<br>preferred<br>stock |                        | Series H<br>convertible<br>preferred<br>stock |                        | Common Stock |        | Additional<br>paid-in<br>capital | Accumulated<br>deficit |
|---|---|--------------|------------------------|--------------|------------------------|---|------------------------|---|------------------------|--------------|--------|----------------------------------|------------------------|
|   | Number<br>of<br>shares                        | Par<br>value | Number<br>of<br>shares | Par<br>value | Number<br>of<br>shares | Par<br>value                                  | Number<br>of<br>shares | Par<br>value                                  | Number<br>of<br>shares | Par<br>value |        |                                  |                        |
| 68  | \$ 1,306                                      | 900,000      | \$ 900                 | 333,333      | \$ 333                 | 2,300,000                                     | \$ 2,300               | 1,575,229                                     | \$ 1,575               | 208,732      | \$ 209 | \$ 91,501,190                    | \$(1,444)              |
|   |   |              |                        |              |                        |   |                        |   |                        |              |        |                                  | 1,444                  |
|   |   |              |                        |              |                        |   |                        |   |                        |              |        |                                  | 2,087,602              |
|   |   |              |                        |              |                        |   |                        |   |                        | 340,760      | 341    |                                  | 1,755,167              |
|   |   |              |                        |              |                        |   |                        |   |                        | 220,105      | 220    |                                  | 669,452                |
|   |   |              |                        |              |                        |   |                        |   |                        |              |        |                                  | (270,725)              |
|   |   |              |                        |              |                        |   |                        |   |                        |              |        |                                  | 12,734,009             |
|   |   |              |                        |              |                        |   |                        |   |                        |              |        |                                  | (48,470,740)           |



68) (1,306) (900,000) (900) (333,333) (333) (2,300,000) (2,300) (1,575,229) (1,575) 13,338,278 13,337 127,212,872

6,075,614 6,076 31,453,233

3,230,769 3,231 29,778,183

32,634 33 195,773

210,863 211 2,499,789

(454,225)

**23,657,755 \$23,658 \$250,693,024 \$(**

See accompanying Notes to Consolidated Financial Statements.

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**ACORDA THERAPEUTICS, INC. AND SUBSIDIARY**  
**Consolidated Statements of Changes in Stockholders' Equity (Continued)**

|  | <b>Stockholders' equity</b>                 |   |   |   |   | <b>Common Stock</b> | <b>Number</b> | <b>Par value</b> | <b>Additional paid-in capital</b> | <b>Accumulated Deficit</b> | <b>Accumulated Other Comprehensive Income</b> | <b>Stock</b> |
|--|---|---|---|---|---|---------------------|---------------|------------------|-----------------------------------|----------------------------|---|--------------|
|  | <b>Series A convertible preferred stock</b> | <b>Series B convertible preferred stock</b> | <b>Series C convertible preferred stock</b> | <b>Series F convertible preferred stock</b> | <b>Series H convertible preferred stock</b> |                     |               |                  |                                   |                            |   |              |
|  | Number of shares                            | Number of shares                            | Number of shares                            | Number of shares                            | Number of shares                            | Number of shares    | of            | value            | capital                           | Deficit                    | Income  | of           |
| Research and development expense for issuance of stock options to nonemployees           |   |   |   |   |   |                     |               |                  | \$ 357                            |                            |   | \$           |
| Compensation expense for issuance of stock options to employees                          |   |   |   |   |   |                     |               |                  | 5,890,879                         |                            |   |              |
| Compensation expense for issuance of restricted stock to employees                       |   |   |   |   |   | 342,682             | 343           |                  | 1,904,897                         |                            |   |              |
| Exercise of stock options  |   |   |   |   |   | 367,912             | 368           |                  | 2,325,666                         |                            |   |              |
| Common stock issued pursuant to follow-on offering, net of offering costs of \$5,290,961 |   |   |   |   |   | 4,189,460           | 4,189         |                  | 72,209,859                        |                            |   |              |
| Expense related to private placement   |   |   |   |   |   |                     |               |                  | (80,615)                          |                            |   |              |
| Common stock issued pursuant to exercise of warrants                                     |   |   |   |   |   | 16,869              | 17            |                  | 199,983                           |                            |   |              |
| <i>Comprehensive loss</i>  |   |   |   |   |   |                     |               |                  |                                   |                            |   |              |
| Unrealized gain on investment securities   |   |   |   |   |   |                     |               |                  |                                   |                            |   | 282,453      |
| Net loss   |   |   |   |   |   |                     |               |                  |                                   | (37,974,467)               |   |              |

*Total  
comprehensive  
loss*

**Balance at  
December 31,  
2007**

**28,574,678 \$28,575 \$333,144,050 \$(270,035,770) \$ 295,793 \$**

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ACORDA THERAPEUTICS, INC. AND SUBSIDIARY  
 Consolidated Statements of Changes in Stockholders' Equity (Continued)

|   | Stockholders' equity  |   |   |   |   | Common Stock<br>Number<br>of<br>shares | Common Stock<br>Par<br>value | Additional<br>paid-in<br>capital | Accumulated<br>Deficit | Accumulated<br>Other<br>Comprehensiv<br>Income | Total |
|---|---|---|---|---|---|--|------------------------------|----------------------------------|------------------------|--|-------|
|   | Series A<br>convertible<br>preferred<br>stock<br>Number<br>of Par<br>shares | Series B<br>convertible<br>preferred<br>stock<br>Number<br>of Par<br>shares | Series C<br>convertible<br>preferred<br>stock<br>Number<br>of Par<br>shares | Series F<br>convertible<br>preferred<br>stock<br>Number<br>of Par<br>shares | Series H<br>convertible<br>preferred<br>stock<br>Number<br>of Par<br>shares |  |                              |                                  |                        |  |       |
| Research and development expense for issuance of stock options to nonemployees            |   |   |   |   |   |  |                              | \$ 252,754                       |                        |  | \$    |
| Compensation expense for issuance of stock options to employees                           |   |   |   |   |   |  |                              | 8,046,376                        |                        |  |       |
| Compensation expense for issuance of restricted stock to employees                        |   |   |   |   |   | 102,886                                | 103                          | 1,505,753                        |                        |  |       |
| Exercise of stock options   |   |   |   |   |   | 523,792                                | 524                          | 3,835,461                        |                        |  |       |
| Common stock issued pursuant to follow-on offerings, net of offering costs of \$9,686,600 |   |   |   |   |   | 8,312,000                              | 8,312                        | 201,213,089                      |                        |  | 20    |
| Stock issued pursuant to NRI asset acquisition  |   |   |   |   |   | 100,000                                | 100                          | 2,685,900                        |                        |  |       |
| <i>Comprehensive loss</i>   |   |   |   |   |   |  |                              |                                  |                        |  |       |
| Unrealized gain on investment securities  |   |   |   |   |   |  |                              |                                  |                        | 516,965  |       |
| Net loss  |   |   |   |   |   |  |                              |                                  | (74,340,640)           |  | (7)   |
| <i>Total comprehensive loss</i>   |   |   |   |   |   |  |                              |                                  |                        |  | (7)   |
|   |   |   |   |   |   | 37,613,356                             | \$37,614                     | \$550,683,383                    | \$(344,376,410)        | \$ 812,758                                     | \$ 20 |

**Balance at  
December 31,  
2008**

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## ACORDA THERAPEUTICS, INC. AND SUBSIDIARY

## Consolidated Statements of Cash Flows

|  | Year ended<br>December 31,<br>2008 | Year ended<br>December 31,<br>2007 | Year ended<br>December 31<br>2006 |
|--|------------------------------------|------------------------------------|-----------------------------------|
| Cash flows from operating activities:  |                                    |                                    |                                   |
| Net loss   | \$ (74,340,640)                    | \$ (37,974,467)                    | \$ (24,019,372)                   |
| Adjustments to reconcile net loss to net cash used in operating activities:  |                                    |                                    |                                   |
| Stock compensation expense   | 9,804,986                          | 7,796,476                          | 3,844,554                         |
| NRI asset acquisition  | 2,686,000                          |                                    |                                   |
| Amortization of note discount  |                                    |                                    | 55,944                            |
| Amortization of discount on short-term investments                           | (3,124,056)                        | (2,973,325)                        | (332,069)                         |
| Cumulative effect of change in accounting principle                          |                                    |                                    | (454,225)                         |
| Amortization of revenue interest issuance cost                               | 89,235                             | 65,861                             | 72,741                            |
| Accretion of discount  |                                    |                                    | 47,282                            |
| Realized/unrealized gain/loss on warrants                                    |                                    |                                    | 46,782                            |
| Depreciation and amortization expense  | 3,480,768                          | 2,252,462                          | 1,785,941                         |
| Gain (loss) on put/call liability  | (125,000)                          | 112,500                            | (50,000)                          |
| (Gain) loss on disposal of property and equipment                            |                                    | (23,750)                           | 587                               |
| Changes in assets and liabilities:   |                                    |                                    |                                   |
| (Increase) decrease in accounts receivable                                   | (356,905)                          | 50,518                             | (3,726,847)                       |
| (Increase) decrease in prepaid expenses and other current assets             | (1,300,560)                        | (969,651)                          | 1,426,341                         |
| (Increase) decrease in inventory held by the Company                         | 3,330,916                          | 343,180                            | 1,165,466                         |
| Increase in inventory held by others   | (598,287)                          | (354,341)                          | (349,461)                         |
| Decrease (increase) in other assets  | 48,430                             | (8,536)                            | (18,528)                          |
| Increase (decrease) in accounts payable, accrued expenses, other liabilities | 8,793,339                          | 4,623,743                          | (4,817,846)                       |
| Decrease in returns liability  |                                    |                                    | (1,831,211)                       |
| Decrease in deferred product revenue Zanaflex tablets                        | (46,730)                           | (1,203,199)                        | (2,392,623)                       |
| Increase in deferred product revenue Zanaflex Capsules                       | 2,512,693                          | 2,599,620                          | 6,098,054                         |
| Restricted cash  | (9,461)                            | (13,813)                           | (11,388)                          |
| Net cash used in operating activities  | (49,155,272)                       | (25,676,722)                       | (23,459,878)                      |
| Cash flows from investing activities:  |                                    |                                    |                                   |
| Purchases of property and equipment  | (1,806,443)                        | (1,336,068)                        | (527,458)                         |
| Purchases of intangible assets   | (5,000,000)                        | (10,000,000)                       |                                   |
| Purchases of short-term investments  | (326,034,154)                      | (147,148,940)                      | (46,293,380)                      |
| Proceeds from maturities of short-term investments                           | 191,550,000                        | 107,750,000                        | 12,986,000                        |

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|   |               |               |               |
|---|---------------|---------------|---------------|
| Net cash used in investing activities                                       | (141,290,597) | (50,735,008)  | (33,834,838)  |
| <b>Cash flows from financing activities:</b>                                |               |               |               |
| Net proceeds from issuance of common stock and option and warrant exercises | 205,057,386   | 74,659,467    | 61,910,395    |
| Proceeds from sale of revenue interest                                      |               | 5,000,000     | 5,000,000     |
| Repayments of revenue interest liability                                    | (1,621,371)   | (3,494,281)   | (2,245,012)   |
| Repayments of notes payable   | (187,645)     | (1,043,949)   | (1,031,058)   |
| Net cash provided by financing activities                                   | 203,248,370   | 75,121,237    | 63,634,325    |
| Net increase (decrease) in cash and cash equivalents                        | 12,802,501    | (1,290,493)   | 6,339,609     |
| Cash and cash equivalents at beginning of period                            | 16,810,415    | 18,100,908    | 11,761,299    |
| Cash and cash equivalents at end of period                                  | \$ 29,612,916 | \$ 16,810,415 | \$ 18,100,908 |
| <b>Supplemental disclosure:</b>   |               |               |               |
| Cash paid for interest  | \$ 3,874,525  | \$ 2,312,453  | \$ 1,950,420  |
| <b>Non-cash charges related to convertible preferred stock:</b>             |               |               |               |
| Beneficial conversion feature   |               |               | 48,470,740    |
| Accretion of issuance costs   |               |               | 270,725       |
| Preferred dividend  |               |               | (12,734,009)  |
| <b>Non-cash activities:</b>   |               |               |               |
| Conversion of preferred stock to common stock                               |               |               | 127,219,795   |
| Accrued inventory   | 1,151,936     | 1,492,084     | 279,649       |
| Accrued Zanaflex milestone payments   |               |               | 5,000,000     |
| Conversion of note payable into common stock                                |               |               | 2,500,000     |
| Conversion of warrant payable into common stock                             |               |               | 207,501       |

See accompanying Notes to Consolidated Financial Statements.



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

**and Business Activities**

Acorda Therapeutics, Inc. ("Acorda" or the "Company") is a commercial stage biopharmaceutical company dedicated to the identification, development and commercialization of new drugs for the treatment of neurological disorders in people with multiple sclerosis (MS), spinal cord injury and other disorders of the central nervous system.

The Company completed an initial public offering in February 2006. As part of that offering, 6,075,614 shares of the Company's common stock were sold, resulting in net proceeds of \$10.5 million, net of underwriting discount and offering expenses payable by the Company.

The Company completed a private placement in October 2006. As part of that offering, 3,230,769 shares of the Company's common stock were sold, resulting in proceeds to the Company of \$10.5 million, net of issuance costs.

The Company completed a follow-on public offering of its common stock in July 2007. As part of that offering, 4,189,460 shares of the Company's common stock were sold, resulting in net proceeds of \$10.5 million, net of issuance costs.

The Company completed a follow-on public offering of its common stock in February 2008. As part of that offering, 3,712,000 shares of the Company's common stock were sold, resulting in net proceeds of \$10.5 million, net of issuance costs.

The Company completed a follow-on public offering of its common stock in August 2008. As part of that offering, 4,600,000 shares of the Company's common stock were sold, resulting in net proceeds of \$10.6 million, net of issuance costs.

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 able to obtain an adequate level of financing needed to fund its development and commercialization efforts. The Company believes that its current financial resources and sources of financing are sufficient to meet financial obligations through 2010 based on the Company's currently projected revenue and spending levels. To the extent the Company's capital resources are exhausted, 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 financing on favorable 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 certain product candidates 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 have developed independently.

**Significant Accounting Policies**

**Consolidation**

The Company's 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 wholly owned subsidiary. All intercompany accounts and transactions have been eliminated in consolidation.

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 at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the period. Significant items requiring estimates include research and development (clinical trial accrual) and share-based compensation accounting, which are largely dependent on the fair value of the Company's equity securities 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 estimates.

***Equivalents***

The Company considers all highly liquid debt instruments with original maturities of three months or less from date of purchase to be cash equivalents. All cash and cash equivalents include money market fund and US Treasury bonds, which are unrestricted as to withdrawal or use. To date, the Company has not experienced any losses on its cash and cash equivalents. The carrying value of cash equivalents approximates its fair value due to its short-term and liquid nature.

The Company represents a certificate of deposit placed by the Company with a bank for issuance of a letter of credit to the Company's lessor for office space.

***Investments***

The Company's investments consist of highly rated corporate securities including industrial issuers and US Treasury bonds with maturities greater than three months. In accordance with SFAS No. 115 (SFAS 115), *Accounting for Certain Investments in Debt and Equity Securities*, the Company classifies its short-term investments as available-for-sale. The carrying value of the investments based on quoted market prices. The Company considers all of these investments to be available-for-sale.

Realized gains and losses on available-for-sale securities, which are determined to be temporary, are excluded from earnings and are reported as a separate component of other comprehensive income.

Discounts on investments are amortized over the life of the related available-for-sale security as an adjustment to yield using the effective-interest method. Dividend income, net of amortized premiums and discounts, dividend and interest income and realized gains and losses are included in interest income.

Inventory is stated at the lower of cost or market value and includes amounts for both Zanaflex tablet and Zanaflex Capsule inventories. Inventories consist of finished goods. Cost of sales (COGS) is determined on a first-in, first-out (FIFO) basis for all inventories. The Company adjusts its inventory value based on an estimate of inventory that may be returned or not sold based on sales projections and historical sales. Excess inventory is written down to its estimated market value.

**ment**

equipment are stated at cost, net of accumulated depreciation. Depreciation is computed on the straight-line basis over the estimated useful lives of the assets, which are determined based on historical experience and industry practice. Repairs and maintenance are recorded at cost, less accumulated amortization, which is computed on the straight-line basis over the shorter of the useful lives of the assets or the remaining useful life of the asset. Repairs are charged to expense as incurred.

The Company has recorded intangible assets related to its Zanaflex acquisition. These intangible assets are amortized on a straight line basis over the period in which the Company expects to benefit from the assets. The Company reviews for impairment when facts and circumstances indicate that the carrying value of the asset may not be recoverable. The determination of the expected life will be based on the characteristics of the intangible asset. In the Company's evaluation of the intangible assets, it considers the term of the underlying patent life and the expected life of the product. Impairment is measured as the amount by which the carrying value exceeds its estimated fair value. Fair value is generally estimated based on either appraised value or other market data.

**g-Lived Assets**

In accordance with the Financial Accounting Standards Board (FASB) SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, the Company continually evaluates its long-lived assets to determine if any impairment indicators have occurred that indicate that the estimated remaining useful life of its long-lived assets may warrant revision or that the carrying value of these assets may be impaired. The Company evaluates its long-lived assets based on profitability and cash flow expectations for the related assets. Any write-downs are treated as permanent reductions in the carrying amount of the assets. The Company believes that, as of each of the balance sheet dates presented, none of the Company's long-lived assets was impaired.

Repairs and maintenance costs are expensed as incurred.

**lopment**

Research and development expenses include the clinical development costs associated with the Company's product candidates and research and development costs associated with the Company's product candidates. Research and development expenses include internal research and development costs and the costs of research and development conducted on behalf of the Company by third parties, including sponsored research, clinical study vendors and preclinical contract manufacturers. All research and development costs are expensed as incurred except where Emerging Issues Task Force (EITF) 03-02, *Research and Development Costs*, applies. In these cases, non-refundable advance payments for goods and services 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. Costs incurred in obtaining regulatory approval for a product are expensed as incurred. Costs incurred in obtaining regulatory approval for a product are expensed as incurred. Costs incurred in obtaining regulatory approval for a product are expensed as incurred. Costs incurred in obtaining regulatory approval for a product are expensed as incurred. Costs incurred in obtaining regulatory approval for a product are expensed as incurred.

**Income Taxes**

are accounted for under the asset and liability method with deferred tax assets and liabilities recognized for the future tax consequences attributable to differences between existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the periods in which the assets are expected to be reversed or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the change. A valuation allowance for the amounts of any tax benefits which, more likely than not, will not be realized.

The FASB issued FASB Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes, An Interpretation of FASB Statement No. 109*, Accounting for Income Taxes. The FASB issued FASB Staff Position FIN 48-1 which provided guidance on how an enterprise should determine whether a tax position is effectively settled for the purpose of recognizing and measuring the financial statement tax effects of positions taken on a company's tax returns. A tax position is only recognized if a more likely-than-not test that the tax position will be sustained upon examination and the tax position is measured at the largest amount of benefit expected upon ultimate settlement. The Company adopted FIN 48 as of January 1, 2007. The adoption of this Interpretation had no impact on the Company's results of operations for uncertain tax positions.

**Revenue Recognition**

The Company applies the revenue recognition guidance in SFAS No. 48, *Revenue Recognition When the Right of Return Exists*, which among other criteria requires that future returns be estimated. The amount of future tablet returns is uncertain due to generic competition and customer conversion to Zanaflex Capsules. Zanaflex Capsules has limited history for both products, the Company is accounting for these product shipments using a deferred revenue recognition model. Under the deferred revenue model, the Company records revenue when the product is 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 Company's 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 based 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 are based on 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 recorded in accordance with EITF Issue No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer*, which states that cash consideration given by a vendor is recorded at the selling prices of the vendor's

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, a  
cks, rebates, and discounts. These reserves are established by management as its best estimate based on available information and are adjusted to reflect known chang  
for chargebacks, rebates and discounts are established based on the contractual terms with customers, analysis of historical levels of discounts, chargebacks and rebat  
ventory remaining in the distribution channel, as well as expectations about the market for each product and anticipated introduction of competitive products. In additi  
d 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 h  
nce 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 datin  
is charge represents the cost basis for the low end of the range of the Company's estimated returns.

**on Grants**

nd to research and development grants is recognized when the related research expenses are incurred and the Company's specific performance obligations under the te  
ent expended, grant funding related to purchases of equipment is deferred and amortized over the shorter of the equipment's useful life or the life of the related contra  
olidated financial statements is not subject to repayment. Payments, if any, received in advance of performance under the contract are deferred and recognized as reve

**isk**

uments that potentially subject the Company to concentrations of credit risk consist principally of investments in cash and cash equivalents, restricted cash, accounts  
s cash and cash equivalents, restricted cash and debt securities with approved financial institutions. The Company is exposed to credit risks and liquidity in the event o  
rs of investments in excess of FDIC insured limits. The Company performs periodic evaluations of the relative credit standing of these financial institutions and limits

is substantially dependent upon Elan for several activities related to the development and commercialization of Fampridine-SR. The Company will rely on Elan to as  
(A) review of the New Drug Application (NDA) for Fampridine-SR in multiple sclerosis. If Elan fails to assist the Company in a complete and timely manner the Cor  
mercialization of Fampridine-SR in MS.

relies on a single manufacturer, Elan, for the supply of Zanaflex Capsules. Zanaflex Capsules are manufactured using Elan's proprietary SODAS multiparticulate dru  
ent of a failure to supply Zanaflex Capsules, to use commercially reasonable efforts to assist the Company in either producing Zanaflex Capsules itself or in transferri  
party manufacturer, provided that such third-party manufacturer is not a technological competitor of Elan. In the event production is transferred to a third party, the F  
h bioequivalence studies and laboratory testing that the product made by the new supplier is equivalent to the current Zanaflex Capsules before the Company could di

2007, the Company relied on a single manufacturer, Novartis, for the manufacture of Zanaflex tablets and for the supply of tizanidine, the active pharmaceutical ingredient. Novartis has discontinued production of tizanidine and will no longer supply tizanidine to Elan for the production of Zanaflex Capsules or to the Company for the production of Zanaflex tablets. The Company recently received FDA approval to use the tizanidine manufactured by a new supplier, Farmak, as the active ingredient in the production of Zanaflex Capsules. However, the Company is currently in contract negotiations with Patheon regarding the manufacture of Zanaflex tablets, and Patheon has agreed to manufacture Zanaflex tablets prior to the end of 2008. In the event the Company experiences any disruption in their operations, a delay or interruption in the supply of our Zanaflex products could result until the affected supplier cures the problem or until the Company is able to qualify a new supplier. The Company may not be able to enter into alternative supply arrangements on terms that are commercially favorable, if at all. Any new supplier would also be required to meet the Company's regulatory requirements through the first quarter of 2010. If the Company fails to gain FDA approval of a new tizanidine supplier for Zanaflex tablets prior to February 2010, the Company may not be able to supply Zanaflex tablets.

The Company is currently in contract negotiations with Patheon regarding the manufacture of Zanaflex tablets, and Patheon has agreed to manufacture Zanaflex tablets prior to the end of 2008. In the event the Company experiences any disruption in their operations, a delay or interruption in the supply of our Zanaflex products could result until the affected supplier cures the problem or until the Company is able to qualify a new supplier. The Company may not be able to enter into alternative supply arrangements on terms that are commercially favorable, if at all. Any new supplier would also be required to meet the Company's regulatory requirements through the first quarter of 2010. If the Company fails to gain FDA approval of a new tizanidine supplier for Zanaflex tablets prior to February 2010, the Company may not be able to supply Zanaflex tablets.

The Company also relies exclusively on Elan to supply it with its requirements for Fampridine-SR. The Company and Elan rely on a single third-party manufacturer to supply fampridine-SR. Under the Company's supply agreement with Elan, the Company is obligated to purchase at least 75% of its yearly supply of Fampridine-SR from Elan, and Elan is obligated to supply the Company with its requirements if it does not purchase 100% of its requirements from Elan, subject to certain exceptions. The Company and Elan have agreed that it may purchase up to 25% of its requirements from an agreed-upon and qualified second manufacturing source, with compensatory payment.

For pharmaceutical companies, the Company's principal customers are wholesale pharmaceutical distributors. The Company periodically assesses the financial strength of its customers to estimate potential credit losses, if necessary. To date, such losses have been minimal. Sales to the Company's top three customers, McKesson, Cardinal and AmerisourceBergen, represented 11%, 10% and 9% of the Company's sales for the years ended December 31, 2008 and 2007.

#### ***Accounts Receivable***

The Company's accounts receivable may not be collected due principally to customer disputes and sales returns. The Company provides reserves for these situations based on its historical experience, the composition of its customer portfolio and an analysis of high-risk customers. The Company has not recognized an allowance as of December 31, 2008 or 2007, as management believes all outstanding accounts receivable are collectible.

#### ***Financial Instruments***

The fair value of a financial instrument represents the amount at which the instrument could be exchanged in a current transaction between willing parties, other than in a forced sale or liquidation. The difference between the fair value and carrying amounts of financial instruments that are recognized at historical cost amounts. Effective January 1, 2008, the Company adopted the provisions of FASB ASC 820, which defines fair value, establishes a framework

value and expands required disclosures about fair value measurements. Under the standard, fair value refers to the price that would be received to sell an asset or paid to settle a liability in an orderly market transaction with market participants in the market in which the reporting entity transacts. The standard clarifies the principle that fair value should be based on the assumptions market participants would use to develop the price to receive for an asset or to pay to settle a liability.

methods are used to estimate the Company's financial instruments:

Cash equivalents, grants receivables, accounts receivable, accounts payable and accrued liabilities approximate their fair value due to the short-term nature of these instruments.

Available-for-sale securities are recorded based primarily on quoted market prices;

Notes payable carrying value approximate fair value as the interest rates on these notes approximate market rate of interest; and

Convertible notes payable for the Company to estimate the fair value of the convertible notes payable due to the specific provisions of these notes including the uncertainty of the timing of the conversion of certain products. The terms of these notes are disclosed at Note 10. See Note 16 for our discussion of fair value measurements.

Net loss per share is computed in accordance with SFAS No. 128, *Earnings Per Share*, by dividing the net loss allocable to common stockholders by the weighted average number of common shares outstanding. The Company has certain options, warrants, convertible preferred stock and mandatorily redeemable convertible preferred stock (see Notes 3 and 8), which have not been used in the computation of net loss per share as their use to do so would be anti-dilutive. As such, the numerator and the denominator used in computing both basic and diluted net loss per share allocable to common stockholders are the same.

The following table shows dilutive common share equivalents outstanding, which are not included in earning per share calculations, as the effect of their inclusion is anti-dilutive during the periods presented.

|                             | <b>Year Ended December 31,</b> |             |             |
|-----------------------------|--------------------------------|-------------|-------------|
|                             | <b>2008</b>                    | <b>2007</b> | <b>2006</b> |
| Convertible promissory note | 67,476                         | 67,476      | 67,476      |
| Options                     | 3,284,323                      | 2,999,513   | 2,534,663   |
| Warrants                    |                                |             | 16,869      |
|                             | 3,351,799                      | 3,066,989   | 2,619,008   |

The following table has reflected the beneficial conversion feature for Series E, Series I and Series J, accretion of issuance costs for Series E, Series I, Series J and Series K, and preferred dividend for the periods presented, which are not included in the computation of net loss per share allocable to common stockholders as set forth below.

|                                      | <b>Beneficial<br/>conversion<br/>feature</b> | <b>Accretion<br/>of<br/>issuance<br/>costs</b> | <b>Preferred<br/>dividend</b> |
|--------------------------------------|--|--|-------------------------------|
| For the year ended December 31, 2008 | \$   | \$   | \$                            |
| For the year ended December 31, 2007 |  |  |                               |
| For the year ended December 31, 2006 | 48,470,740                                   | 270,725  | (12,734,009)                  |

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**ensation**

has various share-based employee and non-employee compensation plans, which are described more fully in Note 8.

2006, the Company adopted the provisions of SFAS 123 (revised 2004), *Share-Based Payment* (SFAS No. 123R), which requires that the costs resulting from all share-based payment arrangements be recognized in the consolidated financial statements at their fair values. The Company adopted SFAS No. 123R using the modified prospective application method under which the provisions of SFAS 123R apply to awards granted, modified, repurchased, or cancelled after the adoption date. Additionally, compensation cost for the portion of the awards for which the requisite service has not been rendered is recognized in the consolidated statement of operations over the remaining service period after the adoption date based on the award's original estimate of fair value. Res

accounts for stock options granted to non-employees on a fair-value basis in accordance with EITF No. 96-18, *Accounting for Equity Instruments That Are Issued to Non-employees in Connection with Selling, Goods or Services*, and FASB Interpretation No. 28, *Accounting for Stock Appreciation Rights and Other Variable Stock Option or Award Plans*, paragraph 25.

**on**

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 report to any of its product candidates. Accordingly, the Company does not prepare discrete financial information with respect to separate product candidates or by location. The Company is defined by SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*.

**ome**

, *Reporting Comprehensive Income* (SFAS No. 130) establishes standards for the reporting and display of comprehensive income (loss) and its components in a full statement of comprehensive income. Unrealized gains (losses) from the Company's investment securities be included in other comprehensive income (loss).

period amounts have been reclassified to conform to current year presentation.

**Pronouncements**

2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, which permits an entity to measure certain financial assets and liabilities at fair value on an instrument-by-instrument basis. Under SFAS 159, entities that elect the fair value option will report unrealized gains and losses in earnings at each subsequent reporting date beginning on January 1, 2008, but the Company did not elect to measure any additional financial instruments at fair value as a result of this statement. Therefore, the adoption of SFAS 159 did not impact the Company's financial statements.

EITF Issue No. 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities* was issued in 2007. It prescribes the accounting for non-refundable advance payments for goods and services that will be used in future R&D activities and requires that they be expensed when the goods or services are received and not at the time of payment. The Company adopted EITF No. 07-3 as of January 1, 2008. The adoption has not had an impact on our consolidated financial statements.



007, the FASB issued SFAS No. 141R, *Business Combinations*. This statement is effective for fiscal years beginning on or after December 15, 2008, with early adoption for acquisitions completed after December 31, 2008. Among other things, the new standard requires that all acquisition-related costs be expensed as incurred, that acquired intangible assets 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 requires accounting for assets and liabilities arising from contingencies acquired or assumed and, for acquisitions both prior and subsequent to December 31, 2008, requires the recognition of 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 consolidated net income. The Company does not expect the adoption of SFAS No. 141R to have a material impact on its consolidated financial statements.

007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements*. SFAS No. 160 will change the accounting for minority 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, with early adoption for acquisitions completed after December 31, 2008. SFAS No. 160 requires retroactive adoption of the presentation and disclosure requirements for existing minority interests and prospective adoption for all other requirements. The Company does not expect the adoption of SFAS No. 160 to have a material impact on its consolidated financial statements.

007, the FASB issued Final FASB Staff Position (FSP), FAS 142-3, *Determination of the Useful Life of Intangible Assets*, which amends the factors that should be considered in determining the useful life of a recognized intangible asset used to determine the useful life of a recognized intangible asset under SFAS No. 142, *Goodwill and Other Intangible Assets*. This FSP shall be effective for financial statements issued after December 15, 2008, and interim periods within those fiscal years. Early adoption is prohibited. The Company will ascertain its impact, if any, during the three-month period ending on March 31, 2009.

008, the FASB issued FASB Staff Position (FSP), FAS 157-3, *Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active*, which clarifies the application of *Fair Value Measurements*, in a market that is not active and illustrates key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. The Company does not expect these amendments to have an impact on our financial statements.

#### **Common Stock**

The Company completed an initial public offering (IPO) on February 9, 2006. As part of that offering, 6,075,614 shares of the Company's common stock were sold, resulting in net proceeds of \$100.0 million, after deducting the underwriting discount and offering expenses payable by the Company.

As a result of the IPO, all of the Company's convertible preferred stock and mandatorily redeemable convertible preferred stock was converted into 13,338,278 shares of common stock. The conversion resulted in the following: (a) recognition of the unamortized portion of a beneficial conversion charge of \$48.5 million; (b) recognition of the unamortized portion of issuance costs related to the convertible preferred stock of \$271,000; and (c) net reversal of accrued preferred dividends on Series J and Series K preferred stock of \$12.7 million.

completed a private placement of its common stock in October 2006. As part of that offering, 3,230,769 shares of the Company's common stock were sold, resulting in net proceeds of \$18 million net of issuance costs.

completed a follow-on public offering in July 2007. As part of that offering, 4,189,460 shares of the Company's common stock were sold, resulting in proceeds of approximately \$40 million net of issuance costs.

completed a follow-on public offering in February 2008. As part of that offering, 3,712,000 shares of the Company's common stock were sold, resulting in proceeds of approximately \$35 million net of issuance costs.

completed a follow-on public offering in August 2008. As part of that offering, 4,600,000 shares of the Company's common stock were sold, resulting in proceeds of approximately \$43 million net of issuance costs.

Under the Elan Zanaflex purchase agreement, warrants to purchase 16,869 shares of common stock were issued for an aggregate exercise price of \$11.856. These warrants were exercised by Saints Capital V, L.P., together with Saints Capital, in December 2005 and were exercised in January 2007 for an aggregate of \$200,000.

**Investments**

The Company has accounted for its investments in accordance with SFAS No. 115 and determined that all of its short-term investments are classified as available-for-sale. Available-for-sale investments on these securities included in interest income. Available-for-sale securities consisted of the following:

|                   | <b>Amortized<br/>Cost</b> | <b>Gross<br/>unrealized<br/>gains</b> | <b>Gross<br/>unrealized<br/>losses</b> | <b>Estimated<br/>fair<br/>value</b> |
|-------------------|---------------------------|---------------------------------------|--|-------------------------------------|
| <b>2008</b>       |                           |                                       |  |                                     |
| Commercial paper  | \$ 119,302,891            | \$ 585,564                            | \$                                     | \$ 119,888,455                      |
| US Treasury bonds | 96,319,767                | 228,848                               | (1,654)                                | 96,546,961                          |
| <b>2007</b>       |                           |                                       |  |                                     |
| Commercial paper  | 77,018,656                | 295,855                               |  | 77,314,511                          |
| Corporate bonds   | 995,792                   |                                       | (62)                                   | 995,730                             |

All maturities of available-for-sale debt securities at December 31, 2008 and 2007 are within one year.

The market value of any available-for-sale security below cost that is deemed to be other-than-temporary results in a reduction in carrying amount to fair value in accordance with SFAS No. 115-1, *The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments*. The impairment would be charged to earnings for the difference between the carrying amount and a new cost basis for the security established. Factors evaluated to determine if an investment is other-than-temporarily impaired include significant deterioration in the issuer's financial condition, quality, or business prospects of the issuer; adverse changes in the general market condition in which the issuer operates; the intent and ability to retain the investment until maturity; a decline in the market value of the investment; and, issues that raise concerns about the issuer's ability to continue as a going concern. The Company has determined that there is no other-than-temporary impairment of any of its available-for-sale securities.

ry declines in the fair values of its short term investments as of December 31, 2008.

estments with maturity of three months or less from date of purchase have been classified as cash and cash equivalents, and amounted to \$27,283,767 and \$15,766,93

## Equipment

quipment consisted of the following:

|                               | December 31,<br>2008 | December 31,<br>2007 | Estimated<br>useful<br>lives |
|-------------------------------|----------------------|----------------------|------------------------------|
| Laboratory equipment          | \$ 1,746,163         | \$ 2,299,170         | 5 years                      |
| Furniture and fixtures        | 753,258              | 626,649              | 5 years                      |
| Computer equipment            | 2,265,644            | 1,800,791            | 3 years                      |
| Websites(1)                   | 439,681              |                      | 3 years                      |
| Capital in Progress(2)        | 137,585              |                      | 3 years                      |
| Leasehold improvements        | 2,885,695            | 2,542,277            | 2 to 7 years                 |
|                               | 8,228,026            | 7,268,887            |                              |
| Less accumulated depreciation | (5,879,879)          | (5,617,148)          |                              |
|                               | \$ 2,348,147         | \$ 1,651,739         |                              |

(1) Website development has been capitalized in conformity with EITF 00-2, "Accounting for Web Site Development Costs".

(2) Capital in Progress represents website development for a site that is not complete and has not been launched as of December 31, 2008.

and amortization expense on property and equipment was \$1,102,336 and \$1,018,758 for the years ended December 31, 2008 and 2007, respectively.

## Liabilities and Other Current Liabilities

Liabilities and other current liabilities consisted of the following:

|  | December 31,<br>2008 | December 31,<br>2007 |
|--|----------------------|----------------------|
| Accrued research and development expenses              | \$ 2,888,791         | \$ 2,172,364         |
| Bonus payable  | 2,212,713            | 1,498,520            |
| Sales force commissions and incentive payments payable | 2,287,211            | 1,044,881            |
| Legal accruals   | 1,321,882            | 173,413              |
| Royalties payable                                      | 906,695              | 962,831              |
| Regulatory accruals                                    | 895,810              |                      |
| Fees for distributor services payable                  | 621,000              | 1,084,932            |
| Other accrued expenses                                 | 2,859,651            | 1,840,704            |
|  | \$ 13,993,753        | \$ 8,777,645         |

Research and development expenses include amounts relating to the clinical trials as well as preclinical operating costs. Legal accruals are primarily comprised of expenses that include amounts for activities and consultants related to

the NDA for Fampridine-SR. Other accrued expenses include payroll liabilities, vacation accruals, sales and marketing accruals, and other operating expense accruals.

Company entered into a \$6 million senior secured term loan with General Electric Capital Corporation that bears an annual fixed interest rate of 9.93%. The Company February 2008, with interest-only payments for the first six months starting March 2005 followed by principal and interest payments for the remaining 30 months. The property and fixtures owned at closing or subsequently acquired. The Company repaid \$3 million of the loan in December 2005. As of February 2008 this loan was

convertible notes payable see Note 10.

### **Options and Restricted Stock**

1999, the Company's board of directors approved the adoption of the Acorda Therapeutics, Inc. 1999 Employee Stock Option Plan (the 1999 Plan). All employees of the 1999 Plan, including executive officers, as well as directors, independent contractors, and agents of the Company. The 1999 Plan also covers the issuance of restricted stock. The Compensation Committee of the Board of Directors, which selects the individuals to be granted options and stock appreciation rights, determines the time or times awards shall be granted under the 1999 Plan, determines the number of shares to be granted subject to any option or stock appreciation right under the 1999 Plan and the duration, and makes any other determinations necessary, advisable, and/or appropriate to administer the 1999 Plan. Under the 1999 Plan, each option granted expires no later than 10 years from the date of grant. Compensation expense is calculated using a Black-Scholes calculation with the expense being recognized over the vesting period. The number of shares authorized for issuance

2006, the Company's board of directors approved the adoption of the Acorda Therapeutics, Inc. 2006 Employee Incentive Plan (the 2006 Plan). This 2006 Plan serves as a replacement for the 1999 Plan, as amended, and no further option grants or stock issuances shall be made under the 1999 Plan after the effective date, as determined under Section 14 of the 2006 Plan. The 2006 Plan also covers the issuance of restricted stock. The Compensation Committee of the Board of Directors, which selects the individuals to be granted options and stock appreciation rights, determines the time or times awards shall be granted under the 2006 Plan, determines the number of shares to be granted subject to any option or stock appreciation right under the 2006 Plan and the duration, and makes any other determinations necessary, advisable, and/or appropriate to administer the 2006 Plan. Under the 2006 Plan, each option granted expires no later than 10 years from the date of grant. The number of shares of common stock reserved for issuance pursuant to awards made under the 2006 Plan as of December 31, 2008 is 4,144,576 shares of stock. The total number of shares of common stock reserved for issuance under this 2006 Plan, including shares of common stock subject to the then outstanding awards, shall automatically increase on January 1 of each year during the term of the 2006 Plan by the number of shares of common stock equal to 4% of the outstanding shares of common stock on that date, unless otherwise determined by the Board of Directors. The Board determined the number of shares of common stock reserved for issuance under the 2006 Plan for 2007. The

that the automatic increase of 4% should take effect for 2008. Upon the exercise of options in the future, the Company intends to issue new shares.

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

|                                 | <b>Year ended<br/>December 31,</b> |             |             |
|---------------------------------|------------------------------------|-------------|-------------|
|                                 | <b>2008</b>                        | <b>2007</b> | <b>2006</b> |
| <b>Employees and directors:</b> |                                    |             |             |
| Estimated volatility            | 80.17%                             | 71.84%      | 71.49%      |
| Expected life in years          | 5.30                               | 6.17        | 5.40        |
| Risk free interest rate         | 2.85%                              | 4.66%       | 4.64%       |
| Dividend yield                  |                                    |             |             |

The estimated volatility for purposes of computing compensation expense on its employee and non-employee options using a combination of the volatility of the Company and the volatility of public companies that the Company considered comparable. The expected life used to estimate the fair value of employee options is 5.3 years. The Company based its expected life on 10 peer companies' choices for expected life for their valuations.

The average fair value per share of options granted to employees and directors for the years ended December 31, 2008, 2007 and 2006 amounted to approximately \$14.20, \$12.50 and \$11.50, respectively. No options were granted to non-employees for the year ended December 31, 2008 and no options were granted to non-employees for the years ended December 31, 2007 and 2006.

For the year ended December 31, 2008, the Company granted 1,134,484 stock options and restricted stock awards to employees and directors under the 2006 Plan. These stock options have an exercise price of \$21.31 per share. 1,100 of these options vested immediately, 95,000 of these options vest over a one-year vesting schedule and 813,384 will vest over a three-year vesting schedule. The stock awards granted in 2008 will vest over a three-year vesting schedule. As a result of these grants the total compensation charge to be recognized over the service period is \$10.5 million, of which \$9.5 million was recognized during the year ended December 31, 2008.

The compensation costs for options and restricted stock granted to employees and directors amounted to \$9,552,236, \$7,796,118, and \$3,843,110 for the years ended December 31, 2008, 2007 and 2006, respectively. Compensation costs capitalized in our inventory balances. Compensation expense for options and restricted stock granted to employees and directors are classified between research and development expense and general and administrative expense based on employee job function.

share-based compensation activity for the year ended December 31, 2008 is presented below:

|  | Number of Shares | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term | Intrinsic Value |
|--|------------------|---------------------------------|---|-----------------|
| Balance at January 1, 2008                       | 2,999,513        | \$ 10.17                        |   |                 |
| Granted  | 924,484          | 21.29                           |   |                 |
| Forfeited  | (115,882)        | 16.21                           |   |                 |
| Exercised  | (523,792)        | 7.32                            |   |                 |
| Balance at December 31, 2008                     | 3,284,323        | \$ 13.55                        | 7.5   | \$24,751,341    |
| Vested and expected to vest at December 31, 2008 | 3,196,736        | \$ 13.38                        | 7.4   | \$24,555,730    |
| Vested and exercisable at December 31, 2008      | 1,735,910        | \$ 9.42                         | 6.5   | \$19,512,382    |

| Range of exercise price | Options Outstanding                 |   | Options Exercisable             |                                     |                                 |
|-------------------------|-------------------------------------|---|---------------------------------|-------------------------------------|---------------------------------|
|                         | Outstanding as of December 31, 2008 | Weighted-average remaining contractual life | Weighted-average exercise price | Exercisable as of December 31, 2008 | Weighted-average exercise price |
| \$2.45-\$4.81           | 601,531                             | 4.70  | \$ 2.68                         | 585,295                             | \$ 2.65                         |
| \$4.82-\$8.14           | 774,398                             | 6.73  | 6.99                            | 572,801                             | 7.21                            |
| \$8.15-\$19.41          | 772,279                             | 8.17  | 16.40                           | 334,377                             | 16.40                           |
| \$19.42-\$21.74         | 666,732                             | 9.25  | 20.08                           | 106,967                             | 19.93                           |
| \$21.75-\$34.70         | 469,383                             | 8.54  | 24.34                           | 136,470                             | 22.39                           |
|                         | 3,284,323                           | 7.47  | \$ 13.55                        | 1,735,910                           | \$ 9.42                         |

compensation cost for unvested stock options and restricted stock awards as of December 31, 2008 totaled \$19.1 million and is expected to be recognized over a weighted average period of approximately 7.5 years.

activity

| Restricted Stock               | Number of Shares |
|--------------------------------|------------------|
| Nonvested at January 1, 2008   | 39,722           |
| Granted                        | 225,000          |
| Vested                         | (102,886)        |
| Forfeited                      | (11,673)         |
| Nonvested at December 31, 2008 | 150,163          |

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had available net operating loss carry-forwards (NOL) of approximately \$262.2 million and \$179.9 million as of December 31, 2008 and 2007, for federal and state income tax purposes. The Company also has research and development tax credit carryforwards of approximately \$100.0 million as of December 31, 2008 and 2007, for 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 \$100.0 million as of December 31, 2008 and 2007, for

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reporting purposes that are available to reduce federal income taxes, if any, and expire in future years beginning in 2018.

of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities as of December 31, 2008 and 2007 are presented below.

|                                     | <b>December 31,<br/>2008</b> | <b>December 31,<br/>2007</b> |
|-------------------------------------|------------------------------|------------------------------|
| Net operating loss carryforwards    | \$ 88,829,117                | \$ 64,949,570                |
| Research and development tax credit | 1,577,897                    | 1,406,750                    |
| Property and equipment              | 834,527                      | 756,420                      |
| Intellectual property               | 3,154,808                    | 3,289,572                    |
| Stock options and warrants          | 8,155,122                    | 11,722,929                   |
| Deferred revenue                    | 7,724,122                    | 7,342,693                    |
| Inventory reserve                   | 167,362                      | 220,651                      |
| Revenue interest liability          | 6,728,310                    | 7,242,903                    |
| NRI acquisition                     | 892,276                      |                              |
| Other temporary differences         | 1,390,290                    | 898,298                      |
|                                     | 119,453,831                  | 97,829,786                   |
| Less valuation allowance            | (119,453,831)                | (97,829,786)                 |
| Net deferred tax assets             | \$                           | \$                           |

The valuation allowance for the years ended December 31, 2008 and 2007 amounted to approximately \$21.6 million and \$3.6 million, respectively. Since inception, the Company has not incurred 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 credits (R&D credits), as defined by the Act) that could significantly limit the Company's ability to utilize these carryforwards. The Company has experienced various ownership changes. Consequently, 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 can be utilized, 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 a tax benefit for the periods presented. As of December 31, 2008, management believes that it is more likely than not that the net deferred tax assets will not be realized based on future operations. 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.

#### Research Agreements

In 2007, the Company entered into several agreements with Elan, including a License and Supply Agreement (the Agreement) to develop Elan's sustained-release formulation of Fampridine. The term of the agreement is equal to the greater of 20 years or the duration of relevant Fampridine-SR patent rights. The Company is responsible for all clinical trials and manufacturing, subject to certain exceptions, products for the Company upon regulatory approval at specified prices as a percentage of net selling price. In the event Elan develops a product, the Company will receive a royalty as a stated percentage of the products' net selling price.

reement, Elan also loaned to the Company an aggregate of \$7.5 million pursuant to two convertible promissory notes. On December 23, 2005, Elan transferred these p  
One promissory note in the amount of \$5.0 million bears interest at a rate of 3% beginning on the first anniversary of the issuance of the note. The unpaid principal i  
principal and interest are repayable, if not converted, ratably over a seven-year period beginning one year after the Company receives certain regulatory approval for the  
d to gross margin on product sales. If it is determined by both parties that regulatory approval will not likely occur, the \$5.0 million promissory note will automaticall  
the License and Supply Agreement is otherwise terminated, the principal and interest is repayable ratably over 15 years. The \$5.0 million promissory note restricts the  
senior to the notes, subject to certain exceptions, including for the Company's revenue interest assignment arrangement (See Note 15).

omissory note was in the amount of \$2.5 million and was non-interest bearing. In December 2006, Saints Capital exercised the conversion of this note into 210,863 sh

se convertible promissory notes has been imputed using 9% on 50% of the \$5 million note and 8% on the \$2.5 million note. In the case of the \$5 million note, the Co  
on note based on the provision in the License and Supply Agreement that provided for a recovery of up to \$2.5 million of the license fee paid, which was dependent u  
ty approval of the product is received, the convertible note would be repayable and the Company would be entitled to recovery of up to \$2.5 million based on the afor  
at regulatory approval will not likely occur, the note will not be repayable and the Company would not receive recovery of up to \$2.5 million of the license fee. Elan  
ownership interest in the Company, significant license agreements entered into and involvement with research and development activities of the Company. The aggreg  
tible note payable is convertible into 67,476 shares of common stock.

#### *ated License*

2003, the Company entered into an amended and restated license agreement with Elan, which replaced two prior licenses for Fampridine-SR. Under this agreement, E  
e rights to Fampridine-SR, as well as Elan's formulation for any other mono- or di-aminopyridines, for all indications, including spinal cord injury and multiple sclero  
ments and royalties based on net sales of the product if and when approved.

y termination provisions, the Elan license terminates on a country by country basis on the latter to occur of fifteen years from the date of the agreement, the expiration  
petition in that country.

2003, the Company entered into a supply agreement with Elan relating to the manufacture and supply of Fampridine-SR by Elan. The Company agreed to purchase at  
mpridine from Elan, unless Elan is unable or unwilling to meet its requirements, for a purchase price based on a specified percentage of net sales. In those circumstan  
00% of its requirements from

agreed to make certain compensatory payments to Elan. Elan agreed to assist the Company in qualifying a second manufacturer to manufacture and supply the Company.

**Benefit Plan**

On September 1, 1999, the Company adopted a defined contribution 401(k) savings plan (the 401(k) plan) covering all employees of the Company. Participants may elect to contribute to the 401(k) plan, subject to defined limitations. Effective January 1, 2007, the Company amended the plan to include an employer match contribution to employees. Up to 6% of his or her earnings, the Company will contribute an additional 50 cents into the funds. The Company's expense related to the plan was \$548,000, \$388,000, 2007 and 2006, respectively.

**Leases and Contingencies**

The Company entered into a lease agreement for its facility. During November 2000, May 2001, February 2007, July 2008 and February 2009, the Company entered into amendments, the Company increased the total leased space and extended the lease term for its original leased space. After the first six months of the February 2009 amendment, upon 12 months notice with no penalty. During 2008, the Company entered into a lease agreement through November 2009 for a corporate apartment. Future minimum payments required subsequent to December 31, 2008 are as follows:

|      |                    |
|------|--------------------|
| 2009 | \$ 1,021,000       |
| 2010 | 1,000,000          |
| 2011 | 1,000,000          |
| 2012 | 1,000,000          |
|      | <b>\$4,021,000</b> |

Under these operating leases during the years ended December 31, 2008, 2007 and 2006 was \$882,378, \$799,006 and \$676,834, respectively.

Under its Zanaflex purchase agreement with Elan, the Company is obligated to make milestone payments to Elan of up to \$19.5 million based on cumulative gross sales of Zanaflex. Through December 31, 2008, the Company has made all \$19.5 million of these milestone payments. Under its Zanaflex supply agreement with Elan, the Company is required to provide to Elan a monthly forecast and a two-year forecast not later than July 1 of each year. The Company is bound to order one hundred percent of the forecast required quantities for each month of the monthly forecast report. At December 31, 2008, the forecast requirement for the five month period following December 31, 2008 amounted to approximately \$3.8 million.

Under the employment agreement with the Company's chief executive officer, the Company is obligated to pay severance under certain circumstances. If the employment of the Company's chief executive officer for reasons other than for cause, the Company must pay (i) an amount equal to the base salary the chief executive officer would have received immediately following the date of termination, plus (ii) bonus equal to last annual bonus received by the chief executive officer multiplied by a fraction, the numerator of which shall be the number of months elapsed as of the termination date and the denominator of which shall be 365.

is also party to employment agreements with its other executive officers, who are the Company's chief scientific officer, executive vice president and general counsel and conditions of their employment. If any of the employment agreements are terminated by the Company or by the executives for reasons other than for cause, the Company would pay the executive the amount of the bonus the executive would have received during the nine month period immediately following the date of termination in the case of the chief scientific officer and a seven month period in the case of the executive vice president and general counsel and chief financial officer, plus (ii) a bonus equal to the last annual bonus received by the executive multiplied by a numerator of which shall be the number of days in the calendar year elapsed as of the termination date and the denominator of which shall be 365.

In October 2007, the Company received a Paragraph IV Certification Notice from Apotex Inc. advising that it had submitted an Abbreviated New Drug Application to the FDA seeking approval for Zanaflex Capsules. In October 2007, the Company filed a lawsuit against Apotex Corp. and Apotex Inc. (collectively, Apotex) for patent infringement in relation to the filing of the Paragraph IV Certification Notice. Apotex answered the Company's complaint, asserting patent invalidity and non-infringement and counterclaiming, seeking a declaratory judgment of patent invalidity and non-infringement and counterclaims. In March 2008, Apotex filed a motion, which the Company opposed, for partial judgment on the pleadings dismissing the Company's request for relief on the grounds that the Company's claims are unpatentable under 35 U.S.C. §§ 271(e)(4) or 285. The court ruled in the Company's favor and denied Apotex' motion in December 2008. The Company and Apotex are currently proceeding with litigation for amounts related to legal matters if it is probable that a liability has been incurred and the amount is reasonably estimable. As of December 31, 2008 there have been no accruals for legal matters.

#### Product Returns

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

At the time of the Zanaflex acquisition, the Company purchased certain tablet inventory from Elan that expired within one year. The majority of this product was sold by the Company through June 2006 at which point the right of return expired and the Company recognized the \$2.2 million deferred revenue liability.

#### Contingent Assets

The Company acquired all of Elan's U.S. sales, marketing and distribution rights to Zanaflex Capsules and Zanaflex tablets in July 2004 for \$2.0 million plus \$675,000 for finished goods inventory. The Company is entitled to receive up to \$19.5 million in future contingent milestone payments based on cumulative gross sales of Zanaflex tablets and Zanaflex Capsules. As of December 31, 2008, there have been no contingent milestone payments which were

able assets in the consolidated financial statements. The final \$5.0 million milestone was reached in January 2008 and was paid during the three-month period ended June 30, 2008.

With this transaction, the Company acquired the rights to the tradename "Zanaflex®", one issued U.S. patent and two patent applications related to Zanaflex Capsules and Zanaflex Tablets. Additionally, the Company assumed Elan's existing contract with Novartis to manufacture Zanaflex tablets and entered into a separate contract with Elan to manufacture Zanaflex Capsules. The Company separately launched Zanaflex Capsules in April 2005. The Company did not acquire any receivables, employees, facilities or fixed assets. The Company allocated, on a relative basis, the payments made to Elan to the assets acquired, principally the Zanaflex tradename and the capsulation patent. There is no expected residual value of these intangible assets. The Company expects the value of the tradename and patent over their estimated future economic benefit to be achieved.

The intangible assets consisted of the following:

|                               | December 31,<br>2008 | December 31,<br>2007 | Estimated<br>remaining<br>useful lives as<br>of<br>December 31,<br>2008 |
|-------------------------------|----------------------|----------------------|---|
| Zanaflex patents              | \$ 19,350,000        | \$ 14,850,000        | 13 years  |
| Zanaflex tradename            | 2,150,000            | 1,650,000            | 0 years   |
|                               | 21,500,000           | 16,500,000           |   |
| Less accumulated amortization | 4,934,544            | 2,556,112            |   |
|                               | \$ 16,565,456        | \$ 13,943,888        |   |

The Company recorded \$2,378,431 and \$1,233,704 in amortization expense related to these intangible assets in the years ending December 31, 2008 and 2007, respectively.

The estimated future amortization expense for these intangible assets subsequent to December 31, 2008 for the next five years is as follows:

|      |              |
|------|--------------|
| 2009 | \$ 1,282,696 |
| 2010 | 1,282,696    |
| 2011 | 1,282,696    |
| 2012 | 1,282,696    |
| 2013 | 1,282,696    |
|      | \$6,413,480  |

#### Revenue Interest

In November 2005, the Company entered into an agreement with an affiliate of Paul Royalty Fund (PRF), under which the Company received \$15 million in cash. In exchange, the Company granted the PRF a revenue interest in Zanaflex Capsules, Zanaflex tablets and any future Zanaflex products. The agreement covers all Zanaflex net revenues (as defined in the agreement) generated from the Company's operations from January 1, 2005 to December 31, 2015, unless the agreement terminates earlier. In November 2006, the Company entered into an amendment to the revenue interest assignment agreement with PRF, which provided that the Company would pay the Company \$5.0 million in November 2006. An additional \$5.0 million was due if the Company's net revenues during the fiscal year 2006 equaled or exceeded \$15 million. The amount payable was reflected in the Company's December 31, 2006 financial statements. Under

endment, the Company is required to pay PRF \$5.0 million on December 1, 2009 and an additional \$5.0 million on December 1, 2010 since the net revenues milestone

ement and the amendment to the agreement, 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

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.

g the foregoing, once PRF has received and retained payments under the amended agreement that are at least 2.1 times the aggregate amount PRF has paid the Company, PRF is entitled to 15% of Zanaflex net revenues. If PRF is entitled to 15% of net revenues as described above, the Company will remit 8% of cash payments received from wholesalers to PRF in connection with the distribution and settlement.

with the transaction, the Company recorded a liability, referred to as the revenue interest liability, in accordance with EITF 88-18, *Sales of Future Revenues*. The Company records the liability using the effective interest rate method and records a corresponding accrued interest liability. The effective interest rate is calculated based on the rate that would be in effect at the time 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. The imputed interest rate associated with this liability will be approximately 6.2%. Payments made to PRF as a result of Zanaflex sales levels will reduce the accrued interest liability. The Company recorded approximately \$5.4 million, \$2.4 million and \$2.1 million in interest expense related to this agreement in 2008, 2007 and 2006. The Company also included a \$1.4 million out-of-period adjustment made during the second quarter of 2008 to correct an error identified in the previously recorded effective interest expense. The Company's interests assignment agreement with PRF. This out-of-period adjustment did not increase the total interest expense associated with this agreement. Through December 31, 2008, the Company has made payments to PRF as a result of Zanaflex sales levels.

The agreement also contains put and call options whereby the Company may repurchase the revenue interest at its option or can be required by PRF to repurchase the revenue interest if the Company experiences a change of control, undergoes certain bankruptcy events, transfers any of their interests in Zanaflex (other than pursuant to a license agreement, development agreement, collaboration, partnering or similar agreement), transfers all or substantially all of its assets, or breaches certain of the covenants, representations or warranties made under the agreement. The Company refers to as PRF's put option, to require the Company to repurchase the rights sold to PRF at the "put/call price" in effect on the date such right is exercised. If the Company exercises the right, which the Company refers to as the Company's call option, to repurchase the rights sold to PRF at the "put/call price" in effect on the date such right is exercised. If the Company exercises the option as a result of this trigger, the Company will have a period of 180 days during which to exercise the option. The Company does not currently intend to

on if it becomes exercisable as a result of such a transaction but may reevaluate whether it would exercise the option during the 180-day period. The put/call price on payments made by PRF as of such date, less all payments received by PRF as of such date, and (ii) an amount that would generate an internal rate of return to PRF of 25% into account the amount and timing of all payments received by PRF as of such date. The Company has determined that PRF's put option and the Company's call option are added derivative and should be accounted for as such. The Company recorded a net liability of \$337,500 as of December 31, 2008 related to the put/call option to reflect SFAS No. 133, *Accounting for Derivatives Instruments and Hedging Activities*. This liability is revalued on a semi-annual basis to reflect any changes in the fair value and is recorded in earnings. For the year ended December 31, 2008, a gain of \$125,000 has been recorded as a result of the change in the net put/call liability balance from

#### Measurements

On January 1, 2008, the Company adopted SFAS No. 157, *Fair Value Measurements*, which defines fair value, establishes a framework for measuring fair value and expands the scope of SFAS No. 157. Under the standard, fair value refers to the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in a principal market for the asset or liability. The standard clarifies the principle that fair value should be based on the assumptions market participants would use when pricing the asset or liability. The impact of SFAS No. 157 was not material to our consolidated financial statements.

On January 1, 2009, the Company adopted SFAS No. 157-1, *Application of FASB Statement No. 157 to FASB Statement No. 13 and Other Accounting Pronouncements That Address Fair Value Measurements for Purposes of Other Accounting Standards*, which amended SFAS No. 157. SFAS No. 157-1, *Application of FASB Statement No. 157 to FASB Statement No. 13 and Other Accounting Pronouncements That Address Fair Value Measurements for Purposes of Other Accounting Standards*, removed leasing transactions accounted for under SFAS No. 13, *Accounting for Leases*, and related guidance from the scope of SFAS No. 157. FSP FASB No. 157 deferred the effective date of SFAS No. 157 for the Company in relation to all nonfinancial assets and nonfinancial liabilities to January 1, 2009.

SFAS No. 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 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 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 presents information about our assets and liabilities measured at fair value on a recurring basis as of December 31, 2008 and indicates the fair value hierarchy of fair value.

|   | Level 1       | Level 2 | Level 3 |
|---|---------------|---------|---------|
| <b>Assets Carried at Fair Value:</b>      |               |         |         |
| Cash equivalents                          | \$ 27,283,767 | \$      | \$      |
| Short-term investments                    | 216,435,415   |         |         |
| <b>Liabilities Carried at Fair Value:</b> |               |         |         |
| Put/call liability                        |               |         | 337,500 |

table presents additional information about assets and/or liabilities measured at fair value on a recurring basis and for which the Company utilizes Level 3 inputs to determine

|   | Balance as of<br>December 31,<br>2007 | Realized<br>gains<br>included<br>in net<br>loss | Unrealized<br>losses included<br>in other<br>comprehensive<br>loss | Balance as of<br>December 31,<br>2008 |
|---|---------------------------------------|---|--|---------------------------------------|
| <b>Liabilities Carried at Fair Value:</b> |                                       |   |  |                                       |
| Put/call liability                        | \$ 462,500                            | \$ (125,000)                                    | \$   | \$ 337,500                            |

evaluates the fair value of positions classified within the Level 3 category based on revenue projections, business, general economic and market conditions that could

vents

, 2009, the Company submitted a New Drug Application to the U.S. Food and Drug Administration for Fampridine-SR.

**Consolidated Financial Data (unaudited)**

|   | 2008         |              |              |              |
|---|--------------|--------------|--------------|--------------|
|   | March 31     | June 30      | September 30 | December 31  |
| Net sales   | 11,487,326   | 11,359,021   | 12,442,431   | 12,439,173   |
| Gross profit  | 8,527,166    | 8,556,135    | 9,764,756    | 9,623,828    |
| Net loss allocable to common stockholders basic and diluted           | (16,430,875) | (18,822,458) | (18,855,762) | (20,231,545) |
| Net loss per share allocable to common stockholders basic and diluted | \$ (0.54)    | \$ (0.58)    | \$ (0.53)    | \$ (0.54)    |

|   | 2007        |             |              |              |
|---|-------------|-------------|--------------|--------------|
|   | March 31    | June 30     | September 30 | December 31  |
| Net sales   | 8,310,772   | 9,484,250   | 10,439,028   | 11,191,961   |
| Gross profit  | 6,762,468   | 7,483,821   | 8,277,740    | 8,606,004    |
| Net loss allocable to common stockholders basic and diluted           | (7,548,740) | (8,163,712) | (8,532,440)  | (13,729,575) |
| Net loss per share allocable to common stockholders basic and diluted | \$ (0.32)   | \$ (0.33)   | \$ (0.30)    | \$ (0.48)    |

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Exhibits are incorporated herein by reference or are filed with this Annual Report on Form 10-K as indicated below.

### Description

Amended and Restated Certificate of Incorporation of the Registrant. Incorporated herein by reference to Exhibit 3.1 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on November 20, 2006.

Amended and Restated Bylaws of the Registrant. Incorporated herein by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed on March 21, 2007.

Specimen Stock Certificate evidencing shares of common stock. Incorporated herein by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.

Amended and Restated Accord Therapeutics 1999 Employee Stock Option Plan. Incorporated herein by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.

Amendment to 1999 Employee Stock Option Plan. Incorporated herein by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.

Amendment No. 2 to 1999 Employee Stock Option Plan. Incorporated herein by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.

Amended and Restated Accord Therapeutics 2006 Employee Incentive Plan. Incorporated herein by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.

Amended and Restated Accord Therapeutics 2006 Employee Incentive Plan, as amended as of January 13, 2005. Incorporated herein by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 18, 2006.

Sixth Amended and Restated Registration Rights Agreement, dated March 3, 2004, by and among the Registrant and certain stockholders named therein. Incorporated herein by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.

Employment Agreement, dated August 11, 2002, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.

Amendment to August 11, 2002 Employment Agreement, dated September 26, 2005, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.

Letter Agreement, dated November 30, 2004, by and between the Registrant and Mark Pinney. Incorporated herein by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.

Employment Agreement, dated as of December 19, 2005, by and between the Registrant and Andrew R. Blight. Incorporated herein by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on



### Description

employment Agreement, dated as of December 19, 2005, by and between the Registrant and Mary Fisher. Incorporated herein by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.

employment Agreement, dated as of December 19, 2005, by and between the Registrant and David Lawrence. Incorporated herein by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.

employment Agreement, dated as of December 19, 2005, by and between the Registrant and Jane Wasman. Incorporated herein by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.

Amended and Restated License Agreement, dated September 26, 2003, by and between the Registrant and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.

Supply Agreement, dated September 26, 2003, by and between the Registrant and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.

License Agreement, dated September 26, 2003, by and between the Registrant and Rush-Presbyterian-St. Luke's Medical Center. Incorporated herein by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.

Side Agreement, dated September 26, 2003, by and among the Registrant, Rush-Presbyterian-St. Luke's Medical Center, and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.11 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.

Payment Agreement, dated September 26, 2003, by and among the Registrant, Rush-Presbyterian-St. Luke's Medical Center, and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.

Amendment No. 1 to the Payment Agreement, dated as of October 27, 2003, by and between the Registrant and Elan Corporation, plc. Incorporated herein by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.

Amended and Restated License Agreement, dated August 1, 2003, by and between the Registrant and Canadian Spinal Research Organization. Incorporated herein by reference to Exhibit 10.20 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.

License Agreement, dated February 3, 2003, by and between the Registrant and Cornell Research Foundation, Inc. Incorporated herein by reference to Exhibit 10.21 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.



## Description

License Agreement, dated November 12, 2002, by and between the Registrant and eNeS Pharmaceuticals, plc. Incorporated herein by reference to Exhibit 10.22 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.

License Agreement, dated November 12, 2002, by and between the Registrant and eNeS Pharmaceuticals, plc. Incorporated herein by reference to Exhibit 10.23 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.

License Agreement, dated September 8, 2000, by and between the Registrant and Mayo Foundation for Medical Education and Research. Incorporated herein by reference to Exhibit 10.24 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.

Side Letter Agreement, dated June 1, 2005, by and between the Registrant and Mayo Foundation for Medical Education and Research. Incorporated herein by reference to Exhibit 10.25 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.

Asset Purchase Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.26 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.

Supply Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharma International Limited. Incorporated herein by reference to Exhibit 10.27 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.

Assignment and Assumption Agreement, dated as of July 21, 2004, by and among the Registrant, Elan Pharmaceuticals, Inc., and Novartis Pharma AG. Incorporated herein by reference to Exhibit 10.28 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.

License Agreement, dated April 17, 1991, by and between Sandoz Pharma, now Novartis Pharma AG and Athena Neurosciences, Inc., now Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.29 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.

Patent Assignment Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.24 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.

Trademark License Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.25 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.

Agreement Relating to Additional Trademark, dated as of July 2005, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.32 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.

Domain Name Assignment Agreement, dated as of July 21, 2004, by and between the

Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to  
Exhibit 10.27 to the Registrant's Registration Statement on Form S-1,  
No. 333-128827, filed on October 5, 2005.

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## Description

Bill of Sale and Assignment and Assumption Agreement, dated as of July 21, 2004, by and between the Registrant and Elan Pharmaceuticals, Inc. Incorporated herein by reference to Exhibit 10.28 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.

Limited Recourse Convertible Promissory Note issued to Elan International Services, Ltd. Incorporated herein by reference to Exhibit 10.29 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.

Full Recourse Convertible Promissory Note issued to Elan International Services, Ltd. Incorporated herein by reference to Exhibit 10.30 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.

Note Modification and Amendment, dated as of December 23, 2005, by and between the Registrant and Elan Pharma International Limited. Incorporated herein by reference to Exhibit 10.36 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.

Ampridine Tablet Technical Transfer Program Proposal for Commercial Registration, dated February 26, 2003, by and between the Registrant and Amgen, Inc. Incorporated herein by reference to Exhibit 10.38 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.

Securities Amendment Agreement, dated September 26, 2003, by and among the Registrant, Elan Corporation plc and Elan International Services, Ltd. Incorporated herein by reference to Exhibit 10.31 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.

Indicated Sales Force Agreement, dated as of August 1, 2005, between the Registrant and Cardinal Health PTS, LLC. Incorporated herein by reference to Exhibit 10.40 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.

License Agreement, dated as of December 19, 2003, by and among the Registrant, Cambridge University Technical Services Limited, and King's College London. Incorporated herein by reference to Exhibit 10.41 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 25, 2006.

Promissory Note issued to General Electric Capital Corporation. Incorporated herein by reference to Exhibit 10.35 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.

Revenue Interests Assignment Agreement, dated as of December 23, 2005, between the Registrant and King George Holdings Luxembourg IIA S.à.r.l., an affiliate of Paul Royalty Fund II, L.P. Incorporated herein by reference to Exhibit 10.41 to the Registrant's Registration Statement on Form S-1/A, No. 333-128827, filed on January 5, 2006.

Securities Purchase Agreement, dated as of October 3, 2006, by and among the Registrant and the purchasers listed on Exhibit A thereto. Incorporated herein by reference to Exhibit 10.44 of the Registrant's Current Report on Form 8-K filed on October 5, 2006.

First Amendment to Revenue Interests Assignment Agreement and to Guaranty, dated November 28, 2006 by and among the Registrant, King George Holdings Luxembourg IIA S.à.r.l. and Paul Royalty Fund II, L.P. Incorporated herein by

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reference to Exhibit 10.45 to Registrant's Current Report on Form 8-K filed on November 29, 2006.

amendment to August 11, 2002 Employment Agreement, dated May 10, 2007, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.1 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.

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**Description**

amendment to December 19, 2005 Employment Agreement, dated May 10, 2007, by and between the Registrant and Andrew R. Blight. Incorporated herein by reference to Exhibit 10.2 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.

amendment to December 19, 2005 Employment Agreement, dated May 10, 2007, by and between the Registrant and Mary Fisher. Incorporated herein by reference to Exhibit 10.3 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.

amendment to December 19, 2005 Employment Agreement, dated May 10, 2007, by and between the Registrant and David Lawrence. Incorporated herein by reference to Exhibit 10.4 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.

amendment to December 19, 2005 Employment Agreement, dated May 10, 2007, by and between the Registrant and Jane Wasman. Incorporated herein by reference to Exhibit 10.5 to Registrant's Quarterly Report on Form 10-Q filed on May 14, 2007.

Registration Rights Agreement, dated as of February 1, 2008, by and among the Registrant and Edward A. Labry III. Incorporated herein by reference to Exhibit 10.51 to Registrant's Annual Report on Form 10-K filed on March 14, 2008.

amendment to August 11, 2002 Employment Agreement dated December 28, 2007, by and between the Registrant and Ron Cohen. Incorporated herein by reference to Exhibit 10.52 to Registrant's Annual Report on Form 10-K filed on March 14, 2008.

Employment Offer Letter, dated October 20, 2008, by and between the Registrant and Thomas C. Wessel.

List of Subsidiaries of the Registrant. Incorporated herein by reference to Exhibit 21.1 to the Registrant's Registration Statement on Form S-1, No. 333-128827, filed on October 5, 2005.

Consent of KPMG LLP, Independent Registered Public Accounting Firm.

Certification by the Chief Executive Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.

Certification by the Chief Financial Officer pursuant to Rule 13a-14(a) under the Securities Exchange Act of 1934.

Certification Pursuant to 18 USC, Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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Special treatment granted as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission

Management contract or compensatory plan or arrangement.

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**SIGNATURES**

requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, Acorda Therapeutics, Inc. has duly caused this report to be signed on its behalf by the undersigned, a duly authorized officer of the registrant, at the State of New York, on this 2<sup>nd</sup> day of March 2009.

**ACORDA THERAPEUTICS, INC.**

By:           /s/ RON COHEN          

Ron Cohen  
*President and Chief Executive Officer*

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

| <b>Signature</b>      | <b>Title</b>   | <b>Date</b>   |
|-----------------------|--|---------------|
| _____<br>M.D.         | President, Chief Executive Officer and Director (Principal Executive Officer)          | March 2, 2009 |
| _____<br>ENCE, M.B.A. | Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) | March 2, 2009 |
| _____<br>I.B.A.       |  |               |
| _____<br>NE           | Director   | March 2, 2009 |
| _____<br>EY           | Director   | March 2, 2009 |
| _____<br>EM, PH.D.    | Director   | March 2, 2009 |
| _____<br>D.           |  |               |
| _____<br>PHILLIPS     | Director   | March 2, 2009 |
| _____<br>DALL         | Director   | March 2, 2009 |
| _____<br>USCHER,      | Director   | March 2, 2009 |
| _____<br>r, M.B.A.    | Director   | March 2, 2009 |

Director

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March 2, 2009